

LOUISIANA DEPARTMENT OF INSURANCE TIMOTHY J. TEMPLE COMMISSIONER

September 9, 2024

The Honorable Cameron Henry President, Louisiana State Senate P.O. Box 94183 Baton Rouge, LA 70804

The Honorable Phillip DeVillier Speaker, Louisiana House of Representatives P.O. Box 94062 Baton Rouge, LA 70804

The Honorable Kirk Talbot Chairman of the Senate Insurance Committee P.O. Box 94183 Baton Rouge, LA 70804

The Honorable Michael "Gabe" Firment Chairman of the House Insurance Committee P.O. Box 94062 Baton Rouge, LA 70804 **ELECTRONIC TRANSMISSION** apa.senatepresident@legis.la.gov

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RE: Notice of Intent to Amend Regulation 90 – Payment of Pharmacy and Pharmacist Claims

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

The Department of Insurance, pursuant to the authority of the Louisiana Insurance Code, <u>R.S. 22:1 et seq.</u>, and in accordance with the Administrative Procedure Act, R.S. <u>49:950 et seq.</u>, hereby gives notice of its intent to amend Regulation 90 — Payment of Pharmacy and Pharmacist Claims. The purpose of the amendment to Regulation 90 is to add regulatory language to incorporate and clarify audit and claim review requirements and to require the filing of policies and procedures to bring Pharmacy Benefit Management processes into compliance.

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

NOTICE OF INTENT

Department of Insurance

Office of the Commissioner

Regulation 90 — Payment of Pharmacy and Pharmacist Claims

(LAC 37:XIII.Chapter 115)

The Department of Insurance, pursuant to the authority of the Louisiana Insurance Code, R.S. 22:1 et seq., and in accordance with the Administrative Procedure Act, R.S. 49:950 et seq., hereby gives notice of its intent to amend Regulation 90.

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

Title 37

INSURANCE

Part XIII. Regulations

Chapter 115. Regulation Number 90 — Payment of Pharmacy and Pharmacist Claims §11501. Purpose

A. The purpose of Regulation 90 is to implement R.S. 22:1851-1862 relative to the making of the prompt and correct payment for prescription drugs, other products and supplies, and pharmacist services covered under insurance or other contracts that provide for pharmacy benefits, and for the review and auditing of claims or records pertaining to such services.

B. ...

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

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

§11503. Scope and Applicability

A. Except as otherwise specifically provided, the requirements of Regulation 90 apply to all health insurance issuers including health maintenance organizations that offer coverage in their insurance contracts for pharmacy services in accordance with the statutory requirements Subpart C of Part II of Chapter 6 of Title 22 of the Louisiana Revised Statutes of 1950, R.S. 22:1851 et seq. Additionally, Regulation 90 applies to all contracts between a pharmacist and/or, pharmacy and/or a health insurance issuer, its agent, or any other party responsible for reimbursement for prescription drugs, other products and supplies, and pharmacist services. Any and all contracts entered into after July 1, 2005 shall be required to be in compliance with R.S. 22:1851 et seq. Additionally, Regulation 90 shall apply to all contracts in existence prior to July 1, 2005. Regulation 90 shall include but not be limited to those contracts that contain any automatic renewal provisions, renewal provisions that renew if not otherwise notified by a party, any provision that allows a party the opportunity to opt out of the contract, evergreen contracts, or rollover contracts and therefore these contracts shall be required to come into compliance. Regulation 90 shall apply to all contracts and therefore these contracts shall be required to come into compliance. Regulation 90 shall apply to all contracts and therefore these contracts shall be required to come into compliance. Regulation 90 shall apply to all contracts and therefore these contracts shall be required to come into compliance. Regulation 90 shall apply to all contracts and upply to all contracts shall be required to come into compliance. Regulation 90 shall apply to all contracts as enumerated above as of the first renewal date, first opt out date, first rollover date or first annual anniversary on or after July 1, 2005.

B. ...

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

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

§11505. Definitions

Agent—...

Commissioner— ...

Covered Person-...

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

Department— ...

Evergreen Contract

1. – 5. ...

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

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

Rollover ...

1. – 5. ...

Paid Date ----

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

Uniform Claim Forms--are forms prescribed by the department and shall include the National Uniform Bill-04 (UB-04) or its successor for appropriate hospital services, and the current Health Care Financing Administration Form 1500 or its successor for physical and other appropriate professional services. If, after consultation with insurers, providers, and consumer groups, the commissioner determines that the state assignable portions of either form should be revised, he shall make a revision request to the State Uniform Bill Implementation Committee and if approved, prescribe the use of the revised form.

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

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

§11507. Claim Handling Procedures for Non-Electronic Claims

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

1. a process for documenting the date of actual receipt of non-electronic claims;

2. a process for reviewing non-electronic claims for accuracy and acceptability;

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

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

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

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

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

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

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

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

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

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

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

a. describe any triggers or criteria which may give rise to a fraud or willful misrepresentation audit; such triggers or criteria shall be clearly defined and easily distinguishable from the selection criteria or algorithms used by the company for pharmacy record audits, claim reviews, and quality assurance reviews; b. implement a function sufficiently narrow in purpose, scope, and invoking criteria to prevent the use of fraud or willful misrepresentation audits in place of pharmacy record audits, claim reviews, and quality assurance reviews.

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

С. ...

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

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

§11509. Claim Handling Procedures for Electronic Claims

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

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

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

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

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

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

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

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

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

b. specify the selection criteria or algorithm used in determining when a claim review is to be performed. This shall include safeguards to ensure the scope of the review is not unduly

burdensome or overly broad. Such safeguards shall include limits on the number of reviews a pharmacy may be subject to in any 30-calendar-day period and limits on the type and quantity of material produced by the pharmacy in complying with the review;

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

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

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

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

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

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

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

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

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

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

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

- B. Claim reviews shall be limited to a determination of whether a claim is payable or has been paid correctly. Inappropriate aggregation of claim reviews, excessive application of claim reviews upon a single pharmacy, and similar activities serve to convert a claim review into a pharmacy record audit and therefore subject to the requirements of and limitations on such audits.
- C. Quality assurance reviews shall be limited to reviews of pharmacy compliance with contractual and claim filing requirements and shall only be performed prior to reimbursement. The purpose of a quality assurance review must be to test and maintain compliance with contract terms or agreed-upon claim filing requirements, and the health insurance issuer shall design and implement such reviews to be remedial in nature, rather than to deny, recover, or otherwise non-pay claims based on correctable or harmless errors.

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

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

§11513. State of Emergency

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

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

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

§11515. Severability Clause

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

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

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

§11517. Effective Date

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

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

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

Family Impact Statement

1. Describe the Effect of the Proposed Regulation on the Stability of the Family. The proposed amended 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 amended regulation should have no impact upon the rights and authority of parents regarding the education and supervision of their children.

 Describe the Effect of the Proposed Regulation on the Functioning of the Family. The proposed amended 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 amended 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 amended 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 amended 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 amended 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 amended 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 amended regulation should have no effect on employment and workforce development.

4. Describe the Effect on Taxes and Tax Credits. The proposed amended 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 amended 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 amended 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 amended regulation should have no measurable impact upon small businesses.

 A Statement of the Probable Effect on Impacted Small Businesses. The proposed amended 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 amended regulation should have no measurable impact on small businesses; therefore, will have no less intrusive or less cost alternative methods.

Provider Impact Statement

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

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

Public Comments

Interested persons who wish to make comments may do so by writing to Evelyn Danielle Linkford, Staff Attorney, Louisiana Department of Insurance, P.O. Box 94214, Baton Rouge, LA 70804-9214, by faxing comments to (225) 342-7821, or electronically at <u>regulations@ldi.la.gov</u>. Comments will be accepted through the close of business, 4:30 p.m., October 10, 2024.

Timothy J. Temple

Commissioner

Fiscal and Economic Impact Statement

1. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS. (Summary)

The proposed regulation change will not result in additional costs or savings for state or local governmental units. The regulation revisions amend Regulation 90 to add regulatory language to incorporate and clarify audit and claim review requirements and to require the filing of policies and procedures to bring Pharmacy Benefit Management processes into compliance.

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

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

3. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS, SMALL BUSINESSES, OR NON-GOVERNMENTAL GROUPS. (Summary)

The proposed regulation change will not result in any costs and/or economic benefits to directly affected persons or non-governmental groups. The regulation revisions amend Regulation 90, to add regulatory language to incorporate and clarify audit and claim review requirements and to require the filing of policies and procedures to bring Pharmacy Benefit Management processes into compliance.

4. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT. (Summary)

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