STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING _____ B. WING _____	01/31/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(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
L 000	Initial Comments An on-site, unannounced allegation survey was conducted at this facility from 01/30/13 - 01/31/13. Complaint MO00082879. A state licensure inspection was conducted in conjunction with the allegation survey. The complaint (MO00082879) was found to be unsubstantiated. Deficiencies as a result of the licensing inspection are as follows:	L 000		
L1111	19 CSR 30-30.060(1)(A)(8) The governing body shall ensure that The governing body shall ensure that the abortion facility abides by all applicable state and federal laws. This regulation is not met as evidenced by: Based on employee personnel file review, and review of the state statute, the facility failed to perform periodic Employee Disqualification List (EDL) checks on three of three employee personnel files reviewed. The facility does an average of 340 cases per month. On the first day of the inspection there were 25 scheduled cases. Findings included: 1. EDL checking requirements are as follows: Section 660.315, RSMo Entities required to check the EDL: 1. Licensed as operator under Chapter 198; 2. Provides in-home services under contract with the department; 3. Temporary nurse staffing agencies;	L1111		

	STATE OF MISSOURI PLAN OF CORRECTION	
Provider/Supplier Name: ➡	Reproductive Health Services / Planned Parenthood St. Louis Region & SW MO	Survey Date ⬇
STREET ADDRESS, CITY, ZIP: ➡	4251 Forest Park Ave, St. Louis MO 63108	1/30 - 1/31/13
	(X1) PROVIDER/SUPPLIER/CLIA INDENTIFICATION NUMBER 17- ➡	26D0438374

The Administrator signing and dating the first page of the CMS-2567/State Form is indicating their approval of the plan of correction being submitted on this form.

(X4) ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERRENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
L1111	A new human resource policy has been initiated to ensure that all RHS staff, prior to hiring, will be checked through the EDL data base. RHS of PPSLR will not hire a person on this list. In addition the existing, current staff will be checked against the EDL. (RHS of PPSLR has already registered under the MO State Dept of SS and is awaiting and log ins)	
	Attached: New Policy	
	Person Responsible: VP of Human Resources	3.15.13
	Monitoring and Incorporation into QAPI process: a report of activity will be forwarded to VP of Patient Services for incorporation into meeting minutes	Starting w/April '13 meeting
L1128	The Pharmaceutical Standards section of the policy and procedure manual has been updated to ensure single use medications are discarded after use on each patient	
	Attached: New Policy, Page 7	
	Person Responsible: VP of Patient Services	2.27.13
	Training of staff: Staff training on this updated policy and procedure will include the nursing and medical assistant staff.	2.27.13
	Person Responsible: Director of Surgical Services, Clinical Manager	
	Monitoring and Incorporation into QAPI process: Training and Quality Systems Coordinator will spot check this weekly for the first month and then monthly. A consolidated report on all Infection Control activities will be shared with the VP of Pt Services and at the CQA meeting	First checks wk of 3/4 and continuing
	The Pharmaceutical Standards section of the policy and procedure manual has been updated to ensure the multi-dose vials are appropriately dated when they are opened	2.27.13
	Attached: New Policy, Page 7	
	Training of staff: Staff training on this updated policy and procedure will include the nursing and medical assistant staff	2.27.13
	Person Responsible: Director of Surgical Services, Clinical Manager	

David L. Eisenberg, MD, MPH — Medical Director (Title) — 2-27-13 (Date)

	Monitoring and Incorporation into QAPI process: Training and Quality Systems Coordinator will spot check this weekly for the first month and then monthly. A consolidated report on infection control activities will be shared with the VP of Pt Services and at the CQA meeting	First checks wk of 3/4 and continuing
	The Pharmaceutical Standards section of the policy and procedure manual has been updated to ensure that expired medications are not available for patient use. The revision clarifies dates on which supplies are checked (i.e. the first working clinic session of every month).	2.27.13
	Person Responsible: VP of Patient Services	
	Training of staff: Staff training on this updated policy and procedure will include the nursing and medical assistant staff	
	Attached: policy, page 3	
	Person Responsible: Director of Surgical Services, Clinical Manager	2.27.13
	Monitoring and Incorporation into QAPI process: Training and Quality Systems Coordinator or a delegate from the infection control committee will spot check this weekly for the first month and then monthly. A consolidated report on infection control activities will be shared with the VP of Pt Services and at the CQA meeting	first full week of every month
	The General Standards section of the policy and procedure manual has been revised to ensure that expired items are not available for patient use. The policy is more specific on when items are checked and how discarded	2.27.13
	Person Responsible: VP of Patient Services	
	Training of staff: Staff training on this updated policy and procedure will include the nursing and medical assistant staff	2.27.13
	Attached: new policy, pages 26 and 27	
	Person Responsible: Director of Surgical Services, Clinical Manager	
	Monitoring and Incorporation into QAPI process: Training and Quality Systems Coordinator or a delegate of the Infection Control Committee will check this in the first week of the month. A consolidated report on infection control activities will be shared with the VP of Pt Services and at the quarterly CQA meeting.	first full week of every month
	To ensure that a sanitary environment is preserved several actions have been taken and are to be taken:	
	1) new footstools have been purchased and the old discarded	2.15.13
	2) bids have been sought for new berkeleys and new IV poles	2.13 & 2.25.13
	3) the maintenance and cleaning crews are using cleaning products to determine if our surfaces are easily cleanable or need replacing	2.13 - 2.28.13
	4) for items that must be purchased, this will occur	3.15.13
	Person Responsible: VP of Patient Services and VP of Finance/Operations	
	5) ongoing monitoring of equipment, cleanable surfaces, and their condition	
	Person Responsible: procedure room staff and Infection Control Committee	
	Staff Training: Training and Quality Systems Coordinator and Clinical Manager	3.1.13

	Monitoring: ongoing monthly auditing and checking of equipment and cleanable surfaces. Recommendations for improvements to VP team as indicated. Audits will be shared at CQA quarterly meetings	Monthly starting in March '13. Reports quarterly
	To ensure the facility is free of dust/debris throughout the medical area, including procedure rooms, storage and supply room:	
	1) the air ducts in the procedure rooms and recovery have been cleaned	2.5.13
	2) the maintenance dept will check them monthly and clean them as necessary	3.5.13 ongoing
	3) a new cleaning schedule has been put into effect - procedure room and utility staff clean their rooms every Tuesday prior to the start of clinic	2.15.13
	4) the cleaning staff will provide heavy cleaning of the entire clinical area every Monday and Thursday	
	5) Medical Assistants will rotate responsibility for storage and shared areas	
	6) a check list is being designed to ensure all items are addressed	2.27.13
	Staff Responsible for Cleaning: Medical Assistants and Housekeeping	
	Staff Responsible for Monitoring: Management (rotating) and Infection Control Committee	
	Timeline for monitoring: weekly checks for first month, then monthly	Tuesdays
	The Infection Control Committee, which was founded in November 2012, invited staff members to join and will be responsible for: updating the manual, designing audits, monitoring outcomes, recommending training, setting standards, ensuring incorporation of changes into QAPI, and reporting to the Clinical Quality Assurance Committee. All of the above will be monitored by them as well as by those stated above.	first meeting week of 3/4/13
	Staff Responsible: Training and Quality Systems Coordinator as manager of the committee	
	Staff Training: For above issues, already stated. For new topics, training will be as indicated and decided upon by committee	
	Monitoring and incorporation into QAPI process: reports to the Clinical Quality Assurance Committee and Medical Director	quarterly reports
L1170	The Quality Assurance Program will be improved via the following actions:	
	1) the agenda will be more specific regarding all of the issues identified by regulations	2.6.13
	2) the review of patient records will include a new log of all cases in which gestational age is 18 weeks or greater and will show a review by a physician (i.e. the Medical Director)	3.1.13
L1171	3) the notes will identify each problem and the accompanying action to be taken to resolve the problem	2.6.13
	4) successive notes will address the action taken and the outcome	Next QA meeting in April 2013
	5) further action will then be addressed as indicated	

	Staff Responsible: VP of Patient Services, Medical Director, and Training and Quality Systems Coordinator	
	Committee Training and Preparedness: was discussed at the 2.6.13 meeting. Follow up with individual members week of 2.25.13 to ensure actions as decided	
L1190	The patient Bill of Rights has been updated with the addition of the address and phone number of the MO Department of Health and Senior Services, Bureau of Ambulatory Care. It is made assessible to patients by being attached clipboards that are given to every patient with their initial paperwork.	2.1.13
	Attached: new bill of rights	
	Staff Responsible: VP of Patient Services	
L1252	PPSLRSWMO pays to have annual inspections of the fire extinguishers. In addition, the maintenance staff will now do a monthly inspection of the fire extinguishers to ensure the pressure is correct, they are in working condition, and there is no blockage.	first week of March 3/4/13
	Staff Responsible: Maintenance	
	Training: none required	
	Monitoring to ensure POA is effective: will be checked for three months by VP of Finance/Operations and then spot checked over the next year	once in March, April, May, then periodically

CLINICAL PROGRAM STRUCTURE
GENERAL STANDARDS
PAGE 26 AND 27
(entire document not sent)

VIII. MEDICAL EQUIPMENT AND SUPPLIES

Medical Equipment and Supplies must —

A. Be appropriate and adequate to provide the services offered. All centers have microscopes, refrigerators, autoclaves, venipuncture and injection supplies, scales, sphygmomanometer, and appropriate gynecologic equipment.

B. Equipment is checked and calibrated annually by a contract service for safety, and written documentation is kept on file at the administrative office.

L1128

A. Equipment is also checked by staff and managers monthly according to the infection control policy

- **a. Check for rust, cleanliness, tape, or any uncleanable surface**
- **b. Worn or defective equipment must be reported to the manager for replacement or fixing by the staff who identified this**

D. Supplies are checked regularly and at least monthly by the assigned staff. The person checking will vary per center and is delegated by the manager of the center.

a. For RHS, staff are the medical assistants assigned to procedure rooms and to storage areas
b. For RHS, the LPN/RN will check the recovery and storage there
c. For HCs, the support staff (MA / Patient Educator) will check the exam rooms, labs, storage area
d. Supplies are rotated to ensure oldest used first
e. Expired supplies must be removed from the active stock and not used for patient care
f. Supplies are checked on the first clinic day of each month
g. Managers and the Infection Control Committee will be providing spot checks periodically

E. See specific sections for additional supply and equipment for that service.

F. Facility Cleaning Standard
As a medical facility, PPSLR/SWMO must maintain sanitary environments for patient

Care. To ensure this:

- **a. Some centers have a contractual agreement with a cleaning service that does heavier cleaning 3 x weekly**
- **b. In the interim between their visits, staff are**

responsible to empty trash, wipe down any spills, disinfect areas that have become contaminated or dirty

c. **Some centers have their own cleaning crew who may perform the heavier cleaning of mopping, baseboards, vacuuming, etc – this must be done according to volume of traffic and may be 2 – 3 times weekly**
d. **At RHS, the procedure rooms, recovery, and storage are closely monitored and cleaned at least once per week – every Monday for the heavier cleaning and every Tuesday before clinic session for dusting and debris management**
e. **The monthly Infection Control audit will check that a sanitary environment has been achieved for patient care**

For additional information, please see the Infection Control Manual and audits

IX. INFECTION PREVENTION/CONTROL

All affiliates **must** have an infection prevention program in place. The ARMS *Infection Prevention Manual* as well as other tools and resources are available at www.armsconnect.org to assist in developing affiliate programs. .

PPSLR/SWMO manual uses the ARMS one as the basis and provides both policy and procedural information. An Infection Prevention Committee has been established through the Patient Services Department and consists of nursing, administrative, and clinical support staff. Their purpose is surveillance, investigation, control and prevention of infection. This will be accomplished by review, revision, and approval of infection prevention policy and procedures.

X. RISK AND QUALITY MANAGEMENT

L1170 and L1171

PPSLR/SWMO and its affiliate RHS of PPSLR/SWMO have a structured and permanent Risk and Quality Management Program in place. The ARMS *manual Risk Management: The Path to Patient Safety* as well as other tools and resources are available at www.armsconnect.org to assist in developing affiliate programs. The affiliate's Quality Management Program includes the following:

1) A CQRM Committee chaired by the Training and Quality System Coordinator and membership of: CEO; VPs from all departments (Patient Services; Political; Education and Diversity; Administration and HR; Finance and Operations; Development), Medical Director, and Board member.
Committee is responsible for agency oversight for QM/RM activities and concerns such as security, technology, personnel issues. The committee is responsible for overseeing goals and identifying processes to evaluate. This is accomplished by the following:

- Review of reporting agency departmental and committee audit findings to identify and explore possible risk and exposure areas
- Develop protocols/procedures as needed to reduce the risk of exposure to loss

- Inclusion of risk management concepts in the annual Quality Management Plan
- Participate in the annual review of the PPFA QM & RM Self-Assessment Survey Review to ensure PPSLR in compliance with standards and guidelines for accrediting agencies such as Planned Parenthood Federation of America, Title X and Medicaid
- Committee members serve in an over-sight capacity for monitoring and improving PPSLR/SWMO facility management in the areas of safety and security for clients, visitors, staff and volunteers

Page 29 addition regarding CQAC

The following agency committees report to the QM committee:
Clinical Quality Assurance Committee for Patient Services (all divisions)

Due to state licensing, the CQAC must address the following issues – this will be done through a detailed agenda, discussion, notes, and analysis of the outcomes of the decided upon actions.

From state regulations:
(J) Each abortion facility shall develop a quality assurance program that includes all health and safety aspects of patient care and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body. The quality assurance program shall include a review of at least the following:

1. ***Completeness of clinical records;***
2. ***Incidence of morbidity and mortality;***
3. ***Intraoperative and postoperative complications;***
4. ***All cases transferred to a hospital'***
5. ***All cases that resulted in a length of stay of more than twelve (12) hours;***
6. ***Errors in diagnosis;***
7. ***Problems in compliance with state and local laws and regulations;***
8. ***All cases in which the gestational age was determined to be beyond eighteen (18) weeks.***

(K) The quality assurance program must show evidence of action taken as a result of the identification of the problems.

L1128

Reproductive Health Services of Planned Parenthood of the St. Louis Region and Southwest Missouri

Infection Prevention Compliance Audit
Sterilization Practices

	Met	Unmet	Improvement Plan/Date to be Completed
1 All medical equipment (i.e. speculums, medical instruments, etc.) are immediately placed in appropriate disinfectant solution after use			
2 Staff can verbalize above disinfectant solution ratio			
3 Proper PPE is worn by staff during cleaning process (utility gloves with instrument cleaning in utility)			
4 Instruments are not allowed to dry before cleaning procedure			
5 Documentation exists for high level solution check for each use			
6 Equipment sterilized in the autoclave contains an indicator for sterilization within each package			
7 No package wrapped for steam sterilization is more than 12x20x12 inches in size			
8 Documentation of weekly steam sterilizer cleaning and spore testing			
9 Supplies of sterile instruments are stored no less than 8-10 inches from the floor and 18-20 inches from the ceiling			
10 Sterile supplies are checked monthly for integrity of the pack			
11 All sterile items are labeled with the date of sterilization and specific autoclave			
12 No expired merchandise or supplies on shelves in active stock			
13 Multi-use vials dated & initialed when opened and discarded according to regulations			
14 Single use medications are used for one patient and discarded after use			
15 All exam tables are wiped with disinfectant after each procedure			
16 Sterilize and non-sterile items are stored separately			
17 All equipment is sterilized in "open" position			
18 Sterile supplies are rotated to ensure use of most recently sterilized equipment last			
19 Antimicrobial hand rinse available			
20 No biohazard in white bag trash			
21 Sharp containers easily accessible (in lab, exam, utility, procedure and recovery areas)			
22 PPE available (masks, protective eyewear, utility gloves, plastic apron, etc)			
23 Vaginal probes are disinfected between each patient			
24 Condoms are used to cover vaginal ultrasound probe			
25 Tubing labeled by manufacturer as single use tubing is disposed of infectious waste after a single use.			
26 Multi-use suction tubing is cleaned, then disinfected as for a semi-critical item			
27 Abortion procedure bottles are changed, cleaned and disinfected between patients			
28 MVA is completely disassembled, cleaned and receive high-level disinfection			
29 If Cidex used, must be checked and documented on day of use to ensure effectiveness			
30 MSDS log current with supplies used in surgical center			

Auditor Name:_____Title_____ Date_____

L1128

Signature & Title of reviewer:_____

Reproductive Health Services of Planned Parenthood of the St. Louis Region and Southwest Missouri

Infection Prevention Compliance Audit
Standard Precautions, Hand Hygiene and PPE

	Met	Unmet	Improvement Plan/Date to be Completed
1 Sharp containers are leak proof, puncture resistant, labeled with biohazard label, sealed and disposed of when they are no more than ¾ full and sealed completely before disposal			
2 All sharps are disposed of in designated sharps containers (include hypodermic, intravenous or other medical needles, syringes with an attached needle or other sharps, scalpel blades, blood vials, slides & cover slips, syringes that have come in contact with blood or infectious agents, etc.)			
3 Employees demonstrate proper hand washing or disinfecting technique before putting gloves on /removal of gloves and before each patient encounter.			
4 Eye protection/face shields are used when activity holds possibility of splash			
5 Safety needles are used when available; includes needle devices containing built-in safety features			
6 When sterile gloves are used, proper technique is followed for putting on and removal			
7 Appropriate PPE (i.e. various gloves, masks, face shield, lab coats, CPR shield) is readily available in each area of health center (lab, procedure, utility rooms, etc)			
8 Gloves are worn by staff when contact with blood, OPIM, mucous membranes and non-intact skin may occur			
9 Gloves are worn when giving injections, drawing blood and performing Venipuncture			
10 Red bags are used for non-sharps, regulated medical waste (i.e. products of blood & anything caked, soaked or dripping with blood; saturated materials containing blood)			
10 PPE is disposed of in proper container (red bags if contaminated)			
11 Every hand washing station contains soap, hand disinfectant and towels available for proper hand hygiene			
12 Surgical scrub is employed for hand hygiene by physician/clinician before clinic surgical session and waterless alcohol foam product used between patients			
13 Sterile packages are used that have outside tape that indicates the package has been processed			
14 Non-sterile persons avoid reaching over a sterile field; sterile persons avoid leaning over a non-sterile area			
15 When sterile packs are opened, the outside of the package never touches the inside			
16 Routine schedule and guidelines for housekeeping & cleaning is followed			
17 Patient care equipment is free from dust and debris in procedure, storage and supply areas			
18 Environmental surfaces are thoroughly cleaned/disinfected in patient care areas between patients			
19 Staff can verbalize guidelines for cleaning/disinfecting after a blood/body fluid spill			
20 Emergency Surgical Cart free from dust & debris			

L1128

Auditor Name:_____ Title:_____ Date:_____

Signature &Title of reviewer:_____

L1128

Staff Training
2.27.13

Trainers:

Lead Clinician Susan Bender, NP

Director of Surgical Services Celeste Smith, LCSW

I. Time for a change
   a. What are some things you think we need to change?
   b. What gets in the way of us being excellent?
   c. What can we start doing differently?
II. Single Use Medication Vials for One Patient
III. Multi-Dose Medication Containers are Labeled with Date Opened
IV. Labeling Pre-Drawn Medications
   a. Date
   b. Time
   c. Initials of Staff Drawing Up Meds
V. Expired Medications
   a. Plan to check the last working day of each month
VI. Expired Supplies
   a. Plan to check the last working day of each month
VII. Clean and Sanitary Environment
   a. Environment Includes
      i. Dressing Room
      ii. Recovery Room
      iii. Procedure Rooms
      iv. Utility
      v. Supply Areas
      vi. Storage Areas
      vii. Hallways
      viii. Floors
      ix. Ceilings
   b. Targeted clean each Monday/Tuesday Morning
      i. Dust
      ii. Debris
      iii. Clutter
      iv. Appearance Matters
      v. Day to Day Upkeep
      vi. Leave your workstation clean
   c. Un-cleanable Surfaces
      i. What are they?
      ii. How do we fix them?
      iii. How do Monitoring them?
VIII. Infection Prevention Committee
   a. What is it?
   b. Who is on it?
   c. How can it help us?
IX. Questions?

AS A PATIENT OF PLANNED PARENTHOOD OF THE ST. LOUIS REGION AND SOUTHWEST MISSOURI, YOU HAVE THE FOLLOWING RIGHTS:

The RIGHT to no discrimination regardless of race, color, national origin, disability, age, ethnicity, sexual orientation, financial ability, education level, marital status, religion, number of pregnancies, method of referral, contraceptive preference or other factor;

The RIGHT to be treated with dignity and respect without harassment;

The RIGHT to decide whether or not to bear children and if so, to determine the timing and spacing;

The RIGHT to privacy and confidentiality in all aspects of the service we provide;

The RIGHT to know of the effectiveness, possible side effects, and complications of all contraceptives;

The RIGHT to participate in selecting the contraceptive methods to be used;

The RIGHT to know the results and the meaning of all tests and examinations;

The RIGHT to access your records and have them explained;

The RIGHT to know the meaning and implication of all forms we ask you to sign;

The RIGHT to consent to or refuse any contraceptive method, test, examination or treatment;

The RIGHT to an explanation of fees and services before services are provided.

- You will not be denied access to services if unable to pay
- We accept Medicaid and Medicare
- We accept commercial health insurance
- Please discuss any special concerns with our staff

If any problems should arise during your visit, please ask to speak to the Health Center Coordinator or contact the Director of Surgical Services at 314-531-7526 ext. 231.

Planned Parenthood®

You may also contact the State of Missouri Department of Health and Senior Services, Bureau of Ambulatory Care. PO Box 570, Jefferson City, MO 65102. Telephone: 573 751-6083.

L1111

BACKGROUND CHECKS AND INVESTIGATIONS POLICY

PPSLRSWMO recognizes the importance of maintaining a safe and productive workplace with honest, trustworthy, qualified, reliable and non-violent employees. For the benefit of all employees and PPSLRSWMO, in furthering these interests and enforcing PPSLRSWMO policies, PPSLRSWMO **will** perform, or request that third parties perform, "background checks" or other types of investigations. These background checks and investigations may be performed by PPSLRSWMO at its discretion. **The Vice President of Human Resources will be responsible for performing all "background checks" that are applicable under Federal, State and Planned Parenthood of America (PPFA) laws and requirements.**

Background checks and investigations performed for PPSLRSWMO may include the use of consumer reporting agencies which may gather and report information to PPSLRSWMO in the form of consumer or investigative consumer reports. Such reports, if obtained, may contain, but are not limited to, information concerning an applicant's or employee's credit standing or worthiness, credit capacity, character or general reputation. The types of reports that may be requested from consumer reporting agencies under this policy include, but are not limited to, credit reports, criminal records checks, driving records, and/or summaries of educational and employment records and histories. The information contained in these reports may be obtained by a consumer reporting agency from private or public records sources or through personal interviews with an employee's co-workers, neighbors, friends, associates, current or former employers or other personal acquaintances.

Pursuant to this policy, PPSLRSWMO may request consumer reports, including records checks and investigative reports based on interviews, in connection with an individual's application for employment, or at any time during the course of an employee's employment with PPSLRSWMO, for purposes of evaluating their suitability for employment, promotion, reassignment or retention as an employee.

All PPSLRSWMO Reproductive Health Services (RHS) candidates prior to hire will have a criminal background check and Employee Disqualification List (EDL) search completed prior to hire per the Missouri Revised Statutes Chapter 660 section 317.

Employees are expected to cooperate fully with the background checks and investigations policy. Such cooperation includes, among other things, providing truthful and complete information in response to inquiries made by PPSLRSWMO or third party investigations during the course of investigations and providing appropriate written authorizations that may be required by law so that

L1111

PPSLRSWMO may obtain complete investigation reports. Failure to cooperate in these checks or investigations, or any attempt to interfere with PPSLRSWMO attempts to obtain information, may result in disciplinary action, up to, and including, termination.

L1128
PHARMACEUTICAL SERVICES
See pages 3 and 7

I. PHARMACEUTICAL SERVICES

Affiliate Staff

1. **Medical Director** — is responsible for developing policies and procedures for pharmaceuticals that **must** include
   - formulary of all drugs stocked in the affiliate that is reviewed annually
     i. Consider the potential for medication errors when developing formulary. Look-alike, sound-alike drugs should be identified as being at "high risk" for potential error. Extra steps should be taken to ensure safety.
   - list of additional therapeutic/pharmacologic classifications of drugs that may be ordered for clients to obtain at outside pharmacies
     - The formulary is approved annually with medical protocol updates
     - All drugs, devices, and medications stocked in the affiliate are approved by the Medical Director in advance of purchasing / acquiring and providing.
     - The Medical Director only approves drugs that are FDA approved and only from manufacturers certified by the FDA, unless the medication is part of a research study.
     - All research study medications must be approved by the IRB and Medical Director prior to use.
     - PPSLR has both an internal (for items stocked in-house) and external formulary (inclusive of in-house and by written/e-prescription).
     - RHS has a formulary specific to abortion care approved by the Medical Director.
     - The Medical Director, Lead Clinician, and VP of Patient Services review the formularies at least annually. The Medical Director approves and signs off on the formulary of both departments.
     - RHS has a formulary. The surgical physicians have discretion to provide other medications as needed.
   - provision of pharmaceuticals in accordance with all state/local laws and regulations
     - PPSLR/SWMO and RHS of PPSLR/SWMO pharmaceuticals are provided by physicians, by clinicians or by physician designee.
     - APNs work under collaborative practice agreements with the PPSLR Medical Director and Associate Medical Directors. They have prescriptive and dispensing privileges.
     - RNs/LPNs work under standing orders with the PPSLR Medical Director.
     - Physicians have the ability to prescribe as indicated for patient care.
   - a drug control system that covers the interval from the time pharmaceuticals are ordered until they are provided to the client
     - PPSLR/SWMO's system includes the interval from issuing a request for order from health and surgical centers to the purchasing clerk, to ordering them from the pharmaceutical companies, to delivery and storage, to client provision.
   - inspection of all drug storage areas to remove expired drugs
   - designation of which staff may have access to bulk storage areas
   - management of pharmaceutical product irregularities and drug and device recalls
2. There **must** be documentation that in-service education pertaining to the nature

and safety aspects of pharmaceuticals is provided to staff involved in the preparation and provision of medications.

- PPSLR/SWMO provides an annual training for staff, primarily clinicians and licensed providers

FYI — Look-alike, Sound-alike (LASA) Medications

Confused drug names are one of the most common causes of medication error. With tens of thousands of drugs currently on the market, the potential for error due to confused drug names is significant and exists worldwide. Contributing to the risk of confusion are illegible handwriting, incomplete knowledge of drug names, newly available products, similar packaging or labeling, similar clinical use, similar strengths, dosage forms, frequency of administration, and the failure of manufacturers and regulatory authorities to recognize the potential for error and to conduct rigorous risk assessments, both for nonproprietary and brand names, prior to approving new product names.

Go to the Institute of Safe Medication Practices for a list of LASA medications. The list includes those medications that are known to have been involved in medication errors, as well as the Joint Commission's list of LASAs.

(WHO 2007); (ISMP 2010)

Procurement

1. There **must** be a written order for all drugs/pharmaceuticals/chemicals brought into the affiliate.
   - A copy of the purchase order or the prescription **must** be kept in the affiliate's files. A signed receipt **must** be obtained for pharmaceuticals shipped from a central location to outlying centers or clinics. If the delivery is made by affiliate staff, a signed receipt is not necessary.
     - The original order is issued by the supervisory staff of the health center or surgical center;
     - The order is sent to the Payroll/Purchasing Clerk via internal e-mail or fax;
     - Each facility has its own account number with each supply or pharmaceutical company;
     - The order is placed by the purchasing clerk at the administrative office;
     - Most deliveries are sent directly to the service location from the company;
     - Specific items are shipped centrally to control pricing;
     - Upon delivery, products are checked for accuracy and security, the packing slip is dated and initialed;
     - A copy of the purchase order or the prescription is and must be kept in the affiliate's files.
     - For items shipped to a central location, supervisory staff is responsible for picking up the supplies and completing a form that is sent to purchasing detailing amount and to which budget to allocate costs.
     - Finance maintains all purchase orders, packing slips, invoices, and paid statements for all pharmaceuticals.
   - Controlled substance order and receipt records **must** be filed separately from

the other pharmaceutical purchase records. RHS is the only facility that orders controlled substances.

2. If pharmaceuticals are routinely purchased from a community or hospital pharmacy and if the items are not supplied in manufacturer original containers, there should be a written contract specifying, as a minimum, requirements for labeling. PPSLR/SWMO seldom, if ever, purchases, pharmaceuticals from other than manufacturers. An exception is the free meds provided by the states of MO and of IL for the IPP programs.
3. If available, pharmaceuticals should be purchased in manufacturer prepared unit-of-use packages.
    - An exception is limited STD medications provided free to the health centers from the Illinois Department of Health and the MO Department of Health and limited medications for RHS. In these cases repackaging standards in this section are followed.
4. Only drugs and devices approved by the Federal Food and Drug Administration (FDA), and manufactured for sale in the United States may be used. Affiliates may not import drugs and/or medical devices from other countries for use in their health centers.
5. For any additional drugs that must be prescribed and are not purchased, the "out-of-house" formulary is utilized.

Storage

1. Access to stored pharmaceuticals
    a. The bulk storage area **must** be secure. The clinician or nurse on duty has the key in her possession to enable easy provision to clients. Other staff may have access via the clinician. Limited supplies are accessible to clinic staff working the receptionist desks.
    b. Controlled substances **must** be under double lock and in a secure area at all times. RHS is the only facility with controlled substances and follows MO law regarding storage of the drugs.
    c. Access to pharmaceuticals dispensed from within client care areas should be limited to health care providers responsible for dispensing these items.

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2. **Pharmaceuticals in all storage areas**
    a. Arrange medications so that the oldest stock is used first
        i. On the first clinic session of each month, a delegated staff reviews the inventory to ensure that stock is being properly rotated and has not expired
        ii. Expired inventory must be removed from active stock and marked as expired to ensure it is not available to patient care. It will be returned or discarded according to the vendor or manufacturer's instruction.
        iii. The senior management team, during routine audits, will also check the inventory for proper stock rotation.
    b. Do not store look-alike, sound-alike medications alphabetically. Store them out of order or in a separate location (The Joint Commission 2001)
    c. Pharmaceuticals meant for internal use **must** be stored separately (i.e. on a separate shelf) from those for external (i.e. topical) use only. Clear and highly visible labeling is required.
3. Other PPSLR/SWMO policies related to storage
    a. Inventory levels for pharmaceuticals that are not high volume should not exceed six-month stock.
    b. All pharmaceuticals, contraceptives, and therapeutics will be stored

according to the manufacturers' suggestions to ensure preservation (i.e. refrigeration, limited access to light exposure, etc).

c. An inventory check is performed monthly by supervisory staff to ensure accurate counts and to limit misappropriated medications and supplies.
d. Expired pharmaceuticals should be disposed of by throwing them into the biohazard box, sending them back to manufacturer, or taking them to appropriate and identified pharmacies that PPSLR/SWMO has approved for disposal (see VP of Patient Services or Clinical Manager). (Varies with product) Some items may be used for demonstration and educational purposes. Expired items must be accounted for on the Monthly Inventory Form and deleted from the inventory as soon as discovered to be expired.
e. The supervisory staff of all centers is responsible for discarding pharmaceuticals appropriately. The Purchasing Clerk will contact the manufacturer to determine if a rebate on expired products exists.
f. For any centralized inventory the Purchasing Clerk will remove it from the shelves.
g. No client will be dispensed a drug with an expired date.
h. Controlled substances must be destroyed by two nurses and documented on the Controlled Substance Dispensing or Administration Log Sheet. (see below for more policies/procedures on controlled substances)

4. At the end of each fiscal year, a full manual inventory is performed in each site.

Repackaging — i.e., the preparation of multiple containers of dispensing size from a bulk container (for example, repackaging a bottle of 1000 tetracycline tablets into vials of 20 tablets each). Repackaged vials are stored and dispensed to clients as needed.

1. Repackaging **must** be done in accordance with state/local laws/regulations. For PPSLR/SWMO and affiliates this is under the supervision of a physician who is on the premises at the time of repackaging.

2. A log **must** be maintained to document the supervision (by signature), the person doing the repackaging (by signature) and the identification of the bulk drug being repackaged. Logs **must** be archived according to state/local laws/regulations. 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 or some other unique (code) identification that will link that manufacturer and drug lot with the repackaged units

3. 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 affiliate
   - name of the drug and quantity
   - 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 expiration date for drugs that are repackaged from unit dose

containers should be no greater than 60 days from the date of repackaging, or the manufacturer's expiration date on the original container, whichever is earlier.
  - State laws may be applicable to expiration date for repackaged pharmaceuticals.
- 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 (as below, where 01=month, 21=day of repackaging, and 04=fourth item repackaged that day)

Sample label for drugs repackaged in tight containers:

Planned Parenthood of St. Louis Region 888 Main St., City, State, ZIP
Acetaminophen Tablets 325 mg, Qty. 25 Exp. 12/81, Control #012104

4. Safety precautions should be taken to indicate if the original repackaging unit has been opened prior to this dispensing, e.g., such as putting latex seals over the cap of the original vial after carrying out repackaging. An "x" could also be marked on the bottle cap or label to indicate it has been opened.

Compounding
PPSLR is not involved in the compounding of any medications in any of its facilities.

Labeling Prescription Vials for Clients
1. Prescription labels should be designed to enhance client safety. Click here (http://www.ismp.org/tools/guidelines/labelFormats/comments/default.asp) to access recommendations from the Institute for Safe Medication Practices.
2. All prescription vials **must** have a permanently adhering label affixed directly to the container with at least the following information (currently provided by wholesaler):
   - name and address of the affiliate — The acronym, PPSLR/SWMO, may be used
   - name, strength, quantity dispensed of the drug
   - expiration date
   - lot number

   The label **must** also include the following information, which may be added by hand at the time of dispensing
   - date of the prescription
   - name of the client
   - directions for use including frequency and route of administration
   - name of the prescriber
   - number of refills, if applicable

   Sample label for prescription vial for client

Planned Parenthood of the St. Louis Region 888 Main St., City, State, ZIP
{date}

{client name} Take ____ tablets every ____ hours as needed for pain. {Dr. _____}
Acetaminophen Tablets 325 mg, Qty. 25 # refills Exp. 12/81, Control #012104

3. Auxiliary labels should be used to provide other information to the client, such as, "Do not drink alcohol." in the case of metronidazole. The label(s) that should appear on the prescription container can be found in the literature about each drug including the manufacturer's package insert. The labels come with the medications from the supplier and should be attached to the vial upon dispensing. PPSLR/SWMO standardizes the use of auxillary labels for consistency.

4. 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.

Containers

1. Coin envelopes **must not** be used to dispense solid dose pharmaceuticals, since these do not meet the requirements of the Poison Prevention Packaging Act, a 1970 amendment to the Federal Food, Drug and Cosmetic Act requiring child-proof containers for pharmaceuticals. Self-contained packages, such as oral contraceptives or intravaginal creams, are exempted. PPSLR/SWMO does not use coin envelopes for any purpose.

2. All prescription medications should be stored in containers that protect them from light.

Controlled Substances

1. All controlled substances dispensed for out-patient use **must** bear the federally mandated auxiliary label: "Caution. Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

2. A daily count at the beginning and at the end of the clinic day **must** be taken on days when controlled substances are administered or prescribed. Discrepancies **must** be immediately reported to the supervisor, and recorded in the controlled substances inventory:
   - two countersignatures are required at the time of the count

     or
   - one person signing the daily count, and two persons taking and signing a full count every thirty days

     or
   - as required by state law
     1. RHS has two nurses (LPNs or RNs) doing the count
     2. Staff record on the Controlled Substance Dispensing or Administration Log: date of count, lot number of drug, first initial, last name and title of counting nurses.
     3. If the nurses who count recognize that the levels of the medication have fallen below the designated levels, they will notify the supervisory for reordering.

a. Fentanyl: ordered when it falls to 6 vials
b. Versed: ordered when it falls to 40 vials
c. Diazepam: ordered when it falls to 400

4. Approximately one month's supply of controlled substances will be kept in stock at all times to prevent the clinic from running out of stock. In cases where a national shortage is expected, more inventory will be approved by the manager

3. All inventory and purchase records for controlled substances **must** remain on file for the duration specified in state law if greater than the federal standard of five years. PPSLR/SWMO and its affiliate RHS maintains them for a minimum of seven years.

4. All Level IV controlled substances must be ordered and signed by the Vice President of Patient Services or the Clinical Manager (an APRN).

Other
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1. **Single use medications are used for one client only and are discarded after use on each patient.**
    a. **Staff must follow manufacturer's labeling on how to use the medication**
    b. **The medication is discarded according to the manufacturer**
2. **Manufacturers' recommendations for storage of opened and unopened multi-dose vials must be followed.**
    a. **When a multi-dose vial is used, appropriate infection prevention procedures to prevent contamination should be employed. (CDC 2011)**
    b. **Vials must be discarded if there is evidence of contamination.**
    c. **If a multi-dose vial has been opened or accessed (e.g., needle-punctured) the vial must be dated and discarded in accordance with manufacturer's instructions and state/local regulations**
        i. **If no specific guidelines are provided, CDC recommends discarding the vial within 28 days (CDC 2011)**
3. Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings. (Note: Medication containers include syringes, medicine cups, and basins.) (The Joint Commission 2010)
4. **Syringes taken from a multi-dose vials must be labeled with date, time, and staff initials. If not used within 24 hours, it must be discarded no later than 24 hours.**
5. All clients receiving medications also **must** receive written or verbal instructions including the name, purpose and appropriate administration technique for each drug.
6. Patient package inserts **must** be available for IUCs, hormonal contraceptives, and other estrogenic and progestational substances.
7. Patient drug information should be provided on all other drugs dispensed.
8. The nature of the client education provided should be documented in the medical record.

Planned Parenthood of the St. Louis Region and Southwest Missouri

Staff Inservice/Training/Meeting

Date 2/27/13 Topic Medical Staff Training

Presenter/Trainer Susan Bender, NP & Celeste Smith, LCSW

Time 9:45am -10:45 Site RHS (Attach agenda and handouts)

Print Name	Signature & Title	Site
1 Carla Garner		RHS
2 Florine Dost		RHS
3 Stacey Honda		RHS
4 Elaine Lanier	Elaine Lanier	RHS
5 Kimberly Jones	Kimberly Jones RN	RHS
6 Alicia King		RHS
7 Calvette (Tisa) Dykes	Calvette Dykes	RHS.
8 S Bender	S Bender WHNP RN	RHS
9 Celeste Smith		RHS
10		
11		
12		
13		
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Planned Parenthood of the St. Louis Region and Southwest MO

Clinical Quality Assurance Meeting

Original Date: 1/30/13; Rescheduled Date: 2/6/13

Agenda

1) Review of Patient Care
    a. Intraoperative and Postoperative Complications and Occurrences — Sevic, Eisenberg
        i. Last Quarterly Report 2012
        ii. Annual Report 2012 (internal) and AIMS Report — Spencer
    b. Care by procedure / gestational age
        i. Medication
        ii. Surgical
            1. 17 weeks and under
            2. 18 weeks and over
    c. Identification of any problems
    d. Action plans

2) Transfers to Hospital — Eisenberg, Gianino, Kogut
    a. Administrative, Physician, Committee Review
    b. Security and HIPAA systems
    c. Identification of any problems
    d. Action plans

3) DOHSS Inspection — Management Team
    a. Results and findings
    b. Action Plan
    c. Ensuring full compliance with state/local laws and regulations

4) Accreditation — Spencer, Gianino
    a. Plans and Time lines to achieve full accreditation
    b. Agency Involvement

5) Audits — Bender, Moran, Spencer

6) Research Report — Eisenberg, Kogut

7) Old Business — All
    a. Follow up to any previously identified issues
        i. Continuing pregnancies
        ii. Consents
        iii. Next gen audits
        iv. Infection Control Committee

New Business and Announcements — All

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Planned Parenthood of the St. Louis Region and Southwest MO

Clinical Quality Assurance Meeting

Original Date: 1/30/13; Rescheduled Date: 2/6/13

Present: Eisenberg, D, Med Dir; Weisbart, E, Board; Gianino, P, CEO; Bender, S, Clinical Manager; Spencer, C, Training and Quality Systems; Moran, J, Dir HCs; Smith, C, Dir SS; Sevic, N, Data and Quality Compliance; Kogut, M, VP Pt Services

1) Review of Patient Care
    a. Intraoperative and Postoperative Complications and Occurrences — Sevic, Eisenberg
        i. Last Quarterly Report 2012
        ii. Annual Report 2012 (internal) and AIMS Report — Spencer
    b. Care by procedure / gestational age
        i. Medication
        ii. Surgical
            1. 17 weeks and under
            2. 18 weeks and over
    c. Identification of any problems
    d. Action plans

- Reports are attached
- All within expected standards of care
- Complication rates are low and within standard of care
- Patients both under and over 18 weeks of care have been managed well
- No specific identification of problems
- Action Plans: Medical Director requests comparison of current year to previous years for our trend in complications – Sevic to provide

2) Transfers to Hospital — Eisenberg, Gianino, Kogut
    a. Administrative, Physician, Committee Review
    b. Security and HIPAA systems
    c. Identification of any problems
    d. Action Plans

- In a three month period of time same number as in full 2011 year
- Upon analysis, appropriate transfers, patient care and decision-making was handled well, good patient care, no consistent theme or medical condition
- Reasonable decision making and time in center before transfer occurred
- Newest provider had 3 of the transfers – for new trainees this is expected, i.e. that transfers may be higher
- Analysis on three fronts:
    - CEO, VP of Pt Services, and Medical Director identified and discussed after the first 3 transfers. While not desired outcome, all fell within potentially expected outcomes

- Physicians – 3 primary attendings – and the administrative management team discussed 1/31/13 and came to same conclusion; recommendations for some limits on who we serve made and under discussion. Medical Director drawing up guidelines based on discussion
- CQ Committee 2/6/13 also looked at data

- Positive – we have greater continuity of care for patients due to our relationship with Wash U and the procedure of notifying the family planning fellow
- Action: Will update our ambulance transfer form to include: when called, when arrived, when pt discharged to EMS (and effective 2/18/13), when ambulance leaves the premises
- Action: CEO to contact BJC ED regarding potential for picketers and how handled
- Action: CEO to contact EMS for guidelines on the minimal information that must be shared with 911 calls to ensure safety and protect confidentiality
- Action: Staff to be retrained on making the calls after we get this information – Management team – ensure we identify if the call is urgent or emergent
- Action: CEO to work with operations regarding a way to limit the picketers from having full visual access to client as she is being transported – increase patient privacy

3) DOHSS Inspection — Management Team

a. Results and findings
b. Action Plan
c. Ensuring full compliance with state/local laws and regulations

- Surprise audit on 1/30 and 1/31 with 4 auditors
- Part of our licensing and partly due to concerted complaints
- Awaiting formal findings from state within 10 days of audit
- Will have 10 days to return our POA
- Summary of findings to committee:
  - Quality medical care with no indication of any violations of regulations
  - Some improvements on medication inventory; dust in select areas; updating some equipment; and increasing our infection control activities
- Committee was given the components that must make up the QA work
  - This agenda was changed to accommodate those issues
- Action Plan: management team to meet and agree upon immediate and long range procedures, training, changes to ensure improvements
- Action Plan: to respond to any cited deficiencies within 10 days of report

4) Accreditation — Spencer, Gianino

c. Plans and Time lines to achieve full accreditation
d. Agency Involvement

- Accreditation is Oct 9 – 11, 2013
- Plan is to send all documents by July 17, 2013
- Currently, all departments working on their EOPs
- Action: Patient Services, complete all manuals by April 30, 2013

5) Audits — Bender, Moran, Spencer

a. Vasectomy

i. Overall very good
ii. First full year at RHS – saw 63 men – a large increase over previous years
iii. One system issue – not enough follow up with patients to remind them of post op semen check
iv. Had turnover in the staff member who was handing this task – new person has been trained

b. Colpo and Pap Audits
i. With new pap standards, many less colpos
ii. Overall very good – a few issues that were resolved quickly
iii. The colpo correlation log is / will be on line and reviewed by MDs
1. Sign off 2 x per year
iv. Lead NP able to audit via electronic record

c. Center audits
i. With Next Gen, trying to audit different medical / clinical issues to ensure documentation
ii. Action: Need to establish standards for what % of compliance is necessary per criteria
1. Ex: consents would want to see 100%
2. Patient Education forms could be lower
iii. Action: Need to ensure NPs and support staff are clear on who doing what and limit redundancy
1. Ongoing discussion – Dir of HCs and Clinical Manager with Training and Quality Systems will continue this
iv. Recommendation: put them in "buckets" by priority / risk
1. Must have for medical; or must have for financial
2. Good to have

d. Infection control audits for HCs and RHS
i. Quarterly audit listing both compliance and non- compliance areas
ii. Overall good with some improvements noted
iii. New Committee will address any new audit tools and how to improve outcomes

6) Research Report — Eisenberg, Kogut
a. Roche project is ending – enrollment has been completed; in final stages of the reviews/audits to ensure all paperwork
b. Snafu with consents that has been remedied.
i. All were signed
ii. Not all clients took one with them – our SOPs state they will be given one
iii. Had to send all of those a certified copy
c. RLP
i. Has begun at SG and CWE
ii. Not yet enrolling enough patients – will be changing our use of staff to meet numbers
d. New industry sponsored one in discussion and analysis right now on the use of progestin contraceptives as quick start when mife is given
i. Not yet approved and no budget yet

7) Old Business — All
a. Follow up to any previously identified issues
i. Continuing pregnancies – No need to continue discussion - resolved
ii. Consents – continue to track this and check for improvements
iii. Next gen audits – continue to track this and decide on thresholds

iv. Infection Control Committee – continue to monitor the establishment of and the work of this group

8) New Business

a. Worker's Comp Claims – up

i. Few more splashes and sticks

ii. Do not think it is a system problem – staff were counseled and systems analyzed

iii. Some increase to our rates; Looking for new carrier as ours is getting out of the WC business

Submitted: Mary M Kogut, VP of Patient Services