

JULY 15, 2021

# TAKE CONTROL OF YOUR 340B PROGRAM WITH AN IN-HOUSE PHARMACY

F | T FELDESMAN + TUCKER  
L | F LEIFER + FIDELL LLP

JASON REDDISH, J.D.  
Partner at Feldesman Tucker  
Leifer Fidell, LLP.



DAVID CHRISTIAN, 340B ACE  
President, CHC Pharmacy  
Partners, Inc.



BEN KELLY, RPh, MBA  
VP, Maxor Pharmacy  
Management

SPONSORED BY:  Maxor 340B

# MEET OUR PRESENTERS



# 340B CONTRACT PHARMACY UNDER UNPRECEDENTED ATTACK

Preparing for Uncertain Outcomes



JASON REDDISH, J.D.

Partner at Feldesman Tucker  
Leifer Fidell, LLP.





## JASON REDDISH, J.D.

Partner at Feldesman Tucker  
Leifer Fidell, LLP.

---

Jason is a Partner at Washington, D.C. law firm, Feldesman Tucker Leifer Fidell. He works primarily on 340B program and pharmacy issues affecting covered entities, 340B administrators, and contract pharmacies.

Assists safety net providers, pharmacies, and other stakeholders by negotiating and reviewing contracts relating to the provision of pharmacy and professional services. Jason has experience with working on dozens of 340B program contract pharmacy and pharmacy services agreements and serves as an authority on 340B program contract pharmacies, including transactional, operational, and compliance concerns.

He received J.D. from Tulane Law School and B.S. with honors in Physiology/Neurobiology from the University of Maryland.

[JReddish@ftlf.com](mailto:JReddish@ftlf.com) | (202) 466-8960

# HISTORY OF CONTRACT PHARMACY MODEL

---

- 340B statute, passed in 1992 does not address contract pharmacies
- Many covered entities (CEs) did not have an in-house pharmacy, limiting benefit of 340B Program
- In 1996, HRSA permitted CEs to contract with a commercial pharmacy to dispense 340B drugs to eligible patients but on a limited basis (61 Fed Reg. 43,549 (August 23, 1996))





# THE MODERN CONTRACT PHARMACY ERA

---

- HRSA issued revised guidance in 2010 (75 Fed. Reg. 10,272 (March 5, 2010))
- Allows contracting with multiple pharmacies, pharmacy chains, and/or operating an in-house pharmacy
  - Applies to all contract pharmacy arrangements
  - Guidance replaces all prior guidance
  - Substantial emphasis on compliance – in fact, not just on paper





# SMOOTH SAILING...

---

The contract pharmacy model has operated effectively for the past decade, allowing many covered entities to expand their programs to provide more comprehensive services to eligible patients.

# ...UNTIL NOW.

---

## Refusal to Ship 340B Drugs

- **Eli Lilly** refusing to ship 340B drugs to contract pharmacies since September 1
- **AstraZeneca and Sanofi** (unless participating with Second Sight Solutions) since October 1
- **Novartis** refusing to ship to hospital contract pharmacies more than 40 miles from “parent” site
- **United Therapeutics** refusing to ship to new contract pharmacies (since November 20); for all contract pharmacies by May 13, 2021, unless participating with Second Sight Solutions
- **Novo Nordisk** refusing to ship to hospital contract pharmacies beginning January 1, 2021
- **Boeringer Ingelheim** announced July 1, 2021 that it would not ship to hospital contract pharmacies





# MANUFACTURER ASSAULTS ON 340B PROGRAM

---

## Limits on Contract Pharmacy Network

- **Eli Lilly, AstraZeneca, United Therapeutics, and Novo Nordisk** will allow you to name one contract pharmacy per ENTITY (*i.e.*, one Walgreens store, not the whole chain)
- **Sanofi** recently created a mechanism to add one contract pharmacy per ENTITY if the entity has no other pharmacy, but you must register on the Second Sight Solutions website and accept Terms of Use to nominate the pharmacy. NO CLAIMS DATA REQUIRED
- **Boeringer and Novartis** - unclear

# GOVERNMENT RESPONSE TO MANUFACTURERS

## HRSA Responds...

Early June 2020

HRSA advised Eli Lilly that it had no authority to enforce contract pharmacy guidance

Early September 2020

HRSA said it was “considering” whether Lilly’s actions constituted an overcharge

September 21, 2020

HHS Counsel wrote a strongly worded letter to Eli Lilly that implied further action

December 30, 2020

HHS Counsel issued an Advisory Opinion clearly concluding that manufacturers have a responsibility to sell 340B drugs to covered entities that dispense through contract pharmacies

# HRSA PUTS MANUFACTURERS ON NOTICE

---

- **On May 17, 2021**, HRSA sent a letter to each offending manufacturer
- **Concluded (like December 30 letter)** that manufacturers are overcharging covered entities
- **Set June 1** compliance deadline
- **Manufacturers** filed suit instead




**WARNING**





# FIGHTING BACK

FELDESMAN + TUCKER + LEIFER + FIDELL 

# COVERED ENTITY LITIGATION

---

## NACHC Litigation

- Due to Supreme Court precedent, covered entities cannot directly sue drug manufacturers to enforce 340B statute
- HHS has not taken substantive action to date
- HRSA was required to implement an Administrative Dispute Resolution (ADR) process prior to September 23, [2010](#), but had not
- NACHC filed suit demanding that HRSA finalize the ADR process immediately
- HRSA did, effective January 13, 2021
- Litigation stayed pending outcome of ADR
- [But...](#) ADR stayed due to Eli Lilly litigation

# COVERED ENTITY LITIGATION

---

## Hospital Litigation

- Demands that HHS order manufacturers to comply and issue refunds to hospitals refused discounts; demands referral to OIG for penalties
- Dismissed

## Other Grantee Litigation

- Demands promulgation of ADR process; enforce right to purchase; refer to OIG for penalties; revoke manufacturer Medicare/Medicaid agreements
- Currently stayed pending ADR and ADR currently stayed for Eli Lilly



# ADR PROCESS

---

## ADR Process was long delayed

- ADR process was required by September 2010. Proposed in 2016. Withdrawn in 2017
- NACHC (through FTLF) filed complaint asking the court to require HHS to establish ADR process
- Re-proposed in December and became active January 13 (after NACHC complaint was filed)
- Administrative complaint to ADR panel filed on January 13; request for preliminary injunction filed next day
- ADR panel appointed in June 2021
- In May, ADR Process Frozen by Federal Court in Indiana (Eli Lilly)

# ADR FILING

---

## NACHC ADR FILING

- NACHC has standing to represent all health centers
- The 340B statute requires drug manufacturers to sell outpatient drugs to covered entities at a price that does not exceed the 340B ceiling price. They do not get to pick and choose which drugs or where to ship them
- HHS December 30 advisory opinion confirms

## OUTCOMES?

- Equitable relief?
- HHS can assess civil monetary penalties
- HHS can terminate manufacturer from Medicare/Medicaid



# MANUFACTURERS CHALLENGE PROCESS

---

- Eli Lilly, AstraZeneca, and Sanofi have **filed suit to invalidate the December 30, 2020, HHS advisory opinion**
- Eli Lilly, AstraZeneca, Sanofi, and PhRMA have **filed suit to invalidate the ADR rule**
  - Claiming it was improperly promulgated due to procedural deficiencies; hoping to buy time
  - Eli Lilly and Sanofi also seeking Preliminary Injunction to stop ADR from moving forward with the pending suit





# MANUFACTURERS CHALLENGE PROCESS

---

- Court GRANTED Lilly request to stop ADR – ADR stayed at least for Lilly
- Court GRANTED AstraZeneca request to vacate Dec. 30, 2020 HHS opinion – HHS removed the opinion, but litigation continues as HHS still plans to sanction manufacturers

# SO NOW WHAT?

---

- Whether HRSA has the authority to require drug manufacturers to ship 340B drugs to contract pharmacies **will likely be decided by a court**
- If HRSA's interpretation of the 340B statute is not persuasive, **the contract pharmacy guidance could be vacated**
  - If manufacturers are not required to ship 340B drugs to contract pharmacies...**they won't**
- If HRSA's interpretation of the 340B statute is persuasive, HRSA will likely be able to compel manufacturers to sell 340B drugs to contract pharmacies
- **It might be all or nothing**

# HOW DOES ALL OF THIS GET RESOLVED

## Legislative

Congress fixes loopholes in law **BUT** dangerous to open up the law

## Litigation

HRSA prevails in contract pharmacy model litigation



# CE-OWNED PHARMACY CONSIDERATIONS



DAVID CHRISTIAN, 340B ACE  
President, CHC Pharmacy Partners



## DAVID CHRISTIAN, 340B ACE

President at CHC Pharmacy Partners

---

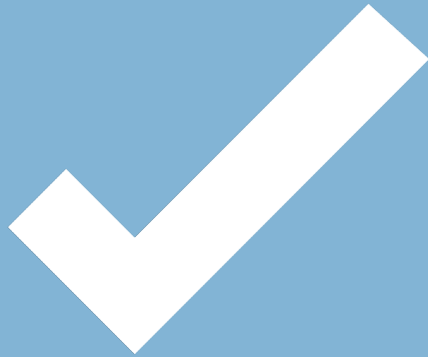
David Christian received his Pharmacy Degree from VCU Medical college of Virginia in 1995, and has been the pharmacy director for Central Virginia Health Services for the last 5 years. He manages the health center's two entity-owned pharmacies and over 100 contracted pharmacies.

He is also a 340B University Faculty member for Apexus and HRSA's designated resource for 340B education. He plays an active role in assisting Apexus with providing guidance throughout the country while serving as the Chairman of the Apexus FQHC Advisory Counsel.

He has assisted health centers around the nation to implement and develop 340B programs.

# PROS of an ENTITY-OWNED PHARMACY

---



1. Protected by statute
2. Leverage 340B savings
3. Eliminate TPA fees
4. Decrease pharmacy dispensing feeds
5. Mail-order pharmacy possibilities
6. Pharmacist works directly for the covered entity, which is beneficial in many ways:
  - Increases CDSS/UDS measures
  - Increase patient compliance
  - Increases positive outcomes
  - Decreases hospitalizations
7. Cost decrease to patients
  - True slide
  - Enroll in MAP (PAP)
  - Different methods of payment

# CONS of an ENTITY-OWNED PHARMACY

---



1. Cost
2. Space
3. Expertise
4. Staffing
5. 3<sup>rd</sup> Parties and Vendors
6. Licensure – DEA, NPI, State
7. Inventory Control
8. Reporting Ability



# OUR SOLUTION

---

CHC Pharmacy Partners supports health centers in opening and managing off-site entity-owned pharmacies. Leveraging the experience of our team, we are able to support all aspects of off-site entity-owned pharmacy services including...

- Contracting
- Licensing
- Staffing
- Clinical Services





# OUR SOLUTION

CONTINUED

---

## Economies of Scale

Leveraging vendor contracts and cost savings through shared services

## Reporting Ability

Monthly and annual reporting to Management and Board of Directors

## Policies and Procedures

Developing and maintaining appropriate operational and 340B policies and procedures

## 340B Compliance

Monthly and annual compliance reviews to ensure a 340B compliant pharmacy program

## Maximizing Prescription Capture

Helping the CE increase the capture of prescriptions through the off-site entity-owned pharmacy

## Shared Resources

Multiple managed off-site pharmacy locations (e.g. Pharmacy A hours 8:30-12:30 and Pharmacy B hours 1:00-5:00)

# IN-HOUSE PHARMACY 101



BEN KELLY, RPh, MBA

Vice President, Maxor Pharmacy Management



[bkelly@maxor.com](mailto:bkelly@maxor.com) | (407) 325-4021

## BEN KELLY, RPh, MBA

### Vice President at Maxor Pharmacy Management

---

Ben Kelly, Vice President of Operations, joined Maxor Pharmacy in December 2006. Ben's more than 20 years of healthcare experience is focused on his passion for customer service and an entrepreneurial spirit to grow multiple companies to a critical size. Ben possesses vast knowledge in specialty pharmacy, 340B operations and health system outpatient pharmacy.

Ben works with Maxor's On-Site Pharmacy Operations throughout the U.S. The role includes serving as C-level account representative for day to day needs, standardizing and driving operational efficiencies among sites, P&L management, ensuring the highest level of customer service and clinical care is provided. Business Development is a key responsibility and client needs have led to a variety of service lines including specialty accreditation, limited distribution drug networking, bedside delivery, patient assistance coordination, employee mail order and benefit coordination, research support, department of defense program compliance and 340B program compliance.

Outside of his day to day responsibilities, Ben is a 340B lead for Maxor's outside consulting engagements.

Ben received his Bachelor of Science in Pharmacy from University of Georgia and his MBA from Crummer Graduate School of Business at Rollins College.



# **TAKE CARE OF PATIENTS**

---

**...in a financially sustainable way**



# BEHIND THE CURTAIN LIES A SOPHISTICATED OPERATION

Licensing

Policy and  
Procedures

Inventory  
Management

Home Delivery

Information  
Systems

Patient  
Experience

Payor  
Contracting

Wholesaler  
Contracting

Provider  
Coordination

Specialty  
Accreditation

340B  
Compliance

Healthcare  
Analytics

Staff Training  
and Oversight

Accounting

Adherence  
Programs

























Sliding Fee  
Programs

PAP  
Assistance

























Compliance  
(Regulatory and  
Payor)



# START-UP PHARMACY OPTIONS

	INVESTMENT	TIME	SPACE	EXPERTISE	PAYOR ACCESS	DRUG ACCESS
Contract Pharmacy						
Offsite Owned Pharmacy (Management Outsourced)						
Onsite Owned Pharmacy (Management Outsourced)						
Onsite Owned Pharmacy						

# ONGOING PHARMACY OPTIONS

	PATIENT CARE	PATIENT FINANCIALS	STAFFING	CLINIC FINANCIALS	PAYOR ACCESS	DRUG ACCESS
Contract Pharmacy						
Offsite Owned Pharmacy (Management Outsourced)						
Onsite Owned Pharmacy (Management Outsourced)						
Onsite Owned and Managed Pharmacy						

# IN-HOUSE PHARMACY 101

---

## PHARMACY MANAGEMENT

- Policy & Procedures
- Staff Oversight
- Metrics and Benchmarking
- Clinic Coordination
  - Provider meetings, Medication safety committee, Patient Assistance Coordination

## INVENTORY CONTROL

- Wholesaler Contract Management
- Ordering Optimization
- Limited Distribution Drug access
- Cycle Counting and auditing
- Pick Point Will Call System\*

# IN-HOUSE PHARMACY 101

---

## COMPLIANCE

- 340B compliance
- Pharmacy Practice Act Compliance
- Controlled Substance Act Compliance
- Recall Management
- Non-Sterile Compounding Compliance
- Drug Quality and Security Act Compliance
- Payment Card Industry Compliance
- Payor Compliance

## LICENSING

- Board of Pharmacy (In state and out of state)
- DEA including CSOS coordination

## LEGAL



# IN-HOUSE PHARMACY 101

---

## CONTRACTING

- NPI & NCPDP
- PSAO (Independent network access)
- Review, negotiation and execution support for direct contracts
- MAC appeals and credential reporting
- PBM Audit support – Preparation and appeal

## ANALYTICS

- Healthcare Analytics
  - Adherence, Gap in Therapy, Narcotic Risk Assessment
- 340B Analytics
  - Program compliance, Program optimization



# IN-HOUSE PHARMACY 101

---

## ACCOUNTING

- Controller
  - Profit & Loss, Audit Support
- Accounts Receivable
  - Centralized payment and detail level reconciliation of claims
- Accounts Payable
- Cash Management
- Financial Planning & Analysis
  - Budgeting, Forecast, Change impact
- Credit Card processing

## SPECIALTY ACCREDITATION

- Patient Management Program
- Metrics tracking
- Mock Audits

# IN-HOUSE PHARMACY 101

---

## HUMAN RESOURCES

- Recruiting
- Compensation
- Training
- Credentialing

## MARKETING

- Advertising
- Signage
- Collateral

# IN-HOUSE PHARMACY 101

## PHARMACY DISPENSING SYSTEM

- Pharmacy Dispensing Software
- Pharmacy system transactions
- Prescription Imaging
- Prescription Authorization
- Prescription Verification
- Bar code verification
- Interactive Voice Response (IVR)
- Web Based Refills
- Smartphone App

## ADDITIONAL SYSTEMS AND INTERFACES

- Sliding Fee Program
- HL7 Interface
- Reporting Interface (manufacturer)
- Integrated Point-of-Sale (POS)
- Mail Order Shipping and Tracking
- Temperature Monitoring
- Patient Management Program



# IN-HOUSE PHARMACY 101

---

## TECHNOLOGY SUPPORT

- Hosting
- 24/7 Help desk
- Pharmacy claims processing support
- Payor files
- Pricing files
- Computers & Network
- Software Licensing
- Security, Availability, Privacy

# MAXOR 340B OVERVIEW



REBECCA RUNYAN

Senior Sales Executive, Maxor 340B





## REBECCA RUNYAN

Senior Sales Executive at Maxor 340B


---

Rebecca brings over 25 years of healthcare pharmacy and 340B experience to help her clients. She spent over 11 years with McKesson Corporation helping clients navigate 340B, drug purchasing optimization and operational efficiency within the pharmacy. In addition, she has worked with several 340B Third Party Administrators giving her a thorough understanding of the challenges encountered by covered entities.

Rebecca's passion to help those who serve the vulnerable in our communities, has led her to Maxor340B. Maxor's solutions are built with transparency, ease of use and compliance in mind. With today's challenges in managing a 340B program, Maxor offers multiple vertically integrated solutions with central reporting to give clients a full view of their financial and operational benchmarks across all solutions. Maxor customizes a solution to meet each covered entity's specific needs.

Rebecca resides in the country outside of Nashville, Tennessee. She is a graduate of the University of California, Davis, with a B.S. in Nutrition Science/Biochemistry.

[rirunyan@maxor.com](mailto:rirunyan@maxor.com) | (615) 714-6330

A person wearing a striped shirt is shown from the waist down, standing on a ledge and stacking wooden blocks. The background is a cityscape with tall buildings. The text is overlaid on the left side of the image.

# AS A LEADER IN YOUR ORGANIZATION, YOU NEED A PARTNER WHO...

- Truly understands your goals and operations
- Thinks outside of the box to solve your challenges
- Treats your business like it is their own
- Is fully transparent
- Successfully moves ideas to solutions through a seamless implementation process
- Creates solutions that drive both patient and staff satisfaction
- Provides a compliant solution that **equips you for success**

# MAXOR 340B IS UNIQUELY POSITIONED

Maxor has **20+** years of experience helping 340B CE's manage and maximize their 340B savings.



Our multiple divisions allow us to customize our solutions to **meet your specific needs.**



We are **uniquely positioned to pivot** as the industry changes.



Our depth of 340B entity experienced professionals is the **foundation to your success.**





# OUR SOLUTIONS

---

**Your Blueprint for 340B  
Success**

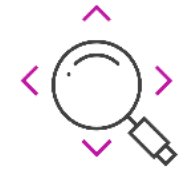
**Contract Pharmacy  
Administration**



**340B Program  
Management**



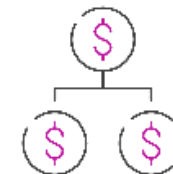
**Referral Capture  
Service**



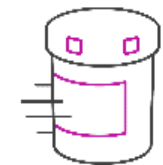
**Onsite Pharmacy  
Management**



**Split Billing**



**Specialty and Mail  
Order Services**



# THANK YOU

## IT'S TIME FOR QUESTIONS!

F | T FELDESMAN + TUCKER  
L | F LEIFER + FIDELL LLP

JASON REDDISH, J.D.  
Partner at Feldesman Tucker  
Leifer Fidell, LLP.



DAVID CHRISTIAN, 340B Ace  
President, CHC Pharmacy  
Partners, Inc.



BEN KELLY, RPh, MBA  
VP, Maxor Pharmacy  
Management