



Jeff Landry  
Attorney General

## State of Louisiana

DEPARTMENT OF JUSTICE  
CIVIL DIVISION  
P.O. BOX 94005  
BATON ROUGE  
70804-9005

To: M. Joseph Fontenot, Jr.  
Executive Director  
Louisiana Board of Pharmacy

From: Terrence "Joe" Donahue, Jr.  
Louisiana Department of Justice, Civil Division  
Occupational Licensing Review Program

Date: October 5, 2023

Subject: OLRP File No. 23-06-OR-0013  
Proposed LAC 46:LIII.Chapter 24.Subchapter E – Marijuana Pharmacy

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### I. Summary

The Louisiana Board of Pharmacy (the "Board") proposes revising LAC 46:LIII.Chapter 24(E) in several respects. The Board published a Notice of Intent to promulgate the proposed amendments on April 20, 2023, invited comments on the proposed amendments, and conducted a public hearing on May 26, 2023. No comments or testimony addressing the proposed revisions to Chapter 24(E) were offered during the public hearing.

The imposition of permitting requirements creates barriers to market entry for individuals desiring to engage in a profession, occupation, or business, and the proposed amendments to Chapter 24(E) of LAC 46:LIII are therefore properly considered occupational regulations with reasonably foreseeable anticompetitive effects.<sup>1</sup> Pursuant to La. R.S. 49:260, the Board submitted the proposed amendments to the Louisiana Attorney General and a review of the regulations was initiated on June 8, 2023. The Attorney General invited public comments on the proposed amendments for a 30-day period ending on July 8, 2023, and received no comments. As set forth below, the Attorney General has determined the Board's proposed amendments to Chapter 24(E) adhere to clearly articulated state policy and therefore approves the amendments for adoption as drafted.

### II. Analysis

The Louisiana Pharmacy Practice Act, La. R.S. 37:1161 *et seq.*, subjects the practice of pharmacy in the state of Louisiana to regulation by the Board for the purpose of

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<sup>1</sup> See La. R.S. 49:260(G)(4).

promoting, preserving, and protecting the public health, safety and welfare.<sup>2</sup> In furtherance of these purposes, the legislature has authorized the Board to control and regulate all persons and sites that sell drugs to consumers within the state.<sup>3</sup> To this end, the legislature has authorized the Board to issue and renew permits allowing individuals to establish, open, operate, and maintain pharmacies within Louisiana, and has further authorized the Board to issue permits to pharmacies that dispense marijuana for therapeutic use.<sup>4</sup> The Board's existing regulations require marijuana pharmacies to comply with the general requirements imposed upon all pharmacies, except where Chapter 24(E) grants exceptions or provides more stringent requirements.<sup>5</sup>

The Board has indicated the existing provisions of Chapter 24(E) are primarily based upon legislation enacted in 2015 and that a comprehensive overhaul of these regulations was undertaken to account for recent legislative changes and to remove requirements identified as obsolete or overly burdensome.<sup>6</sup> The Board has also indicated the proposed revisions are intended to reduce the regulatory burden placed upon applicants and holders of marijuana pharmacy permits to more closely align with the requirements placed upon traditional pharmacies.<sup>7</sup>

#### Act No. 438 of the 2022 Louisiana Legislative Regular Session ("Act 438")

While not specifically referenced by the Board, Act 438 enacted La. R.S. 40:1046.1 into law, which authorizes visiting qualifying patients to obtain therapeutic marijuana from Louisiana marijuana pharmacies.<sup>8</sup> For purposes of the statute, "visiting qualifying patient" is defined as:

... a patient with a debilitating medical condition who is not a resident of Louisiana or who has been a resident of Louisiana for less than thirty days and who is in actual possession of a valid medical marijuana registry identification card, or its equivalent, which has been issued under the medical marijuana laws of another state, district, territory, commonwealth, or insular possession of the United States.<sup>9</sup>

In order to implement the provisions La. R.S. 40:1046.1 as enacted by the legislature, the Board proposes supplementing its existing regulations through the addition of § 2457(E)(3)(c). The proposed amendment consists of two provisions, the first of which reproduces the substance of La. R.S. 40:1046.1(B) and provides that individuals meeting the definition of "visiting qualifying patient" may obtain therapeutic marijuana from a Louisiana marijuana pharmacy "upon producing evidence of his valid marijuana registry card..."<sup>10</sup> As a corollary to this first provision, the second provision of the proposed

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<sup>2</sup> La. R.S. 37:1163; La. R.S. 37:1171.

<sup>3</sup> La. R.S. 37:1163.

<sup>4</sup> See La. R.S. 37:1182(A)(8); La. R.S. 37:1221, and La. R.S. 40:1046(G).

<sup>5</sup> LAC 46:LIII §2457(C)(1).

<sup>6</sup> See June 7, 2023 Rule Submission Form at ¶ 1.

<sup>7</sup> *Id.*

<sup>8</sup> See Act 438; La. R.S. 40:1046.1(B).

<sup>9</sup> La. R.S. 40:1046.1(A)(6).

<sup>10</sup> See Notice of Intent, Louisiana Register Vol. 49, No. 4 (April 20, 2023) at p. 729, § 2457(E)(3)(c)(i).

amendment authorizes pharmacists to dispense therapeutic marijuana to visiting qualifying patients who provide the necessary documentation.<sup>11</sup> Both provisions also specifically state that the provisions of § 2547(E)(3)(b), which limit the amount of therapeutic marijuana that may be dispensed to a patient during a 14-day period, apply to transactions with visiting qualifying patients.<sup>12</sup>

As stated above, the text of La. R.S. 40:1046.1 explicitly provides for the dispensing of therapeutic marijuana to qualifying visiting patients under the circumstances described in proposed § 2547(E)(3)(c). In addition, the limitations § 2547(E)(3)(b) place upon the amount of therapeutic marijuana that may be dispensed to a patient over a 14-day period mirror the provisions of La. R.S. 40:1046(A)(5), which are explicitly stated to apply to “any individual patient.” While the language of proposed § 2547(E)(3)(c) largely reproduces the language of its authorizing statutes, this is an acceptable means of promulgating regulations under the Louisiana Administrative Procedure Act, particularly when they are intended to implement new legislation.<sup>13</sup> As a result, the proposed addition of § 2547(E)(3)(c) adheres to clearly articulated state policy and is appropriate for adoption.

#### Act No. 444 of the 2022 Louisiana Legislative Regular Session (“Act 444”)

As reflected in the existing language of Chapter 24(E), the provisions of La. R.S. 40:1046 once mandated that therapeutic marijuana could only be dispensed pursuant to the recommendation of a licensed physician in good standing with the Louisiana State Board of Medical Examiners.<sup>14</sup> This changed, however, when Act 444 became law and amended the relevant provisions of La. R.S. 40:1046 to also allow therapeutic marijuana to be dispensed upon the recommendation of certain nurse practitioners and medical psychologists.<sup>15</sup> To maintain the statute’s coherency, all references to “physician” that had previously appeared in the text of La. R.S. 40:1046 were also amended to reference “authorized clinician” instead.<sup>16</sup>

Several of the proposed amendments to Chapter 24(E) explicitly incorporate the changes Act 444 made to the language of La. R.S. 40:1046. For instance, the Board has proposed amending the provisions of LAC 46:LIII § 2441(A) to add a new definition for “authorized clinician” and to repeal the existing definition of “physician.”<sup>17</sup> Similarly, the Board has proposed changing existing references to “physician(s)” in Chapter 24(E) to instead reference “authorized clinician(s)” in accordance with the changes made to La. R.S. 40:1046 in Act 444.<sup>18</sup> These amendments explicitly incorporate the changes Act 444 made to the statutes governing therapeutic marijuana into the Board’s regulations and therefore adhere to the state policies adopted by the legislature in enacting the provisions

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<sup>11</sup> *Id.* at § 2457(E)(3)(c)(ii).

<sup>12</sup> *Id.* at § 2457(E)(3)(c); *see also* LAC 46:LIII § 2457(E)(3)(b) (providing that a pharmacist shall not dispense more than two and one-half ounces of raw or crude marijuana every 14 days to any person).

<sup>13</sup> *See Louisiana Vaping Association v. Department of Revenue*, 20-0816, p. 6 (La. App. 1 Cir. 2/19/21), 318 So.3d 221, 225, *writ denied*, 21-0415 (La. 5/11/21), 315 So.3d 869.

<sup>14</sup> *See* Act 444.

<sup>15</sup> *See* La. R.S. 40:1046(B) (defining “authorized clinician”).

<sup>16</sup> *See* Act 444.

<sup>17</sup> *See* Notice of Intent, Louisiana Register Vol. 49, No. 4 (April 20, 2023) at p. 727, § 2441.

<sup>18</sup> *Id.* at p. 727, 729, §§ 2443(B)(8); 2457(D) and (E).

of Act 444.

Act. No. 491 of the 2022 Louisiana Legislative Regular Session (“Act 491”)

Act 491 effected numerous changes to the statutes governing Louisiana’s therapeutic marijuana program. Among these changes was the designation of the Louisiana Department of Health (“LDH”) as the agency responsible for regulating the production, cultivation, processing, and transportation of therapeutic marijuana, a role that had previously been held by the Louisiana Department of Agriculture and Forestry (“LDAF”).<sup>19</sup> To reflect this transfer of responsibility and authority, the Board has proposed removing all references to LDAF, substituting LDH in its place.<sup>20</sup> As these changes merely account for the legislature’s transfer of authority and responsibilities from LDAF to LDH in Act 491, they adhere to state policies the legislature affirmatively expressed when enacting Act 491.

The provisions of Act 491 also curtailed the Board’s duties and authority with respect to the production of therapeutic marijuana by repealing provisions of La. R.S. 40:1046 that previously required the Board to promulgate rules establishing standards, procedures, and protocols to: (1) ensure that all therapeutic marijuana dispensed in Louisiana “is consistently pharmaceutical grade,” and (2) test therapeutic marijuana samples “for levels of tetrahydrocannabinol (THC) or other parameters deemed appropriate by the Board.”<sup>21</sup> At the same time it narrowed the Board’s authority in this area, Act 491 also greatly increased the detail and specificity of the statutes governing such matters, creating three entirely new statutes that address the requirements imposed upon the entities LDH is responsible for regulating.<sup>22</sup> In addition, while Louisiana’s Uniform Controlled Dangerous Substances Law empowers the Board to license and regulate entities that produce controlled dangerous substances like marijuana, this law specifically contemplates that the Board will refrain from exercising this authority when doing so would not further public health and safety interests.<sup>23</sup>

Consistent with the legislature’s curtailment of the Board’s authority in this area, its creation of new statutes providing detailed standards with which producers, cultivators, processors, transporters, and testers of therapeutic marijuana production must comply, and its conferral of authority upon LDH to enforce these standards and promulgate rules to implement them, the Board proposes modifying or repealing several provisions of its existing regulations that address the production of therapeutic marijuana, as addressed below.

The Board proposes repealing numerous provisions included in the existing version of LAC 46:LIII.2443 that address matters involving the production, testing, and transport of therapeutic marijuana. The provisions the Board proposes repealing include §

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<sup>19</sup> See Act 491, § 1; La. R.S. 40:1046(H); La. R.S. 40:1046.2-1046.4.

<sup>20</sup> *Id.* at pp. 727, 729, § 2443(A)(1) and (C)(3)(c); § 2457(E)(4)(a).

<sup>21</sup> Act 491, § 2 (repealing La. R.S. 40:1046(C)(2)(d), (e), and (h)).

<sup>22</sup> Act 491, § 1; La. R.S. 40:1046.2 (contractors); La. R.S. 40:1046.3 (marijuana laboratory); La. R.S. 40:1046.4 (testing).

<sup>23</sup> See La. R.S. 40:972(A); La. R.S. 40:973(C).

2443(A)(2), which provides that “[l]icensed producers shall prepare pharmaceutical grade marijuana products as well as raw marijuana products for distribution to marijuana pharmacies licensed by the Board.”<sup>24</sup> The Board also proposes repealing the detailed laboratory testing standards and specifications currently provided in § 2443(B), and modifying the remaining content to provide:

[t]he marijuana pharmacy shall have access to the laboratory test results from the producer for each final product acquired by the marijuana pharmacy. The pharmacy shall make such testing results available upon request to their patients, caregivers, and authorized clinicians who recommend such marijuana products be dispensed to their patients.<sup>25</sup>

The Board also proposes amending the existing language of §2443(C), pertaining to acceptable product dosage forms of therapeutic marijuana, so that the regulation’s language addresses the dosage forms that marijuana pharmacies may dispense, rather than the dosage forms that may be produced.<sup>26</sup> Consistent with these changes, “bulk raw product” has also been removed from the list of acceptable dosage forms, since bulk product is not dispensed to patients.<sup>27</sup> The Board further proposes repealing the entirety of §§ 2443(D) and 2443(E), which impose packaging, labeling, and recordkeeping requirements upon therapeutic marijuana products distributed to marijuana pharmacies as these areas are now regulated by LDH.<sup>28</sup>

The repeal of the lengthier and more detailed provisions of § 2443 will reduce the potential for conflicts between requirements imposed by the Board and those imposed by LDH, and will bring the Board’s involvement in the production and distribution of therapeutic marijuana in line with its regulation such activities in connection with other controlled dangerous substances and therefore adhere to the affirmatively expressed stated policies embodied in Act 491.

Act 491 also made significant changes to the statutory provisions governing the permitting of marijuana pharmacies in Louisiana.<sup>29</sup> While the legislation left in place the provisions of La. R.S. 40:1046 that limit the number of marijuana pharmacy permits the Board may issue to no more than ten, the statute now requires at least one permitted marijuana pharmacy in each of the LDH administrative regions in existence on August 1, 2022, with an additional permit authorized for the region with the highest population density as of that date.<sup>30</sup> Act 491 also prescribes circumstances under which a permitted marijuana pharmacy may open up to two additional satellite locations in the region covered by its existing permit.<sup>31</sup> If the criteria for opening a second satellite location in a particular region have been met, but the holder of the existing permit declines to do so, Act 491 authorizes

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<sup>24</sup> Notice of Intent, Louisiana Register Vol. 49, No. 4 (April 20, 2023) at p. 727, § 2443(A)(2).

<sup>25</sup> *Id.* at § 2443(B).

<sup>26</sup> *Id.* at § 2443(C).

<sup>27</sup> *Id.* at § 2443(C)(1)(i); *see also* La. R.S. 40:1046(A)(5)(a) (allowing no more than seventy-one grams of marijuana to be dispensed to an individual patient over a fourteen day period).

<sup>28</sup> *Id.* at § 2443(D)

<sup>29</sup> *See* Act 491, § 1; La. R.S. 40:1046(G).

<sup>30</sup> Act 491, § 1; La. R.S. 40:1046(G)(1) and (2).

<sup>31</sup> *See id.*; La. R.S. 40:1046(G)(3)(a) and (b).

the Board to issue a new pharmacy permit in the relevant region, without regard to the ten-permit limitation provided in La. R.S. 40:1046(A).<sup>32</sup>

As a result of the changes Act 491 made to the language of La. R.S. 40:1046(G), the Board proposes repealing the provisions of LAC 46:LIII.2445(G), which previously served to fix the nine regions amongst which marijuana pharmacy permits would be allocated, as well the provisions of § 2445(H), which states that the Board may issue the tenth permit authorized by La. 40:1046 if the Board was convinced of the need for a second permit in one region.<sup>33</sup> As the passage of Act 491 rendered the provisions of § 2445(G) and (H) obsolete and potentially in conflict with their authorizing statute, the Board’s proposal to repeal them is wholly consistent with policies clearly articulated in Act 491. Similarly, since Act 491 now allows marijuana pharmacy permit holders to open additional locations without a new permit being issued, the proposed repeal of LAC 46:LIII.2447(D)(2), stating that duplicate or replacement licenses shall not serve or be used as an additional or secondary license eliminates a potential source of conflict between the regulations adopted by the Board and the current version of La. R.S. 40:1046 as amended in Act 491.

The Board has not proposed any revisions to the existing provisions of § 2445(I) – (L), which set forth Board’s procedures for receiving and processing applications for new marijuana pharmacy permits.<sup>34</sup> These provisions require the Board to: (1) publish a notice identifying the availability of the marijuana pharmacy permit(s), (2) identify the requirements for submitting an application and the criteria to be considered in awarding the permits, and (3) award the permit(s) on a competitive basis.<sup>35</sup> They also state that the Board may: (1) restart the application process by issuing a new notice if all available permits are not awarded to qualified applicants, (2) amend the information provided in its public notice prior to the application submission deadline, and (3) cancel the notice at any time prior to awarding the permit(s).<sup>36</sup> The contents of these portions of § 2445 adhere to the legislature’s directive in La. R.S. 40:1046(G)(1)(a) that the Board shall award each marijuana pharmacy permit “through a competitive process” and are therefore appropriate for adoption.

While unrelated to Act 491, the Board has also proposed amending the language of § 2445(E) to provide that continuing to operate a marijuana pharmacy under an existing permit after the permittee’s ownership has changed by 50 percent or more will subject the owner “to disciplinary review by the board” instead of the owner being “deemed guilty of operating a pharmacy without a valid permit, in violation of R.S. 37:1221.” As demonstrated above, the revised language of § 2445(E) also adheres to the clearly articulated state policies affirmatively expressed in both La. R.S. 40:1046 and the Louisiana Pharmacy Practice Act.<sup>37</sup>

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<sup>32</sup> *Id.*; La. R.S. 40:1046(G)(1) and (3)(c).

<sup>33</sup> Notice of Intent, Louisiana Register Vol. 49, No. 4 (April 20, 2023) at p. 727, § 2445(G) and (H).

<sup>34</sup> *Id.* at p. 728, § 2445(I) – (L).

<sup>35</sup> Existing LAC 46:LIII § 2445(I) and (J).

<sup>36</sup> Existing LAC 46:LIII § 2445(J) – (L).

<sup>37</sup> See La. R.S. 37:1222(E) (pharmacy permits are not transferable); La. R.S. 37:1231(B)(3) (requiring permittees to report changes of ownership); LAC 46:LIII.2445(E) (providing that a new pharmacy permit must be obtained when ownership changes by 50 percent or more); Act No. 311 of the 2023 Louisiana Legislative Regular Session (amending La. R.S. 40:1046 to add Subsection (G)(1)(b), which provides that

### Repeal of § 2440 - Preamble

In addition to the revisions discussed above, the Board proposes repealing the provisions of LAC 46:LIII.2440, titled “Preamble; Warning; Consultation Suggested,” in their entirety. As described above, the laws governing Louisiana’s medical marijuana program have been an area of active legislative activity, and while § 2440 accurately describes the Board’s role as it existed immediately after the passage of Act 261, this description no longer remains accurate.<sup>38</sup> For these reasons, in addition to the maturation of Louisiana’s medical marijuana program since Act 261 became effective more than eight years ago, the proposed repeal of § 2440 adheres to the clearly articulated state policies established in La. R.S. 40:1046 and the Louisiana Pharmacy Practice Act.

### Repeal of Regulatory Provisions Pertaining to Security

The Board also proposes repealing several provisions of Chapter 24(E) that impose heightened security-related requirements on Louisiana marijuana pharmacies.<sup>39</sup> The provisions proposed for repeal are: (1) the definitions of “approved safe” and “approved vault” appearing in LAC 46:LIII.2441; (2) § 3453, titled “Security Requirements for Marijuana Pharmacies; and (3) Subsections (C) and (D) of § 2455, titled “Reportable Security Events.”<sup>40</sup> These provisions contain detailed technical specifications for the security-related equipment and technology used by marijuana pharmacies, and require Board notification not only when marijuana has been lost by or stolen from a marijuana pharmacy, but any time an alarm at a marijuana pharmacy has been activated, there has been a breach of security, or a security alarm system failure caused by a loss of electricity or mechanical failure is expected to last longer than eight hours.<sup>41</sup>

If the foregoing regulatory provisions are repealed the holders of marijuana pharmacy permits would remain subject to the security requirements set forth in Subchapter (C) of LAC 46:LIII.Chapter 27 and LAC 46:LIII § 1103(F), as well as those imposed by §§ 2455(A) and (B).<sup>42</sup> These regulations require the development and use of effective controls and procedures to guard against theft or diversion of controlled substances.<sup>43</sup> The regulations also identify criteria the Board may consider when evaluating such security measures. The retained provisions §§ 2455(A) and (B) require marijuana pharmacies to submit such reports within twenty-four hours, and further require such reports to detail the circumstances of the events surrounding the loss or theft, to include

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requirements applicable to transfers of membership interests in marijuana pharmacies shall be the same as for any other pharmacy permitted by the Board).

<sup>38</sup> See e.g. Act 491, § 2 (repealing La. R.S. 40:1046(C)(2)(d), (e), and (h), discussed above).

<sup>39</sup> See e.g. Notice of Intent, Louisiana Register Vol. 49, No. 4 (April 20, 2023) at pp. 727, 729, §§ 2451, 2453 and 2455(C) and (D).

<sup>40</sup> See Notice of Intent, Louisiana Register Vol. 49, No. 4 (April 20, 2023) at p. 727, 729, §§ 2441, 2453, and 2455(C) and (D).

<sup>41</sup> *Id.*

<sup>42</sup> See LAC 46:LIII.2457(C)(1) (requiring marijuana pharmacies to comply with the provisions of LAC 46:LIII Chapters 11, 25, 27, 29, and 31 unless Chapter 24(E) “grants exceptions or imposes more stringent requirements”).

<sup>43</sup> LAC 46:LIII § 2713(A).

an accurate inventory of the identity and quantity of any marijuana that has been stolen or lost, and to confirm that local law enforcement authorities have been notified.<sup>44</sup>

The legislature has directed the Board to adopt rules establishing security requirements for dispensers of therapeutic marijuana.<sup>45</sup> The Louisiana Pharmacy Practice Act also empowers the Board to establish minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, compounding, and dispensing of drugs and devices.<sup>46</sup> Moreover, Louisiana's Uniform Controlled Dangerous Substances Law generally authorizes the Board to promulgate rules relating to the dispensing of controlled dangerous substances, and specifically contemplates the imposition of required security measures on all permitted pharmacies that dispense these substances.<sup>47</sup> While these statutes give the Board great discretion to determine whether increased security measures for marijuana pharmacies are necessary to protect the public health, safety, and welfare, there is nothing in the legislature's enactments that suggests the existence of a state policy that requires more stringent security measures for marijuana pharmacies than those required for other pharmacies. By contrast, repeal of the more stringent requirements that apply solely to marijuana pharmacies will further the clearly articulated state purpose of using the least restrictive means needed to protect the public from harm when regulating individuals engaged in an occupation or profession.<sup>48</sup>

#### Repeal of § 2447(A)(6)(e)

The Board also proposes repealing the provisions of LAC 46:LIII.2447(A)(6)(e), which require applicants for marijuana pharmacy permits to submit blueprint plans of the proposed marijuana pharmacy containing detailed information identified within the regulation.<sup>49</sup> In its present form, §2447(A)(6)(e) requires applicants for marijuana pharmacy permits to submit the proposed pharmacy's blueprint plans simultaneously with the marijuana pharmacy permit application and requires the plans to demonstrate compliance with requirements imposed upon all pharmacies.<sup>50</sup> Even so, only applicants for marijuana pharmacy permits are currently required to demonstrate compliance through the submission of blueprints in advance of receiving a permit.<sup>51</sup> Other pharmacies' compliance is instead determined via inspection *after* the Board reviews and approves the permit application.<sup>52</sup> Thus, the repeal of § 2447(A)(6)(e) would create parity among applicants for pharmacy permits and require applicants for marijuana pharmacy permits to demonstrate that the proposed facilities comply with applicable requirements by way of an inspection performed after the applicant has been selected to receive a

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<sup>44</sup> LAC 46:LIII §§ 2455 (A) and (B).

<sup>45</sup> La. R.S. 40:1046(C)(2)(i).

<sup>46</sup> La. R.S. 37:1182(A)(13).

<sup>47</sup> See La. R.S. 40:972(A); La. R.S. 40:988(B)(1).

<sup>48</sup> See La. R.S. 49:260(A).

<sup>49</sup> See Existing LAC 46:LIII.2447(A)(6)(e).

<sup>50</sup> See *generally* LAC 46:LIII.1103 – Prescription Department Requirements. As addressed above, the Board has proposed repealing heightened security requirements for marijuana pharmacies, including those requiring marijuana pharmacies to have an “approved safe” and “approved vault.”

<sup>51</sup> See LAC 46:LIII.1131.

<sup>52</sup> *Id.*



permit.

There is nothing in either La. R.S. 40:1046 or the Louisiana Pharmacy Practice Act mandating that the Board require advance proof of compliance with facility standards for marijuana pharmacy permit applicants.<sup>53</sup> While the existing requirements afforded the Board the ability to promptly identify and resolve unanticipated issues as it developed and refined its marijuana pharmacy permitting process during the therapeutic marijuana program's incipency, eliminating this requirement accords with the clearly articulated state policy of imposing the least restrictive regulatory burden needed to protect the public health, safety, and welfare.<sup>54</sup>

#### Repeal of § 2449 and Amendment of § 2457(A)(1) and (B)(5) – Personnel

The Board has also proposed repealing LAC 46:LIII.2449 in its entirety, and to relocate certain provisions of the regulation to § 2457(A)(1) and (B)(5).<sup>55</sup> Many of the provisions proposed for repeal include requirements placed upon the individuals designated as pharmacists-in-charge of marijuana pharmacies that duplicate requirements already imposed by the regulations that apply to all pharmacies.<sup>56</sup> The Board also proposes repealing the existing provisions of § 2449(D), which limit the scope of practice for marijuana pharmacy technicians. These limitations are consistent with the clearly articulated state policy of allowing only pharmacists to counsel patients, interpret a practitioner's orders, or otherwise engage in the practice of pharmacy, while allowing pharmacy technicians to only assist the pharmacist in performing such tasks while under the pharmacist's direct supervision.<sup>57</sup>

The Board also proposes relocating the provisions of § 2449(A), which prohibits any person from being employed by or affiliated with a marijuana pharmacy prior to their eighteenth birthday.<sup>58</sup> The Board proposes inserting this language into § 2457 instead, as well as adding new provisions that prohibit any person less than eighteen years old from entering the prescription department of a marijuana pharmacy unless they are consulting with a pharmacist.<sup>59</sup> The legislature has articulated a strong state policy against the involvement of minors in activities relating to the production, manufacture, distribution, and dispensing of Schedule I substances such as marijuana.<sup>60</sup> As a result,

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<sup>53</sup> Compare La. R.S. 40:1046 (requiring the promulgation of rules establishing "health, safety, and security requirements for dispensers of recommended therapeutic marijuana") with La. R.S. 37:1228 (requiring the promulgation of rules identifying standards and requirements a pharmacy must possess "in order to operate in the best interest of the health, safety, and welfare of the public").

<sup>54</sup> See La. R.S. 49:260(A).

<sup>55</sup> See Notice of Intent, Louisiana Register Vol. 49, No. 4 (April 20, 2023) at p. 728 - 729, §§ 2449, 2457(A)(1) and (B)(5).

<sup>56</sup> Compare existing LAC 46:LIII §§ 2449(B), and (C) with LAC 46:LIII § 1105.

<sup>57</sup> See La. R.S. 37:1164(12), (33), (36), (43), and (44) (contemplating patient counseling and interpretation of orders only by pharmacists).

<sup>58</sup> See Notice of Intent, Louisiana Register Vol. 49, No. 4 (April 20, 2023) at p. 728, § 2449; existing LAC 46:LIII § 2449(A).

<sup>59</sup> *Id.* at p. 729, §§ 2457(A)(1) and (B)(5).

<sup>60</sup> See *e.g.* La. R.S. 40:981; La. R.S. 40:981.2; La. R.S. 14:91.12. As stated above, federal law continues to prohibit the manufacture, distribution, dispensing, possession, and use of marijuana, even when recommended by an authorized clinician.

limiting the presence of minors in the prescription department of marijuana pharmacies to those seeking counseling from a pharmacist furthers the aforementioned state policies, while also adhering the policy of making therapeutic marijuana available to individuals with debilitating medical conditions as provided in La. R.S. 40:1046.

### Repeal of Advertising Regulations

Finally, the Board proposes repealing several provisions of Chapter 24(E) that address advertising by marijuana pharmacies. The proposed revisions include removing the definition of “advertising” provided in LAC 46:LIII.2441(A) and repealing LAC 46:LIII.2459 in its entirety. These regulatory provisions currently prevent marijuana pharmacies from marketing their products to the general public through any public medium while still allowing informational materials to be provided to physicians.<sup>61</sup> The existing regulations also place restrictions on the signage used by marijuana pharmacies.<sup>62</sup> If repealed, marijuana pharmacies would remain subject to the provisions of LAC 46:LIII.1115, which applies to all pharmacies.<sup>63</sup>

Louisiana Revised Statutes 37:1241(19) authorizes the Board to take adverse action against applicants, licensees, and permittees who engage in false, misleading, or fraudulent advertising as defined by the Board. The Board has exercised this authority in adopting LAC 46:LIII § 1115(A), which provides that any public misrepresentation done or made with actual or constructive knowledge of its untruth or illegality constitutes false, fraudulent, deceptive, or misleading advertising.<sup>64</sup> The definition of “advertisement” currently provided in LAC 46:LIII § 2441(A) similarly considers “all representations disseminated by any manner or any means other than by labeling” to be an advertisement, and removal of this definition from the Board’s regulations would therefore effect no substantive change to the existing regulatory scheme.

The legislature has authorized the Board to regulate the advertising of marijuana not only in the Louisiana Pharmacy Practice Act, as stated above, but also in the Uniform Controlled Dangerous Substances Act and additional statutes prohibiting unfair and deceptive trade practices.<sup>65</sup> Moreover, the legislature has granted the Board authority to regulate the actions of unlicensed and unpermitted individuals insofar as these actions implicate the provisions of the Louisiana Pharmacy Practice Act.<sup>66</sup> The numerous legislative enactments authorizing the Board to regulate the advertising and promotion of drugs and controlled substances, along with the history of both state and federal regulation of such actions, establish a clearly articulated state policy of strictly regulating representations intended to influence the consumers of drugs and other controlled substances, as well as a rational basis for the promulgation of § 1115(B) and (C).

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<sup>61</sup> See Existing LAC 46:LIII §§ 2441(A) and 2459.

<sup>62</sup> *Id.* at § 2459(D).

<sup>63</sup> *Id.* at § 1115(D). The rule exempts coupons or vouchers for controlled dangerous substances accompanying legitimate prescriptions.

<sup>64</sup> As the sale and dispensing of marijuana remains illegal under federal law, the Board may wish to clarify through future rulemaking how it applies this definition to public representations involving therapeutic marijuana.

<sup>65</sup> See La. R.S. 40:625; La. R.S. 51:523.

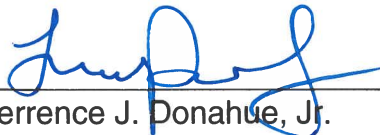
<sup>66</sup> La. R.S. 37:1241(F).

Finally, little analysis is needed to determine that the provisions of § 1115(D) adhere to clearly articulated state policy, as the contents of the Subsection explicitly adopt statutory language enacted by the Legislature.<sup>67</sup> As a result, these revisions are also appropriate for the Board to adopt.

**III. Determination**

As the Attorney General has determined the proposed revisions to LAC 46:LIII.Chapter 24(E) adhere to clearly articulated state policy, these amendments are approved and may be finally adopted as drafted by the Board.

JEFF LANDRY  
ATTORNEY GENERAL

BY:   
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Terrence J. Donahue, Jr.  
Assistant Attorney General

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<sup>67</sup> See La. R.S. 37:1241(A)(20) (prohibiting solicitation “by means of providing physicians or other practitioners with prescription blanks imprinted with any material referring to a pharmacy or pharmacist,” and La. R.S. 37:1241(A)(21) (prohibiting advertisements that “include any reference, direct or indirect, to any controlled dangerous substances as provided for in Schedules II, III, IV, and V of R.S. 40:964); *but see also* 21 U.S.C. § 843(c) (“[i]t shall be unlawful for any person to place in any newspaper, magazine, handbill, or other publications, any written advertisement knowing that it has the purpose of seeking or offering illegally to receive, buy, or distribute a Schedule I controlled substance”).