

LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

630 Camp Street, New Orleans, LA 70130
www.lsbme.la.gov



Telephone: (504) 568-6820
FAX: (504) 568-8893
Writer's Direct Dial:

(504) _____

October 25, 2018

Hon. Fred H. Mills, Jr.
Chairman
Committee on Health and Welfare
Senate of the State of Louisiana
P.O. Box 94183
Baton Rouge, LA 70804
apa.s-h&w@legis.la.gov

Hon. John A. Alario, Jr.
President
Senate of the State of Louisiana
P.O. Box 94183
Baton Rouge, LA 70804
apa.senatepresident@legis.la.gov

Hon. Frank A. Hoffmann
Chairman
Committee on Health and Welfare
House of Representatives of the
State of Louisiana
Post Office Box 4486
Capitol Station
Baton Rouge, Louisiana 70804
apa.h-hw@legis.la.gov

Hon. Taylor F. Barras
Speaker
House of Representatives of the
State of Louisiana
Post Office Box 4486
Capitol Station
Baton Rouge, Louisiana 70804
apa.housespeaker@legis.la.gov

Re: Final Report: Proposed Adoption of Administrative
Rules Governing Practice; La. Uniform Prescription
Drug Prior Authorization (LAC 46:XLV.8001-8003)

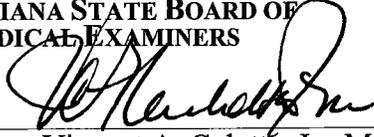
Dear Sirs:

Pursuant to La. Rev. Stat. §49:968(D), the Board of Medical Examiners respectfully submits the enclosed report on the final adoption of the captioned rules. Notice was previously published in the August 2018 edition of the *La. Register*, Vol. 44, No. 8, pp. 1480-1484. Subject to Joint Legislative Oversight Committee review, the Board plans to adopt the rules, in the identical form originally noticed, upon publication in the December 20, 2018, edition of the *La. Register*, with a delayed effective date of January 1, 2019.

Very truly yours,

**LOUISIANA STATE BOARD OF
MEDICAL EXAMINERS**

By: _____


Vincent A. Culotta, Jr., M.D.
Executive Director

Enclosure
cc: Editor, *Louisiana Register*

**FINAL REPORT RELATIVE TO PROPOSED
ADOPTION OF ADMINISTRATIVE RULES
GOVERNING LOUISIANA UNIFORM PRESCRIPTION
DRUG PRIOR AUTHORIZATION FORM**

(La. Rev. Stat. § 49:968(D))

By The
LOUISIANA STATE
BOARD OF MEDICAL EXAMINERS

Submitted To The
COMMITTEE ON HEALTH AND WELFARE,
LOUISIANA SENATE,

COMMITTEE ON HEALTH AND WELFARE,
LOUISIANA HOUSE OF REPRESENTATIVES,

PRESIDENT OF THE SENATE

And
SPEAKER OF THE HOUSE OF REPRESENTATIVES

October 25, 2018

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ADOPTION OF ADMINISTRATIVE RULES
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Oct. 25, 2018

(La. Rev. Stat. § 49:968(D))

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This Report is respectfully submitted by the Louisiana State Board of Medical Examiners (the “Board”), within the Department of Health and Hospitals, pursuant to La. Rev. Stat. §49:968(D).

By Notice of Intent published in the August 20, 2018, edition of the *Louisiana Register*, Vol. 44, No. 8, pp. 1480-1484, the Board, in collaboration with the Louisiana Board of Pharmacy, proposed to adopt rules governing a single uniform prescription drug prior authorization form for use by all payors in the state. Concurrently with submission of the Notice of Intent, in accordance with La. Rev. Stat. §40:968, the Board submitted a Report to the Senate and House Committees on Health and Welfare, the President of the Senate and the Speaker of the House of Representatives.¹ Thereafter the Board received three (3) written comments and a joint public hearing by the Board and the Louisiana Board of Pharmacy was noticed and held at the Board’s offices on September 28, 2018. One individual, who provided written comments, attended the hearing and provided oral comments.

During its meeting on October 15, 2018, the Board considered the written and oral comments received (*See* Summary of the Comments and the Board’s Response below), and determined that no changes to the proposed rule or form originally noticed are necessary. Therefore, subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to promulgate the rule and form as Final Rules, in the December 20, 2018, edition of the *Louisiana Register*, with a delayed effective date of January 1, 2019.

This Report, submitted by the Board pursuant to and as prescribed by La. Rev. Stat. §49:968(D), includes: (i) a copy of the Notice of Intent published in August 20, 2018 edition of the *Louisiana Register* (Appendix A); (ii) a summary of the comments received by the Board on the subject administrative rules, along with a statement of the Board's response to each comment, including a concise statement of the principal reasons for or against adoption of any modifications or changes suggested; and (iii) copies of the comments received by the Board and its written responses to the commenters (Appendix B).

I. Background—The Louisiana State Board of Medical Examiners proposes to adopt administrative rules governing Medical Professions, LAC Title 46:XLV, Subpart 3

¹*Electronic Mail*, Vincent A. Culotta, Jr., M.D., Exec. Dir., La. State Bd. Med. Exam., RE: Report Relative to La. Uniform Prescription Drug Prior Authorization Form, LAC 46:XLV.8001-8003 (Report, Aug. 10, 2018; Email Aug. 13, 2018).

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(Practice), Chapter 80 (Louisiana Uniform Prescription Drug Prior Authorization Form), Section 8001 (Louisiana Uniform Prescription Drug Prior Authorization Form; Requirements; Referral for Enforcement) and Section 8003 (Louisiana Uniform Prescription Drug Prior Authorization Form). In accordance with the specific requirements of La. Rev. Stat. §49:968(D), the Board submits the following information regarding the proposed rules.

As noted in its initial Legislative Report,² the adoption of the proposed rules is mandated by Act 423, of the 2018 Regular Session of the Louisiana Legislature, which provides that Louisiana State Board of Pharmacy and Louisiana State Board of Medical Examiners shall promulgate rules and regulations prior to January 1, 2019, establishing a uniform prescription drug prior authorization form that shall be utilized by all health insurance issuers.

II. Summary of Proposed Rules—Consistent with the legislative mandate of Act 423 of the 2018 Regular Session of the Legislature, the rules being promulgated create a single uniform prescription drug prior authorization form for use by all payers.

III. Summary of the Comments and Board Response—The Board received a total of three (3) written comments on the proposed rules.³ One of the individuals who submitted a written comment also attended the public hearing on September 28, 2018.⁴

Written Comments in Response to Notice of Intent (August 2018 *Register*)
and Oral Comments Submitted at the Public Hearing (September 28, 2018)

Commenter No. 1. Kim Diehl-Boyd (CoverMyMeds). Ms. Diehl-Boyd's written comments did not request any amendments to the proposed rules but did request guidance on three (3) questions, offered two (2) comments and made six (6) recommendations for the Board's consideration. At the public hearing on September 28, 2018, Ms. Diehl-Boyd spoke to the same written questions, comments and recommendations that were included in her written submission and she answered questions that were posed.

²See Legislative Report, footnote 1, Item Nos. 2, 4.

³Written comments were received from: Kim Diehl-Boyd, CoverMyMeds (Sept. 28, 2018); Elisa Y. Muller, Quarles & Brady LLP (Sept. 25, 2018); and Merlyn Monteiro, CVS Health (Sept. 27, 2018).

⁴Oral comments were provided at the public hearing on September 28, 2018, by Kim Diehl-Boyd.

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Questions:

Q. 1. — If a prescriber, pharmacy, payer are already utilizing ePA to process medication PA's for their patients, they will not need to modify their processes and begin using this form.

Response. The enabling legislation requires the use of the form jointly promulgated by the medical and pharmacy boards. The proposed rule requires the use of the form promulgated by the board, either in written form or its electronic equivalent. If an entity is using an ePA process and the process is equivalent to the form in the proposed rule, then the entity will not need to modify their process. If their process is not equivalent to the form in the proposed rule, they will need to modify their process to conform to the electronic equivalent of the form promulgated.

Q. 2 — If the adopted form is utilized for a specialty medication, we would want to ensure that the plan will not have the authority to cease the process and have the prescriber start all over but would be required to continue with the determination process, asking additional questions, etc. as necessary to make that determination.

Response. While the enabling legislation excludes specialty medications from the requirement to use the form promulgated by the two boards (or its electronic equivalent), the legislation did not address the use of prior authorization forms for specialty medications. Without legislative authority, the LSBME has no basis to regulate the process for prior authorizations for such medications. The legislation identifies the enforcement agencies for the failure to comply with the law – the Louisiana Medicaid program relative to Medicaid managed care organizations and the La. Dept. of Insurance for all other health insurance issuers. You may wish to contact those agencies for their guidance on the scenario you posed.

Q. 3 — Many times, the medication prior authorization process is started by the pharmacy (69%), even if the prescription is sent electronically. We ask for clarification that should the prescription be sent via e-prescribing and the PA process is facilitated by the use of the adopted form, again, the plan will not have the authority to cease the process and have the prescriber start all over.

Response. While the enabling legislation excludes medications that were electronically prescribed from the requirement to use the form promulgated by the two boards (or its electronic equivalent), the legislation did not address the use of prior authorization forms

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for medications that were electronically prescribed. Without legislative authority, the LSBME has no basis to regulate the process for prior authorizations for such medications. The legislation identifies the enforcement agencies for the failure to comply with the law – the Louisiana Medicaid program relative to Medicaid managed care organizations and the La. Dept. of Insurance for all other health insurance issuers. You may wish to contact those agencies for their guidance on the scenario you posed.

Comments:

Comment No. 1. — The provider-administered drugs section wouldn't be necessary since this form is not to be used for specialty medications.

Response. There are many physician-administered drugs that are not specialty medications, and the LSBME has determined this data field is necessary.

Comment No. 2. — Since this form is not necessary for use if it is a specialty medication or the prescription was e-prescribed, we suggest placing a message/notation at the top of the form advising the prescriber of those facts.

Response. The enabling legislation allows the appendage of instructions or guidance information to the form. The LSBME believes that document is the best place to communicate such exclusionary information to the prescriber.

Recommendations:

Recommendation No. 1. — Expand the tried and failed section to accommodate more drug history.

Response. The enabling legislation limits the form itself to two pages in length. The stakeholder group composing the form evaluated multiple data elements and determined which items were most relevant in most situations.

Recommendation No. 2. — Create a separate section for non-pharmacologic therapies.

Response. There is a section for non-pharmacologic therapies. The limit on document size persuaded the document drafters to be efficient in their construction of the data fields.

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Recommendation No. 3. — Add a section/question for expansion of clinical criteria. For example, “Please provide clinical rationale and any additional information pertinent to the request.”

Response. The limitation on the size of the document convinced the stakeholder work group to use efficiency in their construction of data fields.

Recommendation No. 4. — Add a field for the provider to indicate urgency of the request.

Response. The prescribers and dispensers in this state should be aware of the existing rule for pharmacies which authorize pharmacists to dispense up to a 72-hour supply of a medication while prescriber approval is pending.

Recommendation No. 5. — Date of diagnosis, ICD-10 and diagnosis description should be given more area for completion. These can get pretty lengthy.

Response. Again, the limitation on the size of the document convinced the stakeholder work group to use efficiency in their construction of data fields.

Recommendation No. 6. — Consider adding a note instructing the provider to attach any relevant documentation that would be helpful to make a determination.

Response. The LSBME believes such instructions to the provider are best placed on the accompanying guidance document in lieu of the form itself, which has a legislatively-mandated size limit.

Commenter No. 2. Elisa Y. Muller (Quarles & Brady LLP). Ms. Muller did not request any amendments to the proposed rules but did pose the following questions.

Q. 1-2. — We would like to inquire whether or not issuers may be permitted to utilize their own form as long as it conforms to the regulatory requirements? Alternatively, are issuers permitted to include other fields for physicians to complete when submitting the prior authorization form?

Response. The LSBME has interpreted the enabling legislation (Act 423 of 2018 Legislature) to require the use of the form jointly promulgated by the medical and pharmacy boards, subject to the two exclusions identified in the legislation (specialty medications and medications electronically prescribed). The requirement to use the form

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(La. Rev. Stat. § 49:968(D))

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promulgated by the two boards would seem to exclude any other forms. With that said, the proposed rule requires the use of the form developed and promulgated by the boards, either in written form or its electronic equivalent.

The legislation specifies the form shall not exceed two pages in length, excluding any instructions or guiding information. Further, the statute permits the insurance issuer to include issuer specific information on the form including the issuer's name, address, logo and other contact information for the issuer. The LSBME has interpreted the legislation to exclude the placement of any other data fields on the form not contained within the form promulgated by the two boards.

Commenter No. 3. Merlyn Monteiro (CVS Health). Ms. Muller did not request any amendments to the proposed rules but did pose the following questions.

Q. 1. — We would like to confirm that we can utilize electronic prior authorization (ePA) and not require that requests be made on the uniform prescription drug prior authorization form when submitting prior authorizations electronically.

Response. The LSBME believes the legislation allows for an electronic PA process that is substantially similar to the written form. The LSBME also believes the law does not require a PA for electronically prescribed medications.

Q. 2. — it would be beneficial if the form that would be utilized for non-ePA requests included a checkbox for the provider to indicate that a request is urgent when appropriate.

Response. The prescribers and dispensers in this state should be aware of the existing rule for pharmacies which authorize pharmacists to dispense up to a 72-hour supply of a medication while prescriber approval is pending.

* * *

Appendix

A

Provider Impact Statement

The proposed rulemaking should not have any known or foreseeable impact on providers as defined by HCR 170 of 2014 Regular Legislative Session. In particular, there should be no known or foreseeable effect on:

1. the effect on the staffing level requirements or qualifications required to provide the same level of service;
2. the total direct and indirect effect of the cost to the providers to provide the same level of service; or
3. the overall effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments on these proposed Rule changes to Arthur Hickham, Jr., Executive Director, Louisiana State Board of Dentistry, P.O. Box 5256, Baton Rouge, LA 70821. Written comments must be submitted to and received by the board within 20 days of the date of the publication of this notice. A request pursuant to R.S. 49:953 (A)(2) for oral presentation, argument, or public hearing must be made in writing and received by the board within 20 days of the date of the publication of this notice.

Public Hearing

A request pursuant to R.S. 49:953 (A)(2) for oral presentation, argument, or public hearing must be in writing and received by the board within 20 days of the date of the publication of this notice.

Arthur Hickham, Jr.
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Dental Hygienists

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

The proposed rule change will result in a one-time SGR expenditure of \$500 in FY 18 for the LA State Board of Dentistry (LSBD) to publish the notice of intent and proposed rule change in the Louisiana Register. The proposed rule change will not affect expenditures of local governmental units.

The proposed rule change restates provisions of the present rules where dental hygienists may practice under general supervision in Louisiana, and further adds Federally Qualified Health Centers (FQHCs) as an eligible institution where dental hygienists may practice under general supervision. For reference, practicing under general supervision allows dental hygienists to perform services without a dentist present under certain circumstances. Furthermore, dental hygienists can currently practice at FQHCs provided their supervising dentist is present.

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

The proposed rule change will not affect revenue collections for state or local governmental units.

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

The proposed rule change allows Federally Qualified Health Centers to have hygienists work under the general supervision of a dentist, something already allowed in private dental clinics, schools, and public institutions. There will be no increased costs, workload or paperwork as a result of the proposed action. The proposed rule changes may benefit FQHCs and their patients by streamlining the service delivery process.

For reference, a dental hygienist practicing under general supervision is able to provide services without a supervising dentist present, provided the supervising dentist has seen or developed a treatment plan for a patient within the last 9 months, the hygienist notifies the patient that the dentist is not present, and the hygienist has one or more years of experience. Furthermore, dental hygienists are limited to practicing under general supervision for no more than 20 days in a calendar year, and may only practice under general supervision for up to 5 days consecutively.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule change will not affect competition or employment.

Arthur F. Hickman, Jr.
Executive Director
1808#018

Evan Brasseaux
Staff Director
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health
Board of Medical Examiners

Uniform Prescription Drug Prior Authorization Form
(LAC 46:XLV.8001 and 8003)

Notice is hereby given that in accordance with the Louisiana Administrative Procedure Act, R.S. 49:950 et seq., pursuant to the authority of the Louisiana Medical Practice Act, R.S. 37:1261 et seq., the Louisiana State Board of Medical Examiners (Board) hereby gives notice of its intent to promulgate a new Rule establishing the Louisiana Uniform Prescription Drug Prior Authorization Form. This rule-making effort is required by Act 423, of the 2018 Regular Session of the Legislature, and is in collaboration with the Louisiana Board of Pharmacy. The proposed Rule is set forth below.

Title 46

PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part XLV. Medical Professions

Subpart 3. Practice

Chapter 80. Louisiana Uniform Prescription Drug Prior Authorization Form

Subchapter A. General Provisions

§8001. Louisiana Uniform Prescription Drug Prior Authorization; Requirements; Referral for Enforcement

A. A prescriber or pharmacy required to obtain prior authorization from a third party payor shall complete the Louisiana Uniform Prescription Drug Prior Authorization Form referenced below in §8003, either in written form or its electronic equivalent.

B. In the event a third party payor demands the completion of an alternative authorization process, the prescriber or pharmacy shall refer the demand to the appropriate enforcement agency.

1. If the demand is made by a Medicaid-managed care organization, the prescriber or pharmacy shall refer the demand to the Department of Health.

2. If the demand is made by any other third party payor, the prescriber or pharmacy shall refer the demand to the Department of Insurance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:1006.1(C) and 46:460.33(B).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

§8003. Louisiana Uniform Prescription Drug Prior Authorization Form

LOUISIANA UNIFORM PRESCRIPTION DRUG PRIOR AUTHORIZATION FORM

SECTION I - SUBMISSION

Submitted to:	Phone:	Fax:	Date:
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SECTION II - PRESCRIBER INFORMATION

Last Name, First Name MI:		NPI# or Plan Provider #:	Specialty:	
Address:		City:	State:	ZIP Code:
Phone:	Fax:	Office Contact Name:	Contact Phone:	

SECTION III - PATIENT INFORMATION

Last Name, First Name MI:		DOB:	Phone:	<input type="checkbox"/> Male	<input type="checkbox"/> Female
Address:		City:	State:	<input type="checkbox"/> Other	<input type="checkbox"/> Unknown
Plan Name (if different from Section I):	Member or Medicaid ID #:	Plan Provider ID:			
Patient is currently a hospital inpatient getting ready for discharge? ___ Yes ___ No		Date of Discharge:			
Patient is being discharged from a psychiatric facility? ___ Yes ___ No		Date of Discharge:			
Patient is being discharged from a residential substance use facility? ___ Yes ___ No		Date of Discharge:			
Patient is a long-term care resident? ___ Yes ___ No		If yes, name and phone number: _____			
EPSDT Support Coordinator contact information, if applicable: _____					

SECTION IV - PRESCRIPTION DRUG INFORMATION

Requested Drug Name:						
Strength:	Dosage Form:	Route of Admin:	Quantity:	Days' Supply:	Dosage Interval/Directions for Use:	Expected Therapy Duration/Start Date:
To the best of your knowledge this medication is: ___ New therapy/Initial request ___ Continuation of therapy/Reauthorization request						
For Provider Administered Drugs only:						
HCPCS/CPT-4 Code: _____		NDC#: _____		Dose Per Administration: _____		
Other Codes: _____						
Will patient receive the drug in the physician's office? ___ Yes ___ No						
- If no, list name and NPI of servicing provider/facility: _____						

SECTION V - PATIENT CLINICAL INFORMATION

Primary diagnosis relevant to this request:	ICD-10 Diagnosis Code:	Date Diagnosed:
Secondary diagnosis relevant to this request:	ICD-10 Diagnosis Code:	Date Diagnosed:
For pain-related diagnoses, pain is: _____ Acute _____ Chronic		
For postoperative pain-related diagnoses: Date of Surgery _____		
Pertinent laboratory values and dates (attach or list below):		
Date	Name of Test	Value

SECTION VI - THIS SECTION FOR OPIOID MEDICATIONS ONLY

Does the quantity requested exceed the max quantity limit allowed? ___ Yes ___ No (If yes, provide justification below.)

Cumulative daily MME _____

Does cumulative daily MME exceed the daily max MME allowed? ___ Yes ___ No (If yes, provide justification below.)

	YES	NO	THE PRESCRIBER ATTESTS TO THE FOLLOWING:
	(True)	(False)	
SHORT AND LONG-ACTING OPIOIDS			A A complete assessment for pain and function was performed for this patient.
			B The patient has been screened for substance abuse / opioid dependence. (Not required for recipients in long-term care facility.)
			C The PMP will be accessed each time a controlled prescription is written for this patient.
			D A treatment plan which includes current and previous goals of therapy for both pain and function has been developed for this patient.
			E Criteria for failure of the opioid trial and for stopping or continuing the opioid has been established and explained to the patient.
			F Benefits and potential harms of opioid use have been discussed with this patient.
			G An Opioid Treatment Agreement signed by both the patient and prescriber is on file. (Not required for recipients in long-term care facility.)
LONG-ACTING OPIOIDS			H The patient requires continuous around the clock analgesic therapy for which alternative treatment options have been inadequate or have not been tolerated.
			I Patient previously utilized at least two weeks of short-acting opioids for this condition. Please enter drug(s), dose, duration and date of trial in pharmacologic/non-pharmacologic treatment section below.
			J Medication has not been prescribed to treat acute pain, mild pain, or pain that is not expected to persist for an extended period of time.
			K Medication has not been prescribed for use as an as-needed (PRN) analgesic.
			L Prescribing information for requested product has been thoroughly reviewed by prescriber.
IF NO FOR ANY OF THE ABOVE (A-L), PLEASE EXPLAIN:			

**SECTION VII - PHARMACOLOGIC & NON-PHARMACOLOGIC TREATMENT(S) USED FOR THIS DIAGNOSIS
(BOTH PREVIOUS & CURRENT):**

Drug name	Strength	Frequency	Dates Started and Stopped or Approximate Duration	Describe Response, Reason
Drug Allergies:			Height (if applicable):	Weight (if applicable):
Is there clinical evidence or patient history that suggests the use of the plan's pre-requisite medication(s), e.g. step medications, will be ineffective or cause an adverse reaction to the patient? ___ Yes ___ No (If yes, please explain in Section VIII below.)				

SECTION VIII - JUSTIFICATION (SEE INSTRUCTIONS)

By signing this request, the prescriber attests that the information provided herein is true and accurate to the best of his/her knowledge. Also, by signing and submitting this request form, the prescriber attests to statements in the 'Attestation' section of the criteria specific to this request, if applicable.

Signature of Prescriber: _____

Date: _____

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:1006.1(C) and 46:460.33(B).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of the proposed rule on the family has been considered. It is not anticipated that the proposed Rule will have any impact on family, formation, stability or autonomy, as described in R.S. 49:972.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the impact of the proposed Rule on those that may be living at or below one hundred percent of the federal poverty line has been considered. It is not anticipated that the proposed Rule will have any impact on child, individual or family poverty in relation to individual or community asset development, as described in R.S. 49:973.

Provider Impact Statement

In compliance with HCR 170 of the 2014 Regular Session of the Louisiana Legislature, the impact of the proposed Rule on organizations that provide services for individuals with developmental disabilities has been considered. It is not anticipated that the proposed Rule will have any impact on

the staffing, costs or overall ability of such organizations to provide the same level of services, as described in HCR 170.

Small Business Analysis

It is not anticipated that the proposed rule will have any adverse impact on small businesses as defined in the Regulatory Flexibility Act, R.S. 49:965.2 et seq.

Public Comments

Interested persons may submit written data, views, arguments, information or comments, via United States Postal Service or other mail carrier, or in the alternative, by personal delivery, to Rita Arceneaux, Confidential Executive Assistant, Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA 70130, (504) 568-6820, Ex. 242. She is responsible for responding to inquiries regarding the proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Friday, September 28, 2018, at 9:00 a.m., at the office of the Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA 70130. At that time, all interested persons will be afforded an opportunity to submit data, views, or arguments, either orally or in writing. The deadline for the receipt of all comments is 12 noon that same day.

Vincent A. Culotta, Jr., M.D.
Executive Director

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

**RULE TITLE: Uniform Prescription Drug
Prior Authorization Form**

NOTICE OF INTENT

**Department of Health
Board of Pharmacy**

**Uniform Prescription Drug Prior Authorization Form
(LAC 46:LIII.1129 and 1130)**

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

The LA State Board of Medical Examiners anticipates one-time printing expenditures of \$2,000 in FY 19 to publish the Notice of Intent and the final rule publication. The proposed rules implement Act 423 of the 2018 Regular Session regarding the use of a single prior authorization form for prescription drugs.

Furthermore, to the extent local governmental units utilize prior authorization forms, there may be a nominal cost to change their existing form to comply with the uniform document in the proposed rules. To the extent governmental units use multiple prior authorization forms for different payors, there may be future cost savings associated with the use of a single form, however any potential savings from this source is speculative.

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

The proposed rules will not affect revenue collections for state or local governmental units.

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

The proposed rules may benefit insurance companies and other entities that pay for prescription drug claims, as they may require the use of a prior authorization process for some drugs to manage their costs for such claims. Different entities may use different forms and some entities have initiated the use of electronic web portals to receive the information in lieu of printed forms. The proposed rules provide for a single form for use by all payors in the state, which may streamline the prior authorization process for payors.

Furthermore, some entities will incur printing costs for printing replacement forms. Furthermore, to the extent any of those providers have implemented information systems for the prior authorization process, they may incur a one-time expense to update their system to accommodate the uniform process proposed by the rule.

In addition, the prescribers and dispensers of prescription drugs required to complete the prior authorization process may benefit from the use of a single form for all payors in the state, as it may streamline the prior authorization process to the extent multiple forms are currently being used.

**IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT
(Summary)**

The proposed rules will not affect competition or employment.

Vincent A. Culotta, Jr., MD
Executive Director
1808#060

Evan Brasseaux
Staff Director
Legislative Fiscal Office

In accordance with the provisions of the Administrative Procedure Act (R.S. 49:950 et seq.) and the Pharmacy Practice Act (R.S. 37:1161 et seq.), the Louisiana Board of Pharmacy hereby gives notice of its intent to promulgate a new rule to establish the Louisiana Uniform Prescription Drug Prior Authorization Form. The Rule will require all pharmacies, prescribers, and third-party payors to use this form when prior authorizations for prescription drugs are required. This rulemaking activity is required by Act 423 of the 2018 Legislature and is in collaboration with the Louisiana State Board of Medical Examiners.

Title 46

**PROFESSIONAL AND OCCUPATIONAL
STANDARDS**

Part LIII. Pharmacists

Chapter 11. Pharmacies

Subchapter B. Pharmacy Records

**§1129. Louisiana Uniform Prescription Drug Prior
Authorization Form; Requirements; Referral
for Enforcement**

A. A prescriber or pharmacy required to obtain prior authorization from a third party payor shall complete the Louisiana Uniform Prescription Drug Prior Authorization Form referenced below in Section 1130, either in written form or its electronic equivalent.

B. In the event a third party payor demands the completion of an alternative authorization process, the prescriber or pharmacy shall refer the demand to the appropriate enforcement agency.

1. If the demand is made by a Medicaid managed care organization, the prescriber or pharmacy shall refer the demand to the Dept. of Health.

2. If the demand is made by any other third party payor, the prescriber or pharmacy shall refer the demand to the Dept. of Insurance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:1006.1(C) and 46:460.33(B).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 44:

Appendix

B

covermymeds

2 MIRANOVA PL, 12TH FLOOR • COLUMBUS, OH 43215
22901 MILLCREEK BLVD, SUITE 240 • HIGHLAND HILLS, OH 44122

September 28, 2018

Vincent A. Culotta, Jr., M.D.
Executive Director
Louisiana State Board of Medical Examiners
630 Camp Street, New Orleans, LA 70130

Re: LAC 46:XLV.8001 and 8003 – Uniform Prescription Drug Prior Authorization Form

Dear Dr. Culotta,

CoverMyMeds appreciates the opportunity to provide comments pertaining to the modification to LAC 46:XLV.8001 and 8003 associated with the adoption of a Uniform Prescription Drug Prior Authorization Form.

As way of background of our experience regarding this topic, CoverMyMeds was formed in 2008 specifically with the vision of improving access for patients to their needed medications by improving the medication prior authorization (PA) process. Presently, we process over 2 million medication prior authorizations monthly, a majority of which are processed electronically utilizing the industry recognized and adopted NCPDP SCRIPT Standard.

Louisiana plans and providers are readily utilizing electronic prior authorization (ePA) as a way to save on both time and costs. Presently, a high percentage of medication PAs are administered via the NCPDP SCRIPT Standard. The real-time ePA process supports the physician so they can best treat the patient, improves the payers speed and efficiency in making coverage determinations, and positively impacts medication adherence by preventing the time-consuming back and forth of the PA process when using paper forms. ePA gives time back to the physician, pharmacist or nurse, which allows them to spend more time with patients and increases speed to therapy through real-time determinations of prescription benefit coverage.

Given the significant benefits of ePA to payers, providers and patients, we would like to ensure that the Uniform Prescription Drug Prior Authorization Form being considered, doesn't negatively impact the utilization of the ePA transactions. While we do not believe the intent was to impact ePA, we would like to confirm that payers and providers can continue to utilize ePA rather than paper forms. This is important as ePA provides a determination in real-time versus the multiple days it can take to receive a response from a faxed form request sent to a payer for review.

The legislation (Senate Bill 29) requiring the Board of Pharmacy and the State Board of Medical Examiners to establish a uniform PA form does state that the adopted form is not required when a medication has been electronically prescribed or when the prescription was written for a specialty medication.

We are looking for guidance from the two boards ensuring the following:

4. If a prescriber, pharmacy, payer are already utilizing ePA to process medication PA's for their patients, they will not need to modify their processes and begin using this form;
5. If the adopted form is utilized for a specialty medication, we would want to ensure that the plan will not have the authority to cease the process and have the prescriber start all over but would be required to continue with the determination process, asking additional questions, etc. as necessary to make that determination;
6. Many times, the medication prior authorization process is started by the pharmacy (69%), even if the prescription is sent electronically. We ask for clarification that should the prescription be sent via e-Prescribing and the PA process is facilitated by the use of the adopted form, again, the plan will not have the authority to cease the process and have the prescriber start all over.

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2 MIRANOVA PL, 12TH FLOOR • COLUMBUS, OH 43215
22901 MILLCREEK BLVD, SUITE 240 • HIGHLAND HILLS, OH 44122

After reviewing the Uniform Prescription Drug Authorization Form, we have concerns about information that is lacking that could cause confusion and increase the back and forth dialogue between the provider and the plan, increasing the time it would take to get the patient on the medications they need to live healthy lives. The following are our observations and recommendations regarding the proposed form:

- Comments:
 - The provider-administered drugs section wouldn't be necessary since this form is not to be utilized for specialty medications.
 - Since this form is not necessary for use if it is a specialty medication or the prescription was e-prescribed, we suggest placing a message/notation at the top of the form advising the prescriber of these facts.
- Recommendations:
 - Expand the tried and failed section to accommodate more drug history.
 - Create a separate section for non-pharmacologic therapies
 - Add a section/question for expansion of clinical criteria. For example, "Please provide clinical rationale and any additional information pertinent to the request"
 - Add a field for the provider to indicate Urgency of the request.
 - Date of diagnosis, ICD-10 and diagnosis description should be given more area for completion. These can get pretty lengthy.
 - Consider adding a note instructing the provider to attach any relevant documentation that would be helpful to make a determination.

We appreciate the opportunity to submit these comments and questions for your consideration. Should you have any questions or comments regarding the content and points provided, I would be happy to schedule a meeting with the you to discuss in greater detail.

Thank you,



Kim Diehl-Boyd
Director of Industry Relations and Government Affairs
CoverMyMeds
(615) 663-5579
kdiehlboyd@covermymeds.com



300 N. LaSalle Street
Suite 4000
Chicago, Illinois 60654-3406
312.715.5000
Fax 312.715.5155
www.quarles.com

Attorneys at Law in
Chicago
Indianapolis
Madison
Milwaukee
Naples
Phoenix
Scottsdale
Tampa
Tucson
Washington, D.C.



Writer's Direct Dial: 312-715-5170
E-Mail: Elisa.Muller@quarles.com

September 25, 2018

VIA U.S. MAIL

Malcolm J. Broussard
Executive Director
Louisiana State Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, LA 70809-1700

RE: Comment Regarding Proposed Louisiana Uniform Prescription Drug Prior Authorization Form

Dear Mr. Broussard:

We have reviewed the proposed rule and form promulgated by the Louisiana State Board of Pharmacy and Louisiana Board of Medical Examiners as a result of Act 423 of the 2018 Louisiana State Legislature.

We understand the statute allows a health insurance issuer to include issuer-specific information on the form, including but not limited to the issuer's name, address, logo and other contact information. We would like to inquire whether or not issuers may be permitted to utilize their own form as long as it conforms to the regulatory requirements. Alternatively, are issuers permitted to include other fields for physicians to complete when submitting the prior authorization form?

Please feel free to contact me with any questions.

Very truly yours,

Elisa Y. Muller

SEP 27 2018

From: Frey-Branning, Meghan <[Meghan.Frey-Branning@CVSHealth.com](mailto: Meghan.Frey-Branning@CVSHealth.com)>
Sent: Friday, September 28, 2018 11:48 AM
To: Rita Arceneaux <[Rarceneaux@lsbme.la.gov](mailto: Rarceneaux@lsbme.la.gov)>
Cc: Monteiro, Merlyn L. <[Merlyn.Monteiro@CVSHealth.com](mailto: Merlyn.Monteiro@CVSHealth.com)>; Frey-Branning, Meghan <[Meghan.Frey-Branning@CVSHealth.com](mailto: Meghan.Frey-Branning@CVSHealth.com)>; Navale, Sujeet <[Sujeet.Navale@CVSHealth.com](mailto: Sujeet.Navale@CVSHealth.com)>
Subject: Uniform Prescription Drug Prior Authorization Form

Ms. Arceneaux,

Please see attached comments related to LAC 46:LIII §1129 and §1130-Uniform Prescription Drug Prior Authorization Form.

Thank you for the opportunity for us to provide questions and feedback.

Meghan Branning

Meghan Frey-Branning, Pharm.D. | Manager, PA Admin, Clinical Services Operations, CVS/caremark
p 972-813-3032 | f 480-860-3702
CVS Health | 1300 E Campbell Rd, Mail Code 512, Richardson, TX 75081

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September 27, 2018

Malcolm J Broussard
Executive Director,
Louisiana Board of Pharmacy
3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700

Re: LAC 46:LIII §1129 and §1130-Uniform Prescription Drug Prior Authorization Form

Dear Mr. Broussard:

CVS Health appreciates the opportunity to ask for clarification and provide feedback regarding LAC 46: LIII §1129 and §1130 associated with the adoption of a uniform prescription drug prior authorization form.

The legislation (Act 423) requiring the Board of Pharmacy and the State Board of Medical Examiners to establish a uniform prior authorization form does state that the adopted form is not required when a medication has been electronically prescribed. We would like to confirm that we can utilize electronic prior authorization (ePA) and not require that requests be made on the uniform prescription drug prior authorization form when submitting prior authorizations electronically.

The current ePA process that we have adopted follows the NCPDP SCRIPT standard and it allows the provider to answer, in real-time, specific clinical criteria questions the plan has assigned to the requested drug. This saves time and cost for the providers and allows us to render faster decisions thus resulting in a positive provider and member experience.

If the proposed rule requires use of the uniform prescription drug prior authorization form for electronic requests, it will have a negative impact on the benefits that are afforded by the real-time ePA process that we have adopted.

Additionally, it would be beneficial if the form that would be utilized for non-ePA requests included a checkbox for the provider to indicate that a request is urgent when appropriate.

Should you need any further clarification or details, please do not hesitate to contact me.

Thank you.

Sincerely,

Merlyn Monteiro
Director, Clinical Services
Clinical Operations Management
1300 E Campbell Road
Richardson TX 75081
Phone: 972-8213-3291
Email: Merlyn.Monteiro@CVSHealth.com

LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

630 Camp Street, New Orleans, LA 70130
www.lsbme.la.gov



Telephone: (504) 568-6820

FAX: (504) 568-8893

Writer's Direct Dial:

(504) _____

October 16, 2018

Kim Diehl-Boyd
Director of Industry Relations & Government Affairs
Covermymeds
2 Miranova Pl., 12th Floor
Columbus, OH 43215
kdiehlboyd@covermymeds.com

Re: Notice of Intent – Proposed Rules
LA Uniform Prescription Drug Prior Authorization Form
LSBME (LAC 46:XLV.8001-8003)
LSBOP (LAC 46:LIII.1129-1130)

Dear Ms. Diehl-Boyd,

Thank you for your interest in the Board's ("LSBME") proposed rule relative to prior authorization forms. You did not request any amendments to the proposed rule but you did request guidance on three questions and offered comments and recommendations for the Board's consideration.

Your questions:

If a prescriber, pharmacy, payer are already utilizing ePA to process medication PA's for their patients, they will not need to modify their processes and begin using this form.

The enabling legislation requires the use of the form jointly promulgated by the LSBME and the Louisiana State Board of Pharmacy ("LSBOP"). The proposed rule requires the use of the form promulgated by the Boards, either in written form or in its electronic equivalent. If an entity is using an ePA process and the process is equivalent to the form in the proposed rule, then the entity will not need to modify their process. If their process is not equivalent to the form in the proposed rule, they will need to modify their process to conform to the electronic equivalent of the form promulgated.

If the adopted form is utilized for a specialty medication, we would want to ensure that the plan will not have the authority to cease the process and have the prescriber start all over but would be required to continue with the determination process, asking additional questions, etc. as necessary to make that determination.

While the enabling legislation excludes specialty medications from the requirement to use the form promulgated by the two boards (or its electronic equivalent), the legislation did not address the use of prior authorization forms for specialty medications. Without legislative authority, the LSBME has no basis to regulate the process for prior authorizations for such medications. The legislation identifies the enforcement agencies for the failure to comply with the law – the Louisiana Medicaid program relative to Medicaid managed care organizations and the La. Dept. of Insurance for all other health insurance issuers. You may wish to contact those agencies for their guidance on the scenario you posed.

Many times, the medication prior authorization process is started by the pharmacy (69%), even if the prescription is sent electronically. We ask for clarification that should the prescription be sent via e-prescribing and the PA process is facilitated by the use of the adopted form, again, the plan will not have the authority to cease the process and have the prescriber start all over.

While the enabling legislation excludes medications that were electronically prescribed from the requirement to use the form promulgated by the two boards (or its electronic equivalent), the legislation did not address the use of prior authorization forms for medications that were electronically prescribed. Without legislative authority, the LSBME has no basis to regulate the process for prior authorizations for such medications. The legislation identifies the enforcement agencies for the failure to comply with the law – the Louisiana Medicaid program relative to Medicaid managed care organizations and the La. Dept. of Insurance for all other health insurance issuers. You may wish to contact those agencies for their guidance on the scenario you posed.

Your comments:

The provider-administered drugs section would not be necessary since this form is not to be used for specialty medications.

There are many physician-administered drugs that are not specialty medications, and the LSBME has determined this data field is necessary.

Since this form is not necessary for use if it is a specialty medication or the prescription was e-prescribed, we suggest placing a message/notation at the top of the form advising the prescriber of those facts.

The enabling legislation allows the appendage of instructions or guidance information to the form. The LSBME believes that document is the best place to communicate such exclusionary information to the prescriber.

Your Recommendations:

Expand the tried and failed section to accommodate more drug history.

The enabling legislation limits the form itself to two pages in length. The stakeholder group composing the form evaluated multiple data elements and determined which items were most relevant in most situations.

Create a separate section for non-pharmacologic therapies.

There is a section for non-pharmacologic therapies. The limit on document size persuaded the document drafters to be efficient in their construction of the data fields.

Add a section/question for expansion of clinical criteria. For example, "Please provide clinical rationale and any additional information pertinent to the request."

The limitation on the size of the document convinced the stakeholder work group to use efficiency in their construction of data fields.

Add a field for the provider to indicate urgency of the request.

The prescribers and dispensers in this state should be aware of the existing rule for pharmacies, which authorizes pharmacists to dispense up to a 72-hour supply of a medication while prescriber approval is pending.

Date of diagnosis, ICD-10 and diagnosis description should be given more area for completion. These can get pretty lengthy.

Again, the limitation on the size of the document convinced the stakeholder work group to use efficiency in their construction of data fields.

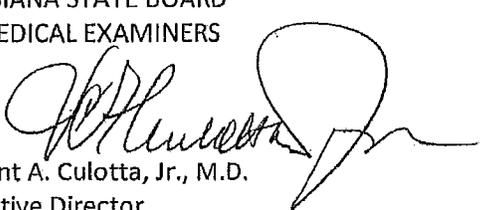
Consider adding a note instructing the provider to attach any relevant documentation that would be helpful to make a determination.

The LSBME believes such instructions to the provider are best placed on the accompanying guidance document in lieu of the form itself, which has a legislatively-mandated size limit.

We trust this information is responsive to your request for guidance, comments and recommendations. The L has determined no revisions to the proposed rule are necessary. We will submit the required report to the Joint Legislative Oversight Committee on Health and Welfare with our recommendation to publish the proposed rule as a Final Rule in the Louisiana Register with an effective date of January 1, 2019.

Yours very truly,

LOUISIANA STATE BOARD
OF MEDICAL EXAMINERS


Vincent A. Culotta, Jr., M.D.
Executive Director

LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

630 Camp Street, New Orleans, LA 70130

www.lsbme.la.gov



Telephone: (504) 568-6820

FAX: (504) 568-8893

Writer's Direct Dial:

(504) _____

October 23, 2018

Elisa Y. Muller
Quarles & Brady, LLP
300 N LaSalle St Ste 4000
Chicago, IL 60654-3406

Re: Notice of Intent – Proposed Rules
LA Uniform Prescription Drug Prior Authorization Form
LSBME (LAC 46:XLV.8001-8003)
LSBOP (LAC 46:LIII.1129-1130)

Dear Ms. Muller:

Thank you for your interest in the Louisiana State Board of Medical Examiners ("LSBME") proposed rule relative to prior authorization forms. Your comments were forwarded from the Louisiana Board of Pharmacy. You did not request any amendments to the proposed rule but you did pose the following questions: This is the LSBME's response in the joint rule making effort.

Your question:

We would like to inquire whether or not issuers may be permitted to utilize their own form as long as it conforms to the regulatory requirements? Alternatively, are issuers permitted to include other fields for physicians to complete when submitting the prior authorization form?

The LSBME has interpreted the enabling legislation (Act 423 of 2018 Legislature) to require the use of the form jointly promulgated by the medical and pharmacy boards, subject to the two exclusions identified in the legislation (specialty medications and medications electronically prescribed). The requirement to use the form promulgated by the two boards would seem to exclude any other forms. With that said, the proposed rule requires the use of the form developed and promulgated by the boards, either in written form or its electronic equivalent.

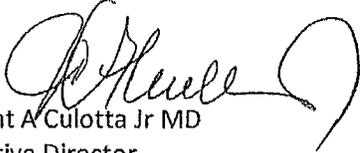
The legislation specifies the form shall not exceed two pages in length, excluding any instructions or guiding information. Further, the statute permits the insurance issuer to include issuer specific information on the form including the issuer's name, address, logo and other contact information for the issuer. The LSBME has interpreted the legislation to exclude the placement of any other data fields on the form not contained within the form promulgated by the two boards.

We trust this information is responsive to your request for guidance. The LSBME has determined no

revisions to the proposed rule are necessary. We will submit the required report to the Joint Legislative Oversight Committee on Health and Welfare with our recommendation to publish the proposed rule as a Final Rule in the Louisiana Register with an effective date of January 1, 2019.

Yours truly,

LOUISIANA STATE BOARD
OF MEDICAL EXAMINERS



Vincent A Culotta Jr MD
Executive Director

LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

630 Camp Street, New Orleans, LA 70130

www.lsbme.la.gov



Telephone: (504) 568-6820

FAX: (504) 568-8893

Writer's Direct Dial:

(504) _____

October 16, 2018

Merlyn Monteiro
Director, Clinical Services
Clinical Operations Management
1300 E Campbell Road
Richardson TX 75081
Phone: 972-8213-3291
Email: Merlyn.Monteiro@CVSHealth.com

Re: Notice of Intent – Proposed Rules
LA Uniform Prescription Drug Prior Authorization Form
LSBME (LAC 46:XLV.8001-8003)
LSBOP (LAC 46:LIII.1129-1130)

Dear Ms. Monteiro,

This will acknowledge receipt and thank you for your comment received by electronic correspondence on September 28, 2018 at 11:48 a.m., wherein you provide a copy of your comments addressed to the Louisiana State Board of Pharmacy.

We provide the following response to your comments:

Your comments:

We would like to confirm that we can utilize electronic prior authorization (ePA) and not require that requests be made on the uniform prescription drug prior authorization form when submitting prior authorizations electronically.

The LSBME believes the legislation allows for an electronic PA process that is substantially similar to the written form. The LSBME also believes the law does not require a PA for electronically prescribed medications.

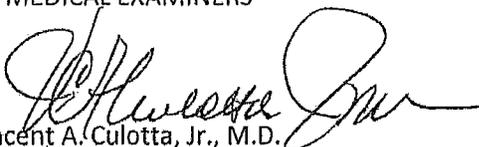
....it would be beneficial if the form that would be utilized for non-ePA requests included a checkbox for the provider to indicate that a request is urgent when appropriate.

The prescribers and dispensers in this state should be aware of the existing rule for pharmacies which authorizes pharmacists to dispense up to a 72-hour supply of a medication while prescriber approval is pending.

We trust this information is responsive to your request for guidance. The LSBME has determined no revisions to the proposed rule are necessary. We will submit the required report to the Joint Legislative Oversight Committee on Health and Welfare with our recommendation to publish the proposed rule as a Final Rule in the Louisiana Register with an effective date of January 1, 2019.

Yours very truly,

LOUISIANA STATE BOARD
OF MEDICAL EXAMINERS


Vincent A. Culotta, Jr., M.D.
Executive Director