

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE BOARD OF HEALTH

Notice of Public Hearing and Opportunity to Comment on Proposed Amendment to Article 203 of the New York City Health Code

What are we proposing? The New York City Department of Health and Mental Hygiene ("Department" or "DOHMH") is proposing that the Board of Health ("Board") amend Article 203 of the New York City Health Code ("Heath Code") to specify that reporting of medication-induced terminations of pregnancy is required and to provide the manner of such reporting.

When and where is the hearing? The Department will hold a public hearing on these proposed rules. The public hearing will take place at 1:00PM to 3:00PM on Tuesday, November 28, 2023. The hearing will be conducted by video conference accessible via internet or telephone:

- Internet: To participate in the public hearing, enter to register at this Webex URL:
 https://nycdohmh.webex.com/nycdohmh/j.php?MTID=m418f36244a3aba3525acf35fd7d63bff
 If prompted to provide an event number or password, enter the following:
 Event number: 2338 631 1392, Password: Health (432584 from phones and video systems)
- **Phone:** For access, dial: (408) 418-9388; (646) 992-2010 (New York City) and enter the following Access code: **233 863 11392**, Password: **Health** (432584)

How do I comment on the proposed amendments? Anyone can comment on the proposed amendments by:

- **Website.** You may submit comments to the Department through the NYC rules website at http://rules.cityofnewyork.us.
- Email. You may email comments to resolution comments@health.nyc.gov.
- **Mail.** You may mail comments to:

New York City Department of Health and Mental Hygiene Gotham Center, 42-09 28th Street, CN 30 Long Island City, NY 11101-4132

- **Fax.** You may fax comments to Department at 347-396-6087.
- By speaking at the hearing. Anyone who wants to comment on the proposed rules at the public hearing must sign up to speak. You can sign up before the hearing by calling Svetlana Burdeynik at (347) 396-6078 or by emailing at resolutioncomments@health.nyc.gov before the hearing begins at 1:00PM on November 28, 2023. While you will be given the opportunity during the hearing to indicate that you would like to comment, we prefer that you sign up in advance. You can speak for up to three minutes.

Is there a deadline to submit comments? Written comments must be received on or before November 28, 2023, at 5:00 pm.

What if I need assistance to participate in the hearing? You must tell the Office of Legal Affairs if you need a reasonable accommodation of a disability at the hearing. You must tell us if you need a sign language interpreter. You can tell us by mail at the address given above. You may also tell us by telephone at 347-396-6078. Advance notice is requested to allow sufficient time to arrange the accommodation. Please tell us by November 14, 2023.

Can I review the comments made on the proposed amendment? You may review the comments made online at http://rules.cityofnewyork.us/ on the proposed amendments by going to the website at http://rules.cityofnewyork.us/. All written comments and a summary of the oral comments received by the Department will be made available to the public within a reasonable period of time by the Department's Office of the General Counsel.

What authorizes the Board to make this amendment? Section 558(b) and (c) of the Charter empower the Board to amend the Health Code and to include in the Health Code all matters to which the Department's authority extends. Section 558(c) of the Charter authorizes the Board to include in the Health Code provisions related to maintaining a registry of births and deaths. Section 556(c)(1) of the Charter authorizes the Department to supervise and control the registration of births and deaths. Section 1043(a) of the Charter grants rulemaking powers to the Department.

Where can I find the Department's rules? The Department's rules and the Health Code are located in Title 24 of the Rules of the City of New York.

What laws govern the rulemaking process? The Department must satisfy the requirements of Section 1043 of the Charter when adding or amending rules. This notice is made according to the requirements of Section 1043(b) of the Charter.

The proposed amendments were not included in the Department's regulatory agenda for this fiscal year because it did not contemplate this amendment at the time the regulatory agenda was published.

Statement of Basis and Purpose of Proposed Rule

Medication-induced termination of pregnancy involves the intentional use of medicines to end a pregnancy. More than half (54%) of induced terminations of pregnancy ("ITOPs") in the United States are conducted using this method. Eligible patients who opt for medication ITOPs can receive their medication from a licensed provider, or from a retail or mail-order pharmacy.

Currently, the most common medication ITOP in the United States is a two-drug regimen using mifepristone and misoprostol. This regimen is approved for use up to 10 weeks of pregnancy,² and research has shown provision beyond 10 weeks is safe and effective.³ The U.S. Food and Drug Administration ("FDA") first approved mifepristone for medication abortion in 2000, and issued subsequent updates to its approved use in 2016 and 2021. Since 2016, the FDA labeling for mifepristone no longer indicates that the medication should be used only in the clinician's office. Since 2021, the FDA

¹ https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions

² Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation | FDA

³ Abortion care guideline (who.int)

has allowed patients to receive the medication either in person or via mail delivery. As of January 2023, the FDA also authorized retail pharmacies to dispense mifepristone. With the removal of the requirement for in-person dispensing, telemedicine has increasingly become a more common modality for patient access. Patients can safely and effectively receive and use mifepristone along with misoprostol at home and routine in-person follow up is not normally necessary after a medication ITOP.⁴

All ITOPs in New York City must be reported to the Department pursuant to Article 203 of the Health Code. However, there remains some uncertainty among health care providers about whether medication ITOPs should be reported pursuant to Article 203 because the Health Code does not include an explicit provision for a medication ITOP that occurs in the home without a health care provider in attendance then or afterwards.

The Department is therefore proposing to amend Article 203 to specifically include medication ITOPs within the existing definition of ITOP, clarify that they must be reported to the Department when the patient is within New York City at the time the abortion medication is prescribed or ordered, and specify the timing of the reporting. Updating Article 203 in this manner is necessary to ensure full and accurate reporting of medication ITOPs occurring in the city. In addition, the Department is proposing to modify section 203.07(a) of the Health Code to add the words "certification and" preceding "confidential medical report" in the first sentence, which had been inadvertently omitted when this section was recently amended.

The proposed amendment is as follows:

New material is underlined.

[Deleted material is in brackets.]

"Shall" and "must" denote mandatory requirements and may be used interchangeably in the rules of this department, unless otherwise specified or unless the context clearly indicates otherwise.

RESOLVED, that subdivision (c) of section 203.01 of Article 203 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, be amended, and a new subdivision (f) be added to such section, to read as follows:

- (c) "Induced termination of pregnancy" means the purposeful interruption of an intrauterine pregnancy with the intention other than to produce a live-born infant and which does not result in a live birth.
 - (1) This definition includes "medication-induced termination of pregnancy" as defined in this article.
 - (2) This definition excludes management or prolonged retention of products of conception following a spontaneous termination of pregnancy.

⁴ National Academies of Sciences, Engineering, and Medicine. The safety and quality of abortion care in the United States. Washington, DC: National Academy of Sciences; 2018.

(f) "Medication-induced termination of pregnancy" means an induced termination of pregnancy using medication prescribed or ordered by a licensed heath care practitioner. A medication-induced termination of pregnancy occurs in the City when a licensed heath care practitioner prescribes or orders the medication for a patient, regardless of the location of such patient when the medication is taken.

RESOLVED, that subdivisions (a) and (c) of section 203.03 of Article 203 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, be amended to read as follows:

- (a) When a termination of pregnancy occurs in the City it shall be reported as follows:
- [* * *]
 - (4) If the event is investigated by the office of chief medical examiner, by a medical examiner within that office; or
 - (5) If the event is a medication-induced termination of pregnancy, by the licensed health care practitioner prescribing the medication.
- (c) A certificate of termination of pregnancy required by this section shall be filed within 24 hours after the event if a <u>disposition</u> permit [to dispose of the conceptus] <u>issued</u> pursuant to Article 205 of this Code is required or requested, and in all other cases a certificate of termination of pregnancy shall be filed [within five business days after the event] with any office maintained and designated by the Department for such purposes <u>within five business days after the date the medication for a medication-induced termination of pregnancy was prescribed or ordered.</u>

RESOLVED, that subdivision (a) of section 203.07 of Article 203 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, be amended to read as follows:

(a) The <u>certificate and</u> confidential medical report of a spontaneous termination of pregnancy and the certificate of induced termination of pregnancy shall be confidential and not subject to disclosure or to inspection by persons other than the Commissioner or authorized personnel of the Department. The Commissioner or the Commissioner's designee may, however, approve the inspection by others of such medical reports and certificates for scientific purposes or in accordance with federal, New York State, or New York City law.

NEW YORK CITY MAYOR'S OFFICE OF OPERATIONS 253 BROADWAY, 10th FLOOR NEW YORK, NY 10007 212-788-1400

CERTIFICATION / ANALYSIS PURSUANT TO CHARTER SECTION 1043(d)

RULE TITLE: Amendment of Rules Relating to Reporting of Medication-Induced Termination of Pregnancy (Health Code Article 203)

REFERENCE NUMBER: DOHMH-133

RULEMAKING AGENCY: Department of Health and Mental Hygiene

I certify that this office has analyzed the proposed rule referenced above as required by Section 1043(d) of the New York City Charter, and that the proposed rule referenced above:

- (i) Is understandable and written in plain language for the discrete regulated community or communities;
- (ii) Minimizes compliance costs for the discrete regulated community or communities consistent with achieving the stated purpose of the rule; and
- (iii) Does not provide a cure period because it does not establish a violation, modification of a violation, or modification of the penalties associated with a violation.

/s/ Francisco X. Navarro	<u>October19, 2023</u>
Mayor's Office of Operations	Date

NEW YORK CITY LAW DEPARTMENT DIVISION OF LEGAL COUNSEL 100 CHURCH STREET NEW YORK, NY 10007 212-356-4028

CERTIFICATION PURSUANT TO

CHARTER §1043(d)

RULE TITLE: Amendment of Rules Relating to Reporting of Medication-Induced Termination of Pregnancy (Health Code Article 203)

REFERENCE NUMBER: 2023 RG 075

RULEMAKING AGENCY: Department of Health and Mental Hygiene

I certify that this office has reviewed the above-referenced proposed rule as required by section 1043(d) of the New York City Charter, and that the above-referenced proposed rule:

- (i) is drafted so as to accomplish the purpose of the authorizing provisions of law;
- (ii) is not in conflict with other applicable rules;
- (iii) to the extent practicable and appropriate, is narrowly drawn to achieve its stated purpose; and
- (iv) to the extent practicable and appropriate, contains a statement of basis and purpose that provides a clear explanation of the rule and the requirements imposed by the rule.

Date: October 19, 2023

/s/ STEVEN GOULDEN Acting Corporation Counsel