Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

RECEIVED

Independent Regulatory Review Commission

October 3, 2024

(1) Agency
Department of State,
Bureau of Professional and Occupational Affairs,
State Board of Medicine

(2) Agency Number: 16A

Identification Number: 4962

IRRC Number: 3418

(3) PA Code Cite:

49 Pa. Code § 16.92

(4) Short Title: Opioid Treatment Programs

(5) Agency Contacts (List Telephone Number and Email Address):

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(6) Type of Rulemaking (check applicable box):

- ☐ Proposed Regulation
- ☐ Final Regulation
- ☒ Final Omitted Regulation
- ☐ Emergency Certification Regulation;
- ☐ Certification by the Governor
- ☐ Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

This final-omitted rulemaking amends the Board's regulations at § 16.92 by allowing the initial physical examination required for prescribing, administering and dispensing controlled substances to be conducted by means of telehealth for those patients being admitted into an Opioid Treatment Program (OTP) for treatment of opioid use disorder with either buprenorphine or methadone, provided that the health care provider determines that an adequate evaluation of the patient can be accomplished via telehealth and a full in-person physical examination is completed within 14 days after admission to the OTP. This standard is the same physical examination standard utilized as a result of the Bureau of Professional and Occupational Affairs regulatory waiver issued during the COVID-19 epidemic, which proved to be safe and effective during and after the COVID-19 epidemic. This final-omitted regulation 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. This final-omitted regulation also deletes the definition

of the term "drug" and replaces it with the term "controlled substance" to reflect the classification of scheduled controlled substances under The Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. §§ 780-101—780-144). 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 paragraph, but rather, provides clarity to this long-standing standard promulgated by the Board.

(8) State the statutory authority for the regulation. Include specific statutory citation.

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

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case, or regulation as well as, any deadlines for action.

Yes. Section (8) of the act requires the Board to promulgate regulations necessary to carry out the act.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The regulation of controlled substance prescribing by this Board commenced in 1986. Since that time, Board regulations have required an initial physical examination prior to the prescribing, administering or dispensing certain drugs and controlled substances. Currently, under § 16.92(b)(1) (relating to prescribing, administering and dispensing), prior to prescribing, administering or dispensing controlled substances and certain drugs, as defined under § 16.92(a), a person licensed in this Commonwealth to practice medicine and surgery 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 the Controlled Substances Act at 21 U.S.C.A. § 823(h)(1). The Substance Abuse and Mental Health Services Administration (SAMSHA) is the regulatory body which oversees OTPs at the Federal level. The Pennsylvania Department of Drug and Alcohol Programs (DDAP) regulates OTPs at the state level. See 28 Pa. Code Ch. 715. 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, 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.

In 2024, SAMHSA published several considerations when updating the OTP regulations to include COVID-era flexibilities that were implemented during the pandemic. The amended Federal regulations at 42 CFR § 8.12 (f)(2)(iii) now require that each OTP patient undergo a "full in-person physical examination … within 14

calendar days following a patient's admission to the OTP." Subsection 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 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 Pennsylvania, 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 website, "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 the Department of Drug and Alcohol Programs, 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 addiction 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 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. All 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. The Board is concerned that the incongruence among the laws and regulations of the Federal government, DDAP and the Board will result in confusion among the licensees treating patients suffering from opioid use disorder. However, with consistent regulatory oversight, this robust body of law can ensure that OTPs operate in a manner protective of the public health and welfare.

It is difficult to approximate the number of people who will benefit from this regulation, but certainly the statistics attributing over 5,000 Pennsylvanian deaths each year due to overdose deaths is a good place to start. Additionally, the opioid crisis touches so many other Pennsylvanians who might be vulnerable to overdosing or who have family members affected by opioid use disorder. This regulation is imperative to the continuity of care provided to patients who require opioid use disorder treatment. This final-omitted regulation will be beneficial to patients and their families as well as health care providers and facilities that treat patients with opioid use disorder.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

The amendments will make the Board's regulations requiring an initial physical examination for prescribing, administering and dispensing controlled substances consistent with Federal regulations for admission to OTPs by allowing a telehealth examination, provided that the provider determines that an adequate evaluation of the patient can be accomplished via telehealth and a full in-person physical examination is completed within 14 days after admission to the OTP. If the Board does not amend its regulations at § 16.92(b) (relating to prescribing, administering and dispensing), the Board's regulations will be more stringent than the Federal Substance Abuse and Mental Health Services Administration (SAMSHA) regulations.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

The option for citizens of this Commonwealth to obtain proven methods of life-saving and life-altering treatment from their home may not best be characterized as a competitive advantage. Nevertheless, the Board compared its decision to follow the SAMSHA regulations regarding telehealth examinations for the initial examination for admission to OTPs with the states in the Northeast Region and found that the final-omitted rulemaking will positively affect Pennsylvania's ability to compete with other surrounding states in the Northeast Region. The states in the Northeastern Region include Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Ohio, Rhode Island, Vermont and West Virginia. Most of the surrounding states, including Delaware, Ohio, New Hampshire, Maine Connecticut, Rhode Island, Massachusetts and Vermont follow the SAMSHA regulations regarding telehealth examinations for the initial examination for admission to OTPs. Other states, including Maryland, New Jersey, New York and West Virginia have more stringent requirements than the new SAMSHA regulations. Virginia and Washington D.C., like the Board, are in the process of incorporating the SAMSHA standards regarding telehealth examinations for the initial examination for admission to OTPs.

The regulations will not have a negative impact on its ability to compete with other states. 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. Absent this rulemaking, the Board's regulations would be unnecessarily more stringent than Federal requirements.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

No, the regulation will not affect other regulations of the Board or the Department. These regulations will impact the Department of Drug and Alcohol Programs (DDAP) because DDAP regulates OTPs at the state level. A DDAP regulation for OTPs, 28 Pa. Code § 715.9(a)(4) (relating to intake) requires licensed clinicians to conduct a face-to-face determination prior to the administration of an opioid for treatment. The Department

has worked closely with DDAP in drafting this regulation. DDAP supports this regulation because it will increase access to necessary treatment and because DDAP intends to grant regulatory exceptions pursuant to 28 Pa. Code § 701.11 (relating to exceptions to this part), to allow appropriately licensed clinicians in OTPs to perform initial evaluations at intake by telehealth, consistent with Federal rules.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses, and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

All rulemaking activities of the Board are discussed and voted on in public board meetings which are routinely attended by representatives of the public and the regulated medical community. The Board discussed the final-omitted rulemaking in its May 21, 2024, and June 25, 2024, board meetings.

This rulemaking is extremely narrow and is necessary to make the Board's regulations consistent with new Federal standards. The Board considered the SAMHSA regulations, the support of the SAMSHA regulations by other State agencies and the opioid overdose epidemic. The Board is expediting this regulation to continue the enhancement and encouragement of opioid use disorder care and decrease in the stigma associated with opioid use disorder. Telehealth for admission to OTPs was basically field-tested during the Covid pandemic and was found to be an effective, efficient means of getting treatment to people with opioid use disorder to prevent additional overdose deaths. Opioid use disorder and the consequent overdose deaths are 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. Absent this rulemaking, the Board's regulations would be unnecessarily more stringent than Federal requirements.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

Allowing the use of a telehealth examination for admission to an OTP will be beneficial to individuals who have opioid use disorder, health care providers and facilities that operate OTPs. 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 addiction 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 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.

According to the 2023 Small Business Administration (SBA) Profile, there are approximately 1.1 million businesses in Pennsylvania, with 99.6 percent of those being small businesses. Of the 1,082,027 small businesses, 1,077,699 are small business employers (those with fewer than 500 employees) and employ approximately 2,552,530 employees. The remaining small businesses are non-employers. Thus, the majority of businesses in Pennsylvania are considered small businesses.

Small businesses are defined in Section 3 of the Regulatory Review Act, (71 P.S. § 745.3) which provides that a small business is defined by the SBA's Small Business Size Regulations under 13 CFR Ch. 1 Part 121. These size standards have been established for types of businesses under the North American Industry Classification System (NAICS). In applying the NAICS standards to the types of businesses that may be impacted by this regulation, outpatient care centers (NAICS code 621498) are considered small businesses if they have $25.5 million or less in average annual receipts; and Residential Mental Health and Substance Abuse Facilities (623220) are considered small businesses if they have $19.0 million or less in average annual receipts.

Based on this variety of employers, the Board believes that small businesses may be impacted by this regulation. Regardless, as explained in Question #17, all businesses whether they are small businesses or not, would be positively impacted by this regulation.

(16) List the persons, groups, or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

Licensed physicians and physician assistants in this Commonwealth will be positively impacted by this regulation because they will have the ability to use telehealth for the initial examination required for admission to an OTP. This regulation does not mandate use of telehealth to admit an individual to an OTP. Rather, the health care provider makes that determination consistent with the standard of care set forth in the SAMSHA regulations and the standard required at the state level. As such, neither OTP facilities or clinics or health care providers who work for OTPs are required to provide telehealth for the initial examination. However, a health care provider who elects to use telehealth for this purpose will have to comply with the regulation, but since the Board's regulation mirrors Federal law, there is no additional burden to licensees. Allowing telehealth for this purpose will only have a positive impact on individuals with opioid treatment disorder because individuals will have the option of a telehealth visit to be admitted to an OTP.

(17) Identify the financial, economic, and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

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 addiction 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 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 not only consistent with modern treatment methods for opioid use disorder treatment, but with SAMSHA regulations as well. 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. Therefore, there will be a positive social impact as a result of this regulation.

The Board does not anticipate a financial or economic impact as a result of this regulation.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

This rulemaking will not have an adverse effect; the Board believes this rulemaking will be beneficial to health care providers, OTPs and individuals seeking admission to an OTP.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no estimated cost or savings to the regulated community.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no expected costs or savings for local governments.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no expected costs or savings for state governments.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping, or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

The Board is unaware of any legal, accounting or consulting procedures which will be required for implementation of the regulation by organizations or individuals.

(22a) Are forms required for implementation of the regulation?

No.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here.** If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

N/A

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY 24-25	FY +1 25-26	FY +2 26-27	FY +3 27-28	FY +4 28-29	FY +5 29-30
SAVINGS:						
Regulated Community	$0	$0	$0	$0	$0	$0
Local Government						
State Government	$0	$0	$0	$0	$0	$0
Total Savings	$0	$0	$0	$0	$0	$0
COSTS:						
Regulated Community	$0	$0	$0	$0	$0	$0
Local Government	$0	$0	$0	$0	$0	$0
State Government	$0	$0	$0	$0	$0	$0
Total Costs	$0	$0	$0	$0	$0	$0
REVENUE LOSSES:						
Regulated Community	$0	$0	$0	$0	$0	$0
Local Government	$0	$0	$0	$0	$0	$0
State Government	$0	$0	$0	$0	$0	$0
Total Revenue Losses	$0	$0	$0	$0	$0	$0

(23a) Provide the past three-year expenditure history for programs affected by the regulation.

Program	FY -2 21-22	FY -1 22-23	FY -1 23-24 (estimated)	Current FY 24-25 (budgeted)
State Board of Medicine	$6,789,149.62	$6,978,000.00	$6,993,000.00	$7,187,000

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

(a) An identification and estimate of the number of small businesses subject to the regulation.
(b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
(c) A statement of probable effect on impacted small businesses.
(d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

(a) This rulemaking will not have an adverse impact on small businesses.

(b) This rulemaking will not impose additional reporting, recordkeeping, or other administrative costs on small businesses.

(c) This rulemaking will not have a fiscal impact on small businesses but will benefit small businesses that are involved in OTPs because they will be permitted to use telehealth for admission to OTPs.

(d) This regulation does not have a negative fiscal impact and the Board does not anticipate costs associated with this regulation.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

Section § 16.92(b) may have a positive impact on affected groups because it provides access to healthcare through telehealth for vulnerable individuals who have opioid use disorder. This regulation removes barriers by allowing telehealth.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No alternative regulatory proposals were considered. The amendments remove barriers that exist and make the standard for admission to OTPs consistent with Federal law.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

a) The establishment of less stringent compliance or reporting requirements for small businesses;
b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

c) The consolidation or simplification of compliance or reporting requirements for small businesses;

d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and

e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

a) & b) The Board did not consider less stringent reporting requirements or deadlines for small businesses. There are no deadlines for compliance or reporting requirements imposed by this regulation.

c) There is no compliance or reporting requirements that could be consolidated or simplified.

d) The regulations do not contain design or operational standards that need to be altered for small businesses.

e) There is no need for exemptions. This regulation lessens the burden imposed by the existing regulation and allows telehealth for admission to OTPs.

(28) If data is the basis for this regulation, please provide a description of the data, explain <u>in detail</u> how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

No data, studies or references were used to justify the regulation.

(29) Include a schedule for review of the regulation including:

A. The length of the public comment period: 30 days

B. The date or dates on which any public meetings or hearings will be held:

T The Board discussed this final-omitted regulation at its Board meetings on May 21, 2024, and June 25, 2024. The Board meets in public session 9 times each year. Upcoming dates are set forth in (30) below.

C. The expected date of delivery of the final-form regulation: ..... N/A

D. The expected effective date of the final-form regulation: ..... Upon publication as final

E. The expected date by which compliance with the final-form regulation will be required: Upon publication as final

F. The expected date by which required permits, licenses or other approvals must be obtained: N/A

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Board continuously evaluates the effectiveness of the Board's regulations and implementation of regulations. The Board discusses all regulatory proposals in conjunction with its regularly scheduled public meetings. The Board meets 9 times a year. The Board is scheduled to meet on the following upcoming dates in 2024: September 17, November 5, and December 17. In 2025, Board meetings are scheduled on January 28, March 4, April 8, May 20, July 1, August 19, September 30, November 18 and December 30.

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FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

RECEIVED

Independent Regulatory
Review Commission

October 3, 2024

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Copy below is hereby approved as to form and legality. Attorney General	Copy below is here by certified to be a true and correct copy of a document issued, prescribed or promulgated by:	Copy below is hereby approved as to form and legality. Executive or Independent Agencies.
BY: _____ (DEPUTY ATTORNEY GENERAL)	State Board of Medicine (AGENCY)	BY: _____ (Deputy General Counsel)
_____ DATE OF APPROVAL	DOCUMENT/FISCAL NOTE NO. 16A-4962 DATE OF ADOPTION: _____	9/25/2025 DATE OF APPROVAL
☐ Check if applicable Copy not approved. Objections attached.	BY: _____ Mark B. Woodland, M.S., M.D. TITLE Chairman (EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)	☐ Check if applicable. No Attorney General approval or objection within 30 days after submission.

FINAL (WITH PROPOSED OMITTED) RULEMAKING

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE

TITLE 49 PA CODE
CHAPTER 16
§ 16.92

OPIOID TREATMENT PROGRAMS

The State Board of Medicine (Board) amends Chapter 16, Subchapter F 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 such regulations as are reasonably necessary to carry out the purposes of the act. Additionally, under section 41(8) of the act, 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 commenced in 1986. Since that time, Board regulations have required an initial physical examination prior to the prescribing, administering or dispensing certain drugs and controlled substances. Currently, under § 16.92(b)(1) (relating to prescribing, administering and dispensing), 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 the Controlled Substances Act at 21 U.S.C.A. § 823(h)(1). The Substance Abuse and Mental Health Services Administration (SAMSHA) is the regulatory body which oversees OTPs at the Federal level. The Pennsylvania Department of Drug and Alcohol Programs (DDAP) regulates OTPs at the state level. *See* 28 Pa. Code Ch. 715. 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, 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 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 Pennsylvania OTPs 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)(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 one 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-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." Subsection 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 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 Pennsylvania, 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 website, "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 the 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 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. All 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 SAMSHA 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 SAMSHA regulations. DDAP, the Department of Health and the Department of Human Services support the of 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 SAMSHA regulations, was placed on the Board's June 25, 2024, agenda (the Board meets approximately every six 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 proposed rulemaking was impracticable and contrary to the public interest because of the importance of expediting this regulation to continue the enhancement and encouragement of opioid use disorder care and decrease in the stigma associated with opioid use disorder. Telehealth for this purpose was basically field-tested during the Covid 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 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 SAMSHA 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 SAMSHA 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 rulemaking, During the public comment period for the SAMHSA regulations, 373 public comments were received and considered by SAMHSA. Therefore, the Board finds that a 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 regulation 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 of 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 via 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 (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 paragraph, but rather, provides clarity to this long-standing standard promulgated by the Board.

Fiscal Impact and Paperwork Requirements

The 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 _____ , and IRRC met on _____, 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 Medical Practice Act.

Order

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

(a) The regulations of the Board at 49 Pa. Code § 16.92 are hereby amended to read as set forth in Annex A.

(b) The Board shall submit this final-omitted regulation 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 regulation 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 regulation and deposit it with the Legislative Reference Bureau as required by law.

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

Mark B. Woodland, M.S., M.D.
Chairperson
State Board of Medicine

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

* * * * *

SUBCHAPTER F. MINIMUM STANDARDS OF PRACTICE

* * * * *

§ 16.92. Prescribing, administering and dispensing <u>controlled substances</u>.

(a) [For purposes of this section, ‘‘drug’’ includes the following:

(1) Controlled substances under The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § § 780-101—780-144) or substances that are controlled substances under Federal law.

(2) Carisoprodol or agents in which carisoprodol is an active ingredient.

(3) Butalbital or agents in which butalbital is an active ingredient.

(4) Tramadol hydrochloride or agents in which tramadol hydrochloride is an active ingredient.]

<u>The following words and terms, when used in this section have the following meanings, unless the context clearly indicates otherwise:</u>

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.A. § 812 (relating to schedules of controlled substances).

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.A. § 823(h)(1)) (relating to registration requirements).

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

(b) When prescribing, administering or dispensing [drugs regulated under this section] 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.* [An] 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 [drug therapy] controlled substance shall be made consistent with the condition diagnosed, the [drug or drugs] 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 [drug] 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.

(i) On the initial occasion when a [drug] 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 [drug] controlled substance is being given.

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

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

(ii) After the initial occasion when a [drug] controlled substance is prescribed, administered or dispensed, the medical record must include the information required in subsection (b)(4)(i)(D) and changes or additions to the information recorded under subsection (b)(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 [drug] 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 [drug] 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 [drugs] 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 [drugs] 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 opioid treatment programs (OTP), 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 in an OTP with either buprenorphine or methadone provided that the provider determines that an adequate evaluation of the patient can be accomplished via 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).

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE
Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
(717) 783-1400

October 3, 2024

The Honorable George D. Bedwick, Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Final-Omitted Regulation
State Board of Medicine
16A-4962: Opioid Treatment Program

Dear Chairman Bedwick:

Enclosed is a copy of a final rulemaking package of the State Board of Medicine pertaining to 16A-4962: Opioid Treatment Program.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

Mark B. Woodland, MS, MD
State Board of Medicine

MBD/JCG/elb
Enclosure

cc: Arion Claggett, Acting Commissioner of Professional and Occupational Affairs
K. Kalonji Johnson, Deputy Secretary for Regulatory Programs
Andrew LaFratte, Deputy Policy Director, Department of State
Jason C. Giurintano, Deputy Chief Counsel Department of State
Jacqueline A. Wolfgang, Senior Regulatory Counsel, Department of State
Shana M. Walter, Senior Counsel, Board of Medicine
Board of Medicine

Shani Shenk

From: Monoski, Jesse <Jesse.Monoski@pasenate.com>
Sent: Thursday, October 3, 2024 11:25 AM
To: Stewart, Erica
Cc: Vazquez, Enid; joseph.kelly
Subject: RE: DELIVERY NOTICE: REGULATION 16A-4962 OPIOID TREATMENT PROGRAM

Received.

Jesse Monoski
Executive Director, Consumer Protection & Professional Licensure Senator Lisa M. Boscola, Minority Chair Rm 458 Main Capitol Building Harrisburg, PA, 17120
O: 717-787-4236

-----Original Message-----
From: Stewart, Erica <ericstewar@pa.gov>
Sent: Thursday, October 3, 2024 11:24 AM
To: Monoski, Jesse <Jesse.Monoski@pasenate.com>
Cc: Vazquez, Enid <Enid.Vazquez@pasenate.com>; Kelly, Joseph <joseph.kelly@pasenate.com>
Subject: DELIVERY NOTICE: REGULATION 16A-4962 OPIOID TREATMENT PROGRAM

■ EXTERNAL EMAIL ■

Could you please email me a receipt confirmation. I just need your confirmation yet to complete delivery. Thank you.

Erica L. Stewart| Legal Assistant 2
Office of Chief Counsel | Department of State Governor's Office of General Counsel P.O. Box 69523 | Harrisburg, PA 17106-9523 Office Phone 717.775.8145 | Fax: 717.787.0251 ericstewar@pa.gov |
https://gcc02.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.dos.pa.gov%2F&data=05%7C02%7Cericstewar%40pa.gov%7Ce472f62a93034536e45608dce3bf9265%7C418e284101284dd59b6c47fc5a9a1bde%7C0%7C0%7C638635659129367708%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=cJCuMDxMqW90sdu47%2BFxAYdLjkAv3KBKbnctLDgXtgU%3D&reserved=0
(preferred pronouns: she, her, hers)

-----Original Message-----
From: Monoski, Jesse <Jesse.Monoski@pasenate.com>
Sent: Thursday, October 3, 2024 11:14 AM
To: Stewart, Erica <ericstewar@pa.gov>

Subject: Read: DELIVERY NOTICE: REGULATION 16A-4962 OPIOID TREATMENT PROGRAM
Importance: High

This message and any attachment may contain privileged or confidential information intended solely for the use of the person to whom it is addressed. If the reader is not the intended recipient then be advised that forwarding, communicating, disseminating, copying or using this message or its attachments is strictly prohibited. If you receive this message in error, please notify the sender immediately and delete the information without saving any copies.

RECEIVED

Independent Regulatory
Review Commission

October 3, 2024

Shani Shenk

From: Orchard, Kari L. <KOrchard@pahouse.net>
Sent: Thursday, October 3, 2024 10:07 AM
To: Stewart, Erica; Brett, Joseph D.; Barton, Jamie
Subject: RE: DELIVERY NOTICE: REGULATION 16A-4962 OPIOID TREATMENT PROGRAM

Received!

Kari Orchard
Executive Director (D) | House Professional Licensure Committee
Chairman Frank Burns, 72nd Legislative District

From: Stewart, Erica <ericstewar@pa.gov>
Sent: Thursday, October 3, 2024 8:56 AM
To: Orchard, Kari L. <KOrchard@pahouse.net>; Brett, Joseph D. <JBrett@pahouse.net>; Barton, Jamie <JBarton@pahouse.net>
Subject: DELIVERY NOTICE: REGULATION 16A-4962 OPIOID TREATMENT PROGRAM
Importance: High

Please provide a written (email) confirmation of receipt of delivery of the attached rulemaking.

Please be advised that the State Board of Medicine is delivering the below final-omitted rulemaking.

Thank you for your attention to this matter.

- 16A-4962: Opioid Treatment Program

Erica L. Stewart| Legal Assistant 2
Office of Chief Counsel | Department of State
Governor's Office of General Counsel
P.O. Box 69523 | Harrisburg, PA 17106-9523
Office Phone 717.775.8145 | Fax: 717.787.0251
ericstewar@pa.gov | www.dos.pa.gov

(preferred pronouns: she, her, hers)

Protecting public health and safety.

Preserving the integrity of every vote.

Promoting business excellence.

Shani Shenk

From: Nicole Weaver <Nweaver@pahousegop.com>
Sent: Thursday, October 3, 2024 10:42 AM
To: Stewart, Erica; Nicole Sidle
Subject: RE: [EXTERNAL]: DELIVERY NOTICE: REGULATION 16A-4962 OPIOID TREATMENT PROGRAM

This has been received. Thank you.

Nicole Weaver
AA to Professional Licensure Committee
Chairman Carl Walker Metzgar
69th Legislative District
216 Ryan Building
717-783-8756

From: Stewart, Erica <ericstewar@pa.gov>
Sent: Thursday, October 3, 2024 8:56 AM
To: Nicole Sidle <Nsidle@pahousegop.com>; Nicole Weaver <Nweaver@pahousegop.com>
Subject: [EXTERNAL]: DELIVERY NOTICE: REGULATION 16A-4962 OPIOID TREATMENT PROGRAM
Importance: High

Please provide a written (email) confirmation of receipt of delivery of the attached rulemaking.

Please be advised that the State Board of Medicine is delivering the below final-omitted rulemaking.

Thank you for your attention to this matter.

- 16A-4962: Opioid Treatment Program

Erica L. Stewart| Legal Assistant 2
Office of Chief Counsel | Department of State
Governor's Office of General Counsel
P.O. Box 69523 | Harrisburg, PA 17106-9523
Office Phone 717.775.8145 | Fax: 717.787.0251
ericstewar@pa.gov | www.dos.pa.gov

(preferred pronouns: she, her, hers)

Shani Shenk

From: Abelson, Addie
Sent: Thursday, October 3, 2024 9:51 AM
To: Stewart, Erica; Rizzi, Alicia (GC); Keys, Jaclyn (GC); GC, Regulations
Subject: FW: [EXTERNAL] DOS Final-Omitted Regulation #16A-4962: Opioid Treatment Programs
Attachments: RE: [EXTERNAL] DOS Final-Omitted Regulation #16A-4962: Opioid Treatment Programs

Receipt attached.

Addie A. Abelson
Deputy General Counsel
(717) 214-9535
adabelson@pa.gov | www.ogc.pa.gov

From: Elliott, Amy M. <aelliott@attorneygeneral.gov>
Sent: Thursday, October 3, 2024 9:51 AM
To: Abelson, Addie <adabelson@pa.gov>; Trotter, Carolyn <ctrotter@attorneygeneral.gov>
Cc: Montgomery, Cynthia <cymontgome@pa.gov>; GC, Regulations <RA-GCREGULATIONS@pa.gov>
Subject: RE: [EXTERNAL] DOS Final-Omitted Regulation #16A-4962: Opioid Treatment Programs

Receipt acknowledged

Amy M. Elliott
Chief Deputy Attorney General
Legal Review Section
717-783-6316 (w)
717-941-0523 (c)
aelliott@attorneygeneral.gov

From: Abelson, Addie <adabelson@pa.gov>
Sent: Thursday, October 3, 2024 9:48 AM
To: Elliott, Amy M. <aelliott@attorneygeneral.gov>; Trotter, Carolyn <ctrotter@attorneygeneral.gov>
Cc: Montgomery, Cynthia <cymontgome@pa.gov>; GC, Regulations <RA-GCREGULATIONS@pa.gov>
Subject: [EXTERNAL] DOS Final-Omitted Regulation #16A-4962: Opioid Treatment Programs

Hi Amy:

****At your earliest convenience, please confirm receipt of this final-omitted rulemaking so that DOS can complete delivery to IRRC. Thanks!**

Attached for your review please find the Department of State's final-omitted regulation #16A-4962. This one probably looks familiar: I sent a "request to proceed as final omit" for this one on July 25, 2024, and then we discussed it on a phone call with DOS on August 1, 2024. Please feel free to reach out if you have any questions.

Warm regards,

Addie A. Abelson
Deputy General Counsel
Office of General Counsel
333 Market Street, 17th Floor
Harrisburg, PA 17101
Phone: (717) 214-9535

Shani Shenk

From: Smeltz, Jennifer <jmsmeltz@pasen.gov>
Sent: Thursday, October 3, 2024 8:59 AM
To: Stewart, Erica
Subject: RE: DELIVERY NOTICE: REGULATION 16A-4962 OPIOID TREATMENT PROGRAM

Received.

Jennifer Smeltz, Executive Director
Consumer Protection and Professional Licensure Committee
Office of Senator Pat Stefano
Phone: (717) 787-7175

From: Stewart, Erica <ericstewar@pa.gov>
Sent: Thursday, October 3, 2024 8:56 AM
To: Smeltz, Jennifer <jmsmeltz@pasen.gov>
Subject: DELIVERY NOTICE: REGULATION 16A-4962 OPIOID TREATMENT PROGRAM
Importance: High

Please provide a written (email) confirmation of receipt of delivery of the attached rulemaking.

Please be advised that the State Board of Medicine is delivering the below final-omitted rulemaking.

Thank you for your attention to this matter.

- 16A-4962: Opioid Treatment Program

Erica L. Stewart| Legal Assistant 2
Office of Chief Counsel | Department of State
Governor's Office of General Counsel
P.O. Box 69523 | Harrisburg, PA 17106-9523
Office Phone 717.775.8145 | Fax: 717.787.0251
ericstewar@pa.gov | www.dos.pa.gov

(preferred pronouns: she, her, hers)