OHIO PSYCHIATRIC PHYSICIANS ASSOCIATION

A District Branch of the American Psychiatric Association

Dedicated to promoting the highest quality care for people with mental disorders and to serving the professional needs of Ohio's psychiatric physicians.

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Sallie Debolt
General Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, Ohio 43215-6127

Dear Ms. Debolt:

The Ohio Psychiatric Physicians Association (OPPA), representing more than one thousand physicians specializing in psychiatry, would like to thank the State Medical Board of Ohio for giving us the opportunity to comment on the board's draft rules on office based outpatient treatment (OBOT) of opioid addiction.

Members of the OPPA Committee on Addiction and Pain Control reviewed the proposed rules and the OPPA would like to provide the comments below (please note that the rules for physician assistants and physicians are essentially identical, therefore, the following comments address only the rules for physicians in 4731-33.

- The OPPA has no concerns with 4731-33-01, which is comprised of definitions.
- The OPPA supports 4731-33-03 A-D, which require physicians providing OBOT to abide by all federal and state regulations and to complete full assessments and treatment plans for their patients. This is consistent with the OPPA mission to promote the highest quality care for patients with mental disorders.
- Likewise, the OPPA is pleased that 4731-33-03 E is replacing the previously mandated, non-evidence-based induction protocols with broad practice guidelines from leading medical associations.
- As representatives of the psychiatric field, OPPA is concerned with aspects of 4731-33-01 F. While we support the expectation that physicians providing OBOT seek collaboration with behavioral healthcare providers, we are troubled by the Board's decision to mandate the required components of treatment, and in particular to require at least one of five particular behavioral interventions. We believe that the appropriate behavioral interventions are best determined by the behavioral health provider or collaborating team of providers.

  We also question the choice of the five particular interventions selected, some of which are quite specialized and others of which are so broad as to be practically

meaningless. Like all areas of medicine, behavioral medicine is an ever developing field, and by limiting the choice of treatments we are potentially precluding patients from receiving access to, as yet undeveloped, highly effective treatment modalities. We believe the Board will recognize that limiting treatment options in this way is not typical for other areas of medicine and is potentially stigmatizing for patients suffering from mental health and addictive diseases.

- The OPPA strongly supports the intent of 4731-33-03 H to ensure that patients receive access to naloxone for overdose prevention.
- The OPPA has significant concerns with 4731-33-03 I.1-2. The wording used would make it impossible for a physician to prescribe mono-buprenorphine without risking his or her medical license except in the very limited and specific cases defined in 4731-33-03 I.2. We believe that these cases do not represent the breadth of situations encountered by physicians in practice and that limiting a physicians' right to prescribe this medication is unnecessary and potentially harmful to patients. Several obvious examples, such as in cases of breastfeeding women or patients with allergy to naloxone, are immediately obvious, but even if these were added to the list provided in section 4731-33-03 I.2, we do not believe this would suffice.

  Buprenorphine is approved by the FDA for treatment of opioid use disorder and is safe and effective when used as prescribed. The theoretical risk for diversion of buprenorphine is no different than the theoretical risk for diversion of oxycodone or any other opioid. Prohibiting the prescribing of an effective treatment for opioid use disorder in the midst of an opioid epidemic, particularly when the medications that caused that epidemic are not prohibited in such a manner, will simply make it harder for patients to receive appropriate treatment and result in physicians being more reluctant to prescribe for them.

  The OPPA would suggest that the Board express its concern about the higher risk for diversion with the mono-buprenorphine product by using the same phrasing used in 4731-33-03 I.3. That is: "Due to the higher risk for diversion with the mono-buprenorphine product, the physician shall prescribe buprenorphine without naloxone (buprenorphine mono-product) only when there are extenuating circumstances to justify this, and shall fully document the evidence for the decision to use buprenorphine mono-product in the medical record."
- The OPPA would like to request clarification of 4731-33-03 I.4. Does the Board intend that the physician must prescribe no more than 8 mg buprenorphine daily for the first week of treatment or only for the first day of treatment? The OPPA would also like to note that the National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use, cited in 4731-33-03 E.2 as an acceptable treatment protocol for OBOT, does not recommend limiting the initial daily dose to any particular amount.
- The OPPA questions the necessity of creating rules to manage provision of treatments which are FDA approved, not experimental, and either use medication formulations that are not possible to divert or are non-scheduled medications. Section 4731-33-03 I.9, related to extended-release buprenorphine (which is injectable and therefore not divertible), and 4731-33-03 J, discussing oral and injectable naltrexone, either reiterate behaviors already required of a physician practicing any type of medicine (i.e., "prescribe extended-release buprenorphine strictly in accordance with the food and drug administration's approved labeling for the drug's use"), or offer medical guidance that should be, and normally is, left to the discretion of the physician (dosing guidelines, reasons for use of a particular medication, appropriate laboratory testing).

Naltrexone is not a controlled substance, is not addictive, and is not used illicitly, so it is difficult to understand why the Board would require physicians to take steps to reduce the chances of naltrexone diversion and mandate urine or serum drug testing.

Again, we sincerely appreciate the State Medical Board of Ohio providing the OPPA with an opportunity to comment on the proposed rules on office based outpatient treatment (OBOT) of opioid addiction.

Sincerely,

Tamara Campbell, MD
President

Christine Wilder, MD
Chair, Committee on Addiction and Pain Control