Louisiana Board of Pharmacy

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March 1, 2021

Senator Fred H. Mills, Jr., Chair
Committee on Health and Welfare
Louisiana Senate
Post Office Box 94183
Baton Rouge, Louisiana 70804
Via E-mail: MillsF@legis.la.gov

Senator Regina A. Barrow, Vice Chair
Committee on Health and Welfare
Louisiana Senate
Post Office Box 94183
Baton Rouge, Louisiana 70804
Via E-mail: BarrowR@legis.la.gov

Re: Senate Resolution 39 of 2nd Extraordinary Session of 2020 Legislature

Dear Senators Mills and Barrow:

As requested by Senator Barrow's resolution, the Board reviewed the status of the collaborative drug therapy management program in the state as well as the desirability and feasibility of written statewide protocols for pharmacists to test or screen for and initiate treatment or therapy for qualified health conditions. We now submit our findings, recommendations and proposed legislation to the Senate Committee on Health and Welfare.

We appreciate the opportunity to review current pharmacy legislation and regulation with a goal of improving healthcare access and patient outcomes. Pharmacists are the most well-trained healthcare providers with respect to the management of medication therapy. Given the shortage of primary healthcare providers in the state, pharmacists are in an excellent position to collaborate with those providers in the area of drug therapy management. Moreover, pharmacists are qualified to perform testing and screening and initiate post-diagnostic treatment pursuant to written protocols.

We look forward to working with you to improve healthcare access and outcomes by extending the authority for pharmacist care . If you have any questions or need more information about any of our findings or recommendations, please let us know.

For the Board:

Malcolm J. Broussard Digitally signed by Malcolm J. Broussard
Date: 2021.02.28 14:57:50 -06'00'

Malcolm J Broussard
Executive Director

Collaborative Drug Therapy Management

Collaborative drug therapy management (CDTM) means that practice whereby a pharmacist or pharmacists have, on a voluntary basis, agreed to manage the disease-specific drug therapy of a patient under written protocol, working in conjunction with a physician licensed to practice medicine by the Louisiana State Board of Medical Examiners. [La. R.S. 37:1161(39)] Drug therapy management includes the following activities:

- Collecting and reviewing patient history;
- Obtaining and reviewing patient vital signs, including pulse, temperature, blood pressure, and respiration;
- Ordering, evaluating, and applying the results of laboratory tests directly related to the drug therapy being managed, provided that a pharmacist shall not interpret such testing to formulate a diagnosis;
- Monitoring and modifying a disease specific drug therapy; and
- Providing disease or condition specific patient education and counseling.

The statutory definition goes on to require all collaborative practice protocols to adhere to rules jointly promulgated by the medical and pharmacy boards.

The original legislation authorizing CDTM was adopted in 1999. Unfortunately, the medical board did not prioritize this topic in their rulemaking activity despite multiple requests from the pharmacy board. The 2006 Legislature adopted an addendum to the statutory definition requiring the medical board to initiate their rulemaking on this topic within 180 days of the effective date of that legislative act or allow the pharmacy board to promulgate rules independently from the medical board.

The CDTM rules were jointly promulgated by the medical and pharmacy boards in 2007. The 2007 rule:

- limited CDTM activities to certain specific health conditions – diabetes, asthma, dyslipidemia, anticoagulation therapy, smoking cessation therapy and administration of disease-specific vaccines.
- required physicians and pharmacists to obtain an additional registration from their licensing board to engage in CDTM, and further, required the submission of their contemplated collaborative practice agreements for review and approval by the CDTM Advisory Committee, a subunit of the medical board composed of four

physicians and three pharmacists.

- required the pharmacist to submit monthly patient reports to the collaborating physician; required the use of patient-specific protocols; and required significant administrative recordkeeping.

The Board received complaints from both pharmacists and physicians of the significant regulatory burden. From the promulgation of the rule in 2007 until the rule was amended in 2013, the Board issued CDTM registrations to only 44 pharmacists; by comparison, the 2013 census reflected 4,980 pharmacists in the state.

The CDTM rule amendments were jointly promulgated by both boards in 2013. The 2013 rule:

- removed the limitation on specific health conditions;
- maintained the requirement for an additional registration from the licensing board but removed the requirement for submission and approval of the contemplated collaborative practice agreement, requiring instead the disclosure of the health conditions contemplated for management.
- reduced the required patient reports by the pharmacist from monthly to quarterly; replaced patient-specific protocols with patient-specific order sets; and retained the administrative recordkeeping.

The Board continues to receive comments from both pharmacists and physicians of the still significant regulatory burden. Since the promulgation of the rule amendment in 2013, the Board has issued an additional 60 CDTM registrations. Of the total 104 CDTM registrations issued since 2007, 95 registrations are still active. By comparison, the current census reflects 5,730 pharmacists in the state.

Our analysis of the health conditions under management by the pharmacists seeking CDTM registrations reflects a limited range of conditions. 34.9% of the declared health conditions submitted by pharmacists were for diabetes, 24.5% for hypertension, 14.3% for chronic obstructive pulmonary disease (COPD), 12.4% for anticoagulation therapy, 4.8% for congestive heart failure, with other entries including antimicrobial therapy, human immunodeficiency virus (HIV), hepatitis C, dyslipidemia, smoking cessation, depression and anxiety. Our analysis of the sites of care of those pharmacists seeking CDTM registrations reflect an overwhelming limitation to large health systems with Ochsner Health System accounting for 80%. There was only one community clinic pharmacy setting in the central part of the state. We are aware of one

independent study of the impact of the current regulatory burden on the utilization of CDTM in Louisiana; the August 2020 edition of *Preventing Chronic Disease* included an essay by Hamilton and Darr with their findings.

We recently approached the medical board and they agreed to work with the Board to review our CDTM rules and look for opportunities to reduce the regulatory burden.

With respect to the current statute, the pharmacy law limits pharmacist collaboration with physicians. Of the 48 states which permit CDTM, 23 states permit pharmacists to collaborate with any practitioner with prescriptive authority, and an additional three states authorize such collaboration with physicians or nurse practitioners. Louisiana has several categories of practitioners with prescriptive authority, all of whom with patients who could benefit from collaborative drug therapy management by pharmacists. The Board recommends an amendment of the statutory definition to include all practitioners with prescriptive authority.

Limited Prescriptive Authority by Protocol

The Clinical Laboratory Improvement Amendments (CLIA) was adopted by the U.S. Congress in 1988 to improve the quality of testing in all laboratories. CLIA recognizes three levels for all laboratory testing – waived, moderately complex and high complexity. CLIA-waived tests are generally simple and non-technical and employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible. There are over 1,400 CLIA-waived tests. The high complexity tests are reserved for accredited medical laboratories. The performance of moderately complex testing requires specialized training, but such testing is not restricted to accredited medical laboratories. The Board has authorized pharmacists to administer waived and moderately complex laboratory testing provided they have obtained the proper education and training and comply with the applicable CLIA requirements.

Most point-of-care testing employs CLIA-waived test methodologies. Over 40 states allow pharmacists to administer screening tests and initiate treatment pursuant to written protocols for certain health conditions. The states vary by the health conditions eligible for such protocol prescribing as well as the process by which such protocols are

established.

Like other health professions, pharmacy education has evolved for the last few decades to provide training for more direct patient care, including physical assessment of patients and laboratory monitoring. The Board received presentations from both colleges of pharmacy in the state outlining contemporary accreditation standards for pharmacy education and how their curricular offerings prepare pharmacy students for direct patient care. For those pharmacists who completed their pharmacy education before such opportunities were available, there are post-graduate certificate programs in place to provide that training.

The Board received comments from multiple pharmacy stakeholders indicating their desire and willingness to participate in point-of-care testing with limited prescriptive authority using protocol-based prescribing. After reviewing approaches used by other states, the Board believes it is feasible and beneficial for patients to establish such a program in Louisiana. The program should include representatives from medicine and nursing in the protocol development process to ensure appropriate patient referral parameters and processes are included in the protocols.

Findings

The Board's administrative rules for collaborative drug therapy management constitute a significant regulatory burden on pharmacists, and by extension, on physicians. While regulatory oversight is necessary for public protection, it is possible to streamline the regulatory structure. The requirement for joint promulgation of rules with another licensing board further hinders the promulgation process.

The restriction allowing pharmacist collaboration only with physicians prevents pharmacists from collaborating with other prescribing practitioners who may have patients who would benefit from collaborative drug therapy management by pharmacists.

Pharmacists are among the most well-trained healthcare providers with respect to drug therapy management as well as testing, screening, and management of self-limiting

health conditions. The use of written protocols to guide pharmacists in those activities is well established in most of the states. Pharmacists provide additional avenues of access to healthcare services, particularly for those with poor or no access to primary healthcare practitioners.

Recommendations

The Board should reduce the regulatory burden in its collaborative practice rule by streamlining the regulatory structure, and further, the Board should continue its collaboration with the medical board to implement similar provisions in its rules.

The Board requests legislative consideration for removing the statutory restriction limiting pharmacist collaborative practice with physicians, to allow collaboration between pharmacists and any other prescribing practitioner.

The Board requests legislative consideration to authorize limited prescriptive authority for pharmacists by statewide written protocols. The protocols should include authority for pharmacists to test or screen for certain health conditions, provide for limited prescriptive authority and include parameters and processes for referral of patients to primary healthcare practitioners as appropriate. Protocol development should be guided by a multidisciplinary advisory committee including representatives from medicine, nursing and pharmacy. The protocols should be promulgated by administrative rule to ensure stakeholder input.

Appendices

A – Senate Resolution 39 of 2nd Extraordinary Session of 2020 Legislature
B – Proposed Amendments to Louisiana Pharmacy Practice Act
1. Collaborative Practice
2. Limited Prescriptive Authority by Protocol

2020 Second Extraordinary Session **ENROLLED**

SENATE RESOLUTION NO. 39

BY SENATOR BARROW

A RESOLUTION

To urge and request the Louisiana Board of Pharmacy to study and make recommendations relative to pharmacists' testing, screening, and treatment of certain health conditions.

WHEREAS, pharmacists are highly educated health care professionals who provide convenient, high-quality health care services, including medication management therapy, immunizations, long-acting injectable medications, disease management, point-of-care testing, and patient assessments and screenings to a great number of patients; and

WHEREAS, Louisiana pharmacists work in partnership with other health care entities and providers to improve patient outcomes and public health in this state; and

WHEREAS, Louisiana law provides for collaborative drug therapy management, the practice in which a pharmacist voluntarily agrees with a physician to manage the disease-specific drug therapy of one or more patients of the physician, within a predetermined range of medication selected by the physician and set forth in patient-specific written orders; and

WHEREAS, drug therapy management involves monitoring and modifying a disease-specific drug therapy; collecting and reviewing patient history; obtaining and reviewing vital signs; ordering, evaluating, and applying the results of laboratory tests directly related to the disease-specific drug therapy being managed under an order; and providing disease- or condition-specific patient education and counseling; and

WHEREAS, due to poor health outcomes and extensive health professional shortage areas, Louisiana has an especially pronounced statewide need for an expansion of access to health care.

THEREFORE, BE IT RESOLVED that the Senate of the Legislature of Louisiana does hereby urge and request the Louisiana Board of Pharmacy to study and make recommendations relative to pharmacists' testing, screening, and treatment of certain health conditions, including but not limited to:

(1) An update on the status of the collaborative drug therapy management program in Louisiana.

(2) A determination of the desirability and feasibility of a written statewide protocol for pharmacists to test or screen for and initiate treatment or therapy for qualified health conditions.

BE IT FURTHER RESOLVED that the Louisiana Board of Pharmacy shall submit a written report of its findings and recommendations, including proposed legislation if necessary, to the Senate Committee on Health and Welfare no later than March 1, 2021.

BE IT FURTHER RESOLVED that in complying with this Resolution, the Louisiana Board of Pharmacy may consult with the Louisiana State Board of Medical Examiners.

BE IT FURTHER RESOLVED that a copy of this Resolution be transmitted to the executive director of the Louisiana Board of Pharmacy.

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PRESIDENT OF THE SENATE

HLS/SLS 21-

Regular Session, 2021

House/Senate Bill No. _____

By Representative/Senator _____

HEALTH CARE: Provides relative to collaborative practice by pharmacists.

AN ACT

To amend and reenact R.S. 37:1164(39), relative to pharmacy collaborative drug therapy management, to enact R.S. 37:1164(60), relative to collaborative practice agreement, and to enact R.S. 37:1220, relative to collaborative practice by pharmacists.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 37:1164(39) is hereby amended and reenacted and R.S. 37:1164(60) is hereby enacted to read as follows:

§1164. Definitions

As used in this Chapter, the following terms have the meaning ascribed to them by this Section:

* * *

(39)~~(a) "Pharmacy collaborative drug therapy management" means that practice whereby a pharmacist or pharmacists have, on a voluntary basis, agreed to manage the disease-specific drug therapy of a patient under written protocol, working in conjunction with a physician licensed to practice medicine by the Louisiana State Board of Medical Examiners. Pharmacy collaborative drug therapy management~~

~~does not include the substitution by the pharmacist of a product that is not an equivalent drug product to the product originally prescribed by the physician or practitioner without the explicit consent of the physician or practitioner. Any pharmacy collaborative drug therapy management protocol shall adhere to rules and regulations promulgated by the board.~~

~~(b) (i) The Louisiana State Board of Medical Examiners and the Louisiana Board of Pharmacy shall initiate the rulemaking process in accordance with the provisions of the Administrative Procedure Act by publishing their respective notices of intent no later than one hundred twenty days following August 15, 2006.~~

~~(ii) If both boards have not initiated the rulemaking process in accordance with the provisions of the Administrative Procedure Act by publishing their respective notices of intent by one hundred twenty days following August 15, 2006, then the board shall appoint a committee composed of three physicians and three pharmacists, the physicians by the Louisiana State Board of Medical Examiners and the pharmacists by the Louisiana Board of Pharmacy. The committee shall compete the drafting process no later than one hundred eighty days following August 15, 2006.~~

~~(iii) If the boards have not initiated the rulemaking process in accordance with the provisions of the Administrative Procedure Act by publishing their respective notices of intent by one hundred eighty days following August 15, 2006, then the Louisiana Board of Pharmacy shall have the authority to promulgate the rule required in R.S. 37:1164(37) independently of the Louisiana Board of Medical Examiners.~~

(39) "Collaborative practice" is that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners to provide patient care services under protocol to achieve optimal medication use and desired patient outcomes. Collaborative practice activities shall comply with administrative rules promulgated by the board.

(60) "Collaborative practice agreement" is a written and signed agreement between one or more pharmacists and one or more practitioners that provides for collaborative practice as defined in this Chapter.

Section 2. R.S. 37:1220 is hereby enacted to read as follows:

§1220. Collaborative practice

A. A pharmacist holding an active and unrestricted license issued by the board may, independently or in conjunction with one or more similarly licensed pharmacists, engage in collaborative practice with one or more practitioners in accordance with a collaborative practice agreement, subject to administrative rules promulgated by the board.

Section 3. The Louisiana State Law Institute is hereby authorized and directed to alphabetize the entries in R.S. 37:1164.

[end]

HLS/SLS 21-

Regular Session, 2021

House/Senate Bill No. _____

By Representative/Senator _____

HEALTH CARE: Provides relative to collaborative practice and limited prescriptive authority by formulary or protocol for pharmacists.

AN ACT

To enact R.S. 37:1220, relative to collaborative practice and limited prescriptive authority by protocol or formulary for pharmacists, and to enact R.S. 37:1220.1, relative to the Pharmacy Formulary and Protocol Advisory Committee.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 37:1220 is hereby enacted to read as follows:

§1220. Collaborative practice; limited prescriptive authority by protocol or formulary for pharmacists

A. A pharmacist holding an active and unrestricted license issued by the board may, independently or in conjunction with one or more similarly licensed pharmacists, engage in collaborative practice with one or more practitioners in accordance with a collaborative practice agreement, subject to administrative rules promulgated by the board.

B. A pharmacist may, pursuant to a statewide drug therapy management protocol developed by the Pharmacy Formulary and Protocol Advisory Committee convened

pursuant to R.S. 37:1220.1 and adopted by administrative rule, provide approved patient care services including, but not limited to, smoking cessation therapy and travel health services.

C. The board shall establish by administrative rule a formulary of drugs and devices, as recommended by the Pharmacy Formulary and Protocol Advisory Committee, that a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a practitioner. The formulary may include post-diagnostic drugs and devices including, but not limited to, emergency refills of insulin, diabetic testing supplies, albuterol inhalers, spacers, epinephrine autoinjectors, smoking cessation aids, discharge medications for transitions of care, and rapid strep tests.

D. A pharmacist may order and interpret post-diagnostic laboratory assessments, subject to administrative rules promulgated by the board.

E. The board shall promulgate administrative rules in accordance with the Administrative Procedure Act to implement the provisions of this Section.

§1220.1 Pharmacy Formulary and Protocol Advisory Committee

A. The board shall convene a Pharmacy Formulary and Protocol Advisory Committee consisting of seven members, appointed by the Governor, for the purpose of advising the board to promulgate administrative rules to implement the provisions of R.S. 37:1220. The members of the committee shall be:

1. Two physicians licensed to practice medicine by the Louisiana State Board of Medical Examiners.

2. Two advanced practice registered nurses with prescriptive authority licensed to practice nursing by the Louisiana State Board of Nursing.

3. Three pharmacists licensed to practice pharmacy by the Louisiana Board of Pharmacy, at least one of whom shall be employed as a community pharmacist and at least one of whom shall be employed as a health system pharmacist.

B. The Louisiana State Board of Medical Examiners, the Louisiana State Board of Nursing and the Louisiana Board of Pharmacy shall each submit to the Governor a list of up to three names of individuals to be considered for membership for each of the vacancies required to be filled by licensees of each board.

C. The term of each member of the committee is two years. A member whose term has expired shall continue to serve until a successor is appointed. If a vacancy occurs, a person who is a representative of the same board as the departing member shall serve for the reminder of the term.

D. A member of the committee who fails to attend two consecutive committee meetings shall be removed from the committee unless the failure to attend was due to a serious health condition of the member or family member of the member.

E. The committee shall elect one of its members to serve as chairperson.

F. Committee members are entitled to reimbursement of their travel expenses as provided by R.S. 39:231, to be paid by the Board of Pharmacy.

G. The committee shall recommend to the board for adoption by administrative rule a formulary of drugs and devices that a pharmacist may prescribe and dispense to a patient pursuant to a diagnosis by a practitioner qualified to make the diagnosis. The committee shall periodically review the formulary and recommend revisions to the board for adoption by administrative rule.

H. A pharmacist or practitioner may petition the committee for the addition of a drug or device to the formulary by submitting such request using a form for this purpose supplied by the board.

[end]