

been considered. It is anticipated that this proposed rule may have an indeterminable impact on staffing level requirements and qualifications, and/or direct or indirect costs for those hospital facilities that choose to have a newborn safety device installed, but will have no impact on the provider's ability to provide the same level of service as described in HCR 170.

Public Comments

Interested persons may submit written comments to Tasheka Dukes, RN, Health Standards Section, P.O. Box 3767, Baton Rouge, LA 70821. Ms. Dukes is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on May 28, 2025.

Public Hearing

Interested persons may submit a written request to conduct a public hearing by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator, Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on May 12, 2025. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:30 a.m. on May 27, 2025 in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Allen Enger at (225) 342-1342 after May 12, 2025. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage, which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

Drew P. Maranto
Interim Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES

RULE TITLE: Hospitals—Licensing Standards

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

It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation. It is anticipated that \$1,296 will be expended in FY 25 for the state's administrative expense for promulgation of this proposed rule and the final rule.

The proposed rule amends the provisions governing the licensing of hospitals in order to comply with the requirements of Acts 122, 398, 588, 666, and 737 of the 2024 Regular Session of the Louisiana Legislature. As such, the department hereby proposes to add the definition of forensic psychiatric hospital, to adjust requirements for the minimum contents of patient medical records, to add requirements for certain resuscitation equipment, supplies, and staff when a newborn safety device is located inside a hospital, and to update client discharge processes. Also, in compliance with Act 666, the department proposes to adopt provisions for the designation of an essential caregiver and circumstances for visitation.

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

It is anticipated that implementation of this proposed rule will have no impact on state revenue collections. This is a licensing rule that does not add any licensing fees.

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

It is anticipated that this proposed rule may have an indeterminable impact on the direct or indirect cost to hospital facilities that choose to have a newborn safety device installed, as well as a potential cost associated with updated documentation required by the updated client discharge process.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

It is anticipated that this proposed rule may have an indeterminable impact on the staffing level requirements or qualifications required to provide the same level of service for those hospital facilities that choose to have a newborn safety device installed.

Tasheka Dukes, RN
Deputy Assistant Secretary
2504#036

Patrice Thomas
Deputy Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Insurance Office of the Commissioner

Regulation 133—Adequate Payment of Pharmacy and Pharmacist Claims (LAC 37:XIII.Chapter 203)

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 133—Adequate Payment of Pharmacy and Pharmacist Claims. Regulation 133 implements R.S. 22:1860.3(E) relative to reimbursement of pharmacy and pharmacist claims at no less than the acquisition cost for covered drugs, devices, or services. To carry out the intent of the legislature based on Act No. 768 of the 2024 Regular Session and assure full compliance with the applicable statutory provisions, this regulation sets forth payment a set of minimum payment system design standards to govern pharmacy benefit manager pharmacy and pharmacist reimbursement strategies.

Title 37

INSURANCE

Part XIII. Regulations

Chapter 203. Regulation Number 133—Adequate Payment of Pharmacy and Pharmacist Claims

§20301. Purpose

A. The purpose of Regulation 133 is to implement R.S. 22:1860.3(E) relative to reimbursement of pharmacy and pharmacist claims at no less than the acquisition cost for covered drugs, devices, or services. To carry out the intent of the legislature and assure full compliance with the applicable statutory provisions, this regulation sets forth payment a set of minimum payment system design standards to govern pharmacy benefit manager pharmacy and pharmacist reimbursement strategies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1860.3, and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 51:

§20303. Scope and Applicability

A. Except as otherwise specifically provided, the requirement of Regulation 133 applies to all reimbursements of a pharmacy or pharmacist by pharmacy benefit managers and all entities acting on behalf of a pharmacy benefit manager where the pharmaceutical drug transaction being reimbursed occurred in Louisiana or is otherwise subject to the laws of the state of Louisiana. This shall exclude, reimbursements made by a pharmacy benefit manager or an entity acting on behalf of a pharmacy benefit manager in administering the pharmacy benefit of an employee welfare benefit plan, as defined in the Employee Retirement Income Security Act of 1974 (ERISA). The requirements of Regulation 133 apply to a health plan of the state or political subdivision unless such plan is governed by the office of group benefits.

B. Notwithstanding any provision to the contrary in any contract, any and all contracts shall comply with Regulation 133 as of January 1, 2025.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1860.3, and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 51:

§20305. Definitions

Acquisition Cost—the price at which the pharmacy or pharmacist making the claim for reimbursement actually acquires a drug, device, or service using customary suppliers and less any discounts, rebates, price concessions, or other reductions reasonably expected to be received by the pharmacy or pharmacist as a result of the acquisition.

Adjustment—a percentage-based change to the prescription drug pricing benchmark, such as average wholesale price or national average drug acquisition cost, applied uniformly across a class of drugs.

Claim Payment Error—a pharmacy or pharmacist claim payment amount that fails to reimburse at or above acquisition cost.

Commissioner—the commissioner of Insurance.

Department—the Louisiana Department of Insurance.

NADAC—the set of National Average Drug Acquisition Costs as calculated by the Centers for Medicaid and Medicare Services and reflected in the most recently released public file.

Pharmacy—a pharmacy, pharmacy owner, pharmacy employee, or agent thereof, where the pharmacy or pharmacy owner does not own more than five shares or a five percent interest in a pharmaceutical wholesale group purchasing organization or vendor of any covered drug, device, or service.

Pharmacy Benefit Manager—an entity that administers or manages a pharmacy benefits plan or program, or person acting on its behalf.

Reimbursement Formula—a prescription drug reimbursement calculation involving an ingredient price, calculated based on a prescription drug pricing benchmark plus an adjustment factor, and a professional dispensing fee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1860.3, and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 51:

§20307. Pharmacy Benefit Manager Compliance Program

A. A pharmacy benefit manager may comply with R.S. 22:1860.3(E) by meeting all of the following requirements:

1. Adopting a reimbursement formula using either NADAC as the prescription drug pricing benchmark or, with prior written approval by the commissioner, an alternative prescription drug pricing benchmark that results in claim payment errors that are both comparable to or less than NADAC in terms of frequency and smaller than NADAC in terms of magnitude;

2. Adopting a reimbursement formula using an adjustment factor that, based on claims experience data available to the PBM, is reasonably expected to result in a claim payment error rate of no more than 2 percent; and

3. Adopting the appeal process described in Paragraph B.

B. A pharmacy benefit manager shall provide an appeal process through which pharmacists may challenge claim payment errors that meets at least the following requirements:

1. A network pharmacy contract executed by and between a pharmacy benefit manager and a pharmacy located in Louisiana shall, at a minimum, contain a provision expressly acknowledging that if a Louisiana pharmacy's reimbursement for any covered drug, or device, is less than the pharmacy's acquisition cost for that drug or device, the pharmacy has the right to appeal that reimbursement and, if successful, receive additional payment so that the total reimbursement is equal to the pharmacy's demonstrated acquisition cost. The contact person shall then direct the pharmacy to the pharmacy benefit manager's electronic and written appeal locations.

2. Permit appeals to be filed for a period of fifteen days following the applicable fill date.

3. If an appeal is filed with the pharmacy benefit manager, the pharmacy must include a written invoice from the wholesaler that includes the drug name, national drug code number, purchase date, and cost of the drug. In addition to providing the invoice, the pharmacist must include an estimate of discounts, rebates, price concessions, or other reductions reasonably expected to be received by the pharmacy or pharmacist as a result of the acquisition that can be allocated to and subtracted from the invoice.

4. If a claim payment error occurred, the pharmacy benefit manager shall make an additional payment to the pharmacy to increase the reimbursement amount to the acquisition cost.

5. If a pharmacy benefit manager determines that a claim payment error did not occur, it shall provide the pharmacy or pharmacist with an explanation of why it has upheld the payment, including a specific documentation of the acquisition cost on the date of service. Such explanation shall be provided electronically or in writing through customary means of communication between the pharmacy benefit manager and the pharmacy or pharmacist. Such

explanation shall also include a notice in at least 10-point font stating that, if the pharmacy or pharmacist disagrees with the decision, the pharmacy or pharmacist may file a complaint with the department at: <https://www.lidi.la.gov/onlineservices/ConsumerComplaintForm>.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1860.3, and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 51:

§20309. Pharmacy Benefit Manager Alternative Compliance Option

A. A pharmacy benefit manager may comply with R.S. 22:1860.3 without adopting the compliance program described in §20307 by adopting a payment system that reimburses based on price invoices from a pharmacy or pharmacist. A pharmacy benefit manager that adopts such structure, however, shall continue to be responsible for meeting all timely claim payment requirements. Verification of the invoiced price is an element of claim review, as described in R.S. 22:1856.1, and not of the adjudication process referenced in R.S. 22:1854. It does not, therefore, toll the running of timely claim payment requirements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1860.3, and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 51:

§20311. Severability

A. If any Section or provision of Regulation 133 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. 22:11, R.S. 22:1860.3, and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 51:

Family Impact Statement

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

4. Describe the Effect on Taxes and Tax Credits. The proposed amended and repealed 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 and repealed 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 amended and repealed regulation on small businesses as defined in the Regulatory Flexibility Act has been considered. It is estimated that the proposed amended and repealed regulation 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 amended and repealed 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 and repealed 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 and repealed regulation should have no measurable impact upon small businesses.

3. A Statement of the Probable Effect on Impacted Small Businesses. The proposed amended and repealed 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 and repealed 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 amended and repealed 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 and repealed 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 and repealed 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) 342-7851, or electronically at regulations@ldi.la.gov. Comments will be accepted through the close of business, 4:30 p.m., May 10, 2025.

Timothy J. Temple
Commissioner

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Regulation 133—Adequate Payment of Pharmacy and Pharmacist Claims

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 change is being implemented to carry out the intent of the legislature based on Act 768 of the 2024 Regular Session and to ensure full compliance with the applicable statutory provisions. Since Act 768 was effective on 1/01/2025, there is no fiscal impact. This regulation sets forth a set of minimum payment system design standards to govern pharmacy benefit manager pharmacy and pharmacist reimbursement strategies. Therefore, this regulation only creates a pathway for complying with Act 768, and industry costs are anticipated to change as a result of this Act.

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

The proposed rule will have no impact on revenue collections of state or local governmental units.

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

The proposed rule will benefit directly affected persons by carrying out the intent of the legislature based on Act 768 of the 2024 Regular Session and ensuring full compliance with the applicable statutory provisions. This regulation sets forth a set of minimum payment system design standards to govern pharmacy benefit manager pharmacy and pharmacist reimbursement strategies. Insurers could choose the cheaper of

direct compliance with the Act or use of the safe harbor in regulation, which could slightly reduce costs, creating modest industry savings, mostly in reduced administrative costs. However, the regulation itself will be cost neutral for the industry.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

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

Chris Cerniauskas
Chief of Staff
2504#001

Patrice Thomas
Deputy Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Insurance Office of the Commissioner

Regulation 134—Insurance Regulatory Sandbox Program
(LAC 37:XIII.Chapter 203)

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 134—Insurance Regulatory Sandbox Program.

The Insurance Regulatory Sandbox Act was enacted through the passage of Act 229 of the 2024 Regular Session of the Louisiana Legislature which allows the Insurance commissioner to grant temporary waivers from certain insurance laws and regulations to facilitate the introduction of innovative insurance products and services. Regulation 134 sets forth the standards and procedures relative to a person's participation in the Insurance Regulatory Sandbox Program.

Title 37 INSURANCE

Part XIII. Regulations

Chapter 203. Regulation Number 134—Insurance Regulatory Sandbox Program

§20301. Purpose

A. The purpose of Regulation 134 is to exercise the authority and carry out the duties and responsibilities of the commissioner for implementation and regulation of the Insurance Regulatory Sandbox Program, hereinafter referred to as the "Regulatory Sandbox." Regulation 134 sets forth rules and procedural requirements which the commissioner deems necessary for participation in the Regulatory Sandbox.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, 22:1430.1 et seq., and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 51:

§20303. Applicability and Scope

A. Regulation 134 shall apply to all persons that apply to participate in the Regulatory Sandbox in Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, 22:1430.1 et seq., and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 51: