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November 14, 2016

VIA ELECTRONIC MAIL

Mr. Larry Pinson
Executive Secretary
431 W. Plumb Lane
Reno, NV 89509

Re: BriovaRx of Nevada, LLC
December 7, 2016 Board Appearance

Dear Mr. Pinson:

I am writing on behalf of BriovaRx of Nevada, LLC to renew a request made earlier this year concerning Nev. Admin. Code § 639.921. As you will recall, this regulation addresses the sharing of information between pharmacy computer systems, and requires that pharmacies that share such information electronically have a common owner. Specifically, this regulation provides that: "Information concerning prescriptions may be shared between the computerized systems of two or more pharmacies licensed by the Board if: (a) The pharmacies are commonly owned".

BriovaRx of Nevada is requesting this change because it desires to participate in a prescription processing and fulfillment services arrangement with another Nevada licensed pharmacy. Such arrangements are permitted under Nev. Admin. Code § 639.7125, and although section 639.7125 does not expressly require that participants in such arrangements be under common ownership, the shared processing and fulfillment services provided by the participants requires the fulfillment pharmacy to enter "the data concerning the prescription into its computer system directly or the dispensing pharmacy enters the data concerning the prescription into its computer system and transfers that data to the computer system of the fulfillment pharmacy in a secure and confidential manner". Nev. Admin. Code § 639.7125. Board staff has advised the

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pharmacy that, in order to share the data in the manner contemplated by 639.7125, the two pharmacies must share a common prescription database, and therefore, must be under common ownership as required by Nev. Admin. Code § 639.921. This prevents pharmacies that are not commonly owned, and cannot share a common prescription database, from participating in shared processing and fulfillment arrangements, and gives commonly owned pharmacies an unfair advantage in the marketplace.

When this issue was brought to your attention last year, you and other members of the board staff explained that when the original rule was drafted, it was contemplated that only chain pharmacies with multiple locations would share computer systems. However, though this may have been the case at one time, it is no longer the case. I am aware of independent pharmacies that share services with central refill pharmacies, specialty pharmacies, compounding pharmacies, and other independent pharmacies, in order to improve patient care and optimize efficiency. In BriovaRx's case, it desires to enter into such an arrangement with other, unrelated pharmacies, to provide prescription fulfillment activities for patients from its state of the art Nevada pharmacy. The arrangement would allow pharmacists at the front end "dispensing" and processing pharmacy to focus on order review and order entry, drug utilization review, and prescriber and patient outreach and patient counseling, while leaving the fulfillment function to BriovaRx. BriovaRx would partner with those other pharmacies to improve the level of pharmacy care provided to patients, in the very same manner that Nevada pharmacies that share a common owner are currently allowed to share services under Nevada law. The common ownership requirement contained in Nev. Admin. Code § 639.921 is outdated, and does nothing to improve care or protect patients. Its existence does nothing but provide an advantage to commonly owned pharmacies, to the detriment of independent pharmacies that desire to engage in shared services in order to improve efficiencies and quality in the provision of pharmacy services.

When this issue was first brought before the Nevada board in January 2016, the board wholeheartedly agreed that the common ownership requirement was not necessary, and that the regulation should be changed. The board supported the revision through the workshop and public hearing phases of the rulemaking process. However, the board ultimately rejected the proposed revision based on a completely different issue related to the accountability of pharmacies and pharmacists that participate in shared services arrangements under Nev. Admin. Code § 639.7125. That accountability issue can be addressed through a separate rulemaking if needed, but regardless of how that issue is addressed, all pharmacies, whether commonly owned or separately owned, would be bound by the same accountability standards. To delay a common sense change in the regulations governing access to a common computer system while sorting through an unrelated accountability issue will simply perpetuate the unfair advantage that is currently provided to pharmacies that share a common owner, to the detriment of pharmacies that are independently owned.

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We note that BriovaRx operates pharmacies in other states, and could simply shift any work load balancing/shared services activities to those pharmacies. As previously discussed, our review of the pharmacy laws of all fifty states plus the District of Columbia reveals that nearly every state that addresses shared services allows pharmacies not having a common owner to share information electronically in order to process or fill prescriptions. Enclosed with this letter are citations to the laws of those states. However, BriovaRx desires to provide those services from its Nevada pharmacy, and to employ Nevada pharmacists and technicians to assist in the provision of those services, and is therefore requesting this revision to Nev. Admin. Code § 639.921.

You have agreed to place this issue before the Nevada pharmacy board for review at the board's December 7, 2016 meeting, and have agreed to allow me to present the issue to the board, accompanied by representatives of BriovaRx of Nevada, LLC. I am enclosing a document that identifies the requested revision to Nev. Admin. Code § 639.921, in the form previously reviewed by the board. I ask that this letter and the enclosed documents be included in the materials to be distributed to the board in advance of the December 7 board meeting.

Thank you. I look forward to seeing you next month.

Respectfully submitted,



Edward D. Rickert

Enclosures

cc: David Wuest
Paul Edwards
Aaron Bukofzer

QB\42512698.1

Proposed Revisions to NAC 639.921

NAC 639.921 Sharing information between systems: Conditions and requirements. (NRS 639.070, 639.0745, 639.236)

1. Information concerning prescriptions may be shared between the computerized systems of two or more pharmacies licensed by the Board if:

(a) The pharmacies are commonly owned; or if not commonly owned, have a written agreement that outlines the services to be provided and the accountabilities of each pharmacy in compliance with federal and state law; and

(b) The computerized systems for recording information concerning prescriptions share a common database that:

(1) Except as otherwise provided in subsection 3, contains all the information concerning a patient that is contained in each computerized system that has access to the common database;

(2) Except as otherwise provided in subsection 3, contains all the information concerning a prescription that is contained in each computerized system that has access to the common database;

(3) After a prescription has been filled, automatically decreases the number of refills remaining for the prescription, if any, regardless of which pharmacy filled the prescription;

(4) Automatically stores any modification or manipulation of information concerning a prescription made by a pharmacy with access to the common database so that the modification or manipulation is available to each pharmacy with access to the common database;

(5) Allows access only by a person who is authorized to obtain information from the common database;

(6) Requires any person who is authorized to modify or manipulate information concerning a prescription, before modifying or manipulating the information concerning the prescription, to identify himself or herself in the computerized system by:

(I) Using a biometric identification technique; or

(II) Entering into the computerized system another unique identifier which is approved by the Board and which is known only to and used only by that person;

(7) Makes and maintains an unchangeable record of each person who modifies or manipulates information concerning the prescription, that includes, without limitation:

(I) The name or initials of the person;

(II) An identifier that can be used to determine the pharmacy in which the person modified or manipulated the information concerning the prescription; and

(III) The type of activity concerning the prescription that the person performed, including, without limitation, modifying or manipulating the information concerning the prescription;

(8) Contains a scanned image of the original prescription if the original prescription is a written prescription; and

(9) Provides contact information for the first pharmacist who verifies the correctness of the information contained in the common database concerning the prescription.

2. If a pharmacy is the initial pharmacy to receive a written prescription, a pharmacist shall ensure that:

(a) The written prescription is numbered consecutively in accordance with NAC 639.914; and

(b) The image of the prescription is scanned into the computerized system of the pharmacy.

3. If a pharmacy other than the pharmacy that initially received a prescription enters information concerning a prescription into a computerized system for recording information concerning prescriptions, the information must not be accessible from the common database for the purpose of filling or dispensing a prescription until a pharmacist verifies the correctness of the information entered into the computerized system. After verifying that information, the pharmacist shall enter a notation in the computerized system that includes the pharmacist's name, contact information and the date on which he or she verified the information.

4. A pharmacy that fills a prescription using the information from the common database, other than the pharmacy that initially received the prescription, shall:

(a) Process the prescription in the same manner as a prescription that is initially received by the pharmacy;

(b) Except as otherwise provided in paragraph (c), dispense the prescription in the same manner as a prescription that is initially received by the pharmacy; and

(c) Place on the label of the container in which the prescription will be dispensed:

(1) The number assigned to the prescription by the pharmacy that initially received the prescription; and

(2) An additional number or other identifier that ensures that the number placed on the label pursuant to subparagraph (1) is not confused with a prescription number of the pharmacy that is filling the prescription.

5. The filling of a prescription pursuant to the provisions of subsection 4 shall not be considered a transfer of the prescription.

Does the state permit shared prescription processing or dispensing between pharmacies that do not share a common owner?

Alabama

Yes. If the pharmacies do not have the same owner, they must have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations. Ala. Admin. Code 680-X-2-.30(3)(a)(1)(i)-(ii).

Alaska

Yes. If the pharmacies do not have the same owner, they must have entered into a written contract or agreement that outlines the services to be provided and the obligation of each pharmacy to comply with federal and state statutes and regulations. Alaska Admin. Code tit. 12, § 52.443(b)(3).

Arizona

Yes. The pharmacies may either have the same owner or have a written contract or agreement that outlines the services provided and the shared responsibilities of each party in complying with federal and state pharmacy statutes and rules. Ariz. Admin. Code R4-23-621(B).

Arkansas

Yes. "Such central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner." Code Ark. R. 070.00.4-04-02-0011 (a)(1).

California

Yes. The pharmacy that is to refill the prescription must have **either** (1) a contract with the pharmacy which received the prescription or (2) the same owner as the other pharmacy. Cal. Code Regs. tit. 16, § 1707.4(a)(1).

Colorado

Yes. A pharmacy may outsource one or more portions of the dispensing of an order to other pharmacies provided the pharmacies:

1. Have the same owner or have entered into a central prescription processing contract; **and**
2. Share a common electronic file or have appropriate technology/interface to allow access to information required to process the order; **and**
3. Are registered with the Board as either prescription drug outlets or non-resident prescription drug outlets, depending on the pharmacy's location, except that a nonresident pharmacy that does not physically ship, mail or deliver dispensed prescriptions directly into this state from the nonresident pharmacy location shall be exempt from the requirement of obtaining a nonresident prescription drug outlet registration pursuant to 12-42.5-130(2). All pharmacies participating in the central prescription processing contract, or who are engaged in shared pharmacy services, must be located within the United States regardless of the requirement of a Colorado registration.

3 Colo. Code Regs. § 719-1:20.00.00 (10.00.60) (emphasis added)

Connecticut

Law is silent.

Delaware

Yes, if performed pursuant to a written agreement that outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations. 24-2500 Del. Admin. Code § 5.1.15.1.2.

District of Columbia

Law is silent.

Florida

Yes. Pharmacies must have the same owner **or** have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations. Fla. Admin. Code Ann. r. 64B16-28.450.

Georgia

Law is silent.

Hawaii

Yes. Service can be provided by pharmacies that share a common owner, or pursuant to a written agreement. Haw. Rev. Stat. § 329-38(h).

Idaho

Yes, if the agreement outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract. Idaho Admin. Code r. 27.01.01.610.01.

Illinois

Yes. A pharmacy licensed by the Illinois Board may perform services for another pharmacy, provided that both pharmacies have the same owner **or** have a written contract specifying: (a) the services to be provided by each pharmacy; (b) the responsibilities of each pharmacy; and (c) the manner in which the pharmacies shall comply with federal and state laws. 225 Ill. Comp. Stat. Ann. 85/25.5(b).

Indiana

Yes. The written agreement must outline the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations. 856 Ind. Admin. Code §§ 1-37-2.

Iowa

Yes, if the written agreement outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations. Iowa Admin. Code r. 657-18.3.

Kansas

Yes, pursuant to a written agreement. The written agreement must outline the services provided and the shared responsibilities of each party in complying with the pharmacy act and the Board's regulations. Kan. Admin. Regs. § 68-7-20(c)(2)(B).

Kentucky

No. The use of a common database to share prescription information requires that all pharmacies involved in the transactions pursuant to which the prescription is dispensed shall be under common ownership. 201 Ky. Admin. Regs. 2:300 (§2).

Louisiana

Yes. State regulations explicitly permit centralized prescription dispensing when the on-site pharmacy and the remote dispenser are under common ownership or “have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations.” La. Admin. Code tit. 46, pt. LIII, § 1141(A)(1)(a).

Maine

Yes. A central fill drug outlet or central processing center that processes, fills or refills a prescription drug order for a retail drug outlet or other health care facility must have a contract with or have the same owner as the retail drug outlet or other health care facility identified in Section 1(1) of this chapter from which it received the prescription drug order. The contract must include provisions that protect the confidentiality of patient information. 20-392-21 Me. Code R. § 3.

Maryland

Yes. Central fill activities are referred to as “outsourcing a prescription order.” Md. Code Regs. 10.34.04.06. Outsourcing of a prescription order involves a primary and secondary pharmacy. The original prescription order must be filed as a prescription order at the primary pharmacy. *Id.* at (D). The regulations do not address or require either common ownership or a contractual relationship to engage in outsourcing of a prescription.

Massachusetts

Not addressed in statutes or regulations. However, this may be permitted upon Board approval.

Michigan

Yes. The pharmacies must have the same owner **or** have a written contract outlining the services to be provided and the responsibilities and accountabilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state laws and regulations. Mich. Comp. Laws Ann. § 333.17753(1).

Minnesota

Yes. Minnesota regulations require that the “parties have the same owner *or have a written contract* outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations. Minn. R. 6800.4075(Subp. 2)(A)(1).

Mississippi

Law is silent.

Missouri

Yes. A pharmacy may perform or outsource centralized prescription processing services provided the parties have the same owner, or “have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations.” Mo. Code Regs. Ann. tit. 20, § 2220-2.650(1)(A)(1).

Montana

Yes. Central fill and central processing arrangements are permitted if the pharmacies “have the same owner *or have entered into a written contract or agreement* that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations.” Mont. Admin. R. 24.174.823(1)(a) (emphasis added).

Nebraska

Law is silent.

New Hampshire

Yes. All pharmacies involved in the transactions pursuant to which the prescription is dispensed shall have either:

- (1) The same owner; or
- (2) A written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws, regulations, and rules. N.H. Code Admin. R. Ph 1203.01(a).

Nevada

Common ownership is not expressly required in the shared services regulations. However, the regulation that addresses computerized records requires that only pharmacies that share common ownership can share information between computer systems. Nev. Admin. Code § 639.921. Note that shared services do not expressly require the use of a shared computer system.

New Jersey

Yes. Two or more pharmacies may engage in central prescription handling provided that any or all of the pharmacies participating in central prescription handling have a contractual agreement to provide such services or have the same owner. N.J. Admin. Code § 13:39-4.19(d).

New Mexico

Yes. N.M.A.C. § 16.19.6.25(B)(1)(b).

New York

Law is silent.

North Carolina

Yes. The pharmacy that is to fill or refill the prescription must have either a contract with the pharmacy which received the prescription or have the same owner as the other pharmacy. 21 N.C. Admin. Code 46.1816.

North Dakota

Yes. Guidance refers to DEA regulation which states that central fill is permitted with respect to controlled substances if the pharmacies are under common ownership or contractual agreement. Central-Fill Pharmacies and Processes Guidance at 1.

Oklahoma

Silent.

Ohio

Not directly addressed. Board approves shared services on a case by case basis.

Oregon

Yes. Pharmacies must either have the same owner or have a written shared pharmacy services contract or agreement that specifies:

- (a) The services to be provided by each pharmacy;
- (b) The responsibilities of each pharmacy; and
- (c) The accountabilities of each pharmacy.

Or. Admin. R. 855-041-3015(2).

Pennsylvania

Yes. The central fill pharmacy or the central processing center that is to process, fill or refill the prescription must have a contract with or have the same owner as the originating pharmacy and the delivering pharmacy. 49 Pa. Code § 27.203.

Rhode Island

Yes. Common ownership is not a requirement. *See* R.I. Admin. Code 31-2-8:22.0. *See also* R.I. Admin. Code 31-2-8:1.15 (defining “central fill pharmacy” as the pharmacy that fills the prescription order for delivery in accordance with *an agreement* with a delivery pharmacy.).

South Carolina

Law is silent.

South Dakota

Law is silent.

Tennessee

Yes. Both pharmacies shall have the same owner or in the event that the pharmacies do not have the same owner, then the pharmacies shall enter a written contract stating the services that will be provided by each pharmacy as well as the responsibilities of each pharmacy in fulfilling the terms of the contract and in complying with federal and state laws and rules. Tenn. Comp. R. & Regs. 1140-03-.16(1)(c).

Texas

Yes. If the pharmacies do not have the same owner, they must have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations. 22 Tex. Admin. Code § 291.125(c)(1)(A)(i)(II).

Utah

Yes. A pharmacy may perform centralized prescription processing or centralized prescription filling services for a dispensing pharmacy if the parties: (a) have common ownership or common administrative control; or (b) have a written contract outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations; and (c) share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription drug order. Utah Admin. Code r. R156-17b-614f.

Virginia

Yes. A pharmacy may outsource certain prescription processing functions to another pharmacy in Virginia or a registered nonresident pharmacy under the following conditions: 1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy; 18 Va. Admin. Code 110-20-276 (B).

Washington

Not addressed in regulations but permitted according to Board guidance.

West Virginia

Law is silent.

Wisconsin

Yes. Permitted if the pharmacy either has the same owner as the originating pharmacy or has a written contract with the originating pharmacy outlining the services to be provided and the responsibilities of each pharmacy in fulfilling the terms of the contract in compliance with federal and state law." Wis. Admin. Code PHAR § 7.12(2)(a).

Wyoming

Yes. A dispensing pharmacy may outsource prescription drug order processing to another pharmacy licensed by the Board, provided the pharmacies: (A) Have the same owner; or (B) Have entered into a written agreement, which complies with federal and State laws and regulations, specifying the services to be provided and the responsibilities and accountabilities of each pharmacy;

Wyo. Admin. Code § AI PHAR Ch. 2 § 32 (f).



NEVADA STATE BOARD OF PHARMACY

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Excerpt of
July 21, 2016

Board Meeting Minutes

21. Notice of Intent to Act Upon a Regulation

A. **Amendment of Nevada Administrative Code (NAC) 639.921 Sharing of information between two or more pharmacies.** The proposed amendment would allow for the sharing of information concerning prescriptions between the computerized system of two or more pharmacies that are commonly owned or contractually related.

Mr. Wuest provided additional information for the Board. He explained that during the last meeting the Board instructed Staff to get industry input. He stated that members of the industry were in the audience.

President Basch opened the Public Comment.

Bill Stilling was present as counsel representing Walgreens.

Mr. Stilling commented in support of pharmacies contractually sharing data, and presented a flow chart comparing persons liable for unprofessional conduct for data check error using different work flow models.

Dan Luce, National Director of Pharmacy Affairs, Walgreens, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Luce commented in support of pharmacies contractually sharing data. He also requested the Board continue to license and discipline the out-of-state facilities instead of licensing each out-of-state pharmacist involved in the prescription filling process.

Board discussion ensued regarding the importance of looking at each discipline case on a single basis and not assigning blame contractually or through regulation.

Charlie Hartig, legal counsel representing CVS, appeared and was sworn by President Basch.

Mr. Hartig commented in support of shared service models added that this work flow model helps reduce distractions.

Dan Heller, pharmacist, appeared and was sworn by President Basch prior to answering questions or offering testimony.

Mr. Heller commented that a segmented work flow is the safest work model.

President Basch closed Public Comment.

The Board discussed who would be held responsible for errors using the contractual data sharing model.

The Board discussed possible unintended consequences for approving or denying this amendment.

Board Action:

Motion: Jason Penrod moved to table LCB File No. R035-16.

Second: Darla Zarley

Jason Penrod withdrew his motion.

Board Action:

Motion: Jason Penrod moved to deny LCB File No. R035-16.

Second: Darla Zarley

Action: Passed unanimously