



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Office of Health Care Quality

Spring Grove Center • Bland Bryant Building

55 Wade Avenue • Catonsville, Maryland 21228-4663

Larry Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Van T. Mitchell, Secretary

May 19, 2014

Administrator

Germantown Reproductive Health Services

13233 Executive Park Terrace

Germantown, MD 20874

**RE: NOTICE OF COMPLIANCE WITH HEALTH
COMPONENT REQUIREMENTS**

Dear

On March 11, 2014, a complaint investigation was conducted at your facility by the Office of Health Care Quality to determine if your agency was in compliance with State requirements for a Surgical Abortion Facility.

This survey found that your facility is in compliance with the health component of the requirements.

If you have any questions, please call Barbara Fagan at (410) 402-8040.

Sincerely,

Patricia Tomsko Nay, MD, CMD, CHCQM, FAAFP, FAIHQ,
FAAHPM

Executive Director and Acting Medical Director
Office of Health Care Quality

Enclosure: CMS-2567

cc: File

Office of Health Care Quality

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: SA000001	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 03/11/2014
--	---	---	---

NAME OF PROVIDER OR SUPPLIER GERMANTOWN REPRODUCTIVE HEALTH SEF	STREET ADDRESS, CITY, STATE, ZIP CODE 13233 EXECUTIVE PARK TERRACE GERMANTOWN, MD 20874
---	---

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
--------------------	--	---------------	---	--------------------

A 000	<p>Initial Comments</p> <p>A complaint investigation survey was conducted at Germantown Reproductive Health Services on March 11, 2014. An exit interview was conducted on March 11, 2014</p> <p>The center performs surgical abortion procedures. Complaint number: MD00083223. The complaint was unsubstantiated. The complaint allegations include patient care.</p> <p>The survey included: an on-site visit; interview of the facility's administrator and the physician; review of the policy and procedure manual.</p> <p>A total of three clinical records were reviewed. The surgical abortion procedures that were performed between July 2013 and March 2014 were reviewed.</p> <p>Findings in this report are based on data present in the administrative records at the time of review. The agency's administrator and physician were kept informed of the survey findings as the survey progressed. The agency administrator and physician was given the opportunity to present information relative to the findings during the course of the survey.</p> <p>A key code for patients, medical staff and employees contained herein was provided to the agency administrator.</p> <p>Germantown Reproductive Health Services is in compliance with the Health Component of Title ten, Department of Health and Mental Hygiene, subtitle twelve Adult Health, 10.12.01 for Surgical Abortion Centers.</p>	A 000		
-------	--	-------	--	--

OHCQ LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
---	-------	-----------



STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Office of Health Care Quality

Spring Grove Center • Bland Bryant Building

55 Wade Avenue • Catonsville, Maryland 21228-4663

Larry Hogan, Governor - Boyd K. Rutherford, Lt. Governor - Van T. Mitchell, Secretary

May 27, 2014

Administrator

Germantown Reproductive Health Services

13233 Executive Park Terrace

Germantown, MD 20874

Dear

Enclosed is a list of state deficiencies resulting from a complaint investigation that was completed at your facility on April 15 and 16, 2014.

Please note that an Acceptable Plan of Correction (POC) for the identified deficiencies must include the following information:

- 1. State how the management team will evaluate the scope of each deficiency cited.**
- 2. State what process changes the management team will make to correct each specific deficiency identified.**
- 3. Define the projected time line for each step in the corrective action plan for each deficiency cited.**
- 4. Define the projected completion date for each deficiency cited.**
- 5. Identify who will be responsible for assuring each step in the plan of correction is implemented.**
- 6. State what specific quality indicators that the management team will monitor and evaluate the effectiveness of the corrective actions.**
- 7. Define what will be the on-going schedule of the quality monitoring activities for each deficiency cited.**

Page Two

IT IS IMPERATIVE THAT YOUR POC CONTAIN THE ABOVE COMPONENTS.

Please complete Forms 2567 as follows:

- 1. Use the official form provided to you for your response.**
- 2. Your Plan of Correction must be entered in the appropriate column on the right.**
- 3. An authorized representative of your facility must sign and date the form in the designated space provided.**

PLEASE RETURN COMPLETED 2567:

**Barbara Fagan, Program Manager
Ambulatory Care Programs
Office of Health Care Quality
Spring Grove Center
Bland Bryant Building
55 Wade Avenue
Catonsville, Maryland 21228**

You have one opportunity to question cited deficiencies through an informal dispute resolution process. To be given such an opportunity, you are required to send your written request, along with the specific deficiency(ies) being disputed, and an explanation of why you are disputing those deficiencies, to Dr. Tricia Nay, Director, Office of Health Care Quality, Bland Bryant Building, Spring Grove Center, 55 Wade Avenue, Catonsville, Maryland 21228. This request must be sent during the same 10 days you have for submitting a PoC for the cited deficiencies. An incomplete informal dispute resolution process will not delay the effective date of any enforcement action.

Please submit a Plan of Correction within 10 calendar days of receipt of this letter. Please be advised that failure to submit an acceptable POC could result in a recommendation to terminate your facility from the Medicare program.

If you have any questions regarding these instructions, please call Barbara Fagan at (410) 402-8040.

Sincerely,

**Patricia Tomsco Nay, MD, CMD, CHCQM, FAAFP, FAIHQ, FAAHPM
Executive Director and Acting Medical Director
Office of Health Care Quality
Cc: file**

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: SA000001	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 04/16/2014
--	--	---	---

NAME OF PROVIDER OR SUPPLIER GERMANTOWN REPRODUCTIVE HEALTH SEF	STREET ADDRESS, CITY, STATE, ZIP CODE 13233 EXECUTIVE PARK TERRACE GERMANTOWN, MD 20874
--	---

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
--------------------	--	---------------	---	--------------------

A 000 Initial Comments

A 000

A420

Surveyor: 01385
A complaint investigation survey was conducted at Germantown Reproductive Health Services on April 15 and 16, 2014. An exit interview was conducted on April 16, 2014.

The center performs surgical abortion procedures.
Complaint number: MD00082935
The complaint was unsubstantiated. A deficiency unrelated to the complaint was cited. JUL 21 2014
The complaint allegations included patient care.

The survey included: an on-site visit; interview of the facility's administrator, registered nurse, medical assistant and physician; review of the policy and procedure manual and review of the personnel files.

A total of five clinical records were reviewed. The surgical abortion procedures that were performed March 2014 were reviewed.

Findings in this report are based on data present in the administrative records at the time of review. The agency's administrator and physician were kept informed of the survey findings as the survey progressed. The agency administrator and physician were given the opportunity to present information relative to the findings during the course of the survey.

A key code for patients, medical staff and employees contained herein was provided to the agency administrator.

Germantown Reproductive Health Services acknowledges that we failed to have proper documentation of training provided to our Medical Assistants. On June 9th, 2014 we received a deficiency (A420) from the Maryland Department of Health and Mental Hygiene. The medical director and clinic administrator held a meeting to discuss the findings and how to proceed with the plan of correction. It was determined that the Clinic Administrator would be responsible for overseeing these changes and assuring the appropriate training is performed since the Medical Assistants report directly to her. It was during that meeting that we also decided that the following changes to our training protocols were necessary;

- 1.) In the Medical Assistants job description portion of our policy and procedural manual we have added "adding medications to intravenous solutions". We have also stated in our policy and procedural manual that the "functions of the Medical Assistant include but are not limited to". (see page 4 of manual)
- 2.) We have also included "adding medications to intravenous solutions" to our staff training check off forms. (See staff Training Form)

A 420 .05 (A)(1)(e)(i) .05 Administration

A 420

ICQ DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

DATE FORM

7-10-14

JUL 21 2014

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: SA000001	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 04/16/2014
NAME OF PROVIDER OR SUPPLIER GERMANTOWN REPRODUCTIVE HEALTH SEF		STREET ADDRESS, CITY, STATE, ZIP CODE 13233 EXECUTIVE PARK TERRACE GERMANTOWN, MD 20874		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE

A 420 Continued From page 1

A 420

(e) Ensuring that all personnel:
(i) Receive orientation and have experience sufficient to demonstrate competency to perform assigned patient care duties, including proper infection control practices;

This Regulation is not met as evidenced by:
Surveyor: 01385
Based on interview of the facility administrator and review of 5 of 6 personnel files, it was determined that the facility staff failed to document that all staff were competent to do their jobs. The findings include:

Employees: 1, 2, 3, 4, 5,

Interview on 4/16/14 at 1:00 pm of the facility administrator, revealed that 5 of 5 of the Certified Medical Assistants (CMA) are allowed to inject Pitocin into IV bags that are administered to the patients. The Facility administrator stated "we all put IV Pitocin in the IV bags, I trained all of the medical assistant's to do bag medications."

Review on 4/16/14 at 1:15 pm of the facility staff training sheet revealed that for 5 of 6 personnel records contained N/A for competency and training, thus reflecting no documentation that CMAs were trained to inject Pitocin into a patient's IV (Intravenous therapy) bag.

Review of the facility policy "Health Services protocol" on 4/16/14 at 2:00 pm revealed that "The function of the Certified Medical Assistant include: Taking patient health histories, Taking vitals, patient education, Laboratory testing, Sterilize and packing instruments, Phlebotomy, Assist the physician during procedures, Setting

- 3.) We held a staff training session that included visual and verbal explanation on techniques for the safe and sterile addition of medications to intravenous solutions on 6-16-14 as part of a staff meeting. (see staff meeting attendance sheet)
- 4.) Adjustments to our policy and procedural manual regarding supervised and unsupervised duties according to the employees scope of practice.
- 5.) Continued documentation of Medical Assistant training will be done in the following manner; upon initial hire (for skills set purposes not to be performed without supervision), after 90 days of training, and then annually thereafter. By doing so will avoid any future deficiency in training documentation.

We have since provided and documented training of medical assistants in a matter that makes us compliant with the DHMH regulations. To date staff training has been completed and all finalized adjustments to our policy and procedural manual will be completed by 8-1-14.

Admission's team, 7-10-14

Office of Health Care Quality

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: SA000001	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED C 04/16/2014
--	--	---	---

NAME OF PROVIDER OR SUPPLIER GERMANTOWN REPRODUCTIVE HEALTH SEF	STREET ADDRESS, CITY, STATE, ZIP CODE 13233 EXECUTIVE PARK TERRACE GERMANTOWN, MD 20874
--	---

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
--------------------	--	---------------	---	--------------------

A 420 Continued From page 2 A 420

up rooms, maintaining a clean and safe environment for patients and Upholding HIPPA (Health Insurance Portability and Accountability Act) guidelines, and protecting confidentiality.

The Failure of the facility staff to ensure that all staff are competent to do their jobs, placed the patients at risk of having care provided by untrained or unqualified individuals.

4/10/14