Guidelines for IV Sedation

Purpose:

These guidelines are designed to provide specific recommendations for safe care of patients during the delivery of medications for the provision of sedation and analgesia during abortion procedures in an outpatient setting.

Policy:

These policies apply to a depth of sedation that is achieved with IV Sedation.

1. **Definitions**
   a. Local Anesthesia: The introduction of a local anesthetic agent by injection into the cervix. All local anesthetics posses both excitatory (seizure) and depressant (loss of consciousness) central nervous system effects in sufficient blood levels.
   b. Conscious Sedation: A minimally depressed level of consciousness that retains the patient's ability to maintain a patent airway independently and continuously, and respond appropriately to verbal commands. Loss of consciousness is unlikely, and the drugs, dosages and techniques utilized are not intended to produce a loss of consciousness.
   c. Deep Sedation: A controlled state of depressed consciousness from which the patient is not easily aroused, accompanied by a partial or complete loss of reflexes, including the ability to maintain a patent airway independently or to respond purposefully to physical stimulation or verbal command.
   d. General Anesthesia: A controlled state of unconsciousness accompanied by a loss of protective reflexes, including the ability to maintain a patent airway independently and continuously, and respond appropriately to verbal commands.

In actuality, a continuum exists among conscious sedation, deep sedation and general anesthesia. The patient's age and pre-existing medical conditions may significantly alter the dosing requirements needed for the conscious sedation.

At Four Women general anesthesia is not an option for the elective termination of pregnancy. In actuality, at Four Women, a total intravenous anesthetic (TIVA) is utilized, titrating medications to produce a state of semi-consciousness, while maintaining spontaneous respirations and hemodynamic stability, and with depressed reflexes so that elective termination of pregnancy can be performed with minimal risk to the patient.

II. **Personnel and Training**

At Four Women IV sedation is given only when a CRNA supervised by a physician is present.

a. The minimum number of available personnel shall be two- the physician and CRNA. In addition, a medical assistant is in the room at all times.
b. The Administrator and Medical Director shall be responsible for credentialing physicians and CRNA administering sedation medications, in accordance with Four Women policy. Physicians and CRNAs must maintain licensure for practice in Massachusetts. Physicians and CRNAs shall remain in good standing with their professional organizations. They shall report potential litigation to Four Women according to Four Women policies.
c. The CRNA under supervision of the physician administers the sedation in accord with the IV Sedation policy and is trained in the pharmacology of these drugs. (Suggested drugs and dosages for sedation are attached.) The CRNA shall be competent in airway management and resuscitative measures and be ACLS certified. The CRNA must develop mechanisms to continually monitor and evaluate the quality of IV Sedation and shall also have knowledge and experience in the use of oximetry, cardiac monitoring equipment and the recognition and treatment of significant cardiac dysrhythmias.
d. Educational and credentialing mechanisms for IV sedation shall be part of the usual Four Women procedures. These mechanisms shall include a process for evaluation and documenting an individual's demonstration of the knowledge, skills and abilities related to the management of patients receiving IV sedation.
e. The physician must be readily available in case of medical complications and emergencies.
f. The triage nurse is available for additional support and to aid in emergency situations.

II. Equipment and Maintenance

a. A self-inflating positive-pressure oxygen delivery system capable of administering 100% oxygen at a 10 liter minute flow rate for at least 45 minutes must be available. Various mask sizes and oral airways shall be available in those circumstances where appropriate.
b. A source of suction must be available, with a vacuum capability of 18-24 inches of mercury, or flow capability of 100L/min with an orifice size of 14mm.
c. A defibrillator and an emergency cart shall be readily available and shall include the necessary drugs and equipment to resuscitate an apneic and unconscious patient and provide continuous support while that patient is being transported to the hospital. The drugs and equipment shall be inventoried monthly and documentation kept on file. Outdated medications and malfunctioning equipment shall be replaced.
d. Equipment appropriate to the technique being used shall be available in good working order during and after the procedure. This shall include means for providing supplemental oxygen delivery via nasal prongs and non-rebreathing or rebreathing oxygen masks.
e. Monitoring with a pulse oximeter, cardiac monitor, and blood pressure, is required for all patients.
f. A specific pharmacological reversal agent for the type of sedation to be used shall be available. (Narcan, Romazicon).

g. All equipment shall be inventoried and maintained on a regularly scheduled basis, in conjunction with Four Women policies.

IV. Consent

The patient shall be informed about the risks, benefits and alternatives of IV Sedation as a component of the procedure. Four Women has a separate consent form for anesthesia which shall be signed by the patient and witnessed by a staff member. Patients will be encouraged and afforded ample time to ask questions and all questions will be answered fully. Documentation of such consent shall be placed on the medical record.

V. Patient Management and Monitoring

a. Written documentation of all aspects of care rendered to the patient shall be reflected in the medical record as well as subject to review for purposes of performance improvement.

b. **Prior to Procedure:** It shall be validated that the patient is an appropriate candidate for IV Sedation, utilizing the following criteria. In addition see Patient Elibility information in the Policy and Procedures.

1. Baseline health evaluation and risk assessment shall include:

a. Age and patient's height and weight. (See Appendix E)

b. Current medications, previous allergic or untoward reactions to medication and family history of untoward reaction to anesthesia including MH.

c. Previous surgery and hospitalizations.

d. Review of systems, including diseases, disorders and abnormalities with emphasis on the cardiopulmonary system.

e. Preprocedure vital signs.

f. Relevant physical examination, including but not limited to (1) general neurologic status (e.g. assessing mental status; presence or absence of stroke deficits) (2) airway evaluation (see Appendix C) (i.e., and evaluation performed in anticipation of possible intubation, e.g., checking condition of teeth, range of neck motion, ability to open mouth, and Mallampati Classification (see Appendix D)) (3) cardiopulmonary exam.

g. **NPO status:** A first trimester patient should be NPO for at least six hours prior to the planned procedure, (see Policies and Procedures Patient Eligibility for Surgical Procedure II). A second trimester patient should be

NPO for eight hours, unless they are over 18.6 and then NPO should be ten hours. Medications may be administered with a sip of water. When patient has not been NPO, IV Sedation may be dangerous. Patient should be rescheduled or should have local anesthesia

h. The patient's medical condition must be appropriate for the use of IV Sedation. Physical status shall be classified and documented according to American Society of Anesthesiologists Physical Status Classification.

c. During the procedure: The CRNA, under the supervision of a physician, shall continually monitor the patient throughout the procedure and record the following (including all baseline measurements):

1. The patient shall have a functioning IV line.
2. Vital Signs:
   i. blood pressure every 5 minutes
   ii. heart rate every 5 minutes (by ECG unless extenuating circumstances exist)
   iii. respiratory rate every 5 minutes
   iv. Physiological data (HR, PB, RR< ECG, SPO_2) shall be documented at any significant event in addition to the required 5 minute interval documentation. IN addition the documentation shall include any untoward or significant reaction and its resolution.
3. Oxygenation by pulse oximetry at a minimum frequency of every 5 minutes.
4. Oxygen Administration:
   i. Each patient's oxygen requirements shall be evaluated.
   ii. Patients shall be given supplemental oxygen by face mask and documented accordingly.
5. Medications given shall be documented with attention to route, site time, dose and drug.
6. The patient's head position shall be checked frequently to ensure a patent airway. If the patient becomes unstable during the procedure, appropriate medical consultation shall be sought immediately. Resuscitation equipment and medication shall be readily available. Succinylcholine shall be available and utilized only when positive pressure ventilation fails to alleviate laryngospasm if same occurs or for emergent intubation should same be deemed necessary. Temperature will be measured when Succinylcholine is used.

VI. PROVISIONS FOR POST PROCEDURE PATIENT CARE AND DISCHARGE PLANNING

A. When the procedure has been completed and the patient is ready for discharge or transfer, the vital signs and patient responsiveness shall be monitored and

recorded until the patient returns to his/her pre-procedure state. (See Four Women Recovery Room Policies and Procedures.) The time of discharge shall only be permitted when:

1. airway, breathing and circulation are adequate and stable,

2. patient's swallow, cough and gag reflexes are present, or appropriate to baseline,

3. nausea and dizziness are absent or minimal,

4. hydration is adequate without evidence of postural vital signs when blood pressure and pulse are taken in a reclining position and standing position.

5. bleeding, cramping, pain levels, and IV site have been checked if applicable

6. discharge order has been written by physician. An R.N. may discharge the patient utilizing appropriate criteria based upon a discharge order.

7. the patient is alert, or appropriate to baseline,

8. the patient can sit unaided, if appropriate to baseline and procedure,

9. the patient can walk without assistance if appropriate to baseline

B. When patients are discharged, they shall be under the care of an appropriate escort and in receipt of written discharge instructions, including:

1. Written instructions that include an explanation of potential or anticipated post-sedation effects and limitations on activities, behavior and diet.

2. A 24 hour emergency contact and telephone number.

3. They shall be advised to refrain from operating heavy machinery, driving a car, consuming alcohol and making important decisions for 24 hours.

C. If patients are to be transferred to further care within the institution, standard criteria shall be applied for transfer of care between medical providers.

MD Date: 3/9/07

APPENDIX A

SUGGESTED DRUGS AND DOSAGES FOR SEDATION

This list is not intended to be all inclusive, but should serve as a guide. Additionally, certain patients may not tolerate even these recommended doses. Furthermore, many of these medications have synergistic respiratory depressant effects; when administered in combination, these drugs should be at lower doses than those stated below. Finally, these medications should not be given without familiarity with the rest of the guidelines, and without having the necessary resuscitation equipment at hand.

Appendix A Continued

Important Notes:
For use by a CRNA supervised by a physician trained in the use of IV sedation:
Medication should be administered with close monitoring of vital signs as outlined in the IV sedation policy and resuscitation equipment readily available. All medications used for these purposes can be associated with the following effects:

Respiratory Depression
Hypotension
Dizziness/drowsiness
Nausea/vomiting

All doses should be individualized. Reduce dosage when using combinations of medications i.e., sedatives with analgesics or if other CNS depressants are used. Dosages should be based on ideal body weight and not actual body weight. Titrate small increments to achieve the appropriate level of sedation. Do not give by rapid or single bolus IV administration. When drugs are administered in combination, lower doses of these drugs (i.e., 50% dose reduction) should be used rather than those stated in the guidelines.

Certain patients with co-morbidities may not tolerate recommended doses of IV sedation medications, patients with a past history of pulmonary, cardiovascular, hepatic or renal disease; patients with known or suspected increased intracranial pressure or other neurological condition, patients with known hypersensitivity or idiosyncratic reaction to any of these medications. These patients may be eligible for local anesthesia or they may be better done in a hospital, according to Four Women policies.

> **Propofol** (2,6- Di-isoPropylphenol) is used for induction or maintenance of general anesthesia. It is prepared as a 1% isotonic oil-in-water emulsion, which contains egg lecithin, glycerol, and soybean oil.

1. **Mode of action**. The mode of action of propofol is not known.

2. **Pharmacokinetics**. Propofol is rapidly redistributed within 2-4 minutes. The half-life is approximately 4 hours. Elimination occurs primarily through hepatic metabolism to inactive metabolites.

3. **Pharmacodynamics**

a. Central nervous system. Propofol rapidly induces unconsciousness (approximately 30-45 seconds). Low doses may produce conscious sedation. Propofol has no analgesic properties. Its pharmacokinetic profile promotes early awakening after a single dose or the termination of an infusion. Cerebral blood flow appears to decrease with administration.

b. Cardiovascular system. Propofol is a cardiovascular depressant; significant decreases in arterial blood pressure and cardiac output occur in a dose-dependent manner similar to that of thiopental. Heart rate is minimally affected.

c. Respiratory system. Propofol produces a dose-dependent decrease in respiratory rate and tidal volume. In addition, the ventilatory response to hypercarbia is diminished. A single induction dose of propofol commonly produces apnea for 30-90 seconds. If used for sedation, appropriate monitoring should be employed and trained personnel and resuscitative equipment should be available.

4. **Dosage and administration**. Propofol may be diluted, if necessary, only in 5% dextrose in water to a minimum concentration of 0.2%. The usual induction dosage is 2.0-2.5 mg/kg IV. For maintenance of general anesthesia, an intial infusion rate of 0.1-0.2 m/kg/min may be employed and adjusted accordingly. A dosage of 3-4 mg/kg/hr is often sufficient for sedation. Dosage should be reduced if administered with other anesthetics. After opening, propofol should be discarded if not administered within 6 hours (to prevent inadvertent bacterial contamination).

5. **Other effects**

a. Allergy. Propofol should not be administered to patients with a history of allergy to egg products.

b. Lipid disorders. Propofol is an emulsion and therefore should be used cautiously in patients with disorders of lipid metabolism (e.g., hyperlipidemia, pancreatitis).

c. Venous irritation. The incidence of pain during IV administration of propofol may be as high as 50-70%. This may be reduced by prior administration of narcotics, addition of lidocaine (0.01%) to the induction dose of propofol, administration through a flowing IV catheter, or administration through a large-gauge IV catheter (e.g., 16 gauge) in a large vein (e.g., antecubital).

d. Nausea and vomiting postoperatively may occur less frequently after propofol-based general anesthesia as compared with other methods of general anesthesia.

e. Excess Propofol:

1. Assure a patent airway with head tilt, head repositioning, jaw thrust, suctioning, etc.

2. Assure adequacy of spontaneous ventilation utilizing criteria such as observation of chest movement, listening for air movement, detection of carbon dioxide with exhalation.

3. And if needed, support ventilation by means of positive pressure ventilation using an ambu bag or the anesthesia machine circuit.

4. Furthermore and if deemed to be of assistance, medications that can be reversed, such as narcotics or benzodiazepams, should be reversed cautiously so as to negate the synergic, additive effect of multiple medications on respiratory efficiency.

Midazolam (Versed)

0.01 mg/kg-0.03 mg/kg Usual dose for 70kg pt. 0.5 to 2.0 mg over 3 min.

Titrate to desired effect. Wait at least two minutes after initial dose to assess effect. May repeat two minutes after dose is completed until desired effect achieved.

Usual dose: 4 mg/hr
Max dose: 8 mg/hr

ONSET: 1-2 minutes, PEAK 20-60 minutes, DURATION 60-90 minutes
CLEARANCE: Hepatic/renal

Fentanyl (Sublimaze)

0.3 mcg/kg- 1.4 mcg/kg
Usual dose for 70 kg pt is 25 to 100 mcg over three minutes
Reduce dose when given with benzodiazepines.

Titrate to desired effect, may repeat dose every 10 minutes to MAX dose.
MAX dose: 3 mcg/kg/hr

ONSET: immed. PEAK 5-15 minutes DURATION 30-60 min CLEARANCE: Hepatic/renal

Caution when used with benzodiazepines or butyrophenones. Dimished sensitivity to CO2 stimulation may persist longer than depression of respiratory rate.

P Bradydysrthmias
C Hypersensitivity
S Muscle rigidity
Bradycardia

Opiate Antagonist:

Naloxone (Narcan)

0.04 mg each dose
Total dose of 0.4 mg

Administer every 2-3 minutes as needed to increase respiratory rate/alertness. Satisfactory responding patients should be kept under continued surveillance due to short duration of action.

If no response after 0.4 mg administered, access the needto transport the patient to the hospital.

ONSET: 2 min DURATION: 1-4 hours CLEARANCE: Hepatic

Is effective ONLY against respiratory depression caused by opiates. Monitor vital signs closely.

P	Opiate dependence
	Hyper/hypotension
	Pulmonary edema
	V tach/fibrillation
	Cardiovascular disease
C	Hypersensitivity
S	Nausea/vomiting
	Tachycardia
	Hypertension
	Pulmonary edema
	Ventricular dysrhythmias

Benzodiazepine Sedation Antagonist

Flumazenil (Romazicon)

0.2 mg over 15 seconds.
Titrate to desired effect; may repeat 45 seconds after initial dose if inadequate response, and again at 1 minute intervals when necessary up to a max dose of 1 mg. Max doses: 1 mg/dose and 3 mg/hour

ONSET: 1 min PEAK: 2-5 min DURATION: 45-90 min CLEARANCE: Hepatic

For reversal of benzodiazepine-induced respiratory depression. Administer into large vein to decrease pain on injection. Monitor vital signs closely.

P Benzodiazepine withdrawal induced seizures
Hypeventilation
Return of sedation
Head trauma
Concurrent neuromuscular blockers
Drug/alcohol dependent patients
Tricyclic antidepressant overdose

C Hypersensitivity
Pts. Controlled with benzodiazepines for potentially life threatening condition
(e.g. intracranial hypertension, status epilepticus)

S Seizure
Cardiac dysrhythmias
Dizziness/agitation

Appendix B

Considerations in the Evaluation of the Airway

- Mallampati classification (ability to review posterior pharynx)
- Menum-to-thyroid distance
- Oral opening
- Quality of dentition (teeth, gums, dentures)
- Intraoral structures (tonsils, uvula, palates)
- Mask fit
- Range of motion of neck
- Obesity (see Four Women height/weight guidelines)

Appendix C

Mallampati Classification for Airway Evaluation

The patient is asked to open his mouth and protrude the tongue maximally while in the sitting position.

Class I Faucial pillars, soft palate, and uvula can be visualized

Class II Faucial pillars and soft palate can be visualized, but uvula is masked by the base of the tongue.

Class III Only soft palate can be visualized

Appendix D

American Society of Anesthesiologist Physical Status Classification

Class I	A normal healthy patient
Class II	A patient with a mild systemic disease
Class III	A patient with a severe systemic disease that limits activity, but is not incapacitating.
Class IV	A patient with an incapacitating systemic disease that is a constant threat to life.
Class V	A moribund patient not expected to survive 24 hours with or without an operation.

Appendix E

Four Women
Height Weight Guidelines

4'10"	165
4'11"	175
5'0"	180
5'1"	185
5'2"	190
5'3"	195
5'4"	200
5'5"	205
5'6"	210
5'7"	220
5'8"	230

5'9"	240
5'10"	250
5'11"	260
6'0"	270
6'1"	280
6'2"	290
6'3"	300

DEVAL L. PATRICK
GOVERNOR

TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD
SECRETARY

JOHN AUERBACH
COMMISSIONER

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Environmental Health
Community Sanitation Program
250 Washington Street, Boston, MA 02108-4619
Telephone (617) 624-5757
Facsimile (617) 624-5777

MPH, RN, MS, WHNP-BC
Administrator
Four Women Health Services
150 Emory Street
Attleboro, MA 02703

December 12, 2009

Re: Complaint investigation re: compliance with requirements for medical waste management

Dear

On November 4, 2009, the Department of Public Health's Community Sanitation Program (CSP) and the Attleboro Health Department conducted a compliance inspection at Four Women Health Services located at 150 Emory Street, Attleboro, MA. This inspection was conducted in accordance with M.G.L. c. 111, §127A, and 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII), in response to an alleged violation of 105 CMR 480.200 – illegal disposal of medical or biological waste as solid municipal waste. In addition, the complaint and this investigation report have been forwarded to the Department's Division of Health Care Quality which is responsible for investigation of complaints involving clinics licensed pursuant to 105 CMR 140.000.

FINDINGS

Based on observations made during the on-site inspection, the CSP determined that Four Women Health Services had numerous deficiencies in its medical or biological waste management and was not in compliance with the following requirements of 105 CMR 480.000:

- The area used for medical waste storage lacked appropriate signage indicating the presence of regulated medical or biological waste. A single loose red bag of unidentified medical or biological waste was present (but not labeled for shipment) on the floor of a multi-purpose storage/hot water heater room without clear signage [105 CMR 480.100(C)(1)].
- The area used for medical waste storage lacked appropriate security to prevent unauthorized access [105 CMR 480.100(C)(2)].

- As currently configured the storage area does not allow clear separation of regulated medical waste (red bags/sharps/pathological waste) [105 CMR 480.100(C)(4)].

- Required written procedures were not maintained for the proper management of medical or biological waste [105 CMR 480.500(A) and 105 CMR 480.500(I)].

- Required medical waste record-keeping log was not maintained [105 CMR 480.500(B) and 105 CMR 480.500(I)].

- Required written contingency plan for spills and accidents was not maintained [105 CMR 480.500(C) and 105 CMR 480.500(I)].

CORRECTIVE ACTIONS

Based on the November 4, 2009 inspection, the Department requires the following corrective actions:

1. Four Women Health Services must evaluate and redesign all existing policies and procedures for the handling of medical and biological waste to ensure compliance with 105 CMR 480.000, as amended in July 2008. This includes procedures at the point of medical or biological waste generation, as well as waste packaging and storage procedures.

2. The current space utilized at Four Women Health Services for the handling and storage of medical or biological waste shall be reconfigured to improve the handling and clear separation of red bags/boxes, sharps and pathological waste. Medical or biological waste being sent off-site for treatment must be properly stored in a designated area identified with appropriate signage, that only allows authorized access, that is not utilized as multi-purpose space and that maintains full compliance with 105 CMR 480.100 and 105 CMR 480.300 pending pickup.

3. Documentation must be provided to the CSP that ventilation for the designated storage area discharges directly to the exterior of the buildings away from any fresh air intakes, and is in accordance with appropriate ASHRAE guidelines.

4. Policies and procedures must be implemented to ensure that waste sent off-site for treatment is properly recorded in the required medical waste record-keeping log according to 105 CMR 480.425 and 105 CMR 480.500.

5. Four Women Health Services must provide to the Department documentation including medical waste record-keeping logs and shipping papers / tracking forms for all waste sent off-site for treatment since August 1, 2008.

6. Four Women Health Services must establish and provide to the Department written policies and procedures for the handling, storage and shipment of all medical or biological waste that ensure compliance with all aspects of 105 CMR 480.000.

7. Four Women Health Services shall provide the Department specific plans for and documentation demonstrating fulfillment of training for all current and future staff involved in the segregation, handling and management of medical or biological waste.

Four Women Health Services must provide a response in writing regarding these corrective actions to the Community Sanitation Program by January 15, 2010. Please be advised that pursuant to 105 CMR 480.600(C), this letter constitutes notice to Four Women Health Services of the nature of these current violations and that any additional violations of 105 CMR 480.000 may result in legal action.

Please feel free to contact me at (617) 624-5757 if you have further questions regarding this matter.

Sincerely,

Steven F. Hughes
Director, Community Sanitation Program

CC:

Suzanne K. Condon, Associate Commissioner, Director, BEH
James Ballin, Deputy General Counsel, DPH
Lisa Noling Snellings, Deputy General Counsel, DPH
Lillian Jette, DHCQ
Sherman Lohnes, DHCQ
James P. Mooney, Health Director, Attleboro

4441-7

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
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Community Sanitation Program
250 Washington Street, Boston, MA 02108-4619
Telephone (617) 624-5757
Facsimile (617) 624-5777

MPH, RN, MS, WHNP-BC

Administrator
Four Women Health Services
150 Emory Street
Attleboro, MA 02703

MA DPH

8 MAR '10

March 5, 2010

Re: Follow-up medical waste management compliance inspection

Dear

On February 17, 2010, the Department of Public Health's Community Sanitation Program (CSP) conducted a follow-up compliance inspection at Four Women Health Services, 150 Emory Street, Attleboro, MA. An initial compliance inspection was conducted on November 4, 2009 by the CSP and the Attleboro Health Department.

Both inspections were conducted in accordance with M.G.L. c. 111, §127A, and 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII), in response to an alleged violation of 105 CMR 480.200 – illegal disposal of medical or biological waste as solid municipal waste. The complaint and subsequent investigation reports have been forwarded to the Department's Division of Health Care Quality (DHCQ) which is responsible for the investigation of complaints involving clinics licensed pursuant to 105 CMR 140.000.

In response to findings made during the initial inspection at Four Women Health Services in 2009, the Department requested and received from you an initial "plan of correction" along with specific documents (i.e. – record-keeping logs, manifests, policies & procedures, etc.).

FINDINGS

Based on a review of these documents and observations made during the follow-up inspection on February 17, 2010, the CSP determined that Four Women Health Services demonstrated improved compliance with the medical and biological waste requirements, including installing dedicated medical waste storage (a secured closet) with appropriate ventilation. However, several remaining deficiencies in

your medical or biological waste management, were identified during the review of the submitted "plan of correction" and the follow-up inspection. These deficiencies relate to the following requirements of 105 CMR 480.000:

- Pathological waste being generated from procedures conducted at Four Women Health Services are not being stored in appropriate primary containers as required by 105 CMR 480.100(A) (incorrect color and labeling). Additionally, the signage for this storage area is inadequate.

- The area used for medical waste storage lacked appropriate secondary containment. All regulated medical or biological waste must initially be placed in a primary container (e.g. - sharps box, red bag) immediately upon disposal and then this box or bag must be placed in a secondary container meeting requirements stated in 105 CMR 480.300(B) when moved to the storage area.

- Completed record-keeping logs provided in response to the Department's initial compliance investigation did not specify the type of waste being shipped off site for treatment according to 105 CMR 480.500(A)(1).

- Procedures for the safe handling and transportation within the facility of regulated medical or biological waste provided in response to the Department's initial compliance investigation did not adequately address policies & procedures for the segregation of medical and biological waste at the point of generation (e.g. – segregation of pathological waste, blood saturated material, sharps or other material meeting the definition of medical or biological waste) according to 105 CMR 480.500(A)(2).

- Required written contingency plan for spills and accidents was not maintained, pursuant to 105 CMR 480.500(C) and 105 CMR 480.500(I).

CORRECTIVE ACTIONS

Based on the February 17, 2010 inspection, the Department requires the following corrective actions:

1. Four Women Health Services must document procedures for medical or biological waste segregation used by staff at the point of generation including the specifications for how determinations match medical waste definitions in 105 CMR 480.020.

2. Documentation must be provided to the CSP that ventilation for the designated storage area discharges directly to the exterior of the buildings away from any fresh air intakes, and is in accordance with appropriate ASHRAE guidelines.

3. Primary containers used for the storage of pathological waste must be replaced with containers in compliance with 105 CMR 480.100(A). Please include policies and procedures in your written contingency plans for the possible malfunction or power interruption for the freezer used for storage of pathological waste.

4. Policies and procedures must be implemented to ensure that waste sent off-site for treatment is properly recorded in the required medical waste record-keeping log according to 105 CMR 480.425 and 105 CMR 480.500 including listing the "type" of waste (sharps versus pathological versus other red bagged waste).

5. Four Women Health Services shall provide the Department specific plans for and documentation demonstrating fulfillment of training for all current and future staff involved in the segregation, handling and management of medical or biological waste.

Four Women Health Services must provide a response in writing regarding these corrective actions to the Community Sanitation Program by April 9, 2010. Please be advised that pursuant to 105 CMR 480.600(C), this letter constitutes notice to Four Women Health Services of the nature of these current violations and that any additional violations of 105 CMR 480.000 may result in legal action.

Please feel free to contact me at (781) 774-6612 if you have further questions regarding this matter.

Sincerely,

David T. Williams, Senior Analyst
Community Sanitation Program

CC:

Suzanne K. Condon, Associate Commissioner, Director, BEH
Steven F. Hughes, Director, CSP
James Ballin, Deputy General Counsel, DPH
Lisa Noling Snellings, Deputy General Counsel, DPH
Lillian Jette, DHCQ
Sherman Lohnes, DHCQ
James P. Mooney, Health Director, Attleboro

INCIDENT SYSTEM: Incident Report Form

Printed: 10/05/11

Incident Report Number: 44H1-7
Date Reported: 11/13/09
Date of Incident: 11/01/09

Time: :
Time: :

Facility: FOUR WOMEN, 150 EMORY STREET GROUND FLOOR, ATTLEBORO ID#: 44H1
Person Making Report: Unknown/Other
Phone #: (508)222-7555

PATIENT INFORMATION
Name: unknown
Age:
Gender:
Status:
ADL Status:
Admitted: / /
Cognitive Level:

Type of Harm: Unknown
Body Part Affected:

Safety Precautions Involved

Activity

Location
Equipment In Use

Individual in Charge:
Facility Report Received: / /
Title:
Log As: Refer to Other Agency

TYPE OF INCIDENT

TYPE #1 **ID: 1**
TYPE: Physical Environment

DESCRIPTION OF INCIDENT AS REPORTED:

Consummer E-mail

It was reported that the clinic from 1/1/09to 11/7/09 is illegally disposing of fetal body parts

awaiting to LJ to consult with Environmental Health.

Municipal Health Department Report forwarded. . It indicated that the Complainat wants to bring in evidnce aof fetal remains that were improprly disposed of in dumpster. Belives other offices also dumping Met with Complainant informed Complainat that facility is system regulated.

12/212
Communitty Sanitation conducted a site visit of the clinic on 11/4
The clinic had multiple defecencies in its medical and biologiacl waste management. The waste stotrage area lacked proper sinage, and apprpraite security. Medical waste keeping log and policies were nor maintained. . The written contingencty plan for spills and accidents was not maintaimed.

The clinic was required was complete corrective actions These include evaluating and redesigning all policies related to the handling of infectious waste, reconfigurating the storage area for medical waste, the clinic must repair the storage area ventilation system,

NOTIFICATION: Family: NO Physician: NO

END OF REPORT

INTAKE REPORT WORKSHEET

Clinic

FACILITY: Four Women - Attleboro

CITY/ TOWN : ______ REF # 4441 - 7

ALLEGATION: Physical Emotional Sexual - REGION ______

HARM: Emotional

FACILITY REPORTED: ______ YES ___✓___ NO HOSPITAL SRE/NQF ______ Yes ______ No

Race/Ethnicity data entered date: ______ **by** ______

1. LEVEL OF HARM	2. IS THE THREAT OF HARM ON GOING?			3. IS INVESTIGATION LIKELY TO EFFECT/IMPROVE DELIVERY OF HEALTH CARE?		
	A. FACILITY PROFILE	B. SOUCE OF REPORT	C. TIME OF OCCURRENCE	A. SPECIFICS OF REPORT	B. WITNESSES	C. NEED FOR ON-SITE
LEVEL 1- OCCURRENCE	NO ENFORCE. PROBLEM	FACILITY	>1 YEAR	NO REG. VIOLATION S	NONE	OTHER AGEN. WILL DO
LEVEL 2- NON-SERIOUS	NEW DON OR ADMIN.	STAFF MEMBER	6 MONTHS – 1 YEAR	VAGUE CONCERNS	UNKNOWN	FACTS CLEAR
LEVEL 3- SERIOUS	OTHER COMPLAINT	ANON	3 MONTHS – 6 MONTHS	GENERAL CONCERNS	RESIDENT-CAN'T TESTIFY	FACILITY TOOK ACTION
LEVEL 4- TRAGIC	SQC LAST SURVEY	RESIDENT OR ADVOCATE	< 3 MONTHS	SOME SPECIFICS	RESIDENT-CAN TESTIFY	? REG's VIOLATED
LEVEL 4- DEATH	IN JEOPARDY OR SQC NOW	SPECIAL REFERRAL	ONGOING	SPECIFICS FACTS	OTHER REL WITNESS	NEEDED TO PREV. HARM

ALLEGATION/SYNOPSIS: **(LAST RECERT SURVEY DATE:** ______**)**

DISPOSITION:

	LETTER TYPE:	
REVIEW & FILE	NO LETTER	
AWAIT INFO	1-ACKN/REVIEW & FILE	SPECIAL (ATTACHED
ON-SITE	2-ACKN/RECENT SURVEY	AWAIT INFO
OFFSITE	3-ACKN/REF TO EOEA	OFF- SITE (ATTACHED)
DEFER UNTIL NEXT SURVEY	4-ACKN/REF BD OF MED	A-REF ONLY TO E OEA
REFER TO EOEA	5-ACKN/REF BD OF NHA	B-REF ONLY BD OF MED
✓ REFER TO OTHER AGENCY	6-ACKN/REF BD OF NSG	C-REF ONLY BD OF NHA
RECENT SURVEY	7-ACKN/REF BD OF SW	D-REF ONLY BD OF NSG
DUPLICATE SEE#	8-ACKN/REF DIV OF REG	E-REF ONLY BD OF SW
ADMINSTRATIVELY CLOSED	9-ACKN/REF TO AG	F-REF ONLY DIV OF REG
REFER TO HCFA	HCFA FORM 565 (A. BONNER, S. LOHNES, J. MAZZOLA)	G- REF ONLY TO AG
OTHER:	ON-SITE (COMPLAINTS)	OTHER

RATIONALE:

community scientific complaint onset

Mass

DATE: REVIEWED ______ **REVIEWEDBY:** ______

*** CONFIDENTIAL ***

Incident System: Incident Report Form

Incident Report Number: 44H1 - 7

Printed: 12/24/2009

Date Reported: 11/13/2009
Date of Incident: 11/01/2009

Time Received:
Time of Incident:

Facility: FOUR WOMEN
150 EMORY STREET GROUND FLOOR

ID: 44H1

Person Making Report: Other

Phone: ( ) -

PATIENT INFORMATION

Name: unknown

Age:

Gender: U

Admitted:

Status:
ADL Status:
Cognitive Level:
Retarded Developmentally Delayed: Unknown

Type of Harm:

Body Part Affected:

Safety Precautions Involved:

Activity:

Location:

Equipment In Use:

Individual In Charge:
Facility Report Received:

Title:
Log As: Refer to Other Agenc

NOTIFICATION

Family: N Physician: N

DESCRIPTION OF INCIDENT AS REPORTED:

Consummer E-mail

It was reported that the clinic from 11/1/09to 11/7/09 is illegally disposing of fetal body parts

awaiting to LJ to consult with Environmental Health.

Municipal Health Department Reort forwarded. . It indicated that the Complainat wants to bring in evidnce aof fetal remains that were improprly disposed of in dumpster. Belives other offices also dumping Met with Complainant informed Complainat that facility is system regulated.

12/2/12
Communitty Sanitation conducted a site visit of the clinic on 11/4
The clinic had multiple defecencies in its medical and biologiacl waste management. The waste stotrage area lacked proper sinage, and apprpraite security. Medical waste keeping log and policies were nor maintained. . The written contingencty plan for spills and accidents was not maintaimed.

The clinic was required was complete corrective actions These include evaluating and redesigning all policies related to the handling of infectious waste, reconfigurating the storage area for medical waste, the clinic musr repair the storage area ventilation system,

INCIDENT SYSTEM: Incident Report Form Printed: 10/05/11

Incident Report Number: AO52-1
Date Reported: 09/21/07
Date of Incident: 07/27/07 Time: 09:00
Time: 03:11

Facility: FOUR WOMEN, 150 EMORY STREET, ATTLEBORO ID#: AO52
Person Making Report: , Quality Assurance Phone #: (508)222-7575

PATIENT INFORMATION
Name:
Age: 31 Gender:
Status: Supervised ADL Status: Independent Admitted: 07/27/07
Cognitive Level: Alert/Oriented

Type of Harm: Decline in Cond
Body Part Affected:

Safety Precautions Involved

Activity

Location Other
Equipment In Use

Individual in Charge: Title:
Facility Report Received: 09/21/07 Log As: On-Site Investigation

TYPE OF INCIDENT

TYPE #1 **ID: 1**
TYPE: Surgical Services

DESCRIPTION OF INCIDENT AS REPORTED:

Hospital Report

It was reported that the Patient was a the clinic for termination of a 14 week pregnancy. Due to low blood pressure the Patient was transported to the Hospital. The Patient was evaluated at the Hospital and it was determined that there was perforation of the Patient's uterus .

On-site. SD

NOTIFICATION: Family: NO Physician: NO

END OF REPORT

INVESTIGATION REPORT

FACILITY: **FOUR WOMEN**
150 EMORY STREET
ATTLEBORO, MA 02703

Reference #: 07-1083
Page 1

DATE RECEIVED: 09/21/2007
DATE INVESTIGATED: 10/09/2007

A. INVESTIGATORY STEPS:

1. **PERSONS INTERVIEWED:**

Medical Director
Physician #1
Nurse #1
Charge Nurse
Nurse Anesthetist
Family Counselor

2. **RECORDS REVIEWED:**

Clinical Record
Credential File(s)
Policies/Procedures/Protocols

3. **PHYSICAL EVIDENCE REVIEWED:**

None Required

B. ISSUES FOR INVESTIGATION

1. SYNOPSIS: It was alleged that a surgical error occurred to the Patient during treatment at the Clinic, which caused a perforation requiring the Patient's transfer to the hospital and further surgical intervention.

Based on record review and staff interview, the allegation was determined to be valid because: 1) the Patient sustained a laceration as a result of the surgical procedure performed at the Ambulatory Surgical Center as reported; 2) the Patient did sign all consents prior to the surgical procedure which stated a laceration was a risk of the procedure; 3) Physician #1 obtained a post operative ultrasound on the Patient and no laceration was detected; 4) Physician #1 notified the hospital emergency department physician that the Patient was being transported for observation and blood work; 5) As a result of the incident at the Ambulatory Surgical Center, the Medical Director took appropriate corrective action and implemented new protocols

1. SYNOPSIS (continued)

and policies for facility staff for the improvement of patient care in the event of an emergency.

2. ISSUES: 1. Surgical Services

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C. ISSUE # 1

Surgical Services

BRIEF EXPLANATION OF FINDINGS

It was alleged that on 7/27/07, a surgical error occurred to the Patient during treatment at the Clinic, which caused a uterine perforation requiring the Patient's transfer to the hospital and further surgical intervention.

State regulations require that surgical procedures must be performed in a safe manner by qualified physicians who have been granted clinical privileges by the governing body of the Ambulatory Surgical Center in accordance with approved policies and procedures of the Ambulatory Surgical Center.

On 10/9/07 at 12:25 PM, the Surveyor interviewed the Ambulatory Surgical Center's Family Counselor in person. The Family Counselor said she reviewed all the consent information with the Patient prior to any surgical procedure. The Family Counselor said she followed the same protocol for the Patient as she did for all the patients coming in for this surgical procedure. The Family Counselor said complications of the procedure were addressed with the Patient and the Patient expressed an understanding prior to signing all the consent forms.

The Consent to Perform Termination of Pregnancy forms were reviewed and indicated that the Patient signed all forms prior to the surgical procedure performed on 7/26/07.

On 7/26/07, the Patient underwent a termination of a 14 week pregnancy at the Ambulatory Surgical Center.

The physician's progress note dated 7/26/07 and written by Physician #1, indicated the Patient was status post surgical termination of pregnancy at 14 weeks gestation. The physician's progress note indicated the Patient had no history of medication allergies. The physician's progress note indicated that the Patient reported multiple episodes of vomiting over the last week. The physician's progress note indicated the Patient underwent a termination of pregnancy procedure under intravenous anesthesia and that the procedure was completed under ultrasound guidance and without complication. The physician's progress note indicated that after the procedure the Patient's uterus was firm and contracted and the ultrasound showed a thin endometrial stripe consistent with a complete procedure. The

C. ISSUE # 1 (continued)

physician's progress note indicated the Patient had minimal vaginal bleeding as expected.

The Patient's Physical Examination report dated 7/26/07 and signed by Physician #1 post surgical procedure at 5:10 PM, indicated the Patient's postoperative condition was good.

On 10/9/07 at 11:40 AM, the Surveyor interviewed Nurse #1 in person. On 7/26/07, Nurse #1 worked in the Ambulatory Surgical Center's recovery room and provided post-operative care to the Patient. Nurse #1 said the Patient arrived in the recovery room at about 5:35 PM. Nurse #1 said that the Patient was able to respond verbally and she was sleepy because she received intravenous anesthesia for the surgical procedure.

The Recovery Room progress note dated 7/26/07 indicated the Patient was admitted to the recovery room after a termination of pregnancy procedure at about 5:30 PM. The Recovery Room progress note indicated physician's orders included monitoring the Patient's vital signs (blood pressure, pulse, and respirations) every 15 minutes until reacted, check for bleeding, Ibuprofen orally as needed, and intravenous fluids. The Recovery Room progress note indicated a physician's order that the Patient could go home when fully reacted.

The Recovery Room progress note indicated that at 5:35 PM the Patient's blood pressure was recorded at 95/47, pulse 60 beats per minute, respirations at 16 breaths per minute, and the Patient was described as "sleepy".

The Recovery Room progress note indicated that at 5:59 PM, the Patient complained of dizziness and nausea and an anti-emetic was administered and the Patient's feet were elevated.

The Recovery Room progress note indicated that at 6:08 PM, the Patient's blood pressure was recorded at 78/34, and at 6:10 PM after standing, the Patient became pale, experienced dizziness and weakness and was assisted back to the chair. The Recovery Room progress note indicated the Patient remained on intravenous fluids with additional intravenous fluids administered and the Patient was given juice.

The Recovery Room progress note indicated that at 6:30 PM, the Patient's blood pressure was recorded at 112/69 and her pulse rate was recorded at 62 beats per minute. At 6:40 PM, the Patient's blood pressure was recorded at 52/27 and her pulse rate was recorded at 81 beats per minute. At 7:10 PM, the Patient's blood pressure was recorded at 125/95 with a pulse rate recorded at 129 beats per minute.

Nurse #1 said that the Patient complained of dizziness and nausea which was not unusual after undergoing the surgical procedure. Nurse #1 said that women frequently felt lightheaded especially when standing after the procedure. Nurse #1 said the Patient was pale when she stood. Nurse #1 said that the only thing which was a bit of a "red flag", was when the

C. ISSUE # 1 (continued)

Patient told her that she could not "see" her. Nurse #1 said it was summer and more of a chance to be fluid depleted so she hung a second bag of intravenous fluids and gave the Patient some juice.

Nurse #1 said that the average time a patient spent in the recovery room after a termination of pregnancy was about one hour or less and then the patient was discharged. Nurse #1 said her cut off for the recovery room was one hour and if a patient was not ready to be discharged, she summoned the physician to the recovery room. Nurse #1 said that on 7/26/07, because she had other patients in the recovery room, when the Patient was still complaining of being dizzy and weak when standing, she called for the physician at about 6:30 PM. Nurse #1 said Physician #1, the Charge Nurse, and the Nurse Anesthesist responded to her call and took over the post-operative care of the Patient. Nurse #1 said they checked the Patient for bleeding and administered a medication to raise the Patient's blood pressure. Nurse #1 said the Patient was then sent to the operating room for an ultrasound.

The Recovery Room progress note dated 7/26/07, indicated that at 7:30 PM the Patient's blood pressure was recorded at 68/49 and a pulse rate recorded at 136 beats per minute.

The Recovery Room progress note indicated the Patient was administered Phenylephrine (medication used to treat hypotension/vasoconstrictor) intravenously at 7:30 PM and 7:32 PM.

On 10/11/07 at 6:30 PM, the Surveyor interviewed the Nurse Anesthesist by telephone. On 7/26/07, the Nurse Anesthesist administered the anesthesia to the Patient during the surgical procedure and responded to the recovery room when called by Nurse #1. The Nurse Anesthesist said he was summoned to the recovery room because the Patient was experiencing orthostatic blood pressures.
The Nurse Anesthesist said when he arrived in the recovery room he observed that the Patient "looked" alert and awake and was assessed to be a bit dehydrated. The Nurse Anesthesist said he administered the medication Phenylephrine to the Patient which was a normal standard of care because of the Patient's low blood pressure. The Nurse Anesthesist said after he administered two doses of Phenylephrine to the Patient she seemed to improve. The Nurse Anesthesist said the Patient was checked for vaginal bleeding with the physician present, and the Patient had some spotting but nothing under the ordinary. The Nurse Anesthesist said he administered additional intravenous fluids to the Patient and the Patient was taken for an ultrasound which was negative for free fluid and blood in the abdomen. The Nurse Anesthesist said he recalculated the Patient's fluid requirements and that the Patient always responded well to the intravenous fluids.

The Recovery Room progress note indicated that at 7:46 PM, an additional 1000 cubic centimeters (cc) of intravenous fluids were administered to the Patient at a rapid rate. The Recovery Room progress note indicated that at 8:10 PM an additional 1000 cc of intravenous fluids were administered to the Patient with pressure for rapid infusion.

C. ISSUE # 1 (continued)

The physician's progress note dated 7/26/07 at 8:10 PM, indicated that upon pelvic exam, the Patient had a normal amount of bleeding and the uterus was well contracted and firm.

The Recovery Room progress note indicated that at 8:16 PM, the Patient's blood pressure was recorded at 82/53 when sitting.

The Recovery Room progress note indicated that at 8:30 PM, while the Patient was assisted with ambulation, she became diaphoretic and pale with a blood pressure recorded at 80/30.

On 10/18/07 at 3:58 PM, the Surveyor interviewed Physician #1 by telephone. On 7/26/07, Physician #1 performed the Patient's surgical procedure. Physician #1 said that after she was called to the recovery room because of the Patient's unstable blood pressure, the Nurse Anesthesist recommended the administration of the medication Phenylephrine based on a possible reaction to the intravenous sedation administered during the procedure.

Physician #1 said that the Patient appeared alert during the time spent in the recovery room.

The physician's progress note indicated that at the recovery room the Patient felt dizzy with blurred vision on standing and orthostatic changes were documented. The physician's progress note indicated that the Patient also had an episode of vomiting and the Patient received intravenous hydration for up to 8000 cc and had shown some improvement. The physician's progress note indicated the patient received two doses of Phenylephrine. The physician's progress note indicated an ultrasound was performed which showed no free fluid in the abdominal pelvic cavity.

The physician's progress note indicated the Patient's lungs were clear to auscultation and an indwelling catheter was placed in the Patient's bladder and urine was obtained. The physician's progress note indicated that the Patient would be transferred to the Hospital for observation and blood work.

Physician #1 said that the Patient's procedure was routine and there had been nothing to indicate that a perforation occurred. Physician #1 said prior to the Patient's transfer to the hospital, a blood test was obtained to test the Patient's hemoglobin and hematocrit levels and the results were reported as low.

The Recovery Room progress note dated 7/26/07 indicated that the Patient continued to be orthostatic. The Recovery Room progress note indicated that a call was placed to the fire department for a non-emergent transport of the Patient to the hospital. The Recovery Room progress note indicated a report was given to emergency personnel and that Physician #1 called the hospital and reported to the emergency room physician a report on the Patient. The Recovery Room progress note indicated that a report was also called to the covering gynecologist by Physician #1.

C. ISSUE # 1 (continued)

The Ambulatory Surgical Center's progress note dated 7/27/07, indicated that the Patient required a hysterectomy at the hospital.

On 10/9/07 at 12:45 PM, the Surveyor interviewed the Ambulatory Surgical Center's Medical Director by telephone. The Medical Director said that as of June, 2007 he was the new owner and medical director of the Ambulatory Surgical Center. The Medical Director said as a result of the incident which occurred to the Patient on 7/26/07, he implemented new policies and protocols at the Ambulatory Surgical Center for the care of patients in the recovery room and the transport of a patient if needed, to the hospital.

The new policies and protocols included Management of Medical Emergencies, Recovery Room Staffing and Safety, Routine Termination of Pregnancy Recovery Procedures, and Patient Transport Protocol.

Although an incident occurred at the Ambulatory Surgical Center on 7/26/07 during a surgical procedure, the Ambulatory Surgical Center staff monitored and assessed the Patient on an ongoing basis, provided the Patient with intravenous fluids and medication to maintain the Patient's blood pressure, and obtained an ultrasound which had not indicated that a perforation/laceration of the Patient's uterus occurred during the surgical procedure. The Ambulatory Surgical Center staff had not notified the Medical Director until after the Patient was admitted to the hospital. The Medical Director of the Ambulatory Surgical Center took appropriate corrective action and implemented new protocols and policies for facility staff for the improvement of patient care in the event of an emergency.

The allegation was determined to be valid because:

1. The Patient sustained a uterine laceration as a result of the surgical procedure performed at the Ambulatory Surgical Center, as reported.

2. The Patient did sign all consents prior to the surgical procedure which stated a laceration was a risk of the procedure.

3. Physician #1 obtained a post operative ultrasound on the Patient and no laceration of the uterus was detected.

4. Physician #1 notified the hospital emergency department physician that the Patient was being transported for observation and blood work.

5. As a result of the incident which occurred on 7/26/07 at the Ambulatory Surgical Center, the Medical Director took appropriate corrective action and implemented new protocols and policies for facility staff for the improvement of patient care in the event of an emergency.

VALIDITY: Valid

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D. RECOMMENDATIONS/COMMENTS

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS

FOUR WOMEN
150 EMORY STREET
ATTLEBORO, MA 02703

LABORATORY DIRECTOR

RNC

CLIA ID NUMBER
22D0945040

EFFECTIVE DATE
08/14/2006

EXPIRATION DATE
08/13/2008

Pursuant to Section 353 of the Public Health Service Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown herein (and other approved locations) may accept human specimens for the purpose of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date shown, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

ASSIGNMENT OF LEASE

This Assignment of Lease is entered into as of June 8, 2007 by and between Four Women, Inc., a Massachusetts corporation (the "Assignor"), Four Women Health Services, LLC, a Massachusetts limited liability company (the "Assignee"), and RJ Realty, LLC a Massachusetts limited liability company (the "Landlord").

RECITALS

A. Assignor is the "Tenant" and Landlord is the "Landlord" under a legally binding Lease dated as of June 20, 2000, as amended by First Amendment to Lease effective February 20, 2002 (collectively, the "Lease").

B Assignor plans to sell certain of its assets to Assignee, and Assignee plans to purchase such assets and to assume certain liabilities of Assignor, in a transaction which is currently expected to be consummated on or about June 15, 2007 (the "Asset Sale").

C. In connection with the Asset Sale, Assignor desires to assign all of Assignor's right, title and interest as Tenant under the Lease to Assignee, and Assignee desires to accept such assignment and assume all obligations associated therewith, on the terms set forth herein.

AGREEMENTS

In consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Assignor hereby assigns to Assignee, effective upon consummation of the Asset Sale, all of Assignor's right, title and interest in and to the Lease and to the Leased Premises therein defined for and during the remainder of the current term of the Lease (the "Assignment"), and any extensions thereof pursuant to the terms of the Lease. Assignor hereby represents and warrants to Assignee that Assignor has full and lawful authority to assign the Lease hereunder.

2. Assignee hereby accepts such assignment, and agrees to assume or perform all the terms and conditions of the Lease that are required to be assumed or performed by the Assignor as Tenant under the Lease, accruing or arising on or after the consummation of the Asset Sale. Assignee hereby represents and warrants that Assignee has full and lawful authority to execute, deliver and perform its obligations under this Assignment of Lease.

3. Landlord hereby accepts and agrees to the Assignment.

4. This Assignment of Lease shall become effective only upon consummation of the Asset Sale pursuant to the Asset Purchase Agreement between Assignor, Assignee and [redacted] dated as of June 8, 2007 (the "Asset Purchase Agreement"). Nothing herein shall alter, amend or otherwise affect any representation, warranty, covenant or obligation between or among Assignor, Belding and Assignee pursuant to the Asset Purchase Agreement. This Assignment of Lease shall be binding on and inure to the benefit of the parties to this agreement, their successors and assigns, and shall be governed and construed in accordance with laws of the Commonwealth of Massachusetts, without giving effect to any choice or conflict of law provision or rule. All terms used but not defined herein shall have the respective meanings ascribed to them in the Lease.

[Remainder of page intentionally left blank]

EXECUTED as of the date first above written.

ASSIGNOR:

Four Women, Inc.

By: _____

Print name: _____

Print title: _____

ASSIGNEE:

Four Women Health ~~Services~~, LLC

By: _____

Print name: _____

Print title: _____

LANDLORD:

RJ Realty, LLC

By: _____

Print name: _____

Print title: _____

BILL OF SALE

This Bill of Sale dated as of June 15, 2007 is executed and delivered by Four Women, Inc., a Massachusetts corporation (the "Seller"), and . the sole shareholder of the Seller (the "Shareholder"), to Four Women Health Services, LLC, a Massachusetts limited liability company (the "Buyer"). All capitalized words and terms used in this Bill of Sale and not defined herein shall have the respective meanings ascribed to them in the Asset Purchase Agreement dated as of June 4, 2007 by and among the Seller, the Shareholder and the Buyer (the "Agreement").

WHEREAS, pursuant to the Agreement, each of the Seller and Shareholder has agreed to sell, transfer, convey, assign and deliver to the Buyer the Acquired Assets, and the Buyer has agreed to assume the Assumed Liabilities from the Seller;

NOW, THEREFORE, in consideration of the mutual promises set forth in the Agreement and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, each of the Seller and Shareholder hereby agrees as follows:

1. Each of the Seller and Shareholder hereby sells, transfers, conveys, assigns and delivers to the Buyer, its successors and assigns, to have and to hold forever, all right, title and interest in, to and under all of the Acquired Assets.

2. Each of the Seller and Shareholder, by execution of this Bill of Sale, and the Buyer, by acceptance of this Bill of Sale, each hereby acknowledges and agrees that neither the representations and warranties nor the rights, remedies or obligations of any party under the Agreement shall be deemed to be enlarged, modified or altered in any way by this instrument.

[*Remainder Of Page Has Intentionally Been Left Blank*]

IN WITNESS WHEREOF, the Seller, the Shareholder and the Buyer have caused this instrument to be duly executed under seal as of and on the date first above written.

SELLER:
FOUR WOMEN, INC.

By: _____
, President

SHAREHOLDER:

_____
, Individually

ACCEPTED:

BUYER:
FOUR WOMEN HEALTH SERVICES, LLC

By: _____
_____
lember

PERSONNEL INFORMATION FORM

Facility Name: Four Women Health Services

Address (if satellite): 150 Emory St. Attleboro, MA 02703

Complete information for administrative/supervisory and clinical staff including fee for service, contracted and intern staff. Do not include business and billing staff.

Name of Staff Member	Professional Discipline	License or Registration # (if applicable)	Identify Days & Hours Worked	Total Weekly Hours	Service(s): Medical, Mental Health, Alcoholism, etc.
	Physician		Saturdays	10	medical
	MD Physician		Thursdays	10	medical
	RN		(All RNs rotate	10	medical
	RN		Wed, Thurs	10	medical
	RN		and Sat	10	medical
	RN		sessions)	32	medical
	RN		M-F 9-5	40	medical
	MD		Sat Session	5	medical
	RN/NA		(All RN/NAs	5	medical
	RN/NA		Alternate Wed,	5	medical
	RN/NA		Thurs and Sat	5	medical
	RN/NA		sessions)	5	medical
	MD		Sat Session	5	medical
	MD		Sat Session	5	medical
	MD		Sat Session	5	medical

The Commonwealth of Massachusetts

DEPARTMENT OF PUBLIC HEALTH

CLINIC LICENSE

In accordance with the provisions of the General Laws, Chapter 111, Sections 51-56 inclusive, and the regulations promulgated thereunder, a license is hereby granted to:

Four Women Health Services, Inc.
Name of Applicant

for the maintenance of

Four Women, 150 Emory Street, Attleboro, MA 02703
Name and Address of Clinic

and Satelites as listed below.

The license is valid until **June 14, 2013**, subject to revocation or suspension, either wholly or with respect to a specific service or specific services, or a part or parts thereof.

SERVICE(S):

- [X] Medical
- [X] Surgical
- [ ] Dental
- [ ] Mental Health
- [ ] Physical Rehabilitation
- [ ] Substance Abuse
- [ ] Birth Center
- [ ] Mobile Medical
- [ ] Radiology (MRI)
- [ ] Pharmacy
- [ ] Limited Services

John Auerbach
Commissioner of Public Health

LICENSE № 44H1

June 15, 2011
Date Issued

POST CONSPICUOUSLY

MEMORANDUM

TO: Sheila Faiella - entire packet

FROM: Ray Cryan

DATE: March 27, 2006

RE: Change of ownership of a Clinic / ASC:

Four Women
150 Emery Street
Attleboro, MA 02703
FAC ID: Clinic # 44H1
ASC # A052

The above Clinic / ASC changed ownership effective **June 15, 2007**. The new owner/licensee is:

Four Women Health Services, LLC
150 Emery Street
Attleboro, MA 02703

Name Change: **None**

Address Change: **None**

BOOKING SHEET INFORMATION

DON # n/a

PLAN APPROVAL: n/a

Suitability Completed: Yes

COMMENTS: This CHOW is the result of this clinic / ASC being purchased by Four Women Health Services, LLC

FOUR WOMEN HEALTH SERVICES, LLC 05-07 1003
150 EMORY ST.
ATTLEBORO, MA 02703

PAY TO THE ORDER OF Commonwealth of Massachusetts DATE 6/12/07 53-13/110 MA 80658

Two Hundred and Fifty - Five 00/100 $ 255.00 DOLLARS

Bank of America
ACH R/T 011000138

FOR DPU Licensure Fee

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF HEALTH CARE QUALITY
99 CHAUNCY STREET, 2ND FLOOR, BOSTON, MA 02111
(617) 753-8000

CLINIC PRESURVEY REPORT FOR LICENSURE

____ Initial Survey of Parent Site
__✓__ Change of Ownership
____ Change of Location: Parent____ Satellite____
____ Addition of Satellite
____ Addition of Service
____ Other_____

6/11/07 SURVEY REQUEST DATE

6/16/07 PROJECTED START DATE OF SERVICE

Please complete **ONE PRESURVEY REPORT FOR EACH CLINIC SITE TO BE SURVEYED.** The applicable sections of this document must be completed and returned to this office prior to survey.

With this form **please attach:** An Organizational Chart
Completed Personnel List Form
Clinic Brocure (if available)
Directions to the Clinic Site
and **Current Certificates:** Fire Safety Inspection Certificate
Department of Public Safety Cert.
Division of Food and Drug Cert.
C.L.I.A./Waiver Cert.

Licensee: Four Women Health Services, LLC

Name of **PARENT** Clinic: Four Women ~~Health Services, LLC~~

Street: 150 Emory St Suite #/Floor

City/Zip Code: Attleboro, MA 02703

Telephone Number: 508 222 7555

Days and Hours of Operation: Wed (afternoons), Thurs & Sat (mornings)

SATELLITES:

1. Name of Clinic: _____

   Street: _____ Suite #/Floor _____

   City/Zip Code: _____

   Telephone Number: _____

   Days and Hours of Operation: _____

2. Name of Clinic: _____

   Street: _____ Suite #/Floor _____

   City/Zip Code: _____

   Telephone Number: _____

   Days and Hours of Operation: _____

3. Name of Clinic: _____

   Street: _____ Suite #/Floor _____

   City/Zip Code: _____

   Telephone Number: _____

   Days and Hours of Operation: _____

4. Name of Clinic: _____

   Street: _____ Suite#/Floor _____

   City/Zip Code: _____

   Telephone: _____

   Days and Hours of Operation: _____

   (Attach addendum for additional sites, if applicable)

Please check off ( ) services offered, by site.

	medical	surgical	dental	mental health	physical rehab.	alcoholism	birthing ctr.	pharmacy	laboratory	radiology	mobile medical
Main site:	✓	✓							✓		
Satellite sites: (list each separately)											
1.											
2.											
3.											
4.											
5.											
6.											
7.											
8.											

Licensure Information:
Information provided below pertains to the **following Clinic Site:**

Four Women's 150 Emory St. Attleboro, MA 02703
(Name, address) *xerox this sheet for additional sites

Clinic Staff:

Clinic Administrator
(140.310) _____

Professional Services Director
(140.311) ___

Responsible M.D.
{140.313(A)} _____ ___

Nursing Director
(140.314) _____ ___

1. Does the licensee provide services separate from the licensed clinic services (e.g., Residential Services, Adoption Services). Explain: no

2. How does the Clinic differentiate licensed clinic services from other non-clinic services offered by the parent agency? services provided on licensed clinic

3. Does this Clinic site have a current Certificate of Inspection issued by the Massachusetts Department of Public Safety? (attach)
Comments: Yes

4. Does this Clinic site have a current Certificate of Inspection and approval issued by the local fire department (issued within the past two years) (attach)
Comments: Yes

5. Is verification of current professional licensure provided for all applicable staff?
Comments: Yes

6. Is this Clinic site handicapped accessible? (Ramps, elevators, bathrooms, etc.)
Comments: Yes

7. Does this clinic have a written agreement with a nearby hospital providing emergency services? Identify hospital Sturdy Hospital coverage Physicians
Inpatient psychiatric services (for mental health clinics)

8. Does this clinic utilize the services of:
Nurses in the Expanded Role? Yes Physician's Assistants? no

Medication Information: (140.340)(140.347)

1. Does this Clinic have a Pharmacy? Yes (No)

2. Name of the Pharmacy Director {140.342(A)}

3. Are any stock prescription medications (including emergency and/or sample drugs) purchased and/or stored at this Clinic site? Yes No

4. Does this Clinic have the following:

Mass. Board of Pharmacy Registration: Yes No
#_____ Expiration Date:_____

Mass. D.P.H. Food & Drug Registration: Yes No
#_____ Expiration Date:_____

U.S. Drug Enforcement Administration (D.E.A.) Yes No
Registration: #_____ Expiration Date:_____

5. If this is an initial survey, have the above applications (if applicable) been filed with the respective agencies?
Comment:

Laboratory (140.350)

Laboratory Test: Includes ALL types of testing (e.g., dipstick, tablet, fingerstick, Point-of-Care, moderate/high complexity) performed on any body fluid (e.g., blood, serum, urine, feces, culture).

1. Are laboratory services offered at this clinic site:

   Directly ✓ Under Arrangement_____ Not Offered_____

   (IF N/A PLEASE CONTINUE TO NEXT SECTION, DIAGNOSTIC RADIOLOGY)

   Name of Laboratory Director:_____

2. Does the clinic contract for the provision of all or part of its clinical laboratory services with a laboratory independent of this clinic?

   (Yes) No

   If yes:

   Name of Laboratory: Quest Diagnostics Incorporated

   Address: 415 Massachusetts Avenue, Cambridge MA 02139

3. Are any of the clinic's patients' laboratory tests performed on site?

   (Yes) No

4. Are on-site laboratory testing services offered to other health care facilities?

   Yes (No)

5. Has the clinic applied for a CLIA (Clinical Laboratories Improvement Act) registration?

   (Yes) No

   Which certificate type? Waiver_____
   Regular ✓
   PPMP_____

   CLIA# 22D0945040

6. Check laboratory tests performed in the clinic (e.g., treatment room laboratory, physician offices, etc.):

CHEMISTRY
___Glucose (any method)
___Cholestrerol, HDL, LDL
___Na, K, Cl, CO2

MICROBIOLOGY
___Strep Screen
___Cultures (urine, throat, other)
___Sensitivities
___Scotch Tape, Wet prep, KOH prep
___GC, Chlamydia screens

HEMATOLOGY
__✓Hgb, Hct, RBC, WBC, Plts, Indices (any parameter, any method)
___Differential (manual, automated)
___SED Rate
___Reticulocytes
___Coagulation (PT/PTT)
___Sperm count
___Sickle Cell

URINE/FECES
___Dipstick urine
___Urine microscopic
__✓Pregnancy Test
___Occult Blood

SEROLOGY
___Mono Test
___RPR, Syphilis
___Rheumatoid Factor

7. Are transfusion services offered at this site?

Yes (No)

8. Are procedures other than those listed above performed on-site?

(Yes) No

If yes, briefly describe the types of procedures performed in the space below: Rh typing

9. Are any laboratory specimens collected by personnel not employed by the clinic?

Yes (No)

If yes:
Name of Laboratory/Facility supplying phlebotomy/specimen collection services:

Is there a separate specimen collection area? Yes No

Diagnostic Radiology: (140.360)

1. Are Diagnostic Radiology Services provided at this Clinic site?

Yes (No)

Are Therapeutic Radiology Services provided at this Clinic site?

Yes (No)

(IF N/A PLEASE CONTINUE TO NEXT SECTION ON FOLLOWING PAGE, MENTAL HEALTH SERVICES)

If yes, type(s) of Services:

X-Ray_____

Laser_____

MRI_____

Fluroscopy_____

Mammography_____

Other_____

2. Does this site have a registration or application on file with the Department of Public Health, Division of Radiation Control, to provide such services?

Yes (No)

Registration Number:_____

Expiration Date:_____

3. Radiologist responsible for the proper performance of Radiological Services:

Name:_____

Board Certification Status:_____

Mental Health Services: (140.500)

1. Are Mental Health Services provided at this site? YES (NO)

(IF N/A PLEASE CONTINUE TO NEXT SECTION, SUBSTANCE ABUSE SERVICES)

2. Average number of patient visits per week: _____

3. D.M.H. area in which the Parent Clinic is located:

_____

4. Does this Clinic site operate a Psychiatric Day Treatment Program? Yes No

Hours of Operation: _____

Average # of Clients: _____

5. Name of M.D. responsible for the establishment of medical policies and supervision of medical services {140.530(D)}:

_____

Qualifications (Licensure, Board Certification)

_____

Multidisciplinary Staff (140.530) (See Definitions 140.020)

6. Which of the following clinical disciplines are involved in developing client treatment plans?

a. Mass. licensed M.D.
Board Certified/Eligible,
Psychiatry and Neurology

b. Psychiatric Social Worker
(Mass. LICSW, LCSW, at least one year post-grad. mental health experience)

c. Mass. licensed Psychiatric Nurse
(R.N., Master's degree in Psychiatric Nursing)

d. Mass. licensed Clinical or Counseling Psychologist

e. Other:

7. Are Mental Health Services offered at outreach locations? (140.560)
Yes (No)

Location	DMH AREA	Total Hrs. of Operation/Wk.	Total Staff Hours/Wk.
1.			
2.			
3.			
4.			
5.			

8. Are any of the above in commercially rented office space?
Yes No

Explain: _____

9. Is an agreement provided with each Outreach Site?
Yes No

10. Where are the records of outreach patients stored?

Explain: _____

11. Are medications stored or administered at any outreach site?
Yes No

Explain: _____

Substance Abuse Services: (140.800)

1. Does the clinic provide a separate, identifiable program specifically designed to care for persons suffering from Alcoholism/Substance Abuse? Yes (No)

(IF N/A PLEASE CONTINUE TO NEXT SECTION, SURGICAL SERVICES)

2. If yes, does the clinic have an approval or license issued by the Department of Public Health's Bureau of Substance Abuse Services? (attach copy) Yes No

Expiration Date: _____

Surgical Services (140.600)

1. Are Surgical Services provided at this site?
(Yes) No

(IF N/A PLEASE CONTINUE TO NEXT SECTION, DENTAL SERVICES)

2. If yes, type of Anesthesia Used:

__v__ Local

____ Regional

__v__ Conscious I.V. Sedation

____ General

____ Other: I.V. sedation

3. Is this Clinic site a Medicare Certified Ambulatory Surgical Center?
(Yes) No

4. Does this Clinic use services of:

Nurse Anesthetists	(Yes)	No
Nurse Midwives	Yes	(No)
Physician Assistants	Yes	(No)

5. Name of Surgical Director (140.603) _____

Qualifications (Licensure, Certification Status)
Licensed physician in MA since and Board Certified in Obstetric & Gynecology renewed (re certified) 05

6. Name of Anesthesia Director (140.606) _____

Qualifications (Licensure, Certification Status)
F.A.C.O.G Board certified 10/6-

7. Number of operating rooms 2

8. Average number of surgical cases per week 45

Please attach a list of approved surgical procedures (140.604).

Dental Services: (140.400)

1. Are Dental Services provided at this site?
   Yes (No)

(IF N/A PLEASE CONTINUE TO NEXT SECTION, PHYSICAL REHABILITATION SERVICES)

2. If yes, what type of anesthesia is used:

   ____ Local

   ____ Conscious I.V. Sedation

   ____ General

   ____ None

   ____ Other: _____

3. Name of Dental Service Director _____

   Qualifications (Licensure, Certification Status)
   _____

Physical Rehabilitation Services: (140.700)

1. Are Physical Rehabilitation Services provided at this site?
   Yes (No)

2. If yes, type of service(s):

   Physical Therapy _____

   Occupational Therapy _____

   Speech Therapy _____

   Other: _____

3. Name of the M.D. responsible for assisting in implementing patient care policies and providing medical consultation, as needed. (140.701) _____

To the best of my knowledge, the information in this Pre-survey Report is accurate.

Signed: _____

Title: President / Medical Director

Date: 6 / 17 / 07

Reviewed and Revised at Survey, as applicable:

Signed: _____

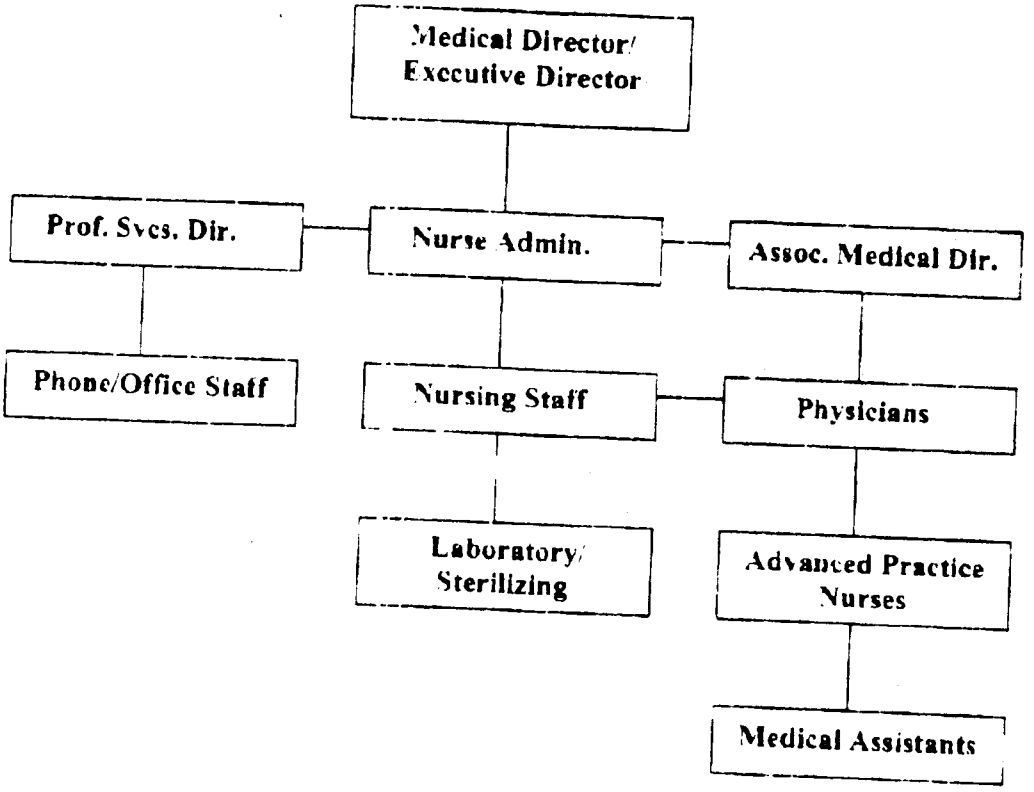
Title: _____

Date: ___ / ___ / ___

Information reviewed by:

_____ Date: ___ / ___ / ___
(Surveyor Name)

Four Women Clinic



DEVAL L. PATRICK
GOVERNOR

TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD
SECRETARY

JOHN AUERBACH
COMMISSIONER

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Environmental Health
Community Sanitation Program
250 Washington Street, Boston, MA 02108-4619
Telephone (617) 624-5757
Facsimile (617) 624-5777

Administrator
Four Women Health Services
150 Emory Street
Attleboro, MA 02703

December 12, 2009

Re: Complaint investigation re: compliance with requirements for medical waste management

Dear

On November 4, 2009, the Department of Public Health's Community Sanitation Program (CSP) and the Attleboro Health Department conducted a compliance inspection at Four Women Health Services located at 150 Emory Street, Attleboro, MA. This inspection was conducted in accordance with M.G.L. c. 111, §127A, and 105 CMR 480.000: Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code, Chapter VIII), in response to an alleged violation of 105 CMR 480.200 – illegal disposal of medical or biological waste as solid municipal waste. In addition, the complaint and this investigation report have been forwarded to the Department's Division of Health Care Quality which is responsible for investigation of complaints involving clinics licensed pursuant to 105 CMR 140.000.

FINDINGS

Based on observations made during the on-site inspection, the CSP determined that Four Women Health Services had numerous deficiencies in its medical or biological waste management and was not in compliance with the following requirements of 105 CMR 480.000:

- The area used for medical waste storage lacked appropriate signage indicating the presence of regulated medical or biological waste. A single loose red bag of unidentified medical or biological waste was present (but not labeled for shipment) on the floor of a multi-purpose storage/hot water heater room without clear signage [105 CMR 480.100(C)(1)].

- The area used for medical waste storage lacked appropriate security to prevent unauthorized access [105 CMR 480.100(C)(2)].

- As currently configured the storage area does not allow clear separation of regulated medical waste (red bags/sharps/pathological waste) [105 CMR 480.100(C)(4)].

- Required written procedures were not maintained for the proper management of medical or biological waste [105 CMR 480.500(A) and 105 CMR 480.500(I)].

- Required medical waste record-keeping log was not maintained [105 CMR 480.500(B) and 105 CMR 480.500(I)].

- Required written contingency plan for spills and accidents was not maintained [105 CMR 480.500(C) and 105 CMR 480.500(I)].

CORRECTIVE ACTIONS

Based on the November 4, 2009 inspection, the Department requires the following corrective actions:

1. Four Women Health Services must evaluate and redesign all existing policies and procedures for the handling of medical and biological waste to ensure compliance with 105 CMR 480.000, as amended in July 2008. This includes procedures at the point of medical or biological waste generation, as well as waste packaging and storage procedures.

2. The current space utilized at Four Women Health Services for the handling and storage of medical or biological waste shall be reconfigured to improve the handling and clear separation of red bags/boxes, sharps and pathological waste. Medical or biological waste being sent off-site for treatment must be properly stored in a designated area identified with appropriate signage, that only allows authorized access, that is not utilized as multi-purpose space and that maintains full compliance with 105 CMR 480.100 and 105 CMR 480.300 pending pickup.

3. Documentation must be provided to the CSP that ventilation for the designated storage area discharges directly to the exterior of the buildings away from any fresh air intakes, and is in accordance with appropriate ASHRAE guidelines.

4. Policies and procedures must be implemented to ensure that waste sent off-site for treatment is properly recorded in the required medical waste record-keeping log according to 105 CMR 480.425 and 105 CMR 480.500.

5. Four Women Health Services must provide to the Department documentation including medical waste record-keeping logs and shipping papers / tracking forms for all waste sent off-site for treatment since August 1, 2008.

6. Four Women Health Services must establish and provide to the Department written policies and procedures for the handling, storage and shipment of all medical or biological waste that ensure compliance with all aspects of 105 CMR 480.000.

7. Four Women Health Services shall provide the Department specific plans for and documentation demonstrating fulfillment of training for all current and future staff involved in the segregation, handling and management of medical or biological waste.

Four Women Health Services must provide a response in writing regarding these corrective actions to the Community Sanitation Program by January 15, 2010. Please be advised that pursuant to 105 CMR 480.600(C), this letter constitutes notice to Four Women Health Services of the nature of these current violations and that any additional violations of 105 CMR 480.000 may result in legal action.

Please feel free to contact me at (617) 624-5757 if you have further questions regarding this matter.

Sincerely,

Steven F. Hughes
Director, Community Sanitation Program

CC:

Suzanne K. Condon, Associate Commissioner, Director, BEH
James Ballin, Deputy General Counsel, DPH
Lisa Noling Snellings, Deputy General Counsel, DPH
Lillian Jette, DHCQ
Sherman Lohnes, DHCQ

FOUR
WOMEN
Health Services

January 12, 2010

Steven F. Hughes
Director, Community Sanitation Program
DPH, Bureau of Environmental Health
250 Washington Street
Boston, MA 02108-4619

Dear Mr. Hughes,

I am writing in response to your letter dated December 12, 2009 (Re: Complaint investigation re: compliance with requirements for medical waste management). Based on your inspection, there were a number of corrective actions that were required by your Department. Please see the attached document addressing each corrective action. Four Women has taken this issue seriously and addressed each requirement in detail. The minimum requirement has been met, and we continue to strive to exceed those requirements. Please contact me if you have any questions regarding this response, or the accompanying documents.

Sincerely

Four Women Health Services

Cc: , Four Women Health Services

150 Emory St. Attleboro, MA 02703 | Tel: 508.222.7555 Fax: 508.226.2218

Corrective Action required	Action taken	Effective date
1. Four Women Health Services must evaluate and redesign all existing policies and procedures for the handling of medical and biological waste to ensure compliance with 105 CMR 480.000, as amended in July 2008. This includes procedures at the point of medical or biological waste generation, as well as waste packaging and storage procedures.	Policies have been reviewed, amended or created to ensure compliance with 105 CMR 480.000. A copy of pertinent polices and procedures is attached.	12/2009
2. The current space utilized at Four Women Health Services for the handling and storage of medical or biological waste shall be reconfigured to improve the handling and clear separation of red bags/boxes, sharps and pathological waste. Medical or biological waste being sent off-site for treatment must be properly stored in a designated area identified with appropriate signage, that only allows authorized access, that is not utilized as multi-purpose space and that maintains full compliance with 105 CMR 480.100 and 105 CMR 480.300 pending pickup.	Contracted builders reconstructed a closet within the clinic for storage of medical and biological waste. The closet is large enough to accommodate the maximum amount of potential stored waste pending pickup. There is clear separation of red bags, sharps containers, and pathological waste. The space is locked and only allows authorized access. Additionally, appropriate signage has been affixed to the door of the closet. A weather strip has been added in order to prevent odors from escaping.	12/2009
3. Documentation must be provided to the CSP that ventilation for the designated storage area discharges directly to the exterior of the buildings away from any fresh air intakes, and is in accordance with appropriate ASHRAE guidelines.	We have contracted with our HVAC provider, Environmental Systems, Inc. to upgrade our biohazard storage closet in order to meet appropriate ASHRAE and DPH guidelines. The proposal is attached and outlines the modification to discharge the air in the storage closet directly to the outdoors. The vent and ductwork is already in place, it only needs to be connected. This project will be completed as soon as possible.	1/31/2010
4. Policies and procedures must be implemented to ensure that waste sent off-site for treatment is properly recorded in the required medical waste record-keeping log according to 105 CMR 480.425 and 105 CMR 480.500.	Policies for waste packaging, storage and disposal have been updated to include medical waste record keeping. Copies of the medical waste record-keeping log have been attached.	12/2009
5. Four Women Health Services must provide to the	Attached are all shipping papers and tracking forms for	12/2009

Department documentation including medical waste record-keeping logs and shipping papers/tracking forms for all waste sent off-site for treatment since August 1, 2008.	waste sent off-site for treatment since August 1, 2008. Also attached is a copy of the record-keeping log.	
6. Four Women Health Services must establish and provide to the Department written policies and procedures for the handling, storage and shipment of all medical or biological waste that ensure compliance with all aspects of 105 CMR 480.000.	Attached is the updated policy regarding the storage and shipment of biological waste. Attention is made to the clear separation of red bags and sharps, and pathological waste.	12/2009
7. Four Women Health Services shall provide the Department specific plans for and documentation demonstrating fulfillment of training for all current and future staff involved in the segregation, handling and management of medical or biological waste.	A staff in-service was performed in order to train existing staff on the handling of regulated waste. All new employees responsible for handling regulated waste will be required to read the Infection Control policy manual, which includes all policies related to regulated waste, and training will be documented in the employee file and the Waste Record Keeping log.	12/2009 and ongoing

Environmental Systems, Inc.

Mechanical Contractors and Engineers

6 Howard Ireland Drive
Attleboro, MA 02703-4612
508 226-6006 f 508-222-1344
www.envsys.net

January 6, 2010

Four Women Health Services
150 Emory Street
Attleboro, Ma. 02703

Re: Bio-hazard closet exhaust

We are pleased to offer the following proposal for HVAC upgrades at the above referenced facility.

This modification will insure that the proposed Bio-hazard storage closet will be exhausted directly to the outdoors and that the termination point for this exhaust will meet the minimum distance criteria in relationship to any fresh air intakes or operable windows.

Bio-hazard exhaust

We propose to replace the existing ceiling grille and run new duct to an adjacent exhaust system. The existing exhaust system is capable of handling the modest increase in exhaust air as the closet totals only 30 cubic feet. At an exhaust rate of 40 CFM the air change rate would approach 80 air changes per hour.

The cost for installation of the exhaust system components as outlined above would be $585.00.

The above proposal does not include a new ceiling tile if required.

Thank you for the opportunity to assist you with this project. If you should have any questions, please do not hesitate to call.

Yours truly,

ENVIRONMENTAL SYSTEMS, INC.

Stericycle

Account/ Site # ____

STERI•SAFE^{SM} SERVICE AGREEMENT

Service Address

Name: Four Women Health Sevices
Address 1: 150 Emory Street
Address 2:
City/State/Zip: Attleboro, MA 02703
E-Mail:
Phone:
Contact:

Billing Address (If Different)

Name: Same
Address 1:
Address 2:
City/State/Zip:
E-Mail: same
Phone: (___) ___-____ ext ____ Fax: (___) ___-____
Contact: _____ Title: _____

The parties agree as follows

1. The Effective date of this agreement is 12/01/2009
2. Stericycle shall remove and dispose of Customer's Regulated Medical Waste (Hazardous Waste as applicable) subject to the terms and conditions set forth below
3. Stericycle will provide additional compliance services for the prices applicable to the service program level Customer has selected below

Services to be Provided

STERI-SAFE w/ RMW

Steri-Safe Program Level Select

Payment Schedule: Billed Monthly

* Monthly payment schedule only available for selected programs with pickup frequency greater than 13 pickups per year

Service Frequency 13 stops year

Maximum Medical Waste Containers per Year 52

Medical Waste Container Size Medium

Each Additional Container Charge $ 35.00

Additional Pick Up Charge $150.00
(For stops in addition to your regular schedule.)

Special Waste Services

Category	Max Cont per yr
☐ Drug Disposal Service	0
Each Additional Container Charge $ 190	
☐ Fixer/Developer (CT, MA, NH, RI, VT)	____
Each Additional Container Charge $ 125.00	
☒ Path/Chemo	6
Each Additional Container Charge $ 0.00	

☒ I certify that I will properly classify and segregate my waste streams and that I will not co-mingle these waste streams with any other.

Total Monthly Fee: $ 243.50

By signing below I acknowledge that I am the Customer's authorized officer or agent and that I have the authority to bind Customer to this Agreement. Customer agrees to be bound by the terms and conditions that appear on following pages hereof and comply with Stericycle's Waste Acceptance Policy, both of which are integral parts of this Agreement.

Stericycle reserves the right to deal solely with the Customer and not with any third party agents of the customer for all purposes relating to this Agreement. Customer represents and warrants to Stericycle that it is the medical waste generator and is acting for its own account and not through a broker or agent. Stericycle shall be entitled to terminate this agreement and seek all available legal remedies including but not limited to liquidated damages, in the amount set forth herein for Customer's breach of this representation and warranty.

CUSTOMER: X_____ PLEASE PRINT:_____ Title _____ Date: _____

STERICYCLE: X_____ PLEASE PRINT:_____ Title _____ Date: _____

STERICYCLE USE ONLY

Type of Agreement Service Change Term of agreement 60 Months

Tax Exempt ☐ YES ☐ NO If YES, ID# ____ (copy must accompany paperwork)

Purchase Order (if applicable) # ____ From __/__/____ to __/__/__

Segment Code ____ Affiliation Code ____

SScode : 181 RXcode : ____ F/Dcode : 62.50

Promo Code _____

SFDC Record #

Routing Information (Operations Department):

Med Waste Container Code _____ Qty ____ Special Waste Container Code ____ Qty ____ None (sharps only) ☐

Service Area ____ Route # ____ Container Setup Date __/__/2008 First Pickup Date (Cycle Begin Date) __/__/2008

Day of Service: ☐ Mon ☐ Tues ☐ Wed ☐ Thurs ☐ Fri Service Hours

Routing Comments _____

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

Medical or Biological Waste Record-Keeping Log

OFF-SITE TREATMENT

Facility Name & Address: Four Woven Health Services - 150 Emory Street Attleboro, MA 02703

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 Wast (State Sanitary Code, Chapter VIII), generators of medical or biological waste, which is shipped off-site for treatment, shall maintain a current record-kee 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 na transporter with transporter identification number (if applicable); the verification (via check box) of shipping papers generated with receipt of correspondi 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	ID# (if applicable)	Please Check: Shipping Paper	Please Check: Tracking Form	Printed I Signat
8/7/09	4	Medium corrugated	16	Stericycle		☑	☑	
8/28/09	1	Medium corrugated	4	Stericycle		☑	☑	
9/16/09	1	Medium corrugated	5	Stericycle		☑	☑	
9/25/09	3	Medium corrugated	12	Stericycle		☑	☑	
10/23/09	3	Medium corrugated	12	Stericycle		☑	☑	
11/24/09	1	Medium corrugated	4	Stericycle		☑	☑	
12/22/09	3	Medium corrugated	12	Stericycle		☑	☑	

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

Facility Name & Address: Four Women Health Services - 150 Emory St. Attleboro, MA 02703

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 Wast (State Sanitary Code, Chapter VIII), generators of medical or biological waste, which is shipped off-site for treatment, shall maintain a current record-kee 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 na transporter with transporter identification number (if applicable); the verification (via check box) of shipping papers generated with receipt of correspondi 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	ID# (if applicable)	Please Check: Shipping Paper	Please Check: Tracking Form	Printed Signat
2/13/09	2	Medium corrugated	8	Stericycle		☑	☑	
3/13/09	3	Medium corrugated	12	Stericycle		☑	☑	
4/10/09	3	Medium corrugated	12	Stericycle		☑	☑	
5/8/09	2	Medium corrugated	8	Stericycle		☑	☑	
6/5/09	2	Medium corrugated	8	Stericycle		☑	☑	
6/26/09	3	Medium corrugated	12	Stericycle		☑	☑	
						☐	☐	
						☐	☐	

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

Facility Name & Address: Four Women Health Services - 150 E Mary St Attleboro, MA 02703

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 Wast (State Sanitary Code, Chapter VIII), generators of medical or biological waste, which is shipped off-site for treatment, shall maintain a current record-kee 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 na transporter with transporter identification number (if applicable); the verification (via check box) of shipping papers generated with receipt of correspondi 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	ID# (if applicable)	Please Check: Shipping Paper	Please Check: Tracking Form	Printed Signat
7/9/08	3	Medium corrugated	12	Stericycle		☑	☑	
8/6/08	4	Medium corrugated	16	Stericycle		☑	☑	
8/29/08	2	Medium corrugated	8	Stericycle		☑	☑	
9/26/08	2	Medium corrugated	8	Stericycle		☑	☑	
10/23/08	2	Medium corrugated	8	Stericycle		☑	☑	
11/21/08	2	Medium corrugated	8	Stericycle		☐	☑	
12/19/08	2	Medium corrugated	8	Stericycle		☑	☑	
1/16/09	2	Medium corrugated	8	Stericycle		☑	☑	

Four Women Health Services
Management of Biological Waste Training Agreement

Employee name: _____
Date: _____

Initial

_____ I have read and understand the information contained in the Infection Control Manual

_____ I have been given the opportunity to ask questions regarding the management of biological waste and have them answered

_____ I have been trained by a proficient staff member in the management of biological waste.

_____ I am confident in my ability to segregate, handle and manage medical or biological waste.

_____
Employee signature

_____
Supervisor signature

Stericycle
Protecting People. Reducing Risk.

IN CASE OF EMERGENCY CONTACT: CHEMTREC 1-800-234-0051
Route # - 0

STANDARD MANIFEST 001-10-06-STD
MM40220B1F

1. Generator's Name, Address and Telephone Number

ATTN: Four Women Health Services
150 Emory St.
Attleboro, MA 02703-2439

CUSTOMER NUMBER -

GENERATOR'S REGISTRATION #

2A. DESCRIPTION OF WASTE	2B. CONTAINER TYPE	2C. NO. OF CONTAINERS	2D. VOLUME
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291 PG II	TB01 - 30 Gal Reusable (4.0 cu ft)		Cu Ft
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291 PG II	WW40 - Medium Corrugated (4.0 cu ft)	3	12 Cu Ft
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291 PG II	WW45 - Medium Corrugated (4.5 cu ft)		Cu Ft
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291 PG II	WW70 - Large Corrugated (7.0 cu ft)		Cu Ft
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291 PG II	KPBX - Large Corrugated (4.3 cu ft)		Cu Ft
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291 PG II	ST75 - 48 Gal Reusable (7.5 cu ft)		Cu Ft
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291 PG II	WP40 Path 4.0 Cu Ft ~~BP10 - Large Path/BD36 Chemo - Incinerate Only (4.5 cu ft)~~	2	8 Cu Ft
REGULATED MEDICAL WASTE, n.o.s. 6.2, UN 3291 PG II			Cu Ft
			Cu Ft
	TOTALS ▶	5	20 Cu Ft

3. Generator's Certification: "I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations."

X Printed/Typed Name ______ Signature ______ Date 12/22/09

GENERATOR

4. TRANSPORTER 1 ADDRESS:

STERICYCLE, INC.
28161 N. Keith Drive
Lake Forest, IL 60045

[ ] This is a Through Shipment

Phone #: (800) 633-9278
Applicable Permit Numbers:
CT-BMW-005 NY-DECIL-033
ME-BWT-033 RI-MW-TRAN-260
NJ-DEP-19713 TNH-0210

TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name ______ Signature ______ Date 12-22-09

PRIMARY TRANSPORTER

5. INTERMEDIATE HANDLER 2 / TRANSPORTER 2 ADDRESS:

Phone #:
Applicable Permit Numbers:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name ______ Signature ______ Date ______

TRANSPORTER 2 / INTERMEDIATE HANDLER

6. INTERMEDIATE HANDLER 3 / TRANSPORTER 3 ADDRESS:

Phone #:
Applicable Permit Numbers

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name ______ Signature ______ Date ______

TRANSPORTER 3 / INTERMEDIATE HANDLER

7. DISCREPANCY INDICATION

2 WP 4.0 sent to Haw River 008T8P

[x] 8A. Designated Facility:	[ ] 8B. Alternate Facility:	[ ] 8C. Alternate Facility:	[ ] 8D. Alternate Facility:
STERICYCLE, INC 369 PARK EAST DRIVE WOONSOCKET, RI 02895 (401) 769 - 5800 Permit#: RI-053	STERICYCLE, INC 1168 PORTER AVENUE HAW RIVER, NC 27258 (336) 578 - 6900 Permit#: 01-02-I	STERICYCLE, INC 3472 PROGRESS DRIVE DUNKIRK, NY 14048 (716) 366 - 4444 Permit# 9-0664-00019/00012	

TREATMENT FACILITY: I certify that I have been authorized by the applicable state agency to accept untreated medical wastes and that I have received the above indicated wastes in accordance with the requirement outlined in that authorization.

Print/Type Name ______ Signature ______ Date 12-23-09

TREATMENT FACILITY
Generator Designated regulated medical waste treatment facility and/or alternate regulated waste treatment facility

000501

Stericycle
Protecting People. Reducing Risk.

IN CASE OF EMERGENCY CONTACT: CHEMTREC 1-800-234-0051

Route # 530 - 1

STANDARD MANIFEST 001-10-06-STD

MDW3008VVY

GENERATOR

1. Generator's Name, Address and Telephone Number

ATTN:

Four Women Health Services
150 Emory St
Attleboro, MA 02703- 2439

12/18/2009

CUSTOMER NUMBER

GENERATOR'S REGISTRATION #

2A. DESCRIPTION OF WASTE	2B. CONTAINER TYPE	2C. NO. OF CONTAINERS	2D. VOLUME
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	TB01 - 30 Gal Reusable (8.0 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	ST75 - 48 Gal Reusable (7.5 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	WW40 - Medium Corrugated (4.0 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	WW45 - Medium Corrugated (4.5 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	WW70 - Large Corrugated (7.0 cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	WP Path Corrugated Incinerate Only (cu ft)		Cu Ft.
REGULATED MEDICAL WASTE, n.o.s., 6.2, UN 3291, PG II	WC Chemo Corrugated Incinerate Only(cu ft)		Cu Ft.
			Cu Ft.
			Cu Ft.
	TOTALS ▶		Cu Ft.

3. Generator's Certification: "I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations."

X Printed/Typed Name _____ Signature _____ Date 12-18-09

PRIMARY TRANSPORTER

4. TRANSPORTER 1 ADDRESS

STERICYCLE, INC.
28161 N. Keith Drive
Lake Forest, IL 60045

☐ This is a Through Shipment

Phone #: (800) 633-9278

Applicable Permit Numbers:
CT-BMW-005 NY-DECIL-033
ME-BWT-033 RI-MW-TRAN-260
NJ-DEP-19713 TNH-0210

TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name _____ Signature _____ Date 12-18-09

INTERMEDIATE HANDLER

5. INTERMEDIATE HANDLER 2 / TRANSPORTER 2 ADDRESS:

Phone #:

Applicable Permit Numbers:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name _____ Signature _____ Date _____

INTERMEDIATE HANDLER

6. INTERMEDIATE HANDLER 3 / TRANSPORTER 3 ADDRESS:

Phone #: ( ) -

Applicable Permit Numbers:

INTERMEDIATE HANDLER / TRANSPORTER CERTIFICATION: Receipt of medical waste as described above.

Print/Type Name _____ Signature _____ Date _____

7. DISCREPANCY INDICATION

Box 4 S/B Blank.

DESIGNATED FACILITY (Generally Designated regulated medical waste treatment facility and/or Alternate regulated waste treatment facility)

☐ 8A. Designated Facility:

STERICYCLE, INC
359 PARK EAST DRIVE
WOONSOCKET, RI 02895
(401) 769 - 5800
Permit#: RI-053

☐ 8B. Alternate Facility:

STERICYCLE, INC
1166 PORTER AVENUE
HAW RIVER, NC 27258
(336) 578 - 6900
Permit#: 01-02-1

☐ 8C. Alternate Facility:

STERICYCLE, INC
3472 PROGRESS DRIVE
DUNKIRK, NY 14048
(716) 366 - 4444
Permit# 9-0664-00019/00012

☐ 8D. Alternate Facility:

TREATMENT FACILITY: I certify that I have been authorized by the applicable state agency to accept untreated medical wastes and that I have received the above indicated wastes in accordance with the requirement outlined in that authorization.

Print/Type Name _____ Signature _____ Date _____

000169

Waste Disposal and Hazard Communication

REGULATED WASTE CONTAINMENT

The bloodborne pathogens standard uses the term "regulated waste" to refer to the following categories of waste which require special handling at a minimum:

A. Liquid or semi-liquid blood or OPIM.

B. Items contaminated with blood or OPIM and which release these substances in a liquid or semi-liquid state if compressed.

C. Items that are caked with dried blood or OPIM and are capable of releasing these materials during handling.

D. Containment sharps.

E. Pathological and microbiological wastes containing blood or OPIM.

GENERAL REGULATED WASTE CONTAINMENT

A. Regulated waste shall be placed in containers which are constructed to prevent leakage, appropriately labeled or color-coded, and closed prior to removal.

B. If outside contamination of a regulated waste container occurs, it shall be placed in a second container which is constructed to prevent leakage, appropriately labeled or

color-coded, and closed.

C. Disposal of regulated waste shall be in accordance with all Federal, State and Local standards.

NEEDLES AND SHARPS DISPOSAL

Discarding and containment of contaminated sharps:

A. Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

1) Closable;
2) Puncture resistant;
3) Leakproof on the sides and bottom;
4) Appropriately labeled or color-coded.

B. During use containers for contaminated sharps shall be easily accessible to areas of use, upright, routinely replaced and not allowed to overfill.

C. When moving containers of contaminated sharps they shall be closed and if leakage is likely, placed in a secondary closable, leakproof, and appropriately labeled or color-coded container.

D. Reusable containers shall not be opened, emptied or cleaned manually.

E. Used needles will be considered "regulated waste" regardless of the presence of infectious agents. Needle sheaths are not considered a "waste container" and self-sheathing devices will be disposed of in a sharps container.

F. Sharps containers shall be sealed and replaced when the container becomes full.

G. When small volumes of regulated waste are generated, they may be placed in a large holding container until the container is filled. The design of the container will be such that it will retain the waste without leakage of fluids during storage, transport or shipping.

H. Full containers will be carefully closed, sealed and picked up for incineration or landfill disposition, according to current local waste disposal policy. Disposal containers will bear the appropriate biological hazard symbol.

SOILED DISPOSABLES AND DRESSINGS

Contaminated dressings and disposable supplies (excluding sharps and needles) will be placed in a closable, leakproof plastic bag. If outside contamination of the primary container is likely, then a second leakproof, closable container will be used. The outside of the container will be labeled with an approved "BIOHAZARD" label or red bags/containers will be used for all infectious waste. The area where contaminated waste is stored will be marked with a biohazard sign. After proper containment and labeling, this waste will be disposed of with office waste for sanitary landfill disposal or incineration, according to current local waste disposal policy.

FLUIDS/EXCRETIONS

Suctioned fluids, excretions and secretions, will be carefully dispensed into drains connected to the sanitary sewage system.

LABELING PROCEDURES/BIOHAZARD WARNING

A. Labels shall contain the word "BIOHAZARD" and the following Biohazard symbol:

B. Shall be fluorescent orange or orange-red with symbols and lettering in a contrasting color;

C. Shall either be an integral part of the container or affixed to it in such a fashion as to prevent their loss or unintentional removal;

D. Shall be affixed to:

1. Containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious materials;

2. All containers used to store, transport, or ship blood or other potentially infectious materials except:

a) Red tags & bags may be substituted for labels.

b) Containers of blood, blood products or components, which have been released for transfusion or clinical use.

c) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal.

E. All Federal, State and Local regulations shall be observed.

LINENS/LAUNDRY

A. Shall be handled as little as possible with a minimum of agitation;

B. Shall be bagged or containerized where used without being sorted or rinsed;

C. If wet and presents a reasonable likelihood of soaking through or leaking, shall be placed and transported in bags or containers which will prevent same;

D. Shall be placed and transported in appropriately labeled or color-coded bags or containers;

E. Employees who have contact with contaminated laundry shall wear protective gloves or other appropriate personal protective equipment;

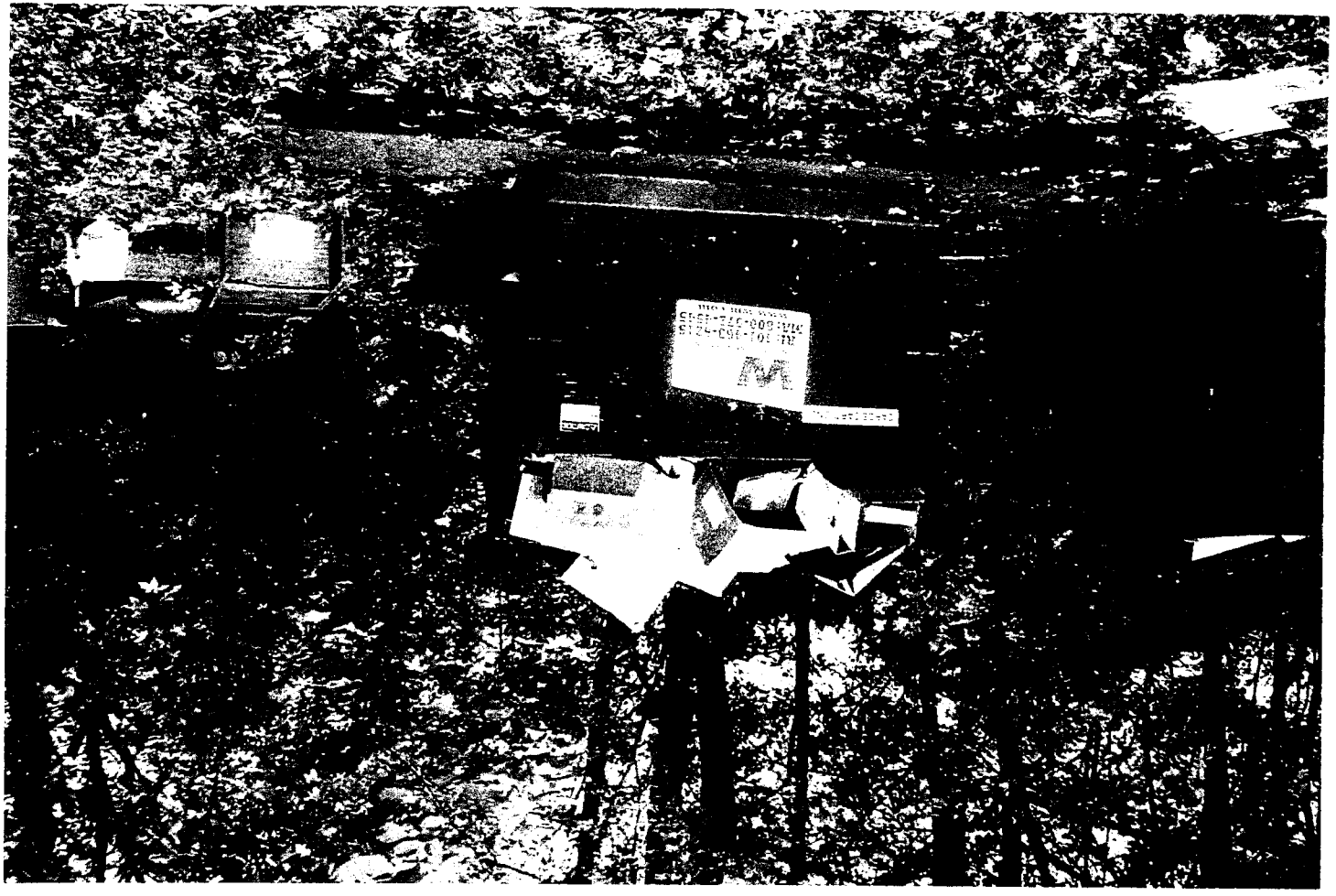
F. When shipping contaminated laundry to a facility that does not utilize universal precautions laundry containers shall be appropriately labeled or color-coded.

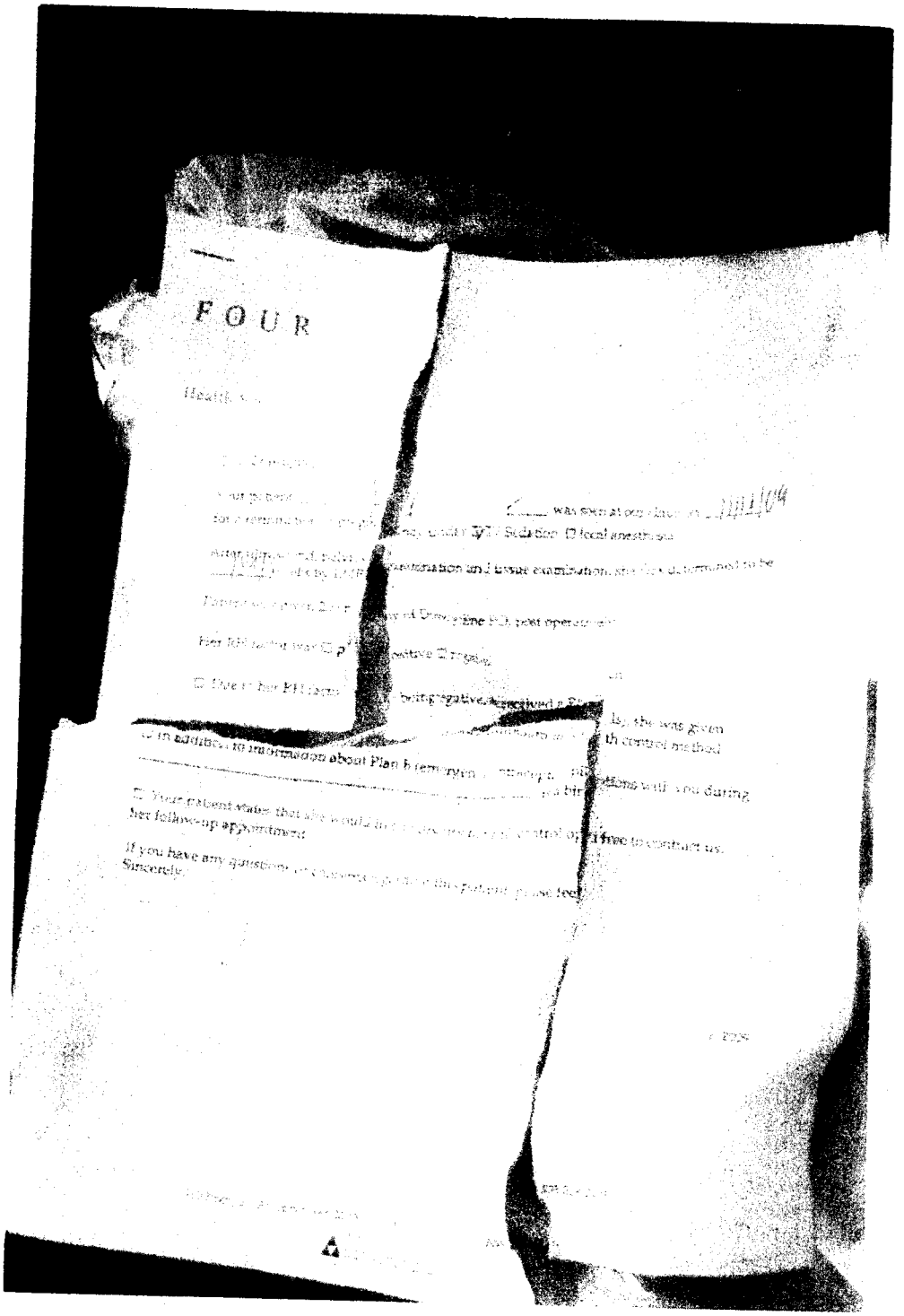
Four Women Health Services

Waste packaging, labeling, and shipping procedures

1. Regulated waste shall be separated in accordance with 105 CMR 480.100. Clear separation between red bags, sharps and pathological waste occurs prior to shipping.
2. Pathological waste is placed in formalin and packaged in containers which are marked prominently with the universal biohazard warning symbol and the word "Biohazard" in a contrasting color; and secured so as to prevent leakage and to preclude loss of contents during handling, storage and/or transport. These containers are placed in a freezer that is labeled with prominent signage indicating that the contents are regulated waste. Pathological waste remains stored in the freezer pending pickup. The freezer is located within a locked room that is labeled with biohazard identification.
3. Red bags and sharps are placed in containers which are marked prominently with the universal biohazard warning symbol and the word "Biohazard" in a contrasting color; and secured so as to prevent leakage and to preclude loss of contents during handling, storage and/or transport. When these containers are full, they are placed in a locked closet used exclusively for waste storage. This closet has prominent signage indicating the space is used for the storage of regulated waste.
4. Off-site disposal is performed by a contacted waste disposal company. They provide corrugated cardboard boxes in which to package regulated waste. Pathological waste is packaged separately from red bags and sharps. Pathological waste is placed in the provided boxes and labeled with yellow "Pathological waste" stickers. Red bags and sharps containers are placed in provided boxes and labeled with red Biohazard stickers only.
5. Regulated waste is picked up monthly by a contracted waste disposal company. The contracted company for Four Women is: **Stericycle**. A record-keeping log is maintained on forms provided by the Department of Public Health. The record-keeping log forms shall be retained for three years and shall include the following information: the exact date of each shipment, the total number of containers, the type of waste, the total combined weight or volume, the name of the transporter, the verification of shipping papers generated with receipt of corresponding medical waste tracking forms for each shipment, and the printed name and signature of the person responsible for shipping the waste.
6. All necessary staff will be trained in the packaging, labeling and shipping of regulated waste. This training will be documented in employee files, and in the Waste Record Keeping log.

, MD _____ Date: _____




FOUR