



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

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

May 6, 2009

Ms. Vicki Piontek
951 Allentown Road
Lansdale, PA 19446

Dear Ms. Piontek:

Thank you for correspondence to the Department of Health and Mental Hygiene requesting information on fines, citations, etc or certain healthcare facilities.

The Office of Health Care Quality is in receipt of your Request for Public Records for three licensed health care facilities in Maryland. One of the three facilities listed is licensed through the Office of Health Care Quality. Our office does not have any information on American Health Care Services or Hillcrest Clinic of Baltimore. Enclosed with this letter is a copy of a health inspection for Gynemed Surgi Center which is the record response to your request. As part of the survey process we do review the credential files of licensed and professional staff at the center, however, we do not obtain copies as part of the survey process.

Thank you again for your correspondence. The Governor appreciates hearing from you and on his behalf, I thank for making us aware of your concerns. If you have any questions, please contact Barbara Fagan, Program Manager at (410) 402-8040.

Sincerely,



Wendy Kronmiller
Director

Encl: Gynemed Surgi Center survey dated March 23 – 25, 2009
cc: John M. Colmers
Barbara Fagan





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April 6, 2009

**Mr. Michael O'Neil, Office Administrator
Gynemed Surgical Center
17 Fontana Lane, suite 201
Baltimore, MD 21237**

Dear Mr. O'Neil:

Enclosed is a list of Federal deficiencies resulting from a survey which was completed at your facility on March 25, 2009.

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 CMS 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 CMS 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 Ms. Wendy Kronmiller, Director, Office of Health Care Quality, Bland Bryant Building, Spring Grove Center, 55 Wade Avenue, Catonsville, Maryland 21228, fax 410-402-8234. 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 business 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 the undersigned at (410) 402-8040.

Sincerely,

**Barbara Fagan
Program Manager
Ambulatory Care
Office of Health Care Quality**

Cc: file

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 04/30/2009
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 21C0001165	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____		(X3) DATE SURVEY COMPLETED 03/25/2009
NAME OF PROVIDER OR SUPPLIER GYNEMED SURGI CENTER			STREET ADDRESS, CITY, STATE, ZIP CODE 17 FONTANA LANE SUITE 201-203 BALTIMORE, MD 21237		
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Q 000	<p>INITIAL COMMENTS</p> <p>A recertification survey was conducted at Gynemed Surgical Center on March 23, 24 and 25, 2009. An exit interview was conducted on March 25, 2009.</p> <p>The facility includes one operating and two procedure rooms.</p> <p>The survey included: an on-site visit; an observational tour of the physical environment; observation of one surgical procedure; observation of instrument cleaning/sterilization process; interview of the facility's administrator and registered nurse (RN); review of the policy and procedure manual; review of the personnel files; review of quality assurance and infection control program; and review of professional credentialing.</p> <p>A total of five clinical records were reviewed. The surgical procedures that had been performed between November 2008 and March 2009 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 was kept informed of the survey findings as the survey progressed. The agency administrator was given the opportunity to present information relative to the findings during the course of the survey.</p> <p>A key code for medical staff and employees contained herein was provided to the agency administrator.</p>	Q 000			
Q 004	<p>416.41(a) HOSPITALIZATION</p> <p>The ambulatory surgical center must have an</p>	Q 004			

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

TITLE

(X6) DATE

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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Q 004 Continued From page 1

effective procedure for the immediate transfer to a hospital of patients requiring emergency care beyond the capabilities of the center. This hospital must be a local, Medicare participating hospital or a local, non-participating hospital that meets the requirements for payment under section 482.2 of this chapter. **The ambulatory surgical center must have a written transfer agreement with such a hospital, or all physicians performing surgery in the center must have admitting privileges at such a hospital.**

This STANDARD is not met as evidenced by: Based on review of the agency policy and procedure, review of the physician credentialing file and interview of the administrator revealed, the administrator failed to assure the **only physician in the ambulatory surgery center (ASC)** has admitting privileges at the local Medicare participating hospital for patient's requiring emergency medical care beyond the capabilities of the ASC. The ASC does not have a transfer agreement with a local Medicare participating hospital.

The findings include:

Review of the policy and procedure manual revealed that all physician's practicing at the ambulatory surgery center (ASC) will have admitting privileges at the local Medicare participating hospital. Interview of the administrator on 3/23/09 at 11 AM revealed that the **only physician practicing at the ASC** does not have admitting privileges at the local hospital. The **ASC does not have a transfer agreement with the local Medicare participating hospital.**

Review of the physician's credentialing file

Q 004

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Q 004	Continued From page 2 confirmed the physician does not have admitting privileges at the local Medicare hospital.	Q 004			
Q 014	416.44(a)(3) ELEMENT of STANDARD PHYSICAL ENVIRONMENT Failure to assure that the physician has admitting privileges at the local Medicare participating hospital, for patient's who require emergency care beyond the capabilities of the ASC placed the patients at risk of not receiving the necessary surgical care needed in the event of an emergency. The ambulatory surgical center must establish a program for identifying and preventing infections , maintaining a sanitary environment, and reporting the results to appropriate authorities. This ELEMENT is not met as evidenced by: Based on a tour of the facility, a review of personnel files, interview of the agency's administrator, registered nurse, and medical assistant, and review of the spore testing logs revealed, the administrator failed to implement their infection control policies for spore testing, develop infection control policies for disinfection of medication vials and for one of one two new employees to obtain baseline Tuberculosis testing. The findings include. 1. Interview of the administrator and medical assistant on 3/23/09 at 1:30 PM and observation of the facility's procedure for sterilization of equipment revealed, biological/spore testing is performed by the medical assistant. The facility has two autoclave machines (Ritter M9 and Ritter M11) for sterilization of instruments. There is documentation and record of the spore testing for	Q 014			

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Q 014	<p>Continued From page 3</p> <p>the Ritter M11 dated weekly from October 14, 2008 to March 6, 2009. However, there is one documented date of September 23, 2008 for the Riter M9. There is no other documentation of spore testing for the Ritter M9 autoclave. Interview of the medical assistant on 3/25/09 at 8:15 AM revealed, the medical assistant "did not know that both autoclave's needed to have spore testing."</p> <p>The failure of the medical assistant maintain a record of spore testing, placed the patients at risk for contamination and infection from unsterile equipment and supplies.</p> <p>2. Review of the agency's policy for tuberculosis screening revealed, that all employees will have tuberculosis screening at hire and annually.</p> <p>Review of employee # 2's (medical assistant) health file revealed that the employee was hired on 3/3/09. There is no documentary evidence of a PPD (purified protein derivative screening test for tuberculosis) prior to working in the clinical area.</p> <p>The failure to implement infection control policies to ensure that all staff received tuberculosis screening placed the patients and staff at risk for infection.</p> <p>3. Observation of the RN (registered nurse) on 3/24/09 at 8:45 AM during medication preparation revealed, the RN failed to follow infection control practices when accessing a medication vial. The RN opened a new vial of 0.9 % (zero point nine per cent) Normal Saline Solution, removed the seal and entered the rubber septum with a new needle removing 21 ML (twenty-one milliliters) of solution. The RN then re-entered the vial with a</p>	Q 014		

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Q 014	Continued From page 4 mini spike (a needless entry system used to withdraw medications from a multi-dose stoppered vial), but failed to disinfect the rubber septum with alcohol prior to piercing after the initial entry The failure to follow infection control practices for medication preparation, placed the patients at risk for infection.	Q 014		
Q 015	416.44(b) SAFETY FROM FIRE Except as otherwise provided in this section, the ASC must meet the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code of the National Fire Protection Association, regardless of the number of patients served. The Director of the Office of the Federal Register has approved the NFPA 101 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes. In consideration of a recommendation by the State survey agency, CMS may waive, for periods deemed appropriate, specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients. The provisions of the Life Safety Code do not apply in a State if CMS finds that a fire and safety code imposed by State law adequately protects patients in an ASC.	Q 015		

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Q 015	Continued From page 5 An ASC must be in compliance with Chapter 21.2.9.1, Emergency Lighting, beginning on March 13, 2006. This STANDARD is not met as evidenced by: Based on interview of the administrator and review of the policy and procedure for fire drills, the administrator failed to perform fire drills. The findings include: Review of agency policy and procedure for fire drills revealed fire drills are held four times a year. Interview of the administrator on 3/23/09 at 10 AM revealed, the administrator replaced the previous administrator in the fall of 2008. The administrator was unable to locate any previous fire drills. The administrator stated that no fire drills had been performed since he took over in the fall of 2008. The administrator stated that the agency staff has never performed an actual drill that included the scenario and location of the fire, evacuation process, the total response time to the drill and an evaluation of the drill. The failure of the administrator to maintain documentation of quarterly fire drills and perform fire drills that evaluates the staff response time and ability to evacuate the patients in a timely manner, placed the patients at risk for injury.	Q 015		
Q 024	416.46(a) ORGANIZATION AND STAFFING Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice. There must be a registered nurse available for emergency treatment whenever there is a patient in the ambulatory surgical center.	Q 024		

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Q 024	<p>Continued From page 6</p> <p>This STANDARD is not met as evidenced by: Based on interview of the administrator and review of the registered nurse (RN) and the medical assistant's (MA) personnel files and interview of the administrator revealed, there was no documentation pertaining to the orientation or verification of the skills, annual evaluations, and job descriptions for five of five of these personnel.</p> <p>The findings include:</p> <p>Employees: #1, #2, #3, #4, #5</p> <p>Interview of the administrator on 3/25/09 at 2 PM and review of the personnel files for the agency's one RN (#1) and three of the four (#2, #4, #5) medical assistants (MA) revealed, that there was no documentation of orientation and a complete skills assessment and demonstration for the duties required of these personnel.</p> <p>Review of employees' #4 and #5 personnel files revealed that the files contained no job descriptions documenting the involvement or responsibility of the MAs. Employees #1, #2 and #3's job descriptions were incomplete for their job qualifications. Employees' #4 (date of hire 1/3/08) and #5 (date of hire 8/29/07) personnel files did not have evidence of an annual evaluation of their job performance. Interview of the administrator on 3/25/09 at 2 PM confirmed the above information.</p> <p>The failure to verify staff credentials, orient staff to their positions, perform a skills assessment and demonstration, provide the RN and MAs with a job description that includes the qualification required, and annual evaluations, placed the patients at risk of receiving inadequate care from</p>	Q 024		
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Q 024	Continued From page 7 unqualified individuals who have not demonstrated skills necessary to perform the job functions.	Q 024		
Q 030	416.48(a) ADMINISTRATION OF DRUGS Drugs must be prepared and administered according to established policies and acceptable standards of practice. This STANDARD is not met as evidenced by: Based on observations during a tour of the facility and interview of the administrator, the registered nurse (RN) and the medical assistants (MA), the registered nurse administered medications to patient's in unlabeled packages and medications to patients in syringes that were incorrectly labeled. The findings included: 1. During the tour on 3/24/09 of the facilities medication preparation room revealed in the locked narcotic box were 528 (five hundred twenty-eight) individual numbered brown envelopes. Interview of the RN and the administrator on 3/24/09 at 8:45 AM revealed, that the medication is Xanax (medication for anxiety). The administrator stated that the facility had problems with missing Xanax and that the administrator decided to package each pill in individual envelopes for better accountability of each Xanax given to the patient's. During a tour of the PACU (post ambulatory care unit) revealed, 26 (twenty-six) individual brown envelopes labeled Doxycycline 100 mg (antibiotic, one hundred milligrams) were observed in a draw. Interview of the administrator and the MA's on 3/24/09 at 1 PM revealed that each pill was	Q 030		

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Q 030	<p>Continued From page 8</p> <p>individually prepared to give to the patients on discharge. The envelopes were not labeled with the name of the medication, the dosage, the expiration date and documentation of the person who placed each pill in the individual envelopes.</p> <p>2. Observation of the RN on 3/24/09 at 8:45 AM revealed, the RN prepared a "cocktail mixture" of medications for conscious sedation, per physician documented instructions located on a bulletin board. The RN obtained a new bottle of 0.9% (zero point nine per cent) Sodium chloride (used for the mixture of medications), withdrew 21 ml/cc (twenty-one milliliters, cubic centimeters) leaving 29 (twenty-nine) ml in the bottle, then withdrew 40 mg or 8 cc (forty milligrams, eight) from four separate bottles of Versed (preoperative sedation), withdrew 50 mg or 1 cc (fifty, one) of Phenergan (preoperative sedation), withdrew one mg or one cc of Ultiva (analgesic/pain) and withdrew 0.4 mg or 1 cc (zero point four) of Atropine (decrease secretion before surgery). The medications were then injected into the bottle of 0.9% Sodium chloride and mixed with the remaining 29 ml. The RN then placed a mini spike (a needless entry system used to withdraw medications from a multi-dose stoppered vial), into the rubber septum of the mixture. The RN withdrew 3 (three) ml/cc into 10 (ten) separate syringes and placed a label on each syringe. The label documented Versed as 0.88 mg/cc (eight-eight) and the Atropine as 0.1 mg/cc. Interview of the physician on 3/25/09 at 2 PM revealed the dosage amounts documented on the syringe label for the Versed and Atropine is incorrect. The correct dosage is Versed 1 mg and Atropine 0.01 mg. and the incorrect dosage on the syringe label is a mistake.</p>	Q 030			

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Q 030	Continued From page 9 The failure to document and label medications and packages correctly placed the patients at risk of receiving unknown medications and dosages, and does not ensure the viability of the medications. This placed the patients at risk for adverse reactions such as allergic reactions and death.	Q 030		
Q9999	FINAL OBSERVATIONS The survey findings were reviewed. The facility staff was directed to submit a written plan of correction in response to the Federal 2567 form, following the attached guidelines, within ten working days. Failure to submit an acceptable plan of correction may result in decertification from the Medicare Ambulatory Surgical Center program.	Q9999		