

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

February 11, 2020

The Honorable Shane E. Pendergrass Chair, House Health and Government Operations Committee Room 241, House Office Building Annapolis, MD 21401-1991

RE: HB0316 – "Public Health – Schedule II Controlled Dangerous Substance – Partial Filling of Prescriptions" – Letter of Information with Amendments

Dear Chair Pendergrass and Committee Members:

The Maryland Department of Health (the Department) respectfully submits this letter of information for House Bill 316 entitled "Public Health – Schedule II Controlled Dangerous Substance – Partial Filling of Prescriptions".

HB 316 proposes adding language to clarify State requirements for partial-filling of Schedule II Controlled Dangerous Substance (CDS) prescriptions related to:

- Authorizing the partial-filling of prescriptions;
- Regulating who may request a partial-filling of a prescription;
- Allowing a partially-filled prescription to be transferred between pharmacies;
- Stating the timeframe in which the remainder of the fill may occur; and
- Regulating the billing process of the partially-filled prescriptions.

Authorizing and regulating partially-filled Schedule II CDS prescriptions will make it easier for some patients to access their medication. According to Federal regulations, however, pharmacies must have a signed, written prescription in order to dispense a Schedule II prescription, and the original prescription must be kept on file at the dispensing pharmacy. HB 316, as written, would allow a second pharmacy to fill the remainder of a partially-filled Schedule II prescription without an original prescription, thereby violating Federal regulations. Even if one assumes that the proposed legislation mandating e-prescribing of Schedule II drugs passes this session, HB 316 will still be in conflict with federal regulations regarding the original prescription. That is because the original written or electronic prescription must stay with the original pharmacy that dispensed the Schedule II drug.

Additionally, this bill allows a pharmacy up to sixty (60) days after the initial partial-filling for a patient to request the rest of a partially-filled prescription, whereas federal law allows only thirty (30) days for a patient to make the same request, except in certain rare circumstances.

The bill also requires carriers to treat a partially-filled prescription that is completed at a later date as a single fill for the purposes of copayment/coinsurance, etc. This prevents the patient from being charged twice for a single prescription, but it concerns the Department when a partially-filled prescription transfers between pharmacies. The bill does not identify how the second pharmacy would submit their claims for payment, nor does it specify any other reimbursement methods.

HB 316 is also in conflict with the Department's Corrective Managed Care (CMC) Program. The CMC Program monitors and promotes the appropriate use of CDS. The program seeks to identify participants who may be utilizing excessive quantities of controlled drug substances, especially when it involves multiple prescribers and pharmacies. The CMC enrolls patients in the program if they receive six (6) controlled substances prescriptions from either three (3) different prescribers or three (3) different pharmacies in a thirty (30) day period. The initial "lock-in" period is for two (2) years. A participant who is "restricted" or "locked-in" must obtain all their prescription medications from a single pharmacy until the restriction is lifted. If a participant attempts to fill a prescription at a different pharmacy, the CMC program rejects it during the claim adjudication process.

This bill would have a significant fiscal impact on the Department. The pharmacy computer systems are not currently built to comply with HB 316, so an additional configuration costing approximately \$500,000 in total funds *per system* would be required. This accounts for approximately \$5 million total funds in development costs between the Department's Fee-For-Service system and the nine MCOs. While not as substantial as the development cost, there will be additional costs to Medicaid in order to pay professional dispensing fees for each partial-fill of a prescription.

The Department joins the Board of Pharmacy in suggesting two technical amendments that would effectuate the intent of HB 316. Please see the next page.

I hope this information is useful. If you would like to discuss this further, please contact Director of Governmental Affairs Webster Ye at (410) 260-3190 or webster.ye@maryland.gov.

Sincerely,

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Robert R. Neall Secretary

Maryland Department of Health and Board of Pharmacy Amendments to HB 316:

AMENDMENT NO. 1

On page 3, line 10, after the word "patient" and before the full stop, insert "<u>OR THE</u> <u>PRACTITIONER WHO WROTE THE PRESCRIPTION"</u>.

Rationale: The bill as currently written appears to only allow a partial fill if it is requested by a patient. The Department advocates including at the request of the prescriber to further protect patients and ensure clinical flexibility for the physician.

AMENDMENT NO. 2

On page 3, line 16, strike "60" and substitute "**<u>30</u>**".

Rationale: Federal statute (21 U.S.C. \$829(f)(2)(ii)) only allows thirty (30) days for the filling of the remaining balance of a partially filled prescription. There are separate provisions in federal law allow for up to sixty (60) days, but only in the case of terminal illness and certain Long-Term-Care scenarios. This technical amendment aligns the proposed bill with federal law.