

NEW YORK
state department of
HEALTH

Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

April 29, 2013

[REDACTED]

Re: Article 28 Diagnostic & Treatment Center Follow Up Survey
November 30, 2012

Dear [REDACTED]

On May 12, 2011, staff in this office performed an Article 28 survey of the [REDACTED]. The purpose of the survey was to assess compliance with Title 10 New York Codes, Rules and Regulations (NYCRR) governing diagnostic & treatment center operations. The Statement of Deficiencies subsequently issued on June 2, 2011 cited several violations of regulations, including those addressing medical staff credentialing, quality assurance and infection control. [REDACTED] submitted a Plan of Correction (POC) and addendums which the Department of Health (DOH) deemed acceptable on November 29, 2011.

The purpose of this November 30, 2012 survey was to again assess [REDACTED] compliance with Title 10 NYCRR, specifically following up the facility's implementation of the previously acceptable POC. The Statement of Deficiencies (SOD) enclosed is based on the findings of the follow up survey. Many of the findings represent repeat deficiencies and demonstrate [REDACTED] did not implement several corrective actions in its prior POC. Please submit a new POC to this office at the following address within 10 business days of receipt of this letter: *New York State Department of Health, [REDACTED]*

The POC should respond directly to the correction of each item identified, include a timetable for completion of the plan (see right side (X5) column on the SOD), and identify the person(s), by position, who are responsible for implementation and monitoring for continued compliance.

Please note that, where applicable, the POC must be implemented at all of your sites, not just the sites visited.

If you have any questions, please feel free to contact [REDACTED]

Sincerely,

[REDACTED]

Enclosure

cc: [REDACTED]

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New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: [REDACTED]	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 11/30/2012
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NAME OF PROVIDER OR SUPPLIER _____ STREET ADDRESS CITY STATE ZIP CODE _____

(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
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Y 000	INITIAL COMMENTS PFI: [REDACTED] OPERATING CERTIFICATE [REDACTED] NOTE: THE NEW YORK OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS (10NYCRR) DEFICIENCIES BELOW ARE CITED AS A RESULT OF A FOLLOW UP SURVEY CONDUCTED IN ACCORDANCE WITH ARTICLE 28 OF THE NEW YORK STATE PUBLIC HEALTH LAW. THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.	Y 000		
Y4336	400.20 (a) (1) HIV INFECTION CONTROL. All facilities regulated under this article shall: (1) implement and enforce a program for the prevention of circumstances which could result in an employee or patient/client becoming exposed to significant risk body substances which could put them at significant risk of HIV infection during the provision of services, as defined in section 63.1 and 63.9 of this Title. This Regulation is not met as evidenced by: Based on findings from observations, the [REDACTED] [REDACTED] does not maintain an environment that is free of circumstances which could result in an employee or patient/client becoming exposed to significant risk body substances. Findings include:	Y4336		

Office of Health Systems Management

TITLE

(X6) DATE

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

STATE FORM

01/10/2013

If continuation sheet: 1 of 18

New York State Department of Health

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Y4336	<p>Continued From page 1</p> <p>See observations during tours of [REDACTED]</p> <p>On 11/05/12, at the [REDACTED] the [REDACTED] bathroom, unsecured, housed the [REDACTED] used/filled sharps containers. The [REDACTED] bathroom was used for storage until the containers could be picked up by the medical waste company, which comes [REDACTED]. This finding was confirmed with the Vice President for Patient Services (VPPS) during the tour.</p> <p>On 11/30/12, at the [REDACTED] the filled sharps containers were stored in an unsecured area [REDACTED] where patients walked through. This was confirmed during the tour with LPN # 1.</p>	Y4336	
T2019	<p>751.2 (f) (7) ORGANIZATION AND ADMINISTRATION. Operator.</p> <p>The responsibilities of the operator shall include but not be limited to:</p> <p>(f) ensuring that the following documents, as applicable, are retained on file in the administrative offices of the center:</p> <p>(7) the applications for admission to staff privileges of all current medical and dental staff, which shall include for each applicant: a statement of training and experience, all supporting documents, satisfactory evidence of conformity with requisite professional licensing laws and records of actions and recommendations of staff committees of the respective professional staff and of the governing authority.</p> <p>This Regulation is not met as evidenced by: Based on findings from document reviews and</p>	T2019	

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T2019	<p>Continued From page 2</p> <p>interview, all credentialing information required by this regulation is not maintained in the [REDACTED] medical staff members' files.</p> <p>Findings include:</p> <ul style="list-style-type: none"> -- Review of medical staff files for the Medical Director, Physician #1 and Nurse Practitioners (NPs) #1 & #2 revealed they did not contain the credentialing information obtained by [REDACTED] [REDACTED], per contract arrangement. (This would be the credentialing information the Board reviews prior to the appointment and reappointment, and the granting and renewing of privileges for the medical staff.) -- This finding was confirmed during interview with the Human Resource Supervisor (HRS) on 11/05/12. <p>This is a repeat deficiency from the previous Article 28 survey completed on 05/12/11. [REDACTED] never implemented the Plan of Correction (POC) accepted by the Department of Health (DOH) on 11/29/11.</p>	T2019		
T2022	<p>751.2 (h) ORGANIZATION AND ADMINISTRATION. Operator.</p> <p>The responsibilities of the operator shall include but not be limited to:</p> <p>(h) the appointment of medical and dental staff, the assignment of their clinical privileges and reviews of such appointments at least every two years.</p> <p>This Regulation is not met as evidenced by: Based on findings from document reviews and interview, in 4 of 4 medical staff files reviewed for [REDACTED] medical staff members, evidence was</p>	T2022		

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T2022	<p>Continued From page 3</p> <p>lacking that the Board appointed all of the medical staff and approved assignments of their privileges. Also, the medical staff files lacked performance-related information required by facility policy and procedure (P&P) to be maintained in the files.</p> <p>Findings include:</p> <ul style="list-style-type: none"> – Per review of the medical staff files for Physicians #1 and #2 (including the Medical Director), and NPs #1 and #2, each lacked documentation addressing the staff member's appointment/reappointments and the clinical privileges assigned. <p>While the Board meeting minutes for [REDACTED] 2011 through [REDACTED] 2012 contained indications Physicians #1 & #2, and NP #1 were appointed or reappointed by the Board, they lacked documentation describing privileges granted. Additionally, there is no evidence NP #2 was appointed by the Board (despite date of hire listed as 02/ [REDACTED] 12 in his/her medical staff file).</p> <p>[REDACTED]</p>	T2022		

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T2022	Continued From page 4 [REDACTED]	T2022		
	-- These findings were confirmed during interview with the HRS on 11/05/12. This is a repeat deficiency from the previous Article 28 survey completed on 05/12/11. [REDACTED] never implemented the POC accepted by the DOH on 11/29/11.			
T2068	751.5 (a) (12) ORGANIZATION AND ADMINISTRATION. Operating Policies and Procedures. The operator shall ensure: (a) the development and implementation of policies and procedures written in accordance with prevailing standards of professional practice which include but are not limited to:	T2068		

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T2068	<p>Continued From page 5</p> <p>(12) the designation of a member of the center staff to be specifically assigned to implement policies and procedures for the coordination of the services of the center with the services of community health facilities and programs and community social agencies.</p> <p>This Regulation is not met as evidenced by: Based on findings from review of [REDACTED] P&P manuals, the facility lacked a written P&P addressing the designation of a specific staff member to coordinate services of the [REDACTED] with services of [REDACTED] and [REDACTED]. This was confirmed during interview with the VPPS on 11/05/12: he/she could only indicate there was a shared responsibility among professional staff for the coordination of services between the [REDACTED].</p> <p>This is a repeat deficiency from the previous Article 28 survey completed on 05/12/11. [REDACTED] never implemented the POC accepted by the DOH on 11/29/11.</p>	T2068	
T2070	<p>751.5 (a) (14) ORGANIZATION AND ADMINISTRATION.</p> <p>Operating Policies and Procedures. The operator shall ensure: (a) the development and implementation of policies and procedures written in accordance with prevailing standards of professional practice which include but are not limited to: (14) ensuring that emergency equipment and staff prepared to care for emergencies are provided in accordance with the services provided at the center, and equipment is maintained in working condition.</p>	T2070	

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T2070	<p>Continued From page 6</p> <p>This Regulation is not met as evidenced by: Based on findings from observations and interviews, [REDACTED] did not store its emergency equipment where it would be immediately available for use at all times.</p> <p>Findings include:</p> <p>-- Per observations during tours of [REDACTED]</p> <p>On 11/05/12, at the [REDACTED] the emergency box was located in exam room #1. It was/is not immediately available when a patient is being evaluated in the room, as was the case during the tour. This finding was acknowledged by [REDACTED] Manager [REDACTED] #1.</p> <p>On 11/30/12, at the [REDACTED] the oxygen tank stored in the bottom of a cupboard was empty and not secured (as required by NFPA 99 per reference in 711.2(a)(20)), and the mask attached to it was exposed.</p> <p>--During interview with LPN #1, he/she indicated they never use oxygen at the [REDACTED] and so don't keep track of it.</p> <p>--However, the P&P titled [REDACTED] [REDACTED] dated 01/2010, does include use of oxygen for emergencies.</p>	T2070	
T2097	<p>751.6 (g) ORGANIZATION AND ADMINISTRATION. Personnel.</p> <p>The operator shall ensure: (g) the assignment of duties and functions to each employee that are commensurate with his/her licensure, registration and/or certification.</p>	T2097	

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T2097	<p>Continued From page 7</p> <p>and experience and competence</p> <p>This Regulation is not met as evidenced by: Based on findings from document reviews and interview, the facility's job descriptions for the Clinical Assistant/Clinical Receptionist (CA/CR), Licensed Practical Nurse (LPN), and [REDACTED] Manager [REDACTED] each contain duties which are not commensurate with the professional licensure and/or lack of licensure of the staff in these positions. Also, the facility failed to determine that LPN staff were competent in performing venipunctures prior to allowing them to perform this procedure.</p> <p>Findings include:</p> <ul style="list-style-type: none"> -- The CA/CR's job description describes duties that include restocking the exam, intake and medication rooms daily to assure efficient patient flow. Medications [REDACTED], [REDACTED], [REDACTED], which the CA/CR [REDACTED]. <p>The [REDACTED] job description indicates this person is responsible for supervision/management of clinical operations at [REDACTED] including supervision of RNs, LPNs, CAs, CRs, NPs, physician's assistants (PAs) and certified nurse midwives (CNMs), as well as medical residents and other clinical visitors. The [REDACTED] at this facility is a registered nurse (RN). The [REDACTED] form that he/she completes for the NP, PA and CNM staff, documents assessments of the staffs' competencies for several clinical skills that are not in the scope of practice for an RN (e.g., applies tenaculum properly during IUC (intrauterine contraception) insertion; demonstrates judgement in reviewing the appropriateness of injectable Depo-Provera</p>	T2097		

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T2097	<p>Continued From page 8</p> <p>for client; formulates appropriate diagnosis, treatment, HRT (hormone replacement therapy), as per protocol; etc).</p> <p>The LPN Clinic Nurse job description indicates this person delivers patient care utilizing the nursing process to assess, plan, implement and evaluate patient outcome. The scope of patient care practice for LPNs in NYS does not include assessment activities.</p> <p>-- Per interview with LPN #1 at the [REDACTED] on 11/29/12, he/she had been [REDACTED] hire [REDACTED] ago, but never received any training or evaluation prior to performing the [REDACTED]. He/she did perform [REDACTED] at prior place of employment.</p> <p>The facility P&P titled [REDACTED] [REDACTED], dated [REDACTED]/2012, contains the following statements:</p> <p>"Staff with previous experience in [REDACTED] still need to review [REDACTED] Protocol and Infection Control Policies, take a written test, and demonstrate [REDACTED] proficiency based on the procedure to a clinician. The proctor may use her discretion to determine the number of procedures (up to 3) needed to demonstrate proficiency.should be documented using the [REDACTED] Training Checklist. No one will be considered trained without demonstrating proficiency to a clinician... all [REDACTED] procedures will need to be observed and cosigned until the Module has been successfully completed and Statement of Competency signed."</p> <p>Although the date of hire for LPN #1 was</p>	T2097		

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T2097	<p>Continued From page 9</p> <p>10 [REDACTED] 11, his/her personnel records contained a [REDACTED] training checklist dated 11/ [REDACTED] 12, with the signed Statement of Competency dated 11 [REDACTED] /12.</p> <p>Although, the date of hire for LPN #2 was [REDACTED] 2012, his/her personnel records contained a [REDACTED] training checklist dated 11 [REDACTED] /12, with the signed Statement of Competency dated 12 [REDACTED] /12.</p> <p>It was confirmed through interview with the VPPS on 12/ [REDACTED] 12 that both LPNs performed [REDACTED] at the facility prior to completion of the competency verification process.</p>	T2097		
T2114	<p>751.7 (d) ORGANIZATION AND ADMINISTRATION.</p> <p>Medical record system. The operator shall: (d) ensure that the medical record for each patient contains and centralizes all pertinent information which identifies the patient, justifies the treatment and documents the results of such treatment.</p> <p>This Regulation is not met as evidenced by: Based on document reviews, 4 of 6 medical records (MR) reviewed for [REDACTED] abortion patients lacked complete documentation, i.e., the [REDACTED] form in the MRs lacked one or more of the following:</p> <ul style="list-style-type: none"> * date of service, * ultrasound date and findings, * vital signs, 	T2114		



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T2114	Continued From page 10 * signature of a nurse or clinical assistant, and/or * follow up visit date.	T2114		
T2140	751.8 ORGANIZATION AND ADMINISTRATION. Quality assurance program. This Regulation is not met as evidenced by: Based on findings from document reviews and interview, the quality assurance (QA) program at [REDACTED] does not include all pertinent services in its QA activities, does not follow up on all significant issues identified, and does not address the requirements at 751.8(d)(1)-(4) and (f) under this regulation. Additionally, issues that are reviewed during meetings of the facility's [REDACTED] ([REDACTED]) committee are not clearly described in its meeting minutes. Findings include: [REDACTED]	T2140		

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T2140	Continued From page 11 [REDACTED]	T2140		
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T2140	Continued From page 12	T2140		
[REDACTED]				



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T2140	Continued From page 13 [REDACTED]	T2140		
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T2240	<p>752-1.5 (e) CENTER SERVICES. Pharmaceutical Provisions.</p> <p>The operator shall ensure that: (e) pharmaceutical services are provided in accordance with current standards of professional practice.</p> <p>This Regulation is not met as evidenced by: Based on findings from observation, document reviews, and interview, the facility was not providing pharmaceutical services in accordance with current standards of professional practice. Specifically, opened, unlabeled pharmaceuticals and other substances were observed in examination rooms at [REDACTED] toured. This problem was previously identified by the facility but not addressed.</p> <p>Findings include:</p> <p>-- Per observations during tours of [REDACTED];</p>	T2240		
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T2240	<p>Continued From page 14</p> <ul style="list-style-type: none"> * On 11/05/12, opened and undated multidose bottles of injectable Lidocaine were observed available for patient use in the examination rooms [REDACTED] and the [REDACTED] * On 11/26/12, 2 opened and undated multidose bottles of injectable Lidocaine were observed available for patient use in the exam room at the [REDACTED] * On 11/30/12, an opened multidose bottle of injectable Lidocaine dated 10/27/12, greater than 30 days earlier, was observed available for patient use in exam room #1 at the [REDACTED] <p>These findings were confirmed with [REDACTED] #1 during the tours of the [REDACTED] with [REDACTED] #2 during the tour of the [REDACTED] and with the Office Manager during the tour at the [REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>For example:</p>	T2240		

New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: [REDACTED]	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 11/30/2012
NAME OF PROVIDER OR SUPPLIER [REDACTED]		STREET ADDRESS CITY STATE ZIP CODE	
(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
T2240	Continued From page 15 [REDACTED]	T2240	
	<p>Also, despite the continued findings illustrating staff were not practicing appropriate infection control measures specific to the handling of medications and other patient care supplies subject to expiration dates, the minutes of the committee meetings from 01/12 through 07/12 lack indication the committee addressed this problem.</p> <p>This is a repeat deficiency from the previous Article 28 survey completed on 05/12/11. PPNCNY never implemented the POC accepted by the DOH on 11/29/11.</p> <p>Also see the findings in Tag T2040 which describe lapses in QA activities relative to pharmacy services.</p>		
U7045	<p>702.4 INFECTION CONTROL AND REPORTING.</p> <p>Infection control and reporting.</p> <p>This Regulation is not met as evidenced by: Based on findings from observations, at [REDACTED] [REDACTED] [REDACTED] [REDACTED] areas used for the following functions were not compliant with generally accepted infection control (IC) practices: blood draw/laboratory, dirty utility,</p>	U7045	

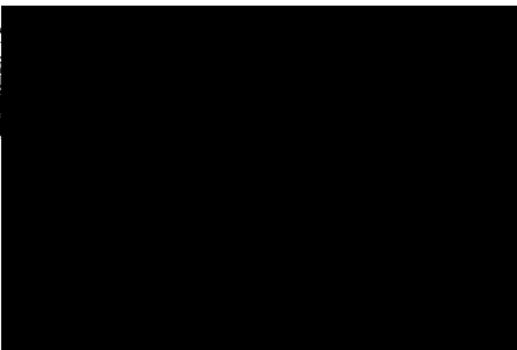
New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER [REDACTED]	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 11/30/2012
NAME OF PROVIDER OR SUPPLIER [REDACTED]		STREET ADDRESS, CITY, STATE, ZIP CODE [REDACTED]	
(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)
U7045	<p>Continued From page 16</p> <p>clean utility, and medication storage and preparation. Also, although the facility has established an [REDACTED] committee and performs [REDACTED] audits, the audits are not performed at [REDACTED] and they lack assessment of staff's injection and handwashing practices. Additionally, not all lapses in [REDACTED] practices identified at the facility are addressed by the [REDACTED] committee.</p> <p>Findings include:</p> <ul style="list-style-type: none"> -- Per observations during a tour of the [REDACTED] on 11/26/12, the dirty [REDACTED] was a combination [REDACTED] and [REDACTED]. It contained the autoclave where dirty equipment is brought in to be washed and autoclaved. The room was also being used for [REDACTED]. -- During a tour of the [REDACTED] on 11/29/12, LPN #1 indicated that urine samples are brought into the [REDACTED] in order to enter patient data into the computer. -- Per observations during a tour of the [REDACTED] on 11/29/12, [REDACTED] equipment was observed in the [REDACTED]. It was confirmed with RN #1 that [REDACTED] were being performed in the [REDACTED] room. <p>[REDACTED]</p>	U7045	

New York State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: [REDACTED]	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED 11/30/2012
NAME OF PROVIDER OR SUPPLIER [REDACTED]		STREET ADDRESS CITY STATE ZIP CODE [REDACTED]		
(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)	
U7045	Continued From page 17 [REDACTED] --Also see finding in Tag Y4336 regarding the facility's failure to store filled sharps containers in a manner that would avoid inadvertent staff or patient contacts with potentially infectious contents. This is a repeat deficiency from the previous Article 28 survey completed on 05/12/11. [REDACTED] never implemented the POC accepted by the DOH on 11/29/11.	U7045		



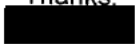


1 Attachment



EHR Documentation Audit-Annual Visit.docx

Good morning [redacted]
Please find attached the corrected audit (revisions are highlighted in yellow)
Please contact me should you have any questions or concerns.
Thanks.



From: [redacted]
Sent: Thursday, January 02, 2014 3:31 PM
To: [redacted]
Cc: [redacted]
Subject: POC

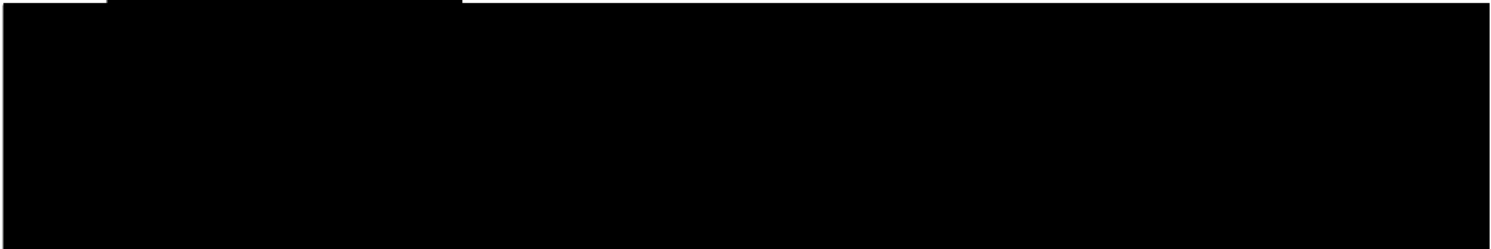
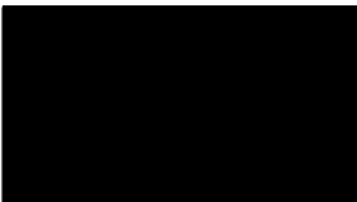


Attached is the "Annual Visit EHR Documentation Audit" which needs to be corrected.

I have written in pencil the changes/additions that need to be made. Next to the Advance Directive completed, HCP given to patient 18 and older....you need to add or parent of a child or married. That is consistent with NYCRR Title 10 Regulation 400.21. Please make the corrections and send the corrections to this email address not BML one. Once I receive it, you will have acceptable POCs and a letter will be sent.

I am out of the office until 1/10/14. If you have any questions please contact me on 1/10/14. [redacted] will not be able to assist you.

Thanks - Hope your holidays were nice.





Re: December 5 DOH submission

Sent by: [redacted] to: [redacted]

12/06/2013 07:28 AM

Thank you.

RESPONSES MUST BE SENT TO THIS E-MAIL ADDRESS ONLY.

[redacted]

[redacted]

Good afternoon [redacted] Please find attached...

12/05/2013 04:30:37 PM

December 5 DOH submission

[redacted] to: [redacted] Hospital BML

12/05/2013 04:30 PM

Cc: [redacted]

Good afternoon [redacted]
Please find attached our documents for the December 5th submission.
Just one zip file this time!
The document index outlines materials submitted .

[redacted]



9 - DOH sent 12-5-13.zip



BOARD LIST

2013

NAME	Terms	Board Position, Committees	Home Address/County	Occupation Emp. Name & Address	All/Home Phone/Work Phone Fax & E-mail Address

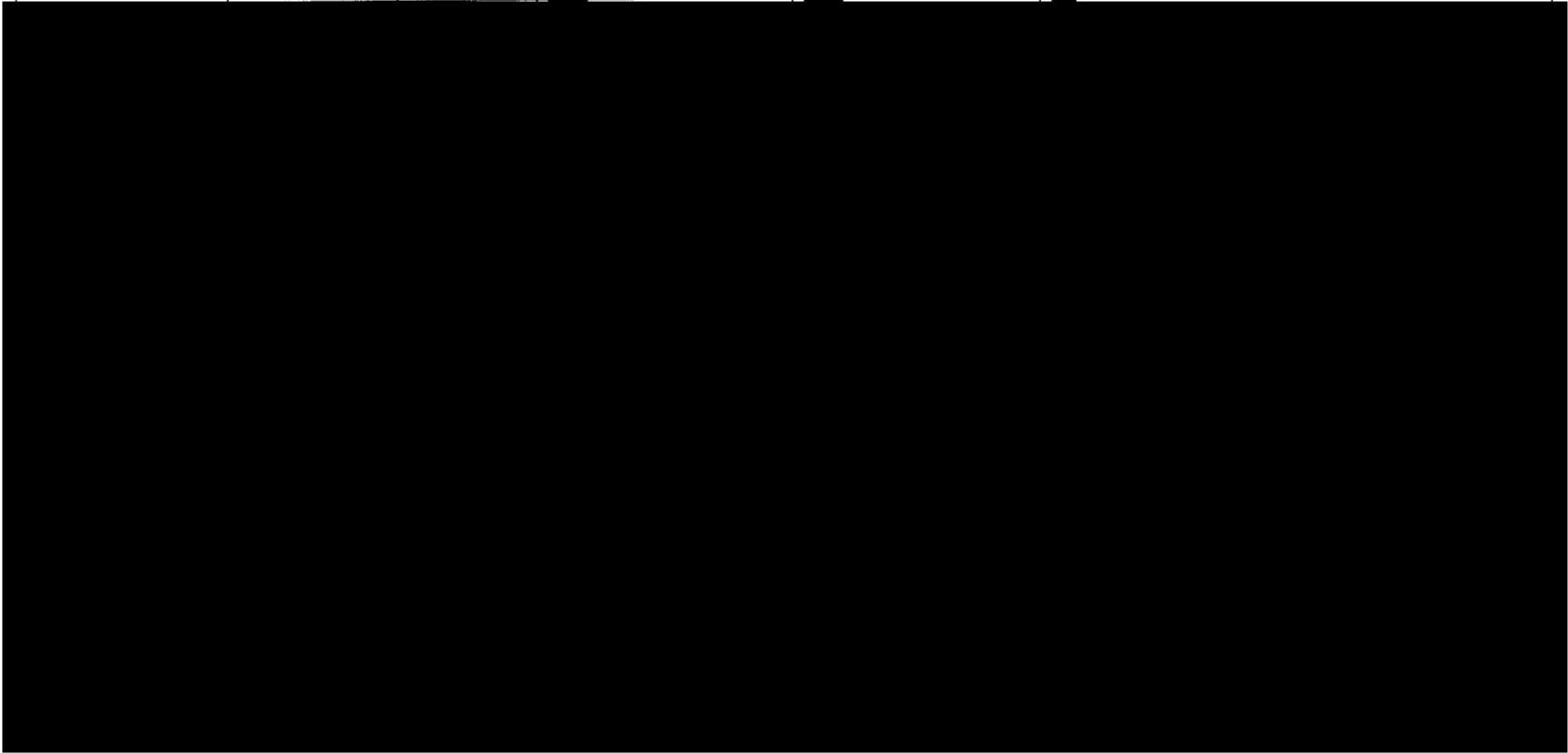
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 2011, [Redacted] 2012 [Redacted] 2012, [Redacted] 2012, [Redacted] 2012

[REDACTED]

BOARD LIST

[REDACTED] 2013

NAME	Terms	Board Position, Committees	Home Address/County	Occupation Emp. Name & Address	All/Home Phone/Work Phone Fax & E-mail Address
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KEY: EC=Executive Committee BDC=Board Development Committee FC=Finance Committee FUNCOM = Fund Development Committee FPA=FPA Board Member BPC=By-Laws & Policies Committee DIV=Diversity Committee SPC= Strategic Planning Committee
PPANY=Planned Parenthood Advocates of NY Board Member LOA=Leave of Absence

[REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2011; [REDACTED] 2011; [REDACTED] 2011; [REDACTED] 2011, [REDACTED] 2011, [REDACTED] 2011, [REDACTED] 2012, [REDACTED] 2012, [REDACTED] 2012, [REDACTED] 2012, [REDACTED] 2012



BOARD LIST
 [REDACTED] 2013

NAME	Terms	Board Position, Committees	Home Address/County	Occupation Emp. Name & Address	All/Home Phone/Work Phone Fax & E-mail Address
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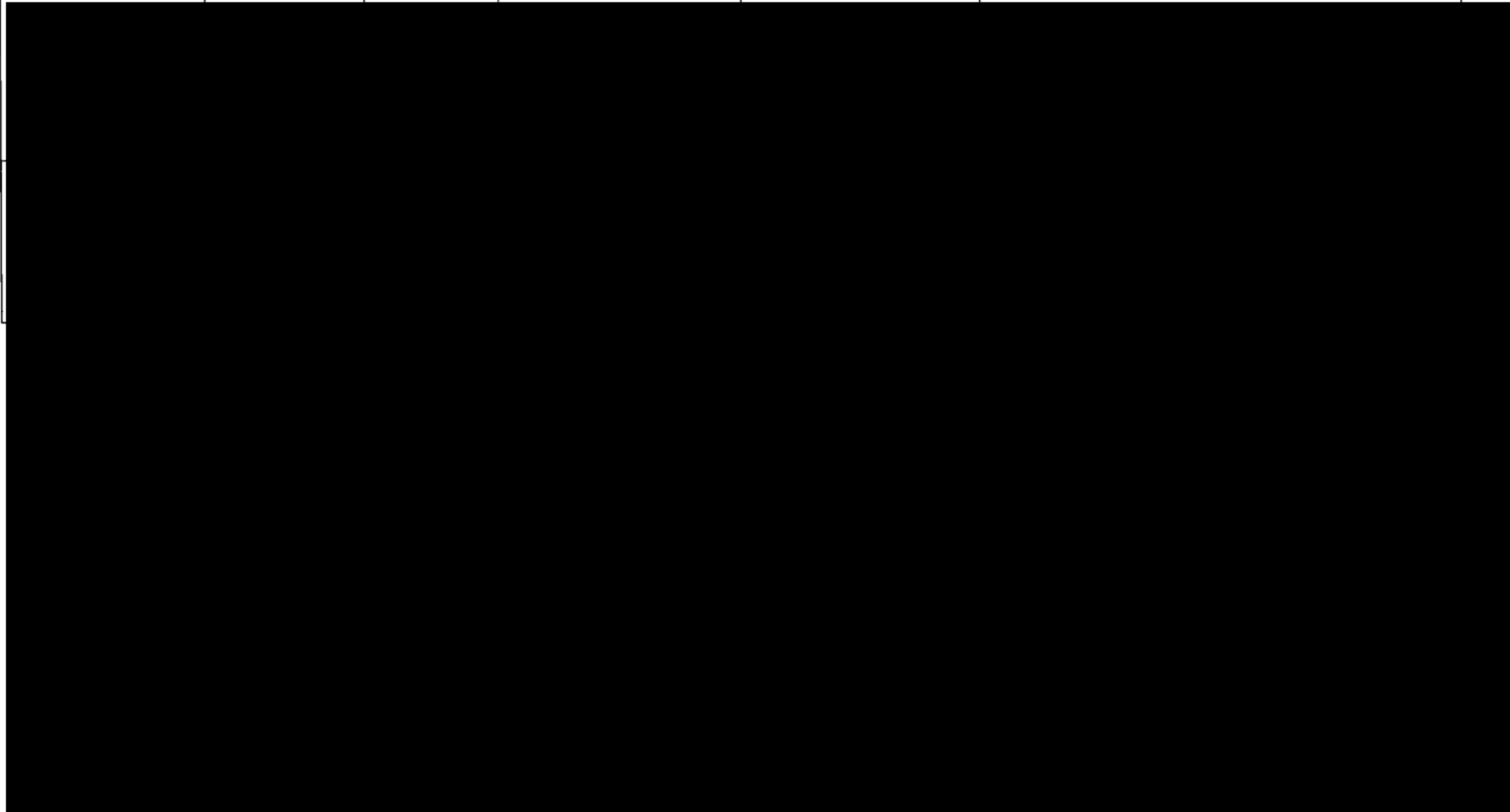
[REDACTED]					
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[REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2010; [REDACTED] 2011; [REDACTED] 2011; [REDACTED] 2011; [REDACTED] 2011; [REDACTED] 2011; [REDACTED] 2011; [REDACTED] 2012; [REDACTED] 2012; [REDACTED] 2012; [REDACTED] 2012; [REDACTED] 2012; [REDACTED] 2012



**BOARD LIST
OCTOBER 2013**

NAME	Terms	Board Position, Committees	Home Address/County	Occupation Emp. Name & Address	All/Home Phone/Work Phone Fax & E-mail Address
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2010; 2010; 2010; 2010; 2010; 2010; 2010; 2010; 2010; 2010; 2011; 2011; 2011; 2011;
2011, 2012, 2012, 2012, 2012

Abbreviated Executive Summary

Earlier this year, [REDACTED] was notified by [REDACTED] that their [REDACTED] in [REDACTED] was scheduled to close and that [REDACTED] services would no longer be available in [REDACTED] County. With the consent of the [REDACTED] board, [REDACTED] began the process of exploring establishment of [REDACTED] services in [REDACTED] county to avoid a hiatus in services for the community. [REDACTED] submitted an application to [REDACTED] and a letter of intent to the NYS Department of Health to add [REDACTED] County to our service area and was approved. In [REDACTED] 2013 we were notified by the DOH's [REDACTED] that our request to set up services was reviewed and that [REDACTED] funding in the amount of \$ [REDACTED] would be allocated to our existing [REDACTED] DOH grant for [REDACTED] County. These funds are contingent upon gaining approval of this certificate of need to establish a service site and are included in the DOH [REDACTED] budget which begins on [REDACTED] 2014. The [REDACTED] County Public Health Department has also indicated their interest in granting [REDACTED] a contract to carry out [REDACTED] services in the county in 2014. This contract is contingent upon [REDACTED]'s ability to open a service site. [REDACTED] currently serves [REDACTED] counties in [REDACTED] New York – [REDACTED]. [REDACTED] are located in [REDACTED]. Adding [REDACTED] County is in keeping with our mission to serve [REDACTED] New York.

Once approval was received, following discussion with the County Public Health Department, an earnest and exhaustive search for professional space in the [REDACTED] area was begun. An inspection of the clinical space currently used by [REDACTED] in [REDACTED] was performed. There were several deficiencies noted that would have to be corrected before approval could be obtained by the NYSDOH. [REDACTED]

[REDACTED] Deemed cost prohibitive, [REDACTED] began to look for alternative sites. [REDACTED] will end all of its services in [REDACTED] in [REDACTED] 2013.

- No existing free standing clinical/professional space was found for sale or lease in [REDACTED].
- Meetings were held with [REDACTED] County Public Health. The public health department could not identify any available Article 28 health center space in either [REDACTED] or [REDACTED].
- A visit to [REDACTED] was done to view their [REDACTED]. The size of the [REDACTED] is limited and has full usage. They have no available space in their [REDACTED].

- Discussions with [REDACTED] revealed they had no space in their [REDACTED] available nor in the building the [REDACTED] sits in. It was suggested by [REDACTED] to inquire about leasing clinical space at [REDACTED] in [REDACTED] occupied the [REDACTED] space several years ago while awaiting [REDACTED] space in [REDACTED]
- A site visit was conducted at [REDACTED] regarding [REDACTED] for lease. Two space options were inspected. The first option is to lease already [REDACTED] A portion of this space is currently leased by [REDACTED] and [REDACTED] and [REDACTED] on specific days of the week. The clinic consists of [REDACTED] and [REDACTED]. The second option is [REDACTED]. [REDACTED] would like to develop this under-utilized space and would work with [REDACTED] to design and construct clinical space for [REDACTED] sole use. This would not be immediately available and would take up to a [REDACTED] to do the renovations to specification, seek approvals and open the [REDACTED]. Based on the needs of the community and a potential hiatus in essential [REDACTED] which cannot be obtained elsewhere in [REDACTED] consulted with County Public Health officials and the New York State Department of Health Article 28 team about leasing space in the [REDACTED] temporarily and begin working with [REDACTED] to develop the space at the [REDACTED]. Several meetings were held with [REDACTED]. [REDACTED] Approval and support was obtained from all.

In this Certificate of Need [REDACTED] is seeking approval to add a new [REDACTED] in [REDACTED] by leasing [REDACTED] space from [REDACTED]. This allows for optimal use of existing space and offers [REDACTED] clients ready access to services that [REDACTED] offers, including laboratory, ultrasound, mammography, x-ray and referral services, immediately [REDACTED] to the [REDACTED]. The [REDACTED] is centrally located in [REDACTED] has ample parking and offers patients an accessible, modern, new site to receive services. [REDACTED] proposes to offer a full range of family planning services [REDACTED]. The site would be staffed by a [REDACTED] advanced practice clinician and a clinic assistant with [REDACTED].

supervision provided by the VP for patient services in [REDACTED] and the [REDACTED] Medical Director.

Once the decision was made to pursue leasing space in the [REDACTED] at [REDACTED] reached out for guidance from NYSDOH agencies including:

- Bureau of Project Management
- Bureau of Maternal and Child Health
- Office of Health Systems Management

We reviewed the information provided to us by officials from these agencies and returned to [REDACTED] to discuss their recommendations. [REDACTED] was able to accommodate the recommendations given to [REDACTED] during our conference calls with NYSDOH officials. [REDACTED] obtained the services of an Article 28 Architectural firm to assess the site and produce certified architectural drawings demonstrating that [REDACTED] will have a [REDACTED] [REDACTED] [REDACTED] to the [REDACTED] area to be leased and certify that all specifications and regulations have been met. (See Schedule 6) During [REDACTED] hours of operation, signage will clearly indicate the entrance for [REDACTED] [REDACTED] will have a [REDACTED] [REDACTED] for patients [REDACTED] staff access to a [REDACTED] [REDACTED] [REDACTED] [REDACTED] There will be no co-mingling of any other provider's patients. A [REDACTED] will be placed in the [REDACTED] to prevent co-mingling of patients. [REDACTED] plans to lease space [REDACTED] [REDACTED] With the use of electronic health records and secure internet connection, no co-mingling of patient charts will occur nor any HIPPA violations. [REDACTED] clinical staff will bring [REDACTED] lap tops for use during the clinical hours. [REDACTED] plans to utilize separate phone lines while in the clinical area by bringing and using [REDACTED] phones. A secured and locked closet will be available for storage of supplies [REDACTED] will need during clinic hours and which no one else will have access to.

The Operating Certificate (Certificate No. [REDACTED] effective date [REDACTED] (03) issued by the NYSDOH Office of Health Systems Management for [REDACTED] contains approved services which include Primary Care O/P indicating that this wing of the hospital is an Article 28 space.

RE: Article 28 site survey response cover letter

to:

09/10/2013 02:40 PM

Show Details

Pod #2

Great!

From: [redacted] **On Behalf Of** [redacted]
Sent: Tuesday, September 10, 2013 2:38 PM
To: [redacted]
Subject: Re: Article 28 site survey response cover letter

Received!

RESPONSES MUST BE SENT TO THIS E-MAIL ADDRESS ONLY.

[redacted]

[redacted] 09/10/2013 02:16:31 PM---Good afternoon [redacted] Please find attached the cover letter for the Article 28 Site Survey Respons

Article 28 site survey response cover letter

Cc: [redacted] to: [redacted]

09/10/2013

Good afternoon [redacted]
Please find attached the cover letter for the Article 28 Site Survey Response.
Due to the size of the zip folders containing the supporting documents for the response to the SOD, we'll be sending an additional two emails.
I'll be sending them with a receipt request.
Please contact me should you have any questions.
Thanks kindly,

[redacted]

[redacted]



second zip file

[Redacted]

to:

[Redacted]

09/10/2013 02:19 PM

Show Details

History: This message has been replied to.

Thanks....

[Redacted]

[Redacted]

Article 28 site survey response cover letter

[REDACTED]
to:

[REDACTED]
09/10/2013 02:16 PM

Cc:
[REDACTED]

History: This message has been replied to.

Good afternoon [REDACTED]

Please find attached the cover letter for the Article 28 Site Survey Response.

Due to the size of the zip folders containing the supporting documents for the response to the SOD, we'll be sending an additional two emails.

I'll be sending them with a receipt request.

Please contact me should you have any questions.

Thanks kindly,
[REDACTED]

[REDACTED]

Doc #2

[REDACTED]

September 9, 2013

Re: Article 28 Diagnostic and Treatment Center Follow Up Survey
November 30, 2012

Dear [REDACTED]

In response to your letter of August 27, 2013 we have made revisions to the plan of correction related to the subject follow-up survey. You will find in the attached file the following changes in [REDACTED] [REDACTED] policies and procedures and forms and documents requested.

Tag 2068:

1. The [REDACTED] policy and procedure has been revised
2. The Lead Clinician Job Description has been revised

Tag 2070:

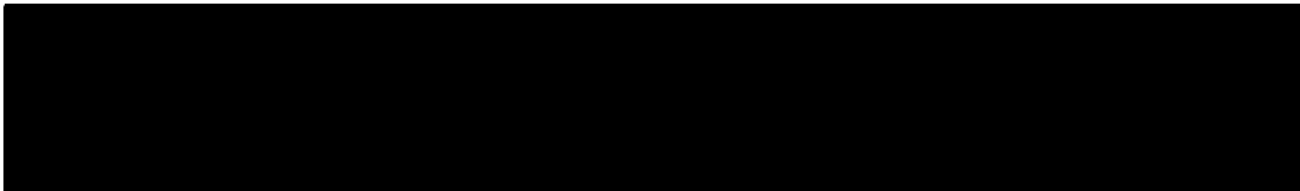
1. The [REDACTED] has been revised
2. Form: [REDACTED]
3. Form: [REDACTED]

Tag 2097:

1. Annual Skills form revised
 2. CA/CR duties revised
- [REDACTED]

Tag 2114:

1. Description of number of [REDACTED] abortion charts to be audited per site.
2. Clinic Work Plan revised



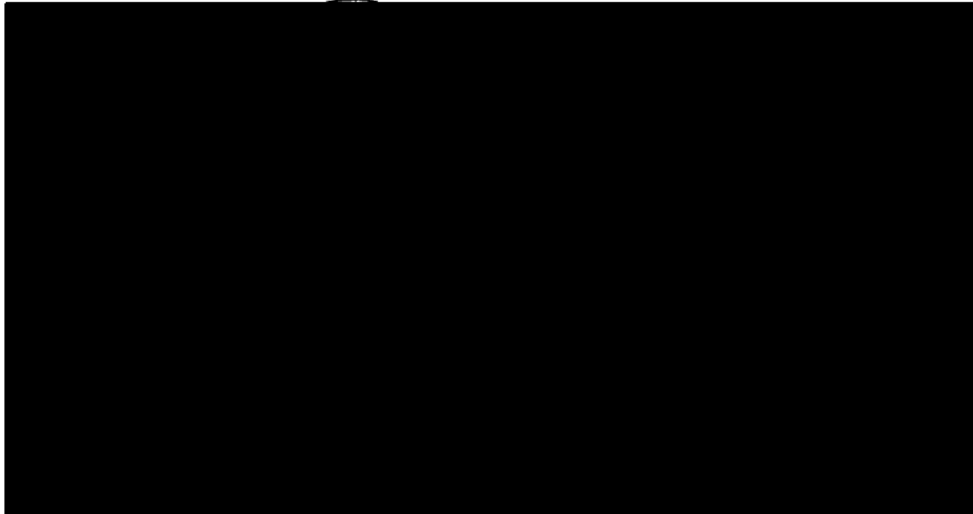
Tag 2240:

1. Response to deficiencies noted in cover letter
2. Revised pharmaceutical policy and procedure that addresses the statement of deficiency surrounding medication distribution
3. Description of audit process for infection control practices
4. Documentation that Pharmacy Consultant is being consulted
5. Credentials of Infection Control Specialist
6. Updated Pharmacy Consultant attestation

Tag U 7045:

1. APIC Infection Control Specialist's review and recommendations

Please contact me should you have questions regarding any of the documents we have submitted.





Re: Article 28 site survey response cover letter



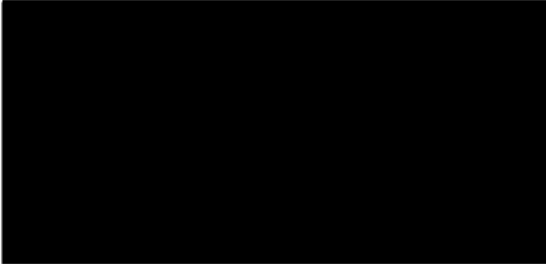
Sent by: [REDACTED]

to: [REDACTED]

09/10/2013 02:38 PM

Received!

RESPONSES MUST BE SENT TO THIS E-MAIL ADDRESS ONLY.



[REDACTED] Good afternoon [REDACTED] Please find attached t...

09/10/2013 02:16:31 PM

Article 28 site survey response cover letter

[REDACTED] to: [REDACTED]

09/10/2013 02:16 PM



Good afternoon [REDACTED]

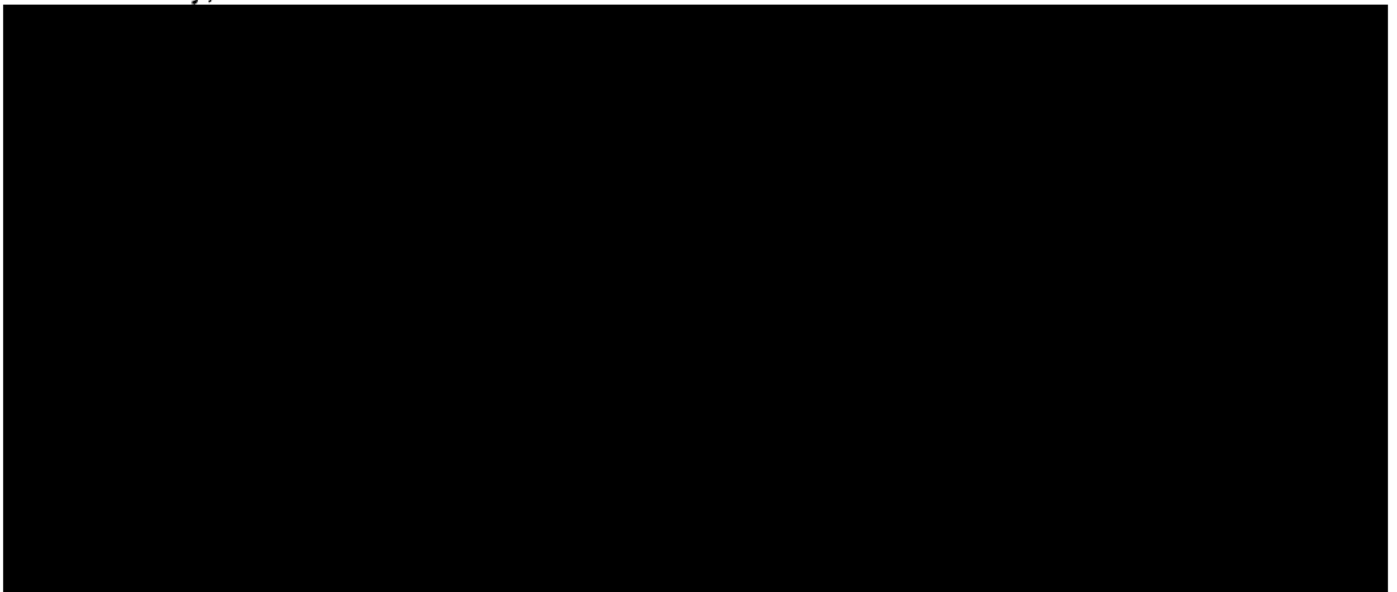
Please find attached the cover letter for the Article 28 Site Survey Response.

Due to the size of the zip folders containing the supporting documents for the response to the SOD, we'll be sending an additional two emails.

I'll be sending them with a receipt request.

Please contact me should you have any questions.

Thanks kindly,





[REDACTED]

[REDACTED]

Policy Statement: In order for [REDACTED] to provide the best services to our patients, [REDACTED] acknowledges that a specific staff person must be assigned to coordinate the services of all affiliate centers with the services of [REDACTED] and [REDACTED]

Procedure:

- The Lead Clinician will be tasked with the coordination of services. This task will be reflected in the Lead Clinician's Job Description
- The Lead Clinician will be responsible for updating each center's referral book annually and as needed
- The Lead Clinician will be responsible for new staff training on the coordination of services.
- Patient referrals will be evaluated monthly by the clinician who has initiated the referral. This will be noted in the referral log book by the ordering provider's initial and date. All NP's and PA's employed by [REDACTED] have been approved to initiate referrals in accordance with [REDACTED] Standards and Guidelines. Lead clinician will evaluate referrals monthly by phone, site visits and/ or staff meetings.
- Recommendations for out of affiliate screening are at the discretion of the patient.
- Any patient who is determined to require emergent care will be referred to the ER immediately and followed up within 24 hours with a phone call, 72 hours if it is a Friday.
- Clinicians will consult with either the lead clinician or medical director on any patient they deem acute and requiring immediate referral

[REDACTED]

Employee: _____ Job Title: _____

Review for: ____ End of Probation ____ Yearly Evaluation

The following section will be completed by lead clinician evaluator:

A. CLINICAL SKILLS	Fully Competent	Needs Improvement	Not Trained
1. General			
Refers to current edition of affiliate protocols as needed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Introduction of self to client:			
Explains NP/PA/CNM role as requested/appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Briefly orients client to procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
History taking:			
Reviews history thoroughly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Elicits additional information in a concise manner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Demonstrates organization in interviewing technique.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Completes thorough chart review.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Documents concisely with appropriate descriptive terminology.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Prepares forms and other written materials in a legible and well-organized manner.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Specimen Collection			
Use of proper technique to collect Pap test:			
Adequately samples endocervix with cytobrush/swab, as appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Samples entire squamo-columnar junction.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Applies cells evenly to slide and fixes within 5 seconds (for slide based Pap).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Rinses liquid-based spatula and brush correctly and within 30 seconds to prevent fixation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of good technique for wet mount preparation:			
Properly handles specimen.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Accurately identifies organisms.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clinician makes sure specimens are labeled correctly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Sexually Transmitted Infections (STI)			
Review of sexual history, including STI risk assessment:			
Offers appropriate screening.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Uses appropriate criteria for diagnosis.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of clean technique:			
Washes hands before and after each patient.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Avoids contamination of "clean" hand throughout entire exam.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Avoids contamination of "clean" inanimate objects during entire exam.			
(supplies, table, lamp, self, chart, counters, lubricant, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Avoids contamination of clean parts of lab specimens (outside tubes, caps, pap, etc.).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Uses the "inside out" technique for removing glove.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Specific Birth Control Methods			
Use of barrier methods:			
<input type="checkbox"/> Direct observation <input type="checkbox"/> Chart review <input type="checkbox"/> Diaphragm			
Chooses appropriate size.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Provides instructions.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

A. CLINICAL SKILLS	Fully Competent	Needs Improvement	Not Trained
Barrier Methods Requests return demonstration when appropriate.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
IUC Insertion: <input type="checkbox"/> Direct observation <input type="checkbox"/> Chart review <input type="checkbox"/> Paraguard <input type="checkbox"/> Mirena	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Obtains appropriate informed consent documentation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does bimanual prior to insertion.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Explains procedure.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Uses good technique in cleansing cervix.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Applies tenaculum properly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sounds uterus using good technique.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Uses measurement obtained by sounding measure expected depth of uterine activity.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Inserts IUC using manufacturer's instructions.			
Use of implants: <input type="checkbox"/> Direct observation <input type="checkbox"/> Chart review <input type="checkbox"/> Implanon <input type="checkbox"/> Norplant (removal only)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Obtains appropriate informed consent documentation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Prior to insertion and removal, skin is prepped properly.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Maintains sterile field during insertion.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Follows manufacturer's instructions for removal.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
For Norplant, in removal, incision is <5 mm.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Implant(s) is removed without undue trauma.			
Clinician demonstrates competency in educating clients about removal.			
Injection of DMPA:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Clinician demonstrates judgment in reviewing appropriateness of DMPA for client.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Completes necessary chart review prior to DMPA administration (LMP, PT, etc.)			
5. GYN Services <input type="checkbox"/> Direct observation <input type="checkbox"/> Chart review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Takes appropriate history & education, as per protocol.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Performs complete exam and identifies normal and abnormal findings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Formulates appropriate diagnoses, treatment, HRT, as per protocol.			
6. Provision of Services Related to Medication Abortion			
Generation of provision of services related to pregnancy termination:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sizes uterus accurately via ultrasound.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Provides thorough post-AB assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is able to discern normal versus abnormal post-AB findings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Obtains appropriate informed consent documentation as needed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Explains procedures as performed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Completes exam systematically and efficiently.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Accurately identifies normal and abnormal findings			
Identification of assessment/clinical impression	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Identifies risk factions for BCM chosen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Accurately interprets lab findings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Accurately interprets physical findings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Synthesizes information from history and physical to form assessment/clinical impression.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



	Fully Competent	Needs Improvement	Not Trained
Medical Abortion-con't Is able to discern normal versus abnormal findings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A. CLINICAL SKILLS			
7. Men's Health Services <input type="checkbox"/> Direct observation <input type="checkbox"/> Chart review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recognizes/assesses deviations from normal.			
Appropriately diagnoses and manages conditions in male patients, per protocol.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Management/Plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Performs/orders lab tests per protocol with respect for individual needs and economy.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Accurately provides BCM with respect for individual needs.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Accurately provides medications based on assessment.			
Refers/recommends as appropriate per protocol and based on individual needs.			
9. Proficiency Testing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test type:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Slide test/other <input type="checkbox"/> Hcg <input type="checkbox"/> Rapid HIV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other:			

Part II ATTACH THE FOLLOWING:

 if indicated





Major Strengths: _____

Major Weaknesses: _____

Developmental Plan: Wherever performance is identified as unsatisfactory or marginal define a plan to bring performance level to acceptable standards. Do the same for identified major weakness.

Overall Evaluation		
()	()	()
Unsatisfactory	Satisfactory	Off Probation

Evaluation Completed by: _____ Date: _____

Employee Signature: _____ Date: _____

VPPS Signature: _____ Date: _____

Medical Director Signature: _____ Date: _____





CLINIC ASSISTANT/
JOB TITLE: CLINICAL RECEPTIONIST

STATUS: Non-exempt

REPORTING TO: [Redacted] Manager

POSITION SUMMARY: Provides education and patient care under the supervision of a RN/Provider related to family planning, pregnancy and options counseling, reproductive health, abortion, colposcopy, LEEP and sexually transmitted infections for males and females.

ESSENTIAL DUTIES:

Customer Service Skills

1. Answers telephones in timely professional manner.
2. Greets patients and visitors in a positive friendly manner.
3. Routes calls appropriately.
4. Receives patient calls, writes accurate messages and puts charts up for clinic staff to review and return patient call.
5. Accurately registers and schedules patients in practice management system.
6. Collaborates with clinical and non clinical team members to provide excellent internal and external customer service and satisfaction.
7. Responds to patient calls in a timely manner while providing accurate information.
8. Adhere to affiliate goals and policies on professionalism, wait time [Redacted] and on the phone, and the system for addressing client complaints.

Clinic Support

1. Understands and demonstrates compliance with [Redacted] policies and procedures related to providing patients with birth control supplies.
2. Accurately documents in the medical records.
3. Retrieves medical records for internal and external quality management audits or as required.
4. Prepares patient charts for all [Redacted] visits.
5. Transfers and receives patient medical records according to policy and procedure.
6. Demonstrates accuracy in receiving, documenting and filing of patient laboratory results in accordance with [Redacted] procedures.

7. Responsible for patient reminder calls, reschedules cancellations and no show patient visits.
8. Works as a part of a team to maximize productivity standards of 4 patients per hour.
9. Reviews monthly financial and patient visit reports.

Financial Support

1. Provides accurate information costs of the visit and collect payment at time of the visit. Assist patients with billing Issues.
2. Accurately collects and enters insurance information in the practice management system, and obtain copies of all insurance cards at each visit. Obtains consents for billing.
3. Completes patient financial interviews, assigns correct fee categories, and facilitates enrollment in the [REDACTED] (FPPD) [REDACTED]
4. Conducts audits to ensure documentation accurately reflects reimbursement and patient pay class assigned is correct.
5. Accurately registers patient in the Practice Management system, assesses demographics and contact status.
6. Participate in health center/affiliate efforts to achieve established revenue cycle goals.

Patient Care

1. Under the supervision of licensed clinical staff, provides non judgemental education and care related to family planning, reproductive health and STI's for males and females.
2. Interviews patients on entrance to the [REDACTED] prior to the exam.
3. Review patient plan of care and reinforces teaching documented by the clinician.
4. Provides interventions as ordered by clinician, and documents in patient medical record according to [REDACTED] DOH, and NAF standards and guidelines.
5. Initiates and completes follow up as ordered by clinical staff regarding abnormal labs and test results according to follow up protocols.
6. Provides support ,under the supervision of a RN/LPN/Provider, to patients receiving colposcopy,LEEP and Abortion services according to surgical standards and protocols.
7. Assures [REDACTED] has adequate supplies in stock to deliver patient care. Completes inventory on a monthly basis and completes request for supplies to be ordered. Prepares [REDACTED] exam rooms for [REDACTED] visits.
8. Restocks exam, intake and medication rooms daily to assure efficient patient flow under the general supervision of licensed staff.

9. Performs various medical lab functions, collecting blood and urine specimens, pregnancy testing, blood pressure, hemoglobin, weight and height while using aseptic technique and universal precautions.
10. Provides HIV counseling and testing under clinical staff guidance.
11. Accurately documents in the medical record. Writes legibly.
12. Complies with HIPAA rules and regulations.
13. Other duties as assigned.

REQUIRED SKILLS AND ABILITIES:

1. Ability to organize, prioritize and manage multiple tasks and data with accuracy, attention to detail, flexibility while maintaining confidentiality.
2. Excellent interpersonal skills with ability work cooperatively with internal and external customers of diverse backgrounds.
3. Excellent verbal, written and computer skills.
4. Commitment to [REDACTED] core values of teamwork, compassion, confidentiality and quality care.
5. Acceptance and understanding of [REDACTED] Personnel Policies.
6. Ability to travel to other centers as needed
7. Current certification in BLS/CPR.
8. [REDACTED]
9. Willingness to work flexible hours.
10. Assists in training of new employees.

QUALIFICATIONS:

1. High School diploma or GED required.
2. Family Planning/GYN office experience preferred.
3. Direct patient care experience and computerized medical office operations experience preferred.

PHYSICAL DEMANDS/WORKING CONDITIONS

1. Lift/carry 10 lbs. or less frequently, and up to 50 lbs occasionally
2. Bend/squat/kneel frequently
3. Twist/turn constantly
4. Climb stairs frequently
5. Type/keyboard constantly

Employee's Printed Name

Employee's Signature

Date

Supervisor's Signature

Date



Emergency Medical Box Contents

- All emergency boxes are immediately accessible and not behind locked doors during clinical sessions.
- A licensed professional is responsible for maintaining the emergency box medications and supplies.
- Monthly checks of the emergency box are performed by licensed personnel and documented with signature. A record is kept of monthly checks.
- A tamper-proof lock is kept on all emergency boxes. It is removed at the time of monthly checks and emergencies, and is then replaced.
- Contact your local state agency for other regulations regarding maintenance of the emergency box (i.e. some states require the emergency box to have a second lock that is fastened when medical services are not being provided).
- The Emergency Medical Box will be audited/inspected monthly and after each procedure if contents used. The staff will document the audit/inspection on the monthly checklist/After Use Inspection Audit

Representative List of Emergency Contents for Centers Providing Surgical Services



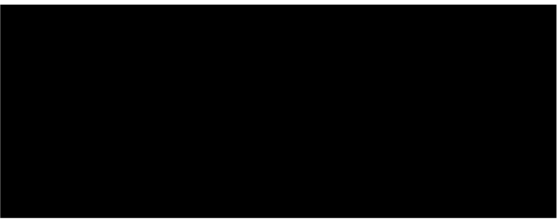
**Note: Misoprostol is used for post-abortion hemorrhage, especially for clinics that do not stock Hemabate. In addition, some affiliates prefer to stock the following medication in their emergency kit (must be refrigerated): Carboprost tromethamine (Hemabate) 250mcg/ml.*

- *Classification: Prostaglandin*
- *Action: Stimulates myometrium contraction of the uterus*
- *Uses: Unlabeled use to reduce blood loss secondary to uterine atony*
- *Dosage: 250mcg IM; may repeat every 10-15 minutes if no response not to exceed 12mg*
- *Side Effects: Fever, flushing, chills, cough, headache*



Executive Summary





Introduction

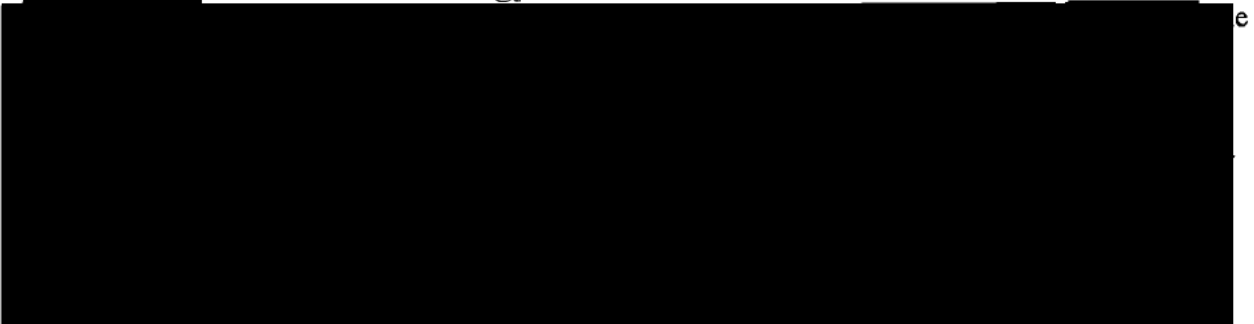
[REDACTED] is a [REDACTED] company specializing in infection prevention and control solutions. Utilizing the expertise of our industry-leading consultants, [REDACTED] works in various healthcare settings to prevent and control healthcare acquired infections (HAIs). With access to leading resources and world-renowned experts in infection control, no other consulting firm offers the level of knowledge and expertise. [REDACTED] is a wholly [REDACTED] of the [REDACTED]. [REDACTED] has been the leader in striving to end healthcare-associated infections for over [REDACTED] years. [REDACTED] was created to assist in these efforts by bringing expertise directly to clients to offer customized solutions.



[REDACTED] contracted by [REDACTED] to conduct a comprehensive assessment of the facility, with the goal of specifically addressing the New York State Department of Health (NYSDOH) Statement of Deficiencies (SOD) associated with breaches in infection control standards for ambulatory care centers. The assessment was to include both a review of relevant data and documents as well as a comprehensive onsite evaluation to identify problem areas and provide recommendations for addressing the infection control SOD's facility specific and/or system-wide. As of March 26, 2013, [REDACTED] had not received the official NYSDOH SOD report.

The assessment was performed by an certified [REDACTED] with over [REDACTED] years of infection control and prevention experience. [REDACTED] all meet the following criteria:


- Must be CIC ®, Certified in Infection Control through the Certified Board of Infection Control and Epidemiology, Inc.
- 15 years + experience within infection control and prevention
- Hold a RN or higher degree from an accredited institution

Background and methodology



- 
-
- 
- Processing of specimens not compliant: cannot bring specimen from dirty utility room to clean utility room to be entered into computer.

A review of these anticipated NYSDOH infection control deficiencies identified the following categories requiring assessment:

- Quality controls for sterilization processing of instruments.
 - Handling and disposal of used needles/syringes.
 - Internal handling/transportation of laboratory specimens.
 - Outdated multi-dose medication vials.
 - Blood drawing activities in medication preparation areas.
 - Availability of personal protective equipment (PPE).
 - Appropriate use of refrigerator thermometers.
- 

[REDACTED]

In preparation for the on-site facility visit, multiple documents were reviewed to assess [REDACTED] organizational system-wide infection control policies/procedures for each of the identified categories identified and consistent with published standards and federal/state infection control regulations. Documents reviewed included:

- [REDACTED]
- [REDACTED]
 - NY state regulations addressing infection control practices.
 - Recognized publications for infection control standards of practices.
 - [REDACTED] policies on competency processes to ensure employee knowledge of the infection control practices related to the anticipated deficiencies and with the identified infection control breaches.



Recommendations

1. Designated areas for autoclaves

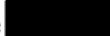


- A. The [REDACTED] autoclave should be relocated from the [REDACTED] office to a dedicated sterilization only work area. Until facility renovations can establish a dedicated work area, the autoclave can be temporarily relocated to the instrument cleaning and laboratory processing room. The autoclave must be physically separated from the designated instrument cleaning area. Signage must be readily visible to designate the physical separation. No instrument cleaning or laboratory processing tasks are to be performed during instrument sterilization activities. At the completion of each instrument sterilization cycle, processed items must be removed from the room and stored in clean area.
- B. The [REDACTED] infection control manuals need to include guidelines designating and identifying the most appropriate work area for autoclaves.


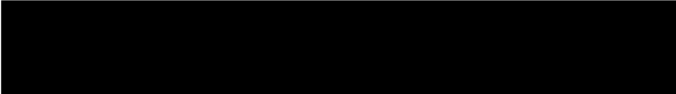
2. Post-sterilization instrument verification

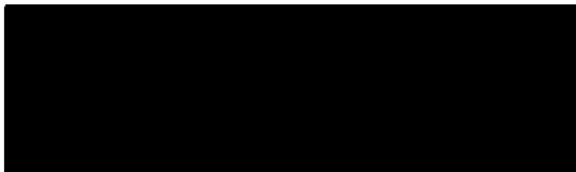
- A. Use of tags to identify instruments awaiting sterilization process are not necessary and should be discontinued in all facilities. Wrapped packs and unwrapped trays should only be placed in the autoclave just prior to initiating the sterilization cycle. A change in either the process heat sensitive tape/integrated tab or chemical indicator strip are one of the tools to be used in verifying if a set of wrapped and/or unwrapped instruments has completed the sterilization cycle.

- 
- B. The tool used to record sterilization parameters at the completion of each processed load should be referenced to verify a completed sterilization cycle. Records need to be maintained per state and local requirements.
 - C. System-wide, all staff, who are directly responsible for the sterilization of instruments, should be retrained and competency assessed for how instruments are verified after completion of the sterilization cycle.
 - D. System-wide, all staff, who access or use wrapped or packaged instruments, should be reeducated and competency measured on how to identify sterilized from unsterilized instruments, both commercial and in-house processed products.
 - E. The /OSHA infection control manuals should update the guidelines for assessment and documentation of sterilization parameters, both mechanical/physical and internal chemical process indicators (tape/chemical indicators), for each autoclave type.

3. Monitoring and implementation of instrument sterilization processing quality controls

- A. A system-wide sterilization quality control program needs to be developed and implemented as outlined in the CDC's *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008, pp 91-92*.
- B. Consider replacing the Ritter® table top autoclave at the  facility, as well as at the other  facilities, with newer and a more efficient models.
- C. Review and confirm what type of autoclaves are used in each facility and ensure they are operated per manufacturers' operating instructions and sterilization parameters are consistent with the  infection control manual guidelines.
- D. Discontinue the practice of sealing instrument peel pouches with heat sensitive process autoclave tape. Peel pouches should be a self-sealing product, or if not available then heat sealed.
- E. It is required that a process indicator (i.e. heat sensitive tape or tab integrated into peel pouch) be affixed to the outside and a multi-variable chemical indicator strip be placed inside of each peel pouch and wrapped pack.
- F. A multi-variable chemical indicator strip classified as class 4 or 5, should be considered for peel pouches and wrapped packs. Refer to *American National Standard (ANSI)/AAMI Sterilization of Healthcare Products-Chemical Indicators-Guidance for Selection, Use and Interpretation of Results, 2008*.

- 
- G. The single-variable class 3 chemical indicator strip currently used, which is intended to respond to only one parameter of the sterilization process, is appropriate for placement in each unwrapped instrument tray being processed.
- H. A label on each peel pouch, wrapped pack and unwrapped autoclave load is required to include; a load number, processing date and operators initials. The same information is required to be documented either manually or if available, or an autoclave digital printout.
- I. At the completion of each sterilization load, the mechanical/physical (time, temperature and psi) and results of the external process and internal chemical indicators needs to be recorded. Records need to be maintained per state and local requirements.
- J. Staff directly responsible for the processing of instruments for sterilization should receive comprehensive training on standards of practice for monitoring and ensuring sterilization of instruments. Ensure staff understand manufactures' operating instructions. Update competency of staff to evaluate understanding of changes aimed at ensuring quality controls for all sterilization processes.
- K. Staff responsible for instrument sterilization may benefit in updating their instrument processing knowledge by shadowing central sterile supply personnel at an area hospital.
- L. A written corporate policy needs to be established for sterilizing instruments from non-affiliated facilities. The policy should establish if and how processing, sterilizing and transporting instruments by facilities not associated with [REDACTED] will be implemented.
- M. Update the [REDACTED] infection control polices and instructions for removing each autoclave load, which should include assessment and documentation of the load meeting sterilization cycle parameters for mechanical/physical and all process/chemical indicators (tape/chemical indicators).
- N. Update all sterilization policies to be in compliance with the Centers for Medicare & Medicaid Services (CMS) CFR 42.416.51 regulations recently published in the CDC's *Guidelines on Infection Control in Ambulatory Surgical Centers 2011* and *Infection Control in Ambulatory Surgical Centers Checklist 2011*.
- O. Review of sterilization monitoring results should be incorporated into the [REDACTED] quality assurance program. Sterilization monitoring results from all facilities should be reviewed quarterly by the infection control committee and semi-annually by corporate quality assurance administrator(s).
- 



4. Storage and rotation of sterile supplies

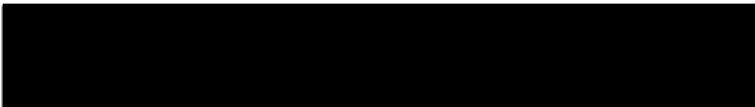
- A. A par-stock system should be established for vaginal speculums in client examination rooms. Only the number of vaginal speculums needed each day should be in the examination warming drawer. At the end of the day, the examination table drawer should be wiped with a PDI™ disposable disinfectant cloth and drawer restocked from the in-room cart drawer. Newly reprocessed vaginal speculums should be placed in either the cart drawer or a covered plastic storage container in each examination room.

5. Separation of instrument cleaning (dirty), sterilization, laboratory processing and medication preparation work areas

- A. [REDACTED] there must be a locked door separating instrument cleaning areas from sterile processing work stations. Doors are necessary [REDACTED] is important to prevent entry of unauthorized non-facility personal into facility work processing areas. [REDACTED] needs a locked door to the instrument cleaning work area and another door separating the [REDACTED] from the hallway entrance into the [REDACTED] work stations. [REDACTED] needs a door separating the [REDACTED] work area from the patient examination area.
- B. There must be separate and designated work areas for instrument cleaning and sterilization activities, laboratory processing and medication preparation tasks. Laboratory specimens cannot be brought into the sterile processing work area for any reason. Laboratory processing cannot be performed in medication preparation and storage areas. Where structural barriers (walls, doors, etc.) cannot be constructed to physically segregate these work areas, signage must be clearly posted identifying the work area and entry by authorized personnel only.
- C. Blood drawing procedures should be performed in patient examination rooms.

6. Outdated multi-dose medication vials

- A. [REDACTED] needs to develop comprehensive client specific safe injection practices program that incorporates; standards for appropriate use of single and multi-use needles, syringes, and multi-dose medication vials [REDACTED] lacks a comprehensive set of written standards addressing safe injection practices to protect patients from exposure to infectious agents. Policies need to be in compliance with the CMS CFR 42.416.51 regulations recently published in the CDC's *Guide to Infection Prevention for Outpatient Settings: Minimum Expectations of Care and Checklist*, 2011.



- [REDACTED]
- B. Staff responsible for the administration and/or handling of single and multi-dose medication vials should receive comprehensive training on safe injection practices to prevent and protect patient exposure to infectious agents. Update staff competency to evaluate understanding safe injection practices aimed at protecting patients from exposure to infectious agents per CMS CFR 42.416.51 regulations.

7. Handling and disposal of used needles and syringes as RMW

- A. Staff responsibilities should be established for changing and replacing sharps containers.
- B. Floor-style in-use sharps collection canisters used in patient examination rooms need to be secured and locked.
- C. Provide address labels for each [REDACTED] facility that can be affixed to the in-use sharps containers.
- D. Develop a written policy and guidelines for transporting RMW to other [REDACTED] facilities for licensed vendor pickup. Guidelines should be consistent with NYSDOH PHL and RMW part 70 regulations.
- E. There needs to be education and competency standards developed and provided to individual(s) responsible for transporting RMW to off-site [REDACTED] facilities.
- F. Staff needs reeducation on differentiating regulated from non-RMW. Request the RMW vendor to provide education to staff on types of regulated and non-RMW and requirements for disposal (facility/vendor) and transporting between facilities. Solicit the licensed vendor to support and conduct RMW education for all [REDACTED] facilities.

8. Availability of PPEs

- A. Staff responsibility should be established for assessing and par-stocking client examination rooms.
- B. PPEs should be visibly and readily accessible, but not overstocked in each room or work area where there is potential/anticipated employee exposure to blood and blood fluids.

[REDACTED]

JOB TITLE: Lead Clinician

STATUS: Non Exempt

REPORTING TO: VP of Patient Services

POSITION SUMMARY: The Lead Clinician assists in the oversight of the medical programs and quality management of patient care provided by [REDACTED]. The Lead Clinician assists in the compliance with [REDACTED] Medical Standards and Guidelines, state and local regulations, community standards, and [REDACTED] policies. The Lead Clinician provides guidance and mentors clinic staff on medical practice issues, policies and procedures. The Lead Clinician is the coordinator of services between [REDACTED] and community health facilities, programs and community agencies. In addition, the Lead Clinician provides direct medical care to family planning and abortion patients.

ESSENTIAL DUTIES:

1. Provides agency orientation, teaching and coaching for Nurse Practitioners and Physicians Assistants.
2. Provides clinical leadership by teaching, coaching and consultation on clinical management issues for all clinical staff.
3. Assists with the facilitation of the semi-annual provider meetings.
4. Conducts annual evaluations for all midlevel clinicians with input from VPPS and Medical director
5. Contributes to the overall effectiveness of the agency by adhering to established agency policies and practices.
6. Addresses provider training needs as directed by the Medical Director and VP of Patient Services.
7. Provides ongoing technical assistance and in-service training for licensed and unlicensed staff on an intermittent basis in collaboration with the Medical Director, VP of Patient Services and Regional Managers.
8. Maintains productivity expectations and compliance of agency standards.
9. Conducts on site Peer Review, chart and referral audits at all clinics as required..
10. Performs medical screening procedures as appropriate for [REDACTED] clients.
11. Performs reproductive health assessments for female and male clients.

12. Refers clients with abnormal conditions found on examination to the Medical Director and/or other physicians or medical facilities as needed per health center guidelines and/or client needs.
13. Serves as the agency coordinator for the referral and coordination of social services for clients requiring these services. The Lead Clinician who will travel across the affiliate will work with all affiliate staff to assure that referrals are made. The Lead Clinician will liaise with the VP of Community Services at provider meetings to obtain updates on referral services.
14. Performs, orders and interprets routine laboratory tests.
15. Responsible for follow up of abnormal lab tests.
16. Performs medical referrals as indicated and appropriate follow up.
17. Participates in in-service training and community education as assigned.
18. Participates in problem solving and root cause analysis.
19. Serves as a resource person for patient or medical information calls.
20. Documents findings and referrals as required.
21. Adhere to affiliate policies on professionalism, wait time [REDACTED] and on the phone, and the system for addressing client complaints.
22. Participates in health center efforts to achieve established goals for productivity.
23. Participates in health center/affiliate efforts to achieve established revenue cycle goals.
24. Works independently to maintain up to date knowledge in the health care field via attending seminars and workshops and reading relevant material.
25. Assists in product evaluation.
26. Performs other duties as assigned.

OTHER

1. Communicates clearly and promotes a customer-focused vision and mission for self and [REDACTED] staff.
2. Acts proactively, anticipates problems and initiatives new and better ways of care delivery.

REQUIRED SKILLS AND ABILITIES:

1. Ability to organize, prioritize and manage multiple tasks and data with accuracy, attention to detail, flexibility and confidentiality.
2. Excellent interpersonal skills with ability to work cooperatively with internal and external customers.
3. Excellent business English, Microsoft Word, database, and Excel skills.
4. Commitment to [REDACTED] core values of teamwork, compassion, patient confidentiality and quality care.
5. Acceptance and understanding of [REDACTED] Personnel Policies.
6. Ability to travel.
7. Embraces the concept of team building ([REDACTED]) and values internal and external customer satisfaction.

QUALIFICATIONS:

1. Valid NP/PA license in New York State.
2. Current DEA license.
3. 5 years of demonstrated experience in reproductive health management is required with at least a year of prior experience with [REDACTED] or other [REDACTED] providers.
4. Proven leadership skills, which build teamwork, enlist cooperation and confidence. Capacity to mentor and build leadership skills in others.
5. Professional positive attitude with proved ability to contribute effectively to highly functioning work teams.

PHYSICAL DEMANDS/WORKING CONDITIONS

1. Lift/carry 10 lbs. or less frequently, and up to 50 lbs occasionally
2. Bend/squat/kneel frequently
3. Twist/turn constantly
4. Climb stairs frequently
5. Type/keyboard constantly

Employee's Printed Name

Employee's Signature

Date

Supervisor's Signature

Date



Year

	Colpo Machine Cleaned	LEEP Machine Cleaned	Sterilizers Cleaned	Lab Refrigerator Cleaned	Emergency Box and Equipment	Spore Checks Completed	Room & Refrigerator Temps. Done	Supplies Ordered & Meds Rotated	Quality Controls Completed	Fire Extinguishers / Safety Checks	Sharps	Protector Count
January												
February												
March												
April												
May												
June												
July												
August												
September												
October												
November												
December												

Please complete this form monthly. Initial and date in the appropriate box.



[REDACTED]

[REDACTED]

In keeping with the guidelines set forth by [REDACTED] and all state/local laws and regulations, the following policies will be implemented by P [REDACTED]

[REDACTED] contracts with a qualified pharmacist(s) to assist in the development of policies and procedures for providing medications and biologics. Moreover, the pharmacist consult will provide an annual and as needed review of practices, policies and procedures. (refer to [REDACTED])

Procurement:

The Medical Director only approves drugs approved by the FDA and only those from FDA certified manufacturers to be prescribed, dispensed and distributed at [REDACTED]

Drugs which may be prescribed by affiliate clinicians for patients to obtain at outside pharmacies include:

- All contraceptives listed in [REDACTED]
- All medications listed in [REDACTED]
- All drugs recommended for treatment of Sexually Transmitted Diseases in the current Summary of CDC Treatment Guidelines.
- [REDACTED] mg [REDACTED] as directed, [REDACTED] mg [REDACTED], as directed, or equivalent short acting anxiolytic, as a pre-medication for any procedure/exam at [REDACTED] including abortion.

Storage:

The drug storage areas of pharmaceuticals at [REDACTED] are secured at all times. The following staff at [REDACTED] may have access to the drug storage area for reason of stocking, inventory management, dispensing or distributing medication: Physicians, Physician Assistants, Nurse Practitioners, RN's, LPN's. Clinical Assistants, Clinical Receptionists and the Inventory Manager may restock under the supervision of licensed staff.

Medications may only be dispensed by licensed staff. Licensed staff may select the medication prescribed by the provider/physician and complete the label requirements as outlined below under Labeling

Distribution of Medications by Non-Licensed Staff

Non-licensed staff may only distribute medication that has been previously dispensed by a provider/physician and placed in a central location for distribution; the non-licensed staff may select the medication labeled with a particular patient's name and provide and/or distribute it to the patient named. In addition, non-licensed staff may also select a medication that has been prescribed by a provider/physician and prepare the medication with the proper label, but prior to the medication distribution, it must be checked by the provider for accuracy and approval for distribution.

[REDACTED]

[REDACTED]

Pharmaceuticals meant for internal use must be separated from those for external use. Clear and visible labeling is required.

Pharmaceuticals in all storage areas must be arranged so that the oldest stock is used first. On a monthly basis designated licensed staff will inspect the drug storage area for expiration dates. All expired medications will be disposed of according to policy. (See Disposal of Pharmaceuticals Policy)

Pharmaceuticals requiring refrigeration will require continuous temperature control monitoring for quality control. All refrigerators will be equipped with a data storage thermometer. Temperatures will be monitored and documented twice daily on the temperature log. When centers are not opened, temperatures will be retrieved from the thermometer's data storage and the minimum and maximum temperatures will be recorded on log. Should temperatures fall below or above recommended guidelines, pharmaceuticals will be disposed of according to the proper disposal procedures (see policy on disposal of pharmaceuticals)

Repackaging: [REDACTED] does not repackage medications

Repackaging must be done in accordance with state/local laws/regulations.

A log must be maintained to document the supervisor (by signature), the person doing the repackaging (by signature) and the identification of the bulk drug being repackaged. Logs must be archived for two years. The log should contain the following information:

- Complete product description-name, strength, manufacturer
- The manufacturer's lot number
- An expiration date, no later than the manufacturer's expiration date of a not previously opened manufacturer's container
- A control number that will link that manufacturer and drug lot with the repackaged units

All repackaged units must have a standard label affixed to each package, bottle, etc... before they are entered into active stock. The label must include at least the following:

- Name and address of the facility
- Name of the drug
- Strength of the drug when appropriate
- The expiration date, for drugs repackaged in "tight" containers such as plastic vials or glass bottles
 - This should be the date specified on the original manufacturer's container, or one year from the date the product was repackaged, whichever is earlier
- The control number linking that unit with the manufacturer's product drug lot- for example, a code showing the month and day of repackaging and number repackaged that day (for example,

[REDACTED]

control # 012104, where 01=month, 21=day of repackaging, and 04=fourth item repackaged that day)

Labeling Prepackaged Prescriptions for Patients:

All prepackaged units are received at [REDACTED] with a permanent label affixed directly to the package with at least the following information:

- Name and address of the affiliate
- Name and strength of the drug
- Manufacturer and distributor if different from the manufacturer
- Standard directions for use including: frequency and route of administration

The label must also include the following information, which may be added by hand at the time of dispensing by the provider/physician, RN, LPN

- Name of provider prescribing medication
- Date of prescription at the time of dispensing
- Name of patient

Auxiliary labels particular to each individual drug will be used and placed on package as needed.

The plastic case or other container for oral contraceptives must bear the full label and include the FDA package insert. The refill units given at the same time need not be individually labeled. If the original case or container is not presented for subsequent refills, then the refill units can be put into a bag and the outside of the bag labeled.

Controlled Substances:

[REDACTED] does not carry, maintain or dispense controlled substances.

Other:

It is the policy of [REDACTED] that multi-dose injectable medication vials must be labeled with the date that they are opened and then be disposed of 28 days later, except for Tubersols which are disposed of 30 days after being opened and vaccines which are disposed of by their expiration date. (For proper disposal see [REDACTED] Disposal of Pharmaceuticals Policy and Procedure")

All patients who receive medications from [REDACTED] receive written or verbal instructions including the name, purpose, and appropriate administration technique for each drug. Patient package inserts must be provided for IUC's, hormonal contraceptives, and other estrogenic and progestational substances. Patient drug information is provided on all other drugs dispensed. All patient education is documented in the medical record.

[REDACTED]

[REDACTED]

Management of Pharmaceutical Product Irregularities

Pharmaceutical product irregularities may be detected in the form of defects in drug or device packaging, tablet discoloration, or dose sequencing. Such problems may be the result of a defective manufacturing or packaging processes, failure of the pharmaceutical company's product inspection mechanism, or tampering with the product at any point between the product's packaging and its use by the patient. Because these products may be dangerous to the patient and because other units may be defective, prompt action is necessary to deal with these events.

When an irregularity of a pharmaceutical product is suspected, the following must be done:

- The package of medication in question must be held in a secure place at the affiliate, as later transfer to the manufacturer or the FDA may be necessary. There must be no attempt to manipulate or otherwise alter the package, as it may constitute evidence in a criminal suit or other action.
- Remaining stock of medication with the same lot number must be identified, put aside, and not dispensed to patients until the problem has been resolved.
- Medical affairs must be notified immediately by telephone for evaluation of the situation and provision of further instructions. [REDACTED] will not take any additional steps (such as notification of the pharmaceutical company, FDA, other patients who may have been exposed to the product, and the media) until it receives guidance from [REDACTED]

Drug and Device Recalls

The FDA initiates drug recalls of drugs or devices that are found to be in violation of federal law. The recalls are classified according to the potential adverse impact of the volatile drug or device upon the health exposed individuals.

Definitions:

Class I recalls are situations in which there is a reasonable probability that the use of or exposure to a volatile product will cause serious adverse health consequences or death.

Class II recalls are situations in which use of or exposure to the volatile product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.

[REDACTED]

[REDACTED]

Class III recalls are situations in which use of or exposure to a volatile product is not likely to cause adverse health consequences.

Procedures:

Class I Recalls

- Purchase logs must be evaluated for a period of not less than two years prior to the date of the recall.
- All volatile product must be quarantined. Product must not be provided to any patient until it is verified that stock does not contain involved lot numbers.
- Any of the volatile product found in stock must be removed from the inventory unless otherwise indicated in the recall information.
- If it is determined that none of the volatile lot(s) have been received at [REDACTED] then the only further action required is to verify that none of the involved lots are shipped to the health center during the next two months.
- If it is determined that product from the volatile lot(s) has been provided to patients within the past two years, the following actions must be taken:
 - Daily computerized tracking logs and/or medical records must be reviewed to determine which patients received product from the volatile lot(s).
 - An attempt must be made to contact identified patients by telephone.
 - If it is determined that the patient received the product from the volatile lot(s), or if the lot cannot be determined, the patient must be instructed to discontinue the medication and bring it back to the [REDACTED] immediately for replacement with an on-involved lot of the same medication, if available. If a non-involved lot cannot be obtained for the patient, the patient must be changed to an alternate medication.
 - If it is determined that the patient received the named medication, but not from the involved lot(s), she or he should be reassured that continuation with their prescribed regimen is safe.
 - If an identified patient cannot be contacted by telephone, a letter must be sent to her/him, explaining the nature of the recall and requesting that the [REDACTED] be contacted.
 - If a patient experiences a significant medical problem resulting from the use of the volatile product, [REDACTED] Medical Affairs and ARMS must be informed.

Class II Recalls

- Purchase logs for the past year must be checked to determine if any of the volatile lots have been received.
- Any volatile product found in stock must be removed from inventory and prepared for return to the supplier.

- [REDACTED]
- If it is determined that the product from the volatile lot(s) has been provided to patients within the last six months, the following actions must be taken:
 - Daily computerized logs and/or medical records must be reviewed to determine which patients received product from the volatile lot(s).
 - An attempt must be made to contact identified patients by telephone.
 - If it is determined that the patient received product from the volatile lot(s), the nature of the recall must be explained and the patient must be requested to return any outstanding supply of the volatile product to the clinic.
 - If it is determined that the patient received the named medication, but not from the involved lot(s), she or he should be reassured that continuation with their prescribed regimen is safe.
 - If an identified patient cannot be contacted by telephone, a letter must be sent to her/him, explaining the nature of the recall and requesting the return of any outstanding volatile product.
 - If a patient experiences a significant medical problem resulting from the use of the volatile product, [REDACTED] Medical Affairs and [REDACTED] must be informed.

Class III Recalls:

- No product lot listed in a Class III recall may be provided to a patient.
- The volatile substance must be removed from inventory and returned to the supplier.

[Redacted]

Statement of Compliance

I have reviewed the attached [Redacted] Pharmacy Services policies and procedures and find them to be in compliance with all New York State Department of Health, SED Board of Pharmacy and [Redacted] regulatory requirements.

[Redacted]
[Redacted] Pharmacist Consultant

9-9-13
Date



PHARMACIST CONSULTANT CONTRACT

This agreement is entered into between [redacted] (hereinafter referred to as [redacted] located at [redacted] and [redacted] (hereinafter referred to as Pharmacist) located at [redacted] N.Y.

[redacted] will schedule an onsite consultation with New York State Licensed Pharmacist annually and other consultants as needed.

The Pharmacist will provide overview and assistance regarding:

- Maintenance and development of policies related to medications and biologics
- Annual review of pharmaceutical practices, policies and procedures
- Disposal of expired or deteriorated medications and biologics
- Storage, dating, labeling and monitoring of expiration dates
- Documentation of written prescriptions
- Medical record review
- Physical plant inspection

Following the onsite audit, the Pharmacist will provide a written report of findings within 30 days to the VP of Patient Services.

The Pharmacist will provide [redacted] a copy of their current NYS License.

The Pharmacist will be paid \$50⁰⁰/hr for services conducted. Travel reimbursement will be \$0.52 per mile.

The Pharmacist will sign confidentiality and HIPAA agreements. (See Attachments A and B)

Signed [redacted] President and CEO

Date 9/9/2013

Signed [redacted] Pharmacist

Date 9-9-13

[REDACTED] New York
Emergency Cart/Equipment Inspection: After Use
[REDACTED]

Date

Albuterol Inhaler	
Expires:	
Atropine 0.4mg/ml	
Expires:	
Compazine 5mg/ml	
Expires:	
Diphenhydramine (Benadryl)50mg cap	
Expires:	
Diphenhydramine (Benadryl) IM 50mg/ml	
Expires:	
Epinephrine 1:1000 (1mg/ml)	
Expires:	
Methergine 0.2mg/ml (Refrigerator)	
Expires:	
Toradol 30mg/ml	
Expires:	
Solu-Medrol 125mg/2ml	
Expires:	
Misoprostol 200mg #4 (Pburgh only)	
Alcohol Prep Pads	
AA Batteries	
Band-Aids	
Bulb Syringe	
4x4 Sterile Gauze Pads	
Exam Gloves (non-latex)	
3ml Syringes with 21g Needles	
TB Syringes	
Angiocaths - 18, 20	
IV Tubing	
IV Solution - LR or NS 500ml	
Expires:	
23 3/4G Butterfly	
Tourniquet	
3-0 Chromic	
Sterile Suture Set	
Airways	
Ambu Bag & Non-Rebreather Mask	
Nasal Cannula	
CPR Shield	
Foley Catheter	
Stethoscope	
Oxygen Tank with liter meter >¼ full	

After completion, please give a copy of this form to your [REDACTED] Manager and the RQM

[REDACTED]

Emergency Cart/Equipment Inspection: After Use

[REDACTED]

Date _____

Albuterol Inhaler	
Expires:	
Atropine 0.4mg/ml	
Expires:	
Compazine 5mg/ml	
Expires:	
Diphenhydramine (Bendryl) PO 50mg caps	
Expires:	
Diphenhydramine (Benadryl) IM 50mg/ml	
Expires:	
Epinephrine 1:1000 (1mg/ml)	
Expires:	
Solu-Medrol 125mg/2ml	
Expires:	
Alcohol Prep Pads	
Adhesive Tape	
4x4 Sterile Gauze	
3ml Syringes with 22g Needles	
TB Syringes	
23 3/4g Butterfly	
IV Solutions - LR or NS 500ml	
Expires:	
IV Tubing	
Tourniquet	
Angiocaths -18 or 20	
Airways	
Ambu Bag	
Nasal Cannula	
CPR Shield	
Non-Rebreather Mask	
Oxygen Tank with liter meter >¾ full	

*After completion, please give a copy of this form to your [REDACTED] Manager and the RQM

Note: All emergency medications must be ordered 2 months prior to expiration date.

[REDACTED]

Plan of Correction in Response to Statement of Deficiencies issued on August 27, 2013
Regarding Article 28 Diagnostic and Treatment Survey of 2012

ID PREFIX TAG: T2068

Plan of Correction	Monitoring and Implementation	Completion Date
<ul style="list-style-type: none">• [REDACTED] staff make appropriate referral to appropriate agencies or providers. If staff need assistance with coordination of referral, they will contact the lead clinician • Lead clinician job description has been revised	<ul style="list-style-type: none">• Lead clinician will be in monthly contact with all providers to review referrals. Contact will be during [REDACTED] visits or monthly staff meeting or by phone. Refer revised Coordination of Services policy • Refer to lead clinician job description #13	<ul style="list-style-type: none">• 9/4/2013 • 9/4/2013

[REDACTED]

Plan of Correction in Response to Statement of Deficiencies issued on August 27, 2013
Regarding Article 28 Diagnostic and Treatment Survey of 2012

ID PREFIX TAG: T2068

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[REDACTED]

Plan of Correction in Response to Statement of Deficiencies issued on August 27, 2013
Regarding Article 28 Diagnostic and Treatment Survey of 2012

ID PREFIX TAG: t2097

Plan of Correction	Implementation/Monitoring	Completion Date
<ul style="list-style-type: none">• Annual skills form reflects lead clinician is evaluating mid level providers • CA/CR may be assigned duties of restocking meds under the general supervision of licensed staff	<ul style="list-style-type: none">• Annual skills form revised to reflect change • In compliance	<ul style="list-style-type: none">• 9/13 • 9/13

[REDACTED]

Plan of Correction in Response to Statement of Deficiencies issued on August 27, 2013
Regarding Article 28 Diagnostic and Treatment Survey of 2012

ID PREFIX TAG: t2097

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[REDACTED]
Plan of Correction in Response to Statement of Deficiencies issued on August 27, 2013
Regarding Article 28 Diagnostic and Treatment Survey of 2012

ID PREFIX TAG: T2070

<u>Plan of Correction</u>	<u>Implementation and Monitoring</u>	<u>Completion Date</u>
<p>Inspections of emergency equipment will be done, at a minimum, monthly and after each use of the equipment and will be documented appropriately.</p>	<p>Emergency response equipment will be inspected, at a minimum, monthly and after each use. Completed inspections will be documented on the Monthly Cleaning/Maintenance and Safety Checklist and After Use Inspection. (see attached)</p> <p>[REDACTED] Managers will be made immediately aware of malfunctioning or out-dated equipment in need of replacement/repair.</p> <p>Checklists will be reviewed by [REDACTED] managers monthly.</p>	<p>This plan will be implemented immediately.</p>

[REDACTED]
Plan of Correction in Response to Statement of Deficiencies issued on August 27, 2013
Regarding Article 28 Diagnostic and Treatment Survey of 2012

ID PREFIX TAG: T2070

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