| 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 _____ | 03/31/2015 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| REPRODUCTIVE HEALTH SERVICES / PLANNE | 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<br><br>An on-site, unannounced, state licensure survey was conducted from 03/30/15 to 03/31/15. An onsite complaint investigation for complaint MO00100367 was also conducted and the complaint was found to be unsubstantiated. See below for findings: | L 000 | | |
| L1128 | 19 CSR 30-30.060(1)(B)(8) The facility shall establish a program<br><br>The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport.<br><br>This regulation is not met as evidenced by:<br>Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to:<br>- Restrict multi-dose vials to a centralized medication area separate from the patient treatment area;<br>- Ensure expired medications were not available for patient use;<br>- Have accessible and follow manufacturer's instructions for use;<br>- Monitor the humidity in the clean and dirty instrument processing area;<br>- Protect sterile items from dust and moisture by placing a solid barrier on the bottom shelves; | L1128 | | |

# MO Bureau of Ambulatory Care—Facility Plan of Correction (POC) Form

| Facility Name | Reproductive Health Services of Planned Parenthood of the St. Louis Region | Survey Exit Date (from CMS 2567) | 03/31/2015 |
|---|---|---|---|
| Facility Address/ City/Zip | 4251Forest Park Avenue St. Louis, Missouri 63108 | State or Federal SOD Q-tags, L-tags, K-tags | |

1. Include a **copy of the first page of *each* of the original forms CMS-2567** Statement(s) of Deficiencies for Federal (Q-tags), State (L-tags) and Life Safety (K-tags) ***signed & dated by administrator*** or designee, along with associated completed POC forms **no later than ten (10) calendar days from receipt**. If you have any questions, contact BAC at BAC@health.mo.gov or call 573-751-6083. Our fax number is 573-751-6158.

2. Complete a **separate POC form for each applicable regulation set of the Statement of Deficiencies** (federal Q tags, state L tags, Life Safety K tags).

3. **Required elements of an acceptable Plan of Correction**. Chapter 2 of the State Operations Manual (2728B) describes necessary elements for an acceptable POC. **Each** deficiency shall be addressed separately by completing the applicable information for **each** element below for **every** citation for Q-tags, L-tags, and K-tags.

   A: **Indicate the prefix or Tag number** for each citation indicated on the form CMS-2567 "Statement of Deficiencies" (Q001, L125, etc)

   B: **Fully describe the plan for correcting the deficiency.** Address the complete deficiency: several underlying problems may be cited under a single Tag number. Address any processes that lead to the deficiency, and what systemic changes will be made to ensure that the deficiency will not recur. The description must be specific, realistic, and complete. A general statement indicating that compliance will be achieved is not acceptable.

   C: For each deficiency, indicate **date correction will be made** or all components for correction put in place. Can NOT be prior to the Exit Date, and generally **must be** no later than 60 days from receipt of the CMS-2567, per 42 CFR 488.28. *(Limited extensions may be granted upon written request should extraordinary circumstances exist.)* To maximize correction opportunities, correction **should be** less than 45 days from Exit. Note: the monitoring required in "E" below will generally extend past this date.

   D: For each deficiency, include the **Title of the person responsible** for implementing the plan of correction for each deficiency.

   E: Describe the **monitoring and/or tracking procedure** that will ensure that the POC is effective and the issue remains in compliance. Include frequency and duration of monitoring, and mechanism of data collection. If the person responsible for ongoing monitoring is different than the person named in "D," note it here.

   F: **Evidence/Exhibit attachment(s).** Each POC form should stand on its own, and Element B should fully explain the actions the facility has taken or will take. Although not formally part of the POC, if written evidence exists to document that corrections have been made, attach the numbered exhibit(s) to this POC and indicate the exhibit number(s) in this column. If documentation is not applicable, indicate "N/A". Examples of routine exhibits expected to be attached (if applicable) would be:
   F1: Copies of applicable portions of any **revised/amended facility policy** to address the deficiency.
   F2: **In-service/staff training attendance sheets**.
   F3: **Work orders** or equipment service reports.
   F4: **Meeting minutes or QA monitoring** tools.

| A | B | C | D | E | F |
|---|---|---|---|---|---|
| ID/tag number (Q0001) | Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice. | Correction Date (within 60 days from receipt) | Title of Person Responsible for Correction | Describe monitoring procedure to ensure continued compliance, to include:<br>- Frequency/duration of monitoring<br>- Method of data collection<br>- Who monitors, if different than "D" | Evidence/ Exhibit Attachment Numbers or "N/A" |
| L1128 | Restriction of multi-dose vials to centralized medication area<br><br>PPSLR Policy titled Pharmaceutical Services reviewed and revised to be consistent with Infection Prevention Manual to include in the policy that multi-dose medications should be restricted to a centralized medication area from patient treatment areas.<br>Plan to:<br>-Identify restricted centralized medication area<br><br>-All staff memo of restricted centralized medication area location<br><br>-Staff training for Pharmaceutical Services Policy to include:<br>1. Revised procedure for restricted medication area for multi-dose medications<br>2. Procedural review of usage, storage & discarding of multi-dose medications and controlled substance inventory management<br><br>-Include in developed Weekly Site Review Form and revised QM Monthly Site System Review multi-dose mediations use, management and restriction to centralized area | by 5/31/2015 | Dir of Quality & Training (for Pharmaceutical Policy)<br><br>Dir of Surgical Services | Supervisory observation monitoring and completion of Site Weekly and Monthly Audit Forms<br><br>Staff sign attendance training sheet for: Revised Pharmaceutical Review of Review of multi-dose medications only in restricted areas | L1128 F-1 Pharmaceuti cal Services Protocol |
| L1128 | Ensure expired medications not available for patient use<br><br>Plan to:<br>-Conduct staff review training of<br>1. Expired inventory management,<br>2. Daily inventory management of controlled substances at the beginning and end of clinic day<br>3. Storage of pharmaceutical supplies in non-clinical treatment areas. | by 5/31/2015 | Dir of Surgical Services | -Completion of weekly and monthly site audits of emergency supply logs that include expired medication management by Health Center Assistants/MAs.<br>-Surgical Nurse Coordinator reviews and signs weekly & monthly site audits<br>-Staff sign attendance training sheet conducted by Supervisor of Nursing/Clinical Manager for expired inventory and management of pharmaceutical supplies<br>-Document observational site audits | L1128 F-4 QM Monthly Site System Review |

| A | B | C | D | E | F |
|---|---|---|---|---|---|
| ID/tag number (Q0001) | Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice. | Correction Date (within 60 days from receipt) | Title of Person Responsible for Correction | Describe monitoring procedure to ensure continued compliance, to include:<br>- Frequency/duration of monitoring<br>- Method of data collection<br>- Who monitors, if different than "D" | Evidence/ Exhibit Attachment Numbers or "N/A" |
| L1128 | Continued from page 2<br><br>**-Perform observational site audits that includes expired merchandise**, pharmaceutical inventory management & ,inventory storage criteria for procedure rooms and merchandise in active inventory areas | | | -Report audit results to Dir of Surgical Services<br>-Include in new staff onboarding orientation/training medication inventory management | |
| L1128 | Have accessible and follow manufactures instruction for use<br><br>Plan to :<br>-Ensure equipment maintenance & operational manuals are accessible on site<br>-Revise Clinical Area Testing Manual in Equipment and Calibration Section of Autoclave Operation to include<br>1. Daily door gasket cleaning<br>2. Weekly air jet cleaning & chamber cleaning<br>3. Monthly safety valve cleaned and checked<br>4. Annually replace door gasket and inspect locking device for wear<br><br>-Ensure documentation by independent calibration & repair vendor technician during annual equipment calibration inspection specific service check items/systems performed including replacement of rubber door gasket<br>-Revise autoclave maintenance documentation for daily, weekly, monthly and annual completed on the Autoclave Cleaning & Testing Log<br>-Conduct staff review training of autoclave operational checks of daily door gasket cleaning, weekly air jet cleaning and monthly safety valve check | by 5/31/2015<br><br>by 5/31/2015 | Dir of Quality & Training<br><br>Dir of Quality & Training | -Revise QM Monthly Site System Review form to include equipment maintenance & operational manuals available to staff<br>-Annual 2015 calibration inspection report by external company lists specific items/systems checked for safety and proper operations (next annual calibration due 8/2015)<br>-Continue with annual equipment calibration listed as a CQRM (Compliance Quality Risk Management) work plan activity<br><br>-Surgical Nurse Coordinator/Infection Prevention Committee Member monthly monitoring & signature acknowledgement on Autoclave Cleaning & Testing log completion<br>-Staff sign attendance training sheet for autoclave operational checks for daily door gasket cleaning, weekly air jet cleaning and monthly safety valve check | N/A |

| A | B | C | D | E | F |
|---|---|---|---|---|---|
| ID/tag number (Q0001) | Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice. | Correction Date (within 60 days from receipt) | Title of Person Responsible for Correction | Describe monitoring procedure to ensure continued compliance, to include:<br>- Frequency/duration of monitoring<br>- Method of data collection<br>- Who monitors, if different than "D" | Evidence/ Exhibit Attachment Numbers or "N/A" |
| | | | | | |
| L1128 | Monitor the humidity in the sterilization and decontamination instrument processing area<br>Plan to:<br>-Purchase humidistat to monitor humidity level of decontamination and sterilization areas<br>-Revise room temperature log to include daily documentation of relative humidity<br>-Train appropriate staff on monitoring and documenting daily humidity | by 5/31/2015 | Dir of Surgical Services | -Supervisory monitoring and signature on form indicating completion by appropriate staff<br>- Include in new staff onboarding orientation/training management of room temperature to include monitoring of humidity level | N/A |
| L1128 | Protect sterile items from dust and moisture by placing a solid barrier on the bottom shelves<br>Plan to:<br>-Purchase and install protective barrier on bottom shelf of sterile instrument storage rack | by 5/31/2015 | Dir of Surgical Services | Include on QM Monthly Site System Review form audit item to check for protective shelf barrier on bottom shelf of sterile instrument storage rack | **L1128 F-4 QM Monthly Site System Review** |
| L1128 | Ensure staff wear personal protective equipment appropriate to the task performed<br>Plan to:<br>-Review and re-train staff that work in decontamination area of PPE selection and use during tasks where possible exposure to potentially infectious materials anticipated | by 5/31/2015 | Dir of Surgical Services | -Decontamination staff sign training attendance sheet for review of selection & use of PPE<br>-Complete QM Monthly site review audit that includes this criteria | N/A |
| L1128 | Replace worn patient-care items with functional easily cleanable surfaces<br>Plan to:<br>-Replace ultrasound room C examination table upholstery covering<br>-Ensure cleanable surfaces, free from tape& adhesive for cabinets, refrigerators, clip boards<br>-Include in QM Monthly Site System Review Audit item of cleanable surfaces for equipment and patient care items | by 5/31/2015 | Dir of Surgical Services | -Include on QM Monthly Site System Review form audit item for cleanable surfaces of patient care areas/items | L1128 F3 repair invoice attached |

| A | B | C | D | E | F |
|---|---|---|---|---|---|
| ID/tag number (Q0001) | Plan of correction for deficiency noted and plan for addressing all related areas affected by deficient practice. | Correction Date (within 60 days from receipt) | Title of Person Responsible for Correction | Describe monitoring procedure to ensure continued compliance, to include:<br>- Frequency/duration of monitoring<br>- Method of data collection<br>- Who monitors, if different than "D" | Evidence/ Exhibit Attachment Numbers or "N/A" |
| L1128 | Ensure clean, free from dust surfaces of equipment, drawers, shelves and other horizontal surfaces<br>Plan to:<br>-Review and re-train staff of environmental area furniture and equipment potential for dust and cleaning expectation<br>-Establish standard for pillows completely covered with plastic covers<br>-Replaced pillows with plastic , non-permeable covers and re-train staff for cleaning standard<br>-Revise Quality Management Checklist, include in Clinical Area Testing Manual I Equipment Operation and Management section Refrigerator cleaning daily and completion of Laboratory Daily Cleaning Checklist<br>-Train staff on Laboratory Daily Cleaning Checklist | by 5/31/2015 | Dir of Surgical Services | -Include on QM Monthly Site System Review form audit item to check for dust<br>-Monitoring for completion Laboratory Daily Cleaning Checklist by staff of daily initials and weekly supervisory signature<br>- Staff sign attendance training sheet for Laboratory Daily Cleaning Checklist conducted by Clinical Manager<br>-Laboratory staff orientation onboarding documentation includes criteria for laboratory daily cleaning | **L1128 F-4 QM Monthly Site System Review** |
| L1136 | Ensure the external pathology service submit tissue reports to the Missouri Department of Health and Senior Services<br>Plan to:<br>-Formalize agreement with letter of understanding from pathologist to file a copy of tissue reports with the State Department of Health and Human Services | by 5/31/2015 | CEO | -Include requirement of external pathology service submitting tissue report to Missouri Department of Health and Human Services in RHS of PPSLR service standards.<br>- Director of Quality and Training will ensure pathologist agreement letter acknowledgement on file as part of annual review of contractual agreements | N/A |
| L1184 | Ensure dating of glucometer test strips for discard date<br>Plan to:<br>-Staff review of procedure for dating on the bottle of test strips the expiration date when they should be discarded | by 5/31/2015 | Clinical Manager | -Observation audit of dating documentation of written discard date during QM Monthly Site System Review | **L1128 F-4 QM Monthly Site System Review** |
| | | | | | |
| | | | | | |
| | | | | | |

1184

**PHARMACEUTICAL SERVICES**

7.1.1 Policies and Procedures – **must** include

Formulary of all drugs stocked in the affiliate that is reviewed annually

A. 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.

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

List of additional therapeutic/pharmacologic classifications of drugs that may be ordered for clients to obtain at outside pharmacies

Provision of pharmaceuticals in accordance with all state/local laws and regulations

A drug control system that covers the interval from the time pharmaceuticals are ordered until they are provided to the client

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

7.1.2 Procurement

I. There **must** be a written order for all drugs/pharmaceuticals/chemicals brought into the affiliate:
   A. 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 delivery is made by affiliate staff, a signed receipt is not necessary.
   B. Controlled substance order and receipt records **must** be filed separately from the other pharmaceutical purchase records.

II. 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, at a minimum, requirements for labeling.

III. If available, pharmaceuticals should be purchased in manufacturer prepared unit-of-use packages.

IV. 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.

7.1.3 Storage

I. Access
   A. The bulk storage area **must** be secure.
   B. Controlled substances **must** be locked and in a secure area at all times.
   C. Access to pharmaceuticals dispensed from within client care areas should be limited to health care providers responsible for dispensing these items.

How to store

   D. Arrange medications so that the oldest stock is used first.
   E. Do not store look-alike, sound-alike medications alphabetically. Store them out of order or in a separate location.[RI]
   F. Pharmaceuticals meant for internal use **must** be stored separately (i.e., on a separate shelf) from those for external (i.e., topical) use only.
   G. All prescription medications should be stored in containers that protect them from light.
   H. All manufacturer recommendations for storage **must** be followed.

Storage for contraceptive vaginal ring (CVR)

I. An expiration date **must** be on the label of each ring package. If needed, use the adhesive labels provided in the carton.
J. For rings that will not be refrigerated, the adhesive label **must** be applied directly over the pre-existing expiration date on each cachet pouch (and on the outer carton). This date should not exceed either 4 months from the date of dispensing, or the product expiration date, whichever comes first.
K. For refrigerated NuvaRing, the product expiration date may be used.
L. NuvaRing packages that need to be refrigerated **must** be clearly marked.
M. NuvaRing should never be stored in direct sunlight or at temperatures above 30°C (86°F).

Store Mifepristone and misoprostol at room temperature.

Storage of multi-dose vials

N. Unopened multi-dose vials – **must** follow manufacturers' recommendation for storage
O. Opened multi-dose vials
    1. When a multi-dose vial is used, appropriate infection prevention procedures to prevent contamination should be employed.[R2]
    2. Vials **must** be discarded if there is evidence of contamination.
    3. 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.
    4. If no specific guidelines are provided, CDC recommends discarding the vial within 28 days. [R2]
    5. Syringes taken from multi-dose vials must be labeled with medication name, date, time and staff initials. If not used within 24 hours, it must be discarded.
    6. Open vials of misoprostol should be discarded after 30 days.
    7. Multi-dose vials (once opened) shall be kept in centralized location, (RHS-the nursing station in Recovery, HC- laboratory area).
P. Single use medications are used for one client only and are discarded after use on each patient.

Prescription pads

Q. Must be secured in medication cabinet when not in use.

**Reproductive Health Services of Planned Parenthood of the St. Louis Region**
**4251 Forest Park Avenue, 63108 314-531-7526**

**QM Monthly Site System Review** **Month_____/_____**
**To be completed monthly by Director of Surgical Services/Delegate**

**Site**_____ **Auditor**_____

| Date | System Reviewed | Guidelines Met | Guidelines Not Met |
|---|---|---|---|
| | **Exit and pathways in the surgical center are clear** | | |
| | **Computer passwords are secured and not visible** | | |
| | **Areas free from dust &debris, tape:** Surfaces of medical equipment, cabinets & drawers, medication refrigerator, ceiling vents | | |
| | **Universal Precautions used by all staff (including before & after pt contact)** | | |
| | **Personal Protective Equipment available & appropriately used** (masks, face shield lab coats, gloves in various sizes, face shield, vinyl gloves, utility gloves) | | |
| | **Steps to follow when an accident occurs involving workers compensation is posted and forms readily available for staff** | | |
| | **Emergency equipment in the surgical center:** ***(audited by a supervisor_____)***<br>Resuscitative equipment First Aid Kit Spill Kit/Supplies *(initials)*<br>Flashlights and back up lighting operable Ammonia Capsules Defibrillator<br>Exit lighting operable Cart with emergency supplies & weekly checklist current | | |
| | **Fire Extinguishers easily accessible, charged, inspection current** | | |
| | **MSDS Log current with supplies that are used in the surgical center** | | |
| | **Housekeeping:**<br>Procedure rooms & equipment clean Overall cleanliness of site (floors, counters, equipment, regular and biohazard trash not over flowing containers)<br>Bleach/Water solution in 1:10 ratio or disinfectant solution with documented change<br>Surface decontamination performed per infection control protocol | | |
| | **Staff use protective equipment for patient interactions, cleaning of rooms and equipment management as necessary** | | |
| | **All specimens labeled, handled appropriately and staff follow general packaging requirements.** | | |
| | **Disposed specimen containers with PHI de-identified before disposal** | | |
| | **Single use suction tubing discarded after each procedure** | | |
| | **Decontamination receiving and clean/sterilized items separated** | | |
| | **Sterile Instrument Storage**-protective shelve barrier present on bottom shelf | | |
| | **Checklist completed by assigned staff**<br>-Daily lab refrig temp - Decontamination & Sterilization Procedures documented<br>-Sterilizer indicator with each autoclave batch -Weekly & Monthly autoclave cleaning & testing<br>Weekly Spore Testing documented for each autoclave machine | | |
| | **NO expired merchandise in active inventory areas (such as storage rooms or drawers; procedure & patient care rooms &shelving; laboratory room, laboratory/patient supply refrigerator; decontamination, sterilization and front desk/reception areas)** | | |
| | **Multi-use medication/vials** are dated upon opening with discard date | | |
| | **Controlled substance log/appropriate documentation completed when applicable** | | |
| | **Sharp Collectors placed on shelves or in wall brackets** | | |
| | **Potentially infectious waste**(i.e. blood soaked products, IV tubing with blood, tissue, POC) **in appropriate containers** | | |
| | **Disposal of sharps** (i.e. needles, lancets, capillary tubes syringes with needles, used microscopic slides & cover slips, etc.) **in appropriate sharp containers** | | |
| | **Unexpired cleaning supplies & equipment accessible to staff** | | |
| | **Clinic Procedure and Laboratory Practices Manual in surgical center** | | |
| | **Proficiency Log in place and current for newly hired staff** | | |
| | **Workstations free of hazards** | | |

**Comments:**

**Corrective Actions:**

# Invoice

**Superior Upholstery**
38 Circle Way Drive
ST PETERS, MO 633 76
United States
Tel: 314-607-8049

**Bill to:**
Planned Parenthood
4251 Forest Park Ave
St Louis, MO

**Invoice number:** 89389
**Invoice date:** April 15, 2015
**Due date:** May 15, 2015

**Amount due : $350.00**

**NOTES**
If you have any questions about this invoice, please call Dan Lorcro at 314-607-8049.Email to Superiorupha@gmail.com

| Product/Service | Qty | Price | Amount |
|---|---|---|---|
| **Exam Table**<br>Recovered | 1 | $350.00 | $350.00 |

**Total $350.00**
**Amount due $350.00**

Thank you for your business.

OK to PAY
P.M
4/18/2015