

2/2/06



# WAIVER REQUEST FORM

DPH – CQAC – DHCQ, 99 Chauncy Street, 2nd Floor, Boston, MA 02111

All waiver requests regarding a PHYSICAL PLANT REQUIREMENT MUST BE ACCOMPANIED BY REDUCED PLANS on 8½" x 11" sheets for clarification of specific physical plant condition to be waived. Physical plant waiver requests received without accompanying plans will be returned as "DENIED".

**NOTE: A SEPARATE WAIVER REQUEST FORM MUST BE SUBMITTED FOR EACH REQUIREMENT FOR WHICH A WAIVER IS REQUESTED.**

Plan: A Planned Parenthood Express Center - Davis Sq Plaza, 260 Elm Street, Suite 109 Somerville, MA 02144

Facility's Licensed Name or Proposed Name \_\_\_\_\_ Address, including zip code \_\_\_\_\_

If Hospital/Clinic Satellite, Name \_\_\_\_\_ Address, including zip code \_\_\_\_\_

Hospital/Clinic Department \_\_\_\_\_ Building/Floor Location \_\_\_\_\_

**I HEREBY REQUEST THE DEPARTMENT WAIVE COMPLIANCE WITH THE REGULATION OR REQUIREMENT:**

**1.A: FOUND AT:** 105 CMR (Section E) 140.560  
(Regulation/Requirement Citation)

**1.B: THAT REQUIRES (Text of Regulation/Requirement):**

- 1) Outreach sites shall not include commercially rented office space.
- 2) Records on outreach patients shall be maintained on the premises of parent clinic. Records shall not be stored at the outreach site.
- 3) Medications shall not be stored or administered at the outreach site.
- 4) Mental Health regulations, 140.560 do not permit onsite lab tests.

**2.A: DESCRIPTION OF PROPOSED ALTERNATIVE TO COMPLIANCE WITH THE REQUIREMENT:**

**2.B: HOSPITALS AND LONG TERM CARE FACILITIES – WHAT WILL BE DONE TO COMPENSATE; CLINIC AND HOSPICE – HOW THE PROVIDER WILL REMAIN IN SUBSTANTIAL COMPLIANCE:**

- 1) We have selected a commercially rented storefront in Davis Square, Somerville (860 square feet) to house our new Express Center.
- 2) Patient charts will be stored onsite in HIPAA compliant, locked storage space.
- 3) We will store hormonal birth control, emergency contraception and Gonorrhea and Chlamydia treatment onsite and ensure adequate refrigeration as necessary.
- 4) We would like to provide waived laboratory tests at our new health center including urine pregnancy testing and HIV OraQuick tests. Each box of pregnancy tests will be controlled at the Planned Parenthood lab in our 1055 Commonwealth Avenue site in Boston before being transported to our new center in Somerville. Each test also has an internal control. Similarly, we would ensure that two external controls are performed at the site of testing any time we offer OraQuick testing at our Somerville location. We would also like to collect urine samples to send for Chlamydia and Gonorrhea testing at an outside facility. For DPH reference, Planned Parenthood's Boston CLIA license #22D0076972.

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Regulation/Requirement Citation: 105 CMR (Section E) 140.560

3. PROVIDER'S EXPLANATION OF HOW MEETING THE REQUIREMENT AS WRITTEN WOULD CAUSE UNDUE HARDSHIP:

- 1) Our commercially rented space is nearby public transportation and ample public parking to provide patients with the most convenient access to Planned Parenthood's contraception, emergency contraception and Gonorrhea and Chlamydia screening services.
- 2) Storing medical records on-site allows the Planned Parenthood clinician to efficiently review medical history in order to provide quality care for patients through walk-in visits.
- 3) Planned Parenthood dispenses hormonal contraception, emergency contraception and treatment for Gonorrhea and Chlamydia on-site at all three of our health centers in the state. Contraceptive consultations with clinicians will be the primary service offered at the new Express Center in Davis Square and on-site dispensing is an integral part of this service to meet patient needs from a convenience perspective. Somerville has been identified by the DPH 2005 RFR Family Planning Needs Assessment as one of the top four Eastern Massachusetts communities with women in need of contraceptive services and supplies.
- 4) Providing on-site urine based lab testing including pregnancy testing as well as sending urine based labs offsite for Gonorrhea and Chlamydia screening enables Planned Parenthood to meet public health needs in more Massachusetts communities.

4. PROVIDER'S ASSURANCE THAT APPROVAL OF THE WAIVER: (A) WILL NOT LIMIT THE CAPACITY TO PROVIDE ADEQUATE CARE; AND, (B) DOES NOT JEOPARDIZE/AFFECT PATIENT OR RESIDENT HEALTH AND SAFETY:

N/A

FACILITY AUTHORIZED REPRESENTATIVE:

Name: Meagan Gallagher  
 Title: Chief Operating Officer/ Vice President  
 Mailing: 1055 Commonwealth Avenue  
Boston, MA 02215-1001

Signature:

FACILITY CLINICAL REPRESENTATIVE:

Name: Karen Loeb Lifford, MD  
 Title: Medical Director  
 Tel #: 617-616-1600

Signature:

For DPH Use Only: The waiver identified above is approved, approved with conditions or denied as indicated below.

Evaluated by: [Signature] 2/10/16  Approved  Approved w/Conditions  Denied

Reviewed by: [Signature] 2/10/16  Approved  Approved w/Conditions  Denied

CONDITIONS:

*Need Drug Control Certificate  
Mass Controlled substance Certificate*

Note: This waiver may be evaluated during on-site visits by Department staff at the facility. The Department reserves the right to revoke the waiver approvals if deficiencies are cited that indicate that the waivers adversely affect patient or resident health and safety.