

BY SENATOR MILLS AND REPRESENTATIVE WESLEY BISHOP

1 AN ACT

2 To enact R.S. 22:1856.1, relative to the audit of pharmacy records by certain entities
3 including pharmacy benefit managers; to provide for definitions; to provide with
4 respect to an appeals process; and to provide for related matters.

5 Be it enacted by the Legislature of Louisiana:

6 Section 1. R.S. 22:1856.1 is hereby enacted to read as follows:

7 **§1856.1. Pharmacy record audits; appeals**

8 **A. As used in this Section, "entity" means a managed care company,**
9 **insurance company, third-party payor, or the representative of the managed**
10 **care company including pharmacy benefit managers, insurance company, or**
11 **third-party payor.**

12 **B. Notwithstanding any other provision of law to the contrary, when an**
13 **on-site audit of the records of a pharmacy is conducted by an entity, the audit**
14 **shall be conducted in accordance with the following criteria:**

15 **(1) The audit may not take place during the first five days of the month.**

16 **(2) No entity shall conduct an on-site audit at a particular pharmacy**
17 **more than one time annually. However, the provisions of this Paragraph shall**
18 **not apply when an entity must return to a pharmacy to complete an audit**
19 **already in progress, or there is an identified history of errors, an identified**
20 **activity which a reasonable man would believe to be inappropriate, or illegal**
21 **activity that the entity has brought to the attention of the pharmacy owner or**
22 **corporate headquarters of the pharmacy.**

23 **(3)(a) The entity conducting the initial on-site audit shall give the**
24 **pharmacy notice at least two weeks before conducting the initial on-site audit**
25 **for each audit cycle.**

26 **(b) If the audit, review, or investigation is initiated based on or involves**
27 **alleged fraud or willful misrepresentation, notice before the initial on-site audit**

1 is not mandatory where it could impede the audit, review, or investigation.

2 (4)(a)(i) Any clerical or record-keeping error, such as a typographical
3 error, scrivener's error, or computer error, regarding a required document or
4 record shall not necessarily constitute fraud.

5 (ii) A claim arising pursuant to the provisions of this Section may be
6 subject to recoupment.

7 (b) No claim arising pursuant to the provisions of this Section shall be
8 subject to criminal penalties without proof of intent to commit fraud.

9 (5) A pharmacy may provide the records of a hospital, physician, or
10 other authorized practitioner of the healing arts for drugs or medicinal supplies
11 written or transmitted by any means of communication for purposes of
12 supporting the pharmacy record with respect to orders or refills of a legend or
13 narcotic drug.

14 (6) Each pharmacy shall be audited under the same standards and
15 parameters as other similarly situated pharmacies audited by the entity.

16 (7)(a) The preliminary audit report shall be delivered to the pharmacy
17 within ninety days after conclusion of the audit.

18 (b) A pharmacy shall be allowed at least thirty days following receipt of
19 the preliminary audit report in which to initiate an appeal to address any
20 discrepancy found during an on-site audit, as provided in Subsection E of this
21 Section.

22 (c) A final audit report shall be delivered to the pharmacy within one
23 hundred twenty days after receipt of the preliminary audit report or notice of
24 appeal, whichever is later.

25 (d) Each entity conducting an audit shall make available a copy of the
26 final audit report to the plan sponsor upon request or as otherwise required by
27 contractual agreement.

28 (8) Any audit which involves clinical judgment shall be conducted by or
29 in consultation with a licensed pharmacist.

30 (9) Interest on recoupment debts shall not accrue during the audit or

1 appeal period.

2 C.(1) Recoupment of any disputed funds, or repayment of funds to the
3 entity by the pharmacy if permitted pursuant to contractual agreement, shall
4 occur after final disposition of the audit, including the appeals process.
5 Recoupment shall not be based on documentation requirements in addition to
6 or exceeding requirements for creating or maintaining documentation
7 prescribed by the Louisiana Board of Pharmacy; or on a requirement that a
8 pharmacy or pharmacist perform a professional duty in addition to or
9 exceeding professional duties prescribed by the Louisiana Board of Pharmacy.

10 (2) The provisions of this Section shall not apply in cases of United States
11 Food and Drug Administration regulation or manufacturer safety programs.

12 (3) The full amount of any recoupment on an audit shall be refunded to
13 the responsible party.

14 (a) Except as provided in this Subsection, a charge or assessment for an
15 audit shall not be based, directly or indirectly, on amounts recouped.

16 (b) Nothing in this Subsection shall be construed to prevent the entity
17 conducting the audit from charging or assessing the responsible party, directly
18 or indirectly, based on amounts recouped if both the following conditions are
19 met:

20 (i) The responsible party and the entity have a contract that explicitly
21 states the percentage charge or assessment to the responsible party.

22 (ii) A commission or other payment to an agent or employee of the entity
23 conducting the audit is not based, directly or indirectly, on amounts recouped.

24 (4) Before recoupment of funds may be made based on an audit finding
25 overpayment or underpayment, a final audit report shall be distributed.

26 D. Recoupment of claims shall be based on the actual financial harm to
27 the entity or on the actual overpayment or underpayment. A finding of an
28 overpayment that is the result of dispensing in excess of the benefit design, as
29 established by the plan sponsor, shall be calculated as the difference between
30 what was dispensed in accordance with the prescriber's orders and the

1 dispensing requirements as set forth by the benefit design. Calculations of
2 overpayments shall not include dispensing fees unless one of the following
3 conditions is present:

4 (1) A prescription was not actually dispensed.

5 (2) The prescriber denied authorization.

6 (3) The prescription dispensed was a medication error by the pharmacy.

7 (4) The identified overpayment is based solely on an extra dispensing fee.

8 (5) The pharmacy was noncompliant with program guidelines.

9 (6) There was insufficient documentation.

10 E. Each entity conducting an audit shall establish an appeal process
11 under which a pharmacy may appeal an unfavorable preliminary audit report
12 to the entity.

13 (1) If, following an appeal, the entity finds that an unfavorable audit
14 report or any portion of an unfavorable audit report is unsubstantiated, the
15 entity shall dismiss the audit report or the unsubstantiated portion of the audit
16 report without any further proceedings.

17 (2) No interest shall be charged to the entity during the appeal period.

18 (3) Following the final audit report, and if not otherwise provided for in
19 the provider contract, either party may seek mediation to address outstanding
20 disagreements.

21 (4) Notwithstanding any other provision of law to the contrary, the
22 agency conducting the audit shall not use the accounting practice of
23 extrapolation in calculating recoupment or penalties for audits, unless otherwise
24 agreed to by the pharmacy or mandated by a government agency or in the case
25 of fraud.

26 F. Unless otherwise provided for in the network agreement, pharmacies
27 or payors may seek mediation to resolve contractual disputes related to pricing
28 or on-site audits.

29 G. This Section shall not apply to:

30 (1) Any quality assurance review, as defined by the time period prior to

1 the reimbursement by the entity to the pharmacy.

2 (2) An investigation that is initiated based on or that involves suspected
3 or alleged fraud, willful misrepresentation, or abuse.

4 (3) Any federally funded activity specifically preempted by law or rule.

5 (4) Any audit conducted pursuant to the participation of a pharmacy in
6 the Louisiana Medicaid Program.

7 Section 2. The provisions of this Act shall apply to contracts entered into, amended,
8 extended, or renewed on or after January 1, 2013.

PRESIDENT OF THE SENATE

SPEAKER OF THE HOUSE OF REPRESENTATIVES

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____