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February 13, 2023

To:	The Honorable Joseline Pena-Melnyk
	Chair, Health & Government Operations Committee
From:	The Office of the Attorney General
Re:	House Bill 0241 (State Board of Physicians – Dispensing Permits):
	Letter of Concern with Amendments

The Office of the Attorney General files this letter of concern because the bill would remove inspection authority over physician dispensing permits from the Office of Controlled Substances Administration (OCSA) and vest that authority exclusively in the Board of Physicians (BOP) – which already has authority to conduct inspections. The fact that ongoing illegal conduct by some physicians contributes to the opioid crisis makes appropriate the continued scheme of OCSA oversight. We therefore urge caution against making any statutory changes that would threaten the independence and power of OCSA to oversee physician dispensing of controlled dangerous substances.

The Controlled Dangerous Substance (CDS) Act was enacted to "prevent [CDS] abuse, which results in a serious health problem to the individual and represents a serious danger to the welfare of the people of the State." Md. Code Ann., Crim. Law § 5-102(b)(1)(ii). OCSA enforces the CDS Act from the point of registration through inspection and revocation or suspension when "an imminent danger exists to public health or safety." Md. Code Ann., Crim. Law § 5-308(d). Of crucial importance is the CDS Act's mandate that the summary suspension or revocation proceedings "shall be independent of and not instead of any criminal prosecution or other proceeding under State law." (emphasis added) Md. Code Ann., Crim. Law § 5-308(c)(1). Indeed, OCSA's inspection authority is integral to its summary suspension or revocation authority and removing physician-dispensing inspection authority from OCSA risks running afoul of the intent of the CDS Act.

Maryland's residents and communities continue to suffer under the opioid crisis. They expect and deserve the State's best efforts to prevent illegal conduct of physicians with CDS registrations and dispensing authority which includes, at a minimum, a fulsome review processes by an independent agency.

The BOP has expressed concern that, among other things, the infrequent OCSA inspections are often incomplete and lack the specificity needed for the BOP to exercise its disciplinary authority over dispensing physicians when problems are found. OCSA has maintained it lacks sufficient resources to meet its statutory obligations. The BOP argues this bill would make the process more efficient, but it does so by diverting already scarce resources from OCSA (transferring investigators from OCSA to BOP), further eroding patient protections which are best served by a robust independent inspection process. An alternative approach would be to provide OCSA with additional resources in order to maintain the independence of inspections, especially while opioid overuse is still epidemic, and ensure the BOP has the inspection information it needs to discipline dispensing physicians when necessary.

Additionally, housing dispensing permit inspections with the BOP creates challenges for law enforcement. While the BOP can provide information to law enforcement when they deem it appropriate, it is important to recognize that Md. Code Ann., Health Occ. § 14-410 could render the investigative information inadmissible at any resulting trial, causing law enforcement to lose valuable time re-investigating to obtain useful evidence that would be admissible without challenge under § 14-410. The duplication of effort the BOP wishes to be relieved of would not be eliminated, but instead would be shifted to the other agencies who have co-responsibilities for enforcing the CDS Act. This is a restriction that does not affect OCSA in their inspection activities and resulting referrals. One advantage of keeping independent inspection authority with OCSA is there is no such prohibition against the admissibility of their investigative information.

The Office offers several amendments to the bill that would ameliorate some of the Office's concerns; with these amendments the Office would be neutral. We offered these amendments to the sponsor of the Senate bill, but they were largely rejected, most importantly the amendment we propose to avoid potential conflicts of interest when inspecting BOP members and the amendment that would allow BOP investigative material to be shared and admissible in criminal proceedings and civil administrative proceedings brought under Md Code Ann., Commercial Law §§ 13-401-407, 13-409-410; Md Code Ann., General Provisions §§ 8-101, et seq.; or Md Code Ann., Health - General § 2-601, et seq. Concern about the latter amendment is not without some merit, as we suspect the BOP prosecutors worry that such an amendment would have a chilling effect on their ability to enter into consent orders with misbehaving practitioners who might be reluctant to cooperate should evidence be admissible outside any disciplinary proceeding. But this conflict is indeed what makes the bill so problematic. At the very least, a legislative mandated work group to iron out the conflicts between administrative

and judicial proceedings and across agencies so that each entity can effectively carry out their charge to protect Marylanders would seem warranted.

Lastly, while the Office recognizes the totality of the physician dispensing permit processes is outside the scope of this bill, we think it merits a comprehensive and critical review, particularly in relation to the dispensing of controlled dangerous substances. The Board of Physicians may issue a dispensing permit if the permit is "in the public interest," meaning the dispensing of drugs or devices by a licensed physician "to a patient when a pharmacy is not conveniently available to the patient." Md. Code Ann., Health Occ. § 12-102(a)(2). Given the continuing opioid epidemic, this standard may be too broad to include controlled dangerous substances in a dispensing permit.

cc: <u>heather.bagnall@house.state.md.us</u>

SB161 – State Board of Physicians – Dispensing Permits OAG Amendments

Board Member Conflict

- 1. On page 10, line 9, after "(E)(1)(I)" INSERT "EXCEPT AS PROVIDED IN (III),"
- 2. On page 10, line 9, after "(II)" INSERT "EXCEPT AS PROVIDED IN (III),"
- 3. On page 10, at the end of line 14, after "PERMIT." INSERT "(III) IF A DISPENSING PERMIT IS ISSUED TO A MEMBER OF THE BOARD, OR IF THE BOARD MEMBER WORKS FOR OR HAS ANY BUSINESS INTEREST IN THE OFFICE TO BE INSPECTED, THE OFFICE OF CONTROLLED SUBSTANCES ADMINISTRATION SHALL ENTER AND INSPECT THE OFFICE. THE OFFICE OF CONTROLLED SUBSTANCES ADMINISTRATION SHALL REPORT TO THE SECRETARY ANY VIOLATION RELATED TO CONTROLLED DANGEROUS SUBSTANCES FOUND DURING AN INSPECTION."

OCSA Records

1. On page 10, line 25, after "(2)" insert "COPIES OF".

Admissible Evidence

On page 10, after line 18, INSERT,

"Article - Health Occupations

§ 14-410. Records not admissible or discoverable

In general

(a) Except by the express stipulation and consent of all parties to a proceeding before the Board, a disciplinary panel, or any of its other investigatory bodies, in a civil [**or criminal**] action:

- (1) The proceedings, records, or files of the Board, a disciplinary panel, or any of its other investigatory bodies are not discoverable and are not admissible in evidence; and
- (2) Any order passed by the Board or disciplinary panel is not admissible in evidence.

Civil actions

(b) This section does not apply to a civil action brought by a party to a proceeding before the Board or a disciplinary panel who claims to be aggrieved by the decision of the Board or the disciplinary panel.

(C) THIS SECTION DOES NOT APPLY TO A CIVIL OR ADMINISTRATIVE ENFORCEMENT PROCEEDING BROUGHT UNDER MD CODE, COMMERCIAL LAW, §§ 13-401-407, 13-409-410; MD CODE, GENERAL PROVISIONS, §§ 8-101, ET SEQ.; OR MD CODE, HEALTH - GENERAL, § 2-601, ET SEQ.

Disclosure in other proceedings

(D) If any medical or hospital record or any other exhibit is subpoenaed and otherwise is admissible in evidence, the

use of that record or exhibit in a proceeding before the Board, a disciplinary panel, or any of its other investigatory bodies does not prevent its production in any other proceeding.

§ 14-411. Records subject to disclosure

Record defined

(a) In this section, "record" means the proceedings, records, or files of the Board or a disciplinary panel.

In general

(b) Except as otherwise expressly provided in this section, § 14-410, AND § 14-411.1 of this subtitle, the Board, a disciplinary panel, or any of its other investigatory bodies may not disclose any information contained in a record.

Disclosure allowed

(c) Nothing in this section shall be construed to prevent or limit the disclosure of:

(1) General licensure, certification, or registration information maintained by the Board, if the request for release complies with the criteria of § 4-333 of the General Provisions Article;

(2) Profile information collected and disseminated under § 14-411.1 of this subtitle; or

(3) Personal and other identifying information of a licensee, as required by the National Practitioner Data Bank for participation in the proactive disclosure service.

Physician discipline

(d) The Board shall disclose any information contained in a record to:

(1) A committee of a hospital, health maintenance organization, or related institution if:

(i) The committee of a medical hospital staff concerned with physician discipline or other committee of a hospital, health maintenance organization, or related institution requests the information in writing;

(ii) A disciplinary panel has issued an order as to a licensed physician on whom the information is requested; and

(iii) The Board determines that the information requested is necessary for an investigation or action of the committee as to a medical privilege of a licensed physician; [or]

(2) The Secretary, the Office of Health Care Quality in the Department, the Maryland Health Care Commission, or the Health Services Cost Review Commission for the purpose of investigating quality or utilization of care in any entity regulated by the Office of Health Care Quality or the Health Services Cost Review Commission;

(3) THE OFFICE OF THE ATTORNEY GENERAL FOR PURPOSES OF INVESTIGATIONS OR CIVIL ENFORCEMENT ACTIONS UNDER MD CODE, COMMERCIAL LAW, § 13-401, ET SEQ.; MD CODE, GENERAL PROVISIONS, § 8-101, ET SEQ.; OR MD CODE, HEALTH - GENERAL, § 2-601, ET SEQ.; OR

(4) ANY LAW ENFORCEMENT AGENCY OF THE STATE WHEN SERVED WITH AN APPROPRIATE SUBPOENA."