RBC Cardinal Health DENVER

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CHC: How Health Centers Can Evolve with the 340B Program Amid Continued Uncertainty

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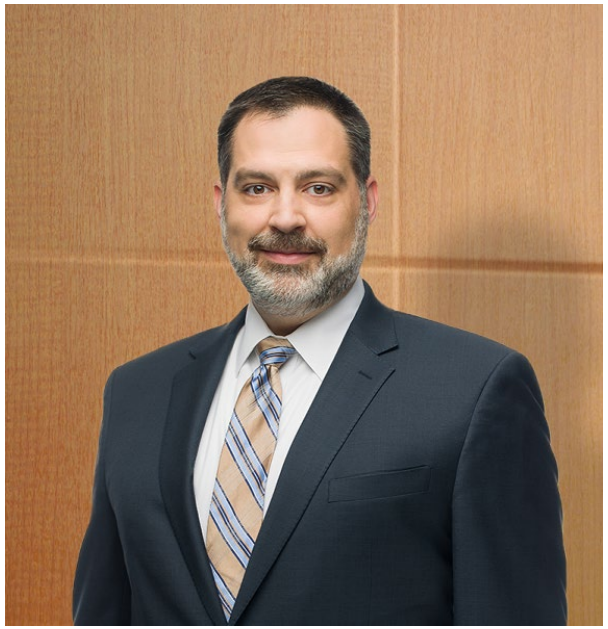
Disclosure Statement

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.

Pharmacist and Technician Learning Objectives

1. Discuss recent trends in pharmacy and vendor contracting, including pitfalls to avoid.
2. Outline how agency restructuring, litigation and legislation might shape the future of 340B shipments, transparency, and reimbursement at the state and federal levels.
3. Summarize recent approaches at health centers to patient definitions and referral prescriptions.

Speaker



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Contracting Trends and Pitfalls

Contract Pharmacies, TPAs, and More

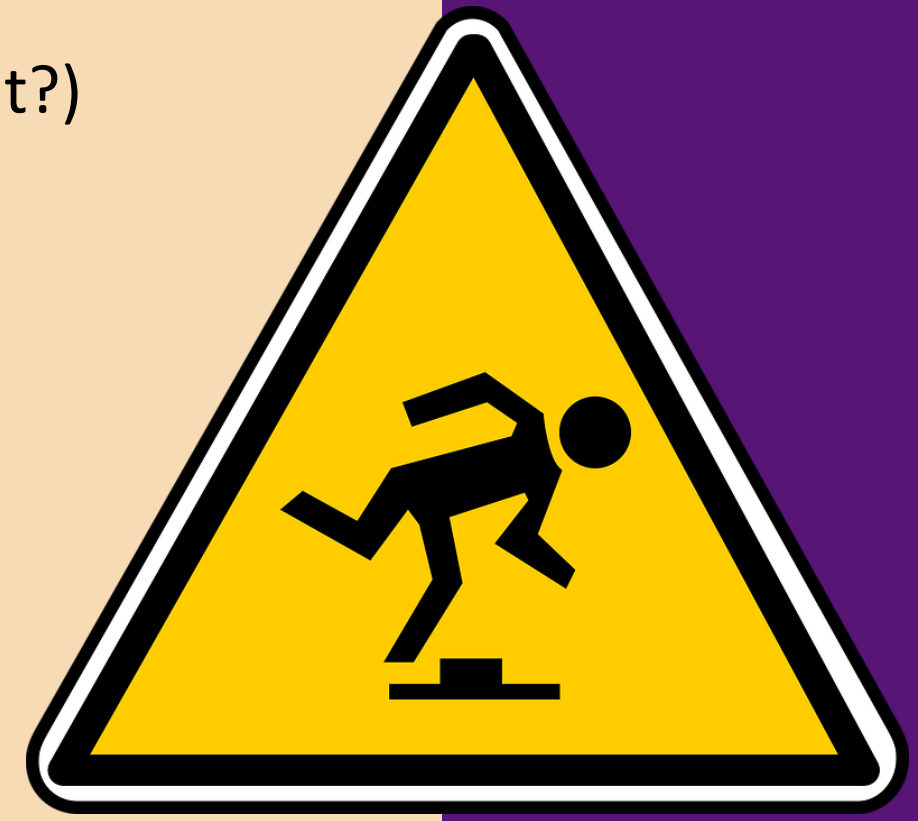
- The 340B landscape has become more complicated in recent years, involving new vendor types
- Joining contract pharmacies and third-party administrators, we now have:
  - Referral capture vendors
  - Direct payer contracting
  - Unwanted contracts (manufacturer audits, Second Sight Solutions)
  - Specialty arrangements (infusion service management, for example)
  - Independent auditor engagements

Contract Pharmacy Arrangements

- Contract pharmacy arrangements remain the most common 340B-themed agreement for health centers.
- Contract pharmacy agreements should all start from a place of compliance with HRSA's 2010 contract pharmacy guidance. These agreements should:
  - Be written and signed prior to the date of registration of the pharmacy in OPAIS
  - Be between a single covered entity and each pharmacy chain
    - Except for FQHCs and hospitals, each grantee location is a separate covered entity
    - HRSA has established policies relating to multisite grantees
  - Include and fully address each of HRSA's essential compliance elements - 72 Fed Reg. 10,272 (March 5, 2010)
  - Fully list all pharmacy locations that may be utilized under the agreement
  - May only include a single identifiable 340B covered entity and may not include a network of multiple covered entities unless authorized by HRSA

Watch Out For…

- Inventory management (physical or replenishment?)
- Claims qualification rules
  - Pharmacy can pre-screen?
  - Winners only?
  - Brand only?
- Dispensing Fee Format
  - Flat fee or percentage?
  - Reference Price?
  - Paid on dispense or replenish?



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Watch Out For…

- Promises to follow payer contracts, including using billing modifiers
- Willingness to permit independent audits, including meaningful access to prescriptions and billing records
- Any pharmacy restriction on your ability to resolve compliance issues in the manner you see fit
- Limitations of liability, failure to indemnify, other terms that greatly limit your recourse in case of an error

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TPAs – What to Consider

- **What services will TPA provide? What will you still need to do?**
- **How flexible and customizable is the TPA?**
    - E.g., will TPA permit and quickly operationalize modifications to prescription qualification metrics; will TPA facilitate reclassifying claims according to various timeframes under different pharmacy contracts (90-days versus 180-days); will TPA be accessible for technical support 24/7; will TPA provide hands-on support pre, during, and post HRSA, manufacturer, and/or PBM audit

TPAs – What to Consider

- Can you really get out? What are the wind-down and transition procedures when exiting TPA relationship or switching TPAs
    - Will inventory and accumulations transition to new TPA or will the Covered Entity reconcile old inventory and start with new inventory and accumulations
    - Transitioning patients (commercial, uninsured and underinsured)
    - Access to data, reports, inventory, etc. during transition
    - Resolving “newly” discovered compliance matters at termination
    - Timeframe and cooperation for transition
- TPA Fees
    - Percentage of gross sales? Flat fee per claim?

PBM/Payer Contracts

- Payers and Pharmacy Benefit Managers (PBMs) are increasingly trying to work directly with covered entities. PBMs manage the pharmacy benefit for insurers, including government programs like Medicare Part D, Medicaid, and TRICARE.
- Know what protections your state extends to 340B covered entities and contract pharmacies (available in 30+ states)
- Do not be afraid to push back on pricing or other terms (though some PBMs will be less flexible than others)
- Consider whether you can reach a mutually beneficial arrangement involving both medical and pharmacy services

Other Vendors

- In general: **know exactly what is being promised and for what price**.
  - Do not rely on promises – if it is not in the contract, it is not enforceable.
  - Do not accept language you do not understand – if you cannot follow, neither can a judge
  - Do not accept assertions that the agreement “has been vetted” or “approved by HRSA” or something like “[Law Firm] reviewed this.”
- Can include referral capture vendors, independent auditors, infusion management, etc.

Litigation, Legislation and Other Challenges

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Make It Stop…

- Contract pharmacy restrictions continue to expand
- Manufacturers continue to press for a rebate model
- The Inflation Reduction Act will reduce reimbursement and require 340B claims identification
- Medicaid MCO reimbursement is vanishing
- Federal 340B legislation is nowhere to be found
- HRSA reorganization poses threats

Contract Pharmacy Restrictions

- More than 40 manufacturers now impose at least some restrictions on contract pharmacy shipments
- 20 states have passed legislation prohibiting restrictions in at least some circumstances (2021 – AR; 2023 – LA; 2024 – KS, MD, MN, MO, MS, WV; 2025 – CO, ME, ND, NE, NM, OK, OR, RI, SD, TN, UT, VT
- The courts are unlikely to help – only one case is outstanding, in the federal appeals court covering Indiana, Illinois and Wisconsin. D.C. Circuit and Third Circuit (PA, DE, NJ, USVI) ruled in favor of manufacturers
- Congress is unlikely to help

Relief from Restrictions?

- Some covered entities have moved toward more in-house pharmacy models
- Some have been able to accommodate manufacturer restrictions
- Some have developed alternative distribution systems where drugs are delivered to the covered entity and then transferred to the pharmacy (though manufacturers are fighting back)
- Some have developed credit models where prior non-340B purchases are re-designated as 340B purchases, with pharmacy refunded for original non-340B purchase and CE paying 340B price instead

Litigation Continues

- Manufacturers continue to file suit in every state that passes contract pharmacy restriction prohibitions
- States have prevailed in every case except:
  - Judge in West Virginia granted injunction to prevent enforcement while case is pending
  - Attorney General in Kansas effectively agreed not to enforce the law

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Rebate Models

- Manufacturers are suing HRSA to attempt to force the agency to approve a 340B rebate model
  - CE would pay full price for all drugs and then submit utilization data to manufacturer (through Second Sight Solutions' Beacon platform most likely)
  - Manufacturer would "approve" claims data and send rebate to CE
- HRSA/HHS have continued to defend the litigation, but some language indicates that HHS might accept rebate model in some form
- Court ruled in favor of HHS' power to deny rebate request, but subject to further litigation
- Watch carefully to see how HHS implements Inflation Reduction Act

Inflation Reduction Act (IRA)

- Most people know the IRA for its impact on drug manufacturers – CMS negotiates a maximum fair price (MFP) for certain drugs. Starts with 10 drugs in 2026, then 15 more in 2027, then 15 more in 2028, then 20 more each year thereafter.
  - Negotiated price/MFP is the most a purchaser (pharmacy, CE) can pay.
  - Negotiated price/MFP is the most a Part D plan or Part B **will reimburse.**
- **Major impact expected** – drugs are selected based on Medicare spend, which means selected drugs are a combination of high-cost and high-volume drugs
- **No reimbursement margin** for selected drugs. Reimbursement = Cost

IRA Poses Logistical Problems

- MFP might be higher or lower than 340B ceiling price (though they should normalize within two quarters).
- Manufacturer likely will issue a standard rebate to each pharmacy that dispenses a negotiation drug to a Medicare beneficiary (WAC minus MFP)
- If drug was replenished/purchased by 340B entity, manufacturer will need to claw back the original rebate paid to the pharmacy and substitute it with no rebate (if the 340B price is less than the MFP) or a smaller rebate (if 340B price is higher than MFP, refunding difference between MFP and 340B price)
- **Requires reporting which drugs are 340B – details to be determined**
- Most likely, contract pharmacies will just stop using 340B for MFP drugs

Medicare and Medicaid Reimbursement Pain

- If nothing changes in IRA, we can expect to have fewer and fewer revenue-generating drugs each year.
- Budget pressures could affect 340B reimbursement for other Part B or Part D drugs, though nothing is imminent
- In some states, covered entities and contract pharmacies can use 340B drugs when billing Medicaid MCOs and get paid market rates
  - Big Beautiful Bill contains provision that requires states to pay cost for 340B drugs, though a state **can voluntarily choose** to pay up to non-340B rate, provided that covered entities must then publicly report on all their Medicaid-derived revenue
  - Why would a state pay more than it has to?

Congress Where Art Thou?

- Very little hope of 340B legislation moving in this Congress
  - Sen. Cassidy (R-LA) is Chairman of the HELP Committee (jurisdiction over 340B), and has floated 340B reform ideas
  - “Gang of Six” has replaced departing members, but still has yet to release a full bill
  - Nothing else really on horizon
- Why so pessimistic?
  - The margins are tight and nobody benefits politically from the fight

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HRSA No More

- HHS has proposed a significant reorganization that would eliminate HRSA
- Most HRSA bureaus would become part of Administration for a Healthy America (AHA).
  - Bureau of Primary Health Care
  - HIV/AIDS Bureau
  - Bureau of Maternal and Child Health
- Office of Pharmacy Affairs (OPA) would be moved to CMS
- Office of Population Affairs (Title X family planning – the "other OPA" since we usually talk about the Office of Pharmacy Affairs in 340B) slated for termination

What Can We Expect from CMS?

340B entities are very concerned about OPA joining CMS. Why?

- CMS is mostly concerned with limiting Medicaid and Medicare expenditures
- CMS has very little grantee knowledge
- CMS is in Baltimore and HRSA is in Rockville – unknown how many existing OPA employees would accept transfer
- CMS typically favors its own initiatives (Medicaid rebates, IRA implementation) over covered entity interests

Patient Definition and Other Mysteries

What Is the Current Patient Definition?

This is my response when asked to describe the current HRSA approach to the patient definition, *Genesis* ruling, referral prescriptions, telemedicine, clinical pharmacy/medication therapy management services, or infusion services:

What We Know…

- HRSA has given the universe very little guidance on most patient definition topics since the *Genesis* ruling in November 2023.
- We know that HRSA is using the 1996 three prong record maintenance + professional care + scope of grant test.
- We know that HRSA has **rejected *Genesis*** in audit reports issued in 2024.
- We know that HRSA **is applying location tests** for prescriptions.
- We know that HRSA will accept referral prescriptions if there is a documented referral out (specific to the outside provider) and notes coming back from the outside provider that describe the prescription

What We Don’t Know…

- We don’t know whether HRSA believes that a telemedicine provider, patient, both, or neither need to be in a site registered in OPAIS when a prescription is issued.
- We don’t know whether HRSA accepts that clinical pharmacy and medication therapy management (MTM) services are standalone health care services that can show that a health center has taken responsibility for an outside prescription
- We don’t know whether HRSA (OPA or BPHC) believes that a health center can infuse or administer any drug regardless of whether the underlying specialty is “in scope”

Horror Stories

- I have an AIDS Service Organization client who contested its 340B audit in February 2023 and has not heard a peep back
- I have a health center client that was forced to undergo an Eli Lilly 340B audit in May 2024 (after six months of fighting with HRSA) focused entirely on MCO duplicate discounts. Lilly still has not issued an audit report.
- I have a hospital and a health center who were cited for diversion after using 340B drugs to fill prescriptions for which they had an explicit referral for the exact same care and full records from the outside provider. We contested those in October 2024 and have not received a response.
- We have seen HRSA approve “good faith inquiries” from manufacturers directed to health centers that include dozens of questions – 47 in one case.

Horror Stories

- All of these horror stories pre-date the Trump Administration. It is unclear how OPA will balance manufacturer interests with covered entity interests under Sec. Robert F. Kennedy, Jr..
- On one hand, RFK Jr. has been consistently opposed to drugmakers on many topics.
- On the other hand, individuals within the Administration have been very critical of 340B program growth and the connections between covered entities and undocumented patients or patients receiving gender-affirming care.
- The first Trump Administration had an on-again off-again relationship with PhRMA – no significant harm to 340B entities.

What Are We Seeing?

- We are seeing a significant uptick in interest in performing infusions or other drug administration services within health centers or through contractual relationships.
  - Some parallels to contract pharmacy and in-house pharmacy models.
- We are seeing payers, especially union health plans and self-funded employer plans, reaching out directly to health centers to negotiate shared savings arrangements (e.g., we will pay you to manage all of our diabetic patients, but you agree to 20% lower drug reimbursement)
- We are seeing health centers with in-house pharmacies consider providing MTM services to enable them to fill outside prescriptions, especially for patients who have no other pharmacy to access
  - Partly a response to contract pharmacy restrictions

Questions? Discussion?

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