

CITY OF PHILADELPHIA
DEPARTMENT OF PUBLIC HEALTH
Board of Health

Regulation Relating to Nuisance Health Establishments

Approved June 13, 2019

WHEREAS, Section 5-301(b) of the Philadelphia Home Rule Charter authorizes the Board of Health to issue Department of Public Health regulations for the preservation and promotion of the health of the people of Philadelphia;

WHEREAS, Philadelphia is in the midst of an unprecedented drug overdose epidemic driven by excessive prescribing of opioids, including in unusually high-volume establishments;

WHEREAS, 1,217 Philadelphians died from unintentional drug overdose in 2017, the vast majority involving opioids, and an additional 1,116 died in 2018, which in each year is more than double the number of Philadelphians who died from unintentional drug overdose in 2013;

WHEREAS, the City Council of Philadelphia passed Bill No. 140452, concerning “Nuisance Health Establishments,” thereby exercising the police power delegated to the City of Philadelphia via the Philadelphia Home Rule Charter to abate public nuisances and protect public health and safety in the City of Philadelphia;

WHEREAS, Section 6-1101(1) of The Philadelphia Code defines a “Nuisance Health Establishment” as “[a]ny Health Establishment determined by the Department to be a menace to public health because of controlled substance use, sale or the exchange of compensation for prescriptions for Controlled Substances or because of conditions arising from those activities” and Section 6-1102 further elaborates on criteria the Department is to consider in making such a determination; and

WHEREAS, Section 6-1102(2) of The Philadelphia Code provides that a requirement for designation by the Department as a Nuisance Health Establishment is that the “Health Establishment provides for the administration, dispensing, delivery, gift or prescription by any Practitioner of a Controlled Substance other than in accordance with generally accepted standards of care for medical practices”;

NOW, THEREFORE, the Board of Health hereby adopts this Regulation Relating to Nuisance Health Establishments, as follows:

(1) Generally Accepted Standards of Care for Prescribing Opioids.

The Philadelphia Board of Health recognizes that dependence, addiction, and overdose are serious and potentially life-threatening risks of treatment with opioids, and that these risks have risen to become a public health crisis in Philadelphia. Given this public health threat, the Board has determined that it is necessary to establish generally accepted standards of care for medical practices prescribing opioids in Philadelphia. Based on a review of the applicable medical literature and accepted standards in the medical community, including those that have been determined by the Centers for Diseases Control and Prevention, the Pennsylvania Department of Health, the Pennsylvania State Board of Medicine, this Board, and other medical expert organizations, the Board of Health adopts the following generally accepted standard of care for the prescription of opioids by medical practices, Health Establishments,* and Practitioners in Philadelphia:

(a) Generally Accepted Standard of Care for the Prescription of Opioids by Medical Practices, Health Establishments, and Practitioners Operating in Philadelphia

Unless such Practitioner is prescribing opioids to treat a patient receiving end of life care, a Practitioner prescribes outside the generally accepted standard of care for medical practices when such Practitioner shows a pattern of prescribing opioids without conducting and documenting appropriate patient evaluations, prescribing opioids at a dangerous dose or duration, or prescribing opioids for contraindicated conditions or for inappropriate indications, all of which are explained in paragraphs (i) through (iv) below.

i. Conducting and Documenting Appropriate Patient Evaluations. A Practitioner fails to conduct and document an appropriate patient evaluation prior to prescribing opioids or before continuing opioid prescriptions when such Practitioner fails to document (.1) a history of the patient's medical condition and (.2) a physical examination. Before initiating the chronic use of opioids, an evaluation will not be considered appropriate unless it includes an assessment and inquiry into any history of substance use disorder, conducting and documenting a urine drug test for controlled substances and, for women of reproductive age, conducting and documenting a discussion of family planning and pregnancy-related risks.

ii. Dangerous Dose or Duration of Opioids. A prescription for opioids shall be considered to be at a dangerous dose or duration if such prescription is for:

(.1) more than 50 Morphine Milligram Equivalents ("MME") per day without a prescription for naloxone.

(.2) more than 90 MME per day without a prescription for naloxone, documentation of an individualized assessment of the risks versus benefits of the dose at issue, and documentation of a consultation by a board-certified pain specialist.

* Capitalized terms not defined in this regulation shall have the definitions provided in Chapter 6-1100 of The Philadelphia Code.

(.3) a duration exceeding seven (7) days for the purpose of treating acute, non-surgical pain.

(.4) a duration exceeding three (3) months for the purpose of treating chronic conditions without documentation of an assessment of functional status and clinical improvement, and whether the benefits of opioids continue to outweigh the risks.

iii. **Contraindications.** An opioid prescription is contraindicated when the patient (.1) has a history of substance use disorder or of drug overdose, unless counseling on risk of overdose is documented and documented steps are taken to mitigate the risk, (.2) has also been prescribed, or is otherwise taking, benzodiazepines, unless counseling on risk of overdose is documented and documented steps are taken to mitigate the risk, including prescribing naloxone, or (.3) has moderate or severe sleep-disordered breathing.

iv. **Inappropriate Indications.** A Practitioner prescribes opioids for an inappropriate indication when such a prescription is made to treat one or more of the following conditions, unless there have been documented prior attempts to treat such conditions with non-addictive forms of pain relief and the prescribing Practitioner has made specific documented findings that the risks of such opioid prescription are outweighed by the benefits:

(.1) Headaches.

(.2) Chronic low back pain.

(.3) Fibromyalgia.

(.4) Other forms of chronic, noncancer pain.

(b) Practices and Procedures in Health Establishments Employing Multiple Practitioners. The owner or owners of a Health Establishment employing multiple Practitioners must implement and document practices and procedures that are reasonably likely to ensure that the prescribing practices of all Practitioners at such Establishment are consistent with the generally accepted standard of care for prescribing opioids set forth in Section (1)(a) of this regulation and that such Establishment is not operating as a Nuisance Health Establishment pursuant to Section 6-1102 of The Philadelphia Code.

(2) Criteria for Investigating. The Department of Public Health (the “Department”) may commence an investigation of a Health Establishment, and a Health Establishment shall be required, when so ordered, to submit certain documentation to the Department in aid of such investigation, upon a finding by the Department that such Establishment satisfies the criteria of subsections (a) and (b), below:

(a) Any of the following:

(i) The Health Establishment employs one or more Practitioners who issued one thousand (1,000) or more prescriptions for opioids (including refills) in any twelve (12) month period.

(ii) The Department has received a credible referral from a health plan or a pharmacy regarding suspicious or insufficiently supported prescribing practices that identifies the Health Establishment or a Practitioner that practices at such Establishment.

(iii) The Health Commissioner determines, based on available information, that a combination of one or more of the following demonstrates a reasonable suspicion that a Health Establishment employs one or more Practitioners who are prescribing opioids outside the generally accepted standard of care for medical practices:

(a.) The dosage of opioids prescribed by such Practitioner relative to such Practitioner's peers.

(b.) The duration of opioid prescriptions written by such Practitioner relative to such Practitioner's peers.

(c.) The number of opioid prescriptions written by such Practitioner relative to such Practitioner's peers.

(d.) The proportions of patients treated by such Practitioner that are prescribed opioids relative to such Practitioner's peers.

(e.) The number of patients who were prescribed opioids by such Practitioner and who died of an opioid overdose.

(f.) Credible complaints, reports, or observations that raise a reasonable suspicion of a Nuisance Health Establishment, including but not limited to complaints or reports concerning large crowds or lines of patients; frequent ingress and egress of patients; presence of armed security guards; drug usage in and around such Establishment; or substantial number of cash customers or payments.

(g.) The totality of information available to the Health Commissioner otherwise raises a reasonable suspicion that a Health Establishment employs one or more Practitioners who are prescribing opioids outside the generally accepted standard of care for medical practices.

(iv) Such other data as, in the judgment of the Health Commissioner is sufficient to raise a reasonable suspicion that the Health Establishment's prescribing practices are outside of generally accepted standard of care for medical practices.

(b) The Department has reviewed publicly available information concerning the Health Establishment and found nothing that would clearly explain and justify the conditions that satisfy subsection (a), above.

(3) Requirement to Submit Documentation

(a) Order to Submit Documentation. As part of an investigation pursuant to Section (2) above, the Department shall issue an order requiring the Health Establishment to submit to the Department, certain records regarding the Health Establishment and certain records for each Practitioner named in the order, upon such reasonable schedule as the Department sets forth in the order (“Order to Submit Documentation”).

Such order may require the production of any practices or procedures implemented by the Health Establishment to reasonably assure that the prescribing practices of the Practitioners at such Establishment are consistent with the generally accepted standard of care for prescribing opioids set forth in Subsection (1)(a) of this regulation and that such Establishment is not operating as a Nuisance Health Establishment pursuant to Section 6-1102 of The Philadelphia Code, and such other information as the Department reasonably determines is necessary to conduct its investigation.

For each Practitioner named in such order, the request may include the following documents and information as of the date specified in such order, and such other documents and information as the Department reasonably determines is necessary to conduct its investigation, provided that the names, social security numbers, insurance ID numbers, home addresses, and the day and month of birth of patients may be redacted from such records:

- (i) the total number of patient visits in past 12 months, by month.
- (ii) the number of patient visits in past month in which patients received prescriptions for opioids, for benzodiazepines, and for both opioids and benzodiazepines
- (iii) A list of the 50 most recently-seen patients who received opioid prescriptions that includes: demographics; opioid formulation, dose, and duration; date of prescription; diagnoses; and medical indication for opioid prescription.
- (iv) Copies of medical records for the 25 most recently-seen patients who received opioid prescriptions, which include: 1) complete medical problem list, 2) complete record of most recent visit in which opioids were prescribed, including patient history, physical examination, radiographic and laboratory tests ordered and results of those tests, diagnostic assessment, treatments prescribed, and information/counseling provided to patient, 3) complete list of medications prescribed for the previous 12 months (including dose and instructions for use).

(b) Failure to Respond and Presumptions. A Health Establishment that does

not respond to an Order for Documentation in accordance with the schedule set forth in such order, or such other schedules as has been agreed to in writing by the Department, shall be presumed to have a demonstrated pattern of prescribing opioids outside the generally accepted standard of care for medical practices.

(4) Review of Investigatory File of Health Establishment by Opioid Prescribing Practices Expert. The Opioid Prescribing Practices Expert shall review all information gathered by the Department in an investigation conducted pursuant to Sections (2) and (3), above, to determine whether one or more Practitioners in a Health Establishment, or such Establishment as a whole, has a demonstrated pattern of prescribing opioids outside the generally accepted standard of care for medical practices based on the information collected. Based on such review, the Opioid Prescribing Practices Expert will take one of the following actions:

(a) If such expert concludes to a reasonable degree of medical certainty based on the investigatory information collected that one or more Practitioners in the Health Establishment, or such Establishment as a whole, has a demonstrated pattern of prescribing opioids in a manner inconsistent with the generally accepted standard of care adopted by the Board, the Prescribing Practices Expert shall recommend that the Health Commissioner declare such Establishment is a Nuisance Health Establishment pursuant to Section 6-1102 of The Philadelphia Code.

(b) If such expert is unable to make a determination as to whether one or more Practitioners in the Health Establishment is prescribing opioids in a manner consistent with the generally accepted standard of care for medical practices, the Expert may conduct a further investigation into such Establishment and make such reasonable requests for additional information from such Establishment as shall reasonably be determined by the Opioid Prescribing Practices Expert.

(c) If such expert concludes to a reasonable degree of medical certainty based on the investigatory information collected that all Practitioners in the Health Establishment are prescribing opioids in a manner consistent with generally accepted standard of care for medical practices, the Expert shall direct the Department to discontinue the investigation of such Establishment.

(5) Determination by Health Commissioner

(a) The Health Commissioner shall consider any recommendation submitted by the Opioid Prescribing Practices Expert pursuant to Section (4)(a) above, and such other information as the Health Commissioner determines is appropriate under the circumstances, and shall determine whether or not the Health Establishment is a Nuisance Health Establishment pursuant to Section 6-1102 of The Philadelphia Code, or whether further investigation is required.

(b) If the Health Commissioner determines that the Health Establishment is a Nuisance Health Establishment pursuant to Section 6-1102 of The Philadelphia Code, the Department shall take steps to immediately abate the nuisance pursuant to Section (7), below, and the Health Commissioner shall refer the matter to the Law Department for appropriate action.

(6) Order to Abate Nuisance

The steps taken by the Health Commissioner to immediately abate the nuisance, pursuant to Section (5)(b) above, may include, among other actions, either or both of the following:

(a) Certifying the matter to the Department of Licenses and Inspections which shall (or in the event a memorandum of understanding is executed delegating such authority to the Department, the Department shall itself) issue a Notice of Violation and Order to Abate the Nuisance (“Notice of Violation and Order”), as further explained in Section (7), below, which Notice of Violation and Order shall be appealable to the Board of License and Inspection Review within thirty (30) days, and which Notice of Violation and Order may include a Notice of Intent to Cease Operations within thirty (30) days, or such other reasonable time period designated by the issuing department.

(b) Sending the Health Establishment a notice informing such Establishment of the Commissioner’s determination; directing such Establishment to abate the nuisance, as further explained in Section (7), below; and informing such Establishment that if such Establishment does not fully abate the nuisance within thirty (30) days the City may file suit against such Establishment, the Department may proceed against such establishment pursuant to Section (6)(a) above, or both (“Notice and Directive to Abate”).

(7) Abatement of Nuisance

The following is a non-exhaustive list of steps that a Health Establishment can be directed or ordered to take to abate a public health nuisance pursuant to Section (6)(a) or (6)(b), respectively.

- (a) Engaging in ongoing communication efforts with the Department to assure future compliance with the generally accepted standards of care for prescribing opioids.
- (b) Holding regular trainings for Practitioners employed by the Health Establishment regarding the generally accepted standards of care for prescribing opioids.
- (c) Instituting an internal review and documentation procedure to identify and document instances where Practitioners employed by the Health Establishment fail to comply with the generally accepted standards of care for prescribing opioids.
- (d) Providing required reporting of information reasonably calculated to assess Practitioner compliance with the generally accepted standards of care for prescribing opioids.

- (e) Documentation of the implementation of quality assurance practices reasonably calculated to ensure that such Establishments are not operating as a Nuisance Health Establishment.
- (f) Supervision or termination of any Practitioner who has failed to comply with the generally accepted standards of care for prescribing opioids.
- (g) Submission of a plan by the Nuisance Health Establishment, at such establishments' own expense, to affirmatively demonstrate steps have been or will be taken to abate the nuisance to the satisfaction of the Department.
- (h) Cease operations until such time as the Department is satisfied that the Health Establishment has in place sufficient remedial and protective measures to prevent such Establishment from continuing as a Nuisance Health Establishment, provided that the Department shall take steps to provide for notice to, and the orderly transition of, patients of such Establishment prior to ceasing the operations of a Nuisance Health Establishment.
- (i) Any other measures deemed likely to abate or prevent the recurrence of the nuisance behavior.

(8) Appeal of Order to Submit Documentation, Notice of Violation and Order, Notice of Intent to Cease Operations

Any person aggrieved by the issuance of the Order to Submit Documentation under Section 3, a Notice of Violation and Order under Section (6)(a), or a Notice of Intent to Cease Operations under Section (6)(a) shall have the right to appeal to the Board of Licenses and Inspections Review within thirty (30) days of the mailing date of such order or notice.

(9) Resolution Through Negotiation

Any person aggrieved by any order, directive, or notice issued pursuant to this regulation may contact the Department to negotiate a resolution acceptable to the parties. A request to commence negotiations shall include documentation of the steps taken to date to remedy any violations raised in such order, directive, or notice as well as a proposed remedial plan to address any remaining violations and to assure the Health Establishment does not function as a Nuisance Health Establishment. Such discussions shall not toll the time period to appeal. Nor shall they toll any applicable time period for compliance, absent express agreement by the Department or the Department of Licenses and Inspections.

(10) Confidentiality of Records

The Department shall maintain the confidentiality of individually identifiable health information collected pursuant to this regulation in accordance with applicable laws and regulations and in a manner consistent with the Department's maintenance of its case records that are subject to 28 Pa. Code 27.5a.