Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov

October 25, 2018

Senator John A Alario Jr., President
Louisiana Senate
Via Email: APA.SenatePresident@legis.la.gov

Electronic Mail – Delivery Receipt Requested

Re: Report No. 2 of 3 for *Regulatory Project 2018-2 ~ Louisiana Uniform Prescription Drug Prior Authorization Form*

Dear Senator Alario:

As we indicated in our first report to you on August 10, the Board of Pharmacy is collaborating with the Board of Medical Examiners to promulgate a single uniform prescription drug prior authorization form for use by all payors in the state. This regulatory project was mandated by Act 423 of the 2018 Legislature. Subsequent to our *Notice of Intent* published in the August 2018 edition of the *Louisiana Register*, we conducted a joint public hearing with the medical board on September 28 to receive comments and testimony on the proposed rule and form.

We received two letters asking questions and offering recommendations for changes in the proposed form. The Board has replied to the commentators and determined that no changes to the proposed rule or form are necessary.

You should find the following documents in this package:

Subject to review by the Joint Legislative Oversight Committee on Health & Welfare, the Board proposes to publish the original proposed rule and form as a *Final Rule* in the December 20, 2018 edition of the *Louisiana Register* with a delayed effective date of January 1, 2019. If you have any questions about the enclosed information or our procedures, please contact me directly at mbroussard@pharmacy.la.gov or 225.925.6481.

For the Board:

Malcolm Broussard

Malcolm J. Broussard
Executive Director

cc: Chair, Senate Committee on Health and Welfare – APA.S-H&W@legis.la.gov
Speaker, House of Representatives – APA.HouseSpeaker@legis.la.gov
Chair, House Committee on Health and Welfare – APA.H-HW@legis.la.gov
Editor, *Louisiana Register* – Reg.Submission@la.gov
Reference File

NOTICE OF INTENT

Department of Health
Board of Pharmacy

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

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:

§1130. Louisiana Uniform Prescription Drug Prior Authorization Form

LOUISIANA UNIFORM PRESCRIPTION DRUG PRIOR AUTHORIZATION FORM

SECTION I - SUBMISSION

Submitted to:	Phone:	Fax:	Date:

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:	☐ Male ☐ Female ☐ Other ☐ Unknown
Address:	City:	State:	ZIP Code:
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 (True)	NO (False)		THE PRESCRIBER ATTESTS TO THE FOLLOWING:
SHORT AND LONG-ACTING OPIOIDS			M	A complete **assessment** for pain and function was performed for this patient.
			N	The patient has been **screened for substance abuse / opioid dependence.** (Not required for recipients in long-term care facility.)
			O	The **PMP** will be accessed **each** time a controlled prescription is written for this patient.
			P	A **treatment plan** which includes current and previous goals of therapy for both pain and function has been developed for this patient.
			Q	**Criteria** for failure of the opioid trial and for stopping or continuing the opioid has been established and explained to the patient.
			R	**Benefits and potential harms** of opioid use have been discussed with this patient.
			S	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			T	The patient requires continuous **around the clock** analgesic therapy for which alternative treatment options have been inadequate or have not been tolerated.
			U	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.
			V	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.
			W	Medication has **not** been prescribed for use as an as-needed (PRN) analgesic.
			X	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 Pharmacy, LR 44:

Family Impact Statement

In accordance with Section 953 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a family impact statement on the Rule proposed for adoption, repeal, or amendment. The following statements will be published in the Louisiana Register with the proposed agency Rule.

1. The effect on the stability of the family. The proposed Rule will have no effect on the stability of the family.

2. The effect on the authority and rights of parents regarding the education and supervision of their children. The proposed Rule will have no effect on the authority and rights of parents regarding the education and supervision of their children.

3. The effect on the functioning of the family. The proposed Rule will have no effect on the functioning of the family.

4. The effect on family earnings and family budget. The proposed Rule will have no effect on family earnings or family budget.

5. The effect on the behavior and personal responsibility of children. The proposed Rule will have no effect on the behavior and personal responsibility of children.

6. The ability of the family or a local government to perform the function as contained in the proposed Rule. The proposed Rule will have no effect on the ability of the family or a local government to perform the activity as contained in the proposed Rule.

Poverty Impact Statement

In accordance with Section 973 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a poverty impact statement on the Rule proposed for adoption, repeal, or amendment.

1. The effect on household income, assets, and financial security. The proposed Rule will have no effect on household income, assets, or financial security.

2. The effect on early childhood development and preschool through postsecondary education development. The proposed Rule will have no effect on early childhood development or preschool through postsecondary education development.

3. The effect on employment and workforce development. The proposed Rule will have no effect on employment or workforce development.

4. The effect on taxes and tax credits. The proposed Rule will have no effect on taxes or tax credits.

5. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance. The proposed Rule will have no effect on child and dependent care, housing, nutrition, transportation, or utilities assistance. To the extent the child requires a prescription drug for which the insurer requires a prior authorization process, the use of a single prescription drug prior authorization form by all parties in the state could simplify that process and improve access to the medication, with a positive impact on health care.

Provider Impact Statement

In accordance with House Concurrent Resolution No. 170 of the Regular Session of the 2014 Legislature, there is hereby submitted a provider impact statement on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, the following effects on the providers of services to individuals with developmental disabilities:

1. The effect on the staffing level requirements or qualifications required to provide the same level of service. The proposed Rule will have no effect on the staffing level requirements or the qualifications for that staff to provide the same level of service.

2. The total direct and indirect effect on the cost to the provider to provide the same level of service. To the extent a provider includes the prescribing or dispensing of prescription medications to their clients, and to the extent that provider has previously established a prescription drug prior authorization process (or some multiple thereof) which is substantially different from the proposed form or its electronic equivalent, the provider may incur a one-time cost to revised its existing process to conform to the proposed process. However, we anticipate savings will accrue from the use of a single form by all parties in the state.

3. The overall effect on the ability of the provider to provide the same level of service. The proposed Rule will have no effect on the ability of the provider to provide the same level of service.

Regulatory Flexibility Analysis

In accordance with Section 965 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a regulatory flexibility analysis on the Rule proposed for adoption, repeal, or amendment. This will certify the agency has considered, without limitation, each of the following methods of reducing the impact of the proposed Rule on small businesses:

1. The establishment of less stringent compliance or reporting requirements for small businesses. There are no specific reporting requirements in the proposed Rule.

2. The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses. There are no specific reporting requirements in the proposed Rule.

3. The consolidation or simplification of compliance or reporting requirements for small businesses. There are no specific reporting requirements in the proposed Rule.

4. The establishment of performance standards for small businesses to replace design or operational standards required in the proposed Rule. The proposed Rule requires the use of a single form by all parties in the state, which could eliminate the need to maintain multiple forms for different third-party payors. In addition, the proposed Rule permits the use of electronic equivalents to the written form.

5. The exemption of small businesses from all or any part of the requirements contained in the proposed Rule. There are no exemptions for small businesses.

Public Comments

Interested persons may submit written comments, via United States Postal Service or other mail carrier, or in the alternative, by personal delivery, to Malcolm J Broussard, Executive Director, at the office of the Louisiana Board of Pharmacy, 3388 Brentwood Drive, Baton Rouge, LA 70809-1700. He is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for 9 am on Friday, September 28, 2018 at the office of the Louisiana State Board of Medical Examiners, which is located at 630 Camp Street in 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.

Malcolm J Broussard
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Uniform Prescription Drug Prior Authorization Form

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

The LA Board of Pharmacy 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.

Malcolm Broussard	Evan Brasseaux
Executive Director	Staff Director
1808#036	Legislative Fiscal Office

Louisiana Board of Pharmacy

3388 Brentwood Drive
Baton Rouge, Louisiana 70809-1700
Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov

Summary of Testimony & Public Comments
re
Regulatory Project 2018-2 ~ Louisiana Uniform Prescription Drug Prior Authorization Form
at
September 28, 2018 Public Hearing

1. September 25, 2018 letter from Elisa Y. Muller, on behalf of Quarles & Brady

Requested no revisions to the rule or the form, but posed two questions:

- Whether health insurance issuer is permitted to use its own prior authorization form as long as it conforms to the regulatory requirements; and
- Whether health insurance issuer is permitted to include other fields for physicians to complete when submitting the prior authorization form.

2. September 28, 2018 letter from Kim Diehl-Boyd, on behalf of CoverMyMeds

Posed three questions, then offered two comments and six recommendations:

- Whether a prescriber, pharmacy, or payor already utilizing electronic prior authorizations (ePA) would be required to modify their process and use the promulgated form;
- Whether a health plan could require the prescriber or pharmacy to start a new PA process if the prescriber or pharmacy had already initiated the promulgated form with respect to a specialty medication;
- Whether a health plan could require the prescriber or pharmacy to start a new PA process if the prescriber or pharmacy had already initiated the promulgated form with respect to a medication ordered with an electronic prescription;
- Suggested the provider-administered section of the form would not be necessary since the form is not to be used for specialty medications;
- Suggested the inclusion of guidance to the prescriber or pharmacy that the form was not necessary for a specialty medication or if the medication was prescribed electronically;
- Recommended an expansion of the tried and failed section to include more drug history information;
- Recommended a separate section for non-pharmacologic therapies;
- Recommended adding a section for additional clinical criteria;
- Recommended adding a field for the prescriber to indicate urgent or non-urgent requests;
- Recommended additional space for date of diagnosis, ICD-10 codes and description of diagnosis;
- Recommended adding an instructional note to the prescriber to attach any relevant documentation to facilitate the decision-making process.

PUBLIC HEARING

FRIDAY, SEPTEMBER 28, 2018

THE LOUISIANA STATE

BOARD OF MEDICAL EXAMINERS

630 CAMP STREET

NEW ORLEANS, LOUISIANA 70130

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A Public Hearing was held at the Louisiana State Board of Medical Examiners Office commencing at 9:01 a.m.

PANEL MEMBERS:

James A. Taylor, Jr., MD
Terrie R. Thomas, MD
Christy L. Valentine, MD
Daniel K. Winstead, MD
Roderick V. Clark, MD
Kweli J. Amusa, MD

Vincent A. Culotta, Jr., MD
LSBME Executive Director

MODERATOR:

Philip Bergeron, Esq.

ALSO PRESENT:

Malcolm Broussard, R.Ph,
Executive Director
Louisiana Board of Pharmacy

REPORTED BY: Shelley A. Sampey, CCR
Certified Court Reporter
State of Louisiana, #93011

P R O C E E D I N G S

DR. VALENTINE:

Good morning everyone. I am Dr. Christy Valentine. I'm the Louisiana State Board of Medical Examiners president. And I have asked Mr. Phil Bergeron to moderate today's hearing. He's going to ensure that everyone that would like an opportunity to speak has that opportunity.

So thank you, Phil, this morning.

MR. BERGERON:

Thank you, Dr. Valentine. Ladies and gentlemen, welcome. This meeting is being called, it's a joint meeting by the Louisiana State Board of Medical Examiners and the Louisiana State Board of Pharmacy. I should say a joint hearing. And they're convening to receive public comments, information, views, data and arguments from all interested persons and organizations on some proposed rules

governing the Uniform Prescription Drug Prior Authorization Form. This form is mandated by Act 423 of the 2018 regular session of the legislature.

Mr. Malcolm Broussard, who is the executive director of the Louisiana State Board of Pharmacy is here as well. He's graciously allowed me to make these opening comments. He may have something to say after I conclude the opening comments. But he is here on behalf of the Pharmacy Board to receive comments as well.

There are several members of the Board present here today. From my left, your right, we have Dr. Kweli Amusa, Dr. Rod Clark, Dr. Daniel Winstead, Dr. Terrie Thomas and Dr. James Taylor. Of course, our president has introduced herself, Dr. Christy Valentine.

A few housekeeping issues quickly. Two emergency exits on this floor, one on my right to your left

next to the elevator, one on my left at the far end of the hall. There are restrooms at the far end of the hall as well. If you would, please mute your phones and avoid talking to anyone in the audience while the speakers are talking.

We don't have a very big audience today, so a lot of the formalities will be skipped over. Notice of Intent for these rules was published in the Louisiana Register in accordance with the Louisiana Administrative Procedure Act. They were electronically filed on both the Board's web page of the LSBME and the Pharmacy Board noticing the intent and the proposed rules and of this hearing that is being held this morning at 9 o'clock. Let Ms. Reporter please note that the hearing started about three minutes ago. It's five after 9 now.

Copies of the proposed rules are available from Ms. Arceneaux. These

are the rules that were published in the August 2018 edition of the Louisiana Register, Volume 44, Number 08. Copies are available, as I've said. These records, these documents, will be made part and parcel of this rule-making effort, as will all of the written comments received during the comment period.

I will note for the audience and the folks present here that the comment period concludes at noon today. So if someone has written comments they would like to offer following this hearing, they can offer them in writing, electronically or hard copy to Ms. Arceneaux or to Mr. Broussard by noon today.

The proceedings are being recorded by a recorder, by a stenographer, and will be made available to the members of the Boards for their review in the rule-making process.

Just a few procedural rules

before we hear the comments. First of all, if you wish to offer a comment, please obtain a speaker request card from Ms. Arceneaux identifying the name of the organization and the capacity in which you are appearing today so that we will have that information available. Also, please sign the attendee register so we will know who is present and wishing to speak. And, finally, because these are joint rules that have been noticed for intent, please specify whether your comments are directed to the Pharmacy Board, the Medical Board or both. The attendance register and the speaker cards, of course, are necessary for the Board to fulfill its obligations under the law, both to report to the legislature on the comments received and to respond to you with respect to the Board's answer to your comments.

We have a microphone here and a chair in the front of the room.

Anyone wishing to speak, I would ask that you come up to the microphone, make sure it's on, state your name, the organization that you're representing and the capacity, and then proceed to give your comments. Keep in mind that today's meeting is to receive public comments, not to respond to them. So while the Board may ask you questions, it's not a hearing capacity to respond to those questions. That, of course, will be handled when the Board issues written responses to all the comments that have been offered.

I believe, Madam President, we have reserved an hour for this morning's hearing?

DR. VALENTINE:

Yes, we have.

MR. BERGERON:

So, again, after that time frame, written comments can still be received if directed to either Ms. Arceneaux with the Board of

Medical Examiners or Mr. Broussard here on behalf of the Board of Pharmacy.

Mr. Broussard, do you have anything that I've omitted that you would like to add?

MR. BROUSSARD:

Good morning, Madam President and members. We appreciate the Board's invitation to collaborate with this public hearing on a rule that we are jointly promulgating.

Mr. Bergeron did an excellent job in summarizing the proceedings.

The only thing we would add is we would like to put into the record that we have received two written correspondences prior to the beginning of today's hearing. And to identify those for us, the first is a letter from the firm Coils & Braden (assumed spelling) in Chicago, and it was received in our office at the Board of Pharmacy in Baton Rouge yesterday on the 27th, and it is primarily

questions and not comments. And today we received a letter from CoverMyMeds, and we understand that person is in the audience. They may choose to supplement their written comments, and we appreciate these are questions as well as comments. So those are the two written documents we have received prior to today's hearing.

Thank you, and we'll be here to participate in the hearing till the very end. Thank you very much.

MR. BERGERON:

Thank you.

DR. CULOTTA:

Mr. moderator, Madam President, and Board Members, we also received a letter from CoverMyMeds as well, and we have got copies for everybody, and we'll get them to you right now.

MR. BERGERON:

Thank you, Mr. Broussard, Dr. Culotta.

With those comments, we do have one speaker request card that has been

completed by Ms. Kim Boyd. Ms. Boyd, thank you for joining the Boards this morning. If you have anything to add to the communication that both Boards received this morning, please feel free to come up to the speaker table, identify your organization and capacity and proceed to give us your comments.

MS. BOYD:

I think I'm the only one in the room. I'm not used to that.

Thank you, Madam President, members of the Board, directors, associate directors. My name is Kim Boyd. I am director of industry relations and government affairs at CoverMyMeds. I've been on board at CoverMyMeds for about three years now, but been in the health care space probably, well, about 20 years now. I'm not as experienced as I'm sure many of you here are. I definitely am not a doctor. But I do appreciate your time today. This is a very

important piece of regulation to the health care industry, more specifically to the medication PA process.

By way of background -- and you have the letter here, so I'm not going to regurgitate everything that's in the letter. But there are some points I would like to make that, you know, by way of background, CoverMyMeds is a health care IT company. We were formed in 2008. We're out of Columbus, Ohio. I'm from Nashville, if you can't hear the accent. But I've been on board with them about three years now.

In 2008, they formed to help expedite or improve the medication PA process. Our founder who is -- I think he's 38, and highly intelligent, more intelligent than I care to think I would ever be, was approached by a really good friend of his who is a doctor and said: I have a real problem. I have patients who need

their medication and it's taking me days, if not weeks, because of the laborious PA process to get the patient the medication. Matt, I know you're a really smart guy, you're a technical guy. What can you do to help me?

So therein formed CoverMyMeds. Basically, the doctor said: I can't get my patients' meds covered. So that's where the name came from. So what we started to do in 2008 is to build this library of all of the prior authorization forms that were in the industry. So as a way for the physician to quickly find those forms instead of having to search each state's website or each directory, go to one location, go to a portal. Today we still house roughly 14,000 forms in that portal. We do process PAs nationwide, so that's why there is this huge library of forms. About 9,000 of them are still currently in play, a lot of them associated more so

with Medicaid, but there are many on the commercial side and many -- you know, there's Medicare as well. So we cover all plans, all medications through the CoverMyMeds process.

But what we started to do shortly thereafter, there was a standard that was named by the National Council for Prescription Drug Programs, or NCPDP. They are the standards development organization that standardizes everything for the pharmacy community. They have been an organization for about 40 years now. They have roughly 26 standards on their books. Each day task groups work to evolve those standards as the industry evolves.

So about 10 years ago the NCPDP script standard was adopted, was created. That standard houses the e-Prescribing standard as well as the ePA transactions that are present today and utilized today. So we went from a very, you know, paper-driven

process -- and the PA process for paper takes about three to five days to get completed. So the patient gets their prescription from the pharmacy, whether it's -- excuse me, not from the pharmacy, from the provider. Whether it's e-Prescribed to the pharmacy or it is written by hand, the ePA process can still take place and it does today. So that standard allows for that. It is a four-part transaction that is done computer to computer that allows the prescriber to quickly identify the patient, the need, the medication, and it's done in real time versus the paper process which takes three to five days. The ePA process takes about one day for the patient to get a determination from the plan, sometimes 10 minutes. It really just depends on the plan and their integration at this point.

Today CoverMyMeds does a little over two million prior authorizations a month. We've helped over one

hundred million patients get the medications they need to live healthy lives. So while we are not completely adverse to the adoption of a Uniform Prescription Form, and we understand that SB29 is calling for the two Boards to come together and create this form, we definitely have some questions and we also wanted to make sure that the Boards were well aware that the State of Louisiana is well down the pathway of adopting the ePA.

Through CoverMyMeds right now, we cover about 75 percent of those PAs that come to us are done electronically today versus via the paper form. So we want to ensure as the Boards consider this rule-making that there is some clarification that is put in the rules. Because I know the SB29 indicated that this form would not need to be utilized if e-Prescribing was done or if it was a specialty medication. So what, again, we would like the Board to help us

understand is that if a payer and a provider and/or a pharmacy are completing the PA process today electronically that they would not need to revert to this form and begin using this form versus using the ePA process. Patients know pretty much that day whether or not their medications are covered and can pick it up at the pharmacy versus having to leave the pharmacy without a medication in hand waiting for the paper form to get completed. So, again, that is one thing that I would like clarification from the Board on is to make sure that the ePA process will not be deterred or be overwritten by this form that is adopted by the two Boards.

Secondly, I also want to make sure that should a prescriber pick out this uniform form and it happens to be a prescription that was electronically prescribed that the plans do not say, oh, it was electronically prescribed,

you don't have to use this form, use another form, that the plan will continue with the PA process through the Uniform Prescription Drug Form and continue to move that process downstream. We have seen instances where the incorrect form was pulled and/or used and a plan has denied the PA, saying, you've used the wrong form. So that's really what I'm trying to get at is to make sure that even if the prescriber pulls this form and uses it for a e-Prescribed medication or for a specialty medication that the process will continue and the patient will not have to wait or the prescriber will not have to start over. That does not bode well for patient access. And I think at the end of the day we're trying to get the patients what they need to live healthy lives.

So those were really the three questions or clarifications that we would seek from the Board on this.

There are a couple of comments that are -- we called the PDA content team. They're the ones who manage all of those forms, and they've seen the 14,000 forms a lot. So I asked that team for their comments about the current proposed form and what is on it, and they gave me a few comments to provide to you for clarification as well, and they are included in the letter that I'm submitting.

But one of the comments that is there that I would like to highlight that is: The provider -- excuse me, I have a cold, I'm so sorry -- the provider-administered drugs section would not be necessary on the current proposed form since the utilization of this section is usually for specialty medications only. And if this form is not to be used for specialty medications, there should really not be an area for that. Secondly, 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 or a notation somewhere on the form letting the physician know that this form will not be utilized in those two instances, just to give them clarification.

Some other recommendations they had was to expand the tried and failed section on the form to accommodate for additional drug history to make sure that all necessary drug history could be completed on the form.

Also, to create a separate action for non-pharmacologic therapies, to also add a section or a question or expansion of the clinical criteria section. I'm sure most of you, as physicians, understand that providing the clinical efficacy information is usually paramount to getting a determination made for a medication PA. It's one of the most critical pieces of the PA process.

Also, to add a field for a

provider to indicate the urgency of this request. There are many times that a patient has an urgent need for the medication that is being requested. And usually a plan, when they are given that information, will put it through an expedited process as required by law.

Also, to add -- excuse me -- a date of diagnosis ICD-10 area. And the diagnosis description area should also be given additional information. There are many times that you -- you obviously probably know this -- you have a primary diagnosis, but you also have secondary symptoms, and so there are medications that could potentially be prescribed for off-label use from a diagnosis. And being able to identify those reasons in that area, we think, would be beneficial.

Also, and last but not least, consider adding a note instructing the provider to attach any appropriate or

applicable documentation so the plan doesn't have to come back and ask for that information, again delaying the PA process.

And that is all for me. Thank you so much. And, of course, I'm happy to answer any questions the Board may have. But if not, I really appreciate your time today.

MR. BERGERON:

Just a clarification. The comments that you have are directed to both Boards?

MS. BOYD:

That's correct, sir.

MR. BERGERON:

And aside from what is on -- I think you've outlined your comments on the form today. Is there anything else that you would like to add? I mean, your comments kind of duplicated what is on the written form -- written communication.

THE WITNESS:

Right. Yes, sir.

MR. BERGERON:

Okay. I just wanted -- Do any of the Board members have any questions this morning?

DR. TAYLOR:

Thank you for coming today. I'm actually doing the real time testing to some of my gynos and colleagues, and they seem to like your process better than the old process, frankly.

MS. BOYD:

Thank you.

DR. TAYLOR:

And I was looking over your recommendations before the meeting. Actually, some of these, I believe, make a good deal of sense. I did want to drill down one question, though. Provider-administered drugs section wouldn't be necessary. In your experience, are there any physician-administrated drugs that are not also designated as specialty drugs? In other words, would there be a situation -- and, again, I'm

thinking of a matter like for a vaccination that as a pharmacy benefit they would have to get that covered or something like whether that be as an every-six-month osteoporosis injection. Are there any medications that you're aware of that would fall outside the specialty drug that would be given in the physician's office or that patient could actually self-administer and not choose to administer in a physician's office?

MS. BOYD:

Great question. I can't think of any -- anyone. I did ask the group, you know, in the content team, and we have six clinical pharmacists who are on staff there. I know the two they reviewed, and that those were their comments. So I can go back and ask more specifically, and I'm happy to do that for the Board.

DR. TAYLOR:

Again, it's an unusual event, but I wouldn't say that it's

nonexistent, at least in my practice. And also back up for -- and to get a better idea, because I actually get CoverMyMeds' faxes -- or responses at my office as well. How do you get -- you as a company -- get involved in the process? Because sometimes I'll get a patient, and I'll see the form with the code numbers on it, and sometimes I don't. Are you contracted to the insurance companies? Are you contracted to the pharmacy medical manager? How does CoverMyMeds come into the process, and what's your relationship on the front and back end of that process?

MS. BOYD:

Sure. So the CoverMyMeds process, we do not charge providers nor pharmacies to utilize our process. We are connected with all pharmacies. A hundred percent of pharmacies are connected through ePA. Providers can utilize -- they can log in individually and use our portal and

still do ePA through a portal or we are connected directly with their EHRs. So we have those -- those are how we connect with those two pieces of the puzzle. It is the plans who compensate CoverMyMeds for the transaction process.

DR. TAYLOR:

And I don't know if you haven't answered this question, but would it be your experience that a majority of those interactions actually start from the pharmacy?

MS. BOYD:

Correct. Roughly -- it used to be a little bit higher, but presently about 65 to 69 percent on any given state. The pharmacy is the one who initiates the PA. So the prescriber will prescribe either paper e-Prescribing, you go to pick up your prescription and it says, sorry, it's been rejected because it needs a PA. So the pharmacy will -- we have what is called an easy button inside the

majority of the 65,000 pharmacies nationwide, and they just touch that button and it automatically creates the start of the PA. So it does the demographic information, it puts in the patient medication information, and it sends it off to the provider to the plan. And the plan will then send the clinical criteria question set which is unique to the patient and the medication. That is the difference between a form and the ePA process as well. A form has general questions on it. Most of the time the plan comes back and asks the prescriber more questions that are specific to you or me and our medication. So the pharmacy will start it off due to that rejection, and then the provider and the plan will then take up the process electronically. Again, the clinical questions that are asked that is unique to you or I and the medication and the doctor's system either pulls the information and answers it or

someone within the physician's office will answer those few questions and send it back to the plan electronically.

In the ePA process, just to dig a little deeper, auto determinations are done. People are not picking up a piece of paper or a book and going through this flow chart of questions and seeing what was answered "yes," "no," that sort of thing. The systems are doing that. That's why ePA is so much faster, because the auto determination happens through ePA.

Does that answer your question?

DR. TAYLOR:

Yes. Thank you.

MS. BOYD:

Perfect. Thank you.

MR. BERGERON:

I'm looking -- just out of curiosity, I'm looking through your suggestions on Page 2 of your communication.

THE WITNESS:

Yes, sir.

MR. BERGERON:

And so your first one is to the provider-administered drugs section wouldn't be necessary since this form is not to be utilized for specialty medications. And then again, since this form is not necessary for use if the prescription for the medication or the prescription, if it was e-filed, we suggest placing a message at the top. Could not that be accomplished simply by the -- by "N/A," by use of the not applicable, not applicable to this drug?

MS. BOYD:

I'm so sorry. Could you repeat that question?

MR. BERGERON:

Could the present form not be utilized simply with the notation "not applicable, specialty drug."

MS. BOYD:

Correct. Correct. And I think that's the recommendation we're making

here, if we could put someplace on the form that specialty medication, not applicable, e-Prescribed, not applicable. So when the physician pulls up -- so, for example, in our portal where we house all of these forms, the prescriber will go in and pick the appropriate form or format to begin that process if they go through the portal process. We want to make sure that they pick the right one. So if it's -- the question's still going to come into play -- the question still comes into play as who defines specialty as well. I did not put that in my comments here, but who defines what's a specialty drug.

You could have a prescriber thinking they're doing a specialty drug for Blue Cross Blue Shield, they send it over, Blue Cross Blue Shield says, no, we consider that a specialty drug. So the definition of specialty still comes into play as well. There's no universal definition of

specialty in our -- we've got CMS who has a definition. But there's no real true universal definition that's been defined yet of what a specialty drug is. So I think if we could get some clarification so they know which form to pick and where to go so it doesn't delay the process...

MR. BERGERON:

Next question: Expand the tried and failed section to accommodate more drug history. What specific section are you referring to?

MS. BOYD:

I'm sorry, sir. I don't have the form in front of me. I might have it in front of me here.

MR. BERGERON:

It's in the rule. Do you have a copy?

MS. BOYD:

It was in the rule. I do not now. Do you have one, Rita?

MR. BERGERON:

Ms. Arceneaux, could you get a

copy? I just want to make sure that we understand exactly the section that you're referring to.

MS. BOYD:

And my apologies for not notating the section specifically. Let me see if I can find it. Sir, where it says continue -- so under Section IV: Prescription drug information, where it says: To the best of your knowledge this medication is for a new therapy or a continuation of therapy or a reauthorization part, that is what our team would call a tried and fail. Is it a reauthorization, is it something that you were taking before, and put information in there. Because we do get a lot of questions. We do basically step therapy. So PA in the system could be, you know, a step therapy request, an exception to an off label, quantity limit, things of that nature. So there could be some additional section here that a

prescriber can indicate that a former medication that might be on a formulated benefit that would not require PA has been tried and failed.

Does that make sense?

MR. BERGERON:

Clarification also: Create a separate section for non-pharmacologic therapies. Section VII currently applies to both pharmacologic and non-pharmacologic treatments. Is that -- is it your view that that needs to be supplemented or changed?

MS. BOYD:

Let me go back. The recommendation was to actually split those out and make those two separate sections so you have pharmacologic and non-pharmacologic. The recommendation would be to split those two out just for clarity.

MR. BERGERON:

A field to indicate the urgency of the request, I think is --

MS. BOYD:

Yes, sir. On many forms you'll have at the top, Urgent/Nonurgent, a box that could be checked. On many other standard forms there's a place to designate that. Usually it is a check box or a line that could be checked.

MR. BERGERON:

I think I just wanted to make sure the Board had clarification on those issues. Thank you so much.

MS. BOYD:

Thank you. I appreciate it.

DR. VALENTINE:

Yes, Mr. Broussard?

MR. BROUSSARD:

Madam President, if I may, I think my members would appreciate if I would ask Ms. Boyd some questions.

DR. VALENTINE:

Absolutely.

MR. BROUSSARD:

I'll pick up this last one first asking for a separate section for the non-pharmacologic therapies. Knowing

that the existing law that legislation addressed at 423, existing law limits the size of the form to two pages, if you wanted to create another section to expand, are you willing to collapse something else so that it could fit, that would make it all fit. I think the drafters of the form are trying to fit as much as they could into the two-page limitation.

MS. BOYD:

Absolutely. I'm wondering on the non-pharmacologic area -- and I can never say that right, so my apologies -- if only a couple of lines would be sufficient. It looks like it if you look at -- so right now, would this be a three-page directive? Would this be a three-page that we're looking at right now?

MR. BROUSSARD:

What we're looking at now is a two-page form.

MS. BOYD:

Okay. There is a little wiggle

room. I would suggest maybe if you can expand that out maybe giving it only a couple of sections or a couple of lines if you could do that. I'm not sure -- they did not indicate when we -- I reviewed it and they reviewed it. We didn't see anything that should be necessarily taken out of here. There was coverage that was applicable to many other forms, so we didn't see any area to really remove.

MR. BROUSSARD:

And so the same question applies to all the other items that you wish to add. It becomes a matter of, logistically, how would the form creators manage all the data fields within the two-page limit when the Boards do not have the option of changing the size of the form --

MS. BOYD:

Correct.

MR. BROUSSARD:

-- that is a statutory limitation?

MS. BOYD:

We just know that historically that we've been able to add this. I know the State of Massachusetts, for example, these were some additional recommendations we gave to them a couple of years ago, and their form is a two-page form as well. So maybe an opportunity to look and maybe compare what they have on their form and how they have it designated and the font and things of that nature might be applicable, just a recommendation.

MR. BROUSSARD:

And my original first question was to your question about whether or not the rule apparently preempts the ePA. I'm not sure if that was the gist of your question, whether or not the rule would preempt an ePA.

MS. BOYD:

Yes, sir.

MR. BROUSSARD:

And when the Board wrote the rule, they required that the form that

was promulgating, either in written form or its electronic equivalent, my members were anticipating that would cover an ePA. Do you have a concern that that language does not address that?

MS. BOYD:

I don't necessarily have a concern, other than when it says electronic equivalent. Sometimes it can be interpreted that if all of the questions that are on the form are not asked in the ePA process, then it's not an equivalent. Not every question that might be on this form would be necessary for every patient and every drug that might require a PA. Those are some of the difficulties that we have run into in jurisdictions where there is a uniform PA form, an ePA is present. An ePA is done in every jurisdiction today. So that's some of the difficulty, just to make sure that we're not saying the ePA process must be identical or the questions that are

here must be identical in the ePA process. Because that would -- that would be a reversal of the expeditious process today.

Does that make sense?

MR. BROUSSARD:

I think it does, and it gets to the heart of the question, I think why the legislature wanted a uniform approach, and the mandate is to create a uniform approach. Our Board did not want to impede the use of ePA, recognizing that we have a statutory mandate. Thank you.

MS. BOYD:

Thank you.

DR. THOMAS:

Ms. Boyd, CoverMyMeds only does e-Prescribing; is that correct?

MS. BOYD:

No, ma'am. We do not do e-Prescribing. We are not an e-Prescribing network. We are an electronic prior authorization network. We do not e-Prescribe today.

Although, the script standard that NCPDP created houses both the transactions for e-Prescribing and ePA.

DR. THOMAS:

Okay.

MS. BOYD:

So we do not do e-Prescribing today. We only do -- and we do fax as well. So not every PA that goes -- like I said, we have the forms in there, and those will go fast as well.

DR. THOMAS:

And then Dr. Culotta, I believe, had --

DR. CULOTTA:

Ms. Boyd, when you talked about for a physician provider, a provider who administers drugs in the office, with the reinitiation and re-upping of patents under the ACA, a lot of drugs that used to be very inexpensive and very easy to stock in a doctor's office have gone up traumatically, for example, bicillin to treat syphilis.

Louisiana has one of the highest syphilis rates in the country, and they really do need to know that they're going to be administered. Because, remember, these companies use cost as well as efficacy to determine PA. So we ought to be able to say you're going to get it filled and bring it to the doctor's office and get it so we can document it. So with regard to your request that it wouldn't be necessary, how are you going to address drugs like that, like bicillin and those very expensive reauthorized drugs under the ACA?

MS. BOYD:

I think my response to you as the professionals and those who truly understand your patient need, that if keeping that in there because of the syphilis administration drugs, we would be perfectly fine with that. You know, I don't think that our clinicians thought through every single scenario that might be there.

They we're really honing in on the specialty side because we have seen a lot of issues being addressed on specialty with the rise in cost and their availability now.

DR. CULOTTA:

Because bicillin has gone out the roof in price.

MS. BOYD:

We would be willing to remove that recommendation.

DR. CULOTTA:

Thank you.

DR. VALENTINE:

Thank you, Ms. Boyd. We appreciate it.

MS. BOYD:

Thank you.

MR. BERGERON:

Madam President, may I suggest the Board stand down for a bit? We have some more time here in case anyone comes up and wishes to offer comments.

DR. VALENTINE:

Sure. Okay. So we can take a break.

(A brief break was taken at 9:37 a.m.)

MR. BERGERON:

Well, thank you very much. The time now is 10:20. Ms. Arceneaux, do we have any more speaker request forms?

MS. ARCENEAUX:

No, sir.

MR. BERGERON:

Is anyone waiting to address the --

MS. ARCENEAUX:

No, sir.

MR. BERGERON:

Thank you very much. Thank you, Dr. Winstead. Mr. Broussard is welcome to remain, if you will. Dr. Culotta will be here. And should anyone else appear, you are more than welcome to accept whatever comments they may wish to offer.

MR. BROUSSARD:

Madam President, and members,

thank you very much for your generous hospitality and collaboration in this process. Thank you very much.

DR. VALENTINE:

Thank you, Mr. Broussard.

(The proceedings were concluded at 10:18 a.m.)

C E R T I F I C A T E

I, SHELLEY A. SAMPEY, Certified Court Reporter/Registered Professional Reporter, in and for the State of Louisiana, do hereby certify that these proceedings were reported by me in stenotype and transcribed by me or under my personal direction and supervision, and is a true and correct transcript to the best of my ability and understanding;

That the transcript has been prepared in compliance with transcript format guidelines required by statute or by rules of the board, as described on the website of the board;

That I have acted in compliance with the prohibition on contractual relationships as defined by Louisiana Code of Civil Procedure Article 1434 and in rules and advisory opinions of the board;

That I am not of counsel, not related to counsel, nor to the parties hereto, and am in no way interested in the outcome of this matter.

_____

SHELLEY A. SAMPEY, CCR
Certified Court Reporter
State of Louisiana,#93011

PUBLIC HEARING
FRIDAY, SEPTEMBER 28, 2018
THE LOUISIANA STATE
BOARD OF MEDICAL EXAMINERS
630 CAMP STREET
NEW ORLEANS, LOUISIANA 70130
****

A Public Hearing was held at the Louisiana State Board of Medical Examiners Office commencing at 9:01 a.m.

PANEL MEMBERS:

James A. Taylor, Jr., MD
Terrie R. Thomas, MD
Christy L. Valentine, MD
Daniel K. Winstead, MD
Roderick V. Clark, MD
Kweli J. Amusa, MD
Vincent A. Culotta, Jr., MD
LSBME Executive Director

MODERATOR:

Philip Bergeron, Esq.

ALSO PRESENT:

Malcolm Broussard, R.Ph,
Executive Director
Louisiana Board of Pharmacy

REPORTED BY: Shelley A. Sampey, CCR
Certified Court Reporter
State of Louisiana, #93011

P R O C E E D I N G S

DR. VALENTINE:

Good morning everyone. I am Dr. Christy Valentine. I'm the Louisiana State Board of Medical Examiners president. And I have asked Mr. Phil Bergeron to moderate today's hearing. He's going to ensure that everyone that would like an opportunity to speak has that opportunity.

So thank you, Phil, this morning.

MR. BERGERON:

Thank you, Dr. Valentine. Ladies and gentlemen, welcome. This meeting is being called, it's a joint meeting by the Louisiana State Board of Medical Examiners and the Louisiana State Board of Pharmacy. I should say a joint hearing. And they're convening to receive public comments, information, views, data and arguments from all interested persons and organizations on some proposed rules governing the Uniform Prescription Drug Prior Authorization Form. This form is mandated by Act 423 of the 2018 regular session of the legislature.

Mr. Malcolm Broussard, who is the executive director of the Louisiana State Board of Pharmacy is here as well. He's graciously allowed me to make these opening comments. He may have something to say after I conclude the opening comments. But he is here on behalf of the Pharmacy Board to receive comments as well.

There are several members of the Board present here today. From my left, your right, we have Dr. Kweli Amusa, Dr. Rod Clark, Dr. Daniel Winstead, Dr. Terrie Thomas and Dr. James Taylor. Of course, our president has introduced herself, Dr. Christy Valentine.

A few housekeeping issues quickly. Two emergency exits on this floor, one on my right to your left next to the elevator, one on my left at the far end of the hall. There are restrooms at the far end of the hall as well. If you would, please mute your phones and avoid talking to anyone in the audience while the speakers are talking.

We don't have a very big audience today, so a lot of the formalities will be skipped over. Notice of Intent for these rules was published in the Louisiana Register in accordance with the Louisiana Administrative Procedure Act. They were electronically filed on both the Board's web page of the LSBME and the Pharmacy Board noticing the intent and the proposed rules and of this hearing that is being held this morning at 9 o'clock. Let Ms. Reporter please note that the hearing started about three minutes ago. It's five after 9 now.

Copies of the proposed rules are available from Ms. Arceneaux. These

5

are the rules that were published in the August 2018 edition of the Louisiana Register, Volume 44, Number 08. Copies are available, as I've said. These records, these documents, will be made part and parcel of this rule-making effort, as will all of the written comments received during the comment period.

I will note for the audience and the folks present here that the comment period concludes at noon today. So if someone has written comments they would like to offer following this hearing, they can offer them in writing, electronically or hard copy to Ms. Arceneaux or to Mr. Broussard by noon today.

The proceedings are being recorded by a recorder, by a stenographer, and will be made available to the members of the Boards for their review in the rule-making process.

Just a few procedural rules

6

before we hear the comments. First of all, if you wish to offer a comment, please obtain a speaker request card from Ms. Arceneaux identifying the name of the organization and the capacity in which you are appearing today so that we will have that information available. Also, please sign the attendee register so we will know who is present and wishing to speak. And, finally, because these are joint rules that have been noticed for intent, please specify whether your comments are directed to the Pharmacy Board, the Medical Board or both. The attendance register and the speaker cards, of course, are necessary for the Board to fulfill its obligations under the law, both to report to the legislature on the comments received and to respond to you with respect to the Board's answer to your comments.

We have a microphone here and a chair in the front of the room.

7

Anyone wishing to speak, I would ask that you come up to the microphone, make sure it's on, state your name, the organization that you're representing and the capacity, and then proceed to give your comments. Keep in mind that today's meeting is to receive public comments, not to respond to them. So while the Board may ask you questions, it's not a hearing capacity to respond to those questions. That, of course, will be handled when the Board issues written responses to all the comments that have been offered.

I believe, Madam President, we have reserved an hour for this morning's hearing?

DR. VALENTINE:

Yes, we have.

MR. BERGERON:

So, again, after that time frame, written comments can still be received if directed to either Ms. Arceneaux with the Board of

8

Medical Examiners or Mr. Broussard here on behalf of the Board of Pharmacy.

Mr. Broussard, do you have anything that I've omitted that you would like to add?

MR. BROUSSARD:

Good morning, Madam President and members. We appreciate the Board's invitation to collaborate with this public hearing on a rule that we are jointly promulgating.

Mr. Bergeron did an excellent job in summarizing the proceedings.

The only thing we would add is we would like to put into the record that we have received two written correspondences prior to the beginning of today's hearing. And to identify those for us, the first is a letter from the firm Coils & Braden (assumed spelling) in Chicago, and it was received in our office at the Board of Pharmacy in Baton Rouge yesterday on the 27th, and it is primarily

questions and not comments. And today we received a letter from CoverMyMeds, and we understand that person is in the audience. They may choose to supplement their written comments, and we appreciate these are questions as well as comments. So those are the two written documents we have received prior to today's hearing.

Thank you, and we'll be here to participate in the hearing till the very end. Thank you very much.

MR. BERGERON:

Thank you.

DR. CULOTTA:

Mr. moderator, Madam President, and Board Members, we also received a letter from CoverMyMeds as well, and we have got copies for everybody, and we'll get them to you right now.

MR. BERGERON:

Thank you, Mr. Broussard, Dr. Culotta.

With those comments, we do have one speaker request card that has been

completed by Ms. Kim Boyd. Ms. Boyd, thank you for joining the Boards this morning. If you have anything to add to the communication that both Boards received this morning, please feel free to come up to the speaker table, identify your organization and capacity and proceed to give us your comments.

MS. BOYD:

I think I'm the only one in the room. I'm not used to that.

Thank you, Madam President, members of the Board, directors, associate directors. My name is Kim Boyd. I am director of industry relations and government affairs at CoverMyMeds. I've been on board at CoverMyMeds for about three years now, but been in the health care space probably, well, about 20 years now. I'm not as experienced as I'm sure many of you here are. I definitely am not a doctor. But I do appreciate your time today. This is a very

important piece of regulation to the health care industry, more specifically to the medication PA process.

By way of background -- and you have the letter here, so I'm not going to regurgitate everything that's in the letter. But there are some points I would like to make that, you know, by way of background, CoverMyMeds is a health care IT company. We were formed in 2008. We're out of Columbus, Ohio. I'm from Nashville, if you can't hear the accent. But I've been on board with them about three years now.

In 2008, they formed to help expedite or improve the medication PA process. Our founder who is -- I think he's 38, and highly intelligent, more intelligent than I care to think I would ever be, was approached by a really good friend of his who is a doctor and said: I have a real problem. I have patients who need

their medication and it's taking me days, if not weeks, because of the laborious PA process to get the patient the medication. Matt, I know you're a really smart guy, you're a technical guy. What can you do to help me?

So therein formed CoverMyMeds. Basically, the doctor said: I can't get my patients' meds covered. So that's where the name came from. So what we started to do in 2008 is to build this library of all of the prior authorization forms that were in the industry. So as a way for the physician to quickly find those forms instead of having to search each state's website or each directory, go to one location, go to a portal. Today we still house roughly 14,000 forms in that portal. We do process PAs nationwide, so that's why there is this huge library of forms. About 9,000 of them are still currently in play, a lot of them associated more so

13

with Medicaid, but there are many on the commercial side and many -- you know, there's Medicare as well. So we cover all plans, all medications through the CoverMyMeds process.

But what we started to do shortly thereafter, there was a standard that was named by the National Council for Prescription Drug Programs, or NCPDP. They are the standards development organization that standardizes everything for the pharmacy community. They have been an organization for about 40 years now. They have roughly 26 standards on their books. Each day task groups work to evolve those standards as the industry evolves.

So about 10 years ago the NCPDP script standard was adopted, was created. That standard houses the e-Prescribing standard as well as the ePA transactions that are present today and utilized today. So we went from a very, you know, paper-driven

14

process -- and the PA process for paper takes about three to five days to get completed. So the patient gets their prescription from the pharmacy, whether it's -- excuse me, not from the pharmacy, from the provider. Whether it's e-Prescribed to the pharmacy or it is written by hand, the ePA process can still take place and it does today. So that standard allows for that. It is a four-part transaction that is done computer to computer that allows the prescriber to quickly identify the patient, the need, the medication, and it's done in real time versus the paper process which takes three to five days. The ePA process takes about one day for the patient to get a determination from the plan, sometimes 10 minutes. It really just depends on the plan and their integration at this point.

Today CoverMyMeds does a little over two million prior authorizations a month. We've helped over one

15

hundred million patients get the medications they need to live healthy lives. So while we are not completely adverse to the adoption of a Uniform Prescription Form, and we understand that SB29 is calling for the two Boards to come together and create this form, we definitely have some questions and we also wanted to make sure that the Boards were well aware that the State of Louisiana is well down the pathway of adopting the ePA.

Through CoverMyMeds right now, we cover about 75 percent of those PAs that come to us are done electronically today versus via the paper form. So we want to ensure as the Boards consider this rule-making that there is some clarification that is put in the rules. Because I know the SB29 indicated that this form would not need to be utilized if e-Prescribing was done or if it was a specialty medication. So what, again, we would like the Board to help us

16

understand is that if a payer and a provider and/or a pharmacy are completing the PA process today electronically that they would not need to revert to this form and begin using this form versus using the ePA process. Patients know pretty much that day whether or not their medications are covered and can pick it up at the pharmacy versus having to leave the pharmacy without a medication in hand waiting for the paper form to get completed. So, again, that is one thing that I would like clarification from the Board on is to make sure that the ePA process will not be deterred or be overwritten by this form that is adopted by the two Boards.

Secondly, I also want to make sure that should a prescriber pick out this uniform form and it happens to be a prescription that was electronically prescribed that the plans do not say, oh, it was electronically prescribed,

you don't have to use this form, use another form, that the plan will continue with the PA process through the Uniform Prescription Drug Form and continue to move that process downstream. We have seen instances where the incorrect form was pulled and/or used and a plan has denied the PA, saying, you've used the wrong form. So that's really what I'm trying to get at is to make sure that even if the prescriber pulls this form and uses it for a e-Prescribed medication or for a specialty medication that the process will continue and the patient will not have to wait or the prescriber will not have to start over. That does not bode well for patient access. And I think at the end of the day we're trying to get the patients what they need to live healthy lives.

So those were really the three questions or clarifications that we would seek from the Board on this.

There are a couple of comments that are -- we called the PDA content team. They're the ones who manage all of those forms, and they've seen the 14,000 forms a lot. So I asked that team for their comments about the current proposed form and what is on it, and they gave me a few comments to provide to you for clarification as well, and they are included in the letter that I'm submitting.

But one of the comments that is there that I would like to highlight that is: The provider -- excuse me, I have a cold, I'm so sorry -- the provider-administered drugs section would not be necessary on the current proposed form since the utilization of this section is usually for specialty medications only. And if this form is not to be used for specialty medications, there should really not be an area for that. Secondly, 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 or a notation somewhere on the form letting the physician know that this form will not be utilized in those two instances, just to give them clarification.

Some other recommendations they had was to expand the tried and failed section on the form to accommodate for additional drug history to make sure that all necessary drug history could be completed on the form.

Also, to create a separate action for non-pharmacologic therapies, to also add a section or a question or expansion of the clinical criteria section. I'm sure most of you, as physicians, understand that providing the clinical efficacy information is usually paramount to getting a determination made for a medication PA. It's one of the most critical pieces of the PA process.

Also, to add a field for a

provider to indicate the urgency of this request. There are many times that a patient has an urgent need for the medication that is being requested. And usually a plan, when they are given that information, will put it through an expedited process as required by law.

Also, to add -- excuse me -- a date of diagnosis ICD-10 area. And the diagnosis description area should also be given additional information. There are many times that you -- you obviously probably know this -- you have a primary diagnosis, but you also have secondary symptoms, and so there are medications that could potentially be prescribed for off-label use from a diagnosis. And being able to identify those reasons in that area, we think, would be beneficial.

Also, and last but not least, consider adding a note instructing the provider to attach any appropriate or

applicable documentation so the plan doesn't have to come back and ask for that information, again delaying the PA process.

And that is all for me. Thank you so much. And, of course, I'm happy to answer any questions the Board may have. But if not, I really appreciate your time today.

MR. BERGERON:

Just a clarification. The comments that you have are directed to both Boards?

MS. BOYD:

That's correct, sir.

MR. BERGERON:

And aside from what is on -- I think you've outlined your comments on the form today. Is there anything else that you would like to add? I mean, your comments kind of duplicated what is on the written form -- written communication.

THE WITNESS:

Right. Yes, sir.

MR. BERGERON:

Okay. I just wanted -- Do any of the Board members have any questions this morning?

DR. TAYLOR:

Thank you for coming today. I'm actually doing the real time testing to some of my gynos and colleagues, and they seem to like your process better than the old process, frankly.

MS. BOYD:

Thank you.

DR. TAYLOR:

And I was looking over your recommendations before the meeting. Actually, some of these, I believe, make a good deal of sense. I did want to drill down one question, though. Provider-administered drugs section wouldn't be necessary. In your experience, are there any physician-administrated drugs that are not also designated as specialty drugs? In other words, would there be a situation -- and, again, I'm

thinking of a matter like for a vaccination that as a pharmacy benefit they would have to get that covered or something like whether that be as an every-six-month osteoporosis injection. Are there any medications that you're aware of that would fall outside the specialty drug that would be given in the physician's office or that patient could actually self-administer and not choose to administer in a physician's office?

MS. BOYD:

Great question. I can't think of any -- anyone. I did ask the group, you know, in the content team, and we have six clinical pharmacists who are on staff there. I know the two they reviewed, and that those were their comments. So I can go back and ask more specifically, and I'm happy to do that for the Board.

DR. TAYLOR:

Again, it's an unusual event, but I wouldn't say that it's

nonexistent, at least in my practice. And also back up for -- and to get a better idea, because I actually get CoverMyMeds' faxes -- or responses at my office as well. How do you get -- you as a company -- get involved in the process? Because sometimes I'll get a patient, and I'll see the form with the code numbers on it, and sometimes I don't. Are you contracted to the insurance companies? Are you contracted to the pharmacy medical manager? How does CoverMyMeds come into the process, and what's your relationship on the front and back end of that process?

MS. BOYD:

Sure. So the CoverMyMeds process, we do not charge providers nor pharmacies to utilize our process. We are connected with all pharmacies. A hundred percent of pharmacies are connected through ePA. Providers can utilize -- they can log in individually and use our portal and

still do ePA through a portal or we are connected directly with their EHRs. So we have those -- those are how we connect with those two pieces of the puzzle. It is the plans who compensate CoverMyMeds for the transaction process.

DR. TAYLOR:

And I don't know if you haven't answered this question, but would it be your experience that a majority of those interactions actually start from the pharmacy?

MS. BOYD:

Correct. Roughly -- it used to be a little bit higher, but presently about 65 to 69 percent on any given state. The pharmacy is the one who initiates the PA. So the prescriber will prescribe either paper e-Prescribing, you go to pick up your prescription and it says, sorry, it's been rejected because it needs a PA. So the pharmacy will -- we have what is called an easy button inside the

majority of the 65,000 pharmacies nationwide, and they just touch that button and it automatically creates the start of the PA. So it does the demographic information, it puts in the patient medication information, and it sends it off to the provider to the plan. And the plan will then send the clinical criteria question set which is unique to the patient and the medication. That is the difference between a form and the ePA process as well. A form has general questions on it. Most of the time the plan comes back and asks the prescriber more questions that are specific to you or me and our medication. So the pharmacy will start it off due to that rejection, and then the provider and the plan will then take up the process electronically. Again, the clinical questions that are asked that is unique to you or I and the medication and the doctor's system either pulls the information and answers it or

someone within the physician's office will answer those few questions and send it back to the plan electronically.

In the ePA process, just to dig a little deeper, auto determinations are done. People are not picking up a piece of paper or a book and going through this flow chart of questions and seeing what was answered "yes," "no," that sort of thing. The systems are doing that. That's why ePA is so much faster, because the auto determination happens through ePA.

Does that answer your question?

DR. TAYLOR:

Yes. Thank you.

MS. BOYD:

Perfect. Thank you.

MR. BERGERON:

I'm looking -- just out of curiosity, I'm looking through your suggestions on Page 2 of your communication.

THE WITNESS:

Yes, sir.

MR. BERGERON:

And so your first one is to the provider-administered drugs section wouldn't be necessary since this form is not to be utilized for specialty medications. And then again, since this form is not necessary for use if the prescription for the medication or the prescription, if it was e-filed, we suggest placing a message at the top. Could not that be accomplished simply by the -- by "N/A," by use of the not applicable, not applicable to this drug?

MS. BOYD:

I'm so sorry. Could you repeat that question?

MR. BERGERON:

Could the present form not be utilized simply with the notation "not applicable, specialty drug."

MS. BOYD:

Correct. Correct. And I think that's the recommendation we're making

here, if we could put someplace on the form that specialty medication, not applicable, e-Prescribed, not applicable. So when the physician pulls up -- so, for example, in our portal where we house all of these forms, the prescriber will go in and pick the appropriate form or format to begin that process if they go through the portal process. We want to make sure that they pick the right one. So if it's -- the question's still going to come into play -- the question still comes into play as who defines specialty as well. I did not put that in my comments here, but who defines what's a specialty drug.

You could have a prescriber thinking they're doing a specialty drug for Blue Cross Blue Shield, they send it over, Blue Cross Blue Shield says, no, we consider that a specialty drug. So the definition of specialty still comes into play as well.

There's no universal definition of

specialty in our -- we've got CMS who has a definition. But there's no real true universal definition that's been defined yet of what a specialty drug is. So I think if we could get some clarification so they know which form to pick and where to go so it doesn't delay the process...

MR. BERGERON:

Next question: Expand the tried and failed section to accommodate more drug history. What specific section are you referring to?

MS. BOYD:

I'm sorry, sir. I don't have the form in front of me. I might have it in front of me here.

MR. BERGERON:

It's in the rule. Do you have a copy?

MS. BOYD:

It was in the rule. I do not now. Do you have one, Rita?

MR. BERGERON:

Ms. Arceneaux, could you get a

copy? I just want to make sure that we understand exactly the section that you're referring to.

MS. BOYD:

And my apologies for not notating the section specifically. Let me see if I can find it. Sir, where it says continue -- so under Section IV: Prescription drug information, where it says: To the best of your knowledge this medication is for a new therapy or a continuation of therapy or a reauthorization part, that is what our team would call a tried and fail. Is it a reauthorization, is it something that you were taking before, and put information in there. Because we do get a lot of questions. We do basically step therapy. So PA in the system could be, you know, a step therapy request, an exception to an off label, quantity limit, things of that nature. So there could be some additional section here that a

prescriber can indicate that a former medication that might be on a formulated benefit that would not require PA has been tried and failed.

Does that make sense?

MR. BERGERON:

Clarification also: Create a separate section for non-pharmacologic therapies. Section VII currently applies to both pharmacologic and non-pharmacologic treatments. Is that -- is it your view that that needs to be supplemented or changed?

MS. BOYD:

Let me go back. The recommendation was to actually split those out and make those two separate sections so you have pharmacologic and non-pharmacologic. The recommendation would be to split those two out just for clarity.

MR. BERGERON:

A field to indicate the urgency of the request, I think is --

MS. BOYD:

Yes, sir. On many forms you'll have at the top, Urgent/Nonurgent, a box that could be checked. On many other standard forms there's a place to designate that. Usually it is a check box or a line that could be checked.

MR. BERGERON:

I think I just wanted to make sure the Board had clarification on those issues. Thank you so much.

MS. BOYD:

Thank you. I appreciate it.

DR. VALENTINE:

Yes, Mr. Broussard?

MR. BROUSSARD:

Madam President, if I may, I think my members would appreciate if I would ask Ms. Boyd some questions.

DR. VALENTINE:

Absolutely.

MR. BROUSSARD:

I'll pick up this last one first asking for a separate section for the non-pharmacologic therapies. Knowing

that the existing law that legislation addressed at 423, existing law limits the size of the form to two pages, if you wanted to create another section to expand, are you willing to collapse something else so that it could fit, that would make it all fit. I think the drafters of the form are trying to fit as much as they could into the two-page limitation.

MS. BOYD:

Absolutely. I'm wondering on the non-pharmacologic area -- and I can never say that right, so my apologies -- if only a couple of lines would be sufficient. It looks like it if you look at -- so right now, would this be a three-page directive? Would this be a three-page that we're looking at right now?

MR. BROUSSARD:

What we're looking at now is a two-page form.

MS. BOYD:

Okay. There is a little wiggle

room. I would suggest maybe if you can expand that out maybe giving it only a couple of sections or a couple of lines if you could do that. I'm not sure -- they did not indicate when we -- I reviewed it and they reviewed it. We didn't see anything that should be necessarily taken out of here. There was coverage that was applicable to many other forms, so we didn't see any area to really remove.

MR. BROUSSARD:

And so the same question applies to all the other items that you wish to add. It becomes a matter of, logistically, how would the form creators manage all the data fields within the two-page limit when the Boards do not have the option of changing the size of the form --

MS. BOYD:

Correct.

MR. BROUSSARD:

-- that is a statutory limitation?

MS. BOYD:

We just know that historically that we've been able to add this. I know the State of Massachusetts, for example, these were some additional recommendations we gave to them a couple of years ago, and their form is a two-page form as well. So maybe an opportunity to look and maybe compare what they have on their form and how they have it designated and the font and things of that nature might be applicable, just a recommendation.

MR. BROUSSARD:

And my original first question was to your question about whether or not the rule apparently preempts the ePA. I'm not sure if that was the gist of your question, whether or not the rule would preempt an ePA.

MS. BOYD:

Yes, sir.

MR. BROUSSARD:

And when the Board wrote the rule, they required that the form that

was promulgating, either in written form or its electronic equivalent, my members were anticipating that would cover an ePA. Do you have a concern that that language does not address that?

MS. BOYD:

I don't necessarily have a concern, other than when it says electronic equivalent. Sometimes it can be interpreted that if all of the questions that are on the form are not asked in the ePA process, then it's not an equivalent. Not every question that might be on this form would be necessary for every patient and every drug that might require a PA. Those are some of the difficulties that we have run into in jurisdictions where there is a uniform PA form, an ePA is present. An ePA is done in every jurisdiction today. So that's some of the difficulty, just to make sure that we're not saying the ePA process must be identical or the questions that are

here must be identical in the ePA process. Because that would -- that would be a reversal of the expeditious process today.

Does that make sense?

MR. BROUSSARD:

I think it does, and it gets to the heart of the question, I think why the legislature wanted a uniform approach, and the mandate is to create a uniform approach. Our Board did not want to impede the use of ePA, recognizing that we have a statutory mandate. Thank you.

MS. BOYD:

Thank you.

DR. THOMAS:

Ms. Boyd, CoverMyMeds only does e-Prescribing; is that correct?

MS. BOYD:

No, ma'am. We do not do e-Prescribing. We are not an e-Prescribing network. We are an electronic prior authorization network. We do not e-Prescribe today.

Although, the script standard that NCPDP created houses both the transactions for e-Prescribing and ePA.

DR. THOMAS:

Okay.

MS. BOYD:

So we do not do e-Prescribing today. We only do -- and we do fax as well. So not every PA that goes -- like I said, we have the forms in there, and those will go fast as well.

DR. THOMAS:

And then Dr. Culotta, I believe, had --

DR. CULOTTA:

Ms. Boyd, when you talked about for a physician provider, a provider who administers drugs in the office, with the reinitiation and re-upping of patents under the ACA, a lot of drugs that used to be very inexpensive and very easy to stock in a doctor's office have gone up traumatically, for example, bicillin to treat syphilis.

Louisiana has one of the highest syphilis rates in the country, and they really do need to know that they're going to be administered. Because, remember, these companies use cost as well as efficacy to determine PA. So we ought to be able to say you're going to get it filled and bring it to the doctor's office and get it so we can document it. So with regard to your request that it wouldn't be necessary, how are you going to address drugs like that, like bicillin and those very expensive reauthorized drugs under the ACA?

MS. BOYD:

I think my response to you as the professionals and those who truly understand your patient need, that if keeping that in there because of the syphilis administration drugs, we would be perfectly fine with that. You know, I don't think that our clinicians thought through every single scenario that might be there.

They we're really honing in on the specialty side because we have seen a lot of issues being addressed on specialty with the rise in cost and their availability now.

DR. CULOTTA:

Because bicillin has gone out the roof in price.

MS. BOYD:

We would be willing to remove that recommendation.

DR. CULOTTA:

Thank you.

DR. VALENTINE:

Thank you, Ms. Boyd. We appreciate it.

MS. BOYD:

Thank you.

MR. BERGERON:

Madam President, may I suggest the Board stand down for a bit? We have some more time here in case anyone comes up and wishes to offer comments.

DR. VALENTINE:

Sure. Okay. So we can take a break.

(A brief break was taken at 9:37 a.m.)

MR. BERGERON:

Well, thank you very much. The time now is 10:20. Ms. Arceneaux, do we have any more speaker request forms?

MS. ARCENEAUX:

No, sir.

MR. BERGERON:

Is anyone waiting to address the --

MS. ARCENEAUX:

No, sir.

MR. BERGERON:

Thank you very much. Thank you, Dr. Winstead. Mr. Broussard is welcome to remain, if you will. Dr. Culotta will be here. And should anyone else appear, you are more than welcome to accept whatever comments they may wish to offer.

MR. BROUSSARD:

Madam President, and members,

thank you very much for your generous hospitality and collaboration in this process. Thank you very much.

DR. VALENTINE:

Thank you, Mr. Broussard.

(The proceedings were concluded at 10:18 a.m.)

C E R T I F I C A T E

I, SHELLEY A. SAMPEY, Certified Court Reporter/Registered Professional Reporter, in and for the State of Louisiana, do hereby certify that these proceedings were reported by me in stenotype and transcribed by me or under my personal direction and supervision, and is a true and correct transcript to the best of my ability and understanding;

That the transcript has been prepared in compliance with transcript format guidelines required by statute or by rules of the board, as described on the website of the board;

That I have acted in compliance with the prohibition on contractual relationships as defined by Louisiana Code of Civil Procedure Article 1434 and in rules and advisory opinions of the board;

That I am not of counsel, not related to counsel, nor to the parties hereto, and am in no way interested in the outcome of this matter.

SHELLEY A. SAMPEY, CCR
Certified Court Reporter
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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

Louisiana Board of Pharmacy

3388 Brentwood Drive
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Telephone 225.925.6496 ~ E-mail: info@pharmacy.la.gov

October 22, 2018

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

Re: Regulatory Project 2018-2 ~ Louisiana Uniform Prescription Drug Prior Authorization Form

Dear Ms. Muller:

Thank you for your interest in the Board's proposed rule relative to prior authorization forms. You did not request any amendments to the proposed rule but you did pose the following questions:

> *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 Board 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 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 Board 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 Board 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.

For the Board:

Malcolm Broussard

Malcolm J Broussard
Executive Director

NOTICE: In compliance with Act 2018-655, the Board gives notice to its licensees and applicants of their opportunity to file a complaint about board actions or board procedures. You may submit such complaints to one or more of the following organizations: (1) Louisiana Board of Pharmacy; 3388 Brentwood Dr.; Baton Rouge, LA 70809; 225.925.6496; info@pharmacy.la.gov. (2) Committee on House & Governmental Affairs; La. House of Representatives; PO Box 44486; Baton Rouge, LA 70804; 225.342.2403; h&ga@legis.la.gov. (3) Committee on Senate & Governmental Affairs; La. Senate; PO Box 94183; Baton Rouge, LA 70804; 225.342.9845; s&g@legis.la.gov.

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LA BOARD OF PHARMACY

September 28, 2018

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

Re: LAC 46:LIII.1129 and 1130 – Uniform Prescription Drug Prior Authorization Form

Dear Executive Director Broussard,

CoverMyMeds appreciates the opportunity to provide comments pertaining to the modification to LAC 46:LIII.1129 and 1130 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:

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;
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;

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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.**

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
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October 22, 2018

Kim Diehl-Boyd
Director, Industry Relations & Government Affairs
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kdiehlboyd@covermymeds.com

Re: Regulatory Project 2018-2 ~ Louisiana Uniform Prescription Drug Prior Authorization Form

Dear Ms. Diehl-Boyd:

Thank you for your interest in the Board's 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.

Guidance Requested

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 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.

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, the legislation did not address the use of prior authorization forms for specialty medications. Without legislative authority, the Board 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

NOTICE: In compliance with Act 2018-655, the Board gives notice to its licensees and applicants of their opportunity to file a complaint about board actions or board procedures. You may submit such complaints to one or more of the following organizations: (1) Louisiana Board of Pharmacy; 3388 Brentwood Dr.; Baton Rouge, LA 70809; 225.925.6496; info@pharmacy.la.gov. (2) Committee on House & Governmental Affairs; La. House of Representatives; PO Box 44486; Baton Rouge, LA 70804; 225.342.2403; h&ga@legis.la.gov. (3) Committee on Senate & Governmental Affairs; La. Senate; PO Box 94183; Baton Rouge, LA 70804; 225.342.9845; s&g@legis.la.gov.

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, the legislation did not address the use of prior authorization forms for medications that were electronically prescribed. Without legislative authority, the Board 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

The provider-administered drugs section wouldn't 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 Board 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 Board believes that document is the best place to communicate such exclusionary information to the prescriber.

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.

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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 Board 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 Board 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.

For the Board:

Malcolm Broussard

Malcolm J Broussard
Executive Director

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Louisiana Administrative Code

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

§1130. Louisiana Uniform Prescription Drug Prior Authorization Form

[Form begins top of next page]

LOUISIANA UNIFORM PRESCRIPTION DRUG PRIOR AUTHORIZATION FORM

SECTION I — SUBMISSION

Submitted to:	Phone:	Fax:	Date:

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:	☐Male ☐Female ☐Other ☐Unknown
Address:	City:	State:	ZIP Code:
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 (True)	NO (False)	THE PRESCRIBER ATTESTS TO THE FOLLOWING:
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 Pharmacy, LR