340B Grantees Conference

Responding to Contract Pharmacy Restrictions

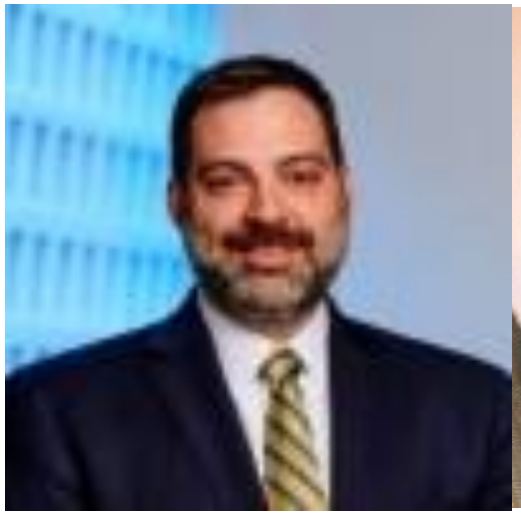
Agenda

- Introduction – Speakers, goals, and resources
- How we got to this point.
- Legal updates
- Successful strategies for mitigating the impact
- Strategies that require a bit of caution

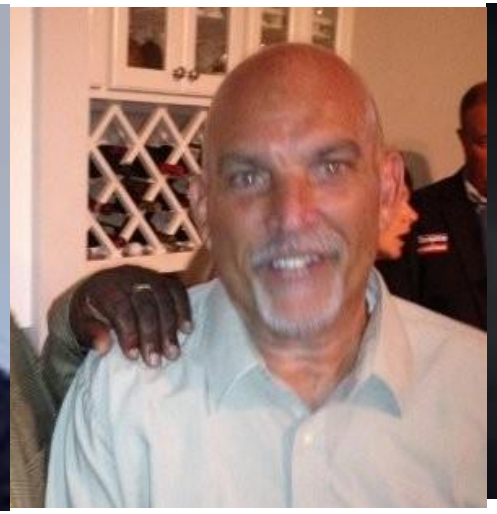
Our Speakers

Colleen Meiman
National Policy Advisor
State Associations of Community Health Centers

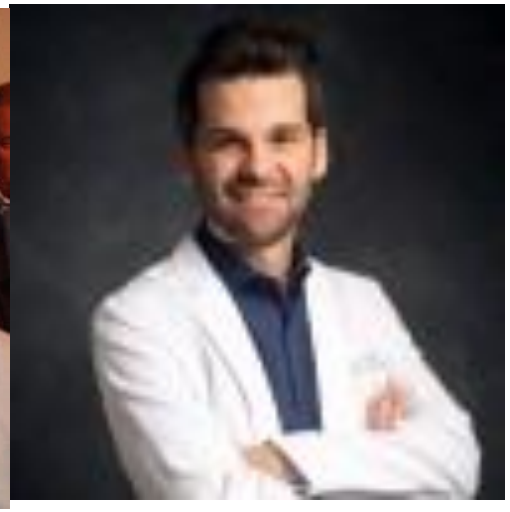
Bill Von Oehsen, JD
Principal
Powers, Pyles, Sutter, & Verville



Jason Reddish, JD
Partner
Feldesman Tucker Leifer Fidell



Rob Renzi
CEO
Big Bends Cares
RWC in Florida



Logan Yoho, RPh
Director of Pharmacy
Hopewell Health Center
FQHC in Ohio

Disclaimer

- William von Oehsen and Jason Reddish represent 340B providers, 340B provider groups and 340B service providers
- This presentation is not to be construed or relied upon as legal advice.

Goals of this session

1. To explain how we got to this point, and where we might be heading.
2. To offer concrete examples of measures that CHCs and RWCs have implemented to mitigate the impact of contract pharmacy restrictions, including:
   - a heads-up about strategies that pose potential risks
   - resources with more information on these mitigation strategies.
3. To emphasize the importance of Congressional advocacy about the need for protections from contract pharmacy restrictions (& other 340B threats.)

Three of tomorrow's session will build on this one:

1. The plenary on Compliant Strategies to Maximize your 340B program.
2. The plenary on 340B-ESP.
3. A breakout on setting up an in-house pharmacy.

KEY TAKEAWAYS: – Responding to Contract Pharmacy Restrictions

1. The 340B program is not on stable statutory footing – and our opponents know that.
2. There is a toolkit on responding to contract pharmacy restrictions at ***shorturl.at/aefJ4***
3. Successful strategies for mitigating the impact of contract pharmacy restrictions include:
    - Maximizing the use of your in-house pharmacy, through involving your whole staff, expanding the services you offer, finding ways to stand out from your competition, establishing creative delivery models
    - Switch patients to clinically-equivalent drugs that are still available at contract pharmacies.
    - Establishing your first in-house pharmacy, if appropriate.
4. Exercise caution when implementing Medication Therapy Management (MTM) programs, adding patients via telehealth, and providing 340B drugs to employees.
5. The path to ending contract pharmacy restrictions lies through Congress (or perhaps Arkansas.)

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The 340B program is not on sound footing.

- HRSA is powerless to enforce any part of the 340B statute/rules unless the statute explicitly give them regulatory/ enforcement authority in that area.
  - The 340B statute only gives HRSA enforcement authority in 3 areas – and contract pharmacies are not one of them.
  - In a recent letter to Congress, HRSA alluded to its limited ability to enforce contract pharmacy rules.

- HRSA's 340B program can't require hospitals to use 340B savings to expand access to underserved patients.
  - Grantees are required by the terms of their grants to use 340B savings this way – but hospitals don't have grants!

Court cases have – and will continue – to highlight these weaknesses.

- 2014: Lawsuit around orphan drugs and HRSA authority.
- 2018-19: First Genesis lawsuit -- around contract pharmacy restrictions.
- On-going: Second Genesis CHC lawsuit -- around patient definition.

Manufacturers with Current Contract Pharmacy Restrictions on CHCs & RWC

- **Eli Lilly** – Both CHCs and RWC
- **Astra-Zeneca** – Both
- **Sanofi** – CHCs
- **United Therapeutics** – Both
- **Boehringer Ingelheim** – CHCs
- **Merck** – CHCs (originally just hospitals)
- **Gilead** – Both, only brand name Hep C drugs
- **Bausch Health** - Both

Nine more manufacturers currently place contract pharmacy restrictions on hospitals but no grantees.

For legal and competitive reasons, I expect more manufacturers to start impose these restrictions soon.

A thought re: the term "PhRMA"

- We often use this term interchangeably to refer to the trade association, and all their individual members.
- It's important to note that there is significant variation among drug manufacturers, and their views on 340B.
- All five of the largest drug makers in the US impose contract pharmacy restrictions on hospitals – but only one (Merck) has placed them on CHCs, and none on RWCs.
    - Novo-Nordisk continues to watch out for grantees.

** Johnson & Johnson, Pfizer, Merck, AbbVie, and Bristol Myers Squibb.*

Legal Updates

So how should grantees respond?

Two general approaches:

1. Implement **strategies that mitigate the impact** of the restrictions on your patients and your organizations.
    - This is the focus of today's session.

2. Start **providing data to 340B-ESP.**
    - All manufacturers except Astra-Zeneca promise to re-instate 340B pricing at contract pharmacies if covered entities submit this data.
    - The pro's, con's, and realities of submitting the data are the focus of tomorrow's session.

Toolkit on responding to contract pharmacy restrictions.

shorturl.at/aefJ4

- While it was written for CHCs, it should be relevant to RWCs also.
- The Toolkit includes:
  - General info on restrictions
  - Strategies to mitigate the impact of restrictions
  - Info about providing data to 340B ESP, including legal and logistical issues.
- The Toolkit is a living document, and will be updated regularly. Please send any suggestions or corrections to colleen@fachc.org

Strategies for Mitigating the Impact
of Contract Pharmacy Restrictions

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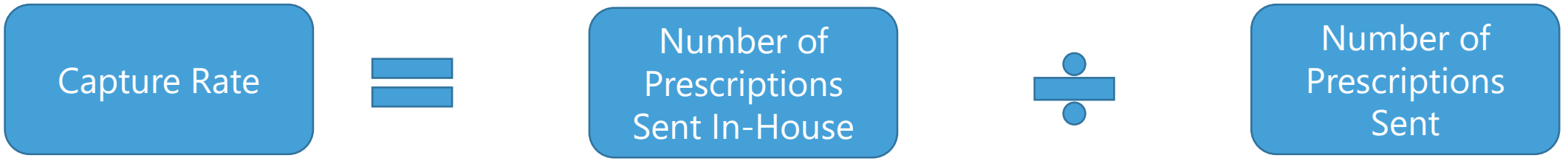
Maximizing In-House Pharmacy Utilization

- It is the responsibility of EVERYONE in the clinic
- How are your staff asking about pharmacy?
- Every staff member needs to know the impact of the loss of 340B Savings
- Show staff the clinical, financial, and operational benefits of your pharmacy to empower them to champion the program
- Consider warm hand-offs – patients trust their providers

Measuring Your Pharmacy Utilization Rate



Pharmacy Services

- Medication Synchronization (MedSync)
- Medication Compliance Packaging
- Delivery Services
- Prior Authorization Services
- Curbside Pickup
- Uninsured prescription assistance program

Identify Ways to Stand Out From Your Competition!

Delivery

- Delivery can be a way to expand the reach out your in-house pharmacy
- Check the state laws prior to implementation
- Home and/or clinic deliveries
- Employee vs. Contracted Service

Specialty Pharmacy

- Requires accreditation (URAC, ACHC, & NABP)
- Lengthy process: can take 9-12 months
- Costly process: ~$50,000
- May consider hiring a consultant to help with implementation process

Mailing Prescriptions

- Often used as a way to expand access to in-house pharmacy
- Check your PBM contracts
- Often restricted to a certain percentage
- You can get mail order contracts with some PBMs with Mail Service Pharmacy Accreditation (URAC)

Big Bend Cares / Care Point

- Rural area serving 8 counties
- RW and STD 340B ID
- Utilize 3 contract pharmacy entities
- Only have 2 major insurers in our location

Big Bend Cares Mitigation Efforts

- Transition In-house contract pharmacy to In-house self owned.
- Mail order
- Exception requests
- Drug reviews and utilization reviews (to ESP or not ESP)
- How you ask is more important than what you ask.
- Bring outside scripts in

Other Successful Strategies

- Switch patients to clinically-equivalent drugs that are still available at contract pharmacies.
- Only report to ESP on a limited number of manufacturers.
- For grantees with no in-house pharmacies, be strategic about which single contract pharmacy site(s) to receive 340B-priced drugs at.
- Plead your case directly to the manufacturer to request an exception.

Mitigation Strategies
(and some cautions)

- Self-Distribution
- Pharmacy Use Incentives
- Medication therapy management (MTM)
- Telemedicine
- Employees and dependents

Distribute the Drugs to Your Contract Pharmacies

- The manufacturer restrictions apply to drugs purchased by a covered entity and shipped to a contract pharmacy
- What if the drugs were shipped to the covered entity, or a covered entity distribution site, and then transferred to the contract pharmacies?
- If operationally feasible and pharmacies will accept transfers, could work, **but**…
- **Watch out for state wholesale distribution licensing requirements and Prescription Drug Marketing Act if ownership will be transferred**
    - Other licensing might be required

Encourage Use of In-House Pharmacies

- If you have in-house pharmacies, you might want to encourage patients to use those pharmacies instead of contract pharmacies
- **You can** explain to patients that you benefit when they use your pharmacy
- **You can** provide low-value non-cash or cash equivalent incentives (less than $15 per incentive; less than $75 per year)
    - No big box gift cards
- **You cannot** provide anything else of value or waive co-pays or cost-sharing obligations for federal payers *unless* specifically authorized to do so by your grant program or can meet Part D need test
- **You probably cannot** waive cost sharing amounts or provide other incentives to patients who have private insurance. Check payer contracts and state laws regarding patient inducement.

Seek New Patients

- You could identify opportunities to treat new patients
    - MTM/clinical pharmacy, employee/dependent programs (will be discussed)
- **Beware** of "too good to be true" proposals
    - Long-distance telemedicine with minimal patient contact
    - Specialist referral arrangements (especially where specialist refers existing patient to covered entity and covered entity pays anything back to the specialist)
    - "Clinical research" projects in name only

Medication Therapy Management (MTM) and Clinical Pharmacy

- *Genesis* case and plain meaning doctrine
- MTM services must be clinically appropriate and beneficial
- Health care records
- Ongoing relationship
- Scope of grant issues

Telemedicine

- Covid pandemic proved that telemedicine is effective
- Telemedicine has been endorsed in both 340B and Medicare programs
- Both patient and prescriber can be remote but conditions apply
- Delivery of telemedicine services must be billed and reflected in medical records like on-site services
- Risks
  - Scope of grant
  - Clinical appropriateness
  - Health outcomes

Employees and Dependents

- Employees and dependents must be CE patients to qualify for 340B
  - Clinically appropriate and beneficial
  - Health care records
- If CE is self-funded for employee health, ERISA provides broader flexibility for waiving copays to incentivize use of CE services
- Consider partnering with large self-funded employers to provide specialized care for high-cost employees, e.g. HIV, etc.
- Same risks – scope of grant, clinical appropriateness and health outcomes

The importance of
Federal Advocacy
re: contract pharmacy
(& other 340B threats)

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Currently, manufacturers are setting the 340B contract pharmacy rules.

- Both mitigation strategies and reporting to 340B-ESP are reactive approaches.
  - A handful of manufacturers are setting the rules, and we are forced to play by them.

- The long-term solution to this situation requires letting the Government set – and enforce -- the rules instead.
  - How do we do that?

The path forward lies through Congress.

- **The Administration** – including the White House – is out of "arrows in its quiver" under the current statute.
- **The Courts:**
  - Best case scenario – the cases drag on, and eventually make their way to the Supreme Court.
  - Worst case scenario – the Appeals Courts decide in favor of drug makers.
- **State laws** – States lack the authority to block all pick-pocketing, and Arkansas is fighting in court to enforce its contract pharmacy law. having . Also, PhRMA is betting that they are not enforceable.
- **Manufacturers** – We continue to reach out to them but are not optimistic that this will lead to broad-scale relief.

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Questions?

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