STATE OF WASHINGTON DEPARTMENT OF HEALTH

Pharmacy Inspection Report
Routine Inspection

June 4-5, 2014 — Total pages: 14

University Medical Center Pharmacy
Inpatient
1959 NE Pacific St
Seattle, WA 98195
Pharmacy Name and Address

PHAR.CF.00001058	(425) 598-6060	ONGOING - ROUTINE
License Number	Telephone Number (w/area code)	Inspection Type
5/5/2014 (routine)	Hospital	Steven A Fijalka PH11708	X2014-595
Last Inspection Date	Pharmacy Type	Pharmacist in Charge	Inspection Number

A. GENERAL REQUIREMENTS (10 POINTS)
UP TO 3 POINTS SUBTRACTED FOR EACH DEFICIENCY

Section A Total Points Deducted: 0

B. PATIENT HEALTH & SAFETY REQUIREMENTS (30 POINTS)
UP TO 5 POINTS SUBTRACTED FOR EACH DEFICIENCY

Section B Total Points Deducted: 0

C. PROFESSIONAL REQUIREMENTS (40 POINTS)
UP TO 5 POINTS SUBTRACTED FOR EACH DEFICIENCY

Section C Total Points Deducted: **15**

D. FACILITIES (20 POINTS)
UP TO 2 POINTS SUBTRACTED FOR EACH DEFICIENCY

Section D Total Points Deducted: 0

Grade Total
85

100 To 90 Points = A | **89 To 80 Points = CONDITIONAL** (WAC 246-869-190) | 79 Points or lower = UNSATISFACTORY

Please note that the deficiencies/violations/observations noted in this report are not all-inclusive, but rather were deficiencies/violations/observations that were observed or discovered during the on-site inspection.

(-5 pts) C.04 Responsible Pharmacy Manager
(-5 pts) C.07 Pharmacy Ancillary Staff
(-5 pts) C.13d Regulation Compliance - Hospital Physical Requirements

Pharmacy interns may not count their hours while the pharmacy does not have a Class A rating, please notify any intern working at this site of this restriction.

Comments (see other pages of this report): [x] Yes [ ] No

Signature of Pharmacist (Steven A Fijalka)

Signature of Investigators (Julie Faun & Heidi Welborn)
Office of Investigations and Inspections
Kent Regional Office
20425 72nd Ave South Suite 310
Kent, WA 98032

Inspection Comments

The Director of Pharmacy is Steven A Fijalka (PHRM.PH.00011708).

A follow-up inspection of the UWMC Inpatient Pharmacy (UWMCIP) was performed from 6/4/2014 to 6/5/2014 with the assistance of Pharmacist Investigator Heidi Welborn. An Inspection Report and Certificate were delivered on 6/13/2014. The inspection was facilitated by Inpatient Pharmacy Managers Jackie Biery and Deborah Frieze, Pharmacists Kathy Tamura and Shabir Somani, UWMC Chief Pharmacy Officer, with considerable assistance provided by pharmacy and hospital support staff. UW Pharmacy Residents Ives Hot and Adam Levin were also present throughout the follow-up inspection.

RPM Fijalka indicated that due to a scheduled vacation, he may not be present during the follow-up inspection. Thus, he drafted a document outlining action items conducted to address deficiencies in sections B.01b, B.06d, C.02, C.07, C.13c. This document was presented for review by Pharmacy Managers Biery and Frieze. When asked to provide a copy, the request was declined. In leu of provided documentation, notes were taken by myself and Investigator Welborn.

All pharmacists and pharmacy technician staff members that were interviewed, freely answered questions and demonstrated procedures. Pharmacy staff permitted access to the pharmacy, records, and hospital units. At the conclusion of inspection, Mr. Somani introduced several clinical pharmacists who provided an overview of the pharmacy's clinical functions (Anticoagulation, Transplant Services, Cardiac Services) in servicing UWMC patients. I noted that all pharmacist clinical staff provide a high level of patient care; however, there needs to be a prioritized and concerted commitment and implementation to bring the facilities up to current acceptable industry standards per RCW 18.64.270(2) to ensure safe and effective patient treatment.

PHARMACY FUNCTIONS OBSERVATION:

1) The Pavilion Pharmacy is designated as a satellite pharmacy operating under the UWMCIP license CF1058. Procedural IV and med orders are processed using the UWMCIP PharmNet system, discharge prescriptions are processed under the retail Cerner Pharmacy system. This pharmacy services the drug needs of some of UWMC's inpatient population for select surgeries/procedures requiring the specialty equipment available in the Pavilion Surgery suites. However, most of the patients serviced by this pharmacy are ambulatory patients, the procedures/surgeries conducted are day surgeries, patients are discharged with prescriptions issued by UW practitioners, processed in the Pavilion pharmacy's Cerner system and picked up from this pharmacy's customer service window. The Pavilion Pharmacy had differential hours posted.

This pharmacy does not appear to function as a hospital inpatient pharmacy by definition in RCW 70.41.020(4) because the patients are not hospital inpatients. It appears to be a pharmacy that serves UW ambulatory outpatient procedure patients. We discussed license functions (what does this pharmacy do?). The pharmacy services provided by the Pavilion Pharmacy are very similar to those provided by the UW Eastside Clinic Pharmacy (retail pharmacy with IV functions, servicing ambulatory patients).

It was noted that this satellite pharmacy has gotten very busy as UWMC ambulatory surgery procedures using this facility has increased. Originally, the rationale for filling ambulatory patient discharge prescriptions in this pharmacy was for patient convenience, facilitated discharge counseling, and work quota. During the survey of the Pavilion Pharmacy, the pharmacist was observed trying to simultaneously fill discharge prescriptions for 3 patients in addition to regular duties on the procedural side and answering phone calls from the procedure unit. Pharmacist Biery noted that discussions have taken place regarding transferring the discharge prescriptions to the UWMC Outpatient Pharmacy, while the Pavilion pharmacy would be responsible for servicing the medication needs of the ambulatory surgery center.

2) The Oncology Pharmacy is designated as a satellite pharmacy operating under the UWMCIP license CF1058. This pharmacy services ambulatory patients requiring on-site chemotherapy infusion, usually by pre-determined appointments. This pharmacy is equipped with IV preparation facilities (ante-room, BSC in chemo room and Clean Bench LAFW in a separate clean room). The Oncology Pharmacy uses the UWMCIP PharmNet system to process IV orders because the retail Cerner system does not provide the pharmacist with adequate and robust IV functionalities to safely perform med reviews and analysis. In the rare occasions where a patient needs to go home with an IV bag, the PharmNet system has been programmed to print auxiliary labels that are affixed to the prepared IV bag compliant with WAC246-869-210. The PharmNet system does not have refill capabilities. Thus, for outpatient orders that authorize multiple dosing schedules, the pharmacist keeps a paper master record of the authorized order, and documents each fill as a new order entered into the patient's profile.

This pharmacy does not appear to function as a hospital inpatient pharmacy by definition in RCW 70.41.020(4) because the patients are not hospital inpatients. It appears to be a pharmacy that serves UW ambulatory outpatient oncology patients. We discussed license functions (what does this pharmacy do?).

It was noted that a new oncology pharmacy is being built on the 8th floor to be completed by August 1. There are also plans to complete a new ICU pharmacy satellite within a year.
Please ensure that remodel applications are timely submitted to WSPQAC/DOH for review. Please also ensure that you notify investigator Greg Lang (Gregory.lang@doh.wa.gov) to update him on the progress of the remodels.

DEFICIENCIES:

(- 5 pts) C.04 Responsible Pharmacy Manager - WAC 246-873-040 and WAC 246-869-070 - REPEAT VIOLATION
Additional points are deducted for failure to correct repeat violations found in this report.

- Absence of policy and procedure addressing annual review of policies and procedures WAC246-873-080(3)

Note from action item document: New policy developed to include annual review of P&Ps. (Policy Number not provided. This policy is pending P&T approval) All pharmacy P&Ps reviewed, revised or archived.

Findings:
Drafted policy for Administrative Guidelines: Policy Guidelines for Pharmacy Policies and Procedures effectively dated 05/26/2014 was provided for review. This policy has not yet been reviewed or accepted by the Hospital P&T committee.

- Absence of appropriate documentation required for scheduled cleaning of sterile compounding areas, inadequate P&Ps regarding documentation of scheduled cleaning of sterile compounding areas, and inadequate training and documentation of training of staff assigned to cleaning and disinfection of sterile compounding areas.

Note from action item document: "IV room cleaning P&P reviewed and updated. Training program developed and administered to staff."

Findings:
It was observed that the required documentation regarding daily cleaning did not meet United States Pharmacopeia standards.

It appeared that required daily/monthly documentation of cleaning began on May 29, 2014. However, there were several days and several entries where required initialing of cleaning performed did not occur between May 29th and June 5th. It was indicated by Ms. Frieze that

cleaning did not occur over the weekend because the Environmental Services department did not realize that they still needed to clean on the weekends.

Documentation was provided of the "Hood Horizontal Surface Wash Documentation – Inpatient Pharmacy – All hoods in IV Room Clean Room." This documentation, observed beginning June 1, 2014, found that the hoods were only being cleaned during the 0730-1530 shift.

The minimum frequency for cleaning and disinfecting compounding areas require that cleaning an ISO-5 PEC occurs: at the beginning of each shift, before each batch (which, according to Ms. Frieze, is occurring every 2 hours), not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or suspected.

It was observed that the Policies and Procedures regarding daily and monthly cleaning of the aseptic preparation area of the inpatient pharmacy (Policy Number 5.06 IV Admixture Service – Facilities, Equipment and Supplies) states that this is a limited access area that should be an ISO-7 Clean Room.

The P&P further states what should be cleaned daily versus monthly. However, a policy was not provided regarding who, what, why, and where of proper documentation of daily/monthly cleaning.

Proper P&Ps should indicate all areas in which proper sterile compounding areas must have cleaning, should include the removal of trash included as a daily task, needs to specify what bactericidal cleaning agent is to be used and also have proper documentation of a cleaning solution preparation log.

The P&P states that the floors of the aseptic admixture area are non-porous and SHOULD be disinfected daily. This must be changed to MUST or SHALL as the word "should" is deemed a suggestion rather than a requirement.

It was observed that the daily cleaning log states that the interior of the laminar flow hoods are cleaned with Cavicide and disinfected with isopropyl alcohol every shift. I could not find anywhere in the P&Ps that stated this.

It was also observed that the ONC satellite pharmacy cleaning log also said "Inpatient Pharmacy." Each sterile compounding area should have its own specifically labeled documentation of cleaning to avoid confusion.

The training of staff responsible for cleaning sterile compounding areas must include: Review of the mechanism for particulate control that is provided by the PEC (primary engineering controls) and SEC (secondary engineering controls), dilution of cleaning agents, cleanroom asepsis, specific areas to be cleaned, employee safety/ use of PPE, cleaning agents used, mechanisms and frequency of cleaning, documentation, and use of environmental sampling to provide feedback for cleaning practices.

Training of personnel that are given the duties of maintaining a sterile environment must be formal and documentation of completion must be in writing. Training must be outlined in a Policy and Procedure. In addition to a formal training program, those that perform cleaning in a sterile compounding environment must also complete and be evaluated on proper hand hygiene and garbing which includes passing 3 glove fingertip samples and the cleaning and disinfecting competency (Appendix V) in USP <797>.

When documentation was requested for P&Ps regarding staff training of outside pharmacy staff, Policies and Procedures were provided from the Environmental Services Department. On the P&P it specifically states what the requirements are for "Surgery Terminal Cleaning." It

would appear that the P&P for this procedure is being revised to adhere to cleaning a sterile compounding environment. This P&P had not been approved at the time of inspection. These P&Ps did not address proper hand washing or fingertip testing, among other USP <797> requirements. A Power Point presentation was also supplied that pharmacy was using to train staff members in the proper cleaning of sterile compounding environments. However, there were inaccuracies found in the training materials. For example, all cleaning supplies necessary must be kept in the sterile compounding area. In the Power Point presentation, one slide specifically says that "prior to entering the room for cleaning, ensure that you have the proper cleaning supplies and equipment for daily use." But on the next slide it states that "all equipment used in the pharmacy IV rooms SHOULD be stored in these immediate areas..."

Deficiencies found do not appear to have been corrected to comply with RCW 18.64.270(2) - any medicinal products compounded for patients or for distribution to a practitioner for patient use must meet official United States Pharmacopeia standards as they apply to non-sterile and sterile products.

(- 5 pts) C.07 Pharmacy Ancillary Staff WAC 246-901 - REPEAT VIOLATION
Observations show that records of pharmacy technician training and demonstration of proficiency for IV specialized functions are deficient.

Findings:
Upon review of the training records and training program most recently implemented since the prior inspection, it was found that a Power Point presentation was emailed to current IV compounding staff. After a review of the Power Point presentation, the staff was asked to take a multiple choice test for competency evaluation. This was a 20 question multiple choice test to review USP <797> Competency. The results of the failure rate (which Ms. Frieze indicated was 95% to pass – which only allows for one wrong answer) was 68% (36 of 53 had to retake the exam). For those that did not pass with a 95%, the exam was taken a second time, utilizing the same questions but in a different order. Even after the second time taking the exam, it was observed that three individuals still had not passed with a score of greater than 95%. One individual who did not pass initially did not take a second exam.

It was also observed that the IV Calculations exam was changed drastically and instead of a written, calculations-based exam, it became a 10 question multiple choice exam. In this case, if an individual had even one wrong answer, they would not achieve the required 95% to pass and would therefore need to take the exam again. It should be noted that the same individual that did not take a second exam after failing the first USP <797> exam also did not pass the IV Calculations exam on two attempts.

Of note, questions developed for this USP <797> exam do not appear to completely address USP <797> competency requirements.

During the inspection, visual observation occurred of a pharmacy technician performing aseptic manipulation of product in the LAFW which still contained a "glue-like" substance in the back vented area of the LAFW. The technician was observed to be garbed in PPE, including non-sterile gloves. The technician was observed to be outside of the LAFW, working on the computer and pulling labels. The individual then went to the LAFW, where product had already been placed, sprayed both palms of his hands with sIPA, did not wait for the alcohol to dry, and then sprayed the tops of all vials lined up in the LAFW. He then proceeded to reach his gloved hand outside of the LAFW to obtain syringes that are placed underneath the bench of the hood. After putting his gloved hands back inside the LAFW, the technician did not spray his hands again with sIPA, but began opening the syringes for product manipulation.

C.12 Regulation Compliance -
RCW 18.64.270(2) - any medicinal products compounded for patients or for distribution to a practitioner for patient use must meet official United States Pharmacopeia standards as they apply to non-sterile and sterile products.

Observations and survey findings confirm that many functions related to IV preparation including but not limited to engineering controls (cleanrooms, LAFWs), personnel training, QA and end product testing do not appear to meet USP standards.

Some of these findings were noted on 3 previous inspections (2014 routine inspection findings, 2011 - current sterile compounding area does not meet USP and ASHP facility guidelines, no sterility or end product testing, 2009 - not having adequate monitoring and assessment of sterile compounding)

Note: Upon discussion with Chief Pharmacy Officer Somani, it was noted that the pharmacy is exploring either a plan to remodel the current inpatient pharmacy to meet USP standards (sample plans provided) or planning to acquire compounding aseptic isolators (CAIs) within 3 months to address medium risk compounding in satellite non-segregated compounding area. Mr. Somani notes that there are also plans to acquire and build a central fill pharmacy (a 30,000 sq. ft building with USP 797 compliant facilities, manufacturer and wholesale licenses, storage of critical drugs, and pharmacy automation of inventory), to service the entire UWMC within 16 months. The acquisition of Simplifi797 software to support IV functions is in the process of contract negotiations.

- **Survey findings did not confirm documented action plans to appropriately correct. It appears that pharmacy staff may require complete training in USP standards compliance.**

(-5 pts) C.13d Regulation Compliance - Hospital Physical Requirements WAC 246-873-070, RCW 18.64.270(2) – REPEAT VIOLATION

Compounded sterile product contamination risk level: The appropriate compounding risk level must be determined by a licensed healthcare professional who supervises compounding. It was indicated by Ms. Donnelly that all IV rooms in the hospital are to be considered "immediate-use" compounding except the ISO-6 (Class 1000) buffer room located adjacent to the IV room in the inpatient pharmacy, which is to be considered the "clean, clean" room.

Findings:
Upon entry to the designated ISO-7 buffer room, it was observed that the chair had open tears that exposed foam, there were several areas of chipped wall paint, a shoe print was found on a metal cart, and there was dust on the wheels of another cart. A BSC had recently been removed from this room and another LAFW hood had been moved in and had been certified as ISO-5. It is unclear if the buffer room itself received recertification after the entry of the new LAFW. Documentation of such was not provided.

Environmental quality and control:

ISO Class-5 air sources, buffer areas, and ante-areas:
This facility most closely resembles the representation of a placement of an ISO Class-5 PEC (primary engineering control) in a segregated compounding area used for low-risk level CSPs with 12-hour or less BUD.

This facility has multiple IV Rooms. Two areas contain an ante and buffer room, the inpatient pharmacy, adjacent to the IV Room and the oncology satellite pharmacy.

It was found that there are 3 LAFW hoods and one biological safety cabinet (BSC) located within the segregated compounding area of the inpatient pharmacy. One of these LAFW hoods in particular had what appeared to be rust and other discoloration behind the grate located on the back of the hood. There also appeared to be a section that had what appears to be glue on the filter. It was indicated that the glue was placed there by TSS or Asepsis during maintenance. However, the glue now appears to be discolored and have discoloration on it as well. The grate at the bottom of the hood appeared to have layers of dust and growth of some sort inside. The back grate of the LAFW in the ICU satellite also contained visible rust/discoloration.

Findings:
After re-inspection, it was observed that that the inpatient pharmacy "IV Room" is continuing to be utilized as a segregated compounding area. It was observed that this area still contains an open, unsealed window and ungarbed personnel entering and exiting the space. Ms. Frieze indicated that all products compounded in this area have a 12 hour BUD but the site does not have proper adherence to USP requirements regarding a segregated compounding area.

It was also indicated that this area is used to prepare batch products. This was specifically addressed in the previous inspection report:

Placement of primary engineering controls: **If the PEC is a LAFW or BSC that cannot be located within an ISO Class-7 buffer area, then only low-risk level nonhazardous CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.**

As stated, there cannot be batch preparation using a PEC in a segregated compounding area. It should be noted that while batch preparation was occurring in the inpatient IV room, there were two LAFW hoods not being utilized in the certified ISO-7 buffer area adjacent to the IV room.

The compounding personnel are continuing to use non-sterile gloves in their sterile preparation of products. When asked why sterile gloves are not being used, Ms. Frieze indicated that it was a cost issue and that spraying the non-sterile gloves with sIPA (sterile isopropyl alcohol) was adequate. USP <797> requires the use of sterile gloves for all compounding activities in all types of primary engineering controls.

It was observed that particle board was still exposed in several areas and there did not appear to be any attempt to cover the exposed particle board.

The inpatient pharmacy IV room is also continuing to use a BSC in a positive pressure segregated compounding area. Hazardous drugs must be prepared in conditions that protect the pharmacy staff. According to USP, all hazardous drugs shall be prepared in a BSC located in an ISO-7 area.

Total particle counts: All certification records shall be maintained and reviewed by supervising personnel or other designated employees to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and ACPHs.

It was observed that two of the IV Rooms tested for nonviable particle testing did not pass certification for ISO Class 7. These two IV rooms were the main OR satellite pharmacy and the Pavilion satellite pharmacy, located within the surgery/operating wing.

Findings:
It was also observed that although the OR satellite pharmacy and the Pavilion satellite pharmacy are located in non-ISO-7 compounding areas, the pharmacy personnel are still continuing to compound sterile products without adhering to the requirements of a segregated compounding area (open window, high traffic flow, non-properly garbed personnel, etc).

Pressure differential monitoring: A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum daily) or by a continuous recording device. This activity does not appear to be done.

Findings:
On the newly formed cleaning log, there are two columns for "Air Flow Check" for the Ante Room and Clean Room on the cleaning log with a space for initials for each column for each day.

As noted in the previous inspection report, USP <797> states: A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The *results shall be reviewed and documented* on a log at least every work shift (minimum frequency shall be at least daily) or by continuous recording device. Therefore, a person's initials stating that they performed an "air flow check" are not sufficient to meet this requirement. Rather, the actual differential airflow observed shall be recorded and maintain 5 Pa between an ISO-7 and the general pharmacy area and 0.2 meters per second between the buffer area and ante area.

Environmental viable airborne particle testing program: The risk of contaminating a CSP prepared under low-risk level conditions is highly dependent on proper hand hygiene and garbing practices, compounding personnel aseptic technique, and presence of surface contamination, assuming that all work is performed in a certified and properly functioning ISO Class-5 PEC. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted. Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. Regardless of the number of cfu identified in the pharmacy, further corrective actions shall be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler.

When asked for the total colony count results from the viable count testing performed on 01/16/2014, the pharmacy manager responsible could not produce the results and needed to contact TSS and have them fax the results to her. The results showed the following:
3 cfu bacterial in NICU – airborne viable
2 cfu fungal in ICU satellite – airborne viable
8 cfu bacterial ICU satellite – airborne viable
4 cfu fungal in Main OR satellite – airborne viable
1 cfu fungal in NICU Inpt – contact plate
3 cfu fungal in Inpatient IV Room – contact plate
1 cfu bacterial in Oncology satellite – contact plate
9 cfu bacterial in ICU satellite – contact plate
3 cfu bacterial in Pavilion surgery satellite – contact plate

Findings:
Certification was conducted in January of 2014. Certification of all primary and secondary engineering controls must be done every six months for low or medium risk compounding. Although the next certification for these areas is not technically due until July 2014, and even in light of the non-class A inspection report, the facility chose not to have all areas re-certified prior to this re-inspection. Therefore, the information provided during the prior inspection cannot be updated regarding the testing program. It should be noted that Ms. Frieze indicated that the cost difference between not having CFU counts plated and having them plated was $20 per plate and that the facility has now added that to their contract for all future certifications.

Additional personnel requirements: Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated compounding areas where components and ingredients of CSPs are present.

It was observed that a non-gowned pharmacist entered the IV Room to check the compounded prescriptions located on a wire metal cart located just within the IV Room. A sign is taped to the window of the IV Room door stating, "IV Room/No food or drinks allowed/All personnel must be gowned upon entering."

Findings:
Again, non-gowned personnel were observed entering the room to take product into the segregated compounding area. It was indicated that this non-gowned individual had sprayed the bin of stock with sIPA before entering. It was observed that the individual had non-gloved hands while carrying the recently sprayed bin.

CORRECTIONS MADE:

(-0 pts) B.01b Patient Medical Records – Significant Chronic Conditions (WAC 246-875-020(2)(c))
Any patient allergies, idiosyncrasies, or chronic conditions which may relate to drug utilization.

After reviewing the patient profiles, it was found that there is a field to enter chronic conditions, but it was not always complete. If the pharmacist wants to review a more complete record, they need to look at the prescriber's original consultation with the patient. Information provided indicated that the pharmacist checks the chronic conditions when the patient is first admitted to the hospital but when new orders are added or changed, the chronic conditions are not checked again. A survey of a patient profile in the Pavilion pharmacy's Cerner Etreby system did not show chronic conditions entered.

Note from action item document: "Pavilion staff were educated on CMC review before dispensing discharge prescriptions. There was confusion regarding the need for CMC in ambulatory surgery patients receiving short term medications."
Policy 2.03 New Medication Orders was updated and staff educated on P&P on 6/2/14.

Findings:
A random survey of 3 patient profiles from admit records to procedure meds filled in Pharmnet to discharge meds filled using Etreby found that chronic conditions were documented. The pharmacist was required to search through multiple fields in the patient's admit history, med history and chart notes to obtain CMC information and copy to the Cerner system. The challenge for the pharmacist is to be able to search and document CMCs consistently at all times to ensure that the system conducts meaningful DURs.

(-0 pts) B.01c Patient Medical Records - DUR Chronic Conditions - WAC 246-875-040
This deficiency was noted in a previous inspection (2011) and does not appear to have been addressed.

The PharmNet system does not appear to utilize as part of its DUR system a module for Chronic Medical Condition (CMC) that is reviewed and maintained by the pharmacists.

The pharmacist can see admission medical histories in ORCA's admission intake, and prior to admission medications are entered into Orca in the patient's electronic chart. When a pharmacy uses an automated patient medical record system, the pharmacists must maintain in this system an up to date record of the patients CMC's as is stated in WAC 246-875-020 (2)(c). These CMC's would then be utilized by the DUR system in the same fashion as Drug/Allergy and Drug/Drug interaction/contraindication reporting. Although this DUR check is assumed to be part of the pharmacists' patient profile review, unless an intervention is documented, there is no other documentation that can ascertain a DUR for Chronic conditions was conducted 100% of the time. If a DUR for Chronic Medical Condition module is not available/turned on in PharmNet, it is required that a process be in place (via P&Ps) attesting that a manual DUR for chronic conditions is performed consistently by all pharmacists, thus complying with the rule.

Finding:
The PharmNet system does not have drug-CMC DUR screening capabilities. Policy 2.03 New Medication Orders states: 3(2): New medication orders require a review of the patient's medical record for chronic conditions which may relate to drug utilization. WAC 246-875-020(2)(c) (TJC MM 04/01/01) A diagnosis, condition or indication for use exists for each medication ordered. Note: This information can be anywhere in the medical record and need not be in the order itself. For example, it might be part of the medical history.

(-0 pts) B.06d Outdated/Deteriorated Stock < 9 items WAC 246-869-150
A random survey of selected areas in the UWMC hospital pharmacy (OR, ICU, Pavilion, Oncology, Inpatient), hospital units (odd numbered floors) and ambulatory clinics (surgical specialties, pre-anesthesia, headache, cancer, otolaryngology) found:

Inpatient Pharmacy:	0 expired items or items exceeding the BUD
Hospital units:	1 expired items or items exceeding the BUD (anesthesia gas inside OR workroom)
Ambulatory clinics:	0 expired items or items exceeding BUD

Note from action item document: Policy 2.17 Inspection Areas was revised to add manager accountability of outdate inspection completion including mandatory audits. More frequent audits will be conducted until requirement hardwired with staff. All medication storage areas within pharmacy and outside in UW Medical Center have been inspected for outdates.

Finding:
It was noted that the most recent unit inspections were conducted on 5/21/2014 and have been scheduled monthly with manager oversight.

(-0 pts) C.02 DEA Inventory record - WAC 246-887-020, 21 CFR 1304.11
Biennial inventory documents a printout of the CS (C2-C5) in Pyxis units located in all the hospital medication rooms at the time of the inventory count. The survey confirmed that it was not a physical count. CFR requires the registrant to "make an exact count or measure of the contents" of all C2's in the possession of the registrant.

Note from action item document: Conducted complete physical inventory of controlled substances on 5/27/2014 including all CS stored in Pyxis.

Finding:
A survey of the inventory documentations shows inventory conducted at "opening of business" in the morning of 5/27/2014 for C2 safe, C2 safe returns, Pyxis all areas, OR, ICU, Surg Pav, Inpt data, drug services. C2 records are separated from C3-C5.

(-0 pts) C.13e Regulation Compliance – Hospital Drug Procurement, Distribution, and Control - WAC 246-873-080
This deficiency was noted at the last routine inspection (2011).
Survey found inspection of inpatient nursing care units the inpatient pharmacy was responsible for were only conducted 2 to 3 times in 2013 and 2 times in 2014 (3/27/14 and 4/4/14 8 days apart) for over 40 locations. Unit inspections of the ambulatory clinics conducted by outpatient pharmacy designees found most areas inspected monthly in 2013-2014. 4 out of 16 areas were not inspected monthly and the maximum number of months a unit was not inspected for the past year was 3).

Note from action item document: Policy 2.17 Inspection Areas was revised to add manager accountability of outdate inspection completion including mandatory audits. More frequent audits will be conducted until requirement hardwired with staff. There is a process ongoing of reassigning current patient care unit areas to a smaller group of staff to maximize training and accountability.

Finding:
It was noted that the most recent unit inspections were conducted on 5/21/2014 and have been scheduled monthly with manager oversight.

When asked if there were any other drugs stored outside of a Pyxis machine, crash cart, or procedure boxes, it was indicated that there was one drawer in the bronchoscopy clinic that keeps controlled substances. When asked to be taken to observe the drawer, there was a challenge on finding someone who knew where it was. First we stopped at the Pulmonary department only to be told that the narcotics had been moved to the surgical wing with bronchoscopy. Upon arrival to the bronchoscopy department, no one could be found that knew where the drawer was. It was then determined that the nurse who would know was at a dentist appointment and would be back later in the day. We then went back to bronchoscopy and had the nurse open the drawer. The nurse indicated that she and the other nurses who work in bronchoscopy were the only ones with the key. She then indicated that the key, which states "broncho" was located in the Pyxis in the surgical wing. It does not have its own cubby, rather, it is stored with all the other keys and it would therefore be a challenge to know just which nurse removed the keys. After accessing the double locked box located in an unmarked open drawer in the clinic, it was found to contain fentanyl , midazolam and cocaine injectables. There is a perpetual log kept outside the drawer and wastage is documented on this log and witnessed by two nurses. The waste is dumped into the sink. They know how much they are wasting by what is remaining in the syringe. It should be noted that the drawer itself is hinged and I was able to remove the whole drawer containing the lock box and walk away.

Note from action item document Bronchoscopy drawer has been locked and key for padlock and interior CS box is located in Pyxis cubie.

Finding:
Photos were provided of the bronchoscopy drawer and lock box. Sufficient to satisfy correction of deficiency finding.

Other correction notes from action item document:
1) General cleanliness: all hoods were professionally cleaned on 6/2/2014
Documentation of hood cleaning was observed to be conducted by "Air Contamination Control."

2) Distribution records: forms were updated to have all required licensing info (copy provided)

Finding:
Please include documentation of lot numbers and expiration date of products that are to be distributed. Distribution records with sufficient and robust information serve to appropriately track the distribution of drugs in the event of recalls.

3) Expired vacutainers: information forwarded to materials management for follow-up

Finding:
A random survey of unit 7SE on follow-up inspection revealed expired vacutainers stored in med room drawers and totes. It was noted that lab services carry their own supplies in a tote. The vacutainers are re-stocked by materials management but materials management does not perform outdate checks. The vacutainers supplied in the med room bins are for nursing use. We discussed multiple ways to address oversight of this finding. Although not in direct purvue of pharmacy, this could pose a patient safety risk, as lab values generated from expired reactants in vacutainers would be inaccurate and affect drug dosing, pharmacist clinical monitoring, and diagnostic decisions.

4) Malignant hyperthermia cart in OR: process changed to be similar to code cart procedures
Note from email addressing malignant hyperthermia cart: Drawers to be locked with yellow seal (managed by materials management), refrigerator to be locked with green seal (maintained by pharmacy).

Medications in the drawer to be kept in trays and medications in fridge both secured by tamper evident bag. Once cart is used, the cart will be secured with white "DO NOT USE" locks. Pharmacy will be notified to replace used medications.

Finding:
A survey of the cart in OR found a green seal on the fridge. Pharmacist Biery notes that the medication drawer has been converted to a sealed tray. Pharmacy has oversight of these drugs.

OBSERVATIONS:

1) It is strongly recommended that all pharmacists and technicians directly involved with preparing and/or checking CSPs to obtain USP 797 training. Such training for pharmacists would provide knowledge in basic principles of CSPs and recognition in addressing/auditing technician process deficiencies when checking IV meds.

Pharmacist Frieze noted that she would be the delegated person to obtain 797 training and thus be the trainer for the rest of the staff. It appears that ALL staff involved in IV preparation and checking need to obtain proper training as observed in the findings noted above.

2) The absence of ante rooms and /or buffer rooms in areas of the inpatient pharmacy (including OR, Pavilion and ICU satellite pharmacies) where CSPs are prepared limits the functionality and type of CSPs that are permitted to be compounded in these unclassified space environments per USP standards. Effectively, in the absence of ante room and buffer area, the BUD for patient specific sterile preparations in an unclassified segregated compounding area cannot exceed 12 hours. No batching is permitted per USP and the segregated compounding area must meet all minimum standards of a segregated compounding area.

Hospital Drug Procurement, Distribution, and Control

3) It appears that pharmacy does not reconcile procedure trays that are unused in OR or Pavilion. Each day, a set number of sealed trays are assembled by pharmacy and placed in the procedure carts. Anesthesia techs are responsible for distributing the trays to the respective procedure rooms for use. Used trays are then collected by anesthesia techs after the procedure and placed into the procedure tray cart for return to pharmacy for billing. The trays are numbered, but pharmacy does not keep a log of outgoing/incoming trays; at any one time, there may be up to 5 prepared trays in the procedure areas/carts that are set aside for emergency procedures/overnight procedures use.

Finding:
Survey of one procedure cart in an OR room that was not used (procedure may have cancelled) found an unused anesthesia tray left in the cart. No other procedures were scheduled in this room for the rest of the day (4pm).

A survey of the OR anesthesia room found a lockable cabinet that stores a considerable amount of anesthesia drugs. This cabinet was not locked. Additionally, the survey found a partial bottle of isoflurane on the top shelf of this cabinet. A sign posted on the outside of the cabinet states "Attention: No storage of Anesthetic Gases Local Anesthetics only."

It was noted that pharmacy is only responsible for ordering the anesthesia gases. Anesthesia department is responsible for storage, distribution and outdate checks.

4) There is a process in OR and Pavilion OR for return of partially used controlled substances to the OR satellite pharmacy for wasting. Partially used syringes are collected in a Ziploc bag after the procedure and deposited by physician in a secured drop-box bolted to the wall. The pharmacy technician empties the drop-box daily and returns to pharmacy to waste items with pharmacy staff witness via compounded syringe wastage log. This may pose an opportunity for diversion. Consider the lag time between when the drug is administered to when the procedure is completed to when

the bag is actually deposited into the drop box (assuming that the physician does not delegate this task to the anesthesia tech), and the lag time between the collection of the drugs from the drop box to when the drugs are actually wasted in the pharmacy.

Finding:

Survey of Pavilion OR found a bin inside the pharmacy where the pharmacy technician had collected the waste bags from the drop-box and placed them in the bin for reconciliation. Some syringes were loose and not placed in bags as required by P&Ps. The pharmacy was busy and it was unknown when the pharmacist/technician would be reconciling and wasting the CS waste. This bin with CS waste was in the Pavilion pharmacy for at least 1 hr during the survey and was not reconciled.

Pharmacy is responsible for control of all drugs in the hospital. Diversion is not limited to controlled substances and there are many documented occurrences of employee diversion due to lax oversight and control in hospitals.

Washington State Pharmacy Quality Assurance Commission and DOH
Telephone Contact Numbers

Management and Other Resources

Chris Humberson, Executive Director	360/236-4853
Doreen Beebe, Program Manager	360/236-4834
Leann George, Program Support	360/236-4946
Timothy Fuller, Consultant Pharmacist	360/236-4827
Cathy Williams, Consultant Pharmacist	360/236-4875
Facilities Licensing Manager	360/236-4825
Individuals Licensing Manager	360/236-4831
Facsimile	360/236-2901
Washington Recovery Assistance Program (WRAPP)	800/446-7220

Licensing Questions 360/236-4700
PO Box 47877
Olympia WA 98504-7877

Pharmacist Investigators

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Websites

Washington State Department of Health	www.doh.wa.gov
Washington State Pharmacy Assurance Commission	WSPQAC@doh.wa.gov
Drug Enforcement Administration (DEA)	www.deadiversion.usdoj.gov
Food & Drug Administration (FDA	www.fda.gov/cder
Consumer Product Safety Commission	www.cpsc.gov
American Pharmacists Association	www.aphanet.org
Washington State Pharmacy Association	www.wspa.org
U.S. Pharmacopeia (USP)	www.usp.org