

340B PROGRAM AUDITS
An Update from the Field
 Thank you for joining us. The presentation will begin shortly.

Thank you to the sponsor of today's webinar:



What is transcendRx?

- Provider Controlled
 - Pharmacy Benefits Manager (PBM)
 - Specialty pharmacy (SP)
 - Hospital/FQHC owned retail pharmacy implementation consultant



Why transcendRx?

- Traditional PBM practices
 - Spread pricing
 - Multiple MAC lists
 - Rebate shell games
- SP environment
 - Capitalize on growing channel allowing ability to provide complete patient care
- Need to engage community beyond four walls
 - Opportunity to partner with local employers
 - Achieve significantly higher levels of revenue and savings



FACTS

- PBM facts
 - Current annual revenue \$350 billion by 2020 \$500 billion half of which driven through SP
 - Big 3 (Optum, Express Scripts, Caremark) fill almost 65% of all prescriptions in US
 - All will say transparent and pass through, almost none are
- Specialty facts
 - Currently 1 to 2% of pt. on SP accounts for 30% + of drug plan dollars
 - SP expected to grow to 10% of pt. accounting for 50% + of drug plan dollars by 2020
 - Experiencing a trifecta of reduction by Manufactures and PBM's
 - Accessible contracts
 - Lack of appropriate payments by payors
 - Network lockouts
 - Entity owned retail pharmacy facts
 - Contract pharmacy relationships breaking down due to PBM pressure (DIR fees, Loss of U&C)
 - Boards will no longer be able to ignore significant revenue and savings



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HRSA 340B AUDITS

Dr. Aaron K. Lott, Pharm. D.

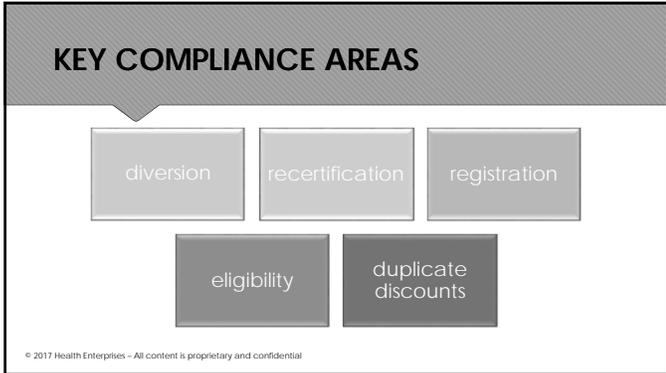
UNDERSTANDING THE PROCESS TO HELP ENSURE SUCCESS

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AGENDA

- Review of key compliance areas
- HRSA audits background
- Audits under the Bizzell Group
- How to Prepare for an audit
- Contract Pharmacy Challenges

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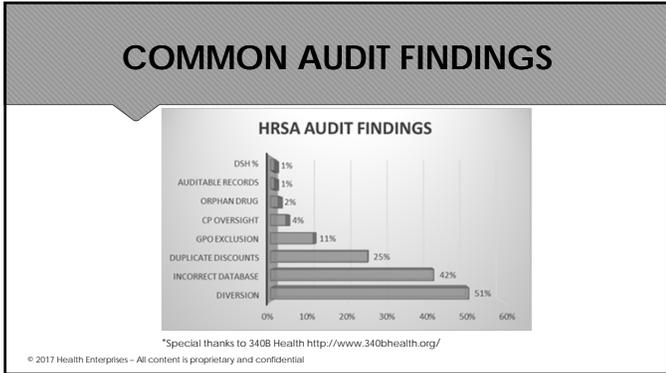


HRSA AUDITS BY THE NUMBERS

- 2012 – 51 HRSA audits completed
- 2015 – 200 HRSA audits completed
- 2016 – 175 HRSA audits completed
- % of audits with at least one finding – 65%
- % of audits requiring repayment to manufactures – 65%
- 3 entities have been removed entirely from 340B Program

*Special thanks to 340B Health <http://www.340bhealth.org/>

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The Bizzell Group

- HRSA contracted with the Bizzell Group to audit 340B covered entities effective October 1, 2016.
- Bizzell auditors are primarily pharmacists or pharmacy technicians. Some have worked as 340B coordinators and performed primary contact roles in 340B entities. Auditors are knowledgeable concerning pharmacy operations and the 340B program.
- The audit process is largely the same under Bizzell. The data request used by Bizzell auditors is the same request that HRSA auditors used.
- Samples pulled
 - 39 Contract pharmacy
 - Expect 15% to 25% of samples to be specialty products
 - 34 In-house samples
 - 28 Administered/dispensed samples

HRSA AUDITS UNDER BIZZELL GROUP

For the most part, audits under the Bizzell Group have remained the same as previous HRSA audits

Pre-audit Data Request	Audit 30 samples per setting	Target several high cost items
Eligible provider	Eligible location	Entity retains responsibility for care
Contract Pharmacy Oversight	Duplicate Discounts	Accumulations and ordering process

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BIZZELL AUDITORS ALSO FOCUS ON...

Replenishment Process <ul style="list-style-type: none"> • Review accumulator • Corresponding 340B Purchase 	Credentialing <ul style="list-style-type: none"> • Match credentialing dates to sample scripts/orders 	Invoices and Purchase Orders <ul style="list-style-type: none"> • Demo creating and sending order • Speak with purchaser 	Prescriptions <ul style="list-style-type: none"> • E-script • Hard copy from contract pharmacy
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**HRSA AUDIT PROCESS
Timeline**

- Day 1-2
 - HRSA Audit letter attached to email 340baudit@hrsa.gov
 - Bizzell email from Auditor(s) @thebizzellgroup.com
 - Data request attached have 10 days from this communication to provide
 - Schedule Welcome/Pre-Site Visit Call
- Day 2-7
 - Welcome/Pre-Site Visit call
 - Turn in Information request form by day 3
- Day 10
 - Turn in data request
- Day 30
 - Onsite portion of audit

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**HRSA AUDIT PROCESS
Notice of 340B Drug Pricing Program Audit**

Notice of 340B Drug Pricing
Program Audit
From HRSA

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Dear -----:

The Health Resources and Services Administration (HRSA) is undertaking additional program integrity measures related to participation in the 340B Drug Pricing Program (340B Program) to ensure compliance with program requirements. Per 42 USC 256b(a)(5)(C), HRSA has the authority to perform audits of a covered entity's records that directly pertain to the entity's compliance with 340B Program requirements. HRSA has contracted with The Bizzell Group, LLC, to perform the audits of covered entities. -----, 340B ID #-----, has been selected for audit. The scope of the audit may also include 340B Program compliance for offsite outpatient facilities, contract pharmacies, and associated 340B ID Numbers. Please be aware that sometimes associated sites are not determined until the first conference call with the entity selected for audit.

In general, the 340B Program audit is designed to (1) Obtain an understanding of the entity's policies, procedures, and drug distribution system; (2) Review the entity's eligibility status, including compliance with the Group Purchasing Organization (GPO) prohibition for certain entity types; (3) Review drug procurement and distribution to determine whether the entity provided 340B drugs to appropriate patients as defined by Section 340B(a)(5)(B) of the Public Health Service Act (PHSA); and (4) Determine whether the entity properly prevented duplicate discounts, as required by Section 340B(a)(5)(A) of the PHSA.

Prior to the onsite portion of the audit, The Bizzell Group will work with the personnel that you select to arrange a welcome conference with you, key management/administrative staff, and those who are closely involved with the activities of the 340B Program and to collect relevant documents at the entity site. HRSA 340B Program audit procedures will, at a minimum, include review of the facility's policies, procedures and processes that pertain to 340B drugs; verification of internal controls in place to prevent diversion and duplicate discounts; and testing, on a sample basis, transactions that pertain to 340B drugs. Specific information pertaining to the sampled transactions will be shared between the auditor and the covered entity at the time of the audit, and it is the responsibility of the covered entity to retain such information to support an understanding of any findings cited in the Final Report.

No formal conclusions or recommendations will be made during the onsite audit. Onsite findings will be considered preliminary and a basis for further review by HRSA's Office of Pharmacy Affairs (OPA). Upon completion of our audit review, we will issue you a report outlining any findings. The covered entity will have the opportunity to respond to this report. Any findings that indicate 340B Program non-compliance will necessitate corrective action by the facility and may generate further follow-up by HRSA prior to completion of the audit.

Please note that any self-disclosure submitted to HRSA between the time the covered entity receives a HRSA audit engagement letter and the time the audit period is concluded, may be subject to inclusion within the audit review and Final Audit Report. HRSA will not audit your financial statements nor offer an opinion on them.

Please make the following items available to The Bizzell Group while they are on site:

- An enclosed, lockable working space for up to three staff;
- Internet access for three computers;
- Access to a telephone, fax machine, and photo copier;
- Parking for up to two vehicles; and
- Access to all financial, transactional documents and patient information related to the 340B Program.

This information will assist HRSA and The Bizzell Group in conducting the audit. The auditors may need to ask for additional information during the course of the audit prior to finalizing the audit. The Bizzell Group will soon contact you on behalf of HRSA's OPA by phone to coordinate the audit.

HRSA looks forward to working with you. Thank you in advance for your cooperation.

HRSA AUDIT PROCESS

Notice of 340B Drug Pricing Program Audit From Bizzell

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Dear ----:

The Bizzell Group has been contracted by the Health Resources and Services Administration (HRSA) to perform your 340B Drug Pricing Program (340B Program) audit.

----- is the auditor that has been assigned to conduct your entity's 340B Program audit. ----- and I, -----, will be your primary contacts throughout your entity's audit process.

At this time, we would like to schedule the Welcome/Pre-Site Visit Call to introduce ourselves, provide an overview of the audit process, and begin coordinating your 340B Program audit. The Welcome/Pre-Site Visit Call is scheduled to run approximately 1 hour. Please ensure that key personnel who are closely involved with the activities of your 340B Program are able to participate in the call to address any questions.

Within the **next 24 hours**, please use the scheduling link below to indicate your availability for the Welcome/Pre-Site Visit Call:
[link](#)

Please complete the attached Information Request Form to confirm a few items and logistics for the on-site visit. The logistics for the on-site visit will be discussed on the Welcome Pre-Site Visit Conference Call. Please email the completed Information Request Form within the **next 3 business days**.

The details of the Data Request List are attached. We are requesting all this data prior to our on-site visit to be due on:
March 27, 2017

We are planning to perform the on-site visit on:

April 17 - 18, 2017 (Please review and confirm the on-site visit dates on the Information Request Form)

Expectations of the Data Request List and dates for the on-site visit will be discussed during the call. Data submissions must be transmitted using the National Institutes of Health (NIH) secure portal: the entity contact will receive a link to access the NIH secure portal.

After receiving access to the NIH secure portal, you are encouraged to immediately begin submissions of the items detailed in the Data Request List attached to this email. Data Request List items do not need to be uploaded all at one time, you can submit them individually as they are ready.

In an effort to maintain complete transparency for all parties involved, we ask that all questions and be communicated through a single email string. At all times, please "reply to all" from [this](#) email string and always ensure your entity's name and 340B ID are in the subject line.

We look forward to speaking with you.

Best,

HRSA AUDIT PROCESS

Information Request Form From Bizzell

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Information request form
 Entity name - Information Request Form

List individuals who will attend the Welcome/Pre-Site Visit Conference Call (this list can be resent after the call if changes are made)
 Name Title

What is the name and email of the person ----- would like to have as their entity contact?
 Name Email Address

On-site Visit Logistics

1. Please confirm if -----can accommodate the site visit dates of March 22-23, 2017?
 Entity Response

2. What is the physical address (or GPS) of the location that the auditor should arrive at on the first day of the site visit?
 Address including zip code GPS (if available)

3. Are there any special directions, parking or other considerations the auditor should be aware of? If yes, please indicate below.
 Directions Parking Other

4. What is the name and telephone number of an entity representative who will meet the auditor when they arrive on the first day?
 Name Number

5. Can Entity accommodate the auditor with the following requirements on March 22-23, 2017 for the on-site visit portion of the audit?
 Requirements Yes/No

- A conference room available that will allow us to speak briefly at the beginning and end of each day.
- For the auditor during the on-site visit:
 - o an enclosed lockable work space,
 - o internet access,
 - o access to a telephone,
 - o fax,
 - o photo copier,
 - o parking,
 - o and access to all financial, transaction documents and patient information related to 340B.

staff members available who have a working knowledge of the organization's IT systems such as the electronic health record, pharmacy operating system, billing system, and any 340B split-billing or vendor software systems.

- provider credentialing staff will need to be available.

Welcome/Pre-Site Visit Call

- Call will last approximately 30 minutes
- The auditor and audit coordinator will be on the call
- Confirm participation in 340B Program and review the purpose of the audit
- Confirm dates of the audit again
- Auditor will review specific items listed on the Data Request Form, how to submit
- Confirm EMR in place, # of contract pharmacies, # of child sites
- Auditor will review who needs to be available for the on site portion of audit
- Entity will have the opportunity to ask any questions

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Welcome/Pre-Site Visit Call Specifics

- Introductions of all parties on call
- Bizzell will request that someone send a list of all those attending the call
- Auditor will confirm the following:
 - Entity currently participates in the 340B program
 - Entity currently purchases drugs under the 340B program
- Auditor states purpose of the audit was to ensure that the CE meets all eligibility requirements for participation in the 340B program and that the CE has mechanisms in place to prevent duplicate discounts and diversion in each eligible area
- Auditor will give an overview of what would be happening during the onsite portion of the audit
 - Review of P&P
 - Walkthrough of pharmacy/clinics
 - Discussions with staff
 - Transaction testing

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Welcome/Pre-Site Visit Call Specifics

- Auditor stated that they will not comment at any time on the program during the audit
- Any questions regarding program rules must be directed to Apexus, not Bizzell
- Auditor will confirm receipt of the Information Request Form that was sent out with the audit notice
- Auditor restates date when the Data Request List is due
- Information may be submitted in batches, does not have to be all at once
- Auditor may request additional information
- All information must be submitted to the NIH portal
- Authorized user confirms receipt of user name and password for NIH portal and that they were able to access without issue
- 340B Universe Discussion- Auditor stated that there would be one "universe" for each area where 340B used. If contract pharmacies use different 340B software, a different universe would need to be submitted for each
- Auditors prefer #3 and #9 on the Data Request Form be in Excel file

Welcome/Pre-Site Visit Call Specifics

- For each child site will need to list clinic name and address, clinic code used in EMR, name listed on MCR and line where child site is listed, corresponding child site name on trial and balance sheet.
- Auditor states if entity has any questions regarding the Data Request that they must submit them using "reply all" to the original email from Bizzell.
- NIH portal has several folders to upload info which correspond to specific data request items.
- The auditor stated that the entity could either leave the folder empty or upload a MS Word document stating "not applicable" to folders that will not be used.
- Bizzell Group still requires Medicaid numbers of the entity even if they carve out Medicaid.
- Auditor stated that often times entities upload an unsigned digital copy of their MCR. They emphasized that they would need the entity to scan a SIGNED copy of worksheet S and upload that signed copy to the portal.
- Auditor stated that if any data was missing, Bizzell would contact entity via email to request.

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Welcome/Pre-Site Visit Call Specifics

- Auditor emphasized that all CPs should be notified of the audit dates and should be told that they will need to be available to pull hard copies of prescriptions; that these prescriptions will be needed on the day of the audit.
- For the CP Universe asked:
 - What EMR software was used
 - How many contract pharmacies
 - Which 3rd party software vendor
 - If entity bills Medicaid for 340B prescriptions
- For the Hospital Mixed Use Pharmacy asked:
 - The number of mixed use pharmacies
 - They used a virtual or physical inventory
 - Software is used for hospital dispenses
 - If hospital pharmacy used a consignment inventory

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Welcome/Pre-Site Visit Call Specifics

- Asked if there is a hospital owned pharmacy
- Asked if there were any other pharmacies (employee pharmacy? Infusion pharmacy?).
- Asked if 340B medications were supplied by the hospital pharmacy to the child sites or if they ordered their own meds
- Auditor will confirm dates of onsite and start time of 0800
- Auditor concluded the call by reiterating that all questions and communications must be submitted by "reply all" to original email string. Make sure 340B ID and Hospital name are in subject line.
- Information Request Form...asks for names and titles of people that will be on call and at audit, confirms contact at the entity to be used during the audit process, confirms audit dates, physical address and directions, parking instructions, lists requirements for on site audit (room requirements, office equipment, etc)
- Who needs to be available - EMR, credentialing

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HRSA AUDIT PROCESS

Bizzell Group Agenda
for 340B

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ONSITE AUDIT PROCESS

- Ask that pharmacies are contacted for copies, if escribed just print through your system if you can, if hard copy given then have pharmacy to provide the copy
- Tour of onsite pharmacy and clinic
 - Clinic visit
 - Asked to explained the entire process of ordering, receiving, tracking and inventory management details for 340B purchased drugs. May ask for a copy of the inventory page for certain drugs.
 - Asked to see communications for ordering and documentation mentioned by entity during explanation
 - Try to ensure consistent use of documentation and processes in all clinics

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ONSITE AUDIT PROCESS

- Pharmacy visit
 - Ask to see non 340B and 340B inventory and checks in place to keep them separated
 - Ask why pharmacy purchases non-340B medications
 - ER scripts, maybe some repacks if used, or inexpensive drugs
 - Asked pharmacists
 - What is process to receive 340B medications
 - What do you know about the 340B program?
 - Do you serve all patients here?
 - What do you check to qualify those scripts are eligible?
 - Do you fill employee scripts?
 - Any spot checking of specific drug inventories-auditor will pick a drug or two

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ONSITE AUDIT PROCESS PRESCRIPTION/ORDER REVIEW

- ✓ Outpatient Status
- ✓ Rx written in eligible location
- ✓ Hospital responsible for patient's care
- ✓ Provider is employed, credentialed, contracted by hospital
- ✓ Medicaid billing

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ONSITE AUDIT PROCESS
Tips for a smooth onsite visit

- Contact 340b Administrator and independent auditor for support ASAP
- Have a team work ahead
 - Audit the transactions not being worked on and identify and resolve issues
 - Notify contract pharmacy and clinics that HRSA will be visiting
 - Prep the employees at the pharmacy and clinics with auditor questions
- Know who your referral docs are
 - **Referral documentation is critical**
- If you have a specialty pharmacy as a CP anticipate 6 to 12 samples from that pharmacy

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ONSITE AUDIT PROCESS
Tips for a smooth onsite visit

- Multiple "runners"
- Have credentialing in the entrance meeting and begin to pull providers on transaction samples
- Answer auditor questions without elaborating
- Member of IT present or extremely close to conference room
- Bring in continental breakfast items and lunch for entire team (H2O/Coffee/Soda available)
- Have a plan as to who is driving auditor to offsite locations

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ONSITE AUDIT PROCESS
Tips for a smooth onsite visit

- If you have a pharmacy or contract pharmacy that qualifies scripts manually plan on the following questions
 - To pharmacists : "What do you check to ensure scripts are eligible?"
 - To tech: "When you get a rx what steps do you take before you type it?" "Show me"
- Have a copier and printer that is networked to computer running the EHR in the same room as the auditor or very nearby
- Ask questions at exit meeting

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AUDIT FEEDBACK FORM

- The engagement letter provided sufficient details to help assist in preparing for the audit.
- We were contacted by the auditor within two weeks of receiving the engagement letter.
- We were given adequate time to prepare for the audit
- The auditor provided a clear explanation of the audit process prior to the on-site portion of the audit.
- The auditor's data request was clear and complete.
- The auditor was reasonably available to answer questions during the pre-audit timeframe.

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AUDIT FEEDBACK FORM

- The auditor provided clear expectations of the on-site audit portion during the kickoff meeting.
- The auditor demonstrated knowledge of the subject matter.
- The audit was completed within the time allotted.
- The covered entity was given the opportunity to clarify any issues that came up during the audit.
- The auditor was courteous and professional at all times.
- General Questions
 1. Was any part of the audit process confusing to the covered entity? *
 2. What aspects of the audit were handled well? Please describe: *
 3. What additional suggestions does the covered entity have for the improvement of the audit process? *

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CONTRACT PHARMACY DISCUSSION

- Different models
- Specialty Pharmacy
- Direct / Indirect Remuneration (DIR)
- Alternative option to contract pharmacy relationships
- Hospital owned retail and filling employee scripts
- CAH member numbers

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All Scripts 225 Flat Fee for Brand and Generic			
CE PROFIT			
Dispensed Count	Profitability	% qualified	
2014/10	52	29.66	0.39%
2014/09	2061	13947.56	15.35%
2014/08	2196	17388.09	16.36%
2014/07	1948	12511.53	14.51%
		43876.84	46.63%
Winners Only Model			
CE PROFIT Dispensing Fee = Nothing < or = to 225			
Dispensed Count	Profitability	% qualified	
2014/10	13	533.61	0.10%
2014/09	556	32843.99	4.14%
2014/08	621	36073.28	4.63%
2014/07	1128	23310.19	8.40%
		92761.07	17.27%
Percentage Model			
CE PROFIT Dispensing Fee = 10% of Revenue			
Dispensed Count	Profitability	% qualified	
2014/10	52	834.5	0.39%
2014/09	2061	44667.88	15.38%
2014/08	2196	47860.19	16.36%
2014/07	1948	41481.6	14.51%
		13884.17	46.63%
Brand Only Model			
CE PROFIT Brand = \$35			
Dispensed Count	Profitability	% qualified	
2014/10	4	369.56	0.03%
2014/09	205	23829.81	1.53%
2014/08	235	27332.76	1.75%
2014/07	900	16845.68	6.70%
		68377.81	10.01%
Brand - Generic Model			
CE PROFIT Brand = \$305 Generic = \$15			
Dispensed Count	Profitability	% qualified	
2014/10	52	263.66	0.39%
2014/09	2061	23059.56	15.35%
2014/08	2196	26415.09	16.16%
2014/07	1948	21077.53	14.51%
		70915.84	46.63%

DIR Fees & 340B

- What are DIR fees?
 - Direct / Indirect Remuneration (DIR)
 - Assessed by Pharmacy Benefits Manager (PBM) on Rxs for Medicare beneficiaries (mostly) as fee for allowing pharmacy in their network
 - All pharmacies are impacted by DIR fees: chain, independent, mail order, specialty, etc.
 - All pharmacies have a Pharmacy Star Rating which impacts fee or what is "clawed back". The rating is based upon CMS and PBM quality measures.
<https://medicare.com/articles/pharmacy-star-ratings-dir-fees-5-myths/>

DIR Fees & 340B

- Why are DIR fees important in 340B?
 - Fee is assessed AFTER claim is adjudicated; either withheld from remittance (payment) or clawed back by PBM via invoice to pharmacy
 - 340B TPA picks up claims at adjudication and have no method for identifying nor assessing DIRs in 340B system
 - Example:
 - Rx adjudicated = \$200; Pharmacy Disp. Fee = \$20; Pharmacy pays CE = \$180
 - DIR Fee = \$20; in reality pharmacy received only \$180 therefore payment to CE should have been = \$160
 - DIR fee impact to pharmacy is compounded by 340B

DIR Fees & 340B

- What should be done if your contract pharmacy has concerns?
 - Let them know you are aware of the DIR's
 - Ask them the percentage of Medicare scripts they fill on 340B
 - You should be able to verify this number by pulling your own report
 - Ask them what percentage of those scripts have been subject to claw back
 - Have them send the examples for a month in the previous quarter

Original Amounts	Response Amounts	Paid
Cost..... 157.62	Cost..... .81	* Reim Basis: 06
Fee..... 5.00	Fee..... .45	* MAC Pricing Ingrednt.
Tax..... .00	Tax..... .00	Cost Paid

Tot Amt... 152.62	Tot Due... 1.26	Pro/Fee: .00
U & C.... 153.81	Copay... 1.26	P/Charg:
Response Auth#: 162873839496038999	3rd Pty... .00	\$Diff: 146.81

DIR Fees & 340B

What should be done if your contract pharmacy has concerns?

Cont.

- Assess the impact to savings if the 340B Medicare scripts were carved out
- If contract pharmacy is adamant about resolving:
 - Ask them what they have in mind
 - Consider adding language to your PSA or restructuring dispense fee
 - DIR fee could be built-in to dispense fee based upon actual calculations and previous data

Do not rush into amending the current PSA and seek advice

Alternative Option to Contract Pharmacy Relationships

- Phase 1
 - Is filling your employee scripts worth it?
 - Is your hospital:
 - 340B eligible
 - Self-insured
 - Currently having the majority of employees see eligible providers
- Phase 2
 - Is hospital owned retail for you?
 - If you answered **yes** to the above questions the answer is **YES**
 - If you answered **no** to one or more above questions the answer is **LIKELY**

Specialty Pharmacy PSA's and Role in 340B

- Look for **independent** specialty pharmacies in your region or State to partner for contract pharmacy relationships
 - Better dispense fee
 - Better flexibility
 - Potential for better patient care and outcomes
- How the big three operate (CVS, ESI, and Optum)
 - Will try and default specialty scripts to own specialty pharmacy
 - Will be able to and likely will keep a significant portion of the rebate
 - Will take a significant percentage of drug margin realized (usually 20% to 30%) as well as a **dispensing fee**

QUESTIONS?

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