



340B Drug Pricing Program

Lessons Learned

Next Steps

HELP Webinars



Why talk about this?

- Government audits continue.
- Drug manufacturers may also be audited.
- Increased scrutiny by manufacturers to ensure compliance.





- America's Essential Hospitals
- Children's Hospital Association
- Hemophilia Alliance
- National Alliance of State and Territorial AIDS Directors
- National Association of Community Health Centers
- National Association of Counties
- National Family Planning & Reproductive Health Association
- National Health Care for the Homeless Council
- National Rural Health Association
- Planned Parenthood Federation of America
- Safety Net Hospitals for Pharmaceutical Access

- What is 340B Coalition?
 - Represents providers and programs participating in the Public Health Service's Section 340B drug discount program.
 - Created to assist providers with accessing and complying with the program while working with the Federal Government to improve implementation of the program.



SNHPA

Safety Net Hospitals for Pharmaceutical Access

- SNHPA is an association of 340B providers.
- SNHPA is not associated with HRSA.
- Advice and guidance is not “official”.
- SNHPA is a good source of peer-to-peer advice.
- SNHPA advocates on behalf of the 340B covered entity (CE) members.



- Apexus is under contract with HRSA to provide guidance and advice to 340B entities.
- Apexus advice can be relied upon.





External Audits of 340B Program

Manufacturer Audits

HRSA Audits

Manufacturer audits

- 7 manufacturer audits to date
 - No disclosure of results
- Must obtain HRSA approval
- Limited to certain compliance issues
 - Duplicate Discounts
 - Diversion
- Must use independent public accountant
- No time limit

Note this...

- Manufacturer will notify the covered entity (CE) of potential issues prior to contacting HRSA.
 - Cooperate
 - Make a good faith effort to resolve
- If not resolved, manufacturer will request permission from Office of Pharmacy Affairs to conduct an audit.
- Audit results will go to:
 - Manufacturer
 - CE
 - OPA/HRSA
 - **Office of Inspector General**



HRSA audits

- FY 2012
 - 51 high risk audits
 - 450 outpatient facilities
 - 400 contract pharmacies
 - 45 risk-based, 6 targeted
- FY 2013
 - 94 audits
 - 700 outpatient facilities
 - 1,930 contract pharmacies



HRSA audit experience

- HRSA mails letter to authorizing official
- One to two months between initial letter and actual audit
- Request list by HRSA (submitted prior to on-site visit)
 - Policies and Procedures
 - Cost report
 - Credentialing file
 - All purchase records
 - All dispense records
 - State/County contract

HRSA audit experience

- HRSA sample for on-site review
 - 30 340B eligible claims
 - 30 contract pharmacy claims
 - 30 inpatient hospital claims
 - 5 high cost drug claims
- Typically on-site less than one week

HRSA audit experience

- Auditors held introductory meeting
- 340B operations were discussed
- Auditors observed process of ordering, receiving, and tracking drugs for inpatients and outpatients*
 - Specifically reviewed NDC to NDC match
- Auditors reviewed sample claims
- Exit conference was held

**Auditors will conduct interviews with staff!*



HRSA audit experience

- Final audit results may take up to one year.
 - During this time, additional data may be requested.
 - May or may not receive preliminary findings.
 - Auditor may not be the one to make the findings.
HRSA may identify findings auditor did not mention.
- OPA publishes limited information to the public about findings.
 - Adverse findings
 - No adverse findings
 - Areas for improvement are not published

HRSA audit experience

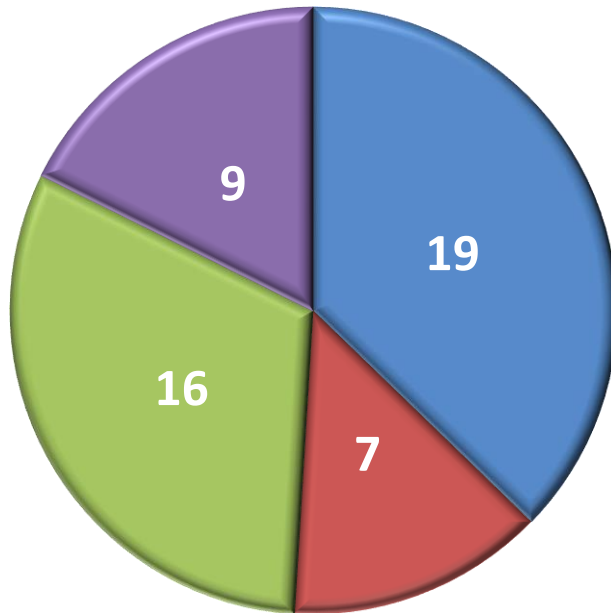
- Corrective action plans must be submitted to HRSA.
 - Simple explanation of actions
 - Documentation of executive support for action plan
- HRSA does not provide a “template” action plan format.

Corrective action plans

- Must correct process that led to issue.
- Must fix past errors.
 - Were there other claims that contained the same error?
 - Identify, quantify, and assess method of resolution with manufacturer.

FY 2012 HRSA audit results

Published January 2014
51 audits



- No adverse findings
- Adverse findings; no sanction
- Adverse findings with sanctions
- Adverse findings; sanctions not yet determined

Type	#
DSH	29
CAH	1
Cancer	1
CHC	10
Children's	2
Health departments	7
HIV	1

HRSA audit results

- Minor technical errors are reported the same as a significant error.
 - Diversion error may be one out of thousands of claims.
- There has been no evidence of neglect or fraud.
- No provider has been removed from the program.

Results by the numbers . . .

Issues noted in HRSA audits	
Diversion	16
Duplicate discounts (Medicaid)	17
Incorrect data in OPA database	15

Sanctions applied	
Refunds to manufacturers	16
To be determined	9
None	7

Corrective actions	
Corrective action plans	7
Pending	25

State	#
AL	1
AR	2
AZ	1
CA	3
CO	1
FL	3
GA	4
ID	1
IL	4
KY	4
LA	1
MI	1
MO	2
NC	3
NE	1
NM	1
NY	2
PA	2
SC	1
TX	6
VA	1
VT	1
WA	2
WI	2
WV	1

NOTE: 11 digit match was audited!

HRSA Staffing Investments - \$6 million

- New branch - Program Performance and Quality
 - Developing covered entity audit reports
 - Ensure assessments are consistent and accurate
 - Work with the covered entities to develop Corrective Action Plans
 - Posting summaries of audit information on website
 - Recertification function
 - Reviewing “self-disclosures” by covered entities
 - Working with Ryan White and Community Health Center Programs on covered entity compliance

HRSA Staffing Investments - \$6 million

- Operations Branch
 - Additional proactive technical assistance and education
 - Revamping the FAQs on the 340B Prime Vendor website
- Information Systems Branch
 - Hiring more specialized assistance in the data areas to better understand the data around covered entities and manufacturers, their purchasing and their pricing.

Types of corrective actions

- Repayment to manufacturers
- Update policies and procedures
- Implement training programs
- Update 340B computer systems
- Increase frequency of self-audits
- Correct OPA database entries
- Improve internal controls



Recommendations from audits

- Have an active 340B committee.
- Review 340B processes often.
- Update policies and procedures to reflect current processes.
- **Conduct self-audits and measure compliance.**
- Continue education and monitor changes in regulations and OPA guidance to ensure compliance.

Self-audit / Self-reporting

- As part of the annual recertification process, CE Authorizing Official must certify the CE's responsibility to:
 - Contact OPA as soon as reasonably possible if the CE discovers a “material breach” of program requirements.
 - Take corrective action which may include repayment to manufacturers, payment of interest, and/or removal from program.

Material breach

- The materiality criteria only refers to the reporting requirement.
 - Corrective action must be taken to prevent future errors regardless of materiality.
- No definition of what constitutes “material”.
 - At 340B conferences, numbers like 2% or 5% of 340B purchases. Nothing official.

Notifying manufacturers

- If you find that you have over bought 340B drugs, notify the manufacturer as to how you will correct.
 - Reduce subsequent allowable purchase
 - Repay



The image features two pill bottles, one white and one red, positioned diagonally. Both bottles are tilted, and a large quantity of small, white, round pills is spilling out from their openings. The pills are scattered on the surface below the bottles. The background is plain white.

Orphan Drugs

Orphan drugs

- A drug that was developed for a rare condition.
- Excluded from definition of covered outpatient drug.
 - Exclusion only applies to **free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals**
 - Only applies when the drug is used for the indication for which they received orphan designation.

Orphan drug exclusion

- RRC, SCH, CAH and Cancer Hospitals
 - Know what is on the orphan drug list and the orphan indication.
 - Can be downloaded from the HRSA/OPA website
 - > 2500 drugs
 - If **opt-in**:
 - How will you maintain auditable records to prove drug only used for non-orphan indication?
 - HRSA and manufacturers can audit compliance including a review of CE's auditable records.

Orphan drug exclusion

- RRC, SCH, CAH and Cancer Hospitals
 - If **opt-out**:
 - Must work with wholesaler to ensure that orphan drugs are not purchased under 340B program.
 - GPO pricing can be used to purchase orphan drugs.

Opt in / Opt out

- Must inform HRSA if CE will opt in or opt out.
 - **Opt in:** Purchase orphan drugs using 340B – must track by indication and maintain auditable records.
 - **Opt out:** Will not maintain auditable records and will purchase all orphan drugs outside of 340B regardless of indication for which drug is used.
- Manufacturers and wholesalers will be able to download quarterly opt-in/out files.

[Home](#)[Covered Entities ▼](#)[Contract Pharmacies ▼](#)[Manufacturers ▼](#)[Reports](#)

Download Orphan Drug Selection File

340B hospitals subject to the orphan drug exclusion (critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers) are responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the Federal Food, Drug, and Cosmetic Act.

The files available below allow drug manufacturers and wholesalers to identify affected hospitals that will purchase orphan drugs under the 340B Program and will maintain auditable records to demonstrate compliance with the orphan drug exclusion (Orphan Drug Participation = Yes), or that cannot or do not wish to maintain auditable records regarding compliance with the orphan drug exclusion and will purchase all orphan drugs outside of the 340B Program regardless of the indication for which the drug is used (Orphan Drug Participation = No).

The 340B database takes a snapshot of affected hospitals' elections at 12:01am ET on the 15th day of the month prior to the start of each calendar quarter, irrespective of weekends or holidays. Covered entities may request changes to their election at any time but changes take effect quarterly and only then if approved by OPA before the time of the snapshot.

Prior quarters' files will remain available for future use.

For purchases made during the selected quarter:

Manufacturers' lawsuit

- Manufacturers do not want these entities to receive 340B pricing when orphan drugs are used for ANY indication.
- Lawsuit by Pharmaceutical Research and Manufacturers of America (PhRMA) to terminate the orphan drug exclusion option.



HRSA Statement on Case

- On May 23, 2014, the U.S. District Court for the District of Columbia issued a ruling that vacated the orphan drug regulation on the grounds that HHS lacks the statutory authority to engage in such rulemaking.
- However, the Court did not invalidate HRSA's interpretation of the statute.

HRSA Statement on Case

- HHS/HRSA continues to stand by the interpretation described in its published final rule.



The screenshot shows the HRSA website header with the U.S. Department of Health and Human Services logo and the HRSA logo. The navigation menu includes links for HRSA Home, Get Health Care, Grants, Loan & Scholarships, Data Statistics, and Public. The main content area is titled "Orphan Drugs Exclusion" and features a "Share" button with social media icons. The text of the statement is as follows:

On May 23, 2014, the U.S. District Court for the District of Columbia issued a ruling in *Pharmaceutical Research and Manufacturers of America v. US Department of Health and Human Services (HHS)* (Civil Action No. 13-1501) that vacated the orphan drug regulation on the grounds that HHS lacks the statutory authority to engage in such rulemaking. However, the Court did not invalidate HRSA's interpretation of the statute. HHS/HRSA continues to stand by the interpretation described in its published final rule, which allows the 340B covered entities affected by the orphan drug exclusion to purchase orphan drugs at 340B prices when orphan drugs are used for any indication other than treating the rare disease or condition for which the drug received an orphan designation. HRSA is continuing to post updated Orphan Drug Designation Lists, found below, as well as the [Orphan Selection File](#), found on the 340B database, in order to assist all 340B stakeholders in complying with HRSA's policy.

The left sidebar contains a list of navigation links: Home, Eligibility & Registration, 340B Implementation, Program Requirements, Medicaid Exclusion, Orphan Drug Exclusion, 340B Peer-to-Peer, Program Integrity, Manufacturers, 340B Database, and FAQs.

The background of the slide features two pill containers. On the left is a white, cylindrical container, and on the right is a red, cylindrical container. Both containers are tilted, and a large quantity of small, white, round pills is spilling out from their openings. The pills are scattered across the white surface below the containers, creating a sense of motion and abundance. The overall image is soft-focused, with a slight blur effect.

Medicaid Billing

Understand your State's
requirement!

Duplicate discount

- A duplicate discount, prohibited by 340B statute, occurs when manufacturers provide both a **340B discount on a drug** AND pay a **Medicaid rebate** to the State on the same drug.
- A duplicate discount would occur if an up-front **340B discount** and back-end **Medicaid rebate** were provided on the same drug/drug claim.

Carve-in / Carve-out

- For each unique Medicaid Provider Number/NPI, entities can either:
 - **“Carve-in”** - Use 340B drugs for Medicaid patients (and list the Medicaid Provider Number/NPI on the OPA website), or
 - **“Carve-out”** - Use a non-340B contract to purchase drugs for Medicaid patients (*Note: GPO use is not permitted by DSH/Children’s/Cancer hospitals.*)

Medicaid provider number

- If a CE uses only one Medicaid provider number and “carves-in”, then all areas using that provider number must be registered as a 340B eligible area.
 - Medicaid will be unable to determine if a claim is from a non-340B eligible area if only one number is used for billing all areas.

Medicaid Exclusion File

Search Results:

The number of rows returned: 338

Rows/Page: 200 ▼ Set

Show Search Criteria

Export Results

<input type="checkbox"/> Select All	340B ID	Medicaid Number	NPI	Medicaid State	Entity Type	Entity Name	Sub Name	City	State	Edit Date
<input type="checkbox"/>	DSH110071	00000052A		GA	DSH	APPLING HEALTHCARE SYSTEM (AHCS)		BAXLEY	GA	05/15/2012
<input type="checkbox"/>	DSH110074	00000074		GA	DSH	ATHENS REGIONAL MEDICAL CENTER, INC		ATHENS	GA	05/31/2013
<input type="checkbox"/>	DSH110074A	008017998B		GA	DSH	ATHENS REGIONAL MEDICAL CENTER, INC	Home Infusion	ATHENS	GA	05/31/2013
<input type="checkbox"/>	DSH110024		1275527889		DSH	CANDLER HOSPITAL		SAVANNAH	GA	07/03/2013
<input type="checkbox"/>	DSH110024	000000327A		GA	DSH	CANDLER HOSPITAL		SAVANNAH	GA	07/03/2013
<input type="checkbox"/>	DSH110024	000113512		SC	DSH	CANDLER HOSPITAL		SAVANNAH	GA	07/03/2013
<input type="checkbox"/>	DSH31405	00000327A		GA	DSH	CANDLER HOSPITAL		SAVANNAH	GA	06/30/2008
<input type="checkbox"/>	DSH31405A	00000327A		GA	DSH	CANDLER HOSPITAL	ACUTE CARE PHARMACY	SAVANNAH	GA	06/30/2008

State billing requirements

- Some states require 340B entities who “carve-in” to bill drugs on a Medicaid claim at actual acquisition cost plus a dispensing fee.
 - Under this method the 340B price “flows through” to Medicaid.
 - The state will not claim the rebate from the manufacturer, but rather will receive it by paying the lower price to the CE.

State billing requirements

- Other states allow “carve-in” entities to bill at usual and customary rates.
 - Generally drugs are paid under cost reimbursement methodology already in existence.
- Maintain written documentation of what your state requires – Traditional Medicaid and Medicaid managed care.
 - HRSA will request this information upon audit!

Finger pointing

- HRSA will point to CE as responsible party for duplicate discounts.
 - If you are correctly listed in the OPA database and Medicaid Exclusion database and have done due diligence with the State, then HRSA may not hold CE as responsible.



The image features two pill containers, one white and one red, lying on their sides with numerous small, white, round pills spilling out. The scene is set against a plain white background. The text is overlaid on the central part of the image.

Policies and Procedures

Critical to a successful audit!

Policies and procedures

- Extremely important!
 - HRSA audit staff will ask hospital staff if they have seen the policies and procedures.
 - HRSA audit staff will review policies and procedures to determine
 - What is a covered outpatient drug
 - What is an eligible patient
 - What is an eligible location
 - Who is an eligible provider



Policies and procedures

- During the 340B Coalition Conference in February, HRSA/OPA official remarked that in some audits it was noted that P&P did not include a discussion of inventory controls.
- Ensure this is covered in your P&P manual.

Be specific

- CE can use templates, but tailor policies and procedures for your entity.
- Keep historical data after updates.
 - Audits are retrospective
- Include in the policy the name of the Medicaid contact for your State.
- Have procedure for response to external audit requests.
- Describe how you will self-audit and DO IT!

Document use of 340B savings

- Policies and procedures should clearly identify what the savings from the 340B program will be used for
 - Describe how use of the Program supports intent of Program.
 - Are savings passed directly to patients?
 - Are savings used in programs to benefit the low-income and underserved populations?

Referrals

- Document in the 340B policies & procedures how referrals will be treated for 340B purchases.
 - Patient medical record should include clear evidence of referral.
 - Ultimately comes down to: Who is responsible for care of patient? (Definition of outpatient)

Policies and procedures

- Policies and procedures are federally mandated and will be reviewed upon audit.
- Sample policies can be found:



340B University Tool Guide

A Summary of Tools and Resources

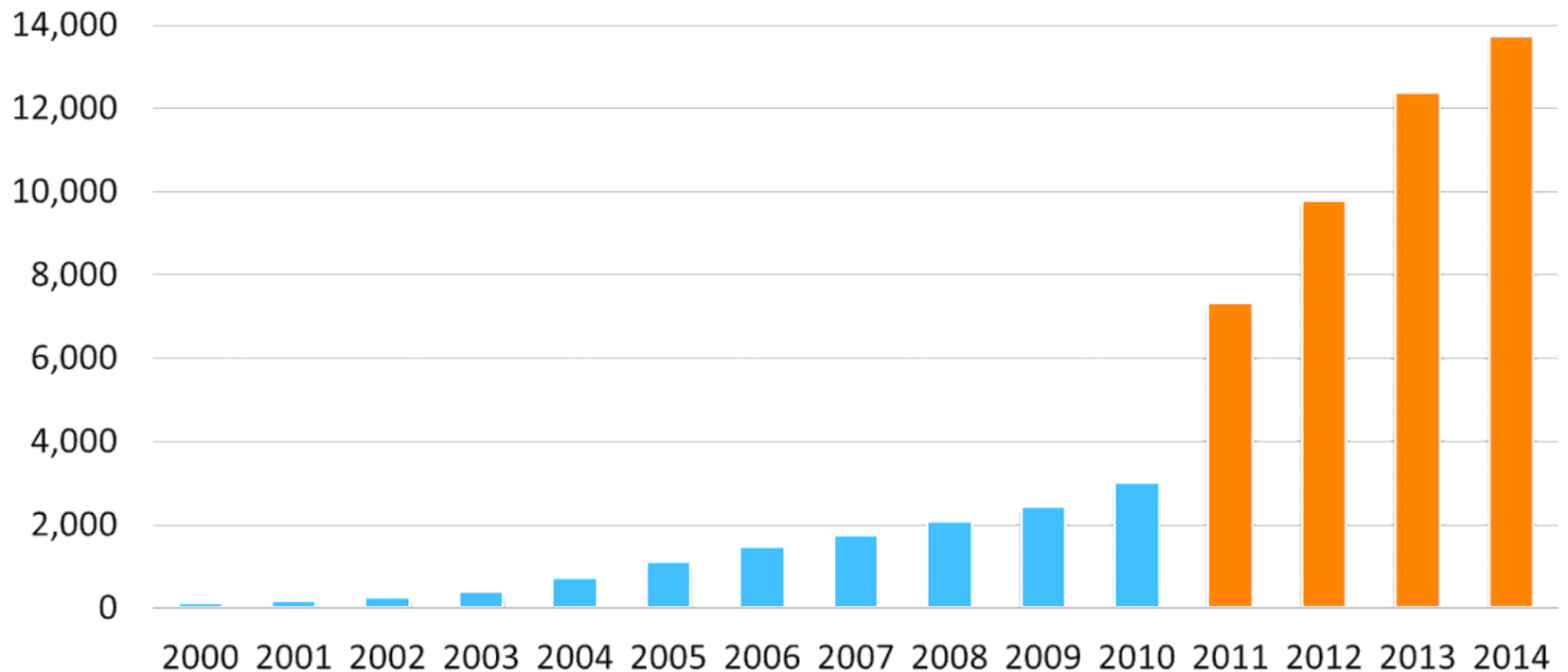
Purpose: The purpose of the 340B University Tool Guide is to provide a link to the most recent version of the tools, as well as a short description of each tool. Find the most recent version of our tools online:
<https://www.340bpvp.com/resource-center/340b-university/>

Tool	Description
Standard Operating Procedures	
CHC 340B Comprehensive Policy and Procedure Manual	Provides an example of a 340B Policy and Procedure Manual that exhibits high program integrity, to assist participating Community Health Center (CHC) leaders in the preparation of a unique, site-specific, manual that supports placing compliant guidance/policy into practice
DSH 340B Comprehensive Policy and Procedure Manual	Provides an example of a 340B Policy and Procedure Manual that exhibits high program integrity, to assist participating Disproportionate Share Hospital (DSH) leaders in the preparation of a unique, site-specific, manual that supports placing compliant guidance/policy into practice
RURAL HOSPITAL 340B Comprehensive Policy and Procedure Manual	Provides an example of a 340B Policy and Procedure Manual that exhibits high program integrity, to assist participating Rural Hospital (Critical Access (CAH), Sole Community (SCH), and Rural Referral Center (RRC)) leaders in the preparation of a unique, site-specific, manual that supports placing compliant guidance/policy into practice



Contract Pharmacies

Total Number of 340B Contract Pharmacies, 2000-2014

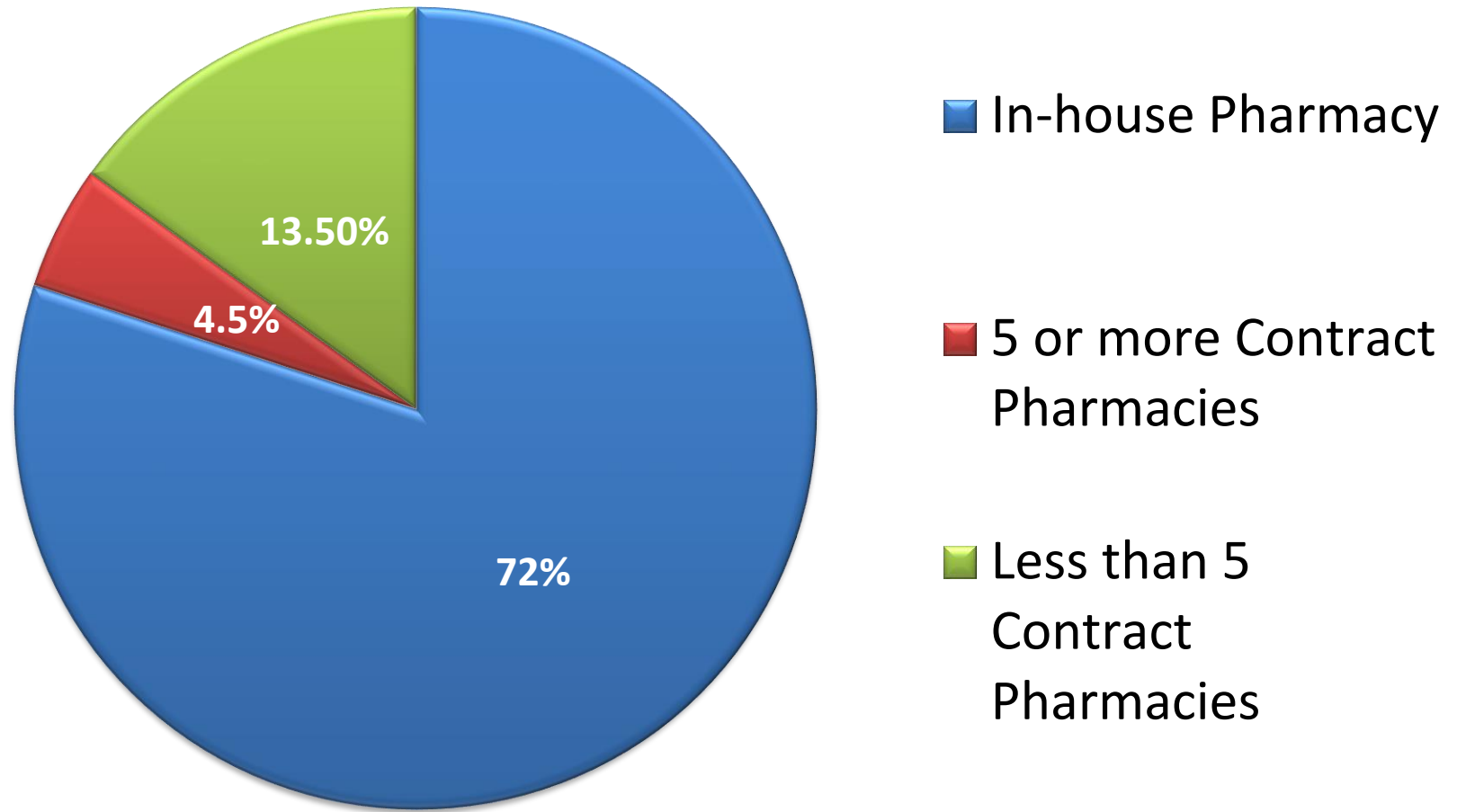


Data show contract pharmacies as of July of each year. For 2014, data show contract pharmacies as of January.

Source: Avalere Health (2000-2012); Pembroke Consulting (2013-2014)

Note: This chart appears as Exhibit 95 in the *2013-14 Economic Report on Retail, Mail and Specialty Pharmacies*, Drug Channels Institute, January 2014. (http://drugchannelsinstitute.com/products/industry_report/pharmacy/)

Types of 340B Entities



Source: HRSA

What are the audit requirements?

- Although not expressly required, the CE must have sufficient information to meet its obligation of ensuring ongoing compliance and the timely recognition of any problem.

Q: What are the audit requirements under the contract pharmacy guidelines?

*A: Although annual independent audits are not expressly required, the covered entity must have sufficient information to meet its obligation of ensuring ongoing compliance and the timely recognition of any problem. All covered entities are required to maintain auditable records and **it is the expectation of HRSA that most covered entities will utilize independent audits as part of fulfilling their ongoing obligation of ensuring 340B Program compliance.** However, HRSA leaves it up to covered entities to determine how to meet their compliance responsibilities.*

Attestation for 340B Program

Authorized Signature



By checking this box, I represent and confirm that I am fully authorized to legally bind the covered entity. I certify that the contents of any statement made or reflected in this recertification are truthful and accurate. Failure to recertify may be grounds for removal from the 340B program.

As an Authorized Official, I acknowledge the 340B covered entity's responsibility to abide by, and further certify on behalf of the covered entity that:

- (1) all information listed on the 340B Program database for the covered entity is complete, accurate, and correct;
- (2) the covered entity meets all 340B Program eligibility requirements, including section 340B(a)(4)(L)(iii) if applicable – the Group Purchasing Organization prohibition - which ensures that the covered entity does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement;
- (3) the covered entity is complying with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity;
- (4) the covered entity maintains auditable records demonstrating compliance with the requirements described in paragraph (3) above;
- (5) the covered entity has systems/mechanisms in place to ensure ongoing compliance with the requirements described in (3) above;
- (6) if the covered entity uses contract pharmacy services, that the contract pharmacy arrangement is being performed in accordance with OPA requirements and guidelines including, but not limited to, that the covered entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the entity has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism);
- (7) the covered entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material change in 340B eligibility and/or material breach by the covered entity of any of the foregoing; and
- (8) the covered entity acknowledges that if there is a breach of the requirements described in paragraph (3) that the covered entity may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and, depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.

Authorize and Submit



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



FEB 04 2014

TO: Mary K. Wakefield, Ph.D., R.N.
Administrator
Health Resources and Services Administration
/s/

FROM: Stuart Wright
Deputy Inspector General
for Evaluation and Inspections

SUBJECT: Memorandum Report: *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431

This memorandum report describes selected covered entities' contract pharmacy arrangements and their oversight of those arrangements to prevent (1) diversion of drugs purchased through the 340B Drug Pricing Program to ineligible patients and (2) duplicate discounts through Medicaid.

SUMMARY

Covered entities participating in the 340B Drug Pricing Program (hereinafter referred to as the 340B Program) may contract with pharmacies to dispense drugs purchased through the program (hereinafter referred to as 340B-purchased drugs) on their behalf. Such pharmacies are referred to as contract pharmacies.

According to Health Resources and Services Administration (HRSA) guidance, covered entities that establish contract pharmacy arrangements must oversee these arrangements to prevent diversion of 340B-purchased drugs to ineligible patients and duplicate discounts through Medicaid. Diversion and duplicate discounts are statutorily prohibited. HRSA guidance recommends that covered entities' oversight activities include periodic comparisons of covered entity records and contract pharmacy records, as well as annual independent audits.

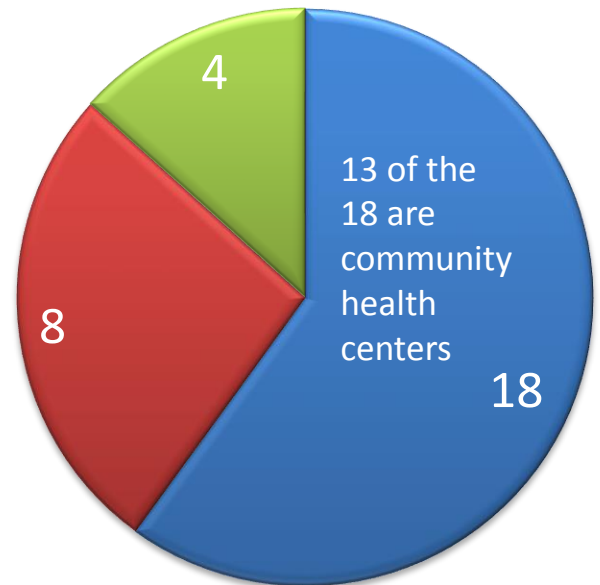
The OIG issued a Memorandum Report:
Contract Pharmacy Arrangements in the 340B Program
on February 4, 2014.

OIG study results

(n=30)

340B Discount

- The OIG found that some CE's do not offer discounted 340B price to uninsured patients at their contract pharmacies.



*Neither the 340B statutes nor HRSA guidance address whether covered entities must offer the discounted 340B price to uninsured patients in their contract pharmacies.

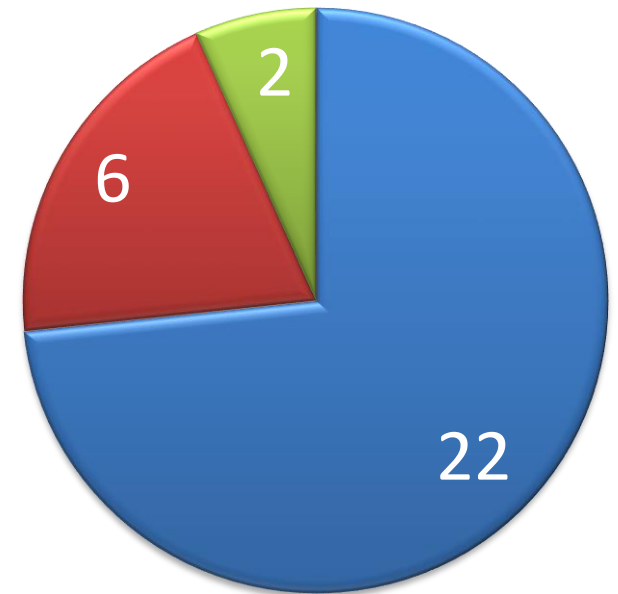
- Offered discount price
- Did not offer discount price
- Unknown

OIG study results

(n=30)

- To avoid **duplicate discounts** in contract pharmacy arrangements, CE's have two options:
 - Do not dispense 340B purchased drugs to Medicaid patients
 - Dispense to Medicaid AND make arrangements with State to prevent duplicate discounts

Medicaid



- No Medicaid dispenses
- Dispense with arrangements
- Dispense no arrangements

OIG study results

(n=30)

Monitoring



- Monitoring in-house
- Independent monitoring
- No monitoring

- Twenty-five of the CE's monitor their contract pharmacy arrangements.
- Only 7 of 25 use independent auditors for monitoring.

Other report findings

- A main theme in the OIG Report Memorandum was the inconsistency in the 30 contract pharmacy arrangements studied.
- Covered entities noted several instances in which they would categorize similar types of prescriptions differently.
 - Based on each entity's policies, the categorization could result in diversion.



What's coming in 2014

Increased manufacturer pressure

Changes in regulations

Medicare Part B

PROTECT THE PROGRAM'S ORIGINAL INTENT: SUPPORT PATIENTS IN NEED

We would like to work with Congress and the federal government to ensure the 340B program maintains its original purpose – to support patients in need – and avoid unintended (and potentially harmful) consequences for patients and providers.

- While the program was intended to benefit needy patients, the facilities actually receive the discount and there is no requirement that the facilities pass along the discount to needy patients. 340B covered entities can access 340B pricing on most outpatient drugs for all of their patients, regardless of patient income or insurance status. **No one is accountable to ensure access for needy patients.**
- The number of entities in the 340B program has increased significantly (6,100 times Congress' original intent) in recent years, yet no measure of the amount of care provided for indigent uninsured has ever been taken to validate this expansion.
- **Another abuse of the system has been the utilization of the program by contract pharmacies—for-profit entities—which are not serving patients in a hospital setting. Discounts given to contract pharmacies are captured by the pharmacies, rather than passed on to patients.**

PROVIDE GREATER OVERSIGHT

Improved transparency and oversight of the 340B program is needed to ensure it remains aligned with its original intent and supports indigent patients who need the program.

- Oversight of the 340B program is currently insufficient. A GAO study found that HRSA's past oversight of the program was inadequate because it primarily relied on participants' self-policing to ensure compliance.
- While the overall number of covered entity sites that participate in the program has risen by 93% in the past 10 years, the number of HRSA staff overseeing the program has declined by 9% annually since 2008, with fewer than a dozen staff at HRSA today.



A diverse group of health care stakeholders, including BIO, the Community Oncology Alliance (COA), the National Community Pharmacists Association (NCPA), the Pharmaceutical Care Management Association (PCMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA), have come together because they believe in the importance of 340B but recognize the need for improving this program to ensure that it is helping those it was intended to help, namely uninsured indigent patients.

Unfulfilled Expectations:

An analysis of charity care
provided by 340B hospitals

AIR_x**340B**
Alliance for **x** Integrity and Reform

The “Mega Reg” – What Now?

- *HRSA is currently working to formalize existing program guidance through regulation, designed to cover a number of aspects of the 340B Program. The regulation under development will address the definition of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria, and eligibility of off-site facilities.*

Closing thoughts

- Watch out for the “Mega Reg” or some version of it to be issued soon.
- Many of the issues identified by HRSA audits and the OIG are expected to result in proposed regulations.

2014 will be a big year for 340B!

For more information:

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