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COMMISSIONER

May 12, 2025

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RE: Summary Report - Notice of Intent to Amend Regulation 90 - Payment of Pharmacy and Pharmacist Claims

Dear President Henry, Speaker DeVillier, Senator Talbot, and Representative Firment:

The Louisiana Department of Insurance (LDI) hereby submits the following summary report required by La. R.S. 49:966(D)(1)(b) and announces its intention to proceed to finalize Regulation 90, which was published as a Notice of Intent in the February 2025 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 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.

The Louisiana Department of Insurance ("LDI") received two comment letters from the Pharmaceutical Care Management Association ("PCMA") regarding the proposed amendments to Regulation 90. The first letter was submitted on September 6, 2024, and the second letter was submitted on October 9, 2024. A summary of PCMA's comments and the LDI's responses is provided below.

September 6, 2024 PCMA Letter

Comment 1: Request to Remove Audit Language from Purpose Section (§11501)

This section of the draft language for Reg. 90 rulemaking states that the purpose of the section relates to the prompt and correct payment for prescription drugs. It also includes language regarding contracts that provide for pharmacy benefits, "and for the review and auditing of claims or records pertaining to such services." This language conflates the issue of prompt payment with pharmacy audits.

Prompt payment refers to a payor, oftentimes a health plan, paying a provider that may be a pharmacy, within a requisite amount of time. A pharmacy audit is an entirely separate issue. An audit of a pharmacy may occur as a routine practice, oftentimes adhering to the contract terms of a contract, and other times may result when FWA is suspected.

As evidence by all the stricken language in the LDI's draft, the existing Reg. 90 language's purpose is for payment of covered (i.e., under the benefit terms of a health plan) prescription drugs. It has no relation to pharmacy audits. PCMA respectfully requests that the LDI determine whether Reg. 90 is the appropriate place in existing law for issues relating to audits.

LDI Response to Comment 1:
The LDI disagrees. Regulation 90 was originally promulgated to implement Subpart C of La. R.S. 22:1851–1862, which governs the payment of claims for covered prescription drugs. Following the enactment of La. R.S. 22:1856.1 through Act 856 of the 2012 Legislative Session, which placed pharmacy audit provisions into Subpart C, the LDI promulgated Regulation 90 to establish statutory provisions specifically governing pharmacy audits.

The deletion of certain language from the Purpose section is intended to remove statements of legislative intent, which are appropriately reflected in statute but are not proper for regulatory text issued by an executive branch agency. The legislative intent underlying these provisions is indicated in La. R.S. 22:1851.

Therefore, the inclusion of both prompt payment and audit provisions within Regulation 90 is appropriate, necessary, and consistent with the statutory framework the regulation is intended to implement.

Comment 2: Request for Explanation of "Pharmacy" Definition (§11505)
The LDI's draft language currently defines "pharmacy" as: includes a pharmacy, pharmacy owner, pharmacy employer, or an agent thereof. As in most states, Louisiana licenses pharmacies. They are generally regulated by the Louisiana Board of Pharmacy, while also having some oversight from the LDI. PCMA respectfully requests that the LDI explain its intent regarding why an "owner," "employer," or "agent," are necessary for the inclusion in this definition of "pharmacy."

LDI Response to Comment 2:
The LDI agrees to revise the definition of "pharmacy" to more closely align with the definition set forth in La. R.S. 22:1852(10). Consistency with statutory definitions is important to maintain

clarity and enforceability across related regulatory and statutory provisions. Accordingly, the LDI revised the NOI draft language to mirror the statutory definition.

Comment 3: Objection to Audit-Related Policies and Procedures Approval Requirement (§11507(A)(3)

This subsection sets forth the parameters for both the content of the policies and procedures ("P&P") governing pharmacy record audits, as well as the approval process for the P&P. At the outset, this draft language does not appear to provide for any reconnaissance and/or ability to cure. Specifically, in the event that the LDI does not approve a P&P, the LDI puts PBMs and other payors at risk for breaching existing contracts. Non-approval may also put PBMs and other payors out-of-compliance regarding federal law pertaining to audits.

And as previously mentioned, audits are distinct and separate from prompt payment. The inclusion of language related to audits in the LDI's draft language for Reg. 90 is outside the parameters of the existing language of Reg. 90.

For example, concurrent reviews should not be considered audits and that this rule has the potential to restrict this type of activity which could actually harm pharmacies. Concurrent reviews of high dollar claims or claims submitted with abnormal quantities or dosages should not be restricted, as they prevent audits and recoupments. These reviews and outreaches occur in near real-time, typically within three days of the claim's original submission, they provide education on proper claims submission, and no chargeback or recoupment is demanded.

Pharmacies will typically voluntarily correct the claims, and are grateful for the outreach, as the interaction allows for the claims to be corrected before it was initially paid (preventing recoupments/chargebacks), and they are able to prevent future errors that may result in an audit. These types of reviews and interaction prevent audits for pharmacies. Restricting this type of activity, which is performed on behalf of all types of payors, will directly hurt pharmacies and could lead to more recoupments.

LDI Response to Comment 3:

The LDI disagrees with PCMA's concern that requiring approval of pharmacy audit policies and procedures could place PBMs and other payors at risk of breaching existing contracts.

All entities operating within Louisiana, including PBMs, must comply with applicable state laws and regulations. Contractual provisions cannot override or negate compliance obligations under Louisiana law. To the extent that a contract does not permit compliance with state law, it is the responsibility of the contracting parties to revise or renegotiate their agreements accordingly.

The regulatory requirements do not create contractual breaches. Compliance with Regulation 90 is necessary to meet legal obligations under Louisiana law.

Comment 4: Request for Clarification of "Selection Criteria or Algorithm" Requirement for Audits (§11507(A)(3)(a))

This subsection of the draft language requires that PBMs and other payors "specify the selection criteria or algorithm used to select pharmacies for auditing." PCMA respectfully requests that the

LDI elaborate on the meaning and intent for this subsection. Pharmacies selected for audits are generally selected as a result of a compilation of contractually-required audits.

Payors, including government/public programs, often drive PBM pharmacy audit contract provisions by placing certain payment integrity contractual requirements on PBMs. Publicly available state and local government requests for proposals (RFPs) provide transparency and insight into this dynamic. For example, a recent RFP for the Tennessee state employee benefits plan (A/K/A "ParTNers for Health") requires any PBM they contract with to "detect and prevent errors, fraud or abusive pharmacy utilization by members, pharmacies or prescribers" and the PBM "shall contact pharmacies with aberrant claims or trends to gain an acceptable explanation for the finding or to submit a corrected claim." Similar provisions are commonplace in RFPs for both Medicaid and state employee benefits plans in other states.

PBMs may also be required to execute performance guarantees, where a plan sponsor requires the PBM to audit a specific number of pharmacies. These performance guarantees frequently do not include the exact same pharmacies that would qualify for every plan sponsor. Payors can also request that specific pharmacies are reviewed for audits when they review their individual data or have patient comments that are relayed to the plan.

Additionally, it is nearly impossible to "specify selection criteria," since it could also include, but not be limited to a plethora of reasons, and/or can be based on an auditor's expertise in the practice of pharmacy to understand when claims show potential outlier behavior and decide that an audit is warranted. This is not something that can necessarily be translated to P&P.

Generally, audits may be initiated for any number of reasons including, but not limited to:
• receipt of an anonymous tip;
• data analysis reveals the pharmacy has outlier billing activity;
• an onsite auditor has concerns with low shelf stock;
• a plan sponsor request that specific pharmacies are reviewed for audits when they review their individual data or have a patient's comments that are replayed to the plan;
• proximity to another location that selected for audit; or
• random audits

LDI Response to Comment 4:
The LDI disagrees with PCMA's concern regarding the requirement to disclose selection criteria or algorithms used to identify pharmacies for audits. The regulation only requires entities to generally describe the criteria they use for audits. It does not require detailed examples.

Additionally, Regulation 90 applies only to regulated health insurance issuers as defined in La. R.S. 22:1852(7) and as stated in Section 11503 of the regulation. Therefore, concerns about compliance with requirements in other states, Medicaid plans, or other non-regulated arrangements are outside the scope of this regulation. PBMs and payors are required to comply with Louisiana law for plans subject to the LDI's jurisdiction.

Comment 5: Request for Clarification of "Claim Review" and "Quality Assurance Review" Definitions (§11507(A)(4))

This subsection establishes P&P parameters for claim reviews, as well as quality assurance reviews. PCMA respectfully requests that the LDI explain how a "claim review" or a "quality assurance review" are different from a pharmacy audit.

LDI Response to Comment 5:
The LDI agrees with PCMA that additional clarification was needed to distinguish between pharmacy record audits, claim reviews, and quality assurance reviews.

In response to this concern, the LDI has revised the regulation to separately address each type of review. Pharmacy record audits are governed under Section 11511, claim reviews are addressed under newly created Section 11513, and quality assurance reviews are addressed under newly created Section 11515. This restructuring makes clear that only pharmacy record audits are considered audits subject to La. R.S. 22:1856.1, while claim reviews and quality assurance reviews are distinct processes not governed by that statute.

Comment 6: Objection to Annual Limitation on Audits (§11507(A)(4)(a))
This subsection misunderstands pharmacy audits. PBM and/or payor audits of pharmacies are not limited to annually. Further, the LDI must understand that audits are done on behalf of all lines of business, including all private payors (i.e., employer-sponsored health plans, etc.), as well as government/public payors (i.e., Medicare, Medicaid, TRICARE, etc.).

Additionally, FWA is a specific audit type, and is a standard of practice for all payors of health care, private and/or public, and not limited to pharmacies. Health systems, medical clinics, and solo-practitioner physicians are all subject to the possibility of FWA audits. The draft language of this subsection again conflates multiple issues.

Moreover, pharmacy audits do not single out pharmacies or create large burdens. The truth is virtually all health care stakeholders are regularly audited in detail. To put in context the scale of audit activities, the federal government alone has been spending over $2 billion per fiscal year since 2019 on audits and related oversight activities of the various providers and entities participating in Medicare, Medicaid, and other government programs. PBMs use pharmacy audits to ensure patients receive high-quality services from network pharmacies and to verify that no FWA is taking place.

Finally, this subsection would require that PBMs and other payors submit and achieve LDI-approval for all audit P&P prior to either sharing the P&P with pharmacies or implementing the P&P. Such a regulatory scheme would put the LDI and the State of Louisiana in category by itself among all 50 states in its attempt to regulate the commercial relationship between pharmacies and payors. It is extreme state government interference, one-sided, and only benefits pharmacies who would have the state acting as its caretaker and protector in a commercial and contractual relationship.

LDI Response to Comment 6:
The LDI disagrees with PCMA's interpretation regarding the requirement for prior approval of alternative terms for claim reviews.

The regulation only requires that entities disclose what terms they are using for claim reviews. It does not restrict their ability to conduct audits for fraud or willful misrepresentation.

To further clarify this point, the LDI has made edits to the draft regulation by moving the "except" clause for fraud and willful misrepresentation audits to the end of the sentence and deleting unnecessary references to "whether paid or unpaid." These changes are intended to improve readability and ensure the regulation's meaning is clear.

Comment 7: Objection to "Unduly Burdensome" and "Overly Broad" Standard for Audit Criteria and Limit on Number of Audits for Claims Review (§11507(A)(4)(b))
The draft language in this subsection elaborates on the "criteria or algorithm used" in determining claim reviews. It states that said determinations may not be "unduly burdensome" or "overly broad." Such terms are subjective on their face. Therefore, the terms do not contain enough specificity for compliance. For these reasons, please also refer to our comments in (A)(3)(a) above.

Also, the draft language continues to state that safeguards in determining said reviews will include "limits on the number of reviews" to which a pharmacy may be subject. PCMA respectfully requests that the LDI rethink this language. Our member companies cannot agree to the limits on audits as set forth in this subsection. If FWA is suspected, PBMs and other payors need to be able to conduct a pharmacy audit, as well as take action to prevent it from continuing and/or repeating.

Lastly, the LDI must understand that audits are done on behalf of a plethora of distinct types of PBM clients, i.e., the payors. These clients may include businesses, families, individual consumers, state or local government entities, or federal government entities. The frequency of audits may be contractually required, set via accreditation standards, or be required under federal law. Because of all these factors, there is no way to commit to only performing a specific number of audits within a 30-day period. And the quantity of information and data a pharmacy being audited must produce depends on the nature of the audit.

LDI Response to Comment 7:
The LDI acknowledges PCMA's comment regarding the use of the terms "unduly burdensome" and "overly broad". The LDI declines to adopt this comment. The language as drafted provides appropriate flexibility and oversight.

The LDI disagrees with PCMA's concern regarding the limits on the number of reviews a pharmacy may be subject to. Section 11507(A)(4)(b) applies only to claim reviews. The 30-day period and the limitations on the number of reviews does not apply to pharmacy record audits or fraud, waste, and abuse (FWA) audits, which are addressed separately under Section 11507(A)(5). The language as drafted, appropriately reflects this distinction.

Comment 8: Objection to "Unduly Burdensome" and "Overly Broad" Standard for Audit Criteria and Limit on Number of Audits for Quality Assurance Review (§11507(A)(4)(c))
The draft language in this subsection mirrors the previous subsection, (b), except it relates to a "quality assurance review" rather than a "claim review." For the sake of brevity, PCMA and its member companies reiterate for subsection (c) all the previous arguments and points made for the immediately preceding subsection (b).

LDI Response to Comment 8:
The LDI disagrees with PCMA's concern. As noted above, the 30-day period and limitations on reviews do not apply to audits, which are addressed separately under §11507(A)(5). Quality assurance reviews are addressed separately to ensure that their requirements are clearly stated and not assumed to be the same as claim reviews.

Comment 9: Request for Clarification Repeated Language for Claim Reviews (§11507(A)(4)(d))
This subsection appears duplicative, as it mirrors the draft language in (3)(b). Thus, PCMA questions its relevance as repeated in this subsection.

LDI Response to Comment 9:
The LDI disagrees with PCMA's concern. As noted above, the 30-day period and limitations on reviews do not apply to audits, which are addressed separately under §11507(A)(5). Quality assurance reviews are addressed separately to ensure that their requirements are clearly stated and not assumed to be the same as claim reviews.

Comment 10: Objection to Narrow Definition of FWA (§11507(A)(5))
This subsection pertains to P&P regarding the performance of FWA audits of pharmacies. However, the draft language specifies, "fraud or willful misrepresentation." This language would make Louisiana unique in not including standard language specifying that FWA actually means fraud, waste, and/or abuse. In other words, it may put out of reach, pharmacy audits related to waste and/or abuse. Thus, pharmacies in Louisiana would have to comply with lower standards than pharmacies in other states, leading to a multitude of patient safety and cost issues.

There are distinct types of behaviors that private and public payors seek to prevent and/or discontinue in payment for health care services, including payments to pharmacies. Limiting pharmacy audits to "willful misrepresentation" puts Louisiana pharmacies on a pedestal, not subject to the same rules as other entities and individuals in the state's health care system.

LDI Response to Comment 10:
The LDI disagrees with PCMA's concern. The language in §11507(A)(5) mirrors the language in La. R.S. 22:1856.1(B)(3), which refers to "fraud or willful misrepresentation." The regulation must remain consistent with the statute.

Comment 11: Request for Clarification of "Triggers or Criteria" for FWA Audits (§11507(A)(5)(a))
The draft language in this subsection continues the language related to the P&P related to FWA audits of pharmacies by requiring that PBMs and other payors specify "any triggers or criteria" that may result in a "fraud or willful misrepresentation audit." PCMA respectfully requests that the LDI specify the meaning and intent of this subsection. Is the LDI's intent for PBMs and the vast array of private and public payors of health care in Louisiana to explain the behaviors the give rise to audits and/or reviews of health care entities such as pharmacies?

LDI Response to Comment 11:
The LDI disagrees with PCMA's concern. The intent of this section is to require PBMs to describe categories of audit triggers, such as suspected billing fraud or unusual claim patterns, not to list specific examples or fact patterns.

Comment 12: Objection to Limitations on FWA Audit Procedures (§11507(A)(5)(b))
This subsection would place limits on PBMs and other payors implementing P&P for FWA audits in contrast to "pharmacy record audits, claim reviews, and quality assurance reviews." As previously stated, some of the terms in the draft language for Reg. 90 rulemaking are confusing.

The terms "claim review" and "quality assurance review" need to be defined for the purposes of the issues at hand in Reg. 90.

Moreover, it is not prudent to limit the ability to detect, prevent, and act against any pharmacy that is either breaking the law or not providing services it is contractually required to provide. It would be improper for the LDI to limit the ability of a PBM or other payor to investigate and act against illegality or failure to contract adherence, including recoupment.

LDI Response to Comment 12:
The LDI acknowledges PCMA's concern regarding potential confusion caused by the original language requiring entities to "implement a function sufficiently narrow in purpose."

In response, the LDI has revised this section to require PBMs and payors to describe the purpose, scope, and a set of invoking criteria for fraud or willful misrepresentation audits. This clarification ensures that fraud audits are distinguished from pharmacy record audits, claim reviews, and quality assurance reviews, while allowing PBMs and payors to continue investigating fraud and seeking recoupments.

LDI Additional Response regarding §11509:
PCMA raises the same concerns regarding §11509 as those raised under §11507. This is expected, as §11509 mirrors the language of §11507 in its entirety, with the only distinction being that §11509 applies to electronic pharmacy claims rather than non-electronic claims. Accordingly, the LDI's responses to PCMA's comments on §11507 apply equally to §11509 and should be read as addressing both sections.

Comment 13: Request for Definition of "Claim Review" and "Quality Assurance Review" (§11511(A))
The draft language in this subsection restricts PBMs and other payors from conducting pharmacy audits. It set forth that only "record audits," for the "purpose of systematic review of the pharmacy's compliance with contract terms and conditions, filing guidelines, and the provider manual," may be conducted. Additionally, the subsection limits FWA audits, along with what the LDI calls "claims reviews" and "quality assurance reviews."

As previously stated, the LDI's draft language does not distinguish the distinct types of audits as outlined in this subsection. PCMA respectfully requests that the LDI explain and/or define what "claims reviews" and/or "quality assurance reviews" are in this context. And we repeat here, the

fact that the LDI's draft language on "willful misrepresentation" would allow Louisiana pharmacies to play by different and more relaxed rules.

LDI Response to Comment 13:
The LDI agrees that clarification was needed regarding the use of the terms "claim review" and "quality assurance review."

As previously addressed, the LDI has separated claim reviews and quality assurance reviews into distinct sections to avoid confusion. Pharmacy record audits are addressed separately under this section of the regulation.

The LDI also revised the language to reflect the phrasing in La. R.S. 22:1856.1 and to clarify that fraud or willful misrepresentation audits are excluded from the scope of pharmacy record audits.

Comment 14: Objection to Limitation of Claim Reviews to "Payable or Paid Correctly" (§11511(B))
This subsection states that "claim reviews" are limited to whether a "claim is payable or has paid correctly." It goes on to restrict the review of other criteria related to a pharmacy claim. However, the restrictions would implement policy by which a PBM is too limited in its ability to review whether a claim has been properly paid. Whether a claim is payable or has been paid is not the purpose of a pharmacy audit. Instead, one of the purposes of a pharmacy audit is to ensure that a prescription drug was filled and billed correctly and according to the contractual terms at issue.

Further, state statute does not appear to align with the draft language in this subsection. Louisiana Revised Statutes § 22.1856:1(G)(1) states:

Any quality assurance review, as defined by the time period prior to the reimbursement by the entity to the pharmacy.

The LDI's draft language for Reg. 90 rulemaking states, "whether paid or unpaid." This does not match existing statutory law.

LDI Response to Comment 14:
The LDI disagrees with PCMA's concern.

As previously addressed, the regulation clarifies that claim reviews are limited to determining whether a claim is payable or has been paid correctly. This reflects the proper scope of a claim review. If a review exceeds this scope, such as through excessive aggregation of claims, it may constitute a pharmacy record audit subject to the requirements of La. R.S. 22:1856.1.

As previously addressed, the LDI has addressed claim reviews separately under §11513 to clarify and distinguish them from pharmacy record audits.

Comment 15: Objection to Limiting Quality Assurance Reviews to Pre-Reimbursement (§11511(C))

The draft language in this subsection states that "quality assurance reviews" are limited to "reviews of pharmacy compliance with contractual and claim filing requirements." It continues in state that said reviews may "only be performed prior to reimbursement." Enacting such a language would not make sense in the reality of reimbursing a pharmacy claim. Pharmacy claims are adjudicated in near real-time. By this fact, they are distinct from medical claims.

PCMA and its member companies do not agree with the concept of remedial audits, nor do we agree with any limitation for denials, recovery, or non-payment of claims for correctable or harmless errors. An error means billing was done incorrectly. PBMs and other payors must be able to recover if there is financial harm being done.

LDI Response to Comment 15:
The LDI disagrees with PCMA's concern.

The regulation reflects the requirement in La. R.S. 22:1856.1(G)(1), which provides that quality assurance reviews occur prior to reimbursement. The limitation is consistent with statutory law and is necessary to distinguish quality assurance reviews from pharmacy record audits under Louisiana law.

As previously addressed, the LDI has addressed quality assurance reviews separately under §11515 to clarify and distinguish them from pharmacy record audits.

October 9, 2024 PCMA Letter

Comment 16: Request for Public Hearing
As part of these written comments, PCMA and its member companies respectfully request that the LDI schedule and conduct a public hearing on the Proposed Rule for Reg. 90. We believe that such a hearing would serve both the LDI, our industry, and the public, in better understanding all of the issues.

LDI Response to Comment 16:
A public hearing on the proposed substantive change was held by the Louisiana Department of Insurance on March 24, 2025, at 10:00 a.m. in the Poydras Hearing Room, Poydras Building, 1702 North Third Street, Baton Rouge, Louisiana. No comments were made by the public at this hearing.

Comment 17: Request for Confidentiality Protections for Proprietary Information
PCMA and its member companies have concerns with the lack of explicit confidentiality protections included in the Proposed Rule for Reg. 90. For example, included in the language of §11507 and §11509, is a requirement for PBMs to share "algorithms" related to pharmacy reviews. While such reviews (or audits) are generally the result of contractual agreements, as well as relevant state and federal laws, there should be confidentiality protections for any information and/or data shared by PBMs with the LDI that may be considered proprietary.

The PBM industry, like the health plan/insurer industry, the pharmacy industry, the pharmaceutical manufacturing industry, the wholesale distributor (A/K/A wholesalers) industry, and the pharmacy services administrative organization (PSAO) industry, are all private industries that must compete

for business. Any public disclosure of proprietary information harms these competitive efforts. Thus, PCMA respectfully requests additional language be added to the Proposed Rule that provides confidentiality protections.

LDI Response to Comment 17:
The LDI agrees that confidentiality protections are appropriate. In response, the LDI added a confidentiality provision to the regulation under §11523 to protect proprietary information, including audit criteria or algorithms submitted.

LDI Response to October 9, 2024, PCMA Letter:
The remainder of the comments raised in PCMA's October 9, 2024, letter repeat concerns already addressed in PCMA's earlier September 6, 2024, letter. The LDI's responses to those prior comments apply equally here.

Subject to legislative oversight, the LDI intends to submit the proposed amendment to Regulation 90 to the Office of the State Register for final publication in the July 2025 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. 49:966(D)(1)(c).

Enclosure: Notice of Intent to Amend Regulation 90 - Payment of Pharmacy and Pharmacist Claims