State of Louisiana

Pharmacy Benefit Manager (PBM) Monitoring Advisory Council

Commissioner, La. Dept. of Insurance President, La. State Board of Medical Examiners President, La. Board of Pharmacv Attorney General

Director, Public Protection Division, La. Dept. of Justice Secretary, La. Dept. of Health

President, La. Academy of Physician Assistants {vacancy}

President, La. State Medical Society

President, La. Association of Nurse Practitioners

President, La. Pharmacists Association

President, La. Independent Pharmacies Association

President, National Association of Chain Drug Stores

President, Pharmaceutical Research & Manufacturers of America {vacancy}

President, La. Academy of Medical Psychologists

President, La. Association of Health Plans

President, of a PBM licensed by the Board of Pharmacy and selected by the Louisiana affiliate of the Pharmaceutical Care Management Association

President, La. Association of Business & Industry {vacancy}

Chief Executive Officer, La. Business Group on Health

President, La. AFL-CIO

President, La. Association of Health Underwriters

The Governor

Chair. House Committee on Insurance Chair, Senate Committee on Insurance Chair. House Committee on Health & Wealth Chair, Senate Committee on Health & Wealth

The advisory council shall provide monitoring of pharmacy benefit managers in Louisiana to advise the legislature, commissioner of insurance, and Board of Pharmacy on the most effective and efficient manner of regulation of pharmacy benefit managers to ensure the protection of the public. The advisory council shall advise on matters that include but are not limited to the licensure and regulation of pharmacy benefit managers set forth in Title 22, Title 37, and Title 40 of the Louisiana Revised Statutes of 1950, applicable rules and regulations of state agencies, and federal laws or rules relative to pharmacy benefit managers. [La. R.S. 40:2869]

Meeting Minutes

January 11, 2023

A regular meeting of the council was held on Wednesday, January 11, 2023 at the Louisiana Board of Pharmacy located at 3388 Brentwood Drive in Baton Rouge, Louisiana 70809.

1. Call to Order

Chairman Mills called the meeting to order at approximately 10:33 AM.

2. Quorum Call

Chairman Mills asked Mr. Fontenot to call the roll of members to establish a quorum.

Members Present:

Mr. Frank Opelka (For the Commissioner of the La. Dept. of Insurance)

Mr. Marty McKay (President of the La. Board of Pharmacy)

Mr. D. Jeddie Smith, Jr. (For the La. Attorney General)

Ms. E. Sue Fontenot (For the Secretary of the La. Dept. of Health)

Ms. Lauren Bailey (For the President of the La. State Medical Society)

Dr. Lisa Bayhi (For the President of the La. Association of Nurse Practitioners)

Mr. Ricky Guidry (President of the La. Pharmacists Association)

Mr. Don Caffery (For the President of the La. Independent Pharmacies Assoc.)

Ms. Shelly Dupre (For the President of the Nat'l Assoc. of Chain Drug Stores)

Mr. Jeff Drozda (For the President of the La. Association of Health Plans)

Mr. Robert Rieger (For the President of a PBM / Prime Therapeutics / PCMA)

Ms. Diane Davidson (For the CEO of the La. Business Group on Health)

Mr. Joshua Sonnier (For the President of the Louisiana AFL-CIO)

Ms. Kristy Copeland (For the President of the La. Assoc. of Health Underwriters)

Ms. Tara LeBlanc (For the Governor)

Rep. Mike Huval (Chairman of the House Committee on Insurance)

Rep. Larry Bagley (Chairman of the House Committee on Health & Wealth)

Sen. Fred H. Mills, Jr. (Chairman of the Senate Committee on Health & Wealth)

Members Absent:

The president of the Louisiana State Board of Medical Examiners

The director of the public protection division of the Department of Justice

The president of the Louisiana Academy of Physician Assistants

The president of the Pharmaceutical Research & Manufacturers of America

The president of the Louisiana Academy of Medical Psychologists

The president of the Louisiana Association of Business & Industry

The chairman of the Senate Committee on Insurance

Staff Present:

Mr. Joe Fontenot (Executive Director, La. Board of Pharmacy)

Mr. Carlos M. Finalet, III (General Counsel, La. Board of Pharmacy)

Guests Present:

Cheryl Tolbert – Louisiana Business Group on Health
Linda Spradley – Spradley & Spradley
Alison Landry – Our Lady of the Lake Retail Pharmacies
Crystal Carter – Louisiana Pharmacists Association
Representative Chris Turner – Louisiana House of Representatives
Christine Peck – Attorney, Senate Health & Welfare Committee

Jennifer Borrillo – Louisiana Center for Bleeding and Clotting Disorders Ellen Palmintier – Director of State & Federal Relations, Tulane University

Mr. Fontenot certified 18 of 25 members were present, constituting a quorum for the conduct of official business.

Chairman Mills informed the council that the legislative session is nearing, bills will be prefiled, and a goal of the PBM Monitoring Advisory Council is to bring issues to the council. He also mentioned the council should look at and consider what is occurring in other states. The Chairman introduced Ms. Christine Peck, Senate Health & Welfare Attorney, who drafts legislation.

3. Consideration of Minutes from Previous Meeting

Chairman Mills asked for a motion to accept the draft minutes of the previous meeting held on October 13, 2022. Mr. Josh Sonnier offered a motion, Ms. Lauren Bailey seconded the motion, and the motion was adopted after a unanimous vote of the remaining members in the affirmative declaring the minutes approved as presented.

4. Opportunity for Public Comment

Chairman Mills solicited general public comments about non-agenda matters; there were none.

5. PBM Practice Impact on 340b Pharmacies

Chairman Mills introduced Ms. Ellen Palmintier and Ms. Jennifer Borrillo with Tulane University to present to the council a presentation entitled "The 340B Program & PBM Discriminatory Reimbursement", hand outs were made available to the council (see attached).

Ms. Palmintier and Ms. Borrillo presented information from the handouts which provided an overview of the federal 340B drug discount program, how it works, and the current issue of discriminatory reimbursement by PBMs. Ms. Palmintier explained the federal response to discriminatory reimbursement is slow and several states have passed laws to address the issue. Ms. Palmintier also explained the impact which will be felt without legislation to address the issue.

Chairman Mills asked the council to present their comments and questions.

Mr. Opelka (LDI) commented in regards to a Section of the federal Public Health Safety Act and asked if anyone approached HHS to enforce in this context. Ms. Palmintier said she would follow up with Mr. Opelka's suggestion.

Ms. Bailey (LSMS) requested a list of different states who have actually taken action in regards to passing legislation. Ms. Palmintier said she would follow-up and provide a list.

Mr. Rieger (PCMA) requested an example of discriminatory reimbursement using a specific drug and reimbursement situation. Ms. Borrillo responded by explaining her experience in dealing with the reimbursement involving clotting factors. Representative Turner offered to provide specific examples to Mr. Rieger as a follow up to the meeting.

Mr. Rieger (PCMA) asked if the impact is across commercial insurance, Erisa self-insured plans, Medicaid, and Medicare. Ms. Borrillo responded that Medicaid is carved out and Medicare is served with no difficulty. However, she stated the impact is felt in the area of self-insured and commercial plans.

Mr. Guidry (LPA) commented that the situation is similar to what has happened to retail pharmacy but the PBMs are taking it a step further by targeting the discount received by 340Bs.

Dr. Bayhi (LANP) asked, what happens to the patients when they can't get their medications from 340Bs. Ms. Borrillo responded by saying the patients end up in emergency departments and the tax payers ultimately incur the expense.

Ms. Davidson (LBGH) asked if the problem is stemming around the health plan having an agreement to exclusively use the specialty pharmacy of the PBM. Ms. Borrillo responded in the affirmative by stating, "sometimes, because the patient does not have a choice."

Mr. McKay (LABP) commented that FQHCs and rural hospitals also depend on 340B funds and they could not stay open without it.

Chairman Mills stated he would like to see any proposed legislation on this topic brought to the council for discussion prior to it going to committee.

6. Review of Industry Trends and Emerging Issues

Chairman Mills provided a handout entitled "Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies, Retail Pharmacies, Mail-Order Pharmacies and Providers, 2022" (see attached). Chairman Mills referenced a conference call that he and Ms. Peck participated in the previous week to discuss trending issues across the country and he stated the next meeting of the council will have this topic on the agenda.

7. Review of Rulemaking Activity

Mr. Fontenot (LABP) reviewed the Board of Pharmacy's current PBM Regulatory Project in response to Act 536 (SB99) of the 2022 regular session.

Mr. Opelka (LDI) provided information regarding recent regulatory action by the Louisiana Department of Insurance (LDI) against Express Scripts pertaining to prompt pay complaints by pharmacists. Mr. Opelka provided a high-level overview of the LDI

complaint process at the request of Chairman Mills.

8. Review of Potential Legislation

None offered for discussion.

9. Calendar Notes

Chairman Mills informed the council members that the next meeting scheduled for April 12 will have to be rescheduled due to conflicts with the legislative session and the new date will be provided.

10. Other Matters

No other matters were discussed.

11. Adjourn

Having completed the tasks itemized on the posted agenda, with no further business pending before the council and without objection, Chairman Mills adjourned the meeting at approximately 11:18 a.m.

Minutes prepared by Joe Fontenot, Executive Director, La. Board of Pharmacy: approved as presented during subsequent meeting of the Council on April 6, 2023

THE 340B PROGRAM & PBM DISCRIMINATORY REIMBURSEMENT

Jennifer Borrillo, MSW, LCSW, MBA

Clinical Faculty & Executive Director of 340B Program & Pharmacy, Louisiana Center for Bleeding and Clotting Disorders

Ellen Palmintier, JD, RN

Director of State & Federal Relations, Tulane University

The 340B Program

- ► The Federal 340B drug discount program was first established in 1992 through bipartisan legislation to allow safety-net providers to buy outpatient medicines for less.
- ► The program is **NOT** funded by taxpayers. Instead, pharmaceutical companies are required to sell drugs at discounted prices to certain types of not-for-profit safety net hospitals and clinics. Those providers then use the 340B savings to underwrite the cost of serving patients in their communities.
- ► The 340B Program enables covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

340B Covered Entities

- Section 340B(a)(4) of the Public Health Service Act specifies which covered entities are eligible to participate in the 340B Drug Program.
- Hospitals
 - For-Profit Hospitals are ineligible for 340B.
 - Only public and nonprofit hospitals that serve large numbers of Medicaid and low-income Medicare patients or are located in rural areas qualify. Many of these hospitals operate at a loss.
- Other Covered Entities
 - Federally Qualified Health Centers (FQHCs)
 - Ryan White HIV/AIDS Program Grantees
 - Specialized clinics such are Sexually Transmitted Disease Clinics, Hemophilia Clinics, Tuberculosis Clinics, etc.
 - ► To find a clinic in your area → https://340bopais.hrsa.gov/



Examples of Nonhospital 340B Covered Entities in Louisiana

- ▶ LDH Region 1 Crescent Care
- LDH Region 2 Care South
- ▶ LDH Region 3 Lafourche Parish Health Unit
- ▶ LDH Region 4 St. Martin Parish Health Unit
- ▶ LDH Region 5 Southwest LA AIDS Council
- ▶ LDH Region 6 Winn Community Health Center
- ▶ LDH Region 7 The Philadelphia Center
- ▶ LDH Region 8 Primary Health Services Center
- ► LDH Region 9 Baptist Community Health Services

340B at Tulane Five Covered Entities

- Two Ryan White HIV/AIDS Clinics
 - ► Tulane Total Health Clinic New Orleans
 - ► Tulane Doctors Ryan White Clinic Alexandria
- Two Sexually Transmitted Disease Clinics
 - Ruth Fertel Clinic New Orleans
 - Tulane Doctors Infectious Disease Clinic Alexandria
- ► Hemophilia Treatment Center
 - ► The Louisiana Center for Bleeding and Clotting Disorders New Orleans, Metairie, Lafayette, and Alexandria
 - ▶ Treating Hemophilia, Thrombosis, and Sickle Cell Disease

How Does 340B Work?

- Covered Entities save 20-50% off the costs of Covered Outpatient Drugs.
- But this does not apply to medications sold to Medicaid patients except in certain circumstances that do not apply in Louisiana (This is known as the <u>Medicaid Carve Out</u>).
- The statute doesn't tell Covered Entities how they must use those savings.
- Some Covered Entities pass the savings on to their patients as a way of providing affordable prescription drugs.
- Others sell the drugs to patients at the retail price and use the "program income" (the difference between the amount received and the 340B price) to provide other services.
- For Covered Entities that are federal grantees, such as Ryan White Clinics, there are restrictions regarding the use of these funds.

Which Drugs are Covered?

► COVERED

- Outpatient prescription drugs
- ► Insulin
- Biologics
- Clinician-administered drugs in the outpatient setting
- Outpatient OTC drugs with a prescription

► NOT COVERED

- Inpatient drugs
- Vaccines
- Drugs not directly reimbursed
- Drugs with no National Drug Code (NDC)

Purchases of covered drugs can be made through "contract pharmacies," which are retail pharmacies contracted by the Covered Entities to provide the drugs to their patients.

Contract Pharmacy Process

Step 1: Covered Entity (CE) purchases drug at 340B price from wholesaler/manufacturer

Step 2: CE has drug delivered directly to contract pharmacy

Step 3: Patient picks up prescription from contract pharmacy

Step 4: Pharmacy collects co-pay and bills patient's insurance

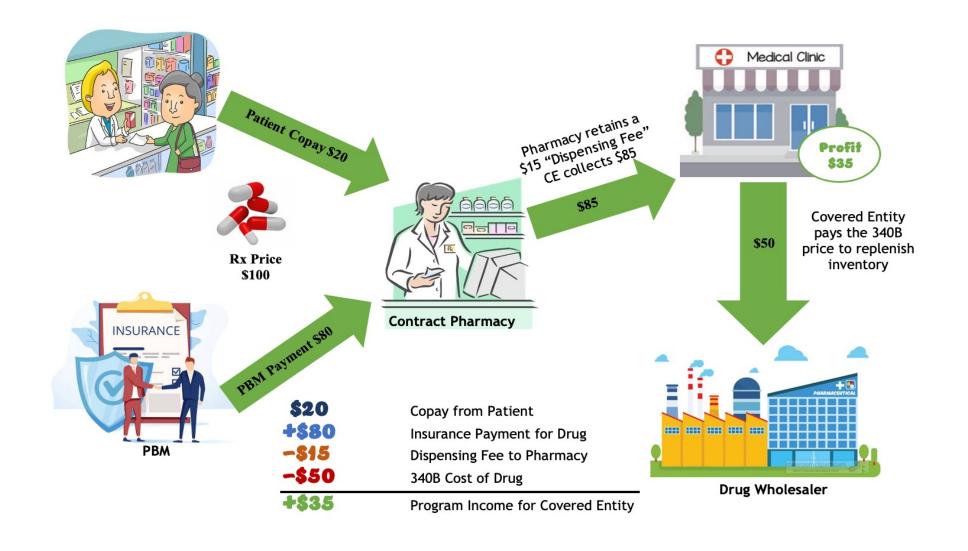
Step 5: Pharmacy receives full insurance rate for Rx

Step 6: Pharmacy keeps a portion of the payment as a dispensing fee

Step 7: Pharmacy sends remainder of reimbursement to CE

Step 8: CE keeps remaining amount as <u>Program Income</u> (after cost of drug and dispensing fee)

From the patient perspective, the RX process works the same, regardless of 340B status.



What is 340B Discriminatory Reimbursement?

Currently, safety net clinics can GET 340B savings - but increasingly, they are unable to KEEP them. This is because PBMs have found creative ways to transfer the benefit of the 340B savings from health care providers to themselves - in other words, to pick the 340B savings out of pockets of the clinics that Congress intended the money to go into.

Discriminatory Reimbursement can occur in many different ways. The most common way is for an outside group with whom healthcare providers must do business (e.g., insurers, PBMs) to force them to accept contracts that offer lower reimbursement for drugs simply because they were purchased under 340B.

Prohibiting Discriminatory Reimbursement

There is nothing in the current federal statute to prohibit discriminatory reimbursement.

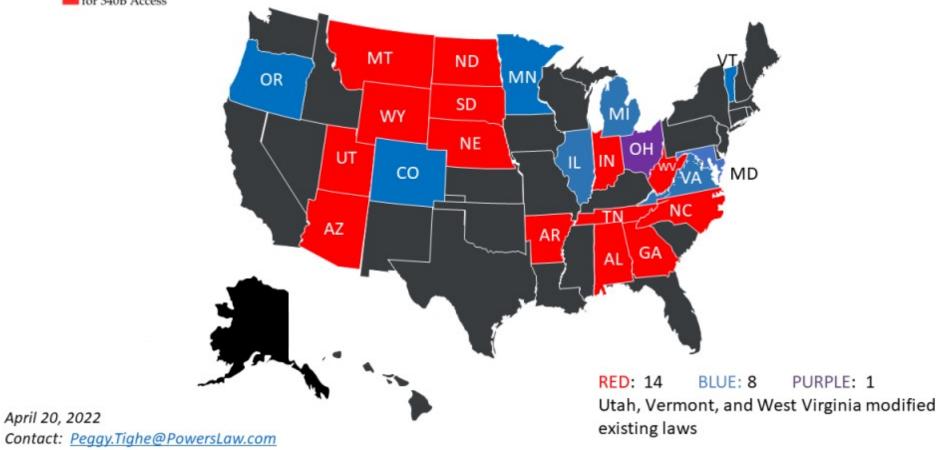
Although there have been attempts to legislate on the federal level, the federal government can be slow to act. Therefore, states have begun to pass their own statutes to prohibit this practice.



April 20, 2022

STATE LAWS PROHIBITING DISCRIMINATORY REIMBURSEMENT

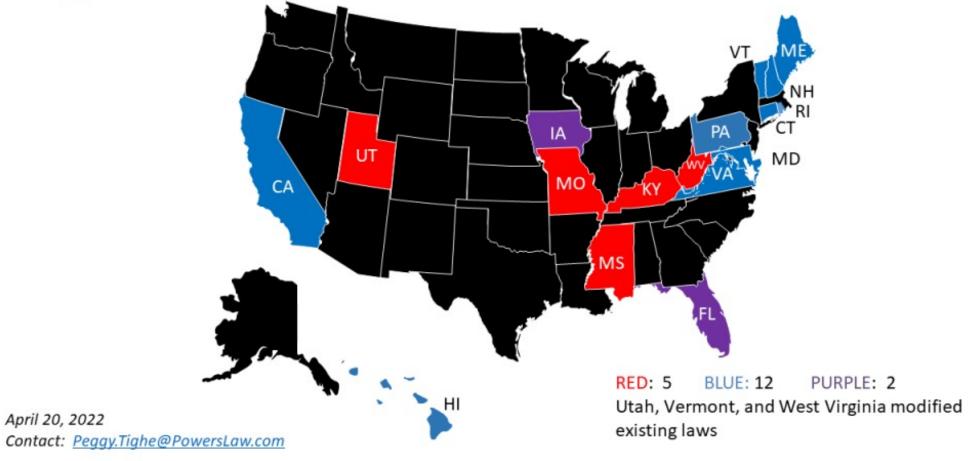






PENDING 2022 STATE BILLS TO PROHBIT DISCRIMINATORY REIMBURSEMENT





What will happen without legislation?

- Safety net providers in Louisiana will have less funds to treat the neediest patients.
- ► This will mean higher costs for government tax-funded programs such as Medicaid and Medicare in the long-term.
- ▶ 340B does not use taxpayer dollars, so failure to make efficient use of 340B funds for the neediest patients will likely result in a need for increased government revenue

Questions???

Jennifer Borrillo - jborrill@tulane.edu Elizabeth Davis, 340B Compliance Officer - edavis23@tulane.edu Ellen Palmintier - epalmintier@tulane.edu

Retail Pharmacies, Mail-Order Pharmacies and Providers, 2022 Vertical Business Relationships Among Insurers, PBMs, Specialty Pharmacies,



PROVIDER SERVICES	MAIL-ORDER PHARMACIES	RETAIL PHARMACIES	SPECIALTY PHARMACIES	PBMs (GPO)	INSURERS
▼ minute clinic Health HUB. Signifyhealth¹	♥CVS caremark	♥CVS pharmacy	◆CVS specialty	♥CVS caremark* Zinc	aetna
CareMore HEALTH Aspire	♥CVS caremark Ingenio ^{Rx}		♥CVS specialty ♥CVS specialty	Indenio	Elevance Health
	EXPRESS SCRIPTS"		allianceRx accredo	PRIME	BlueCross BlueShield
USMM. 15. Medical Group Tomportunity			AcariaHealth	envolve? Solutions	CENTENE
Cigna Medical Group Cigna Cigna collective care	EXPRESS SCRIPTS		accredo"	EXPRESS SCRIPTS*	Cigna
Portners in Primary Care. CONVIVA Cane Center Home Health	CenterWell		Specialty Pharmacy	Humana Pharmecy Solutions	Humana
OPTUMCare	OPTUMRX		OPTUM' Specialty Pharmacy	OPTUMRX EMISAR	 UnitedHealthcare

- In September 2022,CV5 Health announced its acquisition of Signify Health. The transaction is expected to close is 2023.

 Since January 2021, Prime's Blue Cross and Blue Shield plans have had the aption to use Express Scrips or AllianceRx Walgreens Prime for mail and specially pharmacy services. On Dec 31, 2021, Walgreens purchased Prime Therapeutics' 45% interest in AllianceRx Walgreens Prime, so this business has no PBM ownership in 2022. Effective June 2022, the company has been knowns AllianceRx Walgreens Pharmacy.
- In 2021, Centene has announced its intention to consolidate of all PBM operations and a single platform and outsource its PBM operations to an external company
- In 2021, Centene sold a majority stake in its U.S. Medical Management to a group of private equity firms.
- Cigna also partners with providers via its Cigna Collaborative Care program.
- Since 2020, Prime has sourced formularly rebates via Ascent Health Services. In 2021, Humana began sourcing formularly rebates via Ascent Health Services for its commercial plans

In 2022, Humana announced an agreement to divest its majority interest in Kindred at Hame's Hospice and Personal Care Divisions to Clayton, Dublifer & Rice In 2022, Kindred at Home was rebranded as CenterWell Home Health

Sources: Drug Channels Institute research and Nephron, Companies are listed alphabetically by insurer name