Date: 30 July 2012

To: Virginia Department of Health
   Office of Licensure and Certification
   9960 Mayland Drive, Suite 400
   Henrico, Virginia 23233
   Attn: Kathleen Cregan-Tedeschi, Supervisor

Fax Number: 1-804-527-4502

Subject: Amethyst Health Center for Women-
       Signed response to Licensure Inspection Report

Message: Enclosed is the signed 1st page of State form - Licensure Inspection Report - Statement of Deficiencies. Sorry for the omission. Regards

Pages, including cover page: 2
T 000 12 VAC 5-412 Initial comments

An announced Initial Licensee Abortion Facility inspection and two complaint investigations were conducted at the above referenced facility on May 31, 2012 through June 1, 2012 by two (2) Medical Facilities Inspectors from the Virginia Department of Health, Office of Licensure and Certification.

Ten personnel files and twenty eight clinical records were reviewed. Complaint Logs #2012-AC011 and #2012-AC015 were unsubstantiated due to a lack of sufficient information.

The facility was out of compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facility's effective December 29, 2011. Deficiencies were identified, cited, and will follow in this report.

T 175 12 VAC 5-412-220 C Infection prevention

C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:
1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers);
2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;
3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposure);
4. Procedures for handling, storing and transporting clean linen, clean/sterile supplies and equipment;
5. Procedures for handling/sterilizing

T 100: AHCW had not been notified of any complaints filed with VDH/OLC. The inspectors did mention them without providing any other details and indicated the complaints were anonymous, which was interpreted that the identity of the complainant was to be withdrawn from AHCW. AHCW, consequently, was unaware of the complaint reference identification #2012-AC011 and #2012-AC015, until the inspection report arrived. Subsequent to the arrival of the report, AHCW conducted a thorough review of the records to eliminate the possibility of a “missed complaint”. AHCW findings were the same as indicated in the inspection report, insufficient information to identify and substantiate the complaint.

Regarding the Facility Inspection Report, Prefix Tag T-175 through T-400, AHCW acknowledges the inspectors' findings are valid. AHCW has taken immediate action, both physically and procedurally, to rectify the findings. AHCW has conducted in-service training for all Policy and Procedures referenced within this submittal to prevent a recurrence of the deficiencies identified by the VDH/OLC inspectors. To insure the maintenance of compliance, the Administrator, or her designee, as part of her job description and responsibility to the Governing Body, is required to conduct positive verification of adherence to the AHCW Policy and Procedures. This is an integral part of the Administrator's daily duties, augmented by specific spot checks. The actions below are AHCW's response to the items identified as deficiencies describing the plan of corrective action; actions to prevent a recurrence of the deficiency; and the completion date for each item.

RECEIVED
JUL 30 2012
VDH/OLC

LABORATORY DIRECTORS OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Maria Elizabeth Plouzhenz

STATE FORM

FORM APPROVED

07/30/2012 11:09 FAX

FORM #695 2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

(x) PROVIDER/SUPPLIER IDENTIFICATION NUMBER:

FTAF 012

PART A 405

NAME OF PROVIDER OR SUPPLIER

AMETHYST HEALTH CENTER FOR WOMEN, INC

STREET ADDRESS, CITY, STATE, ZIP CODE

9300-B FORESTWOOD LANE

MANASAS, VA 20110

(x) PHONE NUMBER

(x) DATE SURVEY COMPLETED

06/01/2012

(x) ID PREPRT TAG

SUMMARY STATEMENT OF DEFICIENCIES

(EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LEG IDENTIFYING INFORMATION)

(x) ID PREPRT TAG

PROVIDER'S PLAN OF CORRECTION

(SPECIFY CORRECTIVE ACTION SHOULD BE CROSSED-REFERENCED TO THE APPROPRIATE DEFICIENCY)

(x) COMPLETE DATE

07/30/2012
Mr. Erik Bodin, Director
Acute Care Unit /Office of Licensure and Certification
Virginia Department of Health
9960 Mayland Drive, Suite 401
Henrico, VA 23233

Dear Mr. Bodin,

Amethyst Health Center for Women Inc., submits the following Plan of Correction in response to the inspection conducted on 31 May – 1 June, 2012 and your Licensure Inspection Report dated 20 June, 2012.

We have completed the Plan of Correction, as directed, on the Licensure Inspection Report form. Also included are attachments, where applicable, to provide proof of AHCW actions resolving the noted deficiencies.

Please contact me should you or your inspectors have any questions / concerns regarding this Plan of Correction.

Submitted:

[Signature]
Marie Elisabeth Beurskens
Owner and Administrator
Amethyst Health Center for Women, Inc.
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The facility was out of compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facility effective December 28, 2011. Deficiencies were identified, cited, and will follow in this report.

T-100: AHCW had not been notified of any complaints filed with VDH/OLC. The inspectors did mention them without providing any other details and indicated the complaints were anonymous, which was interpreted that the identity of the complainant was to be withheld from AHCW. AHCW, consequently, was unaware of the complaint reference identification #2012-AC011 and #2012-AC015, until the inspection report arrived. Subsequent to the arrival of the report, AHCW conducted a thorough review of the records to eliminate the possibility of a “missed complaint”. AHCW findings were the same as indicated in the inspection report, insufficient information to identify and substantiate the complaint.

Regarding the Facility Inspection Report, Prefix Tag T-175 through T-400, AHCW acknowledges the inspectors’ findings are valid. AHCW has taken immediate action, both physically and procedurally, to rectify the findings. AHCW has conducted in-service training for all Policy and Procedures referenced within this submittal to prevent a recurrence of the deficiencies identified by the VDH/OLC inspectors. To ensure the maintenance of compliance, the Administrator, or her designee, as part of her job description and responsibility to the Governing Body, is required to conduct positive verification of adherence to the AHCW Policy and Procedures. This is an integral part of the Administrator’s daily duties, augmented by specific spot checks. The actions below are AHCW’s response to the items identified as deficiencies describing the plan of corrective action; actions to prevent a recurrence of the deficiency; and the completion date for each item.
storage/transport of soiled linens;
6. Procedures for handling, storing, processing and transporting regulated medical wastes in accordance with applicable regulations;
7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:
(i) the level of cleaning/disinfection/sterilization to be used for each type of equipment,
(ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and
(iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;
8. Procedures for appropriate disposal of non-reusable equipment;
9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer's recommendations;
10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;
11. An effective pest control program, managed in accordance with local health and environmental regulations; and
12. Other infection prevention procedures necessary to prevent/contol transmission of an infectious agent in the facility as recommended or required by the department.

This RULE: is not met as evidenced by:
Based on observation, interview and record review the facility failed to implement processes to prevent the spread of infection as evidenced by:

1. The refrigerator used to store medications was located within the "Soiled" utility room. The staff stored two vials of collected blood inside the same refrigerator along with the medications.
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administered to patients. Clean supplies (disposable gowns, masks, containers of tissue preservative) and paper products were stored in the “Soiled” utility room.

2. One of one Staff working in the soiled utility room did not perform hand hygiene between glove changes.

3. Linens were laundered off-site at a staff’s home. The facility’s procedure did not ensure the linens were laundered at the proper wash temperature of 160 degrees Fahrenheit.

4. Not following manufacturer’s directions or standards by preparing 1:10 bleach to water solutions weekly and failed to label containers with contents.

5. Cleaning supplies and other chemicals were stored under each sink along with, medications, paper and “clean” supplies.

6. Six (6) of six pillows used in the recovery room and one of one pillow used in the procedure room was made of cloth and covered with a cloth pillowcase. The pillows could not be disinfected between patients.

7. Two (2) of two recovery room stretchers did not have intact surfaces and could not be disinfected between patient usage. Six of six recliners in the recovery room had not been disinfected between patient use.

The findings included:

1. An observation and interview conducted on May 31, 2012 at 10:16 a.m. with Staff #1, Staff #2 and Staff #3 revealed a full size refrigerator in the “Soiled” utility room. Staff #1 reported the facility

Re: T-175: A key deficiency within the inspection report were the items stored within the refrigerator located within the “soiled” utility room. AHCW has added a new refrigerator (completed 6/20/2012) and located it within the laboratory.
T 175 Continued From Page 3

was small and the only space available for the refrigerator was within the "Soiled" utility room.

The observation revealed injectable medications and control solutions for determining Rh (Rhesus) factors were stored in the refrigerator. The observation revealed a plastic cup with two tiger top tubes of blood on the top door shelf. Staff #3 reported the blood was used for testing the accuracy of the controls used in determining Rh factors. Staff #3 reported the blood had been collected from two staff one with a negative Rh factor and one with a positive Rh factor. Staff #3 reported the blood was "always kept in the refrigerator." Staff #2 verified the risk of blood exposure, contamination of medication and the spread of infection. Staff #2 acknowledged a refrigerator used in the storage of medication should not be within the "Soiled" utility room. The observation revealed the facility stored clean supplies and paper products in the cabinets within the "Soiled" utility room.

An observation on June 1, 2012 at approximately 10:38 a.m. while Staff #5 processed instruments, containers, and handled tissues from a procedure revealed Staff #1 entered the "Soiled" utility room. Staff #1 acknowledged that Staff #5 was in the process of cleaning and disposing of items from a procedure. Staff #1 had not put on personal protective equipment (PPE) prior to entering the "Soiled" utility room. Staff #1 stated, "I need to get a RhoGam shot from the refrigerator." Staff #1 then retrieved two injectable medications from the refrigerator and exited the "Soiled" utility room. [RhoGam is a immune globulin used to prevent Rhesus (Rh) hemolytic disease of the newborn (HDN). HDN is a serious, often fatal disease caused by incompatibility between an Rh-negative mother and her Rh-positive fetus.] Staff #1 re-entered the "Soiled" utility room to retrieve a roll of paper towel needed for a hand washing sink.

T 175

Now there are 3 refrigerators and a freezer:

- Laboratory Refrigerator — used for unopened single or multi use medications (not controlled) requiring refrigeration

- "Soiled" Utility Room Refrigerator — used for Bio-hazardous reference material for RH blood controls and testing controls for urine pregnancy tests. Also, patient samples of urine and blood drawn for Betas stored while waiting for pickup for outside laboratory analysis.

- "Soiled" Utility Room Freezer — used for products of conception before pickup for disposal.

- Recovery Room Refrigerator — used for patient nourishment items only.

Re: T-175-1 The refrigerator in the "soiled" utility room is no longer used to store any medications. Medications requiring refrigeration are now stored in the Laboratory Refrigerator. (AHCW 3.5.4). (Note: AHCW has conducted in-service training for all Policy and Procedures referenced within this submittal to prevent a recurrence of the deficiencies identified by the VDH/OLC inspectors.) The only items within the “soiled” utility refrigerator are the vials of Rh reference blood and urine dipstick controls to ensure that the urine pregnancy tests function properly; and patient samples of urine and blood Betas which are stored while waiting for laboratory pickup.

(completed 6/20/2012)

Clean Supplies and Paper products previously located in the "soiled" utility room have been relocated. (AHCW 2.4.3).

(Note: AHCW has conducted in-service training for all Policy and Procedures referenced within this submittal to prevent a recurrence of the deficiencies identified by the VDH/OLC inspectors.)

- Disposable gowns, masks are now stored in the clean sterilizing room. (completed 6/20/2012)

- Footwear and Gloves are stored in the Clean sterilizing room. (completed 6/20/2012)

- Paper Products are stored in the Sonogram room. (completed 6/20/2012)

- Containers for POC (with Formalin) are located within the procedure room. (completed 6/20/2012)
within the patient care area.

2. Observations were conducted on June 1, 2012 from 10:20 a.m. to 11:28 a.m. with Staff #5 in the "Soiled" utility room. At 10:30 a.m., Staff #5 removed a single pair of disposable gloves and without washing his/her hands, put on a new pair of disposable gloves and a second pair of disposable gloves over the first pair (double gloved). Staff #5 put on a set of long rubber gloves over his/her double gloved hands. During the processing (removing blood/tissue) from the instruments used in the first procedure, Staff #5 realized the large red bag had not been set up for disposal of the suction pump lines. Staff #5 removed his/her long rubber gloves, set up the red bag, and then removed one set of the disposable gloves from his/her hands. Staff #5 put on a new pair of disposable gloves over the gloves already on his/her hand. Staff #5 put back on the set of long rubber gloves and returned to processing soiled items. When Staff #5 changed task he/she did not remove both pairs of gloves or wash his/her hands after setting up the red bag for disposal of contaminated larger items. After processing the instruments, containers, and tissues from the procedure, Staff #5 did not remove the set of long rubber gloves, the two pair of disposable gloves or wash his/her hands while waiting for the next procedure to begin. Staff #5 from 10:52 a.m. to 11:05 a.m. while wearing the long rubber gloves made adjustments to her face shield and mask, set up an area where cleaned items were going to be placed and touched various surfaces in the "Soiled" utility room. At 11:06 a.m., Staff #5 started processing the instruments, containers, and tissues from the second procedure. Staff #5 completed the process of removing blood and tissue from the instruments, handling the conception material and preparing the cleaned canister for the next procedure/patient. Staff #5

Re: T-175-2 -
The hand hygiene procedure, AHCW 2.4.2.3, remains the same and has been standardized throughout the facility regarding the use of hand sanitation before and after gloving. (completed 6/20/2012)
(Note: long rubber gloves have been eliminated and disposable gloves are now utilized.)

- In order to prevent a recurrence, Hand Hygiene in-service training has been conducted regarding the amended procedure and will initially be conducted more frequently. (Monthly – for the next 6 months then quarterly) (completed 6/26/2012)

- A "Soiled" Room specific procedure (AHCW 2.4.2.6.a) has been established for all (including Staff #1) AHCW personnel regarding entry, work (including not adjusting face shield or mask while working, setting up biohazard bag, and departure. In-service training for this specific procedure will be conducted monthly for the next 6 months then quarterly to prevent a recurrence. (completed 6/26/2612)
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did not have a procedure to ensure the long rubber gloves were clean between procedures and when handling clean suction pump canisters. Staff #6 reported he/she keeps the long rubber gloves and the same double set of disposable gloves until all of the procedures were finished.

Review of the facility's policy for infection control and prevention titled "Guide to Infection Prevention in Outpatient Settings: Minimum Expectations for Safe Care" read "1. Key situations where hand hygiene should be performed ... 1. After glove removal." Under the subheading "Key recommendations for use of PPE in Ambulatory Care Settings ... 4. Wear gloves for potential contact with blood, body fluids, ... contaminated equipment. a. Do not wear the same pair of gloves for care of more than one patient.

3. An interview conducted on May 31, 2012 at 9:30 a.m. with Staff #1 and Staff #2 revealed Staff #1 processed the linens used for patients at home. The facility did not have procedures for processing, handling, storing or transporting clean linens. Staff #1 reported the linens were washed on the "hot" water cycle. Staff #1 was not able to report the temperature of the water utilized.

On June 1, 2012 at 8:44 a.m. an interview and review of the manufacturer's specifications for Staff #1's home washer was conducted with Staff #1 and Staff #2. The manufacturer's specifications indicated the washer had a temperature boost cycle with a water temperature of 150 degrees Fahrenheit. Staff #1 acknowledged he/she had not been washing the linens on the temperature boost cycle. Per the "Guidelines for Design and Construction of Health Care Facilities" the linens needed to be washed at 160 degrees Fahrenheit. Staff #1 and Staff #2

Re: T-175-3: AHCW has evaluated the home laundering of linens and now utilizes a contracted laundry service (completed 6/12/2012) with specific requirements for medical (160-180 degrees Fahrenheit water temperature) linen processing. This change is documented in (AHCW 2.4.3 page 2). (Note: AHCW has conducted in-service training for all Policy and Procedures referenced within this submittal to prevent a recurrence of the deficiencies identified by the VDH/OLC inspectors.)
acknowledged the items had not been washed/processed at the correct water temperature.

4. Observations conducted on May 31, 2012 from 9:00 a.m. through 11:01 a.m. revealed:
A gallon plastic container with an unidentified liquid next to the procedure table. The top of the container had an opened pour spout. The container did not have a label to identify its contents. The date on the spray bottle indicated it had been made on "05/22/2012."
A spray bottle labeled for a brand name cleaner was found under the sink in the procedure room. The label had a handwritten notation "Bleach & (and) Water". The spray bottle did not have documentation of the ratio of bleach to water. The date on the bottle indicated it had been made on "05/21/12."
A spray bottle with an unidentified liquid was found under the sink in the "Soiled" utility room. The spray bottle did not have a label to indicate the contents or a date to indicate when the solution was placed in the bottle.
A spray bottle under the sink in the area designated as the lab, contained an unidentifiable liquid. The bottle did not have a label or a date when the contents had been placed in the bottle.

An interview was conducted on May 31, 2012 at 9:11 a.m. with Staff #1 and Staff #2. Staff #2 identified the liquid in the gallon container next to the procedure table as a bleach and water solution. Staff #2 reported, "it's probably a 1 to 10 bleach solution used to clean the suction pump lines after a procedure. Staff #2 verified the container was not labeled and there was no indication of the contents. Staff #2 reported the 1:10 bleach/water solution was made "monthly". Staff #2 reported the solution had been made on the documented date of "5/22/2012" and

Re: T-175-4 -
AHCW P&Q 2.4.3.a page 3 (Note: AHCW has conducted in-service training for all Policy and Procedures referenced within this submittal to prevent a recurrence of the deficiencies identified by the VDH/OLC Inspectors.)
(completed 6/20/2012), now includes a procedure for making 1:10 bleach solution for disinfecting and specifying that this preparation must be done daily. (completed 6/20/2012)

- Following the inspection report being received, AHCW acquired new containers (spray bottles) utilized for disinfecting the facility. These bottles were cleaned, disinfected and then labeled using the procedure (AHCW 2.4.3.a) (Note: AHCW has conducted in-service training for all Policy and Procedures referenced within this submittal to prevent a recurrence of the deficiencies identified by the VDH/OLC Inspectors).
- Additionally, procedure (AHCW 2.4.3) (Note: AHCW has conducted in-service training for all Policy and Procedures referenced within this submittal to prevent a recurrence of the deficiencies identified by the VDH/OLC Inspectors) now states that 1:10 bleach solution is applied to CHLOROX disinfecting wipes, where required, for disinfecting patient areas and all other areas within the facility.
- These properly labeled cleaning supplies are stored within a locked cabinet within the staff bathroom and a locked closet within the "soiled" utility room. (completed 6/20/2012)
was good until "June 22, 2012". A request was
made for the manufacturer's directions and
evidence the solution was good for one month.
Staff #2 identified the contents of the spray bottles
found under the sink in the procedure room, soiled
utility room and lab as 1:10 bleach/water solutions.

The facility did not have a procedure for mixing
bleach and water to create a 1:10 ratio. The
facility did not have a procedure for labeling and
dating contents when placed in a container. The
facility did not have a policy/procedure that
restricted placing solutions in a container with the
name of a different product. Review of the
manufacturer's recommendations and directions
did not provide evidence the bleach/water 1:10
solution was effective for one month.

According to facilities for Disease Control and
Prevention (CDC) at
<http://www.cdc.gov/hicpid/dvrd/spb/mnpages/vhf
manual/sec5.pdf>: "Bleach solutions must be
prepared daily. They (bleach to water solution)
lose their strength after 24 hours. Anytime the
odour of chlorine is not present, discard the
solution. Note: 1:10 bleach solution is caustic.
Avoid direct contact with skin and eyes. Prepare
the bleach solutions in a well-ventilated area."

5. Observations conducted on May 31, 2012 from
9:20 a.m. to 11:00 a.m. revealed the following
items stored under the sink(s):
Procedure Room: There were three metal pans-
inside one of the pans were two discolored rings
used in the placement of vaginal contraceptives.
Other items included two spray bottles with liquid
contents other than the commercial brand label
and one-gallon container of glass cleaner. Clean
supplies stored with the chemical included three
emesis basins, a suction pump container and a
clear plastic trash bag with multiple suction
container top.

An interview with Staff #1 and Staff #2 revealed the facility had not utilized the type of inter-vaginal contraceptives, which required the rings for placement "in two years or more." Staff #2 stated "I did not know items could not be stored under the sink. This is the first I have ever heard of this." Staff #2 reported not being aware that clean items designated for patient used could not be stored with chemicals.

"Soiled" utility room: The chemicals included three one-gallon jugs of bleach, a gallon of lemon ammonia, a can of insecticide, containers of heptan, stain remover, stain and sticky substance remover, liquid dish detergent, a gallon of white vinegar, a quart of vinegar, a gallon of hand washing soap, a gallon of Maxoxide (disinfectant), a container of powdered disinfectant and a gallon of povidone-iodine (used during procedures).

Staff #1 reported the facility had limited storage space and did not have a locked cabinet or other locked area to store chemicals.

CleanSterilization room: The items included an unstarted spray bottle of 1:10 bleach/water solution, four unopened gallon-containers of distilled water and one opened gallon of distilled water (used for the steam autoclave), three individually packaged isolation gowns and a box with eighty-four (84) medication (high potency iron and vitamin C) sample cards with two pills on each card.

6. An observation on May 31, 2012 at 9:14 a.m. with Staff #1 and Staff #2 in the Procedure room revealed the pillow used to position patients during the procedure was made of cloth. The pillow did not have a surface that allowed for disinfection between patients. Staff #1 reported the cloth pillowcase was changed between patients but the same pillow was used for multiple patients.
An observation conducted on May 31, 2012 (at approximately 10:45 a.m.) in the Recovery room revealed each of the recovery recliners had a pillow, used to position the patients during recovery. The six (6) pillows used within the Recovery room were made of cloth, which could not be disinfected between patients. The cloth pillows did not have a covering material that would prevent contamination of the pillow or that could be cleaned between patients.

An interview was conducted with Staff #1 and Staff #2 during the observation. Staff #1 reported when the pillows became soiled they took them home and washed them. Staff #1 reported the pillows were not washed daily. Staff #1 acknowledged the pillows were made of cloth and could not be disinfected between patients.

7. Observations conducted May 31, 2012 during the initial tour revealed two of two recovery stretches did not have intact surfaces. The stretches were stored in a public hallway across from the Recovery room, which provided multiple exposures to contaminate. The stretches' vinyl-like material had tears at the corners, along the sides and on the top surface (mid section), which allowed contaminants to enter the foam padding. The tears prevented the disinfection of the stretches between patients. An interview with Staff #1 and Staff #2 was conducted during the observations. Staff #1 acknowledged the tears in the stretches surfaces. Staff #2 acknowledged the tears in the stretches' surfaces increased the risk for the spread of infection and cross-contamination between patients. Staff #2 acknowledged the stretches could not be disinfected between patients.

Re: T-175-7 - Following the inspection, two of two of the stretches were recovered with a new vinyl cover. The stretches are disinfected before and after each patient use. (completed 7/6/2012)
- The recliners were inspected for any wear which would prevent disfection. All were found to be serviceable and in accordance with the amended procedure are disinfected before and after each patient use.
- Inspecting for damage which would prevent disfection has been added to AHcw 2.4.3 (Note: AHcw has conducted in-service training for all Policy and Procedures referenced within this submittal to prevent a recurrence of the deficiencies identified by the VDH/OLC inspectors.) to prevent a recurrence of this deficiency. (completed 6/20/2012)
T 175 Continued from Page 10

of six Recovery recliners had not been disinfected between patient use. Six of six Recovery recliners had food crumbs and other substances on the coveted edge of the seat cushion. Six of six Recovery recliners had thick threads/masses of grayish black substance, at the base of the seat when placed in the reclined position. An interview conducted during the observation with Staff #1 revealed the recliners were to "wiped down and disinfected between each patient use." Staff #1 identified the thick threads/masses of grayish black substance as dust. Staff #1 acknowledged the findings and reported the facility staff had not disinfected the Recovery recliners. Staff #1 reported if the staff had disinfected the Recovery recliners the food particles, other substances and dust would not be present.

T 275

12 VAC 5-412-28 C Administration, storage and dispensing of drugs

C. Drugs maintained in the facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18 VAC 110-20-10

This RULE: is not met as evidenced by: Based on observation and staff interview, the clinic staff failed to ensure drugs and supplies available for administration were properly stored and not expired in one of one examination room, and one reception office, as required in 12 VAC 5-4 12-280.

Medications and procedure supplies were found to be expired and/or not dated when opened.

Re: T-275 - Following receipt of the inspection report, AHCW conducted a detailed investigation of all drug storage, administration and dispensing processes and procedures. We have refined our processes, to prevent a recurrence of the deficiencies, as follows: Drug storage locations are:

* Laboratory Refrigerator - The laboratory refrigerator was acquired post inspection specifically to relocate drugs previously stored in the "Soiled"utility refrigerator. These drugs are not controlled drugs and all require refrigeration. * Crash Cart – Located in the Procedure Room – This location is utilized only for drugs utilized for patient emergency * Controlled Drug Safe – Located in business office - This safe is used for all controlled drugs and is segregated to allow easy identification of single use and multi use medications as well as "open" multi use vials. Also located within this safe are oral medications. Under no circumstances will open single use drugs be placed within this storage location. * Open/Used/Expired Drug Safe - This location is utilized for open single use controlled medications and expired out of date medications which require controlled disposal.
The findings included:

During the tour of the clinic conducted 5/31/12 at 10:16 a.m., the following was observed: The medication refrigerator was located in the dirty utility room. The following drugs were found in the medication refrigerator in the dirty utility room: Rhocyn 50 units/bottle (used to prevent fetal death when the baby/mother has negative/positive blood during pregnancy). Methotrexate 250 milligrams/milliliter (used to treat cancer and arthritis). Lidocaine hydrochloride 2% and Epinephrine 1:100,000 one bottle (used for local anesthetic agent.)

The Administrator verified during interview while on tour of the facility, that no clean utility room was available to place the medication refrigerator in. This interview occurred in the agency’s dirty utility room, on 5/31/12, at approximately 11:16 a.m.

At this time in the dirty utility room, the medication refrigerator contained five Protocol 10% Neural Buffered Formain with an expiration date of October 2011. Reception office contained one bottle of 1% Propofol (Narcotic) 20 milliliters in the locked narcotic safe that was opened and not dated, at approximately 11:00. A second bottle of 1% Propofol (Narcotic) 2 milliliters in the locked narcotic safe that was opened and dated 5/19/12 and was approximately 3/4 full. Both bottles of Propofol were labeled for single patient use. Ketorolac Tromethamine (A nonsteroidal antiinflammatory drug used for the short term management of moderately severe acute pain) 60 milligrams per 2 milliliter (a single dose vial) was opened and not dated. In the dirty utility room a Start Tech-Cross Check Sterilization Monitoring Strip to be utilized in Steam Sterilizers expired on 01/31/2008.

On 5/31/12, at 2:30 p.m., the Administrator

Specifically, regarding comments from the inspection report, the two bottles of open Propofol were found with 1 bottle dated and the other undated. The Inspection report also stated that a bottle of Ketorolac Tromethamine was opened and not dated. The Nurse Anesthetist had been verbally counseled (Completed 6/16/2012) regarding her lack of adherence to the AHCW CRNA Consulting Agreement. This counseling focused on the VA Board of Pharmacy requirements to initial and date all medications upon opening and (AHCW 3.5.4 (Tab 17)). The Administrator will confirm initialing and dating upon return of the medication following use to preclude this deficiency recurring. This error has been identified and corrected with those responsible for the administration of medications within the facility as well as amendments to the P&L manual (AHCW 3.5.4 (Tab 17)).
T 275 Continued From Page 12

verified that two bottles of Propofol were opened at the same time, by the Nurse Anesthetist, when the bottles stated that were labeled for single use only.

T 320 12 VAC 5-412-300 B Quality assurance

B. The following shall be evaluated to assure adequacy and appropriateness of services, and to identify unacceptable or unexpected trends or occurrences:

1. Staffing patterns and performance;
2. Supervision appropriate to the level of service;
3. Patient records;
4. Patient satisfaction;
5. Complaint resolution;
6. Infections, complications and other adverse events; and
7. Staff concerns regarding patient care.

This RULE is not met as evidenced by:

Based on the Quality Assurance Meeting Minutes and an interview with the Administrator, it was determined that all the subjects were not addressed in Section 12 VAC 5-412-300.

The findings included:

1. The Quality Assurance Meeting Minutes were dated March 27, 2012. The Quality Assurance Meeting Minutes failed to address the following subjects: staffing patterns and performance; supervision appropriate to the level of service; patient records; patient satisfaction; complaint resolution; infections, complications and other adverse events; and staff concerns regarding patient care.

2. The Administrator verified during interview that

T 276 Re: T-275 Continued

Methergine within the procedure room crash cart was expired. In addition to the surgery day inspection of drugs, a special weekly inspection of the drugs within the crash cart will prevent a recurrence of this deficiency.

Protocol 10 Neural Buffered Formalin is no longer utilized within the facility. POC bottles come with Formalin already in the POC Bottles.

We have established a specific procedure to eliminate any difficulty identifying open and used medicine. This is described within the AHCW P&P Manual (AHCW 3.5.4 (Tab 17)) (Note: AHCW has conducted in-service training for all Policy and Procedures referenced within this submittal to prevent a recurrence of the deficiencies identified by the VDH/OLC inspectors.).
these regulations as identified by the department through submission of Reports of Induced Termination of Pregnancy pursuant to 12 VAC 5-850-120 or other means and that are now subject to licensure may be licensed in their current buildings if such entities submit a plan with the application for licensure that will bring them into full compliance with this provision within two years from the date of licensure.

Refer to Abortion Regulation Facility Requirements Survey workbook for detailed facility requirements.

This RULE is not as evidenced by:
Based on observations, interview, and record review the facility failed to be in full compliance with state and local codes, building ordinances as well as the Uniform Statewide Building Code. The facility also failed to be in compliance with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, as evidenced by: The facility utilized inadequate sedation during procedures and failed to meet the space requirements for their procedure room.
The facility did not have a designated Clean storage area. The facility stored clean supplies and a refrigerator with medications for patient administration with theSoiled utility room.
The facility stored sterile supplies on an open cart in the room where procedures were conducted. The facility did not have a designated area, which was ventilated with humidity and temperature controlled to store sterile supplies.
The facility stored clean linens on an open cart in the the room where procedures were conducted. The facility used the space under their sinks to store housekeeping supplies, oral medications, topical medications, clean supplies and other direct patient care items together. The facility did

Re: T-400 - AHCW, as required in its licensure submittal, provided VDH/OLC with a detailed compliance plan which specifically addressed the following elements:
• Procedure Room space requirements
• Public corridor’s width
• Facility Doors and Windows (Note: the facility doors contain tempered glass evidenced by the manufacturer’s markings)
• Facility Ceilings and Walls
• Establishment of a “clean utility room”

The initial licensure submittal included the process to bring the facility into compliance within 2 years from date of initial licensure.

AHCW has provided, within this submittal, corrections regarding:
• Provision of clean storage
• Sterile supplies storage
• Clean linen storage
• Under sink storage
• Housekeeping supplies storage
• Patient Medication Preparation Area

Now the sterile trays are no longer stored on an open cart, but instead stored within covered storage.

During the on-site inspection, discussion took place regarding AHCW requesting a facility waiver from VDH/OLC. Subsequently, discussions with Kathleen Creegan-Tedeschi, Supervisor, Acute Care Licensing, OLC, indicated that the waiver request was unnecessary, since the AHCW plan of correction was already included within the AHCW Licensure submittal.
T 320 Continued From Page 13

documentation of the discussions of the Meeting Minutes was not available for the Surveyors to review. This interview occurred in the agency, office on 8/12/12, at 10:08 a.m.

T 375 12 VAC 5-412-360A Maintenance

A. The facility’s structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be all be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.

This RULE: is not met as evidenced by:
Based on observations and interview with the Administrator, it was determined that the facility failed to have a clean utility room in which patient medications could be prepared as required in Section 12 VAC-5-412-360A.

Cross-refer 12 VAC-5-412-280.

T 400 12 VAC 5-412-360 Local and state codes and standards

Abortion facilities shall comply with state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code. In addition, abortion facilities shall comply with Part 1 and sections 3.1-1 through 3.1-8 and section 3.7 of Part 3 of the 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute, which shall take precedence over Uniform Statewide Building Code pursuant to Virginia Code 32.1-127.001.

Entities operating as of the effective date of...
not have a separate or secure storage of housekeeping supplies.
The facility's public corridors did not meet the required five feet width.
The facility's doors and windows were not constructed of safety or wired glass. The glass was not glazed to resist breakage or to prevent dangerous cutting edges when broken.
The facility's ceilings are not smooth, washable or resistant to chemical cleaning.

The findings included:

Observations and interviews were conducted on May 31, 2012 from 9:44 a.m. to 11:28 a.m., with Staff #1 and Staff #2 during the entrance conference and initial tour. Staff #1 reported the facility had obtained an architectural inspection and was aware that the facility's procedure room did not meet the space requirements for procedures performed under moderate sedation. During the initial tour, Staff #1 and Staff #2 reported the facility did not have adequate storage space. Staff #2 acknowledged the increased risk for cross-contamination by storing the medication refrigerator and clean supplies in the soiled utility room. The initial tour revealed the facility did not have a ventilated, humidity and temperature controlled area to store sterile supplies. The facility did not have a clean linen storage area that protected the linen from contamination.
Observations revealed the facility's ceilings are not smooth, washable or resistant to chemical cleaning.

Observations and interviews conducted on June 1, 2012 from 8:44 a.m. to 11:08 a.m., with Staff #1 and Staff #2 revealed the public corridors were not five feet in width. Observations on June 1, 2012 at 8:44 a.m. revealed the window and door glass did not have evidence of wire to decrease the creation
of dangerous cutting edges if broken. Staff #1 called the building management company in regards to the door and window glass construction. Staff #1 reported the glass was not safety glass and did not have a protective plastic glazing to resist breakage and prevent sharp cutting edges if the glass was broken.

Review of the architect summary of findings was conducted on May 31, 2014 at 2:44 p.m. with Staff #1 and Staff #2. The architect summary documented the following upgrades necessary to meet the requirements: Increase the square footage of the room where the procedures were conducted under moderate sedation to the required 150 square feet. Perform an upgrade to the finish surfaces of the walls and ceilings in order to meet requirements. The need to create a separate clean storage room and improve the heating and cooling system to provide humidity and temperature control in order to meet requirements.
June 20, 2012

Certified Mail Delivery

Maria Elisabeth Beurkens, Administrator
Amethyst Health Center for Women, Inc.
9380-B Forestwood Lane
Manassas, Virginia 20110

RE: Amethyst Health Center for Women, Inc. – Manassas, Virginia
Abortion Facility Initial Licensure Survey

Dear Ms. Beurkens:

An announced Initial Abortion Facility Licensure survey of the above agency was conducted May 31 – June 1, 2012 by a Medical Facilities Inspector team from the Virginia Department of Health's Office of Licensure and Certification (OLC).

Enclosed is the Licensure Inspection Report. This document contains a listing of deficiencies found at the time of this inspection.

You are required to file a plan for correcting these deficiencies. Your statements shall reflect the specific detailed actions you will take to correct deficiencies, prevent a recurrence of the deficiencies, and measures implemented to maintain compliance. You must also give the expected completion date of each deficiency.

Completion of corrective actions shall not exceed 30 working days from the last day of the inspection (due July 16, 2012) except for those corrective actions for deficiencies cited under 12VAC5-412-380 of the Regulations for the Licensure of Abortion Facilities, for which corrective action must be completed within two years of the issuance of the license.
After signing and dating your Plan of Correction, retain one copy of the report for your files and return the original to Erik Bodin, Director, Office of Licensure and Certification, 9960 Mayland Drive, Suite 401, Henrico, Virginia 23233 within 15 working days of receipt of this inspection report. Please provide written documentation of the corrective actions taken by your agency for each of the deficiencies cited on the enclosed License Inspection Report.

A copy of the completed form “License Inspection Report” will be kept on file in this office and will be available for public review. OLC is required to make copies of this report available to other Federal and State regulatory or reimbursement agencies upon request.

Should you have any questions, please feel free to call Kathleen Creegan-Tedeschi, Supervisor, Acute Care Licensing, Office of Licensure and Certification, at (804) 367-2156.

Sincerely,

[Signature]

Karen Remley, M.D., M.B.A., F.A.A.P.
State Health Commissioner

c: Erik Bodin, Director
Office of Licensure and Certification

Enclosure
Recreated, Expanded Recollection of 3/27/2012 Quality Assurance Committee Meeting – Written 6/16/12

The following members of the Quality Assurance Committee were in attendance:

- Administrator, Owner (Member of administrative staff)
- [Redacted], Medical Director (Physician)
- [Redacted], counselor (Patient advocate)
- [Redacted], LPN (non-physician health care practitioner)
- [Redacted], CNA
- [Redacted], consultant

[Redacted] began the meeting with a reorientation to the policy and procedure manual. There was a discussion of the intent of the Quality Assurance Committee at AHCW and how the self-assessment program supports the quality and appropriateness of care or services provided to our patients. The findings from the discussions will be used to correct identified problems and revise policies and practices at AHCW as necessary.

Topics discussed followed the AHCW Policy and Procedure manual (AHCW 2.6.6 and 12 VAC 5 – 412-300) regarding the conduct of the meeting.

1. The following topics were evaluated to assure adequacy and appropriateness of services, and to identify unacceptable trends or occurrences. Specifically:
   A. Staffing patterns and Performance.

   The staffing, by position was reviewed and the committee agreed that the positions identified within the AHCW Policy & Procedure Manual (P&P) were appropriate. While there has been some turnover within the staff the new employees are performing acceptably. Overall, there was agreement that the staff was performing at levels that maintain patient and employee safety. With the retirement of Dr. [Redacted], it was noted that finding experienced doctors is extremely difficult and [Redacted] asked Dr. [Redacted] to step up his search for capable doctors in the event they are needed. In summary, it is determined by this committee that AHCW is adequately staffed for performance of its duties of health care.

   B. Supervision appropriate to the level of service.

   [Redacted] indicated that the small staff size and collegial environment created a continuous improvement circumstance where individual responsibility was strong. Supervision is moderate, with strong leadership by the Physicians and the non-physician health care practitioners. In summary, at the present time, it is determined by this committee that that supervision is adequate and appropriate to the level of service.
C. Patient Records

The process for administration of patient records was reviewed and the discussion focused upon determining how patient records have produced so few difficulties at AHCW. The committee determined that the nature of the practice produced very few, if any, return visits with the exception of post-ab follow-ups. Patient Records remain confidential in the business office for 2 years, off site for the next 4 years and then destroyed according to the laws of Virginia, with the exception of minors whose charts are kept longer until they reach the age of 18 – plus the 6 years. The committee was polled to identify any problems with patient records and none were identified by any of the committee members. The committee determined that the patient Record handling was appropriate and in compliance with all regulations.

D. Patient Satisfaction.

The committee has determined that there is no empirical method, at present, to determine patient satisfaction at AHCW. The committee judged that a lack of complaints is an unreliable indicator of patient satisfaction. The most likely source of patient satisfaction is the anecdotal utterances of patients throughout their time at AHCW. Specifically, with the small number of patients, significant patient interaction occurs and a number of examples of patients expressing appreciation for the cleanliness of the clinic, attention by and the staff, and surprisingly little mention of the physicians. The most common displeasure is with the amount of time the whole process takes to complete. The committee will continue to evaluate methods, to gain feedback sooner and more directly from patients at AHCW.

E. Complaint Resolution.

The topic of complaint resolution is very difficult at AHCW primarily because it is so rare. The committee was challenged to identify any time when a complaint, formal or informal, was presented. A discussion ensued regarding the anecdotal reports from other clinics regarding anti-choice individuals filing false claims or complaints. It was determined that the first obligation of AHCW when presented with a complaint is to protect patient confidentiality and then determine if, in fact, the complainant was indeed a patient. Once confirmed, the administrator would take direct control of the complainant and would work to resolve the complaint. The requirements under 12 VAC 5-412-210 b were reviewed with the committee. AHCW 3.3.2 was also reviewed regarding the patient complaint procedure. In summary, the committee found the AHCW complaint resolution appropriate and ready for the time when a complaint arrives.

F. Procedure for surveillance, documentation and tracking of reported infections.

The committee reviewed the identification criteria for infection: a temperature greater than 100.4 degrees Fahrenheit. It was agreed that this is a reasonable criteria and when reached is
entered in the Facility infection report. Additionally, this data, with PII removed is submitted into the NAF "Infection Monthly Reporting System". Thus far, AHCW has had no infections to report.

G. Staff concerns regarding patient care.

The staff was polled regarding any concerns about patient care and nothing was identified. [redacted] stated that in addition, she had polled the employees independently and no issues were identified to her. The committee discussed if there were any such concerns regarding patient care and none were voiced.

2. No concerns have been identified and no measures need to be implemented at this time by the Quality Assurance Committee.

3. Results of the Quality Improvement Program will be reported to the licensee at least annually and shall include deficiencies identified and recommendations and improvements. Identified deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee by the Quality Improvement Committee.

After the above, a general question and answer period and discussion regarding the policy and procedure manual took place. [redacted] explained the structure and provided details of 12 VAC -5 -412 and the upcoming licensure and inspection process. A recommendation was given to the staff to familiarize themselves with the manual.

Respectfully submitted to the Record Book 6/18/12

[Signature]

Consultant to AHCW
Policy Description: Personal Protective Equipment (Infection)

<table>
<thead>
<tr>
<th>Manual Section: ADMIN</th>
<th>P&amp;P Manual Reference Number: 2.4.2.6</th>
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**Policy Statement:**

To both protect personnel from infection, and to prevent personnel from spreading infections among patients. Personal Protective Equipment (PPE) will be worn to protect staff from exposure to or contact with infectious agents.

**Procedure:**

All staff will receive training on proper selection and use of PPE.

At the start of each day, clinical staff will assure that sufficient and appropriate PPE is available and readily accessible.

Remove and discard PPE before leaving the patient’s area.

Wear gloves for potential contact with blood, body fluids, mucous membranes, non-intact skin or contaminated equipment.

- Do not wear the same pair of disposable gloves for the care of more than one patient
- Do not wash disposable gloves for the purpose of reuse
- Perform hand hygiene immediately after removing gloves

Wear a gown to protect skin and clothing during procedures or activities where contact with blood or body fluids is anticipated.

Wear mouth, nose and eye protection during procedures that are likely to generate splashes or sprays of blood or other body fluids.

For the “Soiled” Utility Room a special procedure (AHCW 2.4.2.6.a) has been established to proscribe, for all AHCW employees, entry, use of reusable long gloves, and use of Personnel Protective Equipment (PPE) and exit procedures for this bio-hazard area.

**Reference:** 12VAC5-412-220-B


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**Revised: 07/05/2012**

**Date & Initial:** NHC

**Reviewed: 07/05/2012**

**Date & Initial:** MEB

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5 July 2012  AHCW 2.4.2.6 Personal Protective Equipment (Infection) 120705
Policy Description: “Soiled” Room Entry and Exit Procedure

Policy Statement: Protection of all AHCW personnel while working in a bio-hazardous environment is vital for personnel safety. AHCW has established this procedure as part of a reevaluation of facility infection prevention procedures.

Procedure:

Prior to entry into “Soiled” Utility Room:

1. Remove street clothes and put on scrub suit.
2. Put on shoe covers; put on head cover
3. Put on mask, if needed
4. Put on protective eye shield mask
5. Use hand sanitizer
6. Put on 1st pair of gloves (disposable)
7. Put on 2nd pair of gloves (disposable)
8. Put on outer protective gown
9. Put on the disposable apron
10. Put on the disposable 18” sleeves

Conduct the necessary work within the “soiled” room.

Remember: Once gloved hands have started working, do not touch the mask, head cover or eyewear.
To exit the "Soiled" Utility Room:

1. Remove the disposable apron and discard in biohazard trash
2. Remove the disposable 18" sleeves and discard in biohazard trash
3. Remove the inner pair of gloves (disposable) discard in biohazard trash
4. Remove the outer pair of gloves (disposable) discard in biohazard trash
5. Use hand sanitizer
6. Remove the outer PPE (protective gown) and hang it on a hook for reuse. Make sure it is hung inside out
7. Remove the eyewear, head cover and mask
8. Remove the shoe cover
9. Use hand sanitizer
10. Exit the "soiled" utility room

Reference: 12VAC5-412-220-B
Policy Description: Management of Facility, Equipment and Supplies for Infection Prevention

<table>
<thead>
<tr>
<th>Manual Section: ADMIN</th>
<th>P&amp;P Manual Reference Number: 2.4.3</th>
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<tr>
<th>Policy Statement:</th>
<th>AHCW provides necessary equipment and supplies for patients and employees to practice recognized standards of infection prevention</th>
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<tr>
<th>Procedure:</th>
<th>C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:</th>
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<tbody>
<tr>
<td></td>
<td>1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers);</td>
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<td>2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, storage and transport of equipment and supplies;</td>
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<td>3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);</td>
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<tr>
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<td>4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;</td>
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<td></td>
<td>5. Procedures for handling/temporary storage/transport of soiled linens;</td>
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<td>6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;</td>
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<td>7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:</td>
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<td>(i) the level of cleaning/disinfection/sterilization to be used for each type of equipment;</td>
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<td>(ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and (iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved.</td>
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<td>The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;</td>
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<td>8. Procedures for appropriate disposal of non-reusable equipment;</td>
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<td>9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;</td>
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<td>10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;</td>
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<td></td>
<td>11. An effective pest control program, managed in accordance with local health and environmental regulations; and</td>
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<td>12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department.</td>
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<th>Revised: Date &amp; Initial:</th>
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<tr>
<td>Reviewed: Date &amp; Initial</td>
<td>7/5/2012 MEB</td>
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At AHCW:

1. Liquid Soap, Alcohol-based hand rubs, and disposable towels shall be available for use throughout the clinic. However, Alcohol-based hand rubs are the preferred method of hand sanitization at AHCW. Staff shall check availability daily and replenish supplies as needed.

2. Environmental surfaces throughout the clinic shall be cleaned with bleach 1:10 solution. Note: AHCW 2.4.3.a provides preparation instructions for this solution.

3. The procedure rooms, lab, recovery room, and sterilization room, and the “soiled” utility room are “wiped down” daily with bleach 1:10 solution and Lysol® for the floor. During this “wipe down”, surfaces of procedure tables, recovery room lounge chairs, stretchers and other facility fixtures are to be inspected for any damage or wear which precludes proper disinfection. If any defects are found, the administrator should be notified immediately.

4. The clinic shall always maintain an ample supply of bleach solution, Lysol®, Mr. Clean® for cleaning and disinfecting. A locked cabinet shall be available for all cleaning agents. Product-specific instructions shall be available to instruct employees on the appropriate use of cleaning agents.

5. Sinks for use are located throughout the clinic with supplies of soap and water and hand sanitizer.

6. Clean/Sterile supplies and equipment shall be handled, stored and transferred according to manufacturer's instructions. All clean linens shall be handled with clean hands, stored in a closet that is separate from soiled linens and transferred with clean hands.

7. No laundry is to be washed on site. AHCW utilizes a contracted linen service for medical grade laundering of linens (sheets and protective gowns) for use in the facility. Soiled linens shall only be handled with gloves. Soiled linens shall be stored in a leak proof, labeled container marked with a biohazard sticker.

8. Storage areas will be available if needed to store equipment and supplies on the premises.

9. Processing reusable medical equipment is covered under section AHCW 2.4.3.7.b of this manual

10. Regulated medical waste shall be handled with gloves, and stored in a leak-proof container labeled “biohazard”. Biohazard boxes are always located on the premises. This medical waste shall be processed and transported by a licensed
medical waste disposal company.

11. A dumpster shall always be located on the premises for immediate disposal of trash and garbage.

12. Non-reusable equipment that is saturated in blood shall be disposed of in a biohazard container. Non-reusable equipment that is not saturated in blood shall be disposed of in a regular trash container.

13. Equipment shall be tested and calibrated no less than yearly by an outside contractor or on a schedule according to the manufacturer’s recommendations. All equipment shall be repaired according to the manufacturer’s recommendations and shall be calibrated before put back into use for patient care.

14. A Pest Control company shall spray for pests quarterly and any issues that arise in the interim are dealt with in a timely manner.

Reference: 12VAC5-412-220 C
# Policy Description: Bleach Solution(s) Preparation Procedure

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<th>Manual Section:</th>
<th>ADMIN</th>
<th>P&amp;P Manual Reference Number: 2.4.3.a</th>
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## Policy Statement:

AHCW utilizes the following procedure for preparation of Bleach Solution(s) for disinfecting surfaces at the facility. These solutions are prepared daily. The solution(s) are located in locked cabinets or locked areas, to prevent patients gaining direct access to the solution(s).

## Procedure:

C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:

3. Appropriate storage for cleaning agents (e.g., locked cabinets or closets for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);

10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;

At AHCW:

1. Environmental surfaces throughout the clinic shall be cleaned with 1:10 bleach solution regularly.

2. The procedure rooms, lab, recovery room, sterilization room and “Soiled” Utility Room are “wiped down” daily with 1:10 bleach solution and Lysol® for the floor.

3. A locked cabinet is available for all cleaning agents and product-specific instructions shall be available to instruct employees on the appropriate use of cleaning agents.

4. The clinic shall always maintain an ample supply of bleach, bleach solution, Lysol®, for cleaning and disinfecting. Sinks are located throughout the clinic. Any Undersink storage is prohibited.

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At AHCW the bleach solution is prepared daily for disinfection throughout the facility. A 1:10 bleach solution (0.5% chlorine concentration) is a strong solution used to disinfect environmental surfaces. (see AHCW 2.4.2.6.a)

NOTE: The bleach solution must be prepared daily. These solutions lose their strength after 24 Hours. Should the odor of chlorine not be present, discard immediately and prepare fresh solution.

To prepare to make the bleach solution

1. Gather the necessary supplies:
   - 1 container that holds 10 measures (for example, 10 litres) to make the base 1:10 bleach solution labeled “1:10 bleach solution”
   - Chlorine bleach (for example, 1 litre of Clorox©)
   - Clean water
   - A measuring cup or other container (for example, a bottle that holds 1 litre).

2. To prepare the containers for mixing the bleach solutions, determine where to mark the measurements for “9 parts” and “1 part” on each container.
   - Pour 1 measure of water into the container. Mark a line with a permanent marker at the level where “1 part” has filled the container.
   - Add 9 measures of water to the first 1 part. Mark a line at the point where the total volume has filled the container.

To Make the Bleach Solution

3. To prepare 1:10 bleach solution:
   - Fill the marked container with ordinary household bleach up to the
mark for 1 parts.

- Then pour water into the container up to the top mark.
- Verify that container is labeled “1:10 bleach solution”

4.

Disposal of bleach solutions is by carefully pouring them down the drain.

Reference: 12VAC5-412-220 C

Policy Description: Ultrasound Use

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<tr>
<th>Manual Section: Patient Care</th>
<th>P&amp;P Manual Reference Number: 3.4.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Page: 1 of 3</td>
<td>Effective Date:</td>
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</table>

**Policy Statement:** Proper use of ultrasound can inform clinical decision-making and enhance the safety and efficacy of abortion care. As of 1 July 2012, Virginia Law (§ 18.2-76 of the Code of Virginia) mandates that ultrasound must be performed 24 hours before the abortion procedure. See page 3 for legislative language.

**Procedure:**
- The Medical Director and Consulting Physicians perform ultrasound exams and interpret those exams.
- Patients are informed of the purpose and limitations of the ultrasound exam in the abortion care setting, and offered a chance to view the images. The patients are, by law, offered the opportunity to; view the ultrasound picture, and/or see the heartbeat and/or hear the heartbeat.
- The findings of all ultrasound exams and the interpretation of those findings are documented in the medical record. Photos are included as part of the documentation, and will include the name(s) of the staff members who performed and interpreted the exam.
- In the first trimester, the ultrasound exam will include the following:
  a. a full scan of the uterus in both the transverse and longitudinal planes;
  b. measurements to document gestational age;

**Revised:**
- Date & Initial: 7/5/2012 NHC

**Reviewed:**
- Date & Initial: 7/5/2012 MEB
c. views to document the location of the pregnancy;
d. evaluation of fetal number; and
e. evaluation of the presence or absence of fetal cardiac activity.

- Technology permitting both abdominal and transvaginal scanning is available.
- A procedure is in place for further evaluation or referral of a patient in whom an intrauterine pregnancy has not been definitively identified or for whom an initial finding on the ultrasound may affect abortion management or future patient care.
- Real-time ultrasound scanners are used. Ultrasound equipment must be properly calibrated and maintained.
- Ultrasound transducers must be disinfected between patients according to applicable infection control standards. Adequate precautions are taken to protect both staff members and patients from the potential toxicity of chemical agents.

On surgery days, the ultrasound room will be used as the medication preparation room. This area serves as the location to dispense drugs to patients in a quiet, uninterrupted area of the clinic. The counter within the room has a surface which is suitable for disinfection.

Reference: § 18.2-76 of the Code of Virginia
Be it enacted by the General Assembly of Virginia:

1. That § 18.2-76 of the Code of Virginia is amended and reenacted as follows:

§ 18.2-76. Informed written consent required; civil penalty.

A. Before performing any abortion or inducing any miscarriage or terminating a pregnancy as provided in §§ 18.2-72, 18.2-73, or §18.2-74, the physician shall obtain the informed written consent of the pregnant woman. However, if the woman has been adjudicated incapacitated by any court of competent jurisdiction or if the physician knows or has good reason to believe that such woman is incapacitated as adjudicated by a court of competent jurisdiction, then only after permission is given in writing by a parent, guardian, committee, or other person standing in loco parentis to the woman, may the physician perform the abortion or otherwise terminate the pregnancy.

B. At least 24 hours before the performance of an abortion, a qualified medical professional trained in sonography and working under the supervision of a physician licensed in the Commonwealth shall perform fetal transabdominal ultrasound imaging on the patient undergoing the abortion for the purpose of determining gestational age. If the pregnant woman lives at least 100 miles from the facility where the abortion is to be performed, the fetal ultrasound imaging shall be performed at least two hours before the abortion. The ultrasound image shall contain the dimensions of the fetus and accurately portray the presence of external members and internal organs of the fetus, if present or viewable. Determination of gestational age shall be based upon measurement of the fetus in a manner consistent with standard medical practice in the community for determining gestational age. When only the gestational sac is visible during ultrasound imaging, gestational age may be based upon measurement of the gestational sac. If gestational age cannot be determined by a transabdominal ultrasound, then the patient undergoing the abortion shall be verbally offered other ultrasound imaging to determine gestational age, which she may refuse. A print of the ultrasound image shall be made to document the measurements that have been taken to determine the gestational age of the fetus.

The provisions of this subsection shall not apply if the woman seeking an abortion is the victim of rape or incest, if the incident was reported to law-enforcement authorities. Nothing herein shall preclude the physician from using any ultrasound imaging that he considers to be medically appropriate pursuant to the standard medical practice in the community.

C. The qualified medical professional performing fetal ultrasound imaging pursuant to subsection B shall verbally offer the woman an opportunity to view the ultrasound image, receive a printed copy of the ultrasound image and hear the fetal heart tones pursuant to standard medical practice in the community, and shall obtain from the woman written certification that this opportunity was offered and whether or not it was accepted and, if applicable, verification that the pregnant woman lives at least 100 miles from the facility where the abortion is to be performed. A printed copy of the ultrasound image shall be maintained in the woman's medical record at the facility where the abortion is to be performed for the longer of (i) seven years or (ii) the extent required by applicable federal or state law.
Policy Description: Dispensing Controlled Substances

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<td>Page: 1 of 5</td>
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**Policy Statement:**
AHCW controls, accounts for, stores and dispenses controlled substances in accordance with Commonwealth and Federal laws.

**Procedure:**

A. Controlled substances, as defined in § 54.1-3401 of the Drug Control Act of the Code of Virginia, shall be stored, administered and dispensed in accordance with federal and state laws. The dispensing of drugs, excluding manufacturers' samples, shall be in accordance with Chapter 33 of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (18VAC110-20), and Regulations for Practitioners of the Healing Arts to Sell Controlled Substances (18VAC110-30).

AHCW is compliant with all Commonwealth of Virginia and Federal laws pertaining to controlled substances.

Approved Drug storage locations at AHCW are:

- Laboratory Refrigerator
  - The laboratory refrigerator was acquired post inspection specifically to relocate drugs previously stored in the "Soiled" utility refrigerator. These drugs are not controlled drugs and all require refrigeration.

- Crash Cart – Located in the Procedure Room
  - This location is utilized only for drugs utilized for patient emergency

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- Controlled Drug Safe – Located in business office
  - This safe is used for all controlled drugs and is segregated to allow easy identification of single use and multi use medications as well as “open” multi use vials. Also located within this safe are oral medications. Under no circumstances will open single use drugs be placed within this storage location.
- Open/Used/Expired Drug Safe
  - This location is utilized for open single use controlled medications and expired out of date medications which require controlled disposal.

Procedurally, AHCW has implemented the following:

- At the commencement of surgery days, all drugs which will be utilized during the course of the day will be issued or verified in location, confirmed that they are not expired and confirmed to be appropriately marked (Date opened and initialed by person opening). Issued drugs will also be permanently marked to allow identification that they are opened / used. (using a colored ty-wrap or other means)

Following usage the drugs will be returned;

- to the approved storage location, if unopened or multi-use, and

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unexpired.

- or if controlled medication,
  - returned to the administrator where unopened drugs will be returned to the controlled medication safe or
  - opened single use drugs will be stored in the Open/Expired Controlled Drug Safe for disposal (AHCW 3.5.4 (Tab 17)).

We have undertaken to eliminate any difficulty resolving single and multi-use medicine and between open and used medicine. This is described within the AHCW P&P Manual (AHCW 3.5.4 (Tab 17)).

B. Drugs, as defined in § 54.1-3401 of the Drug Control Act of the Code of Virginia, whose intended use is to induce a termination of pregnancy shall only be prescribed, dispensed or administered by a physician.

At AHCW only Physicians prescribe, dispense or administer drugs utilized to induce a termination of pregnancy.

C. Drugs maintained in the facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18VAC110-20-10.

At AHCW drugs utilized for daily administration are verified regarding expiration date, storage temperature and are stored in enclosures with access restricted to authorized employees only. See A above.

D. The mixing, diluting or reconstituting of drugs for administration shall be in accordance with regulations of the Board of Medicine (18VAC85-20-400 et seq.).

AHCW does not mix, dilute or reconstitute any drugs.
E. Records of all drugs in Schedules I-V received, sold, administered, dispensed or otherwise disposed of shall be maintained in accordance with federal and state laws, to include the inventory and reporting requirements of a theft or loss of drugs found in § 54.1-3404 of the Drug Control Act of the Code of Virginia.

AHCW maintains records of all drugs received, administered, dispensed or disposed in accordance with § 54.1-3404 of the Drug Control Act of the Code of Virginia.

Regarding controlled substance disposal, AHCW stores opened, used, expired controlled substances in the “Open/Used/Expired” Drug Safe. The following procedure is provided by DEA.

**Disposal of Controlled Substances**

A practitioner may dispose of out-of-date, damaged, or otherwise unusable or unwanted controlled substances, including samples, by transferring them to a registrant who is authorized to receive such materials. These registrants are referred to as "Reverse Distributors." The practitioner should contact the local DEA field office (See Appendix E) for a list of authorized Reverse Distributors. Schedule I and II controlled substances should be transferred via the DEA Form 222, while Schedule III–V compounds may be transferred via invoice. The practitioner should maintain copies of the records documenting the transfer and disposal of controlled substances for a period of two years.

Reference: 12VAC5-412-260
§ 54.1-3404 of the Drug Control Act of the Code of Virginia

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## DRUG INSPECTION REPORT 2012

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<tr>
<th>Medication Room</th>
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<tbody>
<tr>
<td>1. Medicine Cabinets Clean and Organized</td>
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<td>2. Quantities present conform to inventory</td>
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<td>3. Dated drugs are in date</td>
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<td>4. External and Internal drugs are separated</td>
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<td>5. Opened drugs are properly labeled with date and initials</td>
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### Controlled Drugs

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<tbody>
<tr>
<td>1. Controlled drug cabinet locked and keys secure</td>
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<td>2. Controlled drug disposition sheets complete and accurate</td>
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<td>3. Controlled drugs counted on patient days and signed by two clinic persons</td>
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<td>4. Controlled drug cabinet kept locked</td>
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### Refrigerator

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<tbody>
<tr>
<td>1. Drugs requiring refrigeration stored at proper temperature. Current refrigerator temperature: 38°F.</td>
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<td>2. Refrigerate drugs separate from food</td>
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<td>4. IV solutions in date and properly stored</td>
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### General

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<tbody>
<tr>
<td>1. Emergency crash cart drugs in date complete and checked monthly</td>
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<td>2. Adequate and current drug reference texts</td>
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<td>3. Procedure Room's cabinet drugs in date and complete and checked monthly</td>
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Administrator Signature: ____________________________

**Revised:** 7/5/2012  
**Date & Initial:** NHC  
**Reviewed:** 7/5/2012  
**Date & Initial:** MEB

5 July 2012  
AHCW 3.5.4 Dispensing Controlled Drugs 120705  
Page 5 of 5
AHCW ATTACHMENTS

1. Letter re: requirement for Rh samples for quality testing CCOE, LLC.

2. Receipt for Stretcher recovering (6/19/2012)

3. Receipt for Stretcher recovering (7/6/2012)

4. Hands Sanitizer (2 each) purchased for facility
To Whom This May Concern,

The blood specimens in the refrigerator are for the purpose of Rh Quality Testing. These controls must be kept at 2-8°C to maintain integrity. The other samples are from Proficiency testing which must be stored at the same temperature. I have requested a small refrigerator be purchased to store these blood samples in a bio-hazard refrigerator marked as such. This is a CLIA Rule and regulation that Rh testing be quality controlled each day of patient testing.

Respectfully,

Catherine Obie
Catherine Obie, Technical Consultant
June 28, 2012

Rh: 7-V15-1
Rh reference level requirement.
BROWNING'S CUSTOM UPHOLSTERY, INC.
8451 MAPLEWOOD DRIVE
PHONE 703 369-7360   FAX 703 551-2802
MANASSAS, VIRGINIA 20111-2226

NAME: Luxe Statueborg
Amethyst Health Center
for Women Inc.
9380-B Forestwood Lane
Manassas, VA 20110

DATE RECEIVED: 6/14/12
DATE RETURNED: 

ADDRESS: 

CITY: MANASSAS
STATE: VA
ZIP: 20110

PHONE: 703 901 3353
HOME PHONE #: 
BUS. PHONE #: 

CUSTOMER ORDER NO: 
ORDER WRITTEN BY: 

OPER. NO: 
INSTRUCTIONS: 

TO REPLACE TOP VINYL ON MATTRESS $90.00

TOTAL PARTS

DISCLAIMER OF WARRANTIES

THE SELLER, HEREBY EXPRESSLY DISCLAIMS ALL WARRANTIES, EITHER
IMPLIED OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MER-
CHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, AND NEITHER
ASSUMES NOR AUTHORIZES ANY OTHER PERSON TO ASSUME IT ANY
LIABILITES OR OBLIGATION IN CONNECTION WITH THE SALE OR USE OF OUR PRODUCTS.

NOTE:

REF: T-75-7

LABOR $90.00
SUBLET 
PARTS 
MATERIAL $45.00
TAX $2.75
TOTAL AMOUNT $137.75
<table>
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<tr>
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**NAME:** Luke Storkenborg  
**ADDRESS:** Amethyst Health Center for Women Inc.  
**Phone:** 703-901-3353  
**City:** Manassas, VA 20110  
**Zip:**  

**Customer Copy**  
**Entry Method:** Swiped  
**Terminal ID:** 72529395  
**Date:** 7/3/12  
**Time:** 13:37:54  
**Inv #:** 000083  
**App#:** 026640  
**Customer Comments:**  

---  

**Oper. No:**  
**Instructions:** Recover mattress, resew button, and add velcro  
**Labor Charge:** 180.00  

---  

**Disclaimer of Warranties:** The seller, hereby expressly disclaims all warranties, either expressed or implied, including any implied warranty of merchantability or fitness for a particular purpose, and neither assumes nor authorizes any other person to assume for it any liability in connection with the sale of said products.
**Touch-Free Automatic Wall Dispenser**
- Dispenses proper amount of sanitizer every time
- Optional drip tray protects walls and floors; easy to install
- Refills available in all 3 formulas

**Hygiene Center with Automatic Sanitizer Dispenser**
- Includes hardware for mounting to wall
- Holds 2 boxes of masks, 2 boxes of tissue (in 1 compartment), and 1200mL of hand sanitizer
- Tissues, masks, and sanitizer sold separately

**Items on pages 86-87**: Ship Same Day

---

**ITEM** | **DESCRIPTION** | **PK** | **1-3** | **4+**
--- | --- | --- | --- | ---
**ML1285** | Purell® TFX® Automatic Wall Dispenser and 1200mL Refills | 1ea | $50.90 | —
**ML3674** | Wall-Mount Dispenser Includes batteries | 1ea | 11.00 | —
**ML3657** | Dispenser Tray | 1ea | 25.40 | —
**ML3658** | Original Formula Refill | 1ea | 31.50 | —
**ML1795** | Aloe Formula 1200mL Refill | 1ea | 31.90 | —
**ML3607** | Dermaglycerin System™ Refill | 1ea | 45.20 | 43.20

---

**ITEM** | **DESCRIPTION** | **PK** | **1-3** | **S**
--- | --- | --- | --- | ---
**ML2658** | Premium XL Health & Hygiene Center with Landscape Sign Holder | 1ea | $241.00 | —
**ML4420** | Portrait Sign Holder | 1ea | 31.90 | —

---

**ITEM** | **DESCRIPTION** | **PK** | **S** | **1** | **3** | **4**
--- | --- | --- | --- | --- | --- | ---
**ML4423** | Economy Infection Prevention Station 14"dia Base x 61"H | 1ea | $363.00 | — | — | —

**Call 800.237.3604 • Click MarketLab.com • Fax 416/650-7100**

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Download this sign at MarketLab.com