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September 26, 2017

The Honorable Elizabeth Warren
United States Senate
317 Hart Senate Office Building
Washington, DC 20510

The Honorable Shelley Moore Capito
United States Senate
172 Rayburn Senate Office Building
Washington, DC 20510

Dear Senator Warren and Senator Capito:

On behalf of the physician and medical student members of the American Medical Association (AMA), thank you for your efforts to end the nation's opioid epidemic, including your strong support for state-level implementation of "partial fill" policies. The AMA was proud to support this provision in the Comprehensive Addiction and Recovery Act (CARA) as part of a public health approach to reversing the nation's opioid epidemic.

The AMA strongly supports partial fill because it will:

- Help encourage discussions between physicians and patients about expected duration of pain and strategies to address that pain;
- Empower the physician and the patient to request fewer opioids on a trial basis to reduce the likelihood of unwanted or unused medication available for diversion and misuse; and
- Protect a patient's access to pain relief if the initial partial fill is not sufficient to adequately control his or her pain.

Following enactment of CARA, the AMA drafted model state legislation (attached) that would implement partial fill. We are very pleased that the California Medical Association (CMA) has been a leader in advancing this legislation, and California Assembly Bill 1048 now sits on the governor's desk for signature. We have urged Governor Brown to sign. We also are aware that state regulators in Ohio and Iowa have taken action to implement partial fill.

We continue to urge our state medical association partners to work with legislators to have this bill introduced, and we are encouraged that many have expressed interest. We also have shared the AMA model bill with the National Governors Association and many other stakeholders encouraging their support, and we welcome the opportunity to see partial fill enacted in every state.

In response to your specific questions:

1. Have we communicated to our members about partial fill?

   Yes. As outlined above, we made this a key component of our advocacy efforts to reverse the nation's opioid epidemic.

2. Have we developed successful strategies to increase public awareness, including working with patient groups and advocacy organizations?
   The AMA has promoted its model bill to many patient groups and advocacy organizations. The reality, however, is that partial fill discussions are overshadowed by policies to restrict patients' access to prescription opioids. Many patient groups remain fearful that any effort to implement policies—even those as reasonable as partial fill—will be implemented in a way that prevents patients with cancer or chronic pain, for example, from obtaining the pain relief they need.

3. Have we developed any successful strategies for increasing our members' awareness of the option to partially fill prescriptions?

   We plan on working with the CMA and others to increase awareness. While we regularly promote the option of partial fill, we recognize that state laws need to be enacted to fulfill the partial fill promise. We will also work with additional state medical associations to promote this option as it becomes available.

4. Have we encountered any challenges to implement partial fill legislation?

   In some states, we have encountered concerns that this legislation—particularly with its protections for patient co-pays—has been opposed by some health insurers. We also have heard concerns about how pharmacists will implement the provisions contained in our model bill. While we appreciate those concerns, we believe that the focus should be on empowering patients and physicians to ensure the most effective care. And as the pending law in California demonstrates, the challenges can be overcome.

5. What information or assistance would be helpful on a federal level to support our efforts to encourage members to use partial fill?

   We believe that as more states enact partial fill legislation, our members will use it. An ongoing challenge expressed by our members and their patients, however, is that the incredible amount of new state policy to reduce opioid prescribing may have unintended consequences, including overriding the reasonableness of partial fill. While we believe partial fill encourages patients and physicians to have thoughtful discussions, some new state policies may preclude such discussions.

For example, many new policies have a limit on the "initial" opioid prescription for acute pain. Yet, we continue to hear from patient groups and others that many patients with chronic pain or cancer are caught up in these laws and left without legitimate pain relief. This is clearly not the intent of the laws, but no one has systematically evaluated the effects of these laws on patients. We would welcome your help to determine the effects of these laws so that we can ensure evidence-based prescribing without causing harm to those who benefit from opioid therapy. In addition, we welcome your thoughts on how to help the AMA and our members increase access to non-opioid forms of pain care. It is a constant challenge for our members to prescribe non-opioid treatments because of health insurance policies that impose prior authorization, other utilization management strategies as well as coverage limits on physical therapy and other treatment.

6. Are there additional federal efforts we believe that would be helpful to limit the amount of unused medication in the home?

Generally, the AMA strongly supports efforts by the Drug Enforcement Administration and others to hold "Take Back" days and increase the availability of take back receptacles throughout communities. To the extent that these activities and resources can be made more common, we welcome your support.

Specifically, in addition to the need to expand access to non-opioid pain care, there is a considerable need to increase access to treatment for patients with a substance use disorder. Here are two areas for your consideration:

- Urge Centers for Medicare & Medicaid Services to waive Medicaid's 16-bed federal limit to treat patients with a substance use disorder. This would allow states to quickly eliminate barriers to treatment resulting from the federal Institutes for Mental Diseases (IMD) exclusion within the Medicaid program. Given that only about 10 percent of the nearly two million patients with a substance use disorder can access treatment, it is essential that treatment capacity be increased as expeditiously as possible. Removing the 16-bed IMD exclusion is an important first step to increasing physicians' ability to care for patients with an opioid use disorder.

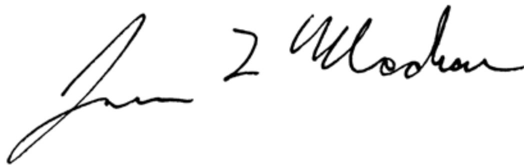
- Urge the Attorney General and state attorneys general to enforce the Mental Health Parity and Addiction Equity Act. This can be done at both the state and federal levels, but America's patients may also need Congress' help to encourage health insurance companies and pharmacy benefit managers to end the type of prior authorization, step therapy, and fail first protocols that only serve as barriers to medication assisted treatment and multimodal pain care. We acknowledge that physicians must continue to educate ourselves and use tools like prescription drug monitoring programs, but when our patients have care delayed or denied due to insurance company policies, it could mean further harm or even death. Some

payers already have taken positive steps to remove some barriers, but this epidemic requires all payers to work with us to ensure access to care.

In closing, I would like to emphasize that the AMA remains committed to ending the nation's opioid epidemic. Through the AMA and our Opioid Task Force, we recently launched a new education and training microsite – www.end-opioid-epidemic.org – that contains nearly 300 state- and specialty-specific resources to encourage physicians' education and training about safe opioid prescribing, increasing access to treatment, prescription drug monitoring programs (PDMPs), co-prescribing naloxone, removing stigma, and safe storage and disposal of opioids. We are very pleased that physicians have made good strides in increasing their use of PDMPs, making more judicious prescribing decisions, increasing co-prescribing of naloxone, and more.

At the same time, we are acutely aware that physicians must continue to be leaders in addressing the nation's opioid epidemic. And we must continue to work with Congress and leaders in the states. We are committed to these actions, and we thank you again for your work to end the nation's opioid epidemic.

Sincerely,



James L. Madara, MD

Attachment

IN THE GENERAL ASSEMBLY STATE OF ____________

An Act to Allow Patients to Partially Fill a Schedule II Controlled Substance

1 Be it enacted by the People of the State of ____________, represented in the General
2 Assembly:

3 **<u>Section 1</u>. <u>Title</u>.** This act shall be known as and may be cited as the "Act to Allow Patients to
4 Partially Fill a Schedule II Controlled Substance.

5 **<u>Section 2</u>. <u>Legislative Findings</u>.**

6 a. The state of [INSERT STATE] is experiencing an opioid epidemic that has resulted in
7 [INSERT MORTALITY FIGURE] deaths due to opioid-related overdose.
8 b. Approximately 70 percent of people who misuse opioids report obtaining them from
9 family, friends or on the street – commonly referred to as "diversion."
10 c. One of the strategies to reduce diversion is to ensure that patients are prescribed the
11 lowest effective dose for the shortest expected duration for expected pain following an
12 acute injury or medical procedure.
13 d. Some patients, however, may not require medication for the full duration of expected
14 pain.
15 e. Rather than rely on a patchwork of efforts to safely dispose of unwanted and unused
16 medication, the [INSERT STATE] Legislature believes that patients and prescribers

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1 should be empowered to request a partial fill of a Schedule II controlled substance, such
2 as Hydrocodone, Morphine and Oxycodone. A full list of Schedule II controlled
3 substances can be found on the U.S. Drug Enforcement Administration website:
4 https://www.deadiversion.usdoj.gov/schedules/orangebook/e_cs_sched.pdf
5 f. Under Section 702 of the federal Comprehensive Addiction and Recovery Act, a
6 pharmacist may partially fill a prescription for a schedule II controlled substance (such as
7 an opioid) if: (1) such partial fills are not prohibited by state law, (2) a partial fill is
8 requested by the patient or prescribing practitioner, and (3) the total quantity dispensed in
9 partial fillings does not exceed the quantity prescribed.
10 **Section 3. Definitions.**
11 a. "Original prescription" shall mean the prescription presented by the patient to the
12 pharmacy or submitted electronically to the pharmacy.
13 b. "Partial fill" shall mean a prescription filled in a lesser quantity than the amount specified
14 on the prescription for a patient.
15 **Section 4. Authorization for Partial Fill of a Controlled Substance Prescription.**
16 a. A prescription for a Schedule II controlled substance may be partially filled if—
17 i. the partial fill is requested by the patient or the practitioner who wrote the
18 prescription; and
19 ii. the total quantity dispensed in all partial fillings does not exceed the total quantity
20 prescribed.
21 b. The pharmacist shall retain the original prescription at the pharmacy where the
22 prescription was first presented and the partially filled prescription dispensed.

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1 c. Any subsequent fills shall occur at the pharmacy that initially dispensed the partial fill
2 subject to the following:
3 i. Any subsequent amount shall be filled within 30 days after the date on which the
4 prescription is written
5 ii. The original prescription becomes null and void 30 days after the date on which
6 the prescription is written.
7 **Section 5. Notification to the Prescriber of a Partial Fill.**
8 a. The pharmacist shall only record in the state prescription drug monitoring program the
9 partial fill actually dispensed.
10 b. The pharmacist shall notify the prescribing practitioner of the partial fill and of the
11 amount actually dispensed by one of the following:
12 i. A notation in the interoperable electronic health record of the patient;
13 ii. Electronic or facsimile transmission;
14 iii. A notation in the patient's record maintained by the pharmacy which shall be
15 accessible to the practitioner upon request.
16 c. Nothing in this subsection shall be interpreted to conflict with or supersede any other
17 requirement established in this section for a prescription of a narcotic substance.
18 **Section 6. Insurance Coverage.**
19 a. A person who presents a prescription for a partial fill pursuant to this Act shall be
20 required to pay the required cost sharing and/or co-pay as required by the person's
21 insurance coverage for the first partial fill.
22 b. A health plan or other payer shall not require the patient to pay any additional cost-
23 sharing for subsequent partial fills of the original prescription.

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1 c. Under no circumstances shall a person be required to pay more in total cost-sharing for
2 partial fills than would be required to pay for the original prescription.

3 **Section 7 Severability.** If any provision of this Act, or the application thereof to any person or
4 circumstance is held invalid, such invalidity shall not affect other provisions of applications of
5 the Act which can be given effect without the invalid provision or application, and to this end the
6 provision of this Act are declared to be severable.

7 **Section 8 Effective Date.** This Act shall take effect on [INSERT DATE].

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