AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Marguerite Quinn
Chair
Workers' Compensation Insurance Committee
National Council of Insurance Legislators
2317 Route 34, Suite 2B
Manasquan, NJ 08736

Dear Chairwoman Quinn:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I am writing to express our strong concerns with the proposed draft of the National Council of Insurance Legislators (NCOIL) "Model Act on Workers' Compensation Repackaged Pharmaceutical Reimbursement Rates" (Model Act). Our concerns stem from multiple provisions within the proposed Model Act that do not take into account the physician's right to dispense drugs and devices when it is in the best interest of the patient and consistent with AMA's ethical guidelines. We urge NCOIL to remove the Model Act from consideration until such time that further study can be done to ensure that its provisions do not have unintended consequences on patients' access to care.

First, we are concerned that the proposed definition of "Compounded Pharmaceutical Products" is overly broad and simultaneously does not include physicians while implicating actions routinely taken by physicians. For example, physicians are among those who prepare sterile drug products or compound pharmaceutical products when in their patients' best interests. As a routine part of medical practice, physicians across a number of specialties frequently prepare sterile drug products in their offices for administration to patients. Preparation of sterile drug products for patients can include activities such as drawing up a steroid joint injection or botulinum toxin injection with a local anesthetic, preparing allergy/ immunotherapy injections for individual patients, buffering lidocaine, and a number of others. In the majority of cases, these activities are routine practices that physicians have been engaging in for years. In many cases, they represent the standard of care for a particular condition. Physicians across specialties have a long history of preparing sterile drug products that provide safe and effective treatments to patients. There is no compelling body of evidence showing these routine activities, when performed in physician offices, pose any increased risk to patients of infection or other adverse event. The physician community maintains that the routine preparation of sterile drug products at the point of care for administration to patients is not a drug compounding activity. These activities, therefore, should not be treated as such and should not be subject to the same oversight and compliance policies as compounding facilities engaged in large volume, high risk manipulations.

As a threshold matter, we urge NCOIL to fully reconsider the premise of what it is seeking to legislate before moving forward with the Model Act.

The second main area of concern, in addition to the need to better understand physicians' clinical practices as described above, are the multiple provisions in Section 5 that could impair patients' access to timely care. For example:

- Section A does not account for physician, in-office compounded medications.
- Section A(1) does not account for situations that might require ongoing care provided directly to a patient. We are not aware of medical evidence that supports a seven-day threshold for ongoing treatment provided directly by a physician.
- Section B, similar to Section A, also suggests that patient care can be provided within a seven-day window from the date of injury when due to factors outside the patient's control, an initial appointment with a physician in the Workers Compensation program of a particular state may not be feasible.
- Section B(1)(a), which we appreciate is titled an "exception" also does not make allowances for the fact that in-office preparations, administration, or dispensing of certain medications would be in the patients' best interests.
- Section C broadly ignores the fact—as described above—that in-office preparation, administration and dispensing of certain medications improve patient care.

Third, in Section 6, the AMA is particularly concerned by both 6(B) and 6(C). Both, of these sections serve to potentially restrict access to products, which allows for potential exclusion of all compounded products. For patients with an allergy or other intolerance to certain drug products or fillers included in branded medications, this could have a severe impact on patient safety. The potential to restrict distribution channels, moreover, potentially creates additional access-to-care issues and presumes that pharmacy benefit management companies will act in the patient's best interests when their fiduciary responsibility is to the health plan and/or employer client.

Finally, given the significant work currently being undertaken by the U.S. Food and Drug Administration (FDA) and United States Pharmacopeia (USP) on a myriad of issues relating to compounding and the in-office preparation of certain medications, the AMA is concerned that NCOIL policy in this area may cause conflicts with federal law. This will result in confusion for physicians and regulators at the state level.

While we understand the desire of state legislators to protect their constituents as well as help restrain costs in workers' compensation programs, the AMA strongly urges NCOIL to consider—at a minimum—delaying further consideration of the Model Act until the finalized work of both FDA and USP can be transmitted to and implemented in the states to ensure the safety of the sterile and non-sterile preparations received by patients.

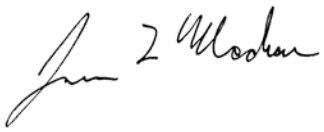
In addition, while we understand that some states may have moved forward with legislation similar to the Model Act, we note that there is deep concern among several state medical societies and physician specialties on the provisions contained in the Model Act due to their unknown impact on patients.

The AMA strongly endorses the physicians' ethical responsibility to hold the patient's interests as paramount, in their role as prescribers and dispensers of drugs and devices. In furtherance of that responsibility, physicians should prescribe drugs, devices, and other treatments based solely on medical considerations, patient need, and reasonable expectations of effectiveness for the particular patient. In addition, physicians should dispense drugs in their office practices only if such dispensing primarily benefits the patient, including respecting the patient's freedom to choose where to fill prescriptions.

In light of the concerns above, the AMA believes that the Model Act would interfere with a physician's ability to provide optimal care. Therefore, we urge that NCOIL not adopt the proposed Model Act.

Thank you for your consideration. If you have any questions, please contact Daniel Blaney-Koen, JD, Senior Legislative Attorney, AMA Advocacy Resource Center at daniel.blaney-koen@ama-assn.org or (312) 464-4954.

Sincerely,



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cc: Thomas B. Considine
William Melofchik