

THE COMMONWEALTH OF MASSACHUSETTS OFFICE OF THE ATTORNEY GENERAL

ONE ASHBURTON PLACE BOSTON, MASSACHUSETTS 02108

(617) 727-2200 (617) 727-4765 TTY www.mass.gov/ago

July 31, 2015

The Honorable James J. Lyons, Jr. House of Representatives State House Boston, MA 02133-1054

Re: Review of Alleged Sale of Fetal Tissue

Dear Representative Lyons:

In your July 16, 2015 letter to Attorney General Healey, you referenced videos recently released by the Center for Medical Progress and expressed concern about whether Planned Parenthood affiliates in Massachusetts might be violating laws that prohibit the sale of fetal tissue. The Attorney General's Office has conducted a review of the policies and practices of Planned Parenthood League of Massachusetts (PPLM) concerning the disposition of fetal tissue.

We found that PPLM has sound policies and practices for the disposition of fetal tissue that conform to relevant laws and public health regulations. While fetal tissue donation and reimbursement of its associated reasonable costs (such as for preservation, storage, and transportation) are lawful under state and federal law, PPLM does not engage in, nor is it planning to engage in, any practices or programs for tissue donation.

Our review comprised the following:

- We researched and confirmed the legal and regulatory framework for tissue donation and medical waste disposition in Massachusetts.
- We issued a written request to PPLM concerning its policies and practices related to the
 disposition of fetal tissue, including any practice of donating or selling fetal tissue and
 any role in the importation of fetal tissue into Massachusetts for medical research.
 (Please see Attachment A to this letter.)

- We reviewed responsive information and documents from PPLM concerning its medical waste disposition practices, which attest that PPLM does not engage in the donation or sale of fetal tissue or have any involvement in the importation of fetal tissue into Massachusetts. (Please see Attachment B to this letter.)
- We interviewed PPLM's CEO and Medical Director regarding PPLM's policies and practices.
- We interviewed three practicing PPLM clinicians concerning PPLM's policies and
 practices related to the disposition of fetal tissue. The clinicians are based in PPLM's
 Boston, Worcester, and Springfield offices, and each has more than a decade of
 experience working and providing health care services at PPLM. Each clinician
 independently reported medical waste disposition practices that conform to relevant state
 regulations and confirmed PPLM does not engage in the donation or sale of fetal tissue.
- We reviewed a sworn statement from PPLM's Medical Director, which confirms that in its 35-year history, PPLM has not had any practice or program concerning the donation or sale of fetal tissue. (Please see Attachment C to this letter.)

We found no evidence that PPLM has acted in any manner other than in conformity with the law in this area, and accordingly, we have closed this review. We are available if you have any questions. Please note that we have redacted certain information in the attachments to this letter to protect the privacy of the individuals involved.

Sincerely,

Mary A. Beckman

Chief, Health Care and Fair Competition Bureau

May S. Bretern

Enclosure

Attachment A



THE COMMONWEALTH OF MASSACHUSETTS OFFICE OF THE ATTORNEY GENERAL

ONE ASHBURTON PLACE
BOSTON, MASSACHUSETTS 02108

July 23, 2015

TEL: (617) 727-2200 www.mass.gov/ago

Susan Kaufman Interim Chief Executive Officer Planned Parenthood League of Massachusetts 1055 Commonwealth Avenue Boston, MA 02215-1001

Dear Ms. Kaufman:

I am writing to inquire about the practices of Planned Parenthood League of Massachusetts ("PPLM") concerning fetal tissue disposition to ensure that such practices are consistent with state and federal law. In order to assist this office in understanding PPLM's practices, and reserving our ability to seek additional information, we request that you provide us with the following:

- 1. Documents sufficient to show PPLM's policies and practices concerning the disposition of fetal tissue.
- 2. Documents sufficient to show PPLM's policies and practices concerning any donation or sale of fetal tissue, including patient consent policies and procedures and any fees or exchange of funds by or on behalf of PPLM associated with any such donation or sale.
- 3. Documents sufficient to show PPLM's role, if any, in importation of fetal tissue into Massachusetts for medical research.
- 4. Documents sufficient to show the name, title, address, and telephone number of the medical director of each Planned Parenthood facility in Massachusetts.

In addition to this information, we note that you have made available your Medical Director to speak with us about PPLM's practices and procedures. We appreciate your cooperation in this matter and look forward to hearing from you. If you have any questions, please call me at (617) 727-2200.

Sincerely,

Karen C. Tseng

Chief, Health Care Division

CC

Attachment B



1055 Commonwealth Avenue Boston, MA 02215 p: 800.258.4448 · f: 617.616.1665 www.pplm.org

Planned Parenthood League of Massachusetts

July 27, 2015

Karen C. Tseng Chief, Health Care Division Office of the Attorney General Commonwealth of Massachusetts One Ashburton Place Boston, MA 02108

Dear Ms. Tseng:

The purpose of this letter is to respond to your letter of July 23, 2015 in which you inquire about the practices of Planned Parenthood League of Massachusetts ("PPLM") concerning fetal tissue disposition to ensure that such practices are consistent with state and federal law.

- 1) Regarding your request for documents sufficient to show PPLM's policies and practices concerning the disposition of fetal tissue, PPLM has a contract in place with a medical waste vendor to remove all medical waste, including products of conception. In compliance with M.G.L. c. 111 §§ 3, 5, and 127A and 105 CMR 480.000, we document all transfers of medical waste, including products of conception, from our facilities to our vendor. In the event that products of conception are requested by law enforcement, with the patient's consent, PPLM follows procedures per our policy "Obtaining Tissue in the Case of a Sexual Assault Prosecution". We have attached the following related documents:
- PPLM Procedure and Schedule for Health Center Medical Waste Disposal (please note that we have redacted the specific name of the medical waste removal vendor and details regarding our pick-up schedule from this, a public document.)
- A sample Waste Management Log
- PPLM Policy for Obtaining a Tissue Sample in the Case of Sexual Assault
- 2) PPLM does not have a program for the donation or sale of fetal tissue nor do we receive any fee or exchange of funds for such tissue. As a result, we have no documents to provide.
- 3) PPLM is not involved in the importation of fetal tissue into Massachusetts. As a result, we have no documents to provide.



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Planned Parenthood League of Massachusetts

4) PPLM has one Medical Director who is responsible for all seven of our health centers. Her contact information is:

MD MPH
Medical Director
Planned Parenthood League of Massachusetts
1055 Commonwealth Avenue
Boston, MA 02215
Phone:

As you acknowledged, Dr. would be more than pleased to address any follow-up issues you may have regarding PPLM's practices and procedures.

Please let us know if you require any additional information.

Sincerely,

Susan L. Kaufman

Interim President and Chief Executive Officer

CC:

Health Center Medical Waste

| All medical waste picked up by | is incinerated. |
|--|--|
| It is incinerated at, State Permit: | This information is recorded on the manifest section 8 and 10. |
| the largest medical waste incinerating facility in | the country. They only have incinerators there. |

Waste Management Log

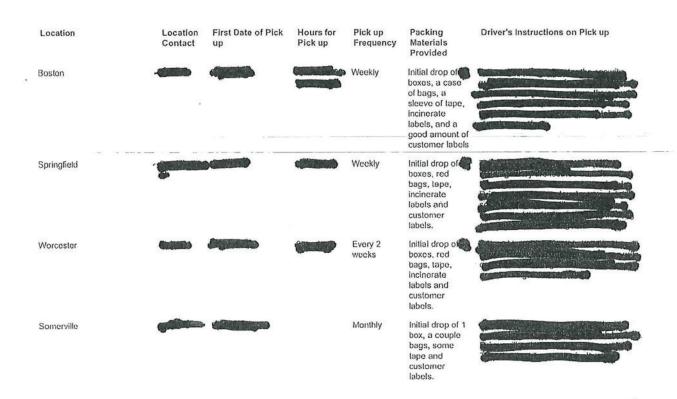
In order to comply with M.G.L. c. 111 §§ 3, 5, and 127A and 105 CMR 480.000 sites must complete the attached waste management log for each pickup.

Vundor



Scheduling

Driver will call all locations to confirm the pick up date.



Marlborough/Milford/Fitchburg

Marlborough/Milford Fitchburg On call

Each site will only need box; some bags, lape, and customer labels.



MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH Medical or Biological Waste Record-Keeping Log OFF-SITE TREATMENT

| Facili In accord (State Sa with the | Facility Name & Address: In accordance with M.G.L. c. 111 §§ 3, 5, and 127A (State Sanitary Code, Chapter VIII), generators of m with the following information: the exact date of shi | Address: 3.L. c. 111 §§ Thapter VIII), i | 3, 5, and 127A generators of n | Facility Name & Address: In accordance with M.G.L. c. 111 §§ 3, 5, and 127A and 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII), generators of medical or biological waste, which is shipped off-site for treatment, shall maintain a current record-keeply with the following information: the exact date of shipment, the total number of containers; the type of waste; the total combined weight or volume; the nam | Minimum Requirement s, which is shipped off- f containers, the type o | is for the Manage site for treatment | ment of Medica L shall maintain | Facility Name & Address: In accordance with M.G.L. c. 111 §§ 3, 5, and 127A and 105 CMR 480,000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII), generators of medical or biological waste, which is shipped off-site for treatment, shall maintain a current record-keeping log with the following information: the exact date of shipment: the total number of containers; the total combined weight or volume; the name of the | |
|--|---|--|-----------------------------------|---|---|--|------------------------------------|---|--|
| forms for | er with transpor r each shipmen | orter identifica it; and the prin | ation number (i | transporter with transporter identification number (if applicable); the verification (via check box) of shipping f forms for each shipment; and the printed name and signature of the person responsible for shipping the waste, | ion (via check box) of ; ponsible for shipping t | shipping papers; he waste. | generated with r | transporter with transporter identification number (if applicable); the verification (via check box) of shipping papers generated with receipt of corresponding tracking forms for each shipment; and the printed name and signature of the person responsible for shipping the waste. | ************************************** |
| Date | Containers | Type | Weight or Volume | Transporter | Please [ID# (if applicable) Shipping Paper | Please Check: Shipping Paper Tracki | Check: Tracking Form | Printed Name Signature | |
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Obtaining a Tissue Sample in the Case of a Sexual Assault Prosecution

Policy Owner

Regional Health Center Directors

Policy Objective To comply with state and federal law while protecting the privacy of patients and to document the procedure followed that ensures that the tissue sample is not contaminated when being obtained.

Policy Statement

PPLM will provide tissue samples resulting from an abortion procedure to law enforcement to assist in a sexual assault prosecution with the patient's consent.

Policy Standards and Procedure

Materials

We work with the law enforcement agent to provide whatever is necessary to allow them to take the evidence. This may include:

- 1. Paper bag
- 2. Plastic bag
- 3. Plastic bag filled with ice
- 4. Sterile suture kit
- 5. Sterile urine cup with the patient's identifying information on it (e.g. pt label)
- 6. Tano
- 7. Sharpie marker

Scheduling

- The patient should be the first patient of the day in one of the procedure rooms scheduled as early as possible (or, if not first patient, room must be thoroughly cleaned before procedure).
- 2. The patient must have previously arranged through the district attorney or detective to have tissue sample transferred to an officer (or detective). The officer must provide a warrant for the tissue sample or the prosecutor must confirm that the sample is to be collected. If the patient arranges for the sample to be picked up directly by a private lab, the results of the DNA testing may not be admissible in court.
- 3. The officer should be asked not to bring any firearms into the Health Center.

- 4. Inform the patient that if she is very early in pregnancy (under seven weeks), the pregnancy tissue may be so small that it may be so small that it may not be possible to provide an adequate sample for testing.
- 5. Usually an officer comes or meets the patient at the Health Center, but if not, he or she should not arrive more than an hour after the patient's appointment time.
- 6. These arrangements must be made in advance; the patient cannot request this the day of her abortion appointment. It usually takes at least a week to make these arrangements.
- 7. Medical staff must be informed before the day of the procedure, so they can be sure that one procedure room is saved for the patient.

The Appointment

- 1. The AB Flow Coordinator (Boston) or Surgical Services Manager or CA Supervisor (Springfield or Worcester) should be alerted as soon as the patient has arrived.
- A Health Center Assistant (HCA) will put a sign on of the procedure room doors stating "WARNING: PT# 12345 MUST BE THE FIRST PATIENT OF THE DAY TO USE THIS ROOM"
- 3. The AB Flow Coordinator, Surgical Services Manager or CA Supervisor will alert the Patient Information HCAs to the situation.

The Procedure

- Directly before the procedure, the AB Flow Coordinator. Surgical Services Manager or CA Supervisor will take the officer into the procedure room and explicitly show him/her that the following items are clean and not contaminated: tubes, specimen jars, strainer, glass viewing dish, and specimen collection container.
- 2. The sample must be handled directly from the physician to the officer in order to preserve chain of evidence. (*Note: The detective does not have to be in the procedure room during the procedure, but will stand outside.*)
- 3. The tissue sample must be "fresh" do not use fixative
- 4. The physician may needs to, according to the needs of the law enforcement officer:
 - 1. place a small piece of the POC in a sterile urine cup (use suture kits to obtain sample from POC)
 - 2. the sterile urine cup then is sealed in a plastic bag
 - 3. the plastic bag is placed in a paper bag
 - 4. another plastic bag is filled with ice and placed on top of the sterile urine cup
 - 5. the bag is rolled closed, sealed with tape, and the physician signs his/her name across the tape/bag with the Sharpie marker. (Note: This is the last step is not often required by the officer, ask before the procedure begins. If the officer is unsure, it is better to do it anyway.)

^{*}If you have any questions about scheduling or handling this type of a situation, please speak with the Regional Center Director.

Attachment C



Planned Parenthood League of Massachusetts

pplm.org - (800) 258-4448

July 28, 2015

Karen C. Tseng Chief, Health Care Division Office of the Attorney General Commonwealth of Massachusetts One Ashburton Pl. Boston, MA. 02108

Dear Ms. Tseng:

In response to your inquiry on July 27, 2015 of this letter serves to attest that to the best of my knowledge, and upon reasonable investigation, Planned Parenthood League of Massachusetts ("PPLM") has never, in its 35 year history, had any program regarding the donation or sale of fetal tissue. Thus, in the absence of any program there has never been any development of policies regarding patient consent, fees, or the exchange of funds by or on behalf of PPLM associated with any such donation or sale. Likewise, PPLM has no foreseeable plans to establish any program regarding the donation or sale of fetal tissue.

I hope this is responsive to your inquiry. I would be happy to provide any additional information.

I certify this letter under the pains and penalties of perjury.

MD MPH

Medical Director

re

Code of Massachusetts Regulations

Title 950: Office of the Secretary of the Commonwealth

Chapter 32.00: Public Records Access (Refs & Annos)

950 CMR 32.08 32.08: Appeals

- (1) <u>Denial by Custodian</u>. Where a custodian's response to a record request made pursuant to 950 CMR 32.05(3) is that any record or portion of it is not public, the custodian, within ten days of the request for access, shall in writing set forth the reasons for such denial. The denial shall specifically include the exemption or exemptions in the definition of public records upon which the denial is based. When exemption (a) of M.G.L. c. 4, § 7, clause Twenty-sixth is relied upon the custodian shall cite the operational statute(s). Failure to make a written response within ten days to any request for access shall be deemed a denial of the request. The custodian shall advise the person denied access of his or her remedies under 950 CMR 32.00 and M.G.L. c. 66, § 10(b).
- (2) <u>Appeal to the Supervisor</u>. In the event that a person requesting any record in the custody of a governmental entity is denied access, or in the event that there has not been compliance with any provision of 950 CMR 32.00, the requester may appeal to the Supervisor within 90 days. Such appeal shall be in writing, and shall include a copy of the letter by which the request was made and, if available, a copy of the letter by which the custodian responded. The Supervisor shall accept an appeal only from a person who had made his or her record request in writing. An oral request, while valid as a public record request pursuant to 950 CMR 32.05(3), may not be the basis of an appeal under 950 CMR 32.08.

It shall be within the discretion of the Supervisor whether to open an appeal concerning a request for public records.

The Supervisor may decline to accept an appeal from a requester where the public records in question are the subjects of disputes in active litigation, administrative hearings or mediation.

The Supervisor may decline to accept an appeal from a requester if, in the opinion of the Supervisor, the request is designed or intended to harass, intimidate or assist in the commission of a crime.

The Supervisor may decline to accept an appeal from a requester if, in the opinion of the Supervisor, the public records request is made solely for a commercial purpose.

Appeals in which there has been no communication from the requester for six months may be closed at the discretion of the Supervisor

- (3) <u>Disposition of Appeals</u>. The Supervisor shall, within a reasonable time, investigate the circumstances giving rise to an appeal and render a written decision to the parties stating therein the reason or reasons for such decision.
- (4) Presumption. In all proceedings pursuant to 950 CMR 32.00, there shall be a presumption that the record sought is public
- (5) <u>Hearings</u>. The Supervisor may conduct a hearing pursuant to the provisions of 801 CMR 1.00. Said rules shall govern the conduct and procedure of all hearings conducted pursuant to 950 CMR 32.08. Nothing in 950 CMR 32.08 shall limit the Supervisor from employing any administrative means available to resolve summarily any appeal arising under 950 CMR 32.00.

(6) <u>In-camera Inspections and Submissions of Data</u>. The Supervisor may require an inspection of the requested record(s) *in camera* during any investigation or any proceeding initiated pursuant to 950 CMR 32.08. The Supervisor may require the custodian to produce other records and information necessary to reach a determination pursuant to 950 CMR 32.08.

The Supervisor does not maintain custody of documents received from a custodian pursuant to an order by this office to submit records for an *in-camera* review. The documents submitted for an *in-camera* review do not fall within the definition of public records. See M.G.L. c. 66, § 10(a) (2002 ed.).

Any public record request made to this office for records being reviewed *in-camera* would necessarily be denied as the office would not be the custodian of those records. *See* 950 CMR 32.03 (defining "custodian" as the government employee who in the normal course of his duties has access to or control over records).

Upon a determination of the public record status of the documents, they are promptly returned to the custodian.

- (7) <u>Custodial Indexing of Records</u>. The Supervisor may require a custodian to compile an index of the requested records where numerous records or a lengthy record have been requested. Said index shall meet the following requirements:
 - (a) the index shall be contained in one document, complete in itself;
 - (b) the index must adequately describe each withheld record or deletion from a released record;
 - (c) the index must state the exemption or exemptions claimed for each withheld record or each deletion of a record; and,
 - (d) the descriptions of the withheld material and the exemption or exemptions claimed for the withheld material must be sufficiently specific to permit the Supervisor to make a reasoned judgment as to whether the material is exempt. Nothing in 950 CMR 32.08 shall preclude the Supervisor from employing alternative or supplemental procedures to meet the particular circumstances of each appeal.
- (8) <u>Conferences</u>. At any time during the course of any investigation or any proceeding, to the extent practicable, where time, the nature of the investigation or proceeding and the public interest permit, the Supervisor, may order conferences for the purpose of clarifying and simplifying issues and otherwise facilitating or expediting the investigation or proceeding.

The Supervisor does not maintain custody of documents received from a custodian pursuant to an order by this office to submit records for an *in-camera* review. The documents submitted for an *in-camera* review do not fall within the definition of public records. See M.G.L. c. 66, § 10(a) (2002 ed.).

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Upon a determination of the public record status of the documents, they are promptly returned to the custodian.

Currency of the Update: October 23, 2015

Mass. Regs. Code tit. 950, § 32.08, 950 MA ADC 32.08

End of Document

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