SB 513- Testimony of Dr. Kashif Firozvi- Oncologis

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February 15, 2021

Re: Senate Bill 513- Cancer Drugs- Dispensing and Coverage: FAVORABLE

Madam Chair and Committee Members,

SB 513 is a bill that aims to improve access to life-saving oral oncology drugs for patients fighting cancer by reducing unnecessary obstacles that result in delays, waste and poor outcomes. It achieves this by ensuring that Medically Integrated Dispensing Pharmacies that are already providing oral drugs for patients, would be able to do so through:

- the ability to prescribe refills and
- to ensure that drugs are able to be delivered to a patient's home when it's not feasible for them to come to the pharmacy because of their underlying medical conditions.

Oncology Care is a complex, multi-disciplinary service that requires careful care coordination and attention to details that can change from minute to minute. Patients have been getting their oncology treatments in oncology clinics in an efficient, coordinated and caring fashion for many years and this success has allowed patients to "live with cancer" and maintain a better quality of life during their battle. Over the years, more and more oncology drugs are manufactured in an oral formulation. Up to 50% of newly approved oncology drugs are oral agents. These drugs are often given alone or in combination with other Intravenous drugs. Oncology Clinics are equipped to quickly prescribe, authorize and deliver IV drugs within 24-72 hours. Sadly, that is not the case with Oral oncology drugs that are often required to be prescribed through PBM owned specialty pharmacies. This requirement results in delays, stress and uncertainty when obtaining these drugs because "patients are forced to wait for medicine to be shipped, rather than walk across a hallway to purchase it." (1)

Medically Integrated Pharmacies achieve several advantages over utilizing PBM Specialty pharmacies.

1. **Better care coordination** – Ensuring that pharmacies, patients, caregivers and physicians are all on the same page is essential to achieving the best outcomes. These drugs are oral but not benign. There are many side effects that can be impacted by changes in a patient's medical condition that require awareness of fluctuations in a patient's lab parameters, their physical condition and their potential for drug-drug interactions. PBMs do not talk to physicians and struggle to connect and communicate with patients. PBMs also do not have access to patient's EMRs. I have never once in my nearly 20 years of practice received a call from a PBM pharmacist asking for information on a patient's medical condition, but I regularly receive emails and communication from my MIDP pharmacists, who are regularly reviewing the patient's medical records.
2. **Reduced Waste** – As PBMs do not know what is happening to the patient outside of asking the patient if they "are still on the drug" they regularly automatically refill drugs to patients with no awareness that these drugs may no longer be appropriate because of progression of their disease or because the drug may need dose modification because of changes in the patient's liver or kidney function. These drugs are very expensive and can cost over $10,000 a month. I regularly receive patients returning drugs that were unnecessarily sent to them, not knowing what to do with these over-refills.
3. **Delays in Delivery** – very often, these drugs require lengthy authorization processes or copay assistance applications. The process entailed requires significant back and forth communication between the office and the patient. PBM Pharmacies regularly struggle with even making contact with the patient through a maze of phone-tags. Patients often do not pick up the phone from unknown numbers out of fear that it is spam. The

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result is that there are delays in obtaining these drugs which can result in increase in mortality. One recent study (2) done demonstrated the turnaround times for integrated pharmacies vs remote specialty pharmacies:

a. Integrated Pharmacy A
    i. Integrated Turnaround time: 2.5 days
    ii. External Specialty Pharmacy: 23 days
b. Integrated Pharmacy B
    i. Integrated Turnaround Time: 2.4 days
    ii. External specialty pharmacy: 14 days
c. Integrated Pharmacy C
    i. Integrated turnaround time: 1.3 days
    ii. External specialty pharmacy: 9.7 days

Patients overwhelmingly prefer obtaining their drugs from medically integrated pharmacies where pharmacists and doctors are in regular communication and where staff can ensure prompt delivery of those drugs to patients. A survey of 1200 patients (3) demonstrated that patients prefer receiving their specialty drugs from MIDs as opposed to specialty pharmacies. In addition, adherence rates for drugs have been shown to be as high as 93% when prescribed through an MID.

- The American Society of Clinical Oncology (ASCO) released a policy statement recommending that CMS "prevent PBMs from excluding qualified in-office dispensing or provider led pharmacies from its networks." (4)
- The Community Oncology Alliance (COA) has been publishing a series of "Pharmacy Benefit Manager Horror Stories" that describe how "the United States' health care system continues to be strangled by the dark presence of these ever-growing corporate middlemen." (1)
- The American College of Physicians (ACP) has issued policy recommendations for PBMs asking for more transparency and a ban on "gag clauses" that prevent pharmacies from sharing pricing information with consumers. (5)

MIDs are more efficient, more coordinated, more preferred and more economic all resulting in better outcomes than the current model that utilizes PBM-owned specialty pharmacies. HB 170 does not overstretch its territory into areas where retail pharmacies remain vital services for patients. MIDs only focus on oncology drugs and other specific oncology-related drugs in an effort to make the lives of our patients easier as they deal with the biggest fight of their lives. It is our responsibility to remove obstacles for these patients, not put more in their way. There is **absolutely no scenario** where using PBMs over MIDs is better for patients and it is our hope that you will put patient interests first and support the passing of SB 513 so that patients can have easier access to life-saving drugs. This bill will not only save money and time, but more importantly- save lives.

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MDCSCO
MARYLAND/DISTRICT OF COLUMBIA SOCIETY OF CLINICAL ONCOLOGY

TO: The Honorable Delores G. Kelley, Chair
Members, Senate Finance Committee
The Honorable Brian Feldman

FROM: Danna L. Kauffman
J. Steven Wise
Pamela Metz Kasemeyer

DATE: February 17, 2021

RE: **SUPPORT** – Senate Bill 513 – *Cancer Drugs – Physician Dispensing and Coverage*

The Maryland State Medical Society (MedChi) and the Maryland/DC Society of Clinical Oncologists **support** Senate Bill 513. Senate Bill 513 authorizes a physician to dispense by mail or other commercial method a starter dosage of a cancer drug or device or an initial or refill prescription of a cancer drug. In addition, the bill requires that an insurer or pharmacy benefits manager allow a covered individual to obtain from a dispensing physician a covered specialty drug that is a cancer drug (oral oncology).

Senate Bill 513 seeks to streamline care for the patient and prescribing physician by allowing the patient to obtain cancer drugs from the prescribing physician rather than from a third party – the specialty pharmacy. Requiring these drugs to come through a specialty pharmacy adds another layer to the care paradigm. The patient's physician develops and executes the treatment plan for the patient, including the prescribing of cancer drugs. As a result of this trusted relationship, patients come to their oncologist for further education and to have questions answered regarding their course of drug treatment rather than the specialty pharmacy, regardless of this being the role and responsibility of the specialty pharmacy. By allowing for the removal of the specialty pharmacy from the equation, the physician can ensure that the patient receives the prescribed drug in a timely manner without communication delays occurring between the specialty pharmacy and the patient, including the ability for the physician to expedite the adjusting of doses and to monitor for side effects. Senate Bill 513 does not negate the need for the physician to be part of the insurer's pharmacy network nor does it circumvent utilization review policies and procedures. We urge a favorable vote.

For more information call:
Danna L. Kauffman
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Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Acting Secretary

Maryland Board of Pharmacy
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February 17, 2021

The Honorable Delores G. Kelley
Chair, Senate Finance Committee
3 East, Miller Senate Office Building
Annapolis, MD 21401-1991

RE: SB 513 – Cancer Drugs—Physician Dispensing and Coverage – Letter of Opposition

Dear Chair Kelley and Committee Members:

The Maryland Board of Pharmacy (the "Board") submits this Letter of Opposition for SB 513 – Cancer Drugs—Physician Dispensing and Coverage and respectfully requests an unfavorable report on this bill.

Our opposition to this bill is primarily based on the fact that the treatment and diagnosis of cancer is outside of the physician's scope of authority. Pharmacists are very familiar with the procedures, supply chain, case management, and methods of cancer drug administration that make them uniquely equipped for the practice of cancer drug administration. In addition, pharmacists are trained to protect their patients from cancer medications and treatments such as chemotherapy by reviewing the patient's medicine regimen with them and managing dosage based on individual factors such as weight, and vital organ function. Removing this check would place patients at a higher risk for adverse effects. Finally, pharmacists work in teams and are familiar with the information needed by insurance companies to receive approval for insurance claims associated with cancer drug treatment. For more information, please see the attached position paper.

I hope this information is useful. If you would like to discuss this further, please contact me at deena.speights-napata@maryland.gov or the Board's legislative liaison, Iman Farid, at iman.farid@maryland.gov.

Sincerely,
DEENA SPEIGHTS-NAPATA

Deena Speights-Napata, MA
Executive Director

MARYLAND BOARD OF PHARMACY

2021 SESSION
POSITION PAPER

BILL NO: SB/513
COMMITTEE: House Health Government and Operations
Committee POSITION: Opposed

TITLE: Cancer Drugs—Physician Dispensing and Coverage

POSITION AND RATIONALE: Opposed

This bill allows physicians to dispense cancer drugs, including refills, through the mail. This would effectively deprive a vulnerable patient population of the drug utilization review and monitoring services of specialty pharmacists under the current medication delivery model. Just as oncologists are specifically trained and experienced in diagnosing and treating cancer, specialty pharmacists are trained and experienced in the appropriate selection, dosing, monitoring and safe utilization of high-risk cancer medications. This bill relegates the vital component of cancer drug therapy from specialty pharmacists, who are the drug experts, to oncologists who do not have the experience, resources or time to effectively monitor a patient's medication therapy in addition to their existing demanding practice. Ultimately, this bill may cause increased risk to an already vulnerable patient population who, due to their compromised medical conditions, make identification of medication errors or adverse reactions more difficult to identify.

There is an entire section of pharmacy and a complicated existing set of processes and supply chains, that go well beyond simply putting a medication into the patient's hands, dedicated to making sure specialty medications such as the cancer drugs cited here are used appropriately and safely.

- Additionally, specialty pharmacists provide valuable case management to their patients that helps to ensure continued adherence as well as side effect management.

While you may hear anecdotal evidence regarding delays to dispensing certain cancer drugs, please understand that the most common reason for delays is often tied directly to the fact that the pharmacist is going through a comprehensive set of safety checks or awaiting necessary labwork. Although pharmacists always make every effort to provide medication to the patient without delay, a pharmacist may not disregard integral processes intended to ensure the accuracy, appropriateness and safety of these high-risk medications. In other words, they have to make sure that they have the lab work and other supporting documentation to ensure that it is the right medication at the right dose for the patient at that time, and ensure all clinical and administrative documentation is complete so that once the regimen is started, there is no interruption of therapy that could interfere in the effectiveness of the regimen. Furthermore, there is no added convenience to the patient in receiving the medication through the mail from the patient's physicians versus the patient's mail-order pharmacy. Conversely, mail-order pharmacies are specifically operationalized to safely deliver medications and timely respond

to patient medication inquiries, whereas physician practices are not designed nor intended to provide these types of services.

- Safety:
    - One of the most valuable services pharmacists provide is protecting our patients from adverse effects of their medications. This service especially comes into play when discussing high-risk medications such as chemotherapy. We look at the patient's entire medication regimen to make sure drugs don't interact with each other. We calculate and verify dosages based on kidney function, liver function, body surface area, and body weight to ensure they are safe for the patient to take at that moment.
    - By removing this check we're placing our patients at higher risk for adverse effects.
    - Almost all chemotherapy agents are part of Risk Evaluation and Mitigation Strategy (REMS) programs setup by the FDA which have specific requirements that must be met before the medication can be dispensed. Specialty pharmacists have expertise in this area to make sure that each strategy is appropriately followed.
    - Specialty pharmacies have established supply chains for obtaining these medications and have processes in place to make sure that the medications are available for patients as they are due for refills. Some of these chemo agents are part of a limited distribution network – providers won't have any better access to these medications than a pharmacy excluded from the network.

- Insurance:

    - Most oral chemotherapy medications require a prior authorization from the patient's insurance company before they can be billed successfully and dispensed.
    - Specialty pharmacies have teams of pharmacists and technicians who specialize in getting the information necessary to get these approvals from the insurance companies so that the process moves smoothly for the patients.
    - Insurance companies may also be very hesitant to allow providers to bill for these high cost medications, without the independent double check that these medications are being used in the most appropriate and safest manner possible. They often have very complex rebate programs in place that allow them to do their best to control the cost of chemo and other specialty medications. Fragmenting the delivery system of these high-risk and high-cost medications can interrupt the rebate structure causing the cost of the medication to increase dramatically and result in delays in patient treatment.

In a time when we're all trying do everything we can to increase the quality and safety of medication use while at the same time containing the skyrocketing costs of care, the last thing we should be doing is fragmenting the drug dispensing process, eliminating the pharmacist safety

check and coordination of care, and interrupting the complex system of checks and balances that ensures that these medications are used safely and appropriately.

For more information, please contact Deena Speights-Napata, Executive Director at deena.speights-napata@maryland.gov or Iman Farid, Legislative Liaison for the Board, at iman.farid@maryland.gov.

THE VIEWS IN THIS POSITION PAPER DO NOT NECESSARILY REFLECT THE MARYLAND DEPARTMENT OF HEALTH OR THE ADMINISTRATION.

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Maryland
DEPARTMENT OF HEALTH

Board of Physicians

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Damean W.E. Freas, D.O., Chair

2021 SESSION
POSITION PAPER

BILL NO: **SB 513**
COMMITTEE: **Education, Health, and Environmental Affairs**
POSITION: **Information**

TITLE: Cancer Drugs – Physician Dispensing and Coverage

BILL ANALYSIS: This bill authorizes a physician with a valid dispensing permit to personally dispense to a patient or a patient of the physician's practice, by mail or other commercial method (1) a starter dosage of a cancer drug or device or (2) an initial or refill prescription of a cancer drug. Carriers must allow an insured or enrollee to obtain a covered specialty drug that is a "cancer drug" from a dispensing physician. A pharmacy benefits manager (PBM) must allow a beneficiary to obtain a cancer drug from a dispensing physician

POSITION AND RATIONALE: The Maryland Board of Physicians (the "Board") is submitting Information for SB 513 – Cancer Drugs – Physician Dispensing and Coverage. SB 513 would expand physician dispensing, as permitted under Md. Code Ann., Health Occ. §12-102(c)(2)(ii), to include dispensing cancer drugs or devices, starter doses or devices, and initial or refills of cancer drugs via mail order.

According to the pharmacy statutes, a physician may only dispense after demonstrating to the satisfaction of the Board that the dispensing is "in the public interest," which is defined as when a pharmacy is not conveniently available to the patient.[1] This is further codified in regulations, which only authorize physician dispensing in cases when the patient determines that a pharmacy is not conveniently available.[2] The Board addressed dispensing via mail order and refill prescriptions with stakeholders during the promulgation of its dispensing regulations and concluded that dispensing through mail order and refills were not permitted because a pharmacy would be conveniently available in these circumstances. As such, the Board's regulations expressly prohibit dispensing through mail order and refills.[3] The Board is unclear how permitting dispensing by mail order and refills would satisfy the requirement of being in the public interest, which is defined as a pharmacy not being conveniently available.

[1] Md. Code Ann., Health Occ. §12-102(c)(2)(ii)2.C

[2] COMAR 10.13.01.04(M)

[3] COMAR 10.32.23.06C

Further, the inclusion of initial doses or refills on page 2, line 10 seems vague, because the dispensing of starter doses is already an exception to the dispensing permit requirement.[4]

Lastly, while "cancer drug" is defined on page 4, lines 26 and 27, this definition is vague; and raises the question of whether it is clear what drugs are considered "cancer drugs". If there is no clear understanding of what are cancer drugs, that may be an enforcement issue.

Out of the 33,273 currently licensed physicians, there are 705 active dispensing permits. Of those active permits, there are 47 physicians that are primarily Internal Medicine/Oncology, with one physician counted twice for two oncology specialties. This data request was run with the identified ABMS/AOA specialties. Out of 33,273 current licensed physicians, this legislation would impact 0.001%.

As the entity for physicians that issues dispensing permits, the Board has encountered ongoing concerns with the dispensing statute. Every legislative session there are dispensing carve out proposals for a unique set of providers. The Board believes that the statute needs to be reviewed and updated instead of piecemeal changes, and would support a workgroup of stakeholders to accomplish this.

For more information, please contact Wynee Hawk, Manager, Policy and Legislation, Maryland Board of Physicians, 410-764-3786.

The opinion of the Board expressed in this document does not necessarily reflect that of the Maryland Department of Health or the Administration.

[4] Md. Code Ann., Health Occ. §12-102(f)

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February 17, 2021

To: The Honorable Delores G. Kelley
Chair, Finance Committee

From: Patricia F. O'Connor, Health Education and Advocacy Unit

Re: Senate Bill 513 (Cancer Drugs – Physician Dispensing and Coverage): Information

The Office of the Attorney General's Health Education and Advocacy Unit (HEAU) submits information relevant to Senate Bill 513 which would allow physicians to dispense oral cancer drugs by mail order to their patients or patients of their practice group. A patient-centric focus and evidence-based decision making about these issues are essential to protecting consumers who require oncology care in Maryland.[1]

Impartial physician judgment is an important consumer protection

Consumers rely on the impartial judgment of physicians to order medically appropriate and necessary treatment for them. In an ethics opinion, the American Medical Association (AMA) stated: "The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. The relationship between a patient and a physician is based on trust, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own

[1] A 2019 article described current market dynamics at odds with a patient-centric focus: "Cancer treatment has never been cheap. But the cost of oncology drugs in the U.S. has become jaw-dropping, and where there are big dollars, business interests compete. And in the world of oncology, that "battle ground" is between cancer doctors and pharmacy benefit managers." https://www.marketplace.org/2019/07/29/the-battle-over-who-gets-to-sell-pills-for-cancer-treatment/

self-interest or obligations to others[.]" Code of Medical Ethics Opinion 1.1.1, https://www.ama-assn.org/delivering-care/ethics/patient-physician-relationships.

A disciplinary panel of the Maryland Board of Physicians ('the Board") may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee is found guilty of immoral or unprofessional conduct in the practice of medicine. Md. Code Ann., Health Occ. § 14-404(a)(3)(i)-(ii). The Board and its disciplinary panels may consider the AMA's Principles of Ethics, but the principles are not binding on the Board or the disciplinary panels. COMAR 10.32.02.16 (Ethics). In an ethics opinion specifically addressing drug prescriptions, the AMA stated: "In keeping with physicians' ethical responsibility to hold the patient's interests as paramount, in their role as prescribers and dispensers of drugs and devices, physicians should [p]rescribe drugs, devices, and other treatments based solely on medical considerations, patient need, and reasonable expectations of effectiveness for the particular patient [and a]void direct or indirect influence of financial interests on prescribing decisions[.]" Code of Medical Ethics Opinion 9.6.6, https://www.ama-assn.org/delivering-care/ethics/prescribing-dispensing-drugs-devices

Cancer treatment decisions require impartial judgment about all options

The bill would allow physician mail order dispensing of oral cancer drugs. However, in addition to surgery and radiation therapy, oncology treatment options typically include periods of watchful waiting; infusions of standard chemotherapeutic agents with long established risks and benefits; and oral cancer drugs, including novel or newer oral cancer drugs with less established risk/benefit profiles. At stake are the potential for a cure, as well as the patient's quality of life and extension of life, when a cure is not possible. Cancer patients understandably report being overwhelmed by treatment decisions and often depend on their oncologists' judgments about the best plan of treatment.

An *Oncology* journal article entitled "Decision Making Criteria in Oncology," stated: "Due to a variety of cancers, healthcare systems, treatment options, and individual factors, a plethora of different criteria are being implemented in routine clinical decision making in oncology. This has been demonstrated in decision making analyses of clinical experts. For example, treatment algorithms for the first-line systemic therapy for metastatic clear cell renal cell carcinoma from 11 international experts were analyzed and up to 6 different treatment options were identified for the same specific presentation of the disease. … When oncologists and patients are confronted with multiple decision options, their choice is influenced by several factors extending beyond rational or analytical decision making models." https://www.karger.com/Article/FullText/492272 (emphasis added).

Legislators cannot verify competing claims about drug costs without full data

Requiring full data transparency about oral oncology drug costs and profits from oncologists and PBMs would be an important first step in ensuring affordability and accessibility for Maryland consumers without undue risk of unintended consequences.

In closing, we urge the General Assembly to act with caution to ensure that allowing physician mail order dispensing of oral cancer drugs will not affect the medical advice that oncology patients receive. We thank the Committee for considering this information.

cc: Sponsor