NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

July 20, 2018

Ryan Hatfield
2310 Kanawha Blvd E
Charleston, WV 25311
Via email: ryan.i.hatfield@wv.gov

RE: Board of Pharmacy Rules for the Substitution of Biological Pharmaceuticals under Title 15 Series 17

Dear Mr. Hatfield:

On behalf of our members operating chain pharmacies in the state of West Virginia, the National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment to the West Virginia Board of Pharmacy (Board) on the proposed rules under Title 15 Series 17 implementing recent statutory changes to establish standards for the substitution of biological pharmaceuticals. We thank the Board for considering our input on this rulemaking.

Chain pharmacy supports policies that enable pharmacists to provide cost-effective healthcare to patients. Over the years, pharmacist generic substitution practices have saved patients and payors trillions of dollars.[1] Given the high cost of biological medicines, policies such as the Board's proposed rules for substitution of biological pharmaceuticals are an important step to similarly facilitate access to more affordable versions of biological medications.

While the proposed rules serve to permit the substitution of interchangeable biological products, we have identified two provisions that go beyond requirements enacted under HB 4524 (2018) and warrant further revision:

First, under §15-17-3 (3.1.1.), the Board has proposed language specifying that a pharmacist may dispense an interchangeable biological product if the medication "costs the patient less than the prescribed drug." While this language is likely intended to ensure that patients receive the medication that will cost them the least amount of money, this rule provision may have unintended consequences of disallowing substitution when there is no cost difference to the patient between the brand biological product and the biosimilar version. For example, as brand biological and biosimilar products are still relatively expensive compared to other medications, some pharmacies have observed health plan coverage of both brand biological and biosimilar

[1] GPhA, Generic Drug Access & Savings in the U.S. (June 2017)

products on the specialty tier with the same patient copay amount. Additionally, the Medicaid program covers both brand biological and biosimilar products, and the associated cost to the patient for both is the same.

To align the rules with today's healthcare payment systems, we urge the Board to revise §15-17-3 (3.1.1.) as follows:

§15-17-3. Substitution Requirements.

3.1. A pharmacist may dispense an interchangeable biological product if:

3.1.1. The interchangeable biological product costs ~~the patient~~ less than the prescribed drug product;

…

The second issue that we ask the Board to address relates to the recordkeeping requirements under §15-17-6 (6.1.1). This paragraph would require pharmacies to maintain records noting any substitution instructions communicated orally to the pharmacist by a prescriber, *as well as a notation if the practitioner does not explicitly provide substitution instructions [emphasis added]*. We are concerned that requiring pharmacists to note when the prescriber has not explicitly provided substitution instructions would create an unnecessary recordkeeping requirement, especially considering that if the prescriber had left specific substitution instructions, those would already be noted in the record. We are further concerned that third party payors could use this requirement as an opportunity to audit pharmacy records for the sole purpose of recouping previously paid claims for (expensive) biosimilar prescriptions that lacked the required notation.

In light of these concerns, we ask the Board to revise §15-17-6 (6.1.1) as follows:

§15-17-6. Records.

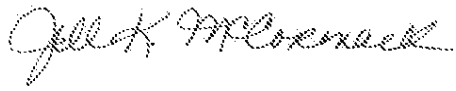
6.1 When a pharmacist dispenses an interchangeable biological product, the following information shall be noted on the original prescription or in the pharmacy's data processing system:

6.1.1. any substitution instructions communicated orally to the pharmacist by the practitioner or practitioner's agent ~~or a notation that no substitution instructions were given~~; and

…

NACDS thanks the Board for considering our view on this rulemaking. Please don't hesitate to contact me with any questions or for further assistance. I can be reached at: 717-525-8962 or jmccormack@nacds.org.

Sincerely,



Jill McCormack
Director, State Government Affairs
jmccormack@nacds.org

Office
2310 Kanawha Blvd. East
Charleston, WV 25311

www.wvbop.com

Phone
(304) 558-0558
(304) 558-0572 (fax)

July 27, 2017

Re: 15 CSR 17 Comments

The Board received comments on 15 CSR 17 from the National Association of Chain Drug Stores ("NACDS"). The Board did not accept the first recommendation of NACDS but did modify the rule as a result of the comment. The Board accepted the recommendation of NACDS's second comment.

Sincerely,

Ryan L. Hatfield
General Counsel