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From: Terrence "Joe" Donahue, Jr.  
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Occupational Licensing Review Program

Date: September 13, 2023

Subject: OLRP File No. 23-06-OR-0016  
Proposed LAC 46:LIII.2511 and 2519 - Prescriptions

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### I. Summary

The Louisiana Board of Pharmacy (the "Board") proposes amending LAC 46:LIII.2511 and 2519 of its rules, pertaining to prescriptions. The Board published a Notice of Intent to amend §§ 2511 and 2519 on February 20, 2023, invited comments on the regulations and proposed amendments, and conducted a public hearing on March 28, 2023. One public comment was received indicating support for the amendments, with the exception of the proposed amendment of § 2519(A)(3), which precludes pharmacies from requesting continuation of therapy from a prescriber unless requested by the patient or his agent.<sup>1</sup> The Board provided a formal response to the comment on June 5, 2023 in accordance with La. R.S. 49:961(B)(3).

Rules that regulate a market or profession, or which confer exclusive or shared rights to dominate a market, serve to limit competition, and §§ 2511 and 2519 are therefore properly considered occupational regulations with reasonably foreseeable anti-competitive effects.<sup>2</sup> Pursuant to La. R.S. 49:260, the Board submitted the proposed amendments to §§ 2511 and 2519 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 that the proposed amendments to §§ 2511 and 2519 adhere to clearly articulated state policy and therefore approves the regulations for adoption as drafted.

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<sup>1</sup> March 28, 2023 Correspondence from Mark Johnston of CVS Health.

<sup>2</sup> La. R.S. 49:260(G)(4); *see also N. Carolina State Bd. of Dental Examiners v. F.T.C.*, 574 U.S. 494, 503 (2015).

## 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 promoting, preserving, and protecting the public health, safety and welfare.<sup>3</sup> In furtherance of these purposes, the legislature has authorized the Board to control and regulate all persons and sites that sell drugs or devices to consumers within the state, to establish minimum specifications and procedures for the dispensing of drugs, to establish and enforce compliance with professional standards and rules of conduct for pharmacists engaged in the practice of pharmacy, and to promulgate rules and regulations that carry out the purposes, and enforce the provisions of the Louisiana Pharmacy Practice Act.<sup>4</sup> In addition, pursuant to Louisiana’s Uniform Controlled Dangerous Substances Law, La. R.S. 40:961 *et seq.*, any person who prescribes or dispenses controlled dangerous substances (CDS) within the state must obtain a CDS license from the Board.<sup>5</sup> The Board is authorized to issue licenses, and to promulgate rules and regulations relative to the control and dispensing of CDS.<sup>6</sup> The legislature has directed the Board to cooperate with other governmental agencies charged with enforcing state and federal laws relating to drugs, devices, and the practice of pharmacy.<sup>7</sup>

“Prescription” is a statutorily defined term referencing an order issued by an authorized practitioner prescribing a drug or device to a specific patient which is communicated to a pharmacist by any means.<sup>8</sup> “Practitioner” is defined to mean an individual who is authorized by a licensing board to prescribe and administer drugs in the course of a professional practice.<sup>9</sup> In the absence of exigent circumstances, pharmacists may only dispense controlled dangerous substances to patients pursuant to a practitioner’s written or electronic prescription, and only as provided by federal law or regulation.<sup>10</sup> Prescriptions for CDS may be partially filled when requested by a patient or a prescriber, so long as each partial filling is recorded, the total quantity dispensed does not exceed the quantity prescribed, and no dispensing occurs beyond the time periods established by law.<sup>11</sup>

While primary responsibility for proper prescribing and dispensing of controlled substances rests with the prescribing practitioner, both state and federal law impose

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<sup>3</sup> La. R.S. 37:1163; La. R.S. 37:1171.

<sup>4</sup> La. R.S. 37:1163; La. R.S. 37:1182(A)(1), (9) and (13).

<sup>5</sup> La. R.S. 40:973(A).

<sup>6</sup> La. R.S. 40:972; La. R.S. 40:974; *see also* La. R.S. 40:961(11), (14), and (15) (defining “deliver,” “dispense,” and “distribute”).

<sup>7</sup> La. R.S. 37:1182(A)(16).

<sup>8</sup> La. R.S. 37:1164(47); *see also* La. R.S. 40:961(37).

<sup>9</sup> La. R.S. 37:1164(45); *see also* La. R.S. 40:961(35).

<sup>10</sup> La. R.S. 40:978.

<sup>11</sup> *See* La. R.S. 40:978; 21 C.F.R. § 1301.13 (effective August 21, 2023) (Schedule II – remaining portions must be filled within 30 days of written prescription and 72 hours of oral prescription); 21 C.F.R. § 1301.23 (Schedules III-V – remaining portion must be filled within 6 months of prescription issuance).

additional corresponding duties upon the pharmacist who fills the prescription.<sup>12</sup> A pharmacist not only has a duty to fill a prescription correctly, but also to warn the patient or notify the prescribing physician of an excessive dosage or of obvious inadequacies on the face of the prescription which could create a substantial risk of harm to the patient.<sup>13</sup> A pharmacist dispensing a prescription must exercise sound professional judgment to ascertain whether a prescription is valid and has been issued for a legitimate medical purpose.<sup>14</sup> These duties are reflected in the Louisiana Pharmacy Practice Act requirement that pharmacists conduct a drug regimen review prior to dispensing prescription drugs, which entails reviewing the prescription order and the patient's record for, among other things, known allergies, therapy contraindications, duplication of therapy, and proper utilization.<sup>15</sup> Pharmacists are also obligated to communicate information to patients and caregivers that will ensure proper use of the drugs they are dispensing.<sup>16</sup>

### LAC 46:LIII § 2511 – Prescriptions and Chart Orders

LAC 46:LIII.2511 sets forth requirements applicable to prescriptions and chart orders. Subsection A of the regulation defines relevant terms, and the Board proposes amending § 2511(A) to modify the definition of “electronic prescription,” delete the definition of “practice affiliation,” and to add a new definition for “practitioner.” The proposed modification to the definition of “electronic prescription” clarifies that electronically transmitted facsimile documents are not considered electronic prescriptions, and that the term encompasses only prescriptions that have been generated and signed electronically, not merely electronically transmitted.<sup>17</sup> This proposed modification accords with federal regulations that differentiate between paper prescriptions transmitted by facsimile and electronic prescriptions meeting specified requirements.<sup>18</sup>

The proposed deletion of “practice affiliation” from § 2511(A) effects no substantive change to the regulation, as the definition already appears in LAC 46:LIII § 2701 and neither the existing language of § 1511 nor the proposed revisions thereto make use of the term. The proposed addition of the term “practitioner” to § 2511(A) merely incorporates the statutory language assigned by the legislature.<sup>19</sup> These changes therefore adhere to the legislative intent expressed in the Louisiana Pharmacy Practice Act and the Uniform Controlled Dangerous Substances Act.

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<sup>12</sup> *Tewelde v. Louisiana Bd. of Pharmacy*, 2011-2244, pp. 9-11 (La. App. 1 Cir. 6/14/12), 93 So.3d 801, 808-809, *writ denied*, 2012-1642 (La. 10/26/12), 93 So.3d 801, citing 21 C.F.R. § 1304.04(a) and LAC 46:LIII.2747(E).

<sup>13</sup> *See e.g. Kampmann v. Mason*, 09-993 (La. App. 5 Cir. 5/11/10), 42 So. 3d 411, 419.

<sup>14</sup> *Tewelde*, at 9-10, 93 So.3d at 808-809, citing 21 C.F.R. § 1306.04(a); LAC 46:LIII.2747(E); *State v. Henry*, 727 F.2d 1373, 1379 (5<sup>th</sup> Cir. 1984).

<sup>15</sup> La. R.S. 37:1164(15); La. R.S. 37:1225.

<sup>16</sup> La. R.S. 37:1164(33); LAC 46:LIII.2517(A)(5).

<sup>17</sup> Notice of Intent, Louisiana Register, Vol. 49, No. 2 at p. 365 (February 20, 2023).

<sup>18</sup> *See* La. R.S. 40:978(D); 21 C.F.R. § 1300.03; 21 C.F.R. Part 1311; 21 C.F.R. § 1306.11; 21 C.F.R. § 1306.21.

<sup>19</sup> La. R.S. 37:1164(45).

The Board also proposes revising § 2511 to introduce entirely new provisions in Subsection (B) of the regulation under the heading “Patient Authority to Acquire Prescription Drug or Device.”<sup>20</sup> The proposed additions include language providing that a prescription or chart order represents lawful authority for a patient, his agent, or caregiver to acquire a prescription drug or device from a pharmacy, and that this authority exists until the total authorized quantity has been dispensed or the prescription expires.<sup>21</sup> The proposed additions acknowledge the above referenced duty of pharmacists to accurately fill prescriptions issued by authorized prescribers, and the inclusion of these revisions is consistent with relevant provisions of applicable law.<sup>22</sup> The language of proposed § 2511(B) also provides that prescriptions may not be refilled in the absence of refill instructions on the original prescription, which implements statutory provisions that prohibit pharmacists from dispensing prescription drugs without a valid order from a practitioner.<sup>23</sup> Similarly, the addition of revised § 2511(B) allows for the transfer of prescriptions between pharmacies upon request and within specified timeframes, which implements other existing provisions of state and federal law.<sup>24</sup> As a result, the proposed provisions of § 2511(B) conform to applicable requirements and are appropriate for adoption.

In addition to the provisions addressed above, proposed § 2511(B) also provides that pharmacists may exercise their professional judgment to dispense less than the full amount of a product authorized in a prescription, and to instead dispense partial quantities over the course of multiple transactions.<sup>25</sup> State and federal law clearly identify certain circumstances in which it is appropriate for a pharmacist to dispense less than the total prescribed quantity of a drug, including where partial fills have been requested by the prescriber or patient, or where the pharmacist is unable to supply the full amount of the prescribed quantity.<sup>26</sup> Partial fills may also be warranted based upon information obtained during the pharmacist’s drug regimen review indicating that dispensing the total prescribed quantity in a single transaction would create the risk of substantial harm. As a result, these additions to § 2511 comport with the legislative intent reflected in the Louisiana Pharmacy Practice Act and Uniform Controlled Dangerous Substances Law. It should be noted, however, that pharmacists may not rely upon professional judgment alone to partially fill a prescription or dispense less than the total prescribed quantity when neither the prescriber nor the patient has requested a partial fill, and there are no circumstances that trigger the corresponding duties discussed above. In the absence of such requests or the risk of substantial harm to the patient, pharmacists are required to fill the prescription as directed by the prescribing practitioner.

Subsection (C) of proposed § 2511 pertains to the persons authorized to issue prescriptions and chart orders, and provides, consistent with the legislative enactments

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<sup>20</sup> Notice of Intent, Louisiana Register, Vol. 49, No. 2 at p. 366 (February 20, 2023).

<sup>21</sup> *Id.* at § 2511(B)(1) and (4).

<sup>22</sup> See La. R.S. 40:961(45); La. R.S. 40:973(B)(3).

<sup>23</sup> See e.g. La. R.S. 40:978(A) – (C); see also 21 C.F.R. § 1306.22(c).

<sup>24</sup> See La. R.S. 37:1224(E); 21 C.F.R. § 1306.25; see also Final Rule - Transfer of Electronic Prescriptions for Schedule II-V Controlled Substances for Initial Filling, 88 FR 48365-01 (7/27/23).

<sup>25</sup> Notice of Intent, Louisiana Register, Vol. 49, No. 2 at p. 366, § 2511(B)(2) – (3).

<sup>26</sup> La. R.S. 40:978(A); La. R.S. 40:978(H)(2); 21 C.F.R. § 1306.13; 21 C.F.R. § 1306.23.

referenced above, that a practitioner with valid prescriptive authority may issue a prescription for a drug or device.<sup>27</sup> Section 2511(C)(2) further provides that a prescription may be prepared and communicated to a pharmacy by an agent of the prescriber, but that the prescriber retains accountability for the contents of the prescription, which also aligns with applicable provisions of state and federal law.<sup>28</sup> Section 2511(C)(3) provides that a pharmacist may issue a prescription when authorized to do so by law, rule, standing order, or practice agreement.<sup>29</sup> The Louisiana Legislature has enacted laws allowing pharmacists to dispense certain medications in the absence of any patient-specific prescription, as is typically required by the Louisiana Pharmacy Practice Act.<sup>30</sup> The Federal Food and Drug Administration has similarly authorized pharmacists to prescribe and dispense certain drugs in connection with declared public health emergencies.<sup>31</sup> In addition, Louisiana pharmacists are authorized to engage in collaborative drug therapy management with licensed physicians, wherein the pharmacist is permitted to modify a patient's disease-specific drug therapy according to a set of written orders signed by the collaborating physician.<sup>32</sup> As a result, § 2511(C) accurately identifies the individuals authorized to issue prescriptions within the state.

Proposed § 2511(D)(1) identifies specific information that must be included in a valid prescription, including identifying information for the prescriber and the patient, the date the prescription was issued, the identity and quantity of the prescribed drug or device, directions for use, refill instructions as appropriate, and the prescriber's signature.<sup>33</sup> This provision is unchanged from the existing regulation and encompasses all information federal law requires to be included in a valid prescription and the information that Louisiana law requires pharmacists to include on the labels of filled prescriptions.<sup>34</sup> Proposed § 2511(D)(2) is a new provision that allows a pharmacist, pharmacist intern, or certified pharmacy technician to consult the prescriber when information is missing from a prescription for the purpose of clarifying the prescriber's intent.<sup>35</sup> As stated above, Louisiana law already imposes a duty upon pharmacists to consult with a prescriber in circumstances when questions regarding the prescription or the prescribed course of treatment arise, and the provisions of proposed § 2511(D)(2) only serve to explicitly authorize actions already required by law. As a result, the provisions of § 2511(D) are also appropriate for adoption by the Board.

Subsection (E) of proposed § 2511 addresses the manner by which prescriptions are issued, and reorganizes the existing provisions of the regulation without any substantive

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<sup>27</sup> Notice of Intent, Louisiana Register, Vol. 49, No. 2 at p. 366, § 2511(C)(1); La. R.S. 37:1164(45) and (47); La. R.S. 40:961(35) – (37).

<sup>28</sup> *Id.* at § 2511(C)(2); *see also* La. R.S. 37:1164(6); 21 C.F.R. §1306.05(f); 21 C.F.R. § 1306.03.

<sup>29</sup> *Id.* at § 2511(C)(3).

<sup>30</sup> *See e.g.* La. R.S. 40:978.2 (providing that Naloxone may be dispensed by standing order); *see also* La. R.S. 37:1164(47) (defining "prescription" to be "patient-specific").

<sup>31</sup> *See* FDA Emergency Use Authorization for Paxlovid (5/25/2023), available at: <https://www.fda.gov/media/155049/download>.

<sup>32</sup> La. R.S. 37:1164(39); LAC 46:LIII.523.

<sup>33</sup> Notice of Intent, Louisiana Register, Vol. 49, No. 2 at p. 366, § 2511(D)(1).

<sup>34</sup> *See* La. R.S. 37:1225; La. R.S. 37:1226; *see also* 21 C.F.R. § 1306.14; 21 C.F.R. § 1306.24.

<sup>35</sup> Notice of Intent, Louisiana Register, Vol. 49, No. 2 at p. 366, § 2511(D)(2).

change.<sup>36</sup> The provisions of § 2511(E) set forth requirements for the three types of prescriptions addressed in the Uniform Controlled Dangerous Substances Law: oral, written, and electronic.<sup>37</sup> The provisions of § 2511(E)(1), which are directed to oral prescriptions, require such prescriptions to be promptly reduced to written form and filed by the pharmacist, as mandated by both state and federal law.<sup>38</sup> The provisions of § 2511(E)(2) set forth certain formatting requirements to which written prescriptions must conform, and which the Board may impose pursuant to the authority conferred upon it by the legislature.<sup>39</sup> With respect to electronic prescriptions, § 2511(E)(3) identifies the information that must be included in such prescriptions, which information is also required by Louisiana statutes and federal regulations.<sup>40</sup> As the provisions of proposed § 2511(E) adhere to the purposes underlying the laws the regulation is intended to implement, adoption by the Board is appropriate.

The proposed amendment to § 2511(F) authorizes pharmacists to modify the quantity or dosage form of a prescribed medication with the permission of the prescriber and the patient's consent.<sup>41</sup> With respect to changes to the quantity of a prescribed drug, the provisions would allow modifications when the prescribed quantity is not commercially available, the change in quantity is related to a change in dosage form, the change is intended to dispense up to the total amount prescribed, or the amount of a maintenance drug is increased by a quantity sufficient to coordinate refills with the prescriber.<sup>42</sup> For alterations to the prescribed dosage form, the proposed provisions would allow changes that are in the best interest of patient care, as long as the change results in an equivalent amount of the drug being dispensed and the directions for use are also modified to account for the change in dosage form.<sup>43</sup> The proposed provisions also reiterate that information missing from a prescription can be added by a pharmacist when evidence exists to support the addition, and requires any such changes to the prescription made by a pharmacist must be documented in the patient's record.<sup>44</sup>

As addressed above, Louisiana pharmacists have a duty to evaluate the prescriptions they fill and to contact the prescriber or notify the patient if any questions or concerns arise. To the extent proposed § 2511(F) contemplates modifications to a prescribed quantity or dosage form after a consultation with the prescriber in which the pharmacist is granted permission to make the alteration, it adheres to the policies embodied in the Louisiana Pharmacy Practice Act and the Uniform Controlled Dangerous Substances Law that allow pharmacists to fill oral prescriptions from licensed practitioners. It merits brief mention that, while the language of proposed § 2511(F) clearly contemplates communication between the pharmacist and prescriber, this language could also potentially be construed to authorize pharmacists to unilaterally modify prescribed

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<sup>36</sup> Notice of Intent, Louisiana Register, Vol. 49, No. 2 at p. 366, § 2511(E).

<sup>37</sup> *Id.*; La. R.S. 40:978.

<sup>38</sup> *Id.* at § 2511(E)(1); La. R.S. 40:973; 21 C.F.R. § 1306.11(d); 21 C.F.R. § 1306.21(a).

<sup>39</sup> *Id.* at pp. 366-367, § 2511(E)(2); La. R.S. 40:972.

<sup>40</sup> *Id.* at p. 367, § 2511(E)(3); La. R.S. 40:973; 21 C.F.R. § 1311.200(a).

<sup>41</sup> *Id.* at § 2511(F).

<sup>42</sup> *Id.* at § 2511(F)(1)(a).

<sup>43</sup> *Id.* at § 2511(F)(1)(b).

<sup>44</sup> *Id.* at § 2511(F)(1)(c) and (F)(2).

quantities and dosage forms without first consulting with or obtaining permission from the prescribing practitioner.<sup>45</sup> Such an interpretation would be inconsistent with the state policies adopted by the legislature as well as the duties and authorities conferred upon pharmacists by Louisiana law.

As stated above, a pharmacist's primary duty is to fill prescriptions according to the prescriber's directives. While this duty is qualified by a pharmacist's corresponding duties to only fill valid prescriptions and to take action when a prescriber's directives appear to have been made in error or create a substantial risk of patient harm, pharmacists lack the authority to unilaterally modify prescriptions, even with the patient's consent. Absent exceptional circumstances such as the public health emergencies referenced above, the legislature has only authorized individuals meeting the statutory definition of "practitioner" to issue prescriptions, and no provision of Louisiana law confers authority upon pharmacists to alter a prescriber's directives after the prescription has been issued. However, since pharmacists do possess the ability to modify prescriptions after consulting with the prescriber and obtaining consent, it cannot be said that no set of circumstances exists under which the application of § 2511(F) would be valid, and the Attorney General will therefore not disapprove the regulation, as doing so could prevent the Board from validly exercising its authority in appropriate circumstances.<sup>46</sup> Even so, given the potentially ambiguous language of § 2511(F), the Board should consider amending the regulation's language in the future to make clear that pharmacists may not unilaterally alter the contents of a prescription without the prescriber's consent, and the Board should discourage such an interpretation of § 2511(F) by its licensees.

#### LAC 46:LIII § 2519 – Prescription Refills; Medication Synchronization and Refill Consolidation

The provisions of LAC 46:LIII.2519 are directed to prescription refills, medication synchronization and refill consolidation, and the amendments proposed by the Board consist of both organizational and substantive changes. Proposed § 2519(A)(1) relocates existing provisions limiting the number of times CDS prescriptions may be refilled, and introduces a new provision that addresses refills for non-CDS drugs.<sup>47</sup> In particular, the provisions of § 2519(A)(1)(a) - (c) impose refill limitations for CDS prescriptions according to the drug's assigned CDS schedule, and the limitations imposed mirror those provided by state and federal law.<sup>48</sup> Proposed § 2519(A)(1)(d) provides that prescriptions for drugs not classified as a CDS, and for medical devices, medical gas, or durable medical equipment may be refilled without limitation, subject to expiration of the prescription one year after its issuance.<sup>49</sup> This newly added provision also accords with state and federal

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<sup>45</sup> See *id.* at § 2511(F)(1) (stating that pharmacists may make the contemplated modifications "unless the prescriber has indicated adaptation is not permitted").

<sup>46</sup> Cf. *Westlawn Cemeteries, L.L.C. v. Louisiana Cemetery Bd.*, 2021-01414, pp. 15-16 (La. 3/25/22), 339 So.3d 548, 561.

<sup>47</sup> Notice of Intent, Louisiana Register, Vol. 49, No. 2 at p. 367, § 2519(A)(1).

<sup>48</sup> Compare *id.* at § 2519(A)(1)(a), La. R.S. 40:978(A), and 21 U.S.C. § 829(a) (Schedule II CDS); *id.* at § 2519(A)(1)(b), La. R.S. 40:978(B), and 21 U.S.C. § 829(b) (Schedule III and IV CDS); *id.* at § 2519(A)(1)(c), La. R.S. 40:978(C), and 21 U.S.C. § 829(c); see also LAC 46:LIII.2525.

<sup>49</sup> Notice of Intent, Louisiana Register, Vol. 49, No. 2 at p. 367, § 2519(A)(1)(d).

law, neither of which place any limitation on the number of times prescriptions for non-CDS drugs or the other items referenced in the regulation may be refilled.

Proposed § 2519(A)(2) addresses pharmacists' authority to dispense prescription refills, and makes no change to the regulation's existing provisions.<sup>50</sup> The substance of § 2519(A)(2) authorizes pharmacists to refill prescriptions as directed by the prescribing practitioner in the original prescription order.<sup>51</sup> In the absence of explicit authorization from the prescriber to provide refills, the regulation provides that additional medication may only be dispensed upon the issuance of a new prescription.<sup>52</sup> These provisions align with the statutory prohibition against dispensing or administering prescription drugs without a valid prescription from a qualified practitioner, and they are therefore appropriate for adoption by the Board.<sup>53</sup>

The contents of proposed § 2519(A)(3) and (4) authorize pharmacies to refill prescriptions or request a new prescription to continue an existing medication therapy only when requested by the patient, the patient's agent, or the patient's caregiver.<sup>54</sup> The regulation also authorizes pharmacies to offer auto-refill services to facilitate such requests, and provides that refill requests are not required for patients residing in long-term care facilities.<sup>55</sup> Materials submitted by the Board indicate that the Louisiana State Medical Society requested the adoption of rules addressing default enrollment in automated prescription renewal programs due to the risk of patient harm.<sup>56</sup> The Board also notes that implementing the proposed regulations could potentially reduce waste associated from the unwanted filling of prescriptions.<sup>57</sup> The federal Drug Enforcement Agency has recently made similar statements when promulgating new rules, adding that limiting the amount of unwanted medication dispensed by pharmacies could also lower the costs paid by consumers and prevent diversion or misuse of unwanted drugs.<sup>58</sup> As the provisions of § 2519(A)(3) and (4) address specific circumstances identified as creating a risk of patient harm, they are consistent with the affirmatively expressed legislative intent of the Louisiana Pharmacy Practice Act and Uniform Controlled Dangerous Substance Law.<sup>59</sup> Allowing refills for residents of long-term care facilities in the absence of an explicit request from the patient is also appropriate given the role such facilities play in monitoring patient health and ensuring proper administration of prescribed medications.<sup>60</sup> The proposed revisions to § 2519(A)(3) and (4) are therefore appropriate for adoption by the Board.

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<sup>50</sup> Notice of Intent, Louisiana Register, Vol. 49, No. 2 at p. 367, § 2519(A)(2).

<sup>51</sup> *Id.*

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

<sup>53</sup> See La. R.S. 40:978(B) and (C); see also 21 C.F.R. § 1306.22.

<sup>54</sup> Notice of Intent, Louisiana Register, Vol. 49, No. 2 at p. 367, § 2519(A)(3) and (4).

<sup>55</sup> *Id.*

<sup>56</sup> June 7, 2023 Rule Submission Form at ¶ 4; December 18, 2020 correspondence from Louisiana State Medical Society (retained in file).

<sup>57</sup> *Id.*

<sup>58</sup> See 88 FR 46983-01, 46984.

<sup>59</sup> See La. R.S. 37:1163; La R.S. 37:1182(A)(1) and (13); La. R.S. 40:972(A).

<sup>60</sup> See La. R.S. 37:1184(25) (defining "long-term care facility").



Lastly, proposed § 2519(B) addresses “medication synchronization” and “refill consolidation,” terms which refer to services a pharmacist may provide at the request of a patient for the purpose of improving adherence to a medication regimen by adjusting the quantity of medication dispensed or the patient’s prescription refill schedule.<sup>61</sup> These provisions appear in the current version of the regulation and the Board has not proposed any amendments to the existing language. As discussed above in connection with § 2511(B), both state and federal law authorize pharmacists to dispense less than the total prescribed quantity of a drug when requested by a patient. Furthermore, as discussed above in connection § 2519(A)(3) and (4), it is also appropriate for a pharmacist to adjust the timing of prescription refills according to a patient’s request. As a result, the proposed provisions of § 2519(B) are appropriate for adoption for the same reasons provided in the above analyses of § 2511(B) and § 2519(A)(3) and (4).

### III. Determination

As the Attorney General has determined the proposed amendments to LAC 46:LIII.2511 and 2519 adhere to clearly articulated state policies, these regulations are approved and may be finally adopted as proposed by the Board.

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BY:   
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<sup>61</sup> Notice of Intent, Louisiana Register, Vol. 49, No. 2 at p. 367, § 2519(B).