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 Pharmacy
Attorney General
Director, Public Protection Division, La. Dept. of Justice
Secretary, La. Dept. of Health
President, La. Academy of Physician Assistants
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
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
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 & Welfare
Chair, Senate Committee on Health & Welfare

Meeting Minutes

July 10, 2024

A regular meeting of the council was held on Wednesday, July 10, 2024 in the Poydras Hearing Room at the Louisiana Department of Insurance (LDI), located at 1702 North Third Street in Baton Rouge, Louisiana 70802. The meeting was conducted in a hybrid meeting format, in-person and by electronic means (Zoom).

1. Call to Order
Chairman Mills called the meeting to order at approximately 10:35 a.m.

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, Louisiana Dept. of Insurance)
Mr. Marty McKay (President, Louisiana Board of Pharmacy)
Mr. D. Jeddie Smith, Jr. (For the Louisiana Attorney General)
Mr. Michael Dupree (Director of the Public Protection Division, La. DOJ)
Ms. E. Sue Fontenot (For the Secretary, Louisiana Dept. of Health) *
Ms. Lauren Bailey (For the President, Louisiana State Medical Society) *
Dr. Lisa Bayhi (For the President, La. Association of Nurse Practitioners) *
Mr. Scott Black (For the President, Louisiana Pharmacists Association) *
Mr. Don Caffery (For the President, La. Independent Pharmacies Assoc.) *
Ms. Shelly Dupre (For the President, National Assoc. of Chain Drug Stores)
Mr. Jeff Drozda (For the President, Louisiana Association of Health Plans)
Mr. Robert Rieger (For the President of a PBM / Prime Therapeutics / PCMA)
Ms. Diane Davidson (For the CEO, Louisiana Business Group on Health)
Mr. Josh Sonnier (For the President, Louisiana AFL-CIO)
Ms. Kristy Copeland (For the President, La. Assoc. of Health Underwriters)
Ms. Kimberly L. Sullivan (For the Governor) *
Senator Kirk Talbot (Chairman, Senate Committee on Insurance)
Mr. Fred H. Mills, Jr. (For the Chairman, Senate Committee - Health & Welfare)
(* - participated by electronic means)

Members Absent:

The President of the Louisiana State Board of Medical Examiners
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 House Committee on Insurance
The Chairman of the House Committee on Health & Welfare

Staff Present:

Mr. Joe Fontenot (Executive Director, Louisiana Board of Pharmacy)
Ms. Sarah Stevens (Director of Licensing, Louisiana Board of Pharmacy)

Guests Present:

Ms. Sarah Perkins, Breazeale, Sachse & Wilson, L.L.P
Ms. Cheryl Tolbert, Louisiana Business Group on Health

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

3. Consideration of Minutes from Previous Meeting

Chairman Mills asked for a motion to approve the draft minutes of the previous meeting held on April 11, 2024. A motion was offered by Mr. Josh Sonnier, seconded by Mr. Robert Rieger, and then adopted after a unanimous vote of the remaining members in the affirmative declaring the minutes approved.

4. Opportunity for Public Comment

Chairman Mills solicited public comments from those in attendance, both in-person and through electronic means. Mr. Fontenot offered a public comment received through email from pharmacist Kyle Stevens. Mr. Stevens' comment was inquiring about the proper submission and review of complaints from pharmacies in regards to pharmacy benefit managers. Chairman Mills advised that meetings can be scheduled to discuss the handling of specific complaints with individual members. (Attachment A)

5. Election of Council Officers

Chairman Mills conducted the annual election of council officers. He reminded the members the two council officer positions were chair and vice chair and that the incumbent vice chair was Representative Chris Turner. He noted the term of office was one year and the officers would assume their respective positions upon their election. He then solicited nominations for the office of chair. Senator Mills was nominated by Mr. Robert Rieger and then re-elected by acclamation. Chairman Mills then solicited nominations for the office of vice chair. Representative Turner was nominated by Mr. Marty McKay and then re-elected by acclamation.

6. Discussion – 2024 Regular Legislative Session

Mr. Frank Opelka provided an overview of SB 444 (Act 768) (effective date 6/19/2024), by Senator Katrina Jackson-Andrews, relative to reimbursement of pharmacy and pharmacist claims at no less than the acquisition cost for covered drugs, devices, and services. He shared and briefly reviewed drafted regulation advising that this is a rough draft. Further, Mr. Frank Opelka advised members that his department is open to and encouraging input. Timelines for publication will depend on feedback received. (Attachments B and C)

Mr. Frank Opelka provided an overview of Act 658, by Rep. Gabe Firment and Act 514, by Sen. Rick Edmonds, stating both are similar acts intended to address extensive claim reviews. He advised that the Department of Insurance will do a revision to current regulation to address the use of claim reviews.

Chairman Mills thanked Sen. Kirk Talbot for his work during the 2024 Legislative Session.

7. Review of Industry Trends and Emerging Issues
Chairman Mills solicited comments from the members. Members discussed various matters including the impact of high cost drugs, PBM initiatives for rural areas, and precision medicine.

Mr. Fontenot provided members with a handout titled *"FTC Releases Interim Staff Report on Prescription Drug Middleman"*. Members expressed interest in reviewing the FTC report in full and reviewing the findings of such with the Council.

8. Review of Rulemaking Activity
The members had no rulemaking activity to report.

9. Calendar Notes
Chairman Mills reminded the members that the one remaining tentative meeting for calendar year 2024 is on October 9.

10. 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 11:13 a.m.

Minutes approved during subsequent meeting of the Council on October 09, 2024.

Attachment A

From: rxlsu
To: Joe Fontenot
Subject: Re: PBM advisory committee__PHY7303__PST17939
Date: Saturday, June 29, 2024 11:19:31 AM

EXTERNAL EMAIL: Please do not click on links or attachments unless you know the content is safe.

Joe, you may share my email. I understand it will be made public.
Thank you
KYLE

On Friday, June 28, 2024 at 08:56:45 AM CDT, Joe Fontenot <jfontenot@pharmacy.la.gov> wrote:

Good morning Kyle,

I appreciate your response. As Executive Director for the Board of Pharmacy, I appreciate all feedback, good and bad. In my role, receiving constructive criticism is the best way to address areas needing improvement. In this case, I know Carlos will appreciate your thoughts because he strives to handle all complaints received by the Board in a manner just as you described.

With respect to your comment regarding the Board of Pharmacy's handling of complaints, you are correct, the Board of Pharmacy has a very narrow regulatory window in regard to PBMs. The vast majority of complaints involving PBMs fall under the purview of the Department of Insurance. I've heard similar compliments as yours in regard to their responsiveness.

With respect to your comments about making the council more impactful, if you agree, I'll share your email for the council's viewing and consideration. In doing so, the email would be made public. I am not a member of the council, but I am assigned to provide administrative staff support to the council for their meeting needs. In my opinion, your words should be heard by the members.

I look forward to your response.

Take Care,
Joe

Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
jfontenot@pharmacy.la.gov

In compliance with Act 2019-256, the Board gives public notice that any information submitted to the

Board may become public record unless specifically exempted by the Public Records Law, R.S. 44:1 et seq.

From: rxlsu <rxlsu@cox.net>
Sent: Thursday, June 27, 2024 5:10 PM
To: Joe Fontenot <JFontenot@pharmacy.la.gov>
Subject: Re: PBM advisory committee__PHY7303__PST17939

Joe, Thank you for the reply. Your question is a little complicated and I reply with full respect. I am very happy with my board of pharmacy, its board members and compliance officers; all members. I've had nothing but positive meetings, discussions and interactions with the board and I do believe we have one of the better, if not best, boards in the country.

Carlos has been great with my complaints against PBMs. No complaints. He is very responsive, professional and pleasant.
However, he is only allowed to investigate PBM complaints in a very narrow regulatory avenue.

The advisory council was created to broadly monitor and report on PBMs and ensure there are no issues that could cause patient harm.

PBMs have been allowed to operate nearly unregulated and their aggressive behavior towards pharmacies has created an environment that could lead to patient harm.

As any pharmacy owner could, I don't want to type a 10 page email about PBMs and their bad behavior. I will be short.

I have virtually attended the previous handful of advisory meetings. They seem to gavel in, talk a bit and gavel out.
Two meetings ago a member suggested bringing PBMs in to sit at the meetings. Prior to the following meeting I inquired if PBMs would be present. There was no mention or recollection of that suggestion.

I feel the advisory committee has potential to be very effective. If they can monitor, report and even make suggestions to legislators, LDI, and the BOP about nefarious PBM activities, they can make meaningful change.

Patients struggle to get their important brand name medications (and many generics) because PBMs have created a financial environment unsuitable to dispense these meds. There are many more examples of aggression towards pharmacy; but I know the committee and the board focus on the safety of Louisiana residents.

How can the advisory committee be more impactful on poor PBM behavior?
What can I, or any pharmacy in the state, do to help the committee be more impactful?

Thanks again for your time,
KYLE STEVENS

On Thursday, June 27, 2024 at 10:11:09 AM CDT, Joe Fontenot <jfontenot@pharmacy.la.gov> wrote:
Hello Kyle,
My answers to your questions can be found in the body of your email below in **blue.**
I would be remiss by not asking, based on the questions and statements made in your email, are you displeased with the Board of Pharmacy's handling of complaints you've submitted in regard to PBMs?
Sincerely,
Joe Fontenot
Executive Director
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700
jfontenot@pharmacy.la.gov

In compliance with Act 2019-256, the Board gives public notice that any information submitted to the Board may become public record unless specifically exempted by the Public Records Law, R.S. 44:1 et seq.
From: rxlsu <rxlsu@cox.net>
Sent: Wednesday, June 26, 2024 4:38 PM
To: Joe Fontenot <JFontenot@pharmacy.la.gov>
Subject: PBM advisory committee__PHY7303__PST17939
Hello Joe,
Who is the current chair and vice chair of the committee?

*The current chair is **Fred Mills** and vice-chair is **Rep. Chris Turner**. The council is scheduled to conduct its yearly election of officers at the next meeting on **July 10, 2024**.*

If a pharmacy has a complaint against a PBM, can that complaint be directed to the advisory committee for review or would it need to go through Mr. Finalet first?

The "PBM Licensing Law" authorizes the commissioner of insurance and the Board of Pharmacy to utilize the expertise of the council or an individual member agency for the purpose of investigating a complaint. That being said, if we receive a complaint addressed to the PBM Monitoring Advisory Council seeking their review, that complaint will be presented as requested to the council.

Last question, I appreciate your time:

Our dept of insurance has done a wonderful job addressing my PBM complaints. Some complaints occur once and are not repeated. Some offences occur regularly. Should I be notifying or copying the advisory committee on such offenses that are currently handled by our insurance commissioner?

I will leave that decision to you.

KYLE STEVENS

NOTICE OF INTENT

Department of Insurance

Office of the Commissioner

Regulation 90 — Payment of Pharmacy and Pharmacist Claims

(LAC 37:XIII.Chapter 115)

The Department of Insurance, pursuant to the authority of the Louisiana Insurance Code, R.S. 22:1 et seq., and in accordance with the Administrative Procedure Act, R.S. 49:950 et seq., hereby gives notice of its intent to amend Regulation 112.

The purpose of the amendment to Regulation 90 is to add regulatory language to incorporate and clarify audit and claim review requirements and to require the filing of policies and procedures to bring Pharmacy Benefit Management processes into compliance.

Title 37

INSURANCE

Part XIII. Regulations

Chapter 115. Regulation Number 90 — Payment of Pharmacy and Pharmacist Claims

§11501. Purpose

A. The purpose of Regulation 90 is to implement R.S. 22:~~250.51-62~~ 1851-1862 relative to the making of the prompt and correct payment for prescription drugs, other products and supplies, and pharmacist services covered under insurance or other contracts that provide for pharmacy benefits. and for the review and auditing of claims or records pertaining to such services. ~~It is the intent of the legislature that payments for covered prescription drugs, other products and supplies, and pharmacist services provided by pharmacists and pharmacies are paid timely. It is also the intent of the legislature that the provisions of this Part shall be interpreted to achieve these ends. Additionally, these statutory provisions establish the intent of the legislature to assure that pharmacists and pharmacies who submit claims for covered prescription drugs, other products and supplies, and pharmacist services are paid timely and payments are based on calculations that reflect nationally recognized pricing references such as average wholesale price and maximum allowable cost.~~

B. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:3 and 22:250.61

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 33:1662 (August 2007)~~.~~, amended LR

§11503. Scope and Applicability

A. Except as otherwise specifically provided, the requirements of Regulation 90 apply to all health insurance issuers including health maintenance organizations that offer coverage in their insurance contracts for pharmacy services in accordance with the statutory requirements ~~of Part VI-F of Chapter One~~ Subpart C of Part II of Chapter 6 of Title 22 of the Louisiana Revised Statutes of 1950, R.S. 22:~~250.51-~~1851 et seq. Additionally, Regulation 90 applies to all contracts between a pharmacist and/or, pharmacy and/or a health insurance issuer, its agent, or any other party responsible for reimbursement for prescription drugs, other products and supplies, and pharmacist services. Any and all contracts entered into after July 1, 2005 shall be required to be in compliance with R.S. 22:~~250.51-~~1851 et seq.

Additionally, Regulation 90 shall apply to all contracts in existence prior to July 1, 2005. Regulation 90 shall include but not be limited to those contracts that contain any automatic renewal provisions, renewal provisions that renew if not otherwise notified by a party, any provision that allows a party the opportunity to opt out of the contract, evergreen contracts, or rollover contracts and therefore these contracts shall be required to come into compliance. Regulation 90 shall apply to all contracts as enumerated above as of the first renewal date, first opt out date, first rollover date or first annual anniversary on or after July 1, 2005.

B. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:3 and 22:250.61

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 33:1663 (August 2007), amended LR

§11505. Definitions

Agent—...

Commissioner— ...

Covered Person— ...

Date upon Which a Correctly Completed Uniform Claim Is Furnished— ...

Date upon Which an Electronic Claim Is Adjudicate— ...

Department— ...

Evergreen Contract— ...

1. – 5. ...

Just and Reasonable Grounds Such as Would Put a Reasonable and Prudent Businessman on His Guard— ...

Pharmacy—includes a pharmacy, pharmacy owner, pharmacy employee, or an agent thereof.

Rollover— ...

1. – 5. ...

Paid Date— ...

Prohibited Billing Activities—those activities outlined in R.S. 22:~~250.41~~1871 et seq.

Uniform Claim Forms--are forms prescribed by the department and shall include the National Uniform Bill-~~8204~~ (UB-~~8204~~) or its successor for appropriate hospital services, and the current Health Care Financing Administration Form 1500 or its successor for physical and other appropriate professional services. If, after consultation with insurers, providers, and consumer groups, the commissioner determines that the state assignable portions of either form should be revised, he shall make a revision request to the State Uniform Bill Implementation Committee and if approved, prescribe the use of the revised form.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:3 and 22:250.61

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 33:1663 (August 2007), amended LR

§11507. Claim Handling Procedures for Non-Electronic Claims

A. Pursuant to R.S. 22:~~250.53.B~~1853.B, health insurance issuers or health maintenance organizations are required to submit to the Department, for approval, a "Prompt Payment Procedures Plan for Non-Electronic Pharmacy Claims" detailing statutory compliance for the receipt, acceptance, processing, payment of non-electronic claims and procedures in place to ensure compliance with R.S. 22:~~250.41~~1851 et seq. and R.S. 22:1871 et seq. The Prompt Payment Procedures Plan for Non-Electronic Pharmacy Claims shall include, but not be limited to, the following:

1. a process for documenting the date of actual receipt of non-electronic claims; ~~and~~
2. a process for reviewing non-electronic claims for accuracy and acceptability.;
3. a set of policies and procedures governing the performance of pharmacy record audits, whether by the health insurance issuer or its agent. Such material shall:
    a. specify the selection criteria or algorithm used to select pharmacies for auditing;
    b specify the potential purpose and scope of the audit function, including all potential recoupment, remedial, and punitive rights reserved to the health insurance issuer or its agent by contract or other agreement with the pharmacy;
    c. expressly demonstrate compliance with all substantive elements of R.S. 22:1856.1 and this Regulation;
4. a set of policies and procedures governing the performance of claim reviews and quality assurance reviews, whether by the health insurance issuer or its agent. Such material shall:
    a. specify any distinctions between claim reviews and quality assurance reviews under the policies and procedures to be used by the company. Any alternative term for a review of a claim, whether paid or unpaid, except for annual audits and fraud- or willful-misrepresentation-related audits, reviews, or investigation, shall be added to the policies and procedures filed with the department as a term for either a claim review or a quality assurance review prior to use in communication with any pharmacy;
    b. specify the selection criteria or algorithm used in determining when a claim review is to be performed. This shall include safeguards to ensure the scope of the review is not unduly burdensome or overly broad. Such safeguards shall include limits on the number of reviews a pharmacy may be subject to in any 30-calendar-day period and limits on the type and quantity of material produced by the pharmacy in complying with the review;
    c. specify the selection criteria or algorithm used in determining when a quality assurance review is to be performed. This shall include safeguards to ensure the scope of the review is not unduly burdensome or overly broad. Such safeguards shall include limits on the number of reviews a pharmacy may be subject to in any 30-calendar-day period and limits on the type and quantity of material produced by the pharmacy in complying with the review;
    d. specify the potential purpose and scope of its claim review function, including all potential recoupment, remedial, and punitive rights reserved to the health insurance issuer or its agent by contract or other agreement with the pharmacy;
    e. specify the potential purpose and scope of its quality assurance review function, including all

potential recoupment, remedial, and punitive rights reserved to the health insurance issuer or its agent by contract or other agreement with the pharmacy; and

5. a set of policies and procedures governing the performance of fraud or willful misrepresentation audits, whether by the health insurance issuer or its agent. Such material shall:

a. describe any triggers or criteria which may give rise to a fraud or willful misrepresentation audit; such triggers or criteria shall be clearly defined and easily distinguishable from the selection criteria or algorithms used by the company for pharmacy record audits, claim reviews, and quality assurance reviews;

b. implement a function sufficiently narrow in purpose, scope, and invoking criteria to prevent the use of fraud or willful misrepresentation audits in place of pharmacy record audits, claim reviews, and quality assurance reviews.

B. The filing of the Prompt Payment Procedures Plan for Non-Electronic Pharmacy Claims document shall indicate compliance by a health insurance issuer or health maintenance organization with the filing requirements of R.S. 22:~~250.53~~1853. However, such documentation shall still be subject to review and disapproval at any time such documentation is deemed to be not in compliance with the substantive requirements of R.S. 22:~~250.53~~1853 or 1856.1.

C. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:3 and 22:250.61

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 33:1664 (August 2007)., amended LR

§11509. Claim Handling Procedures for Electronic Claims

A. Pursuant to R.S. 22:~~250.54~~1851, health insurance issuers and health maintenance organizations are required to submit to the department, for approval, a "Prompt Payment Procedures Plan for Electronic Pharmacy Claims" detailing statutory compliance for the receipt, acceptance, processing, payment of electronic claims and procedures in place to ensure compliance with R.S. 22:~~250.54~~1851et seq. The "Prompt Payment Procedures Plan for Electronic Pharmacy Claims" shall include, but not be limited to, the following:

1. a process for electronically dating the time and date of actual receipt of electronic claims;

~~2. a process for reviewing electronic review of transmitted claims for accuracy and acceptability; and~~

2. a process for reporting all claims rejected during electronic transmission and the reason for the rejection.

3. a set of policies and procedures governing the performance of pharmacy record audits, whether by the health insurance issuer or its agent. Such material shall:

a. specify the selection criteria or algorithm used to select pharmacies for auditing;

b. specify the potential purpose and scope of the audit function, including all potential recoupment, remedial, and punitive rights reserved to the health insurance issuer or its agent by contract or other agreement with the pharmacy;

c. expressly demonstrate compliance with all substantive elements of R.S. 22:1856.1 and this Regulation;

4. a set of policies and procedures governing the performance of claim reviews and quality assurance reviews, whether by the health insurance issuer or its agent. Such material shall:

a. specify any distinctions between claim reviews and quality assurance reviews under the policies and procedures to be used by the company. Any alternative term for a review of a claim, whether paid or unpaid, except for annual audits and fraud- or willful-misrepresentation-related audits, reviews, or investigation, shall be added to the policies and procedures filed with the department as a term for either a claim review or a quality assurance review prior to use in communication with any pharmacy;

b. specify the selection criteria or algorithm used in determining when a claim review is to be performed. This shall include safeguards to ensure the scope of the review is not unduly burdensome or overly broad. Such safeguards shall include limits on the number of reviews a pharmacy may be subject to in any 30-calendar-day period and limits on the type and quantity of material produced by the pharmacy in complying with the review;

c. specify the selection criteria or algorithm used in determining when a quality assurance review is to be performed. This shall include safeguards to ensure the scope of the review is not unduly burdensome or overly broad. Such safeguards shall include limits on the number of reviews a pharmacy may be subject to in any 30-calendar-day period and limits on the type and quantity of material produced by the pharmacy in complying with the review;

d. specify the potential purpose and scope of its claim review function, including all potential recoupment, remedial, and punitive rights;

e. specify the potential purpose and scope of its quality assurance review function, including all potential recoupment, remedial, and punitive rights reserved to the health insurance issuer or its agent by contract or other agreement with the pharmacy; and

5. a set of policies and procedures governing the performance of fraud or willful misrepresentation audits, whether by the health insurance issuer or its agent. Such material shall:

a. describe any triggers or criteria which may give rise to a fraud or willful misrepresentation audit; such triggers or criteria shall be clearly defined and easily distinguishable from the selection criteria or algorithms used by the company for pharmacy record audits, claim reviews, and quality assurance reviews;

b. implement a function sufficiently narrow in purpose, scope, and invoking criteria to prevent the use of fraud or willful misrepresentation audits in place of pharmacy record audits, claim reviews, and quality assurance reviews.

B. ...

C. The filing of the "Prompt Payment Procedures Plan for Electronic Pharmacy Claims" document shall indicate compliance by a health insurance issuer and health maintenance organization with the filing requirements of R.S. 22:~~250.54~~1854. However, such documentation shall still be subject to review and disapproval at any time such documentation is deemed to not be in compliance with the substantive requirements of R.S. 22:~~250.54~~1854 or 1856.1.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:3 and 22:250.61

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 33:1664 (August 2007), amended LR

§11511. Pharmacy Record Audits, Claim Reviews, and Quality Assurance Reviews

A. Pharmacy record audits shall be the sole mechanism a health insurance issuer or its agent may require a pharmacy to participate in for the purpose of systematic review of the pharmacy's compliance with contract terms and conditions, filing guidelines, and the provider manual. Use of any other mechanism, including claims reviews and quality assurance reviews or inappropriate use of fraud or willful misrepresentation audits to perform such a review shall cause such use to be deemed a pharmacy record audit and therefore subject to the requirements of and limitations on such audits.

B. Claim reviews shall be limited to a determination of whether a claim is payable or has been paid correctly. Inappropriate aggregation of claim reviews, excessive application of claim reviews upon a single pharmacy, and similar activities serve to convert a claim review into a pharmacy record audit and therefore subject to the requirements of and limitations on such audits.

C. Quality assurance reviews shall be limited to reviews of pharmacy compliance with contractual and claim filing requirements and shall only be performed prior to reimbursement. The purpose of a quality assurance review must be to test and maintain compliance with contract terms or agreed-upon claim filing requirements, and the health insurance issuer shall design and implement such reviews to be remedial in nature, rather than to deny, recover, or otherwise non-pay claims based on correctable or harmless errors.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:3 and 22:250.61

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR

§~~11511~~11513. State of Emergency

A. Pursuant to any Executive Order issued by the governor transferring authority to the department on matters pertaining to insurance, and pursuant to the plenary authority vested in the commissioner under Title 22, the department shall be authorized to issue emergency regulations during a state of emergency that suspends and/or interrupts any of the provisions found in Title 22 or take any or all such action that the commissioner deems necessary in reference to provisions in Title 22.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:3 and 22:250.61

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 33:1664 (August 2007), amended LR

§~~11511~~11515. Severability Clause

A. If any Section or provision of Regulation 90 or its application to any person or circumstance is held invalid, such invalidity or determination shall not affect other sections or provisions that can be given effect without the invalid sections or provisions or application, and for these purposes, the Sections or provisions of this regulation and the application to any person or circumstance shall be severable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:3 and 22:250.61

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 33:1664 (August 2007), amended LR

§~~1151111~~517. Effective Date

A. Regulation 90 shall become effective upon final publication in the *Louisiana Register*.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:3 and 22:250.61

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 33:1664 (August 2007)~~.~~, amended LR

Chapter XX. Regulation XX—Adequate Payment of Pharmacy and Pharmacist Claims

§XX501. Purpose

The purpose of Regulation XX is to implement R.S. 22:1860.3(E) relative to reimbursement of pharmacy and pharmacist claims at no less than the acquisition cost for covered drugs, devices, or services. To carry out the intent of the legislature and assure full compliance with the applicable statutory provisions, this regulation sets forth payment a set of minimum payment system design standards to govern pharmacy benefit manager pharmacy and pharmacist reimbursement strategies.

§XX503. Scope and Applicability

A. Except as otherwise specifically provided, the requirement of Regulation XX apply to all reimbursements of a pharmacy or pharmacist by pharmacy benefit managers and all entities acting on behalf of a pharmacy benefit manager where the pharmaceutical drug transaction being reimbursed occurred in Louisiana or is otherwise subject to the laws of the state of Louisiana. This shall include, but is not limited to, reimbursements made by a pharmacy benefit manager or an entity acting on behalf of a pharmacy benefit manager in administering the pharmacy benefit of an employee welfare benefit plan, as defined in the Employee Retirement Income Security Act of 1974 (ERISA), of a collectively bargained union welfare plan, of a single employer plan, and of a plan of the state or political subdivision unless such plan is governed by the office of group benefits.

B. Notwithstanding any provision to the contrary in any contract, any and all contracts shall comply with Regulation XX as of January 1, 2025.

§XX505. Definitions

Acquisition Cost—the price at which the pharmacy or pharmacist making the claim for reimbursement may reasonably acquire a drug, device, or service using customary suppliers and through typical purchasing agreements, less any discounts, rebates, price concessions, or other reductions actually received by the pharmacy or pharmacist as a result of the acquisition.

Adjustment—a percentage-based change to the prescription drug pricing benchmark, such as average wholesale price or national average drug acquisition cost, applied uniformly across a class of drugs.

Claim Payment Error—a pharmacy or pharmacist claim payment amount that fails to reimburse at or above acquisition cost.

Commissioner—the Commissioner of Insurance.

Department—the Louisiana Department of Insurance.

NADAC—the set of National Average Drug Acquisition Costs as calculated by the Centers for Medicaid and Medicaid Services and reflected in the most recently released public file.

Pharmacy—a pharmacy, pharmacy owner, pharmacy employee, or agent thereof, where the pharmacy or pharmacy owner does not own more than five shares or a five percent interest in a pharmaceutical wholesale group purchasing organization or vendor of any covered drug, device, or service.

Pharmacy Benefit Manager—an entity that administers or manages a pharmacy benefits plan or program and all entities acting on its behalf.

Reimbursement Formula—a prescription drug reimbursement calculation involving an ingredient price – calculated based on a prescription drug pricing benchmark plus an adjustment factor – and a professional dispensing fee.

§XX507. Pharmacy Benefit Manager Compliance Program

A. A pharmacy benefit manager may comply with R.S. 22:1860.3(E) by meeting all of the following requirements:

(1) Adopting a reimbursement formula using either NADAC as the prescription drug pricing benchmark or, with prior written approval by the commissioner, an alternative prescription drug pricing benchmark that results in claim payment errors that are both comparable to or less that NADAC in terms of frequency and smaller than NADAC in terms of magnitude;

(2) Adopting a reimbursement formula using an adjustment factor that is reasonably expected to result in a claim payment error rate of no more than 2%; and

(3) Adopting the appeal process described in paragraph (B).

B. A pharmacy benefit manager shall provide an appeal process through which pharmacists may challenge claim payment errors that meets at least the following requirements:

(1) A remittance advice provided by a pharmacy benefit manager shall, at a minimum, contain a notice in at least 10-point font stating: "If your reimbursement for any covered drug, device, or service is less than your acquisition cost for that drug, device, or service, you have the right to appeal that reimbursement and, if successful, receive additional payment. The following options may be used to submit such appeal." The notice shall then direct the pharmacy to the pharmacy benefit manager's electronic and written appeal locations.

(2) Permit appeals to be filed for a period of no less than sixty days following final adjudication of the claim.

(3) If an appeal is filed with the pharmacy benefit manager, it shall verify that there was no claim payment error based on pricing available on the date of service.

(4) If a claim payment error occurred, the pharmacy benefit manager shall make an additional payment to the pharmacy to increase the reimbursement amount to the acquisition cost.

(5) If a pharmacy benefit manager determines that a claim payment error did not occur, it shall provide the pharmacy or pharmacist with an explanation of why it has upheld the payment, including a specific documentation of the acquisition cost on the date of service. Such explanation shall be provided electronically or in writing through customary means of communication between the pharmacy benefit manager and the pharmacy or pharmacist. Such explanation shall also include a notice in at least 10-point font stating that, if the pharmacy or pharmacist disagrees with the decision, the pharmacy or pharmacist may file a complaint with the department at: https://www.ldi.la.gov/onlineservices/ConsumerComplaintForm.

§XX509. Pharmacy Benefit Manager Alternative Compliance Option

A pharmacy benefit manager may comply with R.S. 22:1860.3 without adopting the compliance program described in §XX507 by adopting a payment system that reimburses based on price invoices from a pharmacy or pharmacist. A pharmacy benefit manager that adopts such structure, however, shall continue to be responsible for meeting all timely claim payment requirements. Verification of the invoiced price is an element of claim review, as described in R.S. 22:1856.1, and not of the adjudication process referenced in R.S. 22:1854. It does not, therefore, toll the running of timely claim payment requirements.

§XX511. Severability

If any Section or provision of Regulation XX or its application to any person or circumstance is held invalid, such invalidity or determination shall not affect other sections or provisions that can be given effect without the invalid sections or provisions or application, and for these purposes, the Sections or provisions of this regulation and the application to any person or circumstance shall be severable.

FEDERAL TRADE COMMISSION
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For Release

FTC Releases Interim Staff Report on Prescription Drug Middlemen

Report details how prescription drug middleman profit at the expense of patients by inflating drug costs and squeezing Main Street pharmacies

July 9, 2024

Tags: Competition | Office of Policy Planning | Merger | Horizontal | Vertical | Nonmerger | general purchasing organizations (GPOs) | Pharmacy Benefits Managers (PBM) | Health Care | Prescription D

Give Feedback

The Federal Trade Commission today published an interim report on the prescription drug middleman industry t underscores the impact pharmacy benefit managers (PBMs) have on the accessibility and affordability of prescription drugs.

The interim staff report, which is part of an ongoing inquiry launched in 2022 by the FTC, details how increasing vertical integration and concentration has enabled the six largest PBMs to manage nearly 95 percent of all prescriptions filled in the United States.

This vertically integrated and concentrated market structure has allowed PBMs to profit at the expense of patients and independent pharmacists, the report details.

"The FTC's interim report lays out how dominant pharmacy benefit managers can hike the cost of drugs—including overcharging patients for cancer drugs," said FTC Chair Lina M. Khan. "The report also details how PBMs can squeeze independent pharmacies that many Americans—especially those in rural communities—depend on for essential care. The FTC will continue to use all our tools and authorities to scrutinize dominant players across healthcare markets and ensure that Americans can access affordable healthcare."

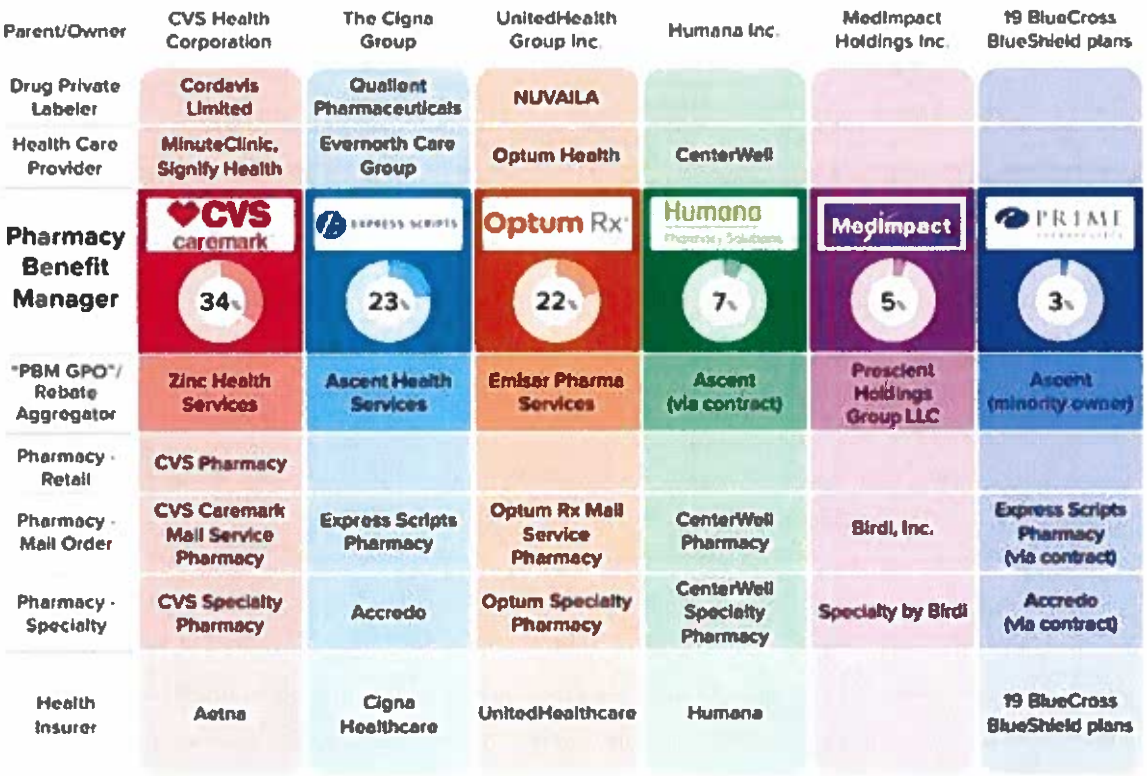
The report finds that PBMs wield enormous power over patients' ability to access and afford their prescription drugs, allowing PBMs to significantly influence what drugs are available and at what price. This can have dire consequences, with nearly 30 percent of Americans surveyed reporting rationing or even skipping doses of their prescribed medicines due to high costs, the report states.

The interim report also finds that PBMs hold substantial influence over independent pharmacies by imposing unfair,

arbitrary, and harmful contractual terms that can impact independent pharmacies' ability to stay in business and serve their communities.

The Commission's interim report stems from special orders the FTC issued in 2022, under Section 6(b) of the FTC Act, to the six largest PBMs—Caremark Rx, LLC; Express Scripts, Inc.; OptumRx, Inc.; Humana Pharmacy Solutions, Inc.; Prime Therapeutics LLC; and MedImpact Healthcare Systems, Inc. In 2023, the FTC issued additional orders to Zinc Health Services, LLC, Ascent Health Services, LLC, and Emisar Pharma Services LLC, which are each rebate aggregating entities, also known as "group purchasing organizations," that negotiate drug rebates on behalf of PBMs.

PBMs are part of complex vertically integrated health care conglomerates, and the PBM industry is highly concentrated. As shown in the below image, this concentration and integration gives them significant power over the pharmaceutical supply chain. The percentages reflect the amount of prescriptions filled in the United States.



The interim report highlights several key insights gathered from documents and data obtained from the FTC's orders, as well as from publicly available information:

- **Concentration and vertical integration:** The market for pharmacy benefit management services has become highly concentrated, and the largest PBMs are now also vertically integrated with the nation's largest health insurers and specialty and retail pharmacies.
  - The top three PBMs processed nearly 80 percent of the approximately 6.6 billion

prescriptions dispensed by U.S. pharmacies in 2023, while the top six PBMs processed more than 90 percent.

  - Pharmacies affiliated with the three largest PBMs now account for nearly 70 percent of all specialty drug revenue.

- **Significant power and influence:** As a result of this high degree of consolidation and vertical integration, the leading PBMs now exercise significant power over Americans' ability to access and afford their prescription drugs.
  - The largest PBMs often exercise significant control over what drugs are available and at what price, and which pharmacies patients can use to access their prescribed medications.
  - PBMs oversee these critical decisions about access to and affordability of life-saving medications, without transparency or accountability to the public.
- **Self-preferencing:** Vertically integrated PBMs appear to have the ability and incentive to prefer their own affiliated businesses, creating conflicts of interest that can disadvantage unaffiliated pharmacies and increase prescription drug costs.
  - PBMs may be steering patients to their affiliated pharmacies and away from smaller, independent pharmacies.
  - These practices have allowed pharmacies affiliated with the three largest PBMs to retain high levels of dispensing revenue in excess of their estimated drug acquisition costs, including nearly $1.6 billion in excess revenue on just two cancer drugs in under three years.
- **Unfair contract terms:** Evidence suggests that increased concentration gives the leading PBMs leverage to enter contractual relationships that disadvantage smaller, unaffiliated pharmacies.
  - The rates in PBM contracts with independent pharmacies often do not clearly reflect the ultimate total payment amounts, making it difficult or impossible for pharmacists to ascertain how much they will be compensated.
- **Efforts to limit access to low-cost competitors:** PBMs and brand drug manufacturers negotiate prescription drug rebates some of which are expressly conditioned on limiting access to potentially lower-cost generic and biosimilar competitors.
  - Evidence suggests that PBMs and brand pharmaceutical manufacturers sometimes enter agreements to exclude lower-cost competitor drugs from the PBM's formulary in exchange for increased rebates from manufacturers.

The report notes that several of the PBMs that were issued orders have not been forthcoming and timely in their responses, and they still have not completed their required submissions, which has hindered the Commission's ability to perform its statutory mission. FTC staff have demanded that the companies finalize their productions required by the 6(b) orders promptly. If, however, any of the companies fail to fully comply with the 6(b) orders or engage in further delay tactics, the FTC can take them to district court to compel compliance.

The FTC remains committed to providing timely updates as the Commission receives and reviews additional information.

Give Feedback

The Commission voted 4-1 to allow staff to issue the interim report, with Commissioner Melissa Holyoak voting no. Chair Lina M. Khan issued a statement joined by Commissioners Rebecca Kelly Slaughter and Alvaro Bedoya. Commissioners Andrew N. Ferguson and Melissa Holyoak each issued separate statements.

The Federal Trade Commission develops policy initiatives on issues that affect competition, consumers, and the U.S. economy. The FTC will never demand money, make threats, tell you to transfer money, or promise you a prize. Follow the FTC on social media, read consumer alerts and the business blog, and sign up to get the latest FTC news and alerts.

Press Release Reference

FTC Launches Inquiry Into Prescription Drug Middlemen Industry

FTC Further Expands Inquiry Into Prescription Drug Middlemen Industry Practices

FTC Deepens Inquiry into Prescription Drug Middlemen

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Give Feedback