Hi Pete,

Thanks for giving me an opportunity to provide the teams thoughts . The Neighborhood internal team respectfully makes the following suggestions. Happy to forward along any specific or clarifying questions to the team as needed.

- There should be limitations around 1.15.A.1 such as specific scenarios (e.g. unable to reach provider, office closed due to state of emergency, member's health in jeopardy without treatment from drug class), drug classes or conditions.
- Also, if an auto-substitution is performed, the pharmacy must inform the prescriber immediately
- The pharmacist performing the auto-substitution must do so within coverage rules of the insurer
- The pharmacist performing the auto-substitution must not adversely impact the member out of pocket costs versus what was initially prescribed

Stay safe and thanks again.

Ed

Edward Curis, MPP
Senior Policy Analyst

Neighborhood Health Plan of Rhode Island
910 Douglas Pike
Smithfield, RI 02917

RIPA and RIMS Comments re: proposed pharmacy regulation changes
December 13, 2020

December 13, 2020

To Paula Pullano
Department of Health
3 Capitol Hill
Room 410
Providence, RI 02906

CC: Paula.Pullano@health.ri.gov , PETER.RAGOSTA@HEALTH.RI.GOV, sranucci@ripcpc.com

Re: Public comments regarding proposed pharmacy regulation changes (216-RICR-40-15-1)
The Rhode Island Pharmacists Association (RIPA) and the Rhode Island Medical Society (RIMS) Legislative Committees recently met to review the proposed regulatory changes to rules covering Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors (216-RICR-40-15-1) that were issued for public comment on November 16, 2020. Together, our two organizations would like to share our thoughts and recommendations for changes to the proposed regulations.
The COVID-19 pandemic has brought numerous challenges both to medicine and pharmacy. During this healthcare access emergency, we are challenged by a slowing down of the normal supply chain (limiting access to some medications); while in some cases facing disrupted/ or delayed communication lines between pharmacists and other healthcare providers. As you are aware, these challenges ultimately can result in potential delays in medication access and care for patients. We appreciate the work by the Department of Health and Board of Pharmacy on these proposed regulation changes that empower pharmacists to enhance patient care during this difficult time.
Below, are the proposed summary of revisions proposed to 216-RICR-40-15-1, by both RIPA and RIMS.

1.15

We propose expanding the emergency authorizations to cover other types of emergencies beyond those that fall under a Governor's State of Emergency order. Examples of other emergencies, or barriers leading to reduced access to patient care include, but are not limited to: snow storms, micro-bursts, floods, hurricanes or large scale gas and power outages. Unfortunately here in RI, these situations are commonplace, and present an opportunity for pharmacists to provide improved patient care. Past emergency authorizations do not clearly address these situations, and would have provided significant benefit to pharmacists, medical providers and patients. We propose expanding the definition of emergency to include these and other types of healthcare access emergencies and events causing disruption in patient care.

1.2 Definition-amended #9

The new definition of auto-substitution captures two separate concepts within the single definition. At this time, we would propose breaking the proposed definition into the two following sections: 1.) auto-substitution and 2.) therapeutic substitution. Further,, at this time, we recommend against pharmacists

overriding Dispense as Written (DAW) orders, and request that such language be stricken from these proposed regulations.
We recommend redefining auto-substitute as meaning the replacing of the prescribed product with an alternative product with the same active ingredient but in a different formulation, including a generic product or another dosage form or delivery device without being required to obtain prescriber authorization as long as it is being used via the same route of administration. Further, both organizations believe that in the absence of a Dispense as Written (DAW) order, the redefined auto-substitution by a pharmacist should be added to the normal scope of practice for a pharmacist (not just during emergencies such as the pandemic).
Outside of an established Collaborative Practice Agreement (CPA), changing active ingredients (even within the same class), would be more commonly defined as therapeutic substitution. There is agreement that this is an activity which requires more guidance than the above auto-substitution. In the absence of a Dispense as Written (DAW) order, we propose allowing emergency therapeutic substitution in cases where a patient /or pharmacy is unable to obtain a medication (for example, due to supply and/or coverage issues) and the pharmacist determines that a delay in obtaining prescriber authorization to switch will cause patient harm, the pharmacist may substitute an alternative within the same therapeutic medication class to cover until the pharmacist is able to obtain prescriber authorization for further dispensing. After the emergency therapeutic substitution, we recommend adding the following requirements: documentation of patient consultation/ counseling, patient consent to the change, and prescriber notification after dispensing .

1.4.22 Prescription Refill Information Amended Section C
Regarding the "allows pharmacists to dispense an amount of non-controlled substance medication beyond the face amount not to exceed the total amount of authorized refills" section of the proposed regulations, our provider colleagues shared concerns. Specifically, especially with some mental health related medications, with pharmacists dispensing more than the face amount of the prescription. If a prescriber has clinical concerns about a patient and purposefully wants the patient to have a limited supply of medications available at any given time, there needs to be a way for the prescriber to communicate this to the pharmacist that would prohibit this section of the regulation.
We propose adding language that if a provider adds a note on the prescription indicating Dispense as Written, that this DAW order would also block this section of these proposed regulations (AKA DAW would not allow automatic conversion to 90 day) .

1.4.24 Emergency Prescription Refill
RIPA received questions from member pharmacists regarding the conflicting allowances in emergency refills. Pharmacists are currently allowed to dispense up to 3 days supply (or 1 unit of unit) for emergency supplies. The language of these proposed regulations, allow for "1 time fill up to 90 days". If the pharmacist dispensed the standard 3 day supply, would that use the " 1 time" and prohibit additional supplies?
RIPA and RIMS propose amending the existing emergency prescription authorization to expand dispensing regulations from the current up to 3 day supply (or 1 unit of use), to up to 30 day supply annually. Even before the COVID-19 pandemic, the 72 hour window was already difficult for some providers, especially those that do not work full time, have multiple practice sites, or limited access to health records, to review and answer refill requests from pharmacists within the 72 hour time frame, especially over weekends and holidays. The short time window regularly leaves patients without medication or leads stressed/panicked patients calling on-call providers over the weekend/ after hours to seek approval of emergency refill prescriptions. These situations also cause unnecessary administrative burden on HCPs and pharmacies, reducing availability for patient-care activities. RIPA and RIMs both agree the proposed 90 day window is

too long, and may increase the risk of harm to some patients. Especially those whose providers depend on prescriptions renewals as a trigger for care plan reviews and/or communication with a prescriber for the continuation of care. We specifically propose “up to a 30 day supply annually” (and not a shorter interval) as many medications are now pre-packed or supplied by manufacturers in 30 day supply increments. Moreover, for patients that are on monthly “med packing” adherence programs, allowing for “up to a 30 day supply” emergency refill would allow them to continue to receive a full med pack vs getting a supplementary bottle which tends lead to confusion for many patients.

Both RIPA and RIMS, we are committed to working together with the Department of Health and Board of Pharmacy to ensure optimal patient access to care during this, and future healthcare access emergencies. We thank you for your consideration in this matter. Please feel free to contact us via email info@ripharmacists.org with any comments, questions or concerns.

Sincerely yours,

Matt LaCroix, PharmD
President RIPA

Kenny Correia, PharmD
RIPA Legislative Committee Chair

Lifespan

Delivering health with care.

Office of the General Counsel

245 Chapman Street
Suite 200
Providence, RI 02905

Tel 401 444-3103
Fax 401 444-6206

VIA ELECTRONIC AND FIRST-CLASS MAIL

December 11, 2020

Paula Pullano
Department of Health
3 Capitol Hill
Room 410
Providence, RI 02906

Re: Written Comments to Regulations on Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors (216-RICR-40151)

Dear Ms. Pullano,

On behalf of Lifespan Corporation, I hereby submit the following written comments regarding the above-entitled proposed regulations.

Section 1.15 – The current version of the Emergency Regulations on Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors dated April 27, 2020 ("Emergency Regulations") contains the following provision that is not included in these proposed regulations and continues to be necessary to effectively operate during the current pandemic:

12. Notwithstanding the provisions of § 1.5.3 (B) of this Part, in the event that a hospital establishes an alternate hospital site (AHS) the license of any retail pharmacy owned by the hospital shall be extended to the AHS. The extension of the retail license shall terminate automatically upon closure of the AHS, or conclusion of the state of emergency declared on March 9, 2020, whichever happens first. In accordance with § 1.5.3 of this Part, the retail pharmacy license extension shall not be transferable to any other site.

The current Emergency Regulations are due to expire on February 21, 2021 and it is likely that the Alternative Hospital Site ("AHS") will be open at that time. Rhode Island Hospital currently operates the AHS and provides retail pharmacy services utilizing its Lifespan Pharmacy retail pharmacy license to allow patients the choice to conveniently fill any prescriptions they may need prior to discharge, just as this service is currently provided on the main hospital campus.

Hospital would lose the ability to provide this much needed service. As we understand that the Proposed Regulations are intended to be permanent and work long after the pandemic, we understand that reference to the March 2020 date would be removed and suggest the following language or its equivalent:

12. Notwithstanding the provisions of § 1.5.3 (B) of this Part, in the event that a hospital establishes an alternate hospital site (AHS) the license of any retail pharmacy owned by the hospital shall be extended to the AHS. The extension of the retail license shall terminate automatically upon closure of the AHS~~, or conclusion of the state of emergency declared on March 9, 2020, whichever happens first~~. In accordance with § 1.5.3 of this Part, the retail pharmacy license extension shall not be transferable to any other site.

We would not support language that would remove the ability to provide retail pharmacy services at the AHS prior to the AHS closing date as there is the possibility that there may be a few days' lag time after the emergency declaration is lifted before all patients are discharged from the AHS.

Thank you for your consideration. Please let us know if you have any questions on the foregoing.

Sincerely,

Jodi Bourque / MCH

Jodi Bourque, Esq.
Associate General Counsel

cc: Christine Collins, RPh, Vice President, Chief Pharmacy Officer, Lifespan

AMERICAN CIVIL LIBERTIES UNION
Rhode Island

128 Dorrance Street, Suite 400
Providence, RI 02903
Phone: (401) 831-7171
Fax: (401) 831-7175
www.riaclu.org
info@riaclu.org

TESTIMONY ON DEPARTMENT OF HEALTH PROPOSED AMENDMENTS TO REGULATIONS GOVERNING PHARMACISTS, PHARMACIES, AND MANUFACTURERS, WHOLESALERS, AND DISTRIBUTORS [216-RICR-40-15-1]
December 11, 2020

The ACLU of RI has no commentary to offer on the specific amendments being proposed to these regulations, but we do wish to point out the need for additional revisions in light of recent legislation approved by the General Assembly.

In July, the Governor signed into law a bill (codified at R.I.G.L §28-5.1-14), which takes effect on January 1, that ensures that an individual's criminal record cannot inappropriately bar them from obtaining an occupational license in a field for which they are qualified. Specifically, under the new law, a criminal record cannot disqualify a person from obtaining an occupational license unless their record "substantially relates" to the occupation. The legislation further guarantees the right to an appeal process for any individual whose application for licensure has been denied due to their criminal record. We urge that the regulations be amended to clarify the applicability of this statute and to explicitly provide the protections that this new law guarantees.

In accordance with the pharmacy statute, these regulations currently require an applicant for licensure within various pharmaceutical occupations to be of "good moral and professional character." §§1.12.1(E)(1)(a); 1.12.1(E)(2)(a); 1.4.10(B)(2). However, this broad standard could be misused in violation of the law by relying on non-occupation-related criminal records as evidence of "bad character" to improperly deny a license to otherwise qualified individuals. Its scope should be explicitly limited by a reference to R.I.G.L §28-5.1-14.

We appreciate that the licensure process does allow for an individual to submit "satisfactory evidence" to waive the preclusion for licensure that a felony conviction for violations involving controlled substances may entail (see §§1.12.1(E)(1)(d); 1.12.1(E)(2)(d); 1.4.3(A)(4)), and we recognize that those particular offenses are likely to be deemed to "substantially relate" to the occupation. But the regulations do not make clear that these are the *only* offenses that could serve to disqualify an individual from licensing. Unless that is the case, the regulations unlawfully fail to provide a similar process for individuals to submit evidence for any other "substantially related" conviction. The regulations should clarify these provisions by referencing the new statute and laying out an appeals process which conforms with the new law.

The regulations additionally require the Board to consider whether an applicant for a wholesale distributor license or a manufacturer license, or any of its owners, have violated *any* Federal, State, local, or foreign laws, pled guilty or nolo contendere, or been found guilty of violating any of such laws. §§1.14.1(C)(1); 1.14.1(E)(1). Similar to our comments above, in the absence of any reference to §28-5.1-14 or mention of an appeals process, this requirement is

inconsistent with the new law by not being limited to consideration of criminal records that are substantially related to the occupation.

Since the proposed amendments to these rules will, like the revisions to §28-5.1-14, be taking place in the new year, we believe they should encompass the changes necessitated by the recently approved statute.

We thank you for your consideration of our concerns, and trust that you will give them your careful consideration. If the suggestions we have made are not adopted, we request, pursuant to R.I.G.L. §42-35-2.6, a statement of the reasons for not accepting these arguments.

Submitted by:
Hannah Stern
Policy Associate