



LOUISIANA DEPARTMENT OF INSURANCE

JAMES J. DONELON
COMMISSIONER

July 21, 2022

The Honorable Patrick Page Cortez
President, Louisiana State Senate
P.O. Box 94183
Baton Rouge, LA 70804

ELECTRONIC TRANSMISSION
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The Honorable Clay Schexnayder
Speaker, Louisiana House of Representatives
P.O. Box 94062
Baton Rouge, LA 70804

ELECTRONIC TRANSMISSION
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The Honorable Kirk Talbot
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The Honorable Mike Huval
Chairman of the House Insurance Committee
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RE: Summary Report – Regulation 122— Roles and Responsibilities
of Pharmacy Benefit Managers and Pharmacy Services
Administrative Organizations

Dear President Cortez, Speaker Schexnayder, Senator Talbot, and Representative
Huval:

The Louisiana Department of Insurance (LDI) hereby submits the following summary
report required by La. R.S. 49:968(D)(1)(b), and announces its intention to proceed to
finalize the promulgation of Regulation 122, which was published as a Notice of Intent in
the March 2022 edition of the *Louisiana Register*.

Interested persons were provided an opportunity to submit comments to the LDI on the
proposed regulation. The LDI received comments from multiple persons in response to
the Notice of Intent and the LDI responded accordingly. These comments and the LDI's
responses are summarized below and enclosed for your review.

Comment by Pharmaceutical Care Management Association (PCMA)

In reviewing the draft rule regarding the Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations, the phrase, “roles and responsibilities solely within the purview of pharmacy benefit managers” contained in proposed §18501 raised our concern that the phraseology might somehow be construed to limit the powers, roles and responsibilities that PBMs exercise in their ordinary operations permitted under applicable Louisiana law. To clarify this uncertainty, PCMA recommends that proposed §18501 contain a second sentence to read as follows:

The purpose of this regulation is to define the roles and responsibilities solely within the purview of pharmacy benefit managers and pharmacy services administrative organizations as required by R.S. 22:1660.9(C). This regulation is not to in any way restrict or confine the powers, roles and responsibilities as authorized to pharmacy benefit managers by federal and/or Louisiana laws.

LDI Response to PCMA

La. R.S. 22:1660.9(C) requires the Commissioner of Insurance to “promulgate rules that define the roles and responsibilities solely within the purview of pharmacy benefit managers and pharmacy services administrative organizations.” The LDI rejects the recommendation made by PCMA to add an additional sentence clarifying that Regulation 122 does not limit the powers, roles and responsibilities authorized by state or federal law as this addition would go beyond the scope of the mandate issued in the statute.

Comment by Gainwell

In summary –

The Louisiana Department of Health administers the Medicaid program in Louisiana which is subject to substantial federal regulation and unique state and federal contracting arrangements with drug manufacturers. States maintain autonomy to establish and manage its Medicaid pharmacy benefit as appropriate for their populations. The Louisiana Medicaid program appoints local physicians in staffing its drug utilization review (DUR) board and pharmacy and therapeutics (P&T) committee to oversee and administer Medicaid pharmacy benefits and clinical policies and contracts directly with Pharmacy Benefit Administrators (PBAs) to process prior authorization requests and adjudicate claims pursuant to the explicit direction of the Medicaid program benefit design and policies as established by the state. Wrapping the state’s PBA into this regulation would fundamentally alter the design and management of the state’s Medicaid pharmacy program and impact its economics.

We respectfully ask the Department of Insurance to exclude pharmacy benefit managers contracted directly with the Louisiana Department of Health from Regulation 122 which is consistent with other states practices.

LDI Response to Gainwell

The LDI rejects the recommendation made by Gainwell to expressly exclude pharmacy benefit managers contracted directly with the Louisiana Department of Health from Regulation 122 because they are not regulated by the LDI and are therefore already not subject to Regulation 122.

Comments by Louisiana Independent Pharmacies Association (LIPA)

Comment 1

In summary –

In accordance with Louisiana Revised Statute 22:1660.9(C), Regulation 122 is attempting to define the roles and responsibilities “solely within the purview” of PBMs and PSAOs. Merriam-Webster defines “solely” as “the exclusion of all else; without another.” LIPA suggests everything in contractual relationships requires input from at least two parties and that nothing can be said to be “solely within the purview” of a PBM or PSAO because of their contracts with health plans, employers, and pharmacies. This is especially true within an industry as dynamic as healthcare, and more particularly pharmacy benefits.

LIPA believes it is bad public policy to enshrine the roles of industry participants in regulations. La. R.S. 22:1660.9 does not require the LDI to revisit this regulation as the healthcare industry evolves, which may lead to consequences for independent pharmacies not contemplated by Acts 2021, No. 192.

LIPA requests LDI revisit Regulation 122 as drafted. As shown above, it is bad public policy to define the roles and responsibilities “solely within the purview” of any market participant, especially a participant in a market as dynamic as healthcare. LDI cannot definitively identify any factor “solely within the purview” of PBMs or PSAOs for the purpose of this Notice of Intent, and should instead withdraw Regulation 122 in its entirety.

LDI Response to Comment 1

The LDI rejects the recommendation made by LIPA to withdraw Regulation 122. La. R.S. 22:1660.9(C) specifically requires the Commissioner of Insurance to promulgate a regulation which defines the roles and responsibilities solely within the purview of pharmacy benefit managers and pharmacy services administrative organizations, and Regulation 122 complies with that mandate.

Comment 2

In an abundance of caution, LIPA will also address the specific defined roles and responsibilities of PBMs and PSAOs, despite its position on these factors generally.

§18507. Roles and Responsibilities of Pharmacy Benefit Managers

(A)(2) formulary and benefit design support and management. Upon information and belief, PBMs do not “design” drug formularies. These are designed by the health plan or employer for the benefit of their beneficiaries or employees. They are integral component of the formulary, so a PBM cannot be “solely” responsible for this factor.

(A)(3) establishing reimbursement rates and making payments on behalf of health plan sponsors. PBMs may remit a portion of the payment, but these dollars also flow to, and ultimately through, PSAOs. Because PSAOs contract with both PBMs and pharmacies to ensure payments are made, PBMs cannot be “solely” responsible for this factor.

(A)(4) establishing and managing pharmacy networks to ensure network adequacy on behalf of health plans. PSAOs also establish networks of pharmacies. Once a network is established, PSAOs contract with PBMs on behalf of those pharmacies. Therefore, PBMs cannot be “solely” responsible for this factor.

§18509. Roles and Responsibilities of Pharmacy Services Administrative Organizations

(A)(1) negotiating contracts, drug reimbursement rates, payments, and audit terms on behalf of pharmacy clients with pharmacy benefit managers

(A)(2) billing and collecting payments from payers on behalf of pharmacies

(A)(3) using contractual agreements to develop networks of member pharmacies.

These agreements generally authorize pharmacy services administrative organizations to interact with third-party payers and pharmacy benefit managers

(A)(5) facilitating the purchase of prescription drugs and other medical products from drug manufacturers and providing for delivery to pharmacies for dispensing

(A)(6) assisting pharmacy clients with business strategy, pricing appeals, claims reconciliation, and certification and credentialing requirements

LIPA helps its members negotiate contracts, including for network access, and assists with audits, strategy, pricing appeals, claims reconciliation, and certification and credentialing requirements which invalidates §18509(A)(1),(3) and (6). More broadly, it supports LIPA’s position that nothing is “solely within the purview” of a PBM or PSAO.

Pharmacies bill directly through their computer systems, not through their PSAO which invalidates §18509(A)(2). For example, Express Scripts only contracts with four PSAOs operating in Louisiana. Every pharmacy in the state that does not use one of those four must bill the PBM or health plan directly, which happens through their computer system.

LDI Response to Comment 2

The LDI rejects the comments made by LIPA because the roles and responsibilities included in Regulation 122 distinguish between activities performed by pharmacy benefit managers and pharmacy services administrative organizations and does not define who is permitted to participate in these activities.

Comment 3

§18509(A)(5) is invalidated because two Louisiana and several national drug wholesale companies purchase prescription drugs and other medical products for delivery to pharmacies, not PSAOs.

LDI Response to Comment 3

The LDI rejects the conclusion by LIPA that pharmacy services administrative organizations do not facilitate the purchase of prescription drugs and other medical products from drug manufacturers and provide for delivery to pharmacies for dispensing. The LDI has received information that this activity outlined in §18507(A)(5) is the role and responsibility of pharmacy services administrative organizations.

Comments by Healthcare Distribution Alliance (HDA)

Comment 1

Below we have identified specific areas in the Intended Rules with which have concern and provided supporting commentary.

Roles and Responsibilities of Pharmacy Benefit Managers

§18507 – A(3): Subsection Three states PBMs “[make] payments on behalf of health plan sponsors.” As this subsection pertains to reimbursement terms, we encourage additional detail. PBMs are responsible for proper claim(s) adjudication (claims for reimbursement submitted by pharmacies) over and above simply being responsible for plan payments and administration.

LDI Response to Comment 1

The LDI rejects the recommendation made by HDA to provide additional detail. The claims adjudication process is sufficiently described when §18507(A)(1) through (A)(4) are considered in conjunction with one another.

Comment 2

Roles and Responsibilities of Pharmacy Services Administrative Organizations

§18509 – A(1): Subsection One identifies PSAOs as responsible for “negotiating contracts, drug reimbursement rates, payments, and audit terms on behalf of pharmacy clients with pharmacy benefit managers.” It is worth noting PSAOs do not sign every contract offered by a PBM, nor enter into contracts without evaluating the options for their pharmacy clients. Respectfully, we ask that “negotiating” be replaced with “evaluating and executing contracts that include...”

LDI Response to Comment 2

The LDI rejects the recommendation made by HDA to change the language in §18509(A)(1) because the proposed change is merely a disagreement about semantics. The act of “negotiating contracts” includes the evaluation of options before the contract is executed, modified, or rejected.

Comment 3

Further, the reference to “payments” following “drug reimbursement rates” is ostensibly the same. As Louisiana statute already codifies PBMs’ reimbursement remittance advice deadline, including “payments” is repetitive.

LDI Response to Comment 3

The LDI rejects the comment made by HDA that “payments” following “drug reimbursement rates” is repetitive. Drug reimbursement rates are distinguishable from payments based on a reimbursement rate.

Comment 4

§18509 – A(2): Subsection Two identifies PSAOs as being responsible for “billing and collecting payments from payers on behalf of pharmacies.” As part of their services, PSAOs streamline the reconciliation process by receiving (and confirming the accuracy of) remittance advice from PBMs, and subsequently passing on pharmacies’

reimbursement. However, PSAOs do not directly bill PBMs. Billing PBMs for medications dispensed would be done via the National Council for Prescription Drug Programs (NCPDP) standards by the pharmacy. Moreover, PSAOs receive claim payments on behalf of pharmacies from PBMs, not payers. This is reflected in the ‘Roles and Responsibilities of PBMs’ (Sec. §18507 – A(3)). Consequently, we ask that “billing” be removed, and further request “collecting payments from payers on behalf of pharmacies” be replaced with “validating remittance advice that meets federally sanctioned standards (i.e., X12 835).”

LDI Response to Comment 4

The LDI rejects the recommendation that the language in §18509(A)(2) be changed to “validating remittance advice that meets federally sanctioned standards (i.e., X12 835)”. As written, §18509(A)(2) accurately describes the pharmacy services administrative organizations role and does not exclude others involved in the billing process. Further, the standards used are not relevant to defining this role.

Comment 5

§18509 – A(3): While PSAOs “[use] contractual agreements to develop networks of member pharmacies,” this is seemingly out of place within the rules, especially as the second sentence goes on to generalize what may be in the contracts between PSAOs and their pharmacy clients. We suggest striking the provision entirely or, alternatively, removing the second sentence.

LDI Response to Comment 5

The LDI rejects the recommendation that §18509(A)(3) be stricken entirely or the second sentence be removed. As written, §18509(A)(3) accurately describes the pharmacy services administrative organizations role.

Comment 6

§18509 – A(4): Subsection four asserts PSAOs “[negotiate] access for pharmacies to networks and patients. It is PSAOs’ objective to seek equitable access to pharmacy networks on behalf of independent pharmacies. In this instance, we ask that “negotiating” be replaced with “obtaining.” Like all members of the healthcare supply chain, access to care is of the utmost importance. However, PSAOs do not represent individual policyholders and, as a result, it is improper to include “and patients” in this provision.

LDI Response to Comment 6

The LDI rejects the recommendation that the language of §18509(A)(4) be changed to replace “negotiating” with “obtaining” and to remove “and patients”. As written, §18509(A)(4) accurately describes the pharmacy services administrative organizations role.

Comment 7

§18509 – A(5): The claims in Subsection Five are entirely inaccurate and must be removed. PSAOs are not wholesale distributors and play absolutely no role in the facilitation of prescription drugs or medical products, nor do they liaise with pharmaceutical manufacturers.

LDI Response to Comment 7

The LDI rejects the conclusion by HDA that PSAOs do not facilitate the purchase of prescription drugs and other medical products from drug manufacturers and provide for delivery to pharmacies for dispensing. The LDI has received information that this activity outlined in §18507(A)(5) is the role and responsibility of pharmacy services administrative organizations.

Comment 8

§18509 – A(6): Subsection Six offers a glimpse of the ad hoc services provided by PSAOs; alas, we respectfully request the addition of “including, but not limited to” following “business strategy.”

LDI Response to Comment 8

La. R.S. 22:1660.9(C) requires the Commissioner of Insurance to “promulgate rules that define the roles and responsibilities solely within the purview of pharmacy benefit managers and pharmacy services administrative organizations.” The LDI rejects the recommendation made by HDA to add an additional language to §18509(A)(6) as this addition would go beyond the scope of the mandate issued in the statute.

Comment by Bert Melancon

Bert Melancon requested that the link to Regulation 122 be emailed to him again.

LDI Response

The request is not relevant to Regulation 122. However, the request was routed to the proper division within the LDI to be addressed.

Comment by David Recker

David Recker requested to be removed from the LDI mailing list.

LDI Response

The request is not relevant to Regulation 122. However, the request was routed to the proper division within the LDI to be addressed.

Subject to legislative oversight, the LDI intends to submit Regulation 122 to the Office of the State Register for final publication in the August 2022 edition of the *Louisiana Register*. A copy of the summary report will be placed on the LDI’s website in accordance with La. R.S. 49:968(D)(1)(c).

Enclosures:

Notice of Intent to Amend Regulation 122 - Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations

Public comments submitted by Pharmaceutical Care Management Association, Gainwell, Louisiana Independent Pharmacies Association, Healthcare Distribution Alliance, Bert Melancon and David Recker

3. A Statement of the Probable Effect on Impacted Small Businesses. The proposed regulation should have no measurable impact upon small businesses.

4. Describe any Less Intrusive or Less Costly Alternative Methods of Achieving the Purpose of the Proposed Rule. The proposed regulation should have no measurable impact on small businesses; therefore, there is no less intrusive or less costly alternative method of achieving the purpose of the proposed regulation.

Provider Impact Statement

1. Describe the Effect on the Staffing Level Requirements or Qualifications Required to Provide the Same Level of Service. The proposed regulation will have no effect.

2. The Total Direct and Indirect Effect on the Cost to the Provider to Provide the Same Level of Service. The proposed regulation will have no effect.

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of Service. The proposed regulation will have no effect.

Public Comments

Interested persons who wish to make comments may do so by writing to Jennifer Land, Staff Attorney, Louisiana Department of Insurance, P.O. Box 94214, Baton Rouge, LA 70804-9214, by faxing comments to (225) 342-1632, or electronically at public@ldi.la.gov. Comments will be accepted through the close of business, 4:30 p.m., April 9, 2022.

James J. Donelon
Commissioner

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Regulation 121—Term and Universal Life Insurance Reserve Financing

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed rule is not anticipated to result in implementation costs or savings to the state or local governmental units. The proposed rule is promulgated to implement the National Association of Insurance Commissioners (NAIC) Term and Universal Life Insurance Reserve Financing Model Regulation. This regulation sets forth rules and procedural requirements to establish uniform, national standards governing reserve financing arrangements pertaining to life insurance policies containing guaranteed nonlevel gross premiums or guaranteed nonlevel benefits and universal life insurance policies with secondary guarantees and to ensure that, with respect to each such financing arrangement, funds consisting of primary security and other security, as defined in §18305 - Definitions, are held by or on behalf of ceding insurers in the forms and amounts required herein.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule will have no impact on state or local governmental revenues.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

The proposed rule benefits all life insurance companies in the state of Louisiana by establishing rules and guidelines for reserve financing for certain covered term and universal life

policies. These policies are defined in this regulation under §18305- Definitions.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will have no impact upon competition and employment in the state.

Denise Gardner
Chief of Staff
2203#058

Evan Brasseur
Interim Deputy Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Insurance Office of the Commissioner

Regulation 122—Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations (LAC 37:XIII.Chapter 185)

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 promulgate Regulation 122—Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations. Regulation 122 defines the roles and responsibilities solely within the purview of pharmacy benefit managers and pharmacy services administrative organizations as required by R.S. 22:1660.9(C).

Title 37 INSURANCE

Part XIII. Regulations

Chapter 185. Regulation Number 122—Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations

§18501. Purpose

A. The purpose of this regulation is to define the roles and responsibilities solely within the purview of pharmacy benefit managers and pharmacy services administrative organizations as required by R.S. 22:1660.9(C).

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1641(8), R.S. 22:1655, R.S. 22:1660.1(B)(1), R.S. 22:1660.8, R.S. 22:1660.9(C) and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 48:

§18503. Applicability and Scope

A. Regulation 122 shall apply to all pharmacy benefit managers and pharmacy services administrative organizations licensed in Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1641(8), R.S. 22:1655, R.S. 22:1660.1(B)(1), R.S. 22:1660.8, R.S. 22:1660.9(C) and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 48:

§18505. Definitions

Pharmacy Benefit Manager—a person, business, or other entity and any wholly or partially owned or controlled subsidiary of such entity that either directly or through an intermediary manages or administers the prescription drug

and device portion of one or more health benefit plans on behalf of a third party, including insurers, plan sponsors, insurance companies, unions, and health maintenance organizations, in accordance with a pharmacy benefit management plan. The management or administration of a plan may include but is not limited to review, processing of drug prior authorization requests, adjudication of appeals and grievances related to the prescription drug benefit, contracting with network pharmacies, and controlling the cost of covered prescription drugs.

Pharmacy Services Administrative Organization—an entity that provides a contracted pharmacy with administrative, contracting, or payment services relating to prescription drug benefits.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1641(8), R.S. 22:1655, R.S. 22:1660.1(B)(1), R.S. 22:1660.8, R.S. 22:1660.9(C) and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 48:

§18507. Roles and Responsibilities of Pharmacy Benefit Managers

A. The roles and responsibilities solely within the purview of pharmacy benefit managers are as follows:

1. administering prescription drug plans for health plan sponsors;
2. formulary and benefit design support and management;
3. establishing reimbursement rates and making payments on behalf of health plan sponsors;
4. establishing and managing pharmacy networks to ensure network adequacy on behalf of health plans;
5. performing drug utilization management;
6. administering disease management and drug adherence programs; and
7. negotiating rebates and discounts from drug manufacturers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1641(8), R.S. 22:1655, R.S. 22:1660.1(B)(1), R.S. 22:1660.8, R.S. 22:1660.9(C) and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 48:

§18509. Roles and Responsibilities of Pharmacy Services Administrative Organizations

A. The roles and responsibilities solely within the purview of pharmacy services administrative organizations are as follows:

1. negotiating contracts, drug reimbursement rates, payments, and audit terms on behalf of pharmacy clients with pharmacy benefit managers;
2. billing and collecting payments from payers on behalf of pharmacies;
3. using contractual agreements to develop networks of member pharmacies. These agreements generally authorize pharmacy services administrative organizations to interact with third-party payers and pharmacy benefit managers;
4. negotiating access for pharmacies to networks and patients;
5. facilitating the purchase of prescription drugs and other medical products from drug manufacturers and providing for delivery to pharmacies for dispensing; and

6. assisting pharmacy clients with business strategy, pricing appeals, claims reconciliation, and certification and credentialing requirements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1641(8), R.S. 22:1655, R.S. 22:1660.1(B)(1), R.S. 22:1660.8, R.S. 22:1660.9(C) and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 48:

§18511. Effective Date

A. This regulation shall become effective upon final publication in the Louisiana Register.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1641(8), R.S. 22:1655, R.S. 22:1660.1(B)(1), R.S. 22:1660.8, R.S. 22:1660.9(C) and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 48:

Family Impact Statement

1. Describe the Effect of the Proposed Regulation on the Stability of the Family. The proposed regulation should have no measurable impact upon the stability of the family.

2. Describe the Effect of the Proposed Regulation on the Authority and Rights of Parents Regarding the Education and Supervision of their Children. The proposed regulation should have no impact upon the rights and authority of parents regarding the education and supervision of their children.

3. Describe the Effect of the Proposed Regulation on the Functioning of the Family. The proposed regulation should have no direct impact upon the functioning of the family.

4. Describe the Effect of the Proposed Regulation on Family Earnings and Budget. The proposed regulation should have no direct impact upon family earnings and budget.

5. Describe the Effect of the Proposed Regulation on the Behavior and Personal Responsibility of Children. The proposed regulation should have no impact upon the behavior and personal responsibility of children.

6. Describe the Effect of the Proposed Regulation on the Ability of the Family or a Local Government to Perform the Function as Contained in the Rule. The proposed regulation should have no impact upon the ability of the family or a local governmental unit to perform the function as contained in the Rule.

Poverty Impact Statement

1. Describe the Effect on Household Income, Assets, and Financial Security. The proposed regulation should have no effect on household income assets and financial security.

2. Describe the Effect on Early Childhood Development and Preschool through Postsecondary Education Development. The proposed regulation should have no effect on early childhood development and preschool through postsecondary education development.

3. Describe the Effect on Employment and Workforce Development. The proposed regulation should have no effect on employment and workforce development.

4. Describe the Effect on Taxes and Tax Credits. The proposed regulation should have no effect on taxes and tax credits.

5. Describe the Effect on Child and Dependent Care, Housing, Health Care, Nutrition, Transportation and Utilities

Assistance. The proposed regulation should have no effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance.

Small Business Analysis

The impact of the proposed regulation on small businesses as defined in the Regulatory Flexibility Act has been considered. It is estimated that the proposed action is not expected to have a significant adverse impact on small businesses. The agency, consistent with health, safety, environmental and economic welfare factors has considered and, where possible, utilized regulatory methods in the drafting of the proposed regulation that will accomplish the objectives of applicable statutes while minimizing the adverse impact of the proposed regulation on small businesses.

1. Identification and Estimate of the Number of the Small Businesses Subject to the Proposed Rule. The proposed regulation should have no measurable impact upon small businesses.

2. The Projected Reporting, Record Keeping, and Other Administrative Costs Required for Compliance with the Proposed Rule, Including the Type of Professional Skills Necessary for Preparation of the Report or Record. The proposed regulation should have no measurable impact upon small businesses.

3. A Statement of the Probable Effect on Impacted Small Businesses. The proposed regulation should have no measurable impact upon small businesses.

4. Describe any Less Intrusive or Less Costly Alternative Methods of Achieving the Purpose of the Proposed Rule. The proposed regulation should have no measurable impact on small businesses; therefore, there is no less intrusive or less costly alternative method of achieving the purpose of the proposed regulation.

Provider Impact Statement

1. Describe the Effect on the Staffing Level Requirements or Qualifications Required to Provide the Same Level of Service. The proposed regulation will have no effect.

2. The Total Direct and Indirect Effect on the Cost to the Provider to Provide the Same Level of Service. The proposed regulation will have no effect.

3. The Overall Effect on the Ability of the Provider to Provide the Same Level of Service. The proposed regulation will have no effect.

Public Comments

Interested persons who wish to make comments may do so by writing to Jennifer Land, Staff Attorney, Louisiana Department of Insurance, P.O. Box 94214, Baton Rouge, LA 70804-9214, by faxing comments to (225) 342-1632, or electronically at public@ldi.la.gov. Comments will be accepted through the close of business, 4:30 p.m., April 9, 2022.

James J. Donelon
Commissioner

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

RULE TITLE: Regulation 122—Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed rule is not anticipated to result in implementation costs or savings to the state or local governmental units. The proposed rule is promulgated to define roles and responsibilities of pharmacy benefit managers and pharmacy services administrative organizations as required by the LA Pharmacy Services Administrative Organization Licensing Act (R.S. 22:1660.9(C)).

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule will have no impact on state or local governmental revenues.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

The proposed rule benefits all pharmacy benefit managers and pharmacy services administrative organizations as it gives them guidance as to what their roles and responsibilities are. The proposed rule shall apply to all pharmacy benefit managers and pharmacy services administrative organizations licensed in Louisiana.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will have no impact upon competition and employment in the state.

Denise Gardner
Chief of Staff
2203#059

Evan Brasseur
Interim Deputy Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

**Department of Natural Resources
Office of Conservation**

**Guidance Manual for Environmental Boreholes
and Monitoring Systems (LAC 56:I.303 and 503)**

The Department of Natural Resources, Office of Conservation proposes to amend LAC 56 I.303.B and LAC 56:I.503.B in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., and pursuant to the power delegated under the laws of the state of Louisiana. The proposed amendment includes reference to the use of the *Guidance Manual for Environmental Boreholes and Monitoring Systems* in the water well registration and plugging and abandonment regulations of Title 56.

Title 56

PUBLIC WORKS

Part I. Water Wells

Chapter 3. Water Well Construction

§303. Purpose

A. ...

April 11, 2022

VIA E-MAIL: public@ldi.la.gov

VIA FAX: (225) 342-1632

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RE: Comments of Pharmaceutical Care Management Association regarding Proposed Regulation 122 – Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations

Dear Ms. Land:

We write to advise of our representation of Pharmaceutical Care Management Association (“PCMA”). PCMA is the trade association for Pharmacy Benefit Managers (“PBM”), a class of entities impacted by this proposed rule.

In reviewing the draft rule regarding the Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations, the phrase, “roles and responsibilities solely within the purview of pharmacy benefit managers” contained in proposed §18501 raised our concern that the phraseology might somehow be construed to limit the powers, roles and responsibilities that PBMs exercise in their ordinary operations permitted under applicable Louisiana law.

To clarify this uncertainty, PCMA recommends that proposed §18501, contain a second sentence to read as follows:

The purpose of this regulation is to define the roles and responsibilities solely within the purview of pharmacy benefit managers and pharmacy services administrative organizations as required by R.S. 22:1660.9(C). **This regulation is not to in any way restrict or confine the powers, roles and responsibilities as authorized to pharmacy benefit managers by federal and/or Louisiana laws.**

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Jennifer Land, Staff Attorney
April 11, 2022

We appreciate your consideration of PCMA's concerns and suggested amendments to the proposed rule. Please place these comments into the record of this rulemaking.

Please let us know if you require additional information.

Respectfully submitted

ADAMS AND REESE LLP

A handwritten signature in black ink that reads "Taylor M. LeDuff". The signature is written in a cursive style with a large, prominent 'T' and 'L'.

Robert L. Bieger, Jr.
Taylor M. LeDuff

*Attorneys for Pharmaceutical Care Management
Association*

RLR/lba



April 9, 2022

James Donelon, Commissioner of Insurance
Attention: Jennifer Land
Louisiana Department of Insurance
P.O. Box 94214
Baton Rouge, LA 70804-9214

RE: Proposed Regulation 122 — Roles and Responsibilities of Pharmacy Benefit Managers (PBMs) and Pharmacy Services Administrative Organizations (PSAOs) (LAC 37:XIII.Chapter 185)

Dear Commissioner Donelon and Ms. Land,

Gainwell appreciates the opportunity to comment on this proposed regulation. Gainwell provides technology, services and solutions vital to the administration and operations of government sponsored health and human services programs. For more than 50 years we have proudly served in excess of 40 Medicaid programs across the country, including the Louisiana Department of Health. We offer clients scalable and flexible solutions for their most complex challenges from eligibility and enrollment, to claims payment, fraud, waste and abuse and benefit administration, including pharmacy benefits. Given our unique experience in the Medicaid program, our comments will focus exclusively on the potential impact of this regulation to it.

Medicaid covers nearly 79 million people nationally and 1.9 million in Louisiana. While jointly funded by the federal and state government, Louisiana Department of Health successfully administers this critical program which includes pharmacy coverage within federal guidelines and with respect to Louisiana's unique needs.

The prescription drug supply chain and pricing in the United States is extraordinarily complex and under scrutiny. Both issues have been, and

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remain, prominent in state and federal policy debates. Medicaid is pivotal in that debate given its program size, disproportionate burden of chronically ill patients and coverage for high-cost specialty drugs, and unique supply chain process.

Simply put, Medicaid pharmacy benefit administration is very different than other markets. For the reasons further articulated below, **we respectfully ask the Department of Insurance to exclude pharmacy benefit managers contracted directly with the Louisiana Department of Health from this regulation.** This is consistent with other states practices, but also affords Louisiana the greatest flexibility to manage a program providing healthcare to more than 40% of the state's population and consuming a significant portion of the state's budget.

Medicaid is Uniquely Different and Should Be Regulated Differently

The Medicaid program is subject to substantial federal regulation and unique state and federal contracting arrangements with drug manufacturers, including Medicaid rebate programs which dramatically reduces the price of drugs for Medicaid and protects the state from price increases greater than the overall rate of inflation (CPI-U), as compared to different pricing dynamics in Medicare and the commercial market.

At the same time, states maintain autonomy to establish and manage its Medicaid pharmacy benefit as appropriate for their populations. The Louisiana Medicaid program appoints local physicians in staffing its drug utilization review (DUR) board and pharmacy and therapeutics (P&T) committee to oversee and administer Medicaid pharmacy benefits and clinical policies and contracts directly with Pharmacy Benefit Administrators (PBAs) to process prior authorization requests and adjudicate claims pursuant to the explicit direction of the Medicaid program benefit design and policies as established by the state. Wrapping the State's PBA into this regulation would

fundamentally alter the design and management of the state's Medicaid pharmacy program and impact its economics.

Gainwell appreciates the Department's consideration of these comments and is available to answer any questions. Please feel free to contact me at joseph.giamfortone@gainwelltechnologies.com.

Sincerely,

Joey Giamfortone
Principal, Government Relations



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Randal Johnson
President & CEO

April 9, 2022

Jennifer Land
Louisiana Department of Insurance
Post Office Box 94214
Baton Rouge, Louisiana 70802
public@ldi.la.gov

Sent Via Email

RE: Public Comment to Regulation 122 – Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations

Dear Ms. Land:

The Louisiana Independent Pharmacies Association (LIPA) represents over 400 independent, community pharmacies across Louisiana. Each interacts daily with multiple Pharmacy Benefit Managers (PBMs) and Pharmacy Services Administrative Organizations (PSAOs) to serve their patients. We appreciate the opportunity to offer comments on their behalf regarding Regulation 122 as required by Act 192 of the 2021 Regular Legislative Session.

§18501. Purpose

In accordance with Louisiana Revised Statute 22:1660.9(C), Regulation 122 is attempting to define the roles and responsibilities "solely within the purview" of PBMs and PSAOs. A cursory search of Louisiana laws did not reveal similar language in the Louisiana Insurance Code, but it was used several times to define jurisdiction or geographic boundaries.

Merriam-Webster defines "solely" as "the exclusion of all else; without another."¹ LIPA suggests everything in contractual relationship requires input from at least two parties and that nothing can be said to be "solely within the purview" of a PBM or PSAO because of their contracts with health plans, employers, and pharmacies. This is especially true within an industry as dynamic as healthcare, and more particularly pharmacy benefits.

CVS Caremark, the nation's largest PBM, serving over ninety million customers annually, is a good example. CVS is turning into a "uniquely powerful platform" for delivering healthcare and is trying to become "a sort of underlying infrastructure for all health activities, much as Amazon is the underlying infrastructure for online retail."² The key to this power is its PBM. Cigna, an insurance company, is another example, skyrocketing 52 spots up the Fortune 500 list after merging with the PBM Express Scripts.³

¹ Merriam-Webster, <https://www.merriam-webster.com/dictionary/solely>

² Matt Stoller, *How CVS Became A Health Care Tyrant*, BIG by Matt Stoller (February 1, 2020), <https://mattstoller.substack.com/p/how-cvs-became-a-health-care-tyrant?s=r>

³ Rebecca Pifer, *Cigna jumps 52 spots on Fortune 500 off Express Scripts Buy*, HEALTHCARE.DIVE.COM (May 19, 2020), <https://www.healthcaredive.com/news/cigna-jumps-52-spots-on-fortune-500-off-express-scripts-buy/578162/>



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Randal Johnson
President & CEO

Rulemaking in Louisiana is a long and arduous task. As the healthcare industry continues to develop, LIPA believes it is bad public policy to enshrine the roles of industry participants in regulations. La. R.S. 22:1660.9 does not require the Louisiana Department of Insurance (LDI) to revisit this regulation, which may lead to consequences for independent pharmacies not contemplated by Acts 2021, No. 192.

If Regulation 122 is implemented with multiple roles and responsibilities for PBMs and PSAOs, PSAOs are not responsible for any activities solely within the purview of PBMs. La. R.S. 22:1660.9(B). As time passes and the healthcare industry evolves, will LDI have to revisit Regulation 122 annually? After each merger or acquisition of a PBM? The Louisiana Board of Pharmacy estimates forty-five (45) PBMs are active in Louisiana.⁴ Are the roles and responsibilities of each universal? Will Regulation 122 prevent other actors within the healthcare industry from performing these roles or responsibilities? To create a loophole in Louisiana law for PSAOs without more clarity is irresponsible public policy. As such, LIPA suggests LDI cannot define *any* role or responsibility "solely within the purview" of PBMs or PSAOs.

In an abundance of caution, LIPA will also address the specific defined roles and responsibilities of PBMs and PSAOs, despite its position on these factors generally. For §18507, upon information and belief, LIPA understands each of these factors are done in conjunction with the health plan or employer, thereby eliminating the possibility they are done "solely" by the PBM.

§18507. Roles and Responsibilities of Pharmacy Benefit Managers

2. formulary and benefit design support and management. Upon information and belief, PBMs do not "design" drug formularies. These are designed by the health plan or employer for the benefit of their beneficiaries or employees. They are integral component of the formulary, so a PBM cannot be "solely" responsible for this factor.

3. establish reimbursement rates and making payments on behalf of health plan sponsors. PBMs may remit a portion of the payment, but these dollars also flow to, and ultimately through, PSAOs. Because PSAOs contract with both PBMs and pharmacies to ensure payments are made, PBMs cannot be "solely" responsible for this factor.

4. establishing and managing pharmacy networks to ensure network adequacy on behalf of health plans. PSAOs also establish networks of pharmacies. Once a network is established, PSAOs contract with PBMs on behalf of those pharmacies. Therefore, PBMs cannot be "solely" responsible for this factor.

§18509. Roles and Responsibilities of Pharmacy Services Administrative Organization

LIPA's representation of independent, community owned pharmacies in Louisiana is comprehensive. We are more familiar with the PSAO-pharmacy relationship because we can assist member pharmacies with that contract, often because of the inability of the PSAO to effectively advocate on behalf of the pharmacy.

⁴ Legislative Fiscal Office, *Fiscal Note on SB99* (March 17, 2022), <https://legis.la.gov/legis/ViewDocument.aspx?d=1260146>



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Randal Johnson
President & CEO

LIPA helps its members negotiate contracts, including for network access, and assists with audits, strategy, pricing appeals, claims reconciliation, and certification and credentialing requirements. These invalidate factors 1, 3, and 6. More broadly, it supports LIPA's position that nothing is "solely within the purview" of a PBM or PSAO.

Regarding factor 2, pharmacies bill directory through their computer systems, not through their PSAO. For example, Express Scripts only contracts with four PSAOs operating in Louisiana. Every pharmacy in the state that does not use one of those four must bill the PBM or health plan directly, which happens through their computer system. This invalidates factor 2.

Regarding factor 5, two Louisiana and several national drug wholesale companies purchase prescription drugs and other medical products for delivery to pharmacies, not PSAOs. This invalidates factor 5.

LIPA requests LDI revisit Regulation 122 as drafted. As shown above, it is bad public policy to define the roles and responsibilities "solely within the purview" of any market participant, especially a participant in a market as dynamic as healthcare. LDI cannot definitively identify any factor "solely within the purview" of PBMs or PSAOs for the purpose of this Notice of Intent, and should instead withdraw Regulation 122 in its entirety.

Please contact my office if we can provide clarity or additional information.

Sincerely,

Randal Johnson
President & CEO



Healthcare Distribution Alliance

PATIENTS MOVE US.

Louisiana Department of Insurance
Attention: Jennifer Land
1702 North 3rd Street
Baton Rouge, Louisiana 70802

April 4, 2022

Re: Public Comment to Regulation 122 - Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations

Dear Ms. Land,

On behalf of the Healthcare Distribution Alliance (HDA), the national trade association representing primary healthcare distributors, we appreciate the opportunity to provide the following comments on Regulation 122 as required per Act 192 of the 2021 Regular Legislative Session. HDA worked with a group of the six largest PSAOs to collect and provide these comments to Regulation 122.

Background

Independent pharmacies rely on Pharmacy Services Administrative Organizations (PSAOs) to interact with third-party payers and Pharmacy Benefit Managers (PBMs). PSAOs provide valuable services to independent pharmacies in their relationship with third-party payers and PBMs to relieve administrative burdens for these small business owners. Below we have identified specific areas in the Intended Rules with which have concern and provided supporting commentary.

Comments in Response to Louisiana Department of Insurance Regulation 122

- **§18507 – Roles and Responsibilities of Pharmacy Benefit Managers**
 - **§18507 – A(3):** Subsection Three states PBMs “[make] payments on behalf of health plan sponsors.” As this subsection pertains to reimbursement terms, we encourage additional detail. PBMs are responsible for proper claim(s) adjudication (claims for reimbursement submitted by pharmacies) over and above simply being responsible for plan payments and administration.

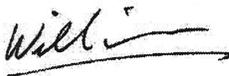
- **§18509 – Roles and Responsibilities of Pharmacy Services Administrative Organizations**
 - **§18509 – A(1):** Subsection One identifies PSAOs as responsible for “negotiating contracts, drug reimbursement rates, payments, and audit terms on behalf of pharmacy clients with pharmacy benefit managers.” It is worth noting PSAOs do not sign every contract offered by a PBM, nor enter into contracts without evaluating the options for their pharmacy clients. Respectfully, we ask that “negotiating” be replaced with “evaluating and executing contracts that include...”
 - Further, the reference to “payments” following “drug reimbursement rates” is ostensibly the same. As Louisiana statute already codifies PBMs’ reimbursement remittance advice deadline, including “payments” is repetitive.
 - **§18509 – A(2):** Subsection Two identifies PSAOs as being responsible for “billing and collecting payments from payers on behalf of pharmacies.” As part of their services,

PSAOs streamline the reconciliation process by receiving (and confirming the accuracy of) remittance advice from PBMs, and subsequently passing on pharmacies' reimbursement. However, PSAOs do not directly bill PBMs. Billing PBMs for medications dispensed would be done via the National Council for Prescription Drug Programs (NCPDP) standards by the pharmacy. Moreover, PSAOs receive claim payments on behalf of pharmacies from PBMs, not payers. This is reflected in the 'Roles and Responsibilities of PBMs' (Sec. §18507 – A(3)). Consequently, we ask that "billing" be removed, and further request "collecting payments from payers on behalf of pharmacies" be replaced with "validating remittance advice that meets federally sanctioned standards (i.e., X12 835)."

- **§18509 – A(3):** While PSAOs "[use] contractual agreements to develop networks of member pharmacies," this is seemingly out of place within the rules, especially as the second sentence goes on to generalize what may be in the contracts between PSAOs and their pharmacy clients. We suggest striking the provision entirely or, alternatively, removing the second sentence.
- **§18509 – A(4):** Subsection Four asserts PSAOs "[negotiate] access for pharmacies to networks and patients. It is PSAOs' objective to seek equitable access to pharmacy networks on behalf of independent pharmacies. In this instance, we ask that "negotiating" be replaced with "obtaining." Like all members of the healthcare supply chain, access to care is of the utmost importance. However, PSAOs do not represent individual policyholders and, as a result, it is improper to include "and patients" in this provision.
- **§18509 – A(5):** The claims in Subsection Five are **entirely inaccurate** and must be removed. PSAOs are not wholesale distributors and play absolutely no role in the facilitation of prescription drugs or medical products, nor do they liaise with pharmaceutical manufacturers.
- **§18509 – A(6):** Subsection Six offers a glimpse of the *ad hoc* services provided by PSAOs; alas, we respectfully request the addition of "including, but not limited to" following "business strategy."

HDA enjoys its rapport with the Department of Insurance and is appreciative of this opportunity to comment. We look forward to continuing discussions to ensure the rulemaking sought in Act 192 is accurate and free of confusion. As always, please do not hesitate to contact Will Dane at (571) 287-3020 or wdane@hda.org.

Sincerely,



Will Dane
Director, State Government Affairs
Healthcare Distribution Alliance

From: John Ford
To: Jennifer Land
Subject: FW: Regulation 122
Date: Monday, March 21, 2022 12:30:30 PM
Attachments: image001.png

John Ford
Deputy Commissioner
Division of Public Affairs
Louisiana Department of Insurance
(225) 342-4950



From: Bert Melancon <bertmelancon@gmail.com>
Sent: Tuesday, March 15, 2022 5:08 PM
To: Public Affairs <public@ldi.la.gov>
Subject: Re: Regulation 122

I am unable to open Regulation 122 file in the email. Can you resend it? To the email address [Bertmelancon@gmail.com](mailto:bertmelancon@gmail.com) so I can review.

Bert Melancon
225.802.5752

From: [John Ford](#)
To: [Jennifer Land](#)
Subject: FW: Notice of Intent to promulgate Regulation 122 – Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations
Date: Monday, March 21, 2022 12:20:15 PM
Attachments: [image001.png](#)

This was just a removal request but didn't know if it was technically a response you'd need to see.

John Ford
Deputy Commissioner
Division of Public Affairs
Louisiana Department of Insurance
(225) 342-4950



From: Public Affairs <public@ldi.la.gov>
Sent: Monday, March 21, 2022 12:19 PM
To: John Ford <John.Ford@ldi.la.gov>
Subject: FW: Notice of Intent to promulgate Regulation 122 – Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations

From: Recker, David <David.Recker@marsh.com>
Sent: Tuesday, March 15, 2022 9:50 AM
To: Public Affairs <public@ldi.la.gov>
Subject: RE: Notice of Intent to promulgate Regulation 122 – Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations

Thank you!!

David Recker, Senior Vice President
Marsh Specialty | FINPRO Central Zone
540 West Madison, #1200
Chicago, IL 60661
(412) 225-0687
David.recker@marsh.com

From: Public Affairs <public@ldi.la.gov>
Sent: Tuesday, March 15, 2022 9:44 AM
To: Recker, David <David.Recker@marsh.com>

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Thank you

From: Recker, David <David.Recker@marsh.com>
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David Recker, Senior Vice President
Marsh Specialty | FINPRO Central Zone
540 West Madison, #1200
Chicago, IL 60661
(412) 225-0687
David.recker@marsh.com

From: Louisiana Department of Insurance <ldinoreply@ldi.la.gov>
Sent: Monday, March 14, 2022 3:38 PM
To: Recker, David <David.Recker@marsh.com>
Subject: Notice of Intent to promulgate Regulation 122 – Roles and Responsibilities of Pharmacy Benefit Managers and Pharmacy Services Administrative Organizations

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The purpose of Regulation 122 is to define the roles and responsibilities solely within the purview of pharmacy benefit managers and pharmacy services administrative organizations as required by R.S. 22:1660.9(C). Interested persons who wish to make comments may do so electronically at public@ldi.la.gov. Comments will be accepted through the close of business,

4:30 p.m., April 9, 2022.

View Regulation 122 [here](#).

J. David Caldwell
Executive Counsel
225-342-4673
David.Caldwell@ldi.la.gov

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