Ohio Osteopathic Association

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April 25, 2017

Sallie Debolt, Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. Debolt:

The Ohio Osteopathic Association is submitting these comments regarding the proposed amendments to Rules 4731-11-01, 02, and 13 of the Ohio Administrative Code. We are also sending a copy of these comments to the State Pharmacy Board of Ohio, since the simultaneous promulgation of opioid-related rules requires coordination and a holistic approach to regulation among state agencies.

The Ohio Osteopathic Association advocates on behalf of more than 6,000 osteopathic physicians who are licensed by the State Medical Board of Ohio and the Ohio University Heritage College of Osteopathic Medicine, which educates future physicians. The OOA has been a member of the Governor's Cabinet Opiate Action Team, since its inception, which was formed to address Ohio's prescription drug addiction epidemic. As such, we were instrumental in helping to develop guidelines for the use of opioids in the emergency department settings, for treating chronic pain patients and, most recently, to treat acute pain. We believe Ohio's physician community has made important strides in addressing the addiction epidemic, and we favor continued education and collaboration with state agencies to continue to address prescription drug abuse in the future. As the State of Ohio moves to the promulgation of rules instead of guidelines, we are concerned about balancing the goals of protecting patient safety with effective treatment and access to pain management. This requires giving physicians the flexibility they need to treat their patients effectively without unintended consequences and barriers.

4731-11-01 Definitions.

4731-11-01 Definitions (R) "Palliative care". We believe it is essential for the Medical Board to work with the physician community to develop a better definition of "palliative care patient." We believe the definition should more closely mirror the definition for hospice patients without the six-month limitation. The designation should require signatures from two physicians stating that the patient has life-limiting and life-threatening illness that may potentially be terminal, with the possible requirement that the documentation be renewed annually. This would enable physicians

to more effectively care for palliative care patients and clearly separate them from chronic pain patients.

4731-11-02 General Provisions

The Pharmacy Board is proposing to amend OAC Rules 4729-5-30, 4729-37-04 and 4729-37-05 to require an ICD-10 code of the primary disease or condition to be placed on all prescriptions for controlled substances. There are more than 68,000 such codes in the new system. We understand that the rationale for including the diagnosis code on the prescription is to assist the pharmacist in clarifying prescriptions and catching prescribing errors. However, this will seriously complicate prescription writing in physician offices and could actually increase the number of unnecessary communications between pharmacists and physicians. Also, we continue to be concerned about patient privacy and do not want to inadvertently increase barriers to having patients get their prescriptions filled. We therefore suggest the creation of a Medical Board – Pharmacy Board study committee with stakeholder representation to discuss this issue in greater detail and limit the instances where diagnoses codes are required to those that will maximize patient safety.

4731-11-13 Prescribing of Opioid Analgesics for Acute Pain

Proposed rule 4731-11-13 (A) (3) (c) states: The total morphine equivalent dose (MED) of a prescription for opioid analgesics for treatment of acute pain shall not exceed an average of thirty MED per day. While this average seems reasonable in most instances, we have concerns about unintended consequences that could evolve in the case of patients who have experienced significant trauma and for patients who are already being treated for chronic pain and are on a maintenance opioid dose.

For example, if a patient has chronic pain and is being treated with long-term opioids and they experience an acute, traumatic injury -- like a broken leg or herniated disc -- the dosage allowed by the proposed rules for that acute pain could be less than the maintenance opioid dose the patient is already receiving. That limit certainly would not be sufficient to cover the new pain because of tolerance. To cover this situation the rules should allow a practitioner to prescribe an acute pain dose that is one-and-a-half to two times stronger than the patient's normal dose for the first 5- 7 days of the injury. An example of the 30 MED dose is a Vicodin 5 mg every four hours.

For severe pain, there should be exceptions to liberalize the dose at discretion of the prescriber with good documentation. We would suggest including language to allow these exceptions with a range of 30-50 MED per day in opioid naïve patients, with rapid tapering to 30 MED as tolerated by the patient, and allowing the physician to determine the initial dosing interval to be 7-10 days based on severity of event. Some of the most severe pains seen acutely in family practice include compression fractures of the spine in the elderly, acute herniated discs and burns. This type of pain can totally disable an elderly individual who may stop eating, sleeping and subsequently decline rapidly. These patients may also require hospitalization because of unmet pain needs. It is not unrealistic, for example, that a patient with an acute rupture of a herniated disc in severe pain, will require two weeks or more from time of event to receive initial

workup and reach a specialist.

In conclusion, the Ohio Osteopathic Association supports the intent of these rules to limit unnecessary prescribing for acute pain. At the same time, we are extremely concerned that pain thresholds vary greatly from patient to patient. Although the proposed rules appear to allow exceptions with documentation in the medical records, we fear that the lower thresholds, without exceptions, could lead to increased law enforcement intervention and medical board scrutiny in cases where the physician is doing the right thing to address the needs of their patients. Therefore, we believe the rules should include the establishment of a joint Pharmacy and Medical Board Prescribing Advisory Committee, with physician association representation, to review outlier exceptions as they are identified, before these cases are referred to the disciplinary process. We further believe that the Board of Pharmacy should establish an OARRS Advisory Committee that would allow physician associations to assist in improving the system, identifying coding problems, and educating physicians on best practices. We look forward to continuing to work with the licensing boards to advance public safety while preserving access to appropriate care.

Sincerely,

Sean D. Stiltner, DO
President

cc Cameron McNamee, Director of Policy and Communications, State of Ohio Pharmacy Board