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April 24, 2017

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

Dear Ms. Debolt:

On behalf of the 4,900 family physician, family medicine resident and medical student members of the Ohio Academy of Family Physicians, we submit the following comments on the State Medical Board of Ohio approved amendments to Rule 4731-11-02 and to new Rule 4731-11-13 of the Ohio Administrative Code:

Rule 4731-11-02.

Requiring the ICD-10-CM medical diagnosis code on the prescription, including the description of the code, the primary disease or condition that the controlled substance is being used to treat, violates patient confidentiality. In order to preserve patient confidentiality, the American Academy of Family Physicians and the Ohio Academy of Family Physicians oppose any requirement that diagnosis information be placed on a prescription form.

It is our understanding from the FAQ document published on the Pharmacy Board website, the diagnosis or procedure code for every controlled substance script will be entered into OARRS by the pharmacist. For what purpose is this confidential information being collected? How will this information be used? Who is authorized to review the patient's confidential information? Will investigations be opened and/or disciplinary actions be taken against prescribers based on this diagnosis code information? It is certainly understandable that prescribers feel they will be judged, but have no idea by what standard or by whom. Since the stated purpose of the governor's restrictions is limiting controlled substance scripts, it can reasonably be assumed that data will be used in this fashion by regulators to further insert themselves into the practice of medicine. This is most concerning.

In addition, electronic medical record systems do not readily allow diagnosis codes and duration of treatment information to be printed on the script. This is a complicated and expensive requirement to implement.

New Rule 4731-11-13.

Rules being implemented are much more stringent than the carefully constructed acute pain prescribing guidelines set during the lengthy GCOAT process. With the changes now proposed prescribers can prescribe opiates in excess of no more than seven days for adults and five days for minors unless the reason is documented in the patient chart. That is big leap from the 14-day re-check/re-assessment proposed in the acute pain prescribing guidelines. And while prescribers can prescribe in excess of the seven and five day limitations if noted

in the chart as to why, there appears to be no clinical judgment allowance for the total morphine equivalent dose (MED). The total morphine equivalent dose (MED) of a prescription for acute pain cannot exceed an average of 30 MED per day. We are told that the 30 MED calculation aligns with CDC guidelines released in March 2016, but it should be noted establishment of those guidelines are based on a study in which MED calculations lie far beyond the ranges spelled out in the acute pain guidelines (≤ 80) and are actually for chronic pain management, not acute pain.

These same 2016 CDC Guidelines for Prescribing Opioids for Chronic Pain that are being used to justify Ohio's restrictions on prescribing opioids for acute pain were based on a review of contextual evidence using inconsistent inclusion and exclusion criteria for different pain management therapies. Because of these inconsistencies in methodology, and because strong recommendations were made on the basis of low-quality or insufficient evidence, the American Academy of Family Physicians (AAFP) did not endorse the CDC guideline.

The number of opioids prescribed by doctors and dispensed to patients decreased in 2016 for the fourth consecutive year. During the process of drafting acute pain guidelines, the Ohio Academy of Family Physicians and other participants in the process were told that if controlled substance prescriptions decreased in number, the guidelines would not be made mandatory. And now that is exactly what is occurring.

As your own data shows, physicians are doing their part to curb doctor shopping and overprescribing but we continue to be the focus of a seemingly very one-dimensional campaign to fight Ohio's opioid crisis. Has the obvious been pointed out? Restricting and reducing opioid prescriptions over the past two years has driven overdose deaths through the roof. Please help us understand how further restricting the legitimate prescribing of these medications will now have the opposite effect?

This is a multi-dimensional problem that requires an approach beyond just continually hitting physicians with more mandates particularly when the mandates violate patient confidentiality and inhibit a physician's ability to provide quality, timely and appropriate care. Treatment for substance abuse is woefully unavailable for those who want help. My county has 15 minutes allotted to drop-in treatment each week - and we wonder why overdose deaths are growing in number.

Thank you for allowing us to submit comments. We hope that they will be given thoughtful consideration.

Sincerely,

A handwritten signature in black ink that reads "Ryan Kauffman MD". The signature is fluid and cursive, with the "MD" written in a slightly larger, more distinct font at the end.

Ryan Kauffman, MD
President

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