HLS 19RS-797 ENGROSSED

2019 Regular Session

HOUSE BILL NO. 538

19

BY REPRESENTATIVE LEBAS

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

PHARMACISTS: Provides relative to pharmacy record audits

1 AN ACT 2 To amend and reenact R.S. 22:1856.1(B)(introductory paragraph), (2), (3), (7)(b), and (8), 3 (D)(1)(introductory paragraph) and (2)(introductory paragraph), and (F), to enact 4 R.S. 22:1856.1(D)(3), and to repeal R.S. 22:1856.1(G)(3) and (4), relative to 5 pharmacy record audits; to provide for applicability of laws relative to such audits; 6 to provide relative to procedures for such audits; to repeal provisions relative to 7 onsite audits; to provide relative to audits conducted by or in consultation with 8 licensed pharmacists; to provide limitations on recoupment of reimbursements paid 9 to pharmacists; and to provide for related matters. 10 Be it enacted by the Legislature of Louisiana: 11 Section 1. R.S. 22:1856.1(B)(introductory paragraph), (2), (3), (7)(b), and (8), 12 (D)(1)(introductory paragraph) and (2)(introductory paragraph), and (F) are hereby amended 13 and reenacted and R.S. 22:1856.1(D)(3) is hereby enacted to read as follows: 14 §1856.1. Pharmacy record audits; recoupment; appeals 15 16 B. Notwithstanding any other provision of law to the contrary, when an 17 onsite audit of the records of a pharmacy is conducted by an entity, the audit shall 18 be conducted in accordance with the following criteria:

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CODING: Words in struck through type are deletions from existing law; words <u>underscored</u> are additions.

(2) No entity shall conduct an on-site audit at a particular pharmacy more
than one time annually. However, the provisions of this Paragraph shall not apply
when an entity must return to a pharmacy to complete an audit already in progress,
or there is an identified history of errors, an identified activity which a reasonable
man would believe to be inappropriate, or illegal activity that the entity has brought
to the attention of the pharmacy owner or corporate headquarters of the pharmacy.
(3)(a) The entity or any vendor or subcontractor of the entity which conducts
the initial onsite audit shall give the pharmacy notice at least two weeks before
conducting the initial onsite audit for each audit cycle.
(b) If the audit, review, or investigation is initiated based on or involves
alleged fraud or willful misrepresentation, notice before the initial on-site audit is not
mandatory where it could impede the audit, review, or investigation.
* * *
(7)
* * *
(b) A pharmacy shall be allowed at least thirty days following receipt of the
preliminary audit report in which to initiate an appeal to address any discrepancy
found during an on-site audit, as provided in Subsection E of this Section.
* * *
(8) Any audit which involves clinical judgment shall be conducted by or in
consultation with a <del>licensed</del> pharmacist <u>licensed in Louisiana</u> .
* * *
D.(1) No pharmacy shall be subject to recoupment of any portion of the
reimbursement for the dispensed product of a prescription unless one or more of the
following has occurred at the point of adjudication:
* * *
(2) Recoupment of claims shall be based on the actual financial harm to the
entity, or on the actual overpayment or underpayment, at the point of adjudication.
A finding of an overpayment that is the result of dispensing in excess of the benefit

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design, as established by the plan sponsor, shall be calculated as the difference between what was dispensed in accordance with the prescriber's orders and the dispensing requirements as set forth by the benefit design. Calculations of overpayments shall not include dispensing fees unless one or more of the following conditions has been satisfied: (3) If any entity determines that the processed or adjudicated claim of a 8 pharmacy qualifies for recoupment based upon the use of manufacturer coupon or copay card, such recoupment shall come from the beneficiary of the reduction if the 10 product is approved by the United States Food and Drug Administration through the new drug application process or abbreviated new drug application, or is an 12 investigational drug which is a biological product as defined in R.S. 40:1169.3. F. Unless otherwise provided for in the network agreement, pharmacies or payors may seek mediation to resolve contractual disputes related to pricing or 16 on-site audits. 18 Section 2. R.S. 22:1856.1(G)(3) and (4) are hereby repealed in their entirety.

## DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB 538 Engrossed

2019 Regular Session

LeBas

**Abstract:** Provides relative to conditions and procedures for pharmacy record audits.

Present law provides criteria for auditing of pharmacy records, including a protocol for onsite audits, by the following entities:

- Managed care companies. (1)
- (2) Insurance companies.
- (3) Third-party payors.
- Representatives of managed care companies including pharmacy benefit managers, (4) insurance companies, and third-party payors.

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<u>Proposed law</u> repeals all provisions relative to onsite audits of pharmacy records by these entities.

<u>Present law</u> requires that any audit involving clinical judgment be conducted by or in consultation with a licensed pharmacist. <u>Proposed law</u> revises <u>present law</u> to require that such audits be conducted by or in consultation with a pharmacist who is licensed in this state.

<u>Present law</u> provides that no pharmacy shall be subject to recoupment of any portion of the reimbursement for the dispensed product of a prescription unless certain conditions are met. <u>Proposed law</u> revises <u>present law</u> to require that these conditions occur at the point of adjudication in order for the pharmacy to be subject to recoupment.

<u>Proposed law</u> stipulates that if any entity determines that the processed or adjudicated pharmacy claim qualifies for recoupment based upon the use of a manufacturer coupon or copay card, then the recoupment shall come from the beneficiary of the reduction if the product is approved by the U.S. Food and Drug Administration through the new drug application process or abbreviated new drug application, or is an investigational drug which is a biological product as defined in <u>present law</u>.

<u>Proposed law</u> repeals <u>present law</u> relative to pharmacy record audits providing that <u>present law</u> shall not apply to any federally funded activity specifically preempted by law or rule, or to any audit conducted pursuant to the participation of a pharmacy in the La. Medicaid program.

(Amends R.S. 22:1856.1(B)(intro. para.), (2), (3), (7)(b), and (8), (D)(1)(intro. para.) and (2)(intro. para.), and (F); Adds R.S. 22:1856.1(D)(3); Repeals 22:1856.1(G)(3) and (4))

## Summary of Amendments Adopted by House

The Committee Amendments Proposed by <u>House Committee on Health and Welfare</u> to the original bill:

- 1. Delete <u>proposed law</u> providing that any audit of a pharmacy with its principal place of business in this state shall be conducted by a pharmacist licensed in Louisiana. Provide instead that any audit which involves clinical judgment shall be conducted by or in consultation with a pharmacist licensed in Louisiana.
- 2. Provide that <u>proposed law</u> relative to recoupment based upon the use of a manufacturer coupon or copay card shall apply only if the product is approved by the U.S. Food and Drug Administration through the new drug application process or abbreviated new drug application, or is an investigational drug which is a biological product as defined in <u>present law</u>.