

**November 2019**

**Economic Impact Statements for Proposed Rules**

The corresponding proposed rule to each of the statements below may be viewed in its entirety in the November 20, 2019 *Louisiana Register*. Each *Louisiana Register* edition is published on the 20<sup>th</sup> of each month and can be viewed here: <https://www.doa.la.gov/Pages/osr/reg/regs2019.aspx>

<b>Promulgating Agency</b>	<b>Proposed Rule Title</b>	<b>Estimated Costs and/or Economic Benefits to Directly Affected Persons, Small Businesses or Nongovernmental Groups</b>
<b>Board of Elementary and Secondary Education</b>	<b>Bulletin 746—Louisiana Standards for State Certification of School Personnel</b>	There are no estimated costs and/or economic benefits for directly affected persons or non-governmental groups as a result of the proposed revisions.
<b>Board of Elementary and Secondary Education</b>	<b>Bulletin 1706—Regulations for Implementation of the Children with Exceptionalities Act</b>	This policy change will not result in estimated costs and/or benefits to directly affected persons or non-governmental groups.
<b>Used Motor Vehicle Commission</b>	<b>Used Motor Vehicles</b>	There will be a cost to continuing education vendors to receive a seminar instructor certificate. Vendors/Instructors may charge a participant fee for the seminar upon approval of the Commission.
<b>Board of Nursing</b>	<b>Officers of the Board and Meetings of the Board</b>	The proposed rule changes will not result in any costs and/or economic benefits to directly affected persons or non-governmental groups.
<b>Board of Pharmacy</b>	<b>Cannabis Metered-Dose Inhaler</b>	The proposed rule change benefits producers of marijuana products as it will permit, but not require, them to prepare products for use in metered dose inhalers in addition to their other oral or topical dosage forms. Furthermore, the proposed rule change benefits consumers of medical marijuana products by allowing them another method of consumption.
<b>Board of Pharmacy</b>	<b>Continuing Education Records</b>	The proposed rule changes affects pharmacists required to comply with continuing education requirements to maintain licensure. The proposed rule changes repeal the current requirement for a pharmacist to maintain copies of their continuing education certificates at their primary place of employment, and instead require a pharmacist to maintain records of their continuing education activities with CPE Monitor®, an electronic repository of continuing education records for pharmacists and pharmacy technicians operated by the National Association of Boards of Pharmacy and the Accreditation Council for Pharmacy Education. There is no cost to the pharmacist or to the Board to participate in CPE Monitor®.

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<b>Board of Pharmacy</b>	<b>Controlled Substance License for Third Party Logistics Providers</b>	Act 186 of the 2018 Legislature amended the state controlled substance law to add third party logistics providers to the list of entities required to obtain a controlled substance license before engaging in certain activities with controlled substances. The proposed rule changes will implement the legislation by establishing a license type for third party logistics providers that elect to distribute controlled substances. Third party logistics providers are currently licensed in the licensure database as distributors, but the proposed rule changes will identify third party logistics providers separately. The costs and recordkeeping requirements will be the same as those currently required of distributors.
<b>Board of Pharmacy</b>	<b>Correctional Center Pharmacy</b>	To the extent private pharmacies dispensing drugs to local law enforcement agencies have products returned for reuse and issue a partial refund, it is assumed that pharmacies would realize a revenue reduction equal to any savings realized by local law enforcement agencies (see Part I). There are a number of variables which complicate any estimate of such revenue reduction, including the number of offenders, the number of offenders receiving prescription drugs, and which of those dispensed prescription drugs are eligible for return and reuse. Therefore, any reduced revenue is indeterminable. However, because returned products may be reused in other prescriptions, pharmacies may only realize a delay in revenue collections.
<b>Board of Pharmacy</b>	<b>Delays of Licensure Examinations</b>	The proposed rule changes repeal the existing one year delay to retake a licensure examination following the third failure of said examination for both pharmacists and pharmacy technicians. The proposed rule amendments will allow the applicant for a pharmacist license or a pharmacy technician certificate to retake a failed licensure examination at a frequency approved by the test administrator, which is presently one month from the date of the previous failed examination. The removal of the one-year delay after the third failed attempt at an exam may advance when potential licensees pay fees to test administrators to take examinations, but will not significantly alter the amount paid in the aggregate.
<b>Board of Pharmacy</b>	<b>Dispensing of Prescription Refills</b>	The proposed changes affect pharmacies, as they prohibit them from dispensing automatic prescription refills to patients that were not authorized or approved by the patient or caregiver, except for patients residing in a long-term care facility. Some pharmacies automatically enroll patients in automatic prescription refill services with the goal of improving medication adherence; the proposed rule changes will require the pharmacy to obtain patient authorization to continue such services. To the extent a pharmacy is unable to dispense prescription refills without patient authorization, the proposed rule changes may decrease their revenue. The extent to which this would occur is unknown, therefore any potential revenue decrease is indeterminable, though likely marginal.

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<b>Board of Pharmacy</b>	<b>Drug Disposal by Pharmacies</b>	The proposed rule changes will require all pharmacies to advise consumers of their drug disposal options and will allow pharmacies to accept drug returns for disposal purposes. For pharmacies electing to accept drug returns for disposal, the proposed rule changes require compliance with federal standards relative to the disposal of controlled substances and hazardous drugs. To the extent pharmacies electing to accept drugs for disposal are unable to comply with the aforementioned requirements, such as quarantining products returned for disposal, they may incur unknown though likely marginal costs to be able to properly accept returned products.
<b>Board of Pharmacy</b>	<b>Investigational Drugs</b>	The proposed rule changes will affect pharmacies electing to participate in clinical drug studies with investigational drugs. Hospital pharmacies electing to participate in clinical drug studies with investigational drugs will be permitted, but not required, to dispense those drugs to all patients enrolled in the studies regardless of whether they are registered patients of the hospital. All pharmacies electing to participate in clinical drug studies with investigational drugs will be required to comply with minimum standards applicable to the handling of investigational drugs, including storing investigational drugs separately from active dispensing stocks, perpetual inventory records of investigational drugs, and adherence to federal policies and procedures for use of investigational drugs. Those activities require human and other resources, the cost of which will vary with each pharmacy depending on their level of activity with such studies. As a result, the aggregate cost for hospitals and pharmacies choosing to participate in such studies is indeterminable.
<b>Board of Pharmacy</b>	<b>License Transfer for Pharmacy Technicians</b>	The proposed rule changes will affect pharmacy technicians licensed and practicing in another state for at least one year who are seeking to transfer their license to Louisiana. The proposed rule changes will remove the current requirement such technicians first obtain a pharmacy technician candidate registration and earn 600 hours of practice in Louisiana, and will authorize them to obtain their pharmacy technician certificate upon demonstration of successful completion of a board-approved pharmacy technician certification examination, potentially allowing them to receive licensure more quickly.
<b>Board of Pharmacy</b>	<b>Licensing of Marijuana Pharmacies</b>	The proposed rule change clarifies the licensing procedure for marijuana pharmacies to specify the requirement for an inspection of the premises prior to issuing the marijuana pharmacy permit awarded by the LBP. This procedure is consistent with all types of pharmacy permits issued by the LBP. There is no separate fee for the inspection, as the cost is included in the application fee.

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<b>Board of Pharmacy</b>	<b>Partial Fills of Schedule II Prescriptions</b>	Act 32 of the 2018 Regular Session amended the state controlled substance law to permit pharmacists to dispense partial fills of prescriptions for all medications listed in Schedule II instead of only the opiate medications listed in Schedule II, and to do so in a manner consistent with federal law. The proposed rule change implements the 2018 legislation. When requested by either the prescriber or the patient, the pharmacist may dispense partial fills of such prescriptions, but shall dispense all partial fills no later than 30 days after the date the prescription was issued. The patient may benefit from having less medication on hand to manage. The patient may also benefit from a reduced acquisition cost for a partial fill; however, it is possible the total cost of all partial fills may be higher than the cost of dispensing the entire amount prescribed.
<b>Board of Pharmacy</b>	<b>Pharmacy Compounding</b>	The proposed rule changes benefits pharmacists, as they update references to current federal law and rule. The standards for the compounding of commercially available products clarify the current limitation of compounding by stating that the strength of the active ingredient must change by more than 10 percent for the compounded preparation to be recognized as an authorized copy of a commercially available product. The proposed rule changes also remove a private website as a source of information for drugs in shortage, in favor of the website maintained for that purpose by the federal Food and Drug Administration. To the extent a pharmacy compounds copies of commercially available products with changes in strength of the active ingredient of less than 10 percent, the proposed rule changes will require the pharmacy to terminate such activity.
<b>Board of Pharmacy</b>	<b>Pharmacy Immunizations</b>	The proposed rule changes require pharmacies conducting immunization activities to provide adequate staffing and minimum equipment and procedures to safely administer immunizations. To the extent a pharmacy is not already compliant with those standards, they may incur additional, indeterminable costs for personnel or equipment. The proposed rule changes require the immunizing pharmacist or his designee to report the immunization within 72 hours of the immunization to the state immunization registry; to the extent the pharmacist is not already compliant with that standard, they will be required to adjust their workflow to meet that timeline.

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<b>Board of Pharmacy</b>	<b>Pharmacy Records</b>	<p>The proposed rule changes update recordkeeping requirements to include chart orders for the dispensing of prescription medications in compliance with Act 602 of 2018. The use of chart orders allows hospitals and long-term care facilities to dispense medication without a hard copy prescription. The proposed changes include provisions for the use of chart orders in various types of pharmacy records, and further, enable remote access to such records from outside the pharmacy.</p> <p>The removal of the notarization requirement for the form used by the pharmacist-in-charge of a pharmacy may reduce operational costs for the pharmacy. The proposed rule change requiring EDK permits to be readily available rather than conspicuously displayed may result in a marginal savings for facilities and/or provider pharmacies. Furthermore, the proposed rule change allowing for relinquishing of an EDK permit prior to renewal is not anticipated to result in significant savings for pharmacies, as the LBP does not anticipate the number of active EDK permits to significantly change.</p>
<b>Board of Pharmacy</b>	<b>Rulemaking Procedures</b>	<p>The proposed rule will benefit members of the public, as it describes a procedure for them to request the LBP to engage in rulemaking on a certain topic.</p>
<b>Board of Pharmacy</b>	<b>Telepharmacy Dispensing Sites</b>	<p>The proposed rule changes benefit communities without pharmacies within a 15-mile radius, as they alter the service area eligible for a telepharmacy dispensing site by 5 miles, from having no pharmacies within a 20-mile radius to a 15-mile radius. With an improvement in the eligibility criteria, it is possible new telepharmacy dispensing sites may open in 'pharmacy deserts' where there are no or few pharmacies serving the area. The proposed rule changes may allow for pharmacies to expand their businesses (and as a result, receipts and income) at a reduced cost, as telepharmacy dispensing sites should have more reduced costs of operation compared to regular community pharmacies. Furthermore, the proposed rule amendments delete the provision requiring a telepharmacy dispensing site to close permanently when another pharmacy opens within a 20-mile radius of the telepharmacy. Instead, the proposed amendment requires the telepharmacy dispensing site to convert to a regular community pharmacy when its dispensing activity increases to an average of 100 prescriptions per day. The conversion of a permit from a telepharmacy dispensing site to a community pharmacy should carry no additional permitting costs, as both types of permits have a fee of \$175. However, the conversion of a telepharmacy dispensing site to a community pharmacy may require additional, indeterminable personnel and monetary resources to the extent such a conversion is required.</p>
<b>Board of Pharmacy</b>	<b>Veterinary Hospital Pharmacy</b>	<p>The proposed rule changes apply only to governmental subdivisions and therefore do not affect non-governmental groups or persons.</p>

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<b>Department of Health</b>	<b>Federally Qualified Health Centers Reimbursement Methodology Mammography Separate Payments</b>	Due to the disapproval of the corresponding State Plan amendment (SPA) by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), this proposed rule amends the reimbursement methodology for federally qualified health centers (FQHCs) in order to repeal the provisions of the December 20, 2018 Rule which allowed a separate payment outside of the prospective payment system (PPS) rate for mammography screening and diagnosis services. Implementation of this proposed rule is necessary to comply with the CMS directive and will not impact recipients or providers, since the December 2018 Rule provisions were not implemented pending approval of the SPA. It is anticipated that implementation of this proposed rule will not result in costs to FQHCs in FY 19-20, FY 20-21 and FY 21-22, but will be beneficial by ensuring that the reimbursement methodology is accurately promulgated in the Louisiana Administrative Code.
<b>Department of Health</b>	<b>Home and Community-Based Behavioral Health Services Waiver Coordinated System of Care Discharge Criteria</b>	This proposed rule amends the provisions governing the home and community-based services waiver to specify discharge criteria for the Coordinated System of Care (CSoC) program which aligns with federal regulations and current practices, since the current administrative Rule does not address the authority to discharge participants who no longer meet CSoc waiver eligibility requirements. Implementation of this proposed Rule will impact recipients that may no longer be eligible for these home and community-based behavioral health waiver services; however, recipients and providers will benefit from clearly identified participation requirements. It is anticipated that implementation of this proposed rule will not result in costs to providers of CSoc waiver services in FY 19-20, FY 20-21 and FY 21-22.
<b>Department of Health</b>	<b>Pregnant Women Extended Services Substance Use Screening and Intervention Services Tobacco Cessation</b>	This proposed Rule amends the provisions governing extended services for pregnant women in order to implement tobacco cessation services mandated by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services and remove outdated references to the Louisiana Health Assessment Referral and Treatment (LaHART) program. This proposed Rule will be beneficial by providing counseling services and pharmacotherapy for pregnant recipients who use tobacco products or are being treated for tobacco use. It is anticipated that implementation of this Rule will increase Medicaid programmatic expenditures by approximately \$128,907 for FY 19-20, \$318,659 for FY 20-21 and \$328,218 for FY 21-22.

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<b>Department of Health</b>	<b>Rural Health Clinics Reimbursement Methodology Mammography Separate Payments</b>	Due to the disapproval of the corresponding State Plan amendment (SPA) by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), this proposed rule amends the reimbursement methodology for rural health clinics (RHCs) in order to repeal the provisions of the December 20, 2018 Rule which allowed a separate payment outside of the prospective payment system (PPS) rate for mammography screening and diagnosis services. Implementation of this proposed rule is necessary to comply with the CMS directive and will not impact recipients or providers, since the December 2018 Rule provisions were not implemented pending approval of the SPA. It is anticipated that implementation of this proposed rule will not result in costs to RHCs in FY 19-20, FY 20-21 and FY 21-22, but will be beneficial by ensuring that the reimbursement methodology is accurately promulgated in the Louisiana Administrative Code.
<b>Department of Health</b>	<b>School-Based Health Services—School-Based Applied Behavior Analysis-Based Therapy Services</b>	This proposed rule amends the provisions governing school-based services in order to remove applied behavior analysis-based (ABA) therapy services as school-based behavioral health services and add ABA to the school-based health services covered in the Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Program. This action is being taken to ensure that these provisions are accurately promulgated in the Louisiana Administrative Code (LAC). It is anticipated that implementation of this proposed rule will not result in costs or benefits to ABA providers in FY 19-20, FY 20-21 and FY 21-22 as this is a technical change to the LAC to correct the placement of school-based ABA provisions.
<b>Department of Insurance</b>	<b>Regulation 116—Stop-Loss or Excess Policies of Insurance</b>	The proposed rules will have no cost to directly affected persons or non-governmental groups. The proposed rule will benefit employers sponsoring “group health plans” in the claim processing of stop-loss or excess policies by having the specific requirements for claim processing align the administrative rules with current statute for clarity. Included in the proposed rules are relevant definitions, requirements for stop-loss/excess policies, a definition of eligible claims, policy form requirements, and the types of stop-loss/excess policy contracts available in Louisiana.
<b>Board of Pardons and Committee on Parole</b>	<b>Committee Procedures</b>	There is no estimated cost and/or economic benefit to directly affected persons or non-governmental groups.

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<b>Uniform Construction Code Council</b>	<b>Temporary Exemption to Certification Requirements</b>	The proposed rule provides for a longer transition period for Inspectors who have previously served in the military. As a result of this extension, it is anticipated that this proposed rule will create a larger pool of potential employees with military service for local jurisdictions.
<b>Department of Transportation and Development</b>	<b>Louisiana Transportation Research Center (LTRC) Transportation Training and Education Fund</b>	There are no anticipated costs and/or economic benefits to directly affected persons or non-governmental groups as a result of this proposed amended rule.
<b>Department of Treasury</b>	<b>Fiscal Administrator Revolving Loan Fund</b>	The proposed rule will directly affect the ability of municipalities to address public health, safety and welfare, including issues concerning urgent needed repairs to public water systems. Citizens of impacted political subdivisions may realize economic benefits afforded through stabilized health and safety services.
<b>Department of Wildlife and Fisheries</b>	<b>Restriction of All Oyster Harvesting on Four New Reefs</b>	To the extent that commercial fishermen are currently using the portion of public land to be incorporated into this protected area, this rule change will effect them. It will reduce the over 650 square mile area available for public oyster harvest in the region by approximately 40 acres. LDWF has conducted studies and scans of the area to ensure that the placement of these artificial reefs will be on water bottoms that are currently considered to be unsuitable habitat for the growth and harvesting of oysters. Because little of the water bottoms to be incorporated within the public fishing reefs are currently suitable for oyster production, the effect on commercial oyster harvesting is expected to be minimal.