Ohio State Medical Board of Ohio

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**MEMORANDUM**

TO: Amol Soin, M.D., Chair, Policy Committee
Members, Policy Committee

FROM: Sallie Debolt, Senior Counsel

RE: Rules for Office-based treatment of opioid addiction

DATE: September 5, 2018

The proposed rules for office-based medication assisted treatment of opioid addiction are pending at the Common Sense Initiative Office ("CSI"). The comment period has ended. Most comments repeat issues raised during the initial gathering of interested party comments and discussed at that time. However, there are two comments that the Medical Board is asked to consider adopting.

Rules 4730-4-03 (Physician Assistant rule) and 4731-33-03 (Physician rule) set the standards for office-based medication assisted treatment of opioid addiction. The rules are virtually the same. Accordingly, this memo's discussion of proposed rule 4731-33-03 should be understood to also be applicable to proposed rule 4730-4-03.

Paragraphs (A) through (F) of the rule set the standards for the provision of office-based medication assisted treatment using any drug. Paragraph (G) of the rules sets the standards for the use of a buprenorphine product. See proposed rule 4731-33-03, attached to this memo.

Paul Johnson, Chief Commercial Officer of Braeburn, Inc., submitted two comments on the wording of paragraph (G). See attached letter from Mr. Johnson.

1. Mr. Johnson states that the language of paragraph (G)(7) may lead to uncertainty as to whether the use of extended-release or implantable forms of buprenorphine are allowable because the paragraph states, in part, that the dosage prescribed shall not exceed twenty-four milligrams per day. However, extended-release and injectable buprenorphine products are only available in 100 mg or 300 mg dosages for thirty days of treatment.

   *Response:* The prescribing of an extended release, injectable, or implanted buprenorphine product is specifically addressed in paragraph (G)(9). It states that the prescribing shall be in accordance with the FDA approved labeling. Accordingly, the limitation in paragraph (G)(7) is not applicable to the prescribing of such buprenorphine products. However, in order to prevent confusion, it is suggested that paragraph (G)(7) be amended to read as follows:

   (G)(7) When using any oral formulation of buprenorphine, the physician shall document in the medical record the rationale for prescribed doses exceeding 16 milligrams of buprenorphine per day. The physician shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day.

2. Mr. Johnson points out unintended consequences for the language of paragraph (G)(9)(d). The language limits the administration of an extended release, injectable, or implanted buprenorphine product to specified licensed practitioners. The language reflects the limitations for who can administer the drugs as specified in the REMS.

   *Response:* Mr. Johnson is correct that the language is too limiting and would prevent a prescribing physician or physician assistant from having another physician administer the medication. It is suggested that the paragraph (G)(9)(d) be amended to read as suggested:

   (G)(9) The physician who orders or prescribes an extended-release, injectable, or implanted buprenorphine product shall require it to be administered by an Ohio licensed health care provider acting in accordance with the scope of their professional license.

**PROPOSED ACTION: Approve the discussed amendments to proposed rules 4730-4-03 and 4731-33-03.**

4731-33-03 Office based treatment for opioid addiction

A. A physician who provides OBOT shall comply with both of the following requirements:
   1. Comply with all federal and state laws and regulations governing the prescribing of the medication; and
   2. Complete at least eight hours of "Category 1" continuing medical education relating to substance abuse and addiction every two years. Courses completed in compliance with this requirement shall be accepted toward meeting the physician's "Category 1" continuing medical education requirement for biennial renewal of the physician's license.

B. The physician who provides OBOT shall perform and document an assessment that includes all of the following:
   1. A comprehensive medical and psychiatric history;
   2. A brief mental status exam;
   3. Substance abuse history;
   4. Family history and psychosocial supports;
   5. Appropriate physical examination;
   6. Urine drug screen
   7. Pregnancy test for women of childbearing age and ability;
   8. Review of the patient's prescription information in OARRS;
   9. Testing for human immunodeficiency virus;
   10. Testing for hepatitis B;
   11. Testing for hepatitis C; and
   12. Consideration of screening for tuberculosis.

C. The physician who provides OBOT shall establish and document a treatment plan that includes all of the following:
   1. The physician's rationale for selection of the specific drug to be used in the medication-assisted treatment;
   2. Patient education;
   3. The patient's written, informed consent;
   4. Random urine-drug screens;
   5. A signed treatment agreement that outlines the responsibilities of the patient and the physician; and
   6. A plan for psychosocial treatment, pursuant to paragraph (E) of this rule.

D. The physician shall provide OBOT in accordance with an acceptable treatment protocol for assessment, induction, stabilization, maintenance, and tapering. Acceptable protocols are any of the following:

   1. SAMHSA treatment improvement protocol publications for medication assisted treatment available from the SAMHSA website at https://store.samhsa.gov/list/series?name=TIP-Series-Treatment-Improvement-Protocols-TIPS-&pageNumber=1.

   2. "National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use," approved by the American Society of Addiction Medicine in 2013, available from the website of the Ohio department of mental health and addiction services at https://www.asam.org/docs/default-source/practice-

support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf.

E. Except if the physician providing OBOT is a board certified addictionologist, board certified addiction psychiatrist, or psychiatrist, the physician shall refer and work jointly with a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as those terms are defined in rule 4731-33-01 of the Administrative Code, to determine the optimal type and intensity of psychosocial treatment for the patient and document the treatment plan in the patient record.

1. The treatment shall, at a minimum, include a psychosocial needs assessment, supportive counseling, links to existing family supports, and referral to community services.

2. The treatment shall include at least one of the following interventions:

    a. Cognitive behavioral treatment;
    b. Community reinforcement approach;
    c. Contingency management/motivational incentives;
    d. Motivational interviewing; or
    e. Behavioral couples counseling.

3. The treatment plan shall include a structure for revision of the treatment plan if the patient does not adhere to the original plan.

4. When clinically appropriate or if the patient refuses treatment from a qualified behavioral healthcare provider, community mental health services provider, or community addiction services provider, as defined in rule 4731-33-01of the Administrative Code, the physician shall ensure that the OBOT treatment plan requires the patient to participate in a twelve step program. If the patient is required to participate in a twelve step program, the physician shall require the patient to provide documentation of on-going participation in the program.

5. Additional requirements related to the provider of behavioral health services:
a. If the physician providing OBOT is a board certified additionologist, psychiatrist, or board certified psychiatrist, the physician may personally provide behavioral health service for addiction.
b. If the physician refers the patient to a qualified behavioral health service provider, community addiction services provider, or community mental health services provider, the physician shall document the referral and the physician's maintenance of meaningful interactions with the provider in the patient record.

F. The physician who provides OBOT shall offer the patient a prescription for a naloxone kit.

1. The physician shall ensure that the patient receives instruction on the kit's use including, but not limited to, recognizing the signs and symptoms of overdose and calling 911 in an overdose situation.

2. The physician shall be exempt from this requirement if the patient refuses the prescription. If the patient refuses the prescription the physician shall provide the patient with information on where to obtain a kit without a prescription.

G. In addition to paragraphs (A) through (F) of this rule, the physician who provides OBOT using buprenorphine products shall comply with all of the following requirements.

1. The provision shall be in compliance with the FDA approved "Risk Evaluation and Mitigation Strategy" for buprenorphine products. With the exception of those conditions listed in paragraph (G)(2) of this rule, a physician who treats the opioid use disorder with a buprenorphine product shall only prescribe buprenorphine products containing naloxone for use in OBOT.

2. The physician shall prescribe buprenorphine without naloxone (buprenorphine mono-product) only in the following situations, and shall fully document the evidence for the decision to use buprenorphine mono-product in the medical record:

a. When a patient is pregnant or breast-feeding;

b. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days;

c. In formulations other than tablet or film form for indications approved by the FDA;

d. For withdrawal management when a combination product of buprenorphine and naloxone is contraindicated, with the contraindication documented in the patient record; or

e. When the patient has an allergy to or intolerance of a combination product of buprenorphine and naloxone, after explaining to the patient the difference between an allergic reaction and symptoms of opioid withdrawal precipitated by buprenorphine or naloxone, and with documentation included in the patient record.

3. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the physician shall only co-prescribe these substances when there are extenuating circumstances.

a. The physician shall verify the diagnosis for which the patient is receiving the other drug and coordinate care with the prescriber for the other drug, including discussing with the prescriber whether it is possible to taper the drug to discontinuation. If the physician prescribing buprenorphine is the prescriber of the other drug, the physician shall taper the other drug to discontinuation, if

possible. The physician shall educate the patient about the serious risks of the combined use.

b. The physician shall document progress with achieving the tapering plan.

4. During the induction phase the physician shall not prescribe a dosage that exceeds the recommendation in the FDA labeling, except for medically indicated circumstances as documented in the medical record. The physician shall see the patient at least once a week.

5. During the stabilization phase, when using any oral formulation of buprenorphine, the physician shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

    a. During the first ninety days of treatment, the physician shall prescribe no more than a two-week supply of the buprenorphine product containing naloxone.

    b. Starting with the ninety-first day of treatment and until the completion of twelve months of treatment, the physician shall prescribe no more than a thirty-day supply of the buprenorphine product containing naloxone.

6. The physician shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of OARRS. The physician shall also require urine drug screens or serum medication levels at twice per quarter for the first year of treatment and once per quarter thereafter.

7. The physician shall document in the medical record the rationale for prescribed doses exceeding 16 milligrams of buprenorphine per day. The physician shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day.

8. The physician shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a qualified behavioral healthcare provider, as defined in rule 4731-33-01 of the Administrative Code, who has the education and experience to provide substance abuse counseling.

9. The physician may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product.

    a. The physician shall strictly comply with any required risk evaluation and mitigation strategy program for the drug.

    b. The physician shall prescribe an extended-release buprenorphine strictly in accordance with the food and drug administration’s approved labeling for the drug’s use.

    c. The physician shall document in the patient record the rational for the use of the extended-release buprenorphine product.

d. The physician shall only delegate the administration of extended-release buprenorphine to a physician assistant licensed under chapter 4730. of the Revised Code or a nurse licensed under chapter 4723. of the Revised Code, when the physician assistant or nurse is acting in accordance with the scope of practice of their professional license.

braeburn

August 20, 2018

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**Re: Proposed Rule for Office-Based Treatment of Opioid Addiction**

Dear Ms. Debolt:

Thank you for the opportunity to provide comments on the proposed rule for office-based treatment of opioid addiction.[1]

Braeburn Inc. is pharmaceutical company in the process of developing long-acting medicines to treat opioid addiction. Braeburn has one mission: to fight the opioid addiction epidemic. Braeburn aims to reduce stigma by raising awareness that opioid use disorder is a chronic brain disease best treated by evidence-based medication-assisted treatment. Braeburn's next generation medicines aim to support patients focusing on the reintegration of their lives with their families and communities. Braeburn's long-acting injectable regimens will be administered directly by healthcare professionals. Therefore, healthcare professionals will be able to maximize medication adherence to the prescribed treatment while potentially minimizing the risks of abuse, misuse and diversion.

We appreciate the State Medical Board of Ohio's efforts to "strike a proper balance between access to opiate addiction treatment and diversion of specifically approved buprenorphine products" by setting forth requirements, including establishing standards and procedures to be followed by physicians and physician assistants in the use of buprenorphine for medication-assisted treatment in an office-based setting. Such standards and procedures would be intended to ensure that treatment can be performed in a safe manner for the patient while reducing the risk of unlawful behavior of patients, practitioners, and others.

Braeburn wishes to provide comments on two specific sections of the proposed rule. First, section (G)(9) of both 4731-33-03 and 4730-4-03, which relate to prescribing and administration of injectable buprenorphine, state that physicians and physician assistants may treat a patient using the administration of an extended-release, injectable, or implanted buprenorphine product provided they comply with the U.S. Food and Drug Administration labeling and Risk Evaluation and Mitigation Strategy and document the medical rationale in the patient record.

[1] http://med.ohio.gov/Laws-Rules/Newly-Adopted-and-Proposed-Rules/Office-Based-Treatment-of-Opioid-Addiction

Yet, section (G)(9) of 4731-33-03 and 4730-4-03 also states that (1) the "physician shall only delegate the administration of extended-release buprenorphine to a [licensed] physician assistant . . . or a [licensed] nurse . . . acting in accordance with the scope of practice of their professional license,"[2] and (2) a "physician assistant who orders or prescribes extended-release buprenorphine shall require it to be administered by a [licensed] physician assistant . . . or a [licensed] nurse. . . acting in accordance with the scope of practice of their professional license."[3] As currently written, these provisions would have two important, unintended consequences. First, if a physician prescribes injectable buprenorphine, then the physician cannot delegate another licensed physician to administer the product. Second, if a physician assistant prescribes injectable buprenorphine, a licensed physician cannot administer it.

Braeburn recommends amending section (G)(9)(d) of 4731-33-03 and 4730-4-03 to state the following:

> The physician or physician assistant who orders or prescribes extended-release injectable or implanted buprenorphine product shall require it to be administered by a health care provider licensed under state law acting in accordance with the scope of practice of their professional license.

This proposed language is consistent with the Board's intention to require practitioners who administer extended-release buprenorphine to patients be licensed and acting within their scope of practice, yet without having the unintended consequences described above.

Second, section (G)(7) of both 4731-33-03 and 4730-4-03 states that a physician or physician assistant shall not prescribe a dosage exceeding 24 milligrams of buprenorphine per day. Historically, such dosage restrictions have been intended to balance clinical efficacy with risk of diversion of *oral* buprenorphine products, whose FDA-approved dosages cannot be fairly compared with those of injectable products that deliver medication over an extended period of time. As such, this restriction may lead to uncertainty for prescribers with respect to prescribing extended-release, injectable and implantable buprenorphine products. For example, the recently FDA-approved injectable buprenorphine product is only available in 100 mg or 300 mg dosages for 30 days of treatment.[4] Therefore, we recommend amending section (G)(7) of 4731-33-03 and 4730-4-03 to state either of the following:

> The physician or physician assistant shall not prescribe a dosage exceeding twenty-four milligrams of buprenorphine per day <u>or daily average equivalent doses of injectable or implantable forms of buprenorphine (e.g., 300 mg or 100 mg, per 30 days)</u>; or

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[2] 4731-33-03 Section (G)(9)(d) http://med.ohio.gov/Portals/0/Laws%20%26%20Rules/Newly%20Adopted%20and%20Proposed%20Rules/CSI/BIA%20MAT%20rules%20and%204731-11-12%20rescind.pdf

[3] 4730-4-03 Section (G)(9) http://med.ohio.gov/Portals/0/Laws%20%26%20Rules/Newly%20Adopted%20and%20Proposed%20Rules/CSI/BIA%20MAT%20rules%20and%204731-11-12%20rescind.pdf

[4] https://www.sublocade.com/Content/pdf/prescribing-information.pdf

The physician or physician assistant shall not prescribe in tablet or film form a dosage exceeding twenty-four milligrams of buprenorphine per day.

In conclusion, Braeburn applauds the Board's efforts to balance access to medication-assisted treatment with buprenorphine and the risk of medication diversion. Yet, we urge the Board to carefully and thoughtfully consider our comments so that the proposed rule does not have the unintended consequences of reducing access to, and causing uncertainty among prescribers of, extended-release injectable buprenorphine products.

Respectfully submitted,

Paul Johnson
Chief Commercial Officer
Braeburn Inc.