October 21, 2021

The Honorable Merrick B. Garland
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Dear Mr. Attorney General:

On behalf of the American Medical Association (AMA) and the undersigned national medical specialty societies, we are writing to ask your assistance to resolve a harmful interpretation of Section 3204 of Public Law 115-271, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act of 2018 (SUPPORT Act). Section 3204 of the SUPPORT Act amended the Controlled Substances Act to provide that pharmacies may dispense controlled substances for the maintenance or detoxification of opioid use disorder directly to practitioners for injection or implantation in patients. The legislative intent and purpose of Section 3204 was to increase access to implantable and injectable prescription formulations of medications to treat opioid use disorder (MOUD).

There has been a major, growing, and persistent gap between the number of people that need MOUD and the number who are able to obtain them. The regulation issued by the U.S. Drug Enforcement Administration (DEA) to implement Section 3204 cited data from the Substance Abuse and Mental Health Services Administration, for example, that two million people had an opioid use disorder in 2018 but only a fraction received treatment for it at a specialty facility. This treatment gap has contributed significantly to the record number of Americans dying as a consequence of drug-related overdose. The AMA strongly supports a multitude of strategies to end the drug overdose epidemic, foremost among them by increasing access to all forms of MOUD, including the injectable and implantable MOUD addressed by Section 3204. In discussing the implementation of Section 3204, the DEA regulation cited above states the following:

> Under section 829a, a pharmacy is allowed to dispense prescribed narcotic drugs in schedule III, IV, or V, or combinations of such drugs, to a practitioner for the purpose of maintenance or detoxification treatment under 21 U.S.C. 823(g)(2) and certain conditions. Specifically, the prescription must be issued by a qualifying practitioner and the prescription issued cannot be used to supply any practitioner with a stock of controlled substances for the purpose of general dispensing to patients. In addition, the practitioner must meet the following conditions:
>
> 1. The practitioner must administer the controlled substance to the patient named on the prescription:
>   a. By implantation or injection;

b. within 14 days after the date of receipt of the controlled substance by the practitioner.

2. The practitioner and pharmacy are authorized to conduct these activities in the State in which such activities take place.
3. The prescribing practitioner and administering practitioner of the controlled substance maintain complete and accurate records of all controlled substances delivered, received, administered, and disposed including the persons to whom controlled substances were delivered and such other information that the Attorney General may require by regulations.

In a subsequent section of this same regulation, titled "Analysis of Benefits and Costs," the DEA stated with respect to Section 3204: "Because this provision of the interim final rule is simply codifying previous DEA practice and the current law, DEA expects this provision of the interim final rule to result in no costs or benefits."

As a result of discussions with DEA staff months after this regulation was issued, however, the AMA has learned that the Department of Justice (DOJ) does not view Section 3204 as "simply codifying previous DEA practice." Instead, it is our understanding that the DOJ now interprets Section 3204 as prohibiting pharmacies, including compounding pharmacies, from delivering any other prescriptions for controlled substances to physicians for implantation or injection in their patients except for MOUD. **If this interpretation of Section 3204 were to be enforced by the DEA, up to 100,000 patients who rely on intrathecal pain pumps to control the symptoms of extremely painful conditions, such as advanced cancer, would lose access to safe and effective pain control.**

It has been longstanding policy and practice that pharmacies, including compounding pharmacies, can dispense prescriptions for controlled substances to physicians for use in intrathecal pain pump devices. We have been told that DOJ's interpretation of Section 3204 is that, by specifically creating authority for one specific use (i.e., MOUD), there is an absence of authority for any other use. This interpretation, we were told, does not extend to hospital orders, but would affect any physician office that provides pain care via an intrathecal delivery system. We strongly disagree with this interpretation as a matter of flawed statutory interpretation and construction, and because of the grave clinical implications.

This new DOJ interpretation, if allowed to stand and be enforced by the DEA, would lead to immediate delays or denials of effective, evidence-based pain care for the many patients with pain who benefit from intrathecal pumps. As part of the Biden Administration's ongoing effort to bring an end to the epidemic of drug-related overdose and death, it is important to recognize that delivery of prescription opioid analgesics via an intrathecal pump can provide patients with greater pain control at a significantly lower opioid dose compared to oral formulations, thus greatly reducing potential adverse effects from use of oral opioid analgesics. Intrathecal pumps are used for patients with cancer, spinal cord injuries, chronic abdominal pain, cervical spine injuries, osteoporosis, and other non-cancer chronic pain conditions. For <u>some patients</u>, this type

of pain modality is literally a life-saver. We would be happy to provide, either in writing or via conference call, additional information about the potential clinical impacts on patients.

Should DEA begin to enforce the harsh DOJ interpretation, physicians would have no choice but to stop filling the pumps in the office setting. This would force patients into situations including painful withdrawal, seeking care in emergency departments, transitioning to oral therapy, or resorting to finding other sources of pain relief. All of these options are sub-optimal and would subject patients to increased harm. We urge the DOJ to provide clear guidance to physicians that they can continue an evidence-based pain modality that provides safe, effective care.

We emphasize that the majority of pumps are refilled in a physician's office with compounded medications prepared at a USP-797 approved facility. Physicians typically send a high security, tamper resistant controlled substance prescription to the compounding pharmacy. The pharmacy then ships the medications in a sealed syringe via overnight courier to the physician's office. Upon receipt, the medications are locked in a secure location until used for the specific patient's pump refill. At the time of the refill, the old pump medications are removed from the pump and discarded and replaced with the new medications using sterile techniques. Failure to refill the pump at the appropriate time can lead to significant harm. Without clarification from the DOJ that current practice may legally continue, we fear that the DEA will have no choice but to begin enforcement of the new DOJ interpretation.

Some patients may have their pumps refilled in a hospital-based setting, which we understand would still be permissible under the DOJ interpretation, but having all patients go to a hospital-based setting raises considerable challenges in terms of medication delivery, preparation, and access. Not all hospitals have the equipment or procedures to prepare USP-797 grade compounded medications. As a result, the physician managing the patient's care is often asked to obtain medications from the compounding pharmacy by sending the high security, tamper resistant controlled substance prescription to the pharmacy. In this situation, the patient-specific compounded medications are shipped directly to the hospital pharmacy and then used to refill the pump by a qualified physician. Unfortunately, community hospitals may not have physicians who can perform a pump refill, and some hospitals may not have open accounts with compounding pharmacies. So even if a hospital pharmacy was able to prepare the medication by other means or obtain the medication, under the DOJ interpretation of Section 3204, patients with no other recourse than going to a hospital could very likely find that even the hospital is unable to help.

Another group of patients who depend upon intrathecal pumps for pain control are homebound patients (e.g., cancer patients on home hospice or those with severe spinal cord or brain injury) whose pain pump refills are performed in the home. Similar to what is described above, for homebound patients the medications are shipped to the ordering physician's office and then taken to the patient's home for a pump refill. Under the current interpretation of Section 3204 that was relayed to us, homebound patients would face interminable suffering in that they would

no longer be able to have their pain medication needs fulfilled in their home. Surely Congress did not intend to harm so many vulnerable patients.

The examples above represent some of the most common clinical scenarios in which patients with intrathecal pumps have their pumps refilled using patient specific compounded medications with controlled substances. In all of these examples, failure to fill the pump prior to the low volume reservoir alarm could result in withdrawal symptoms for patients who depend on intrathecal opioids for pain control. For compounded mixtures that contain clonidine or baclofen, failure to refill the pump can lead to malignant hypertension or cardiovascular collapse and death, respectively.

It is clear that enforcement of the DOJ interpretation of Section 3204 of the SUPPORT Act would cause significant harm to an enormous number of patients. **To avoid this outcome, the undersigned organizations strongly urge the DOJ to reconsider its interpretation of this statute and issue guidance that aligns with the true intent and purpose of the SUPPORT Act. In particular, we ask the DOJ to clarify that pharmacy dispensing of prescriptions for controlled substances to physicians for use in intrathecal pain pumps remains legal and is not a violation of the SUPPORT Act.**

Thank you for your consideration. If you have any questions, please contact Margaret Garikes, AMA Vice President for Federal Affairs, at Margaret.Garikes@ama-assn.org or 202-789-7409.

Sincerely,

American Medical Association
American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American Society of Anesthesiologists
Association for Clinical Oncology
Congress of Neurological Surgeons
North American Neuromodulation Society