RULES AND REGULATIONS

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF MEDICINE

[49 PA. CODE CH. 16]

Opioid Treatment Programs

The State Board of Medicine (Board) amends Chapter 16, Subchapter F (relating to minimum standards of practice) by amending § 16.92 (relating to prescribing, administering and dispensing) to read as set forth in Annex A.

Effective Date

This final-omitted rulemaking will be effective upon publication in the *Pennsylvania Bulletin*.

Statutory Authority

Section 8 of the Medical Practice Act of 1985 (act) (63 P.S. § 422.8) authorizes the Board to adopt regulations as are reasonably necessary to carry out the purposes of the act. Additionally, under section 41(8) of the act (63 P.S. § 422.41(8)), the Board has authority to promulgate regulations that define the accepted standard of care for Board-regulated practitioners under its jurisdiction.

Background and Need for the Amendments

Regulation of controlled substance prescribing by this Board began in 1986. Since that time, Board regulations have required an initial physical examination prior to the prescribing, administering or dispensing of certain drugs and controlled substances. Currently, under § 16.92(b)(1), prior to prescribing, administering or dispensing controlled substances and certain drugs, as defined under § 16.92(a), a person licensed to practice medicine and surgery in this Commonwealth or otherwise licensed or regulated by the Board is required to obtain an initial medical history and conduct an initial physical examination, unless emergency circumstances justify otherwise.

An opioid treatment program (OTP) is a program engaged in treatment of individuals with medication, including controlled substances, for opioid use disorder registered under section 303(h)(1) of the Controlled Substances Act (21 U.S.C. § 823(h)(1)), regarding registration requirements. The Substance Abuse and Mental Health Services Administration (SAMHSA) is the regulatory body which oversees OTPs at the Federal level. The Commonwealth's Department of Drug and Alcohol Programs (DDAP) regulates OTPs at the State level. See 28 Pa. Code Chapter 715 (relating to standards for approval of narcotic treatment program). DDAP certifies and issues licenses to drug and alcohol treatment programs and provides recommendations to SAMHSA regarding Federal certification of OTPs. As such, OTPs are subject to a substantial amount of oversight, including the oversight of licensed practitioners under the authority of this Board. The initial SAMHSA regulations at 42 CFR 8.12 (relating to Federal Opioid Use Disorder treatment standards), effective in 2001, align with the Board's current regulations relative to initial in-person physical examinations of OTP patients. Until recently, SAMHSA regulations required OTP patients utilizing medication for treatment of opioid use disorder to undergo an in-person physical examination prior to receiving treatment.

Nearly two decades after the SAMHSA regulations were promulgated, an unprecedented public health emergency relating to the novel coronavirus (COVID-19) virus upset the traditional delivery method of medication for treatment of opioid use disorder by OTPs. To ensure continuity of care and access, among other things, in April 2020, SAMHSA exempted OTPs from the requirement to perform the in-person evaluation as specified in 42 CFR 8.12(f)(2). However, this exemption did not operate to exempt OTPs in this Commonwealth from the in-person physical examination requirement in § 16.92(b)(1). Thus, on September 4, 2020, the Governor issued a waiver of § 16.92(b)(1). With this waiver, OTPs were not required to perform the initial in-person examination prior to prescribing medication for treatment of opioid use disorder. Instead, physicians were permitted to utilize telemedicine. The duration of this waiver was tied to the Federal public health emergency declaration. By the act of March 30, 2022 (P.L. 51, No. 14), the waiver was continued until the last day of the Federal public health emergency declaration, unless the exemptions were ended sooner by SAMHSA or the Drug Enforcement Agency. Thereafter, through the enactment of the act of June 30, 2022 (P.L. 391, No. 30), (35 P.S. § 448.802-A(a.3)) regarding COVID-19 regulatory flexibility authority, the waiver was extended until "the later of the following. . . (1) the last day of the Federal public health emergency declaration; or (2) the last day Federal exemptions granted under the Federal public health emergency declaration are authorized." On May 9, 2023, SAMHSA extended the in-person examination waiver for 1 year past the end of the Federal public health emergency declaration or until publication of a final rule. The final SAMHSA rules were published on February 2, 2024, became effective on April 2, 2024, and bear a compliance date of October 2, 2024. Therefore, the waiver of the physical examination requirements in § 16.92(b)(1) was no longer in effect as of February 2, 2024.

SAMHSA published several considerations when updating the OTP regulations to include COVID-19-era flexibilities. Of import to this discussion was the desire to make permanent those which were found to be integral to the enhancement and encouragement of opioid use disorder care, as well as a decrease in the stigma associated with opioid use disorder. One of the flexibilities made permanent relates to the in-person physical examination requirement. Specifically, where a provider determines an adequate screening and full evaluation of an OTP patient can be accomplished through telehealth, this practice is acceptable. 42 CFR 8.12(f)(2)(v). The subsection further sets forth the different parameters for telehealth in evaluating a patient for treatment with a schedule II medication (such as methadone) and a schedule III medication (such as buprenorphine) and medications not classified (such as naltrexone). After the initial screening, the OTP obligations relating to an in-person physical examination remain, albeit delayed. The amended 42 CFR 8.12(f)(2)(iii) requires that each OTP patient undergo a "full in-person physical examination. . .within 14 calendar days following a patient's admission to the OTP." Amended 42 CFR 8.12(f)(4)(i) requires "[e]ach patient admitted to an OTP be given a physical and behavioral health assessment. . .within 14 calendar days following admission, and periodically by appropriately licensed/credentialed personnel." With these amendments, the Board's regulations no longer align with the Federal regulation.

According to the Commonwealth's Opioid Data Dashboard, the opioid overdose epidemic is the worst public health crisis in this Commonwealth, and the Nation, in almost a generation. The opioid epidemic is a top public health issue in the United States, with drug overdose deaths ranking as the leading cause of injury death across the country. According to the Department of Health's web site, "each day, at least ten Pennsylvanians die of opioid or heroin overdose. This epidemic is killing our loved ones at an alarming rate. The problem can largely be attributed to the rapid rise in the abuse of opioids, including both prescription pain relievers and heroin." In 2022, approximately 14 Pennsylvanians died each day from a drug overdose, which is 5,158 total drug overdose deaths in 2022. Preliminary estimates show a higher number of overdose deaths in January, February and May of 2023 than the corresponding months in 2022.

According to DDAP, telehealth offers numerous benefits in addressing the opioid overdose epidemic, including increased access to care, continuity of care, convenience and privacy, comprehensive care, cost-effectiveness, enhanced patient engagement, access to crisis management and data-driven approaches. Leveraging these advantages can play a crucial role in enhancing the quality, accessibility and effectiveness of opioid addition treatment and overdose prevention. Recently, the National Institute on Drug Abuse announced that a Federally funded study found that expanded availability of telehealth reduced likelihood of fatal overdose among Medicare beneficiaries. Another study was initiated to examine the association of the receipt of telehealth services and medications for opioid use disorder with fatal drug overdoses before and during the COVID-19 pandemic. This study found that emergency authorized telehealth expansion and medications for opioid use disorder provision during the COVID-19 pandemic were associated with lower odds of fatal drug overdose, demonstrating the benefits of continuing these services.

It is imperative for this Commonwealth to have a regulatory system that is consistent with modern treatment methods for opioid use disorder treatment. The modern methods of opioid use disorder treatment encompass the needs of a society experiencing healthcare worker shortages and stigmatization of opioid use disorder while simultaneously encouraging treatment and accessibility. OTPs within this Commonwealth are required to adhere to the standards set forth in the Federal laws and regulations. OTPs are highly regulated at the Federal and state level. This robust body of law ensures that OTPs operate in a manner consistent with the public health and welfare.

Omission of Proposed Rulemaking

After the SAMHSA regulations were published on February 2, 2024, and became effective on April 2, 2024, coordination among State agencies occurred. The Governor's Policy Office asked the Board to consider amending its regulations so that the Board's regulations would not be an impediment to implementing the SAMHSA regulations. DDAP, the Department of Health and the Department of Human Services support the use of telehealth for the screening and initial examination for patients being admitted for treatment of opioid use disorder at OTPs. A draft annex, which makes the Board's regulations consistent with the SAMHSA regulations, was placed on the Board's June 25, 2024, agenda (the Board meets approximately every 6 weeks) for the Board's consideration, at which time the Board adopted it.

Under section 204(3) of the Commonwealth Documents Law (CDL) (45 P.S. § 1204(3)), the Board is authorized to omit the procedures for proposed rulemaking in sections 201 and 202 of the CDL (45 P.S. §§ 1201 and 1202) if the Board for good cause finds that the specified procedures are impracticable, unnecessary or contrary to the public interest. Based upon the Board's consideration of the SAMHSA regulations as well as the support of the SAMHSA regulations by other State agencies and the opioid overdose epidemic, the Board determined that publication of a proposed rulemaking was impracticable and contrary to the public interest because of the importance of expediting this final-omitted rulemaking to continue the enhancement and encouragement of opioid use disorder care and decrease the stigma associated with opioid use disorder. Telehealth for this purpose was basically field-tested during the COVID-19 pandemic and it was found to be an effective means of getting treatment to people with opioid use disorder efficiently to prevent additional overdose deaths. This is a very real public health crisis, and any delay is contrary to the public interest. The use of telehealth to treat individuals suffering from opioid use disorder treatment saves lives. Using telehealth for this purpose is now the National standard due to the change in SAMHSA's regulations, which were extensively vetted.

Additionally, the Board finds that publication of a proposed rulemaking is contrary to public interest because of the importance of clarifying regulatory standards expeditiously so that the regulated community has clear and consistent standards. OTPs are required to follow the SAMHSA regulations as a condition of certification, but the telehealth provision is permissive and not mandatory. So, currently, OTPs must follow the Board's regulations regarding the in-person physical examination requirement under § 16.92(b)(1), which is inconsistent with the SAMHSA regulations. The Board is concerned that practitioners in OTPs may now believe, based on the changes in the Federal rules, that they are permitted to use telehealth for the examination; however, if they do so, they would be subject to discipline by the Board at the State level. The Board is trying to avoid conflicts such as this.

The Board also finds that public comment is unnecessary and would be duplicative because there was significant public input in the recent amendments to the SAMHSA regulations, which mirror the Board's amendments in this final-omitted rulemaking. During the public comment period for the SAMHSA regulations, 373 public comments were received and considered by SAMHSA. Therefore, the Board finds that this final-omitted rulemaking is an appropriate method to conform the Board's regulations to Federal standards especially given the safeguards that are already in place as well as the importance of modernizing opioid use disorder treatment in this Commonwealth.

Description of the Amendments

This final-omitted rulemaking adopts the same physical examination standard utilized as a result of the COVID-19 waivers, which proved to be safe and effective during and after the COVID-19 pandemic. This final-omitted rulemaking also conforms the Board's regulations to the Federal opioid use disorder treatment standards as the Board does not wish to unnecessarily maintain a more stringent standard than required by Federal law for OTPs given the continued opioid crisis in this Commonwealth.

The Board amends § 16.92(a) by deleting the definition of "drug" and replacing it with the term "controlled substance." In the current regulations, the term "drug" includes butalbital, carisoprodol and tramadol. These drugs were not classified as controlled substances when the Board promulgated the definition of "drug." The Board included these drugs in the definition because they were considered drugs of abuse and the Board wanted them treated the same as controlled substances. However, now that they are scheduled controlled substances under The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144), it is no longer necessary to specify these drugs. The Board also adds a definition for the terms "telehealth" and "opioid treatment program" to § 16.92(a); the definitions of these terms are based upon the definitions in the Federal regulations at 42 CFR 8.2 (relating to definitions).

Regarding OTPs, the Board amends § 16.92(b)(1) and adds paragraph (9) to reflect the Federal regulations at 42 CFR 8.12 with regard to physical examinations. The amendments provide that the initial physical examination required under subsection (b)(1) may be conducted by means of telehealth for those patients being admitted for treatment of opioid use disorder at an OTP with either buprenorphine or methadone, provided that the provider determines that an adequate evaluation of the patient can be accomplished by telehealth and a full in-person physical examination is completed within 14 days after admission to the OTP. Paragraph (9) further requires the initial telehealth examination to comply with the applicable Federal standards at 42 CFR 8.12.

The term "controlled substance" replaces the term "drug" in § 16.92(b) and paragraphs (b)(2)—(6). Additionally, in § 16.92(b)(1), the Board clarifies that an initial physical examination shall be conducted prior to prescribing controlled substances. This amendment does not substantively change this section, but rather, provides clarity to this long-standing standard promulgated by the Board.

Fiscal Impact and Paperwork Requirements

This final-omitted rulemaking will not have a fiscal impact and will not create additional paperwork to the regulated community, the general public or the Commonwealth's political subdivisions.

Sunset Date

The Board continuously monitors the effectiveness of the regulations. Therefore, no sunset date has been assigned.

Regulatory Review

Under section 5.1(c) of the Regulatory Review Act (71 P.S. § 745.5a(c)), on October 3, 2024, the Board submitted copies of the final-omitted rulemaking with a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the chairperson of the Consumer Protection and Professional Licensure Committee of the Senate (SPC/PLC) and the chairperson of the Professional Licensure Committee of the House of Representatives (HPLC). On the same date, the Board submitted a copy of the final-omitted rulemaking to the Office of Attorney General under section 204(b) of the Commonwealth Attorneys Act (71 P.S. § 732-204(b)).

Under sections 5.1(e) and (j.2) of the Regulatory Review Act (71 P.S. § 745.5a(e) and (j.2)), the regulations were deemed approved by the SPC/PLC and the HPLC on November 30, 2024, and IRRC met on December 5, 2024, and approved the final-omitted rulemaking.

Additional Information

Additional information may be obtained by writing to Saiyad Ali, Board Administrator, State Board of Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649, ST-MEDICINE@PA.GOV.

Findings

The Board finds that:

(1) Public notice of the Board's intention to amend the Board's regulations under the procedures in sections 201 and 202 of the Commonwealth Documents Law (45 P.S. §§ 1201 and 1202) has been omitted under section 204 of the CDL (45 P.S. § 1204) because, in consideration of the SAMHSA regulations and the opioid overdose epidemic, publication of proposed rulemaking is impracticable and contrary to the public interest due to the importance of continuing the enhancement and encouragement of opioid use disorder care and decrease in the stigma associated with opioid use disorder. Additionally, public comment is unnecessary because there was significant public input in the recent amendments to the SAMHSA regulations, which mirror the Board's amendments in this rulemaking. During the public comment period for the SAMHSA regulations, 373 public comments were received and considered by SAMHSA. Omitting publication of proposed rulemaking is an appropriate method to conform the Board's regulations to Federal standards, especially given the safeguards that are already in place as well as the importance of modernizing opioid use disorder treatment in this Commonwealth.

(2) The promulgation of the regulations in the manner provided in this order is necessary for the administration of the Medical Practice Act of 1985 (63 P.S. §§ 422.1—422.53).

Order

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 16, are amended by amending § 16.92 to read as set forth in Annex A.

(b) The Board shall submit this final-omitted rulemaking to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(c) The Board shall submit this final-omitted rulemaking to the Independent Regulatory Review Commission, the House Professional Licensure Committee and the Senate Consumer Protection and Professional Licensure Committee as required by law.

(d) The Board shall certify this final-omitted rulemaking and deposit it with the Legislative Reference Bureau as required by law.

(e) This final-omitted rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

MARK B. WOODLAND, MS, MD,
Chairperson

(*Editor's Note*: See 54 Pa.B. 8361 (December 21, 2024) for IRRC's approval.)

Fiscal Note: Fiscal Note 16A-4962 remains valid for the final adoption of the subject regulation.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE—GENERAL PROVISIONS

Subchapter F. MINIMUM STANDARDS OF PRACTICE

§ 16.92. Prescribing, administering and dispensing controlled substances.

(a) When prescribing, administering or dispensing controlled substances, a person licensed to practice medicine and surgery in this Commonwealth or otherwise licensed or regulated by the Board shall carry out, or cause to be carried out, the following minimum standards:

(1) *Initial medical history and physical examination.* Except as provided in paragraph (9), an initial medical history shall be taken and an initial physical examination shall be conducted prior to prescribing controlled substances unless emergency circumstances justify otherwise. Medical history and physical examination information recorded by another licensed health care provider may be considered if the medical history was taken and the physical examination was conducted within the immediately preceding 30 days. The physical examination shall include an objective evaluation of the heart, lungs, blood pressure and body functions that relate to the patient's specific complaint.

(2) *Reevaluations.* Reevaluations of the patient's condition and efficacy of the controlled substance shall be made consistent with the condition diagnosed, the controlled substance or substances involved, expected results and possible side effects.

(3) *Patient counseling.* The patient shall be counseled regarding the condition diagnosed and the controlled substance prescribed, administered or dispensed. Unless the patient is in an inpatient care setting, the patient shall be specifically counseled about dosage levels, instructions for use, frequency and duration of use and possible side effects.

(4) *Medical records.* Accurate and complete medical records must document the evaluation and care received by patients. The following apply:

(i) On the initial occasion when a controlled substance is prescribed, administered or dispensed to a patient, the medical record must include the following:

(A) A specification of the symptoms observed by the licensed health care provider and reported by the patient.

(B) The diagnosis of the condition for which the controlled substance is being given.

(C) The directions given to the patient for the use of the controlled substance.

(D) The name, strength and quantity of the controlled substance and the date on which the controlled substance was prescribed, administered or dispensed.

(ii) After the initial occasion when a controlled substance is prescribed, administered or dispensed, the medical record must include the information required in subsection (a)(4)(i)(D) and changes or additions to the information recorded under subsection (a)(4)(i)(A)—(C).

(5) *Emergency prescriptions.* In the case of an emergency contact from a known patient, a prudent, short-term prescription for a controlled substance may be issued. Neither a refill nor a consecutive issuance of this emergency prescription may be given unless a physical examination and evaluation of the patient is first conducted by a licensed health care provider. The results of this examination and evaluation shall be recorded in the patient's medical record together with the diagnosis of the condition for which the controlled substance is being prescribed. An emergency oral prescription for a Schedule II controlled substance shall be covered by a written prescription delivered to the pharmacist within 72 hours.

(6) *Compliance with other laws.*

(i) This section may not be construed as restricting or limiting the application of The Controlled Substance, Drug, Device and Cosmetic Act or statutes or regulations of the Department of Health and the Department of Public Welfare that govern the prescription, administration and dispensation of controlled substances and medical recordkeeping in certain health care facilities.

(ii) This section may not be construed as restricting or limiting the application of Federal laws or regulations that govern the prescription, administration and dispensation of controlled substances and medical recordkeeping in certain health care facilities.

(iii) This section does not relieve a person from complying with more stringent standards that may be imposed by another statute or regulation.

(7) *Compliance with facility policy.* This section does not relieve a person from complying with more stringent standards that may be imposed by the health care facility in which the person practices or by the person's employer.

(8) *Adherence to standards of practice.* Compliance with this section will not be treated as compliance with the standards of acceptable and prevailing medical practice when medical circumstances require that the licensed health care provider exceed the requirements of this section.

(9) *Opioid Treatment Programs.* For OTPs, the initial physical examination required under subsection (a)(1) may be conducted by means of telehealth for those patients being admitted for treatment of opioid use disorder in an OTP with either buprenorphine or methadone provided that the provider determines that an adequate evaluation of the patient can be accomplished by telehealth and a full in-person physical examination is completed within 14 days after admission to the OTP. The initial telehealth examination must comply with the requirements of 42 CFR 8.12 (relating to Federal opioid use disorder treatment standards).

(b) The following words and terms, when used in this section have the following meanings, unless the context clearly indicates otherwise:

Controlled substance—A drug, substance or immediate precursor included in Schedules I through V of The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144) or that are controlled substances under Federal law as set forth at 21 U.S.C. § 812 (relating to schedules of controlled substances).

OTP—Opioid Treatment Program—A program engaged in opioid use disorder treatment of individuals with medications for opioid use disorder registered under the Controlled Substances Act at 21 U.S.C. § 823(h)(1)) (relating to registration requirements).

Telehealth—The delivery and facilitation of health care services by telecommunications and digital communication technologies, including Health Insurance Portability and Accountability Act (HIPPA)-compliant video and audio-only communication platforms.

[Pa.B. Doc. No. 24-1818. Filed for public inspection December 20, 2024, 9:00 a.m.]