Jorgenson, Debbie [IBPE]

From: Witkowski, Terry [IBPE]
Sent: Tuesday, May 19, 2015 10:53 AM
To: Cory Ernst
Cc: Mike Polich; Dennis Harker; emily@proheights.com; Candace Prashad
Subject: RE: Request for Removal of 32 Hour Restriction from Board Order for Cory J. Ernst, RPh

Cory,

We will add your request to the agenda for the June Board meeting. Thank you.

Therese (Terry) Witkowski
Acting Director/Executive Officer
Iowa Board of Pharmacy
terry.witkowski@iowa.gov
515-281-6676

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices. Iowa Code § 155A.2(1).

From: Cory Ernst [mailto:Coryernst@ucsdsm.org]
Sent: Friday, May 15, 2015 11:11 AM
To: Witkowski, Terry [IBPE]
Cc: Mike Polich; Dennis Harker; emily@proheights.com; Candace Prashad
Subject: Request for Removal of 32 Hour Restriction from Board Order for Cory J. Ernst, RPh

Members of the Board and Interim-Director / Executive Officer Witkowski,

I am writing to request the removal of the 32 hour per week restriction on my employment which was imposed in the Decision and Order dated October 9, 2013 and the Order Modification dated August 26, 2014.

I began working at United Community Services on November 17th, 2014, therefore a period of six months of active employment has passed. I feel confident in requesting an increase in my work hours due to the nature of my work environment at UCS. I'm currently working 32 hours a week at United Community Services, Inc dispensing methadone through their Medication Assisted Treatment program. In this position we have 3 pharmacists dispensing methadone at 2 dosing windows. We see roughly 230 patients a day which we dose over a period of 7 hours in addition to filling "Take Home" doses for patients who have met the guidelines to receive them. We also field the occasional pharmacy-related question from patients. Medication orders are reviewed by the Pharmacy Manager, Dennis Harker, due to his familiarity with the patients in the clinic, though our role in the review of orders will increase as our familiarity increases.

I have complied with the Board's Order concerning my probation, though I have missed 3 call-ins for drug testing since February. The call-ins I missed all occurred on weekends when my schedule changes slightly. This was not done in order to deceive the Board or NTS, but was an oversight on my part. I have since doubled up

on my alarms for my call-ins (set at 4:20am and 7:10am) in order to ensure that I don't miss my call-in. These times are right before I go to work, and at a time when we usually experience a lull in dosing at UCS. Working with my IPRN advocate, Candace Prashad, has also helped as I get a third reminder from her 4 days a week.

I've discussed the possibility of increasing my work hours with my therapist, Erica Krolak, LMHC, my IPRN advocate, Candace Prashad, PharmD, and my direct supervisor at UCS, Dennis Harker, RPh. They have all agreed that I am more than capable of handling any additional stress which may occur due to an increase in my work hours. With an increase in my work hours to full-time, I will be able to obtain health insurance through UCS rather than through my wife's employer, as well as increase my monthly income. This will help family's financial situation immensely and help us pay off bills which have steadily accrued during my time away from work, further decreasing any financial stressors.

I appreciate your consideration of my request.

Sincerely,

Cory J Ernst, RPh
4908 Franklin Avenue
Des Moines, IA 50310
515-280-4906 - work
515-480-8273 - cell

From: Witkowski, Terry [IBPE]
To: Jorgenson, Debbie [IBPE]
Cc: Hall, Becky [IBPE]
Subject: Teleconference Addition
Date: Tuesday, May 26, 2015 12:15:00 PM
Attachments: CA - Rx Unlimited Summary review.docx
CA - Rx Unlimited response to NABP inspection.doc
CA - Rx Unlimited NABP VPP Inspection report.pdf

Debbie,

This is the request that wanted teleconference consideration. If a representative of the pharmacy can be available at the time we set for the teleconference, you can include this on the agenda. Thanks.

Therese (Terry) Witkowski
Acting Director/Executive Officer
Iowa Board of Pharmacy
terry.witkowski@iowa.gov
515-281-6676

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-----Original Message-----
From: Mears, Sue [IBPE]
Sent: Monday, May 11, 2015 2:43 PM
To: Jorgenson, Debbie [IBPE]; Witkowski, Terry [IBPE]
Cc: Gavin, Meghan [AG]; Steffensmeier, Laura [AG]
Subject: Rx Unlimited Applicaiton request

Hi all - Rx Unlimited of California has a pending NR pharmacy license application at the office. The Board reviewed the application at the March meeting and wanted to hold on the application until the resolution of the pending Accusation in California. There were no other ommissions or areas of concern regarding the application. When asked if the pharmacy wished to withdraw the application pending resolution of the Accusation, the pharmacy did not wish to hold on the application. I explained the board's concerns regarding the pending discipline relating to inspection findings. The pharmacy reported that it had recently been inspected by NABP as part of the VPP and offered to provide this information to the board in support of its application. The pharmacy also wished to have the board review the materials prior to the next regular board meeting IF the need for a teleconference arrises and IF there is time on the agenda for such review. I told him I would request it, but would not guarantee it as the teleconferences are for more pressing, emergent needs.

The attached are the updated / pertinant materials that the board would be interested in and could refer back to the March board book for the original application if desired.

If there is an opportunity for the information to be reviewed at a teleconference, the pharmacy would be interested in having someone be available via phone as well for any questions the board might have.

Thanks,

Sue Mears, RPh
Compliance Officer
Iowa Board of Pharmacy

400 SW 8th Street, Suite E
Des Moines, IA 50309
515-408-7824 (cell)
515-281-4609 (Fax)
sue.mears@iowa.gov

Territory: Boone, Buena Vista, Calhoun, Clay, Dickinson, Greene, Palo Alto, Pocahontas, Sac and Webster counties as well as the cities of West Des Moines, Clive and Urbandale in Polk County.

The Iowa Board of Pharmacy promotes, preserves, and protects the public health, safety, and welfare through the effective regulation of the practice of pharmacy and the licensing of pharmacies, pharmacists, and others engaged in the sale, delivery, or distribution of prescription drugs and devices or other classes of drugs or devices which may be authorized. Iowa Code § 155A.2(1).

New Nonresident Pharmacy Application Review

Name:	Rx Unlimited LLC
DBA:	Rx Unlimited Pharmacy
Street Address:	16673 Roscoe Blvd
City, State, Zip:	North Hills, California 91343
Date application received:	03-24-2015
Application reviewed by:	Sue Mears
Date application reviewed:	03-31-2015
Omission(s):	None
Area(s) of Concern:	Disclosure of *pending* discipline, detailed below

On January 31, 2014, the California Board of Pharmacy issued an Accusation against this pharmacy and the pharmacist in charge. To date, there has been no resolution to the case. So, at this time, there is no formal discipline for this pharmacy.

The Accusation details highlights of a May 2012 inspection (along with follow up inspection in September 2012) where the CA BOP inspector noted::

1. Pyrogen testing was not conducted on all high-risk sterile compounded products (noted specifically Tri-Mix[1]). A technician reported to the inspector that the pharmacy conducted in-house testing for pyrogens, but could not produce documentation to prove the claim. The inspector learned later that the pharmacy did possess such testing kits but "never used any of them".
2. Several batches of products were found to be outside of acceptable potency range upon testing. The inspector was told that the lots outside acceptable range were not dispensed to customers. Upon reinspection in September 2012, the inspector reviewed dispensing records and found that the pharmacy had, in fact, dispensed products from the lots found to be outside of the acceptable potency range.
3. Not every lot was tested for sterility.
4. Purportedly sterile products produced in batches from non-sterile components (thus, high-risk) had been dispensed to customers without first conducting end product sterility and pyrogen testing.
5. The pharmacy was not listing the manufacturer of the component ingredients on compounding worksheets.

[1] Tri-mix is a compounded drug product containing alprostidil, phentolamine, and papaverine used to treat erectile dysfunction.

The pharmacy, at the location of the above-mentioned inspections, was inspected last on February 5, 2014. At that time, no deficiencies were noted, including for sterile compounding.

The pharmacy was most recently inspected on July 15, 2014 for a relocation inspection. At that time, the only notes were specific to assembly of the equipment and recommending a deep cleaning prior to initiation of sterile compounding. There have been no other deficiencies identified for the issues in the Accusation.

May 11, 2015 Update:

The Board, at its March 2015 meeting, had asked that the application be held pending resolution of the Accusation and wondered if the pharmacy would be interested in withdrawing the application until resolution of the Accusation. The pharmacy wished to continue to pursue licensure and reported that it had recently been inspected by NABP as part of the Verified Pharmacy Program. The pharmacy provided the report resulting from that inspection. Following review of the inspection report, a request was sent to the pharmacy to provide information on the actions taken by the pharmacy to correct the identified areas of deficiency identified on the NABP report. The pharmacy requested that the Board review the NABP inspection information at its next available opportunity, including at a teleconference if possible if held prior to the next regularly scheduled meeting in June.

Following this summary document is the pharmacy's response to the inspection report issued by NABP (which follows the pharmacy's response letter). For the most part, the pharmacy responded appropriately to the NABP inspection findings and has made adequate adjustments to procedure to become compliant.

Item 105 on the NABP inspection report identified the pharmacy's daily cleaning did not include the floor. The pharmacy responded that there are not sterile compounding activities occurring daily and that cleaning was not required that frequently in the absence of compounding activities. USP <797> specifically states "Floors in the buffer or clean area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress." Floors are also listed in Table 3 of <797> with a "minimum frequency" of "daily".

Item 173 on the NABP Inspection report asks "Were all CFU's detected analyzed to determine the organism down to the genus?" and the pharmacy answered "no". The pharmacy further explained that, since the certification resulted in passing results, the genus level identification was not included in the report, nor was it requested of the pharmacy. USP <797> says this about cfu counts:

> 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. The numbers in Table

2^2 should be used only as guidelines. Regardless of the number of cfu identified in the pharmacy, further corrective actions will 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. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and must be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional or industrial hygienist.

It is unclear at this time if the certification specialist would provide the pharmacy with a written or verbal report of the type(s) of contaminants found during the certification process, if they were highly pathogenic, regardless of the number being in excess of action levels or not.

[2] Table 2 in USP <797> identifies "Recommended action levels for microbial contamination"

National Association of Boards of Pharmacy®
Verified Pharmacy Program™ Inspection Form

General Pharmacy Inspection

Business or Corporation:	Rx Unlimited Pharmacy LLC		Telephone number:	818-781-2400	Date:	4/8/2015
Doing Business As (DBA):	Rx Unlimited Pharmacy		Toll free number:	877-7986583	Start time:	9:00
Address:	16673 Roscoe Blvd		Fax number:	818-781-2401	End time:	18:40
City:	North Hills		Pharmacist-in-Charge (PIC):	Clifton Eugene Braddy		
State:	CA	Zip: 91343	Pharmacy/PIC email:	Gene@RxUnlimited.com		
Pharmacy website:	www.RxUnlimited.com			Inspector(s):		

Hours:	Sun	Mon	Tues	Wed	Thu	Fri	Sat	
Open	Closed	8:30	8:30	8:30	8:30	8:30	Closed	
Close	Closed	17:00	17:00	17:00	17:00	17:00	Closed	

Herb Bobo, NABP

Licensure Information for State of Residence and Federal (DEA, FDA, etc.)

License/Registration Agency:	License/Registration Type or Category:	Business Name on License/Registration:	License/Registration Number:	Expiration Date:
California State Board of	Retail Pharmacy	Rx Unlimited Pharmacy	PHY50302	6/30/2015
California State Board of	Sterile Compounding	Rx Unlimited Pharmacy	LSC99642	6/30/2015
DEA	Retail Pharmacy	Rx Unlimited Pharmacy	FR2137900	4/30/2016

Inspector Notes: The Pharmacy opened in this location in August 2014. Previous location was 6815 Noble Ave, Ste 107, Van Nuys, CA. No traditional pharmacy dispensing of commercial products- just Sterile or Non-Sterile compounded products.

	Inspection Information	Y/N/?/NA	Note
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty in the Note.*	Y	Met with Gene Braddy (PIC) for the General and Non-Sterile and Naomi Parvizi who is in charge of the Sterile operations.
2.00	Do prescribers or other health care providers link to the applicant's Web site or direct patients to the Web site or to this pharmacy? *If so, who?*	N	
3.00	Does the applicant list links to prescribers or clinics on its Web site? *If so, to whom?*	N	
4.00	Does the pharmacy have any other websites? *List other names/URLs.*	N	However, the main website listed above provides a link to this location on its front page as well as two other links--- businesses which use the same Rx Unlimited name and are located in Beverly Hills, CA.
5.00	Are photographs allowed during the inspection (no protected health information (PHI))?	Y	
	Inspector Notes and list of others interviewed as part of the inspection: Naomi Parvizi, Pharm D and Jay Maruki, Compliance Officer		

	Type(s) of practice Type "X" for all that apply				Facility Size in Square Feet		Personnel	
	Traditional retail		Mail Order (in-state)	X	Total Pharmacy:	5000	Total Pharmacists:	2
	HMO/PBM only		Mail Order (out-of-state)	X	Nonsterile Compounding Area	700	Total Technicians:	5
	Institutional		Central Fill/Processing		Sterile Compounding Clean/Buffer Room	150	Total Interns or Students:	0
	Closed Door		Patient Care Programs		Sterile Hazardous Clean/Buffer room:	0	Total Other Personnel:	8
	Open to the Public	X	Nonsterile Compounding	X	Ante Room:	80	Number of Pharmacist Hours Per Week:	80
	Provide products for 'Office Use'		Sterile Compounding	X	**Volume**		Number of Technician Hours Per Week:	200
	Wholesale Distributor		Internet Pharmacy		Total Prescriptions Per Day Dispensed:	25	Total Compounding Pharmacists:	2
	Manufacturer		Telepharmacy		Total Orders Per Day Distributed:	0	Total Compounding Technicians:	3
	Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific.							
	Inspector Notes: Total of eight "Other Personnel" includes five sales representatives, all of whom work as employees of the pharmacy. All sales representatives are local to this area. Total prescriptions per day of 25 consists of Non-Sterile and Sterile Compounded prescriptions- they do not perform Sterile compounding every day and they did none on the day of this inspection- none waiting to be done.							

	Services	Y/N/?/NA	Note
6.00	Does the pharmacy provide delivery service to patients in this state? *Is delivery by an employee or by an outside service?*	Y	Outside service
7.00	Does the pharmacy mail or send prescription products to patients in this state? *Indicate carriers that are used.*	Y	Outside service; UPS and FedEx
8.00	Does the pharmacy deliver, mail or send prescription products to patients in any other states? *View the mailing log. List other states in notes.*	Y	AZ, NV; all of the addresses on the log were in California but the staff indicates they do ship to AZ and NV
9.00	Does the pharmacy have a drive through window?	N	
10.00	Does the pharmacy dispense prescription products for veterinary use? *Indicate the approximate volume or percentage per month.*	N	
11.00	Does the pharmacy DISTRIBUTE prescription products for veterinary use? *Indicate the approximate volume or percentage per month.*	NA	
	Inspector Notes: Applications pending for non-resident permits in several states.		

	General Operations and Licensure If any part of a question is no, enter "N" and explain the observation.	Y/N/?/NA	Note
12.00	Are pharmacy licenses, permits and registrations (state, controlled substance, Drug Enforcement Administration (DEA), etc.) posted in customers' view and current? *(Provide details if 'no'. Answer NA if closed door pharmacy)*	Y	
13.00	If the pharmacy mails or delivers to patients out-of-state, does it have current licenses in all the states into which it sends prescription products? *List other states in which the pharmacy is licensed.*	Y	AZ, NM, OK, NV, MN
14.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection.*	Y	7/15/2014

15.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	Y	Change of location inspection--- prior to dispensing must re-install light cover in PEC and sink must be operational before compounding; PIC states these were done prior to beginning operations here
16.00	Does the pharmacy hold ANY wholesale, distributor or manufacturer licenses? *List the licenses in 'Note' and document information in the license grid above.*	N	
17.00	If the pharmacy distributes any compounded products to practitioners or facilities that are not patient specific, is it registered with the Food and Drug Administration (FDA)? *Indicate if it is registered as a manufacturer or an outsourcing facility, and document the registration in the license grid above. If it is NOT registered, indicate the exemption in the "Note".*	NA	
18.00	Is the pharmacy licensed in any other state as a non-resident pharmacy? *List the states.*	Y	AZ, NM, OK, NV, MN
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If so, note the state and the date of the inspection.*	N	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If so, note the exemption or restriction.*	N	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If so, note the waiver or variance.*	N	
22.00	Has the pharmacy been inspected by DEA? *If so, indicate the inspection date and note any deficiencies.*	N	
23.00	Has the pharmacy been inspected by FDA? *If so, indicate the inspection date and note any deficiencies, significant correspondence, or if a '483' was issued.*	N	
24.00	Does the pharmacy hold any accreditations (DMEPOS, VIPPS, VAWD, Vet-VIPPS, PCAB, etc.)? *If so, indicate which in notes.*	N	Pending application with ACHC
25.00	Has the pharmacy held any accreditations or certifications in the past that it no longer holds? *Provide a list and the reasons for discontinuation (such as expired, rescinded, etc.).*	N	

26.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc.? *If so, record the Clinical Laboratory Improvement Amendments (CLIA) waiver expiration date and the name of lab director listed. Verify that the lab director is current.*	N	
27.00	Does the pharmacy participate in the VFC (Vaccines for Children) program? *Note the date the pharmacy was inspected.*	N	
28.00	Does the pharmacy maintain any emergency kits in nursing homes, long term care facilities, or other entities? *Describe and verify the related policies and procedures (P&Ps) are in place.*	Y	
29.00	Does the pharmacy maintain any automated prescription dispensing devices? *Describe and verify that the relevant P&Ps are in place.*	N	
	Inspector Notes: In 2012, before moving to the current location, the California Board of Pharmacy cited the pharmacy regarding testing of sterile products- this case has not been closed- it involves the pharmacy permit and the PIC license.		
	Policy and Management **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
30.00	Are P&Ps available in the pharmacy? Are they in hard copy or electronic form?	Y	Both
31.00	Do the P&Ps address the processing, compounding, dispensing, delivery, storage, and use of prescriptions products and include the handling of hazardous or infectious waste or spills?	Y	
32.00	Are the P&Ps reviewed and updated regularly by the PIC? *Describe the procedure, including the review frequency and who performs the reviews.*	Y	Opened here in August 2014; still reviewing and revising in preparation for ACHC accreditation; being done by both pharmacists with Jay Maruki (Compliance Manager)
33.00	Are systems in place for the on-going monitoring of state and federal laws/regulations for changes? *Give details of the system and resources or indicate if it is a corporate process.*	Y	Currently applying for licenses in many states- being led by Compliance Manager- as differing requirements are found, the SOPs are changed
34.00	Are resources and related training in place for pharmacy staff to apply changes in law/regulation into current practices? *How is training documented?*	Y	Have a training log that includes records of compounding training, fraud waste abuse, HIPPA, state/federal compliance training
35.00	Is there a responsible member of management identified as the decision-maker when questions of law/regulation arise? *Record his or her name and title and the steps used to resolve a law question.*	Y	Gene Braddy, PIC in consultation with the Compliance Manager

36.00	Is there a statement in the P&P or are other means used to ensure that the most stringent laws/regulations are followed? *Example: Syringes require a prescription in some states and not others.*	Y	Not stated in the P & P at present but that is the practice.
37.00	Does the pharmacy have appropriate law references including state and federal regulations? *Indicate if they are hard copies or are available online, and verify that the pharmacy can access online regulations in all the states in which it is licensed (such as bookmarked).*	Y	Have a California law book and all pharmacists get frequent updates via e-mail directly from the CA Board of Pharmacy; access all states and federal via the internet
38.00	Are Material Safety Data Sheets (MSDS) available to personnel for all drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	Y	Keep a hard copy file by drug name
38.10	Does the pharmacy have a hazardous waste handling and collection system? *For example, empty bottles that contained chemotherapy medications or warfarin. Indicate how often the bin is emptied/collected and the vendor used.*	Y	Use a Sharps container and SteriCycle is the vendor; approximately monthly.
39.00	Does the pharmacy have a clear organizational structure? *The pharmacy staff know who they report to and who the PIC reports to at corporate, if applicable.*	Y	LLC with Brian Goldstein Managing Member- he holds a Pharmacy Technician License; PIC reports to Mr. Goldstein- reviewed the ORG chart which includes all employees
40.00	Does the pharmacy have an annual budget and ongoing financial accounting information to track performance to the budget? *Indicate who develops the budget and if financial information is reviewed by a CPA or finance department.*	N	Owner is active in the business and has a CPA but the PIC is not managing to a formal budget.
41.00	Does the pharmacy have P&Ps for *handling partial fill prescriptions, returning prescriptions to stock if they are not dispensed including reversal of claims, and a "refill too soon" policy?*	Y	
42.00	Are third party claims reconciliations performed and monitored, and are errors tracked? *Indicate if performed these are in-house, by corporate, or are contracted out.*	Y	Done in house by an employee
43.00	Is there a formula or process to determine staffing hours for pharmacists and technicians? *If not, how is staffing determined?*	N	Current volume is only 25 per day; a process will develop as volume increases

44.00	Are patient care programs taken into account when determining staffing?	NA	
45.00	Is there a mechanism for employees to anonymously report unethical, illegal, or compliance and safety concerns or issues? A p*rocedure in place for handling reports received, including investigations, corrective actions or disciplinary processes.*	Y	Compliance SOP
46.00	Does the pharmacy hold regular staff meetings? *How often?*	N	Done on an as-needed basis; minutes not kept at present
47.00	Does the pharmacy have a document retention procedure? *How long are prescription files, invoices, inventory information, quality assurance (QA) data, etc. kept on file?*	Y	Comply with CA law and federal; keep everything at least 3 years- then review; no Medicare Part D or Medicaid
48.00	Are all pharmacy documents kept on site? *If not, where?*	Y	
	Inspector Notes		

	Personnel **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
49.00	Are all pharmacists appropriately licensed or registered in this state and in good standing? *How is this verified and documented?*	Y	Verified online by the Compliance Manager
50.00	Are all technicians appropriately licensed, registered, or certified in this state and in good standing? *How is this verified and documented? (Enter "NA" if this is not required by the state)*	Y	Verified online by the Compliance Manager
51.00	Are pharmacists providing patient services that require additional training or certification appropriately trained and certified? *Are the certifications current? (Immunization, MTM, etc.)*	NA	
52.00	Are the above pharmacist and technician credentials posted in customers' view and current?	Y	
53.00	Does the PIC monitor all licenses to ensure they are current? *If not the PIC, who?*	N	Compliance Manager
54.00	Are all personnel wearing nametags that clearly identify if they are a pharmacist or a technician? What about other positions?	Y	All employees

55.00	Does the pharmacy use relief personnel from outside agencies? *How are licenses, registrations, or certifications verified?*	N	
56.00	Does the pharmacy have a technician policy that specifies what a technician is allowed and not allowed to do?	Y	
57.00	Do employees undergo a background check or drug testing? *Indicate which or both, and whether it is only upon hire or ongoing. Note if the pharmacy relies on checks performed by the board of pharmacy.*	N	Drug testing initial and on-going
58.00	Are employees screened against the Office of the Inspector General (OIG) exclusion list? *Initially, ongoing, or both.*	N	Do not participate in any federal programs
59.00	Is new hire training performed and documented? *View the documentation*	Y	
60.00	Is on-going training performed and documented including HIPAA, OSHA blood borne pathogen or hazardous materials handling, and fraud, waste & abuse? *View the documentation.*	Y	
61.00	Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? *Teratogenicity, carcinogenicity, reproductive issues.*	N	
62.00	Is there documentation of training for other employees (including drivers, warehouse, receiving, admin, clerks, etc.) who may have contact with hazardous drugs or chemicals of chemotherapy spill kit procedures and hazardous material handling?	N	
63.00	Is there a performance review process and is it documented?	Y	
64.00	Is a procedure for corrective or disciplinary action in place and documented?	Y	
	Inspector Notes During the inspection, the PIC asked the Compliance Manager to research a notice concerning hazardous drugs for employees to review and sign.		

	Facility and Security If any part of a question is no, enter "N" and explain the observation.	Y/N/?/NA	Note
65.00	Does the pharmacy have a security/alarm system in place with door alarms and motion detectors?	Y	
66.00	Are alarm codes unique to the individual? *Is a report available to show after hours access and by whom?*	N	Cameras
67.00	Does the pharmacy have cameras? *How long are images kept?*	Y	40 cameras; images kept a minimum of 1 year
68.00	Does anyone have access to the pharmacy (after hours) in the absence of the pharmacist? *Explain.*	N	
69.00	Do pharmacy staff remain in the pharmacy if the pharmacist is absent on a meal break? *If so, is there a policy regarding what activities may or may not be allowed during the pharmacist's absence?*	Y	Complies with CA law
70.00	Is entry to prescription product storage and processing areas limited to task critical employees?	N	No restrictions in place at present
71.00	Are Schedule II controlled substances kept in a locked cabinet or safe? *Indicate if it is locked at all times and who has access.*	N	
72.00	Are there housekeeping standards to ensure the environment is professional, safe, neat, and clean?	Y	
73.00	Is the pharmacy clean and is there appropriate space for the prescription volume? *Look for clutter or crowded counters or stacks of prescriptions to be checked.*	Y	
74.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Indicate ratio used and the maximum number of staff who work at the same time.*	Y	3:2 in the dispensing area; some other employees have technician registrations also
75.00	How many feet (approximately) of free counter space (without computers or other equipment) at least 18 inches deep is available?	Y	156 feet
76.00	Is there a heating and air conditioning system? Indicate which or both and if they are operational	Y	Both are operational
77.00	Is temperature in the drug storage area monitored? *Describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Y	Electronic system for temperature; stored electronically- indefinitely stored
78.00	Is humidity in the drug storage area monitored? *Describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Y	Electronic system for humidity; stored electronically- indefinitely stored
79.00	Is refrigerator temperature monitored 24/7? *Describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Y	Electronic system; stored electronically- indefinitely stored

80.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Y	
81.00	Is freezer temperature monitored 24/7? *Describe the process. Indicate range. How are excursions detected? How long are records maintained? (This is only required if the freezer is used to store products. Enter "NA" if used only for ice/cold packs)*	Y	Electronic system for temperature; stored electronically- indefinitely stored
82.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe processes*	Y	Have generators available nearby that can be brought in; clean room has a separate HVAC; Service contracts to get HVAC operational quickly if it fails
83.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes*	Y	See above
84.00	Are there contingency plans in the event the pharmacy cannot be secured? *How will the drug products be handled?*	Y	Pharmacist would stay on site until repaired; locksmith on call
85.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity if the products has been compromised?	Y	Assess the excursion, possibly evaluate on a product-by-product basis to determine appropriate action-destroy product, test product, or use the product.
86.00	**Does the pharmacy utilize any automated apparatuses for prescription processing (such as robotics, Baker cells, etc.)? *List numbers and types.***	N	
87.00	• Are cleaning, calibration, and maintenance procedures performed on the apparatuses? *View logs*	NA	
88.00	• Is there a procedure available that details who may fill the automated apparatuses, how filling accuracy is checked, and what documentation is kept?	NA	
	Inspector Notes		

	Patient Counseling Areas If any part of a question is no, enter "N" and explain the observation.	Y/N/?/NA	Note
89.00	Are patients able to overhear staff conversations behind the counter? *Note your observations.*	N	Use the lobby area which is locked away from the rest of the pharmacy.
90.00	Are patients able to hear telephone conversations behind the counter? *Note your observations.*	N	Use the lobby area which is locked away from the rest of the pharmacy.
91.00	**Does the pharmacy have a private area for patient counseling and providing patient services?** Is the area:	Y	Have an office available
92.00	• of sufficient size and accommodations to comfortably seat at least three people (pharmacist, patient and caregiver) at a table?	Y	
93.00	• meeting ADA criteria including wheelchair access?	Y	
94.00	• private, so that when a typical patient is sitting or standing in the counseling area, the patient cannot be seen by others (including other patients, customers and employees)?	Y	
95.00	• entirely devoted to enhancing patient outcomes and not used as a storage room for merchandise or other non-related items?	Y	
96.00	• accessible to the patient without having to traverse through dispensing or storage areas?	Y	
97.00	• enclosed sufficiently to prevent typical patient consultation conversation from being heard from other areas of the business?	Y	
98.00	• enclosed sufficiently to prevent noise from other areas of the business to interfere with or distract from typical conversation in the consulting area?	Y	
99.00	• equipped with access to a computer for patient files, documentation, and access to references during counseling or provision of patient care services?	Y	
100.00	**Does the pharmacy use privacy panel areas at the counter for short consultations?**	N	
101.00	• Are the panels opaque and tall enough that a patient cannot be seen above them?	NA	
102.00	• Are the panels sound-dulling (using fabric or acoustic material on the inside surfaces)?	NA	
103.00	• Do the panels extend out past the patient so the patient steps into the 'booth' (at least 18 inches deep) to provide privacy from other customers?	NA	

104.00	• Do the panels extend past the pharmacist (at least 18 inches) so that the pharmacist conversation is private from others at the counter and employees?	NA	
105.00	• Is the paneled counseling area free from merchandise or other products not directly needed for the counseling?	NA	
106.00	• Does the pharmacist have access to the computer and references while counseling the patient in the paneled area?	NA	
107.00	• Does the paneled area open out to a main aisle or the patient waiting area?	NA	
108.00	• Does the paneled area meet ADA criteria including wheelchair access? If not, how are these patients handled?	NA	
109.00	**Does the pharmacy have a drive through window?**	N	
110.00	• Is counseling at the drive through window confidential from the patient side (outside)? *For example, a handset could be used, proximity to parking areas, etc.*	NA	
111.00	• Is counseling at the drive through window confidential from the pharmacist side (inside)? *For example, a handset could be used, proximity to patient areas, etc. If no handset is used, verify that the speaker volume is not loud enough to be heard outside of the pharmacy.*	NA	
112.00	• If the drive through window is not equipped for confidential counseling, is there signage or other indication that the conversation is not confidential?	NA	
113.00	• Does the pharmacist have computer access while counseling at the drive through window?	NA	
	Inspector Notes		

	Product Receipt and Inventory If any part of a question is no, enter "N" and explain the observation.	Y/N/?/NA	Note
114.00	Does the pharmacy restrict ordering to only approved wholesale distributors or manufacturers? *Indicate who approves suppliers and if licensure is verified.*	Y	PIC verifies licenses
115.00	Are orders generated and sent by the computer for prescription products including CIII-CV controlled substances?	Y	By phone for API's
116.00	Who can alter the orders before they are sent?	Y	Pharmacist
117.00	Does the pharmacy utilize paper DEA-222 forms to procure C-II substances? *Who on the staff has the authority (POA) to sign the DEA-222 forms?*	Y	
118.00	Does the pharmacy utilize CSOS (electronic C-II ordering) to procure C-II substances?	N	
119.00	Is the receipt of C-II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification*	Y	
120.00	Are invoices for controlled substances that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Y	
121.00	Are orders sent/received every week day? *If not, how often are orders sent and received?*	N	Open M-F and do not place or receive an order every day
122.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Y	
123.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe*	N	
124.00	**Does the pharmacy make any sterile or nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?**	Y	
125.00	• Does the pharmacy purchase APIs directly from the manufacturer? *If not, indicate the source of APIs.*	N	PCCA, Medisca, Freedom, API and Letco-Repackagers
126.00	• Does the pharmacy verify that the source of the API is an FDA-registered facility? *How?*	N	Only get COA, not Pedigree
127.00	• Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources in the Note section.*	N	Not knowingly
128.00	Does the computer system track on-hand quantities of products? *Who can adjust the on-hand quantities and are adjustments tracked?*	Y	PIC; adjustments not tracked
129.00	Does the computer track on-hand quantities of APIs used for compounding?	Y	

130.00	Does the pharmacy keep a perpetual inventory log of CII controlled substances? *Does this include APIs?*	N	
131.00	Is the CII perpetual inventory log reconciled regularly? *Indicate how often CII controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	NA	
132.00	Does the pharmacy keep a perpetual inventory of any other products? *Indicate which in the Note section.*	N	
133.00	Does the pharmacy have a complete physical inventory of products performed at least once yearly? *If cycle counting, indicate the process.*	Y	
134.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken - minimum every 2 years.*	Y	8/13/14 was done when moving to this location; annual
135.00	Does the pharmacy have any DEA-106 forms (theft or loss of controlled substances) on file? *Indicate how many in the last two (2) years.*	N	
136.00	Are events or discrepancies that are suspected to be due to criminal activity reported to the appropriate agency, if warranted?	N	None to date here but would report if appropriate
137.00	Are all products inspected upon receipt to detect any packaging issues, damage, etc.? *What happens if products are damaged?*	Y	Report to vendor for replacement
138.00	How are outdated, damaged, or recalled products segregated? *How often does the pharmacy check for out-of-date products? Does it include over-the-counter (OTC) products?*	Y	Keep in a box for reverse distributor to pick up; Check weekly; no OTC products
139.00	Are expired or damaged products destroyed on-site? *View documentation. If not, note the name of the reverse distributor.*	N	PharmaLink
140.00	Does the pharmacy repackage bulk containers of prescription medications into smaller containers for ease of use? *Verify there is a P&P including labeling - what expiration date is on the repacked container?*	N	
141.00	Does the pharmacy pre-pack bulk containers of prescription medications into unit-of-use quantities? *Verify there is a P&P including labeling - what expiration date is on the pre-packed container?*	N	
142.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up? *Are the products returned to the bulk stock bottle or set on the shelf with the prescription label? Indicate expiration date given in the Note section.*	Y	Put on the shelf and black out the patient information
	Inspector Notes		

	Prescription Processing If any part of a question is no, enter "N" and explain the observation.	Y/N/?/NA	Note
143.00	Are any portions of the prescription processing performed at a different location? *If so, explain. Is there a central fill/central processing agreement?*	N	
144.00	When a prescription is accepted to fill, is there a procedure to ensure the information is complete?	Y	
145.00	Are adequate processes in place to assure the integrity, legitimacy and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Y	Compounding pharmacy only
146.00	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Y	Have not had any suspicious prescriptions since the pharmacy stopped doing traditional commercial products
147.00	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe - do the processes include comparing the physical addresses of the patient and prescriber?*	Y	
148.00	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both .*	Y	Non-controlled substances only
149.00	Does staff comply with applicable generic substitution and therapeutic substitution statutes and regulations?	NA	Compounding pharmacy only
150.00	Does therapeutic substitution occur without patient or prescriber authorization?	N	
151.00	Are states' generic substitution formularies available? *Are staff familiar with the formularies?*	NA	Compounding pharmacy only
152.00	Does the pharmacy system utilize bar code technology or other systems to improve accuracy and patient safety?	N	
153.00	Is the pharmacy computer system provided routine maintenance and is the information backed up? *Indicate the frequency of backup and if the backup data is stored offsite.*	Y	PK Compounder does the backups
154.00	Is there a continuity plan should the system become inoperable? *How will data be retrieved?*	Y	Contact PK to retrieve the data
	Inspector Notes		

	Patient Profiles If any part of a question is no, enter "N" and explain the observation.	Y/N/?/NA	Note
	Verify the following six bullets by viewing of a minimum 3 patient profiles (select from filled prescriptions to ensure current patients) to determine where the information is documented, that it's retrievable for drug utilization reviews (DURs), and that the information is gathered (the fields are not empty).		
155.00	• Does the patient information gathered include patient contact information, age or date of birth and gender?	Y	All
156.00	• Does patient information gathered include disease states or conditions (including pregnancy or breastfeeding information)?	N	
157.00	• Is allergy and sensitivity information obtained?	N	
158.00	• Is a complete medication history obtained including medications filled by other pharmacies or by mail order, samples, or medications administered at the clinic or hospital? *Note: a PBM/HMO closed door pharmacy that relies solely on claims data does not constitute a complete medication history as prescriptions for which the patient paid cash such as $4 generics are not recorded.*	N	
159.00	• Does the medication history include information on vitamins, herbal products, and other OTC products used?	N	
160.00	• Does the patient profile allow for the pharmacist's relevant comments or notes?	Y	
161.00	Does the pharmacy have access to patients' Electronic Health Record (EHR)? *Provide detail regarding the type of information accessed such as lab values or clinical notes, etc.*	N	
162.00	Does the pharmacy access state PMP/PDMP program data? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Y	For CA only
163.00	Is patient information updated regularly and routinely? Are patients or providers routinely asked if there are changes in disease states, allergy information, or medication use? *How often?*	N	
164.00	Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver?	Y	
165.00	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include species, sex, breed or size, and the age of the animal? *How is it indicated in the computer system that the patient is an animal?*	NA	
166.00	If the pharmacy dispenses veterinary prescriptions, does the pharmacy determine if the animal will be used for consumption (including eggs, milk, or meat)? *What references are used to provide the veterinary customer with wash-out periods for certain medications?*	NA	
	Inspector Notes		

	Drug Utilization Review (DUR) If any part of a question is no, enter "N" and explain the observation.	Y/N/?/NA	Note
167.00	Does staff conduct prospective DUR prior to the dispensing of a medication or product? *At what point in the process does the DUR take place?*	Y	Manual by pharmacist; prior to compounding
168.00	Is the DUR performed by the computer (the drug database is integrated into the prescription processing software)? *If not, describe how the DUR is performed.*	N	
169.00	Is the computer DUR database routinely updated and tested? *Provide details on how often the database is updated and how the pharmacy tests the updates.*	Y	PK Compounder software is updated routinely by that company; they do all the testing
170.00	Does the DUR include: • drug-drug interaction (Rx and OTC) • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse) • disease state or condition contraindication, • Incorrect dosage or duration of therapy • gender or age related contraindications *Indicate if there are other parameters routinely included in the DUR*	N	80% of non-sterile compounding is topical; sterile is mostly IM; no traditional commercial products dispensed
171.00	Does the DUR include screening against OTC, herbal, vitamin products and medications not filled at this pharmacy? *Is this performed by the computer (has fields to enter this information) or is it performed manually by reading notes in the profile?*	N	
172.00	Does the pharmacy have references on hand for: pharmacology, dosage and toxicology, general patient reference, OTC products? *List in the Note section and indicate if they are in hard copy or electronic form.*	Y	Only dispense compounded products- Compounding Today, IACP Journal, USP- all online; Trissels hardcopy; PCCA consults

173.00	Does the pharmacy have references on hand for any special demographics of its patient population or complementary medicine such as pediatrics, geriatrics, homeopathic, natural and herbal medicines, as appropriate? *List in the Note section and indicate if they are in hard copy or electronic form.*	N	
174.00	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database or compendium? *List and note if it is hard copy or electronic.* How does the pharmacy perform a DUR? (*There is no veterinary drug database that is integrated into pharmacy processing software to perform electronic DURs at this time so DUR must be performed manually)*	NA	
175.00	Are DUR overrides/bypasses documented? *Indicate if documentation is via a password/biometric override or by computer logs* . Or if it is a manual system, are DUR issues noted and action documented?	NA	If a patient has received a product from this pharmacy that conflicts with a new one, PK would flag it and the pharmacist would have to address- PK would track that response
	Inspector Notes		

	Patient Counseling and Communication **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
176.00	Do pharmacists provide counseling for all first fill prescriptions? *Is the counseling performed proactively or may a clerk or technician extend the "offer to counsel"?*	Y	Provide written patient information sheets and a written offer; almost all prescriptions are delivered or shipped
177.00	Do pharmacists provide counseling for all refilled prescriptions? *Is the counseling performed proactively or may a clerk or technician extend the "offer to counsel"?*	Y	Provide written patient information sheets and a written offer; almost all prescriptions are delivered or shipped
178.00	Do pharmacists provide counseling on refilled prescriptions if there is a change in therapy or other issue determined by the pharmacist? *Is the counseling performed proactively or may a clerk or technician extend the 'offer to counsel'?*	Y	Based on the professional judgement of the pharmacist
179.00	Is patient counseling provided for delivered prescriptions? *How?*	Y	Phone and written materials
180.00	Is patient counseling provided for mailed prescriptions? *How?*	Y	Phone and written materials
181.00	Are patients contacted for counseling when the prescription is picked up by someone other than the patient or caregiver (such as when a neighbor picks up the prescription)?	Y	

182.00	Does patient counseling meet OBRA90 standards (appropriate medication use, storage, what to do for a missed dose, side effects, etc.)?	Y	
183.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?	Y	
184.00	Do pharmacists provide training to the patient or caregiver on any equipment provided? *Such as blood glucose meters, walkers, etc.*	NA	Do not sell DME , only compounded prescriptions
185.00	Do patient/caregiver training programs include a hands-on and reverse demonstration with actual items that the patient or caregiver is expected to use with parenteral products and/or compounded preparations such as special containers, administration equipment and devices?	NA	Do not sell home infusion or these type products
186.00	Are patient package inserts (PPIs) and printed drug information sheets provided to patients? *How?*	Y	Send with each order; many are custom made
187.00	Are MedGuides provided on every fill and refill of medications for which they are required? *How?*	NA	
188.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin or Tikosyn)*	N	
189.00	Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products? *How?*	Y	Custom materials and general materials
190.00	Do patients receive instruction and directions on reporting any adverse reaction or event?	Y	
191.00	For compounding: Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Y	Especially for hydroquinone - storage instructions and signs of instability

192.00	Are patients or caregivers encouraged to contact the pharmacy if they have any questions or would like more information? *How?*	Y	
193.00	Does the pharmacy provide any follow-up to new prescriptions? *Such as patient calls three days after antibiotic pick-up.*	Y	
194.00	Do patients and other customers have access to pharmacists or interns for other questions including general health and OTC questions?	Y	
195.00	Does the pharmacy have a process to address communication needs with regard to the patient's level of understanding? *Literacy, health literacy, education level, etc.*	Y	
196.00	Does the pharmacy have a process to address communication needs with regard to language and cultural influences? *Provide details of language issues including cultural training*	Y	Use a language service in addition to Spanish speakers on staff
197.00	Does the pharmacy have a process to address communication needs with regard to disabilities such as blindness, deafness, or other barriers to communication? *Explain.*	Y	Relay service with deaf patients
198.00	Is patient counseling documented? *Is it just "yes or no" that counseling is provided or does it include content?*	N	
199.00	Is the pharmacist able to make pertinent notes in the profile of the patient during counseling?	Y	
200.00	Is refusal of counseling documented? *How? Is a reason recorded?*	N	
201.00	Does the pharmacy provide information and resources to patients and the public in other formats such as internet live chat, Web site information or links, etc.?	N	
202.00	Do patients have 24-hour access to a pharmacist? *How?* *(If no, enter "NA" for the next three questions)*	N	Have after hours voice mail
203.00	• Do after hours pharmacists have access to patient files? *How?*	NA	
204.00	• Do after hours pharmacists have access to references? *What are they?*	NA	

205.00	• Are after hours consultations documented? *How?*	NA	
206.00	Does the after-hours voicemail message have instructions on who to contact based on urgency of issue? *For example, if this is an emergency please dial 911; leave message if not urgent; alternative number to call for advice after hours such as a nurse line, etc.)*	Y	
207.00	Are adequate processes in place for contacting the patient/caregiver and prescriber if an undue delay is encountered in delivering a prescribed drug? *What is the process when the pharmacy receives a prescription for a product not in stock? Not available in the marketplace?*	Y	If not available in the marketplace, contact the prescriber or patient or both
208.00	Does staff transfer prescriptions to other pharmacies? *What triggers a transfer?*	Y	Pharmacists only; patient request
209.00	Are adequate processes in place to inform patients or caregivers about drug recalls depending on the type or level or recall? *Who contacts the patient (pharmacist, technician, customer service)?*	Y	The person who contacts the patient would depend on the level of the recall- none to date
210.00	Are adequate mechanisms in place to educate patients and caregivers about the appropriate means to dispose of expired, damaged, and unusable medications (including patches, syringes, and other drug administration equipment and supplies)? *What is the source for the disposal information? (FDA? Other?)*	Y	Respond to individual requests
211.00	Does the pharmacy take prescription returns for redispensing? *If yes, describe program.*	N	
212.00	Does the pharmacy participate in a prescription drug take back program? *If yes, describe program.*	N	
213.00	Does the pharmacy participate in a needle exchange or similar program to supply clean needles and syringes? *If yes, describe program.*	N	
	Inspector Notes		

	Patient Confidentiality **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
214.00	Is the PIC also the HIPAA Privacy Officer? *If not, indicate privacy officer in Note.*	Y	
215.00	Is there a HIPAA policy in place for employees, vendors, and contractors?	Y	
216.00	Is the HIPAA-mandated Notice of Privacy Practices (NPP) been made available for patients? *How? For mailed/delivered prescriptions?*	Y	Written notice with instructions
217.00	How is NPP receipt acknowledgement obtained? Signature stored electronically or hard copy? *How is this performed for prescriptions that are mailed or delivered?*	Y	Document sending and receipt of the package; some forms are signed and returned
218.00	Do employees deemed nonessential to patient care have access to confidential patient information? *Such as delivery services, non-pharmacy store management, etc.*	N	
219.00	Is access to the pharmacy system limited to appropriate personnel? *Password protected, access limited by job type, access revoked as appropriate such as upon termination, access to patient information in the computer is tracked*	Y	
220.00	Are confidential documents shredded? *In-house or by a service?*	Y	United Document Storage, 800-280-5180
221.00	Does the pharmacy appropriately destroy labeled prescription vials?	Y	
222.00	Does the crisis plan includes security of paper and electronic patient information?	Y	
	Inspector Notes		

	Prescription Receipt, Packing, and Transporting **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
223.00	Does the patient sign for prescriptions when they are picked up? *Manual or Electronic?*	Y	Manual
224.00	Does the patient sign for prescriptions obtained at the drive through? *Manual or electronic?*	NA	
225.00	Does the pharmacy obtain signatures for prescriptions that are mailed or shipped? *How?*	N	Have proof of delivery
226.00	Are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Y	

227.00	Does the pharmacy have testing data from the packaging supplier to confirm? *View documentation*	Y	
228.00	Does the pharmacy conduct its own testing of packing materials? *View documentation, ensure includes both high and low temperature extremes.*	Y	Check temperatures in containers after a period of time in temperature extremes
229.00	Does the pharmacy obtain information from carriers regarding shipping conditions to maintain appropriate temperatures of the products? *Indicate carriers used.*	N	
230.00	Is the packaging tamper evident?	Y	
231.00	Are the packages appropriately labeled if they contain hazardous materials?	NA	
232.00	Does the pharmacy ship overnight?	Y	As appropriate
233.00	Do shipments go out on Fridays or weekends where they might sit in a truck for a period of time?	Y	Only in the winter; never ship on weekends in hot weather
	Inspector Notes		

	Patient Care Services **If any part of a question is no, enter "N" and explain the observation.**	**Y/N/?/NA**	**Note**
234.00	Does the pharmacy perform MTM - targeted medication reviews? *Is there a P&P available?*	N	
235.00	Does the pharmacy perform MTM – CMR (Comprehensive Medication Review)? *Is there a P&P available?*	N	
236.00	Does the pharmacy perform any Health and Wellness Screenings such as: blood pressure screening, cholesterol screening, osteoporosis screening? *Is there a P&P available? Is a CLIA waiver posted, if applicable?*	N	
237.00	Does the pharmacy provide any health and wellness programs such as: smoking cessation program, weight loss program. *Is there a P&P available?*	N	
238.00	Does the pharmacy send refill reminders or have an automatic fill program? *Is there a P&P available? Do customers sign up for program?*	Y	Opt-In by patient
239.00	Does that pharmacy provide any adherence programs? *Program is patient specific with follow-up by pharmacy . Is there a P&P available?*	N	

240.00	Does the pharmacy provide patients with medications in blister packs or cards (such as nursing home patients)? *Is there a P&P available?*	N	
241.00	Does the pharmacy provide patients with medications in compliance packaging (where medications are grouped by time of day -- all morning meds in one pack, noon meds in another etc.)? *Is there a P&P available?*	N	
242.00	Does the pharmacy provide any medication synchronization services (to time all medications to come due for refill on the same date)? *Is there a P&P available?*	N	
243.00	Does the pharmacy provide an immunization program? List immunizations or vaccines provided at this pharmacy. *Is there a P&P available including emergency protocol?*	N	
244.00	Does the pharmacy have a care transition program? *Is there a P&P available?*	N	
245.00	Does the pharmacy provide any chronic disease education programs? *If yes, list in notes. Is there a P&P available?*	N	
246.00	Does the pharmacy provide any chronic disease management programs? *If yes, list in notes. Is there a P&P available?*	N	
247.00	Does the pharmacy participate in any collaborative practice agreements? *View agreements, verify they contain signatures of provider(s) and pharmacists(s). Is there a P&P available?*	N	
248.00	Does this pharmacy participate in pharmacist prescribing? *If so, under what circumstances? Is there a P&P available?*	N	
	Inspector Notes		

	Quality Assurance/Quality Improvement Program If any part of a question is no, enter "N" and explain the observation.	Y/N/?/NA	Note
249.00	Is there a documented Quality Assurance/Quality Improvement (QA/QI) program? *Who oversees the program?*	Y	PIC
250.00	Is QA data kept on site? If not, where? *Indicate if documents are kept electronically using software, using an on-line program, or in paper files.*	Y	Paper
251.00	Is QRE (Quality Related Event) defined? May a*lso be referred to as "incidents" or "errors".*	N	
252.00	Is there a form to fill out for a QRE? *Indicate if paper or electronic and who fills it out.*	Y	Paper; filled out by PIC
253.00	Are QREs reported to the board of pharmacy? *If not reported to the Board, indicate how long the files are kept.*	N	Nothing reportable to date; indefinite period of time- have not destroyed any records
254.00	Are QREs reported to an outside peer review committee or patient safety organization? *If so, indicate the name of the organization.*	N	
255.00	Are external errors documented and tracked? *View example documentation*	Y	
256.00	Are internal errors documented and tracked? *View example documentation*	N	This is a compounding pharmacy; if a product does not meet standards, it is destroyed and remade
257.00	Does staff document and report ADRs? *To FDA's MedWatch program or VAERS for immunizations? View example documentation*	NA	Have not had one to date
258.00	Are incidents involving malfunctioning or defective equipment documented and reported to the manufacturer or distributor? *View example of documentation*	Y	
259.00	For compounded products: Are adverse events and defects with compounded products reported to FDA's MedWatch and to USP's MEDMARX programs?	NA	Have not had one to date
260.00	For compounded products: Does the QA program measure all aspects of the preparation and dispensing of compounded products including environmental testing, validation results, etc.?	Y	
261.00	For compounded products: Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded?	Y	Generally 10% depending on the issue
262.00	For compounded products: Are deficiencies in compounding, labeling, packaging, and quality testing and inspection identified and corrected?	Y	

263.00	Are complaints documented and tracked? *Note if response time is tracked.*	Y	Initially put notes in the profile; depends on whether the issue is substantive
264.00	Are reports of contamination or instability of compounded preparations documented, investigated, and tracked? *Is there a recall system in place?*	Y	
265.00	Are patient satisfaction surveys distributed and responses tracked? *Are the surveys pharmacy specific?*	Y	Not lately; used to send surveys with every package- low response rate
266.00	Are pharmacy information systems and technology performance issues measured and tracked? *Automated counting or dispensing apparatuses, computers, etc.*	Y	Computer system- have an IT service
267.00	What other measurements are tracked and analyzed?	Y	Random testing for potency; continually evaluate API's for best pharmaceutical elegance/appearance
268.00	Is data evaluated? *How often and by whom?*	Y	PIC; meeting frequency depends on issue- could be several meetings per month
269.00	Is a root cause analysis process implemented?	Y	Phentolamine potency investigation described as an example
270.00	Is data trended over time (e.g., against previous years' data)?	Y	Quarterly
271.00	Is summary QA/QI report or data shared with staff?	Y	
272.00	Are quality self-audits performed or internal peer-review staff meetings held and documented?	N	
273.00	Have process or policy changes or improvements been made based upon other data collected in the QA/QI program? *Provide example*	Y	Identified issues with capsule weights through random sampling
274.00	Are these improvements or changes evaluated for performance as a way to measure the effectiveness of the CQI program?	NA	Program in place less than a year
	Inspector Notes		

National Association of Boards of Pharmacy
Verified Pharmacy Program™ Inspection – Supplemental Form

Nonsterile Compounding USP Chapter <795> Supplement to the General Inspection

	Business or Corporation:	Rx Unlimited Pharmacy LLC	Telephone number:	818-781-2400	Date:	4/8/2015
	Doing Business As (DBA):	Rx Unlimited Pharmacy	Toll free number:	877-7986583	Start time:	9:00
	Address:	16673 Roscoe Blvd	Fax number:	818-781-2401	End time:	18:40
	City:	North Hills	Pharmacist-in-Charge (PIC):	Clifton Eugene Braddy		
	State:	CA Zip: 91343	Pharmacy/PIC email:	Gene@RxUnlimited.com		

	General Administrative	Y/N/?/NA	Note
1.00	Are non-sterile compounded products for Office Use or DISTRIBUTION listed with the FDA? *Indicate if they have their own NDC numbers and the facility identifier.*	NA	No distribution
2.00	Does the pharmacy have employees or contract personnel who act as representatives (for example sales forces) for the non-sterile compounded preparations? *If so, indicate if they provide samples of products. Provide a list of these samples.*	Y	Five employees- only local
3.00	Does the pharmacy have specific references for non-sterile compounding? *List and indicate if they are in hard copy or electronic format.*	Y	PCCA (online and consults), IACP (online), USP 795 (online),
	Inspector Notes:		

	Product Mix by Volume or Percent (note volume/frequency or % in cell or inspector Notes)	Human	Veterinary	Dispensed total	Dispensed controlled substances	Distributed total	Distributed controlled substances	Hazardous Drugs
	Non sterile compounded product total	100	0	100	40	0	0	15
	Non sterile compounded product - Simple	0	0	0	0	0	0	0
	Non sterile compounded product - Moderate	100	0	100	40	0	0	15
	Non sterile compounded product - Complex	0	0	0	0	0	0	0
	Other special:							
	Inspector Notes: Percentages							

	General Operations *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
4.00	Does the pharmacy dispense non-sterile compounded preparations pursuant to a prescription? *View record for legitimate prescription including a complete patient profile (allergies, disease states, other prescriptions and over the counter meds taken, etc.) and DUR performed. Watch for "list" of patients where the compounded preparation is delivered to the practitioner and no patient profile kept and no DUR performed.*	Y	
5.00	Does the pharmacy distribute non-sterile compounded preparations to practitioners for office use?	N	
6.00	Does the pharmacy distribute non-sterile compounded preparations to hospitals, clinics, or surgery centers?	N	
7.00	Does the pharmacy provide non-sterile compounded preparations to other pharmacies for dispensing? *If so, does the pharmacy have central fill contracts with these pharmacies for patient specific preparations or do they provide non-patient specific compounded preparations to other pharmacies?*	N	
8.00	If the pharmacy compounds non-sterile preparations for animals, does the compounding meet the same standards as compounding for human patients?	NA	
9.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Indicate which in notes*	Y	Tablets, Capsules, Liquids, lozenges, troches, lollypops
10.00	Does the pharmacy compound topicals (creams, ointments, inserts, suppositories, patches, sprays, etc.)? *Indicate which in notes*	Y	Creams, ointments, inserts suppositories, sprays
11.00	Does the pharmacy compound radiopharmaceuticals?	N	
12.00	Does the pharmacy compound vitamin or nutritional supplements?	Y	
13.00	Does the pharmacy make a copy of an approved product? *Indicate under what circumstances and how it is documented. For example, product is in short supply as verified on FDA Web site.* Indicate volume or percent compounded currently in note.	Y	Documented shortage- not available commercially from any source; no percentage provided

14.00	Are products to be compounded appropriately identified as **simple?** 1. *Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s.* *2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer.*				NA	Do not make	
15.00	Are products to be compounded appropriately identified as **moderate?** 1. *Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units.* *2. Making a preparation for which stability data for that specific formula is not available.*				Y		
16.00	Are products to be compounded appropriately identified as **complex?** 1. *Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes.*				NA	Do not make	
17.00	Are products to be compounded appropriately identified as **hazardous**? *National Institute for Occupational Safety and Health (NIOSH) list of drugs. Hazardous drugs exhibit: carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity, organ toxicity at low dose, or genotoxicity--includes hormone powders, chemotherapy, etc.*				Y		
18.00	Does the pharmacist perform an evaluation of the dose, safety and intended use if the preparation to be compounded?				Y		
19.00	For animal compounding, is the pharmacist knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used?				NA		
20.00	For animal compounding, is it determined and documented if the animal is used for food (meat, milk, eggs, etc.)? *Or that the animal is a pet?*				NA		
21.00	For animal compounding, is the pharmacist familiar with drug residues in the food chain and withdrawal times? *How?*				NA		
22.00	For animal compounding, is the pharmacist familiar with regulations regarding drug use in performance animals? *How?*				NA		
	X	**Substantially Compliant**		**Somewhat Compliant**			**Substantially Non-Compliant**
	Inspector Notes: Substantially Compliant						

	Component Selection and Use *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
23.00	**Does the pharmacy make any compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?**	Y	
24.00	Are certificates of analysis (COAs) obtained for all APIs? *Are COAs domestic or foreign in origin? Select several products from the shelf and ask to see the COAs for those products.*	Y	
25.00	Does the pharmacy perform any testing/analysis of APIs? *If so, indicate how API is selected for testing, what tests are performed and if tested in-house or sent to an outside lab - indicate lab in notes.*	Y	Only done one time to-date
26.00	If the source is a foreign FDA facility, does the pharmacy obtain information on the last FDA inspection of that facility and a copy of the report?	NA	Buy from US locations of Repackagers- PCCA, Letco, Medisca, Freedom, API
27.00	Are USP- or NF-grade substances used, if available?	Y	
28.00	If compendial quality components are not available, are chemically pure, analytical reagent grade or American Chemical Society-certified components used? *How is it determined the products are free from impurities that raise human or animal safety concerns?*	NA	
29.00	Are other means used to establish purity and safety? *Describe the means, such as lot analysis, manufacturer reputation, reliability of source.*	Y	Reliability of source
30.00	Examine the labeling on the APIs. Do any of the labels state "For Research Purposes Only" or "Not for Drug Use" or "Veterinary Use only" or similar? Or have non-standard labels (such as handwritten or from another pharmacy)? *If so, view invoices and record the source of these items and photos. Indicate how vet use only products are segregated to prevent them from being used for preparations compounded for humans.*	N	
31.00	Do all substances and components have a complete label including a batch control or lot number, and an expiration date?	Y	
32.00	For substances without an expiration date assigned by the manufacturer or supplier, does the pharmacy have a procedure to assign a conservative expiration date and is it followed? *Containers labeled with date of receipt and the expiration date assigned is not greater than three (3) years, is supported with data and/or testing, and takes into consideration the nature of the component, its degradation mechanism, the container in which it's packaged, and the storage conditions.*	Y	
33.00	Are all APIs labeled with the date they were received?	N	

34.00	Does the pharmacy repackage APIs into smaller containers for ease of use? *If so, how is the expiration date determined for the repackaged product?*				N		
35.00	Are bulk component containers labeled with appropriate Occupational Safety and Health Administration (OSHA) hazard communication labels and are hazardous substances segregated?				Y		
36.00	When manufactured products are used for compounding, do the labels contain a lot number and expiration date?				Y		
37.00	When manufactured products are used for compounding, are all the other excipients in the product considered relative to the use, effectiveness, and stability of the compounded preparation to be made?				NA	Have not compounded products from these types of commercial products	
38.00	Are any preparations made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons? *How does the pharmacy determine this?*				N		
39.00	If compounding for food producing animals, does the compounder have a list of components prohibited for use?				NA		
40.00	If components are used that are derived from ruminant animals (cow, sheep, goat) does the pharmacy obtain documentation that the component is in compliance with federal laws governing processing, use, and importation? *(the animals were free from disease, and that they were born, raised, and slaughtered in locations where bovine spongiform encephalopathy and scrapie are not known to exist)*				NA		
41.00	Do the ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards? *If not, how have the ingredients been determined to meet food-grade quality?*				NA		
42.00	Where water is an ingredient, is purified or distilled water used?				Y	Purified	
	X	**Substantially Compliant**		**Somewhat Compliant**			**Substantially Non-Compliant**
	Inspector Notes: Substantially Compliant						

	BEYOND USE DATING (BUD) *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
43.00	Are BUDs assigned from the day of preparation?	Y	
44.00	Are BUDs for nonaqueous formulations not later than the remaining time until the earliest expiration date of any API and not later than six (6) months?	Y	
45.00	Are BUDs for water-containing oral formulations not later than 14 days when stored at controlled cold temperatures (refrigerated)?	Y	
46.00	Are BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days?	Y	
47.00	Are BUDs assigned based on dispensing in tight, light-resistant containers?	Y	
48.00	Are any extended BUDs assigned? *Provide a list of products with extended BUD and how justified.*	Y	Testosterone- tested; PCCA formulas that PCCA have had tested
49.00	Is any testing done to support the extended BUDs? *Provide a list of products tested and the results of such testing.*	Y	Testosterone- tested
50.00	Are any extended BUDs assigned greater than six (6) months from the date of compounding?	N	
51.00	When using a manufactured product as the active ingredient, is the expiration date of the manufactured product used as the BUD?	N	
52.00	Are appropriate microbiological preservatives (bacteria, yeast, and mold) used? *If not, why not and are products refrigerated?*	NA	
53.00	Are any other processes used to sterilize preservative free products? *List types and ensure procedures include validation of the process.*	N	

	X	**Substantially Compliant**		**Somewhat Compliant**		**Substantially Non-Compliant**

Inspector Notes: Substantially Compliant

	Environment *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
54.00	Is the non-sterile compounding area a controlled environment and separate from the general pharmacy?	Y	
55.00	Is there sufficient space available for the type and amount of compounding performed?	Y	
56.00	Is entry into the non-sterile compounding area limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel)?	Y	
57.00	Is only one preparation compounded at a time?	Y	
58.00	Is the space orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations?	Y	
59.00	Are procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions?	Y	
60.00	Is the compounding area well lit?	Y	
61.00	Are heating, ventilation, and air conditioning systems controlled to maintain the integrity of components, chemicals and reduce risk of contamination?	Y	
62.00	Does the pharmacy perform non-sterile compounding using a powder hood or isolator? *If so, indicate models and types of equipment used.*	Y	Two powder containment hoods
63.00	Is appropriate protective attire (gowns, gloves, masks, etc.) available?	Y	Gown, gloves, mask, hair nets
64.00	Is there a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels?	N	Adjacent, just outside
65.00	Is there adequate space to wash equipment and utensils including access to purified water for rinsing?	Y	Dishwasher also
66.00	Does the nonsterile compounding area have a fan? *View placement and indicate if the airflow affects disbursement of drug residue or contaminants*	N	

67.00	Are both the temperature and humidity monitored 24/7 in the compounding areas? *View documentation.*				Y		
68.00	Are there alarms or alerts when excursions are detected in the compounding area? *Is there an action plan when an excursion occurs?*				N		
69.00	Is the bulk component storage area adequately arranged and maintained in a clean and sanitary condition?				NA		
70.00	Are both the temperature and humidity monitored 24/7 in the bulk component storage areas (if separate from the compounding area)? *View documentation.*				NA		
71.00	Are there alarms or alerts when excursions are detected in the bulk component storage area? *Is there an action plan when an excursion occurs?*				NA		
72.00	Are hazardous drugs appropriately identified and marked, received, handled and stored by appropriately trained personnel? (OSHA regulations and NIOSH Alerts)				Y		
73.00	Are all components, equipment, and containers stored off the floor and handled and stored to prevent contamination?				Y		
74.00	Are all components and packaging containers and closures properly rotated to use oldest first?				Y		
75.00	Is trash disposed of in a safe, sanitary, and timely manner including hazardous waste? *How is hazardous waste disposed of?*				Y		
		Substantially Compliant	**X**	**Somewhat Compliant**			**Substantially Non-Compliant**
	Inspector Notes: No bulk storage areas that contact prescription products; the storage area only contains supplies						

	TRAINING *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
76.00	Are pharmacists and technicians performing compounding appropriately trained and certified? *View documentation of training.*	Y	
77.00	Does the training include cleaning and disinfection, garb, manipulation of ingredients including quality testing, labeling, and hazardous material handling?	Y	
78.00	Does the training process for the preparation of compounds include demonstration of the compounding procedure first followed by the trainee performing the procedure under supervision successfully before allowed to perform compounding?	Y	
79.00	Does training include the operation of any equipment that may be used when preparing compounded products? *Documentation needs to include training on operation, troubleshooting, and annual competency evaluation.*	Y	
80.00	Are employees performing non-sterile compounding evaluated at least annually (including hazardous drug handling) and is the evaluation documented?	Y	
81.00	Does the pharmacy use relief personnel from outside agencies to perform non-sterile compounding? *How are training and certifications verified? View documentation.*	N	

	X	**Substantially Compliant**		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes: Substantially Compliant					

	COMPOUNDING EQUIPMENT *If any part of a question is no, answer the whole question "no" and explain the observation.*	Y/N/?/NA	Note
82.00	Is the appropriate equipment available and in good working order? *View maintenance and calibration logs.*	Y	
83.00	Is all equipment inspected for cleanliness and proper function prior to each use?	Y	
84.00	Is all equipment thoroughly cleaned promptly after each use to prevent cross contamination? *Equipment and utensils washed using potable water with a soap or detergent, rinsing with* ***purified*** *water.*	Y	

85.00	Does the pharmacy use separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products?				NA	Do not make these products	
86.00	If not, are there detailed procedures for meticulous cleaning of the equipment used for allergenic, cytotoxic, or hazardous ingredients immediately after use? *Including personnel performing cleaning are appropriately garbed?*				NA		
87.00	If disposable equipment or supplies are used, are they disposed of appropriately?				Y		
88.00	Are scales, balances, or other equipment used for measurement validated and calibrated at least annually?				Y		
89.00	If a powder hood is used, has it been certified? How often? *Review copy of certification report.*				Y	Just opened this facility in August 2014 and all hoods were certified before use	
90.00	If biological safety cabinet (BSC), compounding aseptic isolator (CAI), or compounding aseptic containment isolator (CACI) hoods are used for hazardous substances, have they been certified? How often? *View copy of certification report. NOTE: If compounding with hazardous materials that are volatile, must use BSC or CACI only, and the cabinet must be vented to the outside.*				NA		
91.00	If the hoods or isolators are located in a closed, controlled room environment, has the room been certified or tested? *View copy of report or testing results*				N		
92.00	If the hoods or isolators are not located in a closed, controlled room environment, is there documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel?				NA		
93.00	Is there any environmental testing performed to detect contamination by drug residue in the pharmacy areas or areas served by the same ventilation system? *Drug residue may cause cross contamination to other products and expose staff. Not required but is recommended if compounding with hazardous materials, not using a hood, or compounding room not segregated.*				N		
	X	**Substantially Compliant**		**Somewhat Compliant**			**Substantially Non-Compliant**
	Inspector Notes: Substantially Compliant						

	DOCUMENTATION ***If any part of a question is no, enter "N" and explain the observation.***	**Y/N/?/NA**	**Note**
94.00	Does the pharmacy create a master formulation record the first time before compounding a new preparation? *Who reviews/approves?*	Y	
95.00	Is every formulation evaluated for incompatibilities and the potential for an ineffective or toxic preparation? *How?*	Y	
96.00	Does the master formulation record contain: 1. Official or assigned name, strength, and dosage form 2. All necessary calculations 3. Description of all ingredients and their quantities 4. Compatibility and stability information including references (when available) 5. Equipment used for the preparation 6. Mixing instructions to include order of mixing, temperatures, duration of mixing, and other pertinent factors 7. Container used and packaging requirements 8. Assigned BUD information 9. Labeling information including the generic name of and quantity or concentration of each active ingredient 10. Description of the finished preparation 11. Storage requirements 12. Quality control procedures and expected results	Y	
97.00	Does the pharmacy create a compounding record for each compound prepared?	Y	

98.00	Does the compounding record include: 1. Official or assigned name, strength and dosage of the preparation 2. Master Formulation Record reference 3. Sources, lot numbers, and expiration dates of all components 4. Total quantity or number of dosage units compounded 5. Person compounding the preparation 6. Person performing the quality control procedures 7. Person who approved the preparation 8. Date of compounding 9. Assigned internal identification number or prescription number 10. Description of the final preparation 11. Assigned BUD 12. Duplicate label 13. Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)? 14. Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate	Y	
99.00	Are all records kept for the length of time specified by the state? *Indicate how long records are kept and where.*	Y	

	X	**Substantially Compliant**		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes: Substantially Compliant; use the PK Compounder software					

	COMPOUNDING PROCEDURES ***If any part of a question is no, enter "N" and explain the observation.***	**Y/N/?/NA**	**Note**
100.00	Have the Master Formulation Record and the Compounding Record been reviewed by the compounder to ensure it is error free?	Y	
101.00	Do compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality? *How?* Does this include a unit-by-unit physical inspection of the products?	Y	Pharmacist checks
102.00	Do the containers and closures selected meet USP standards (from container supplier)?	Y	

103.00	Is container selection determined by physical and chemical properties of the preparation?				Y		
104.00	Do compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed?				Y		
105.00	Do personnel don appropriate protective garb when performing compounding? *Indicate any garb used: including if gloves only, gloves always or sometimes, gloves plus gown, mask, etc.*				Y	Disposable gown, mask, gloves	
106.00	Are routine compounding procedures for batch preparation completed and verified according to written procedures? Including: Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly				Y		
107.00	Are procedures for in-process checks followed? *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product and documentation of the compounding accuracy is by someone other than the compounder to ensure proper measurement, reconstitution and component usage.*				Y		
108.00	If there are any deviations from the master formulation record, are these deviations recorded? *Is it determined if the deviation will affect the BUD?*				Y	Yes	
109.00	Is there a plan for cleaning? *After each preparation, daily tasks, monthly tasks, etc.*				Y	Yes	
110.00	Are personnel appropriately garbed for protection when cleaning?				Y		
	X	**Substantially Compliant**		**Somewhat Compliant**			**Substantially Non-Compliant**
	Inspector Notes: Substantially Compliant						

	FINISHED PREPARATION RELEASE CHECKS AND TESTS *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
111.00	Is the finished preparation observed to appear as expected in the master formulation record and documented?	Y	
112.00	As appropriate, is the final completed preparation assessed for weight, mixing, clarity, odor, color, consistency, pH, and strength? Is it documented?	Y	
113.00	There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity?	Y	
114.00	Is there a process in place to sample prepared products for potency and/or contamination? *Required if using extended BUD.*	Y	
115.00	Does testing include physical, chemical, and microbiological characteristics?	Y	Except microbiology
116.00	Are all products produced in batches tested? *Required if using extended BUD.*	N	BUD testing done before extending; random otherwise
117.00	If any failed tests or discrepancies are observed, is there an investigation and are appropriate corrective actions taken before dispensing to patient?	Y	
118.00	Are any products that are being tested dispensed or distributed before the test results are obtained? *If so, what is the procedure for recall if the test results indicate an issue?*	N	
119.00	Does the pharmacy have its own lab to perform testing? *If so, what testing is performed in house?*	N	
120.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what tests are performed.*	Y	Eagle Analytical for stability and potency
121.00	Are there appropriate control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations? *Validation of equipment and personnel performance documentation*	Y	

122.00	Do labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials?	Y
123.00	Are batch preparations (in anticipation of prescriptions) of an appropriate volume? *Are batch products in stock all within their BUD (not outdated)?*	Y
124.00	Do labels on patient-specific containers, in addition to standard label requirements, also include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials?	Y
125.00	Do labels on compounded preparations for food producing animals contain information regarding withdrawal times?	NA
126.00	Are preparations stored properly prior to dispensing based upon conditions upon which BUD was assigned?	Y
127.00	Are preparations examined immediately after preparation AND again immediately prior to dispensing for any signs of instability?	Y
128.00	If problems occur during compounding of an official USP monograph preparation, is it reported to USP?	NA
129.00	Are all issues that are reported to the pharmacy (adverse events, instability, etc.) documented, investigated, and corrective action taken?	Y

	X	**Substantially Compliant**		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes: Substantially Compliant					

The information and comments obtained in the supplement sections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted.

National Association of Boards of Pharmacy
Verified Pharmacy Program™ Inspection – Supplemental Form

Sterile Compounding USP Chapter <797> Supplement to the General Inspection

	Business or Corporation:	Rx Unlimited Pharmacy LLC	Telephone number:	818-781-2400	Date:	4/8/2015
	Doing Business As (DBA):	Rx Unlimited Pharmacy	Toll free number:	877-7986583	Start time:	9:00
	Address:	16673 Roscoe Blvd	Fax number:	818-781-2401	End time:	18:40
	City:	North Hills	Pharmacist-in-Charge (PIC):	Clifton Eugene Braddy		
	State:	CA Zip: 91343	Pharmacy/PIC email:	Gene@RxUnlimited.com		

	General Administrative	Y/N/?/NA	Note
1.00	Are sterile compounded preparations for Office Use or DISTRIBUTION listed with the FDA? *Indicate if they have their own NDC numbers and the facility identifier.*	NA	No office use
2.00	Does the pharmacy have employees or contract personnel who act as representatives (for example sales forces) for sterile compounded preparations? *If so, indicate if they provide samples of products. Provide a list of these samples.*	Y	No samples; only local representatives for sterile
3.00	Does the pharmacy have appropriate compounding references including USP Chapter 797, injectable drug compatibility, hazardous materials references? List references and indicate if they are in hard copy or electronic format.	Y	
	Inspector Notes: Interviewed Naomi Parvizi, Pharm D and Jay Paruki Compliance Manager; No Sterile compounding done on the day of this inspection- none waiting to be compounded; total volume including Non-Sterile averages 25 per day; moved to this location August 2014. Also, there was no Sterile Compounding or simulated compounding taking place on the day the PECs and rooms were certified.		

	Product Mix by Volume or Percent (note volume/frequency or % in cell or Inspector Notes)	Human	Veterinary	Dispensed Total	Dispensed Controlled Substances	Distributed Total	Distributed Controlled Substances	Hazardous Drugs
	Total compounded sterile product	100	0	100	25	0	0	25
	Compounded sterile product – low risk	1	0	1	0	0	0	0
	Compounded sterile product – medium risk	0	0	0	0	0	0	0
	Compounded sterile product – high risk	99	0	99	25	0	0	25
	Compounded sterile product – immediate use	0	0	0	0	0	0	0
	Compounded sterile **suspensions** for injection	0	0	0	0	0	0	0
	Inspector Notes: Percentages; very low volume							

	General Operations *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
4.00	Does the pharmacy dispense sterile compounded preparations pursuant to a prescription? *View record for legitimate prescription including a complete patient profile (allergies, disease states, other prescriptions and over the counter meds taken, etc.) and DUR performed. Watch for "list" of patients where the compounded preparation is delivered to the practitioner and no patient profile kept and no DUR performed.*	Y	
5.00	Does the pharmacy distribute sterile compounded preparations to practitioners for office use?	N	
6.00	Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers?	N	
7.00	Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing? *If so, does the pharmacy have central fill contracts with these pharmacies for patient specific preparations or do they provide non-patient specific compounded preparations to other pharmacies?*	N	
8.00	If the pharmacy compounds sterile preparations for animals, does the compounding meet the same standards as compounding for human patients?	NA	
9.00	Does the pharmacy compound allergen extracts?	N	
10.00	Does the pharmacy compound radiopharmaceuticals?	N	
11.00	Does the pharmacy compound parenteral preparations?	N	
12.00	Does the pharmacy compound ophthalmic preparations?	Y	
13.00	Does the pharmacy compound inhalation preparations?	N	
14.00	Does the pharmacy compound parenteral suspensions?	N	
15.00	Does the pharmacy compound preservative-free parenterals?	N	
16.00	Does the pharmacy make a copy of an approved product? *Indicate under what circumstances and how it is documented. For example, product is in short supply as verified on FDA Web site.* Indicate volume or percent compounded currently in note.	Y	Only a few occasions when back order documented; two or three prescriptions total
17.00	Are products to be compounded appropriately identified as **low-risk**? 1. Not more than three sterile drug packages used 2. Sterile equipment 3. Compounded in an ISO Class 5 hood in an ISO Class 7 clean room (if ISO Class 5 hood NOT in ISO Class 7 clean room, max BUD 12 hours) 4. Limited basic closed system aseptic transfers and manipulations	Y	

18.00	Are products to be compounded appropriately identified as **medium-risk**? 1. Uses four or more sterile ingredients 2. Complex aseptic manipulations other than single volume transfer 3. Compounded sterile preparation (CSP) is to be administered to multiple patients or to one patient on multiple occasions 4. Compounding process of unusually long duration (dissolution, homogeneous mixing)				Y		
19.00	Are products to be compounded appropriately identified as **high-risk**? 1. Made with nonsterile ingredients, nonsterile devices, or nonsterile containers 2. Prepared with sterile ingredients but exposed to <ISO Class 5 air 3. Greater than a six-hour delay before sterilization 4. Purity of components assumed but not verified				Y		
20.00	Are **immediate use** compounds appropriately identified? 1. Aseptically compounded 2. Simple transfer ≤ 3 commercially manufactured non-hazardous products 3. Not > 2 entries into any container 4. Admin begins ≤ 1 hour from start of compounding				NA		
21.00	Are products to be compounded appropriately identified as **hazardous**? *National Institute for Occupational Safety and Health (NIOSH) list of drugs. Hazardous drugs exhibit: carcinogenicity, teratogenicity, or other developmental toxicity, reproductive toxicity, organ toxicity at low dose, or genotoxicity.*				Y		
22.00	For animal compounding, is the pharmacist knowledgeable about the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used?				NA	0	
23.00	For animal compounding, is it determined and documented if the animal is used for food (meat, milk, eggs, etc.)? *Or that the animal is a pet?*				NA	0	
24.00	For animal compounding, is the pharmacist familiar with drug residues in the food chain and withdrawal times? *How?*				NA	0	
25.00	For animal compounding, is the pharmacist familiar with regulations regarding drug use in performance animals? *How?*				NA	0	
	X	**Substantially Compliant**		**Somewhat Compliant**			**Substantially Non-Compliant**
	Inspector Notes: Substantially Compliant						

	Component Selection and Use *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
26.00	**Does the pharmacy make any compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?**	Y	0
27.00	Are certificates of analysis (COAs) obtained for all APIs? *Are COAs domestic or foreign in origin? Select several products from the shelf and ask to see the COAs for those products.*	Y	0
28.00	Does the pharmacy perform any testing/analysis of APIs? *If so, indicate how API is selected for testing, what tests are performed and if tested in-house or sent to an outside lab - indicate which lab in notes.*	N	Only done one time to-date
29.00	If the source is a foreign FDA facility, does the pharmacy obtain information on the last FDA inspection of that facility and a copy of the report?	NA	Buy from US locations of Repackagers- PCCA, Letco, Medisca, Freedom, API
30.00	Are USP- or NF-grade substances used, if available?	Y	0
31.00	If compendial quality components are not available, are chemically pure, analytical reagent grade or American Chemical Society-certified components used? *How is it determined the products are free from impurities that raise human or animal safety concerns?*	NA	0
32.00	Are other means used to establish purity and safety? *Describe the means, such as lot analysis, manufacturer reputation, reliability of source.*	Y	Reliability of source
33.00	Examine the labeling on the APIs. Do any of the labels state "For Research Purposes Only" or "Not for Drug Use" or "Veterinary Use only" or similar? Or have non-standard labels (such as handwritten or from another pharmacy)? *If so, view invoices and record the source of these items and photos. Indicate how vet use only products are segregated to prevent them from being used for preparations compounded for humans.*	N	0
34.00	Do all substances and components have a complete label including a batch control or lot number, an expiration date, and are marked with the date of receipt?	Y	0
35.00	For substances without an expiration date assigned by the manufacturer or supplier, does the pharmacy have a procedure to assign a conservative expiration date and is it followed? *Containers labeled with date of receipt and the expiration date assigned is not greater than three (3) years, is supported with data and/or testing, and takes into consideration the nature of the component, its degradation mechanism, the container in which it's packaged, and the storage conditions.*	Y	0
36.00	Are all APIs labeled with the date they were received?	N	0
37.00	Does the pharmacy repackage APIs into smaller containers for ease of use? *If so, how is the expiration date determined for the repackaged product?*	N	0

38.00	Are bulk component containers labeled with appropriate OSHA hazard communication labels and are hazardous substances segregated?				Y	0
39.00	When manufactured products are used for compounding, do the labels contain a lot number and expiration date?				Y	0
40.00	When manufactured products are used for compounding, are all the other excipients in the product considered relative to the use, effectiveness, and stability of the compounded preparation to be made?				NA	Have not compounded products from these types of commercial products
41.00	Are any preparations made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons? *How does the pharmacy determine this?*				N	0
42.00	If compounding for food producing animals, does the compounder have a list of components prohibited for use?				NA	0
43.00	If components are used that are derived from ruminant animals (cow, sheep, goat) does the pharmacy obtain documentation that the component is in compliance with federal laws governing processing, use, and importation? *That the animals were free from disease, and that they were born, raised, and slaughtered in locations where bovine spongiform encephalopathy and scrapie are not known to exist.*				NA	
44.00	**Does the pharmacy compound its own stock solutions or components that are then used to compound a finished product? *If so, how are BUDs determined?***				Y	
45.00	• Are the compounded stock solutions prepared in batches that are exposed longer than 12 hours at 2-8°C (25-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before being sterilized?				N	
46.00	• Are all compounded stock solutions that will be used as a component of a finished product tested for sterility and stability? *Explain the process.*				Y	Always test for sterility and endotoxins
47.00	• When using its own compounded stock solution, is it used without dilution in a final preparation (repackaged as-is into smaller or unit-of-use packages)? *If so, are these preparations given extended BUDs? How is the BUD determined?*				N	
48.00	• When using its own compounded stock solution, is it used as a component of a preparation (made less concentrated by the addition of a diluent or other component)? *If so, are these preparations given extended BUDs? How is the BUD determined?*				Y	
	X	**Substantially Compliant**		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes: Substantially Compliant					

	Environment *If any part of a question is no, enter "N" and explain the observation.*	**Y/N/?/NA**	**Note**
49.00	If the facility performs both sterile and nonsterile compounding, are the areas separated and distinct?	Y	
50.00	Is entry into the sterile compounding areas limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel)?	Y	
51.00	Does the ante-room have a line of demarcation or other separation of the dirty to the clean side?	Y	
52.00	Are carts used to bring supplies from the storeroom kept on the outside of the line of demarcation?	NA	Do not use carts to bring products from the storeroom
53.00	Are carts used in the clean room/buffer room kept on the clean side of the line of demarcation?	Y	
54.00	Are all surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating?	Y	
55.00	Are walls painted with white epoxy based paint or other impermeable surface, and are they seamless or have sealed seams where panels meet and corners with no cracks?	Y	
56.00	Are the ceiling tiles composed of a vinyl surface, with the tiles caulked and sealed and are the seams where the walls meet the ceiling caulked and sealed? *If no, describe what is present.*	Y	
57.00	Is the floor overlaid with wide sheet flooring and seamless or with heat welded seams, with coving to the sidewall, and a sealed seam where the coving meets the wall? *If no, describe what is present.*	Y	
58.00	Does the clean room or ante-room have dust collecting overhangs, such as ceiling utility pipes, or ledges? *Are all sprinkler heads flush with the ceiling?*	N	
59.00	Are the exposed surfaces of the light fixtures smooth, mounted flush, and sealed?	Y	
60.00	Is there a sink with hot and cold running water located in the ante room or near the sterile compounding area that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands, and is there an eyewash station?	Y	

61.00	Is there a sink or a floor drain in the clean room/buffer room? (This is not allowed)	N	
62.00	Are all air ducts controlling air flow into the sterile compounding area equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 environment?	Y	
63.00	Are incoming air ducts through HEPA filters on or near the ceiling and are air return ducts low on the walls to facilitate turbulent air flow in the ante-room and clean room?	Y	
64.00	Is there any particle generating equipment (computers, refrigerators, etc.) in the clean room/buffer room or anteroom? *If so, indicate equipment and room.*	N	
65.00	If there is particle generating equipment in the clean room or ante-room, is the equipment located by an air return so air flows over and out of the room taking particles with it, and has this air flow has been confirmed by smoke testing? *View certification report for the room and specifically look at particle counts taken in the area of the equipment.*	NA	
66.00	Does the sterile compounding area have a fan? *Has it been validated to not affect airflow in the ISO Class 5 PEC?*	N	
67.00	Are coffee, water, chewing gum, candy, or food items prohibited from the clean room/buffer area or ante-room?	Y	
68.00	Are sterile compounded products prepared with aseptic manipulations entirely within ISO Class 5 or better air quality hood or shielded laminar flow work area using only sterile ingredients, products, components, and devices?	N	
69.00	If no (for example compounding with non-sterile APIs), does the pharmacy have appropriate equipment to sterilize the finished product? *List sterilizing equipment used in notes (filters, autoclave, etc.).*	Y	Filters
70.00	Is the ISO Class 5 compounding area located within an ISO Class 7 clean room or buffer area? *For laminar airflow workbenches, CAI, or CACI that are NOT located in an ISO Class 7 buffer room fill out the questions at the end of this section.*	Y	
71.00	Does the ISO Class 7 clean room or buffer area door lead into an ISO Class 7 or 8 ante room? *Indicate if the ante room is ISO Class 7 or 8.*	Y	
72.00	Is the ISO 7 clean room positive pressure to the ISO 7 or 8 ante room? *Record pressure differential.*	Y	0.051
73.00	Is the hazardous compounding room and hazardous drug storage area negative pressure to the ISO 7 ante room? *Record pressure differential.*	NA	No hazardous room

74.00	Is the ISO Class 7 or 8 ante room positive pressure to the general pharmacy areas? *Record the pressure differential.*	Y	0.075 from prep room to general pharmacy and 0.92 from the ante room to the general pharmacy
75.00	Are pressure differential monitoring procedures in place including an alarm or alert when there is an excursion? *Verify by viewing daily logs and ensure a plan is in place if discrepancy is found.*	Y	Compounding pharmacist gets an email alert
76.00	If the clean room and anteroom are not fully enclosed, is the air flow measured across the openings? *Record the air flow.*	NA	
77.00	Are air flow monitoring procedures in place including an alarm or alert if the air flow drops below the limit? *Verify by viewing daily logs and ensure a plan is in place if discrepancy is found.*	Y	
78.00	Is the temperature of the compounding area controlled by a thermostat and an adequate air conditioning system (anteroom and cleanroom) maintained between 64-72°F (18-22°C)? *View records and record temperature of the clean room at the time of inspection.*	Y	68 F
79.00	Is the humidity monitored daily and in the range of 35%-60% in the sterile compounding area? *View records and record humidity at the time of inspection.* Relative Humidity levels between 35% and 60% are recommended (below 35% allows static levels above recommended values. Above 60% promotes microbial growth).	N	27%
80.00	Are the blowers on ISO 5 laminar airflow workbenches (LAFW) or barrier isolators operated continuously during compounding activity, including during interruptions of less than eight hours?	Y	
81.00	When the LAFW blower is turned off and before other personnel enter to perform compounding activities, is only one garbed person allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and of sanitizing the work surfaces?	Y	
82.00	Are the doors into the ante-room from the general pharmacy area and from the anteroom into the clean room interlocked to prevent both being open at the same time?	N	
83.00	Are the inside and outside doors of a pass-through interlocked to prevent both being open at the same time?	N	

	LAFW NOT located in ISO Class 7 buffer area:		
84.00	Is compounding restricted to low-risk preparations with a maximum BUD of 12 hours?	NA	
85.00	Are all garbing requirements adhered to?	NA	
86.00	Is the LAFW located in an area that is maintained under sanitary conditions only be traveled by persons engaging in the compounding of sterile preparations?	NA	
87.00	Does the location contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, or are adjacent to construction sites, warehouses, or food preparation areas?	NA	
88.00	Is the sink separated from the immediate area of the ISO Class 5 workbench (not adjacent)?	NA	
	CAI or CACI NOT located in ISO Class 7 buffer area:		
89.00	Does the CAI/CACI maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of CSP? *NOTE: for certification, particle counts must be sampled 6 to 12 inches upstream of the critical exposure site.*	NA	
90.00	Does the pharmacy have documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments?	NA	
91.00	Is the CAI or CACI located in an area that is maintained under sanitary conditions and only be traveled by persons engaging in the compounding of sterile preparations?	NA	
92.00	For <u>hazardous</u> compounding in a CACI that is NOT located in a buffer area, is the CACI located in a physically separated area that maintains a negative pressure of 0.01" water column pressure to adjacent areas and a minimum of 12 ACPH?	NA	

		Substantially Compliant	**X**	**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes:					

	Cleaning and Disinfection *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
93.00	Are all personnel that perform cleaning activities in the compounding areas appropriately trained (including housekeeping or other outside personnel if used for cleaning)?	Y	
94.00	Are all personnel performing cleaning appropriately garbed?	Y	
95.00	Is the sterile compounding area equipped with appropriate nonshedding cleaning equipment and supplies? *All cleaning tools, such as wipers, sponges, and mops, must be nonshedding, dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed).*	Y	
96.00	If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area and are buckets inverted to prevent moisture accumulation?	Y	
97.00	Are tools appropriately labeled to prevent them from being used inappropriately? For example, a mop used for the floors cannot also be used for the ceilings and walls.	Y	
98.00	Are there formulas and instructions for mixing or diluting the cleaning and sanitizing agents prior to use and is the preparation of cleaning supplies documented?	NA	Buy already made products
99.00	Are cleaning and sanitizing agents appropriately labeled including expiration dates? *Note if any cleaning agents are expired.*	Y	
100.00	Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores? *Indicate how often a sporicidal agent is used. List products used in note.*	Y	Bleach once a month; Use 70% isopropyl always
101.00	Are sanitizing agents rotated or alternated to reduce the risk of producing resistant strains of organisms? *How often?*	Y	Every 3 weeks
102.00	Is the ISO 5 PEC cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination?	Y	
103.00	Does the cleaning of the ISO 5 PEC include cleaning with sterile water **and** sanitizing with sterile 70% IPA using a nonlinting wipe?	N	
104.00	Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?	Y	
105.00	Does daily cleaning include the floors starting from the clean room and working outwards? *Floor cleaning is not to occur during compounding.*	N	Twice a week

106.00	If fatigue mats are used, are they cleaned daily and let dry on both sides?				NA		
107.00	Is a tacky mat used and if so, is there a procedure in place regarding replacement? *Note frequency of change.*				Y	Every two days or more often if dirt visible	
108.00	Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls (PECs) thoroughly cleaned monthly? (*This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc.)* Check inside bins and shelving for dust if you are garbed.				Y		
109.00	Is enough time allocated for cleaning activities?				Y		
		Substantially Compliant	**X**	**Somewhat Compliant**			**Substantially Non-Compliant**
	Inspector Notes:						

	Training and Garbing ***If any part of a question is no, enter "N" and explain the observation.***	**Y/N/?/NA**	**Note**
110.00	Is there documentation that all compounding personnel have passed an initial and subsequent annual written exams for quality assurance procedures for the appropriate risk level and including hazardous drugs?	Y	
111.00	Is there documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling hazardous drugs?	Y	
112.00	Are pharmacists and technicians performing compounding using hazardous drugs appropriately trained in the safe handling, garbing, cleaning, and disinfection procedures and waste disposal of hazardous drugs and materials?	Y	
113.00	Does training include operation of any equipment that may be used when preparing compounded sterile products? *Documentation needs to include training on operation, troubleshooting, and annual competency evaluation.*	Y	
114.00	Does the pharmacy use relief personnel from outside agencies to perform sterile compounding? How are training and certifications verified? *View documentation.*	N	
115.00	Are personnel prohibited from entering the clean room or ante room if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection? *Include observations in the comments.*	Y	

116.00	Are personnel required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas? *Include observations in the comments.*	Y	
117.00	Are personnel required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc.? *Include observations in the comments.*	Y	
118.00	Are personnel prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed? *Include observations in the comments.*	Y	
119.00	Is garbing performed from the dirtiest to the cleanest starting with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe)?	Y	
120.00	Does garbing then progress to head and facial hair covers and masks? *Eye shields are optional unless using cleaning agents or preparing hazardous drugs.*	Y	
121.00	Is hand cleaning performed in the ante-room and does it include removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds? Are hands and arms then dried with a non-linting disposable towel or a hand dryer? *Scrub brushes are NOT recommended as they cause skin irritation and damage.*	Y	
122.00	Is the gown nonshedding (and preferably disposable) with sleeves that fit snugly around the wrists (some prefer to cut a small hole for the thumb to keep the sleeves from riding up) and enclosed at the neck?	Y	
123.00	Is all bare skin covered on the arms and the legs (no bare ankles, wrists, etc.)?	Y	
124.00	Prior to donning sterile gloves, is a waterless alcohol based surgical hand scrub with persistent activity used and are hands allowed to dry? *Note: Purell Hand Sanitizer is NOT appropriate. Must have residual activity.*	Y	
125.00	Upon leaving the sterile product compounding area, are gowns taken off and disposed of?	Y	
126.00	If gowns are not disposed of, are they left in the ante-room and not reused for longer than one shift?	NA	

127.00	Do pharmacists or other personnel enter the ante-room and cross the line of demarcation without donning shoe covers or dedicated shoes? *Do personnel traverse back and forth across the line of demarcation without doffing and donning new shoe covers or dedicated shoes?*				N	
128.00	Do pharmacists or other personnel enter the clean room without fully washing and garbing (wearing just a mask to check technician's work, for example)?				N	
129.00	Is there documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests? *Personnel must pass the tests upon initial validation before being allowed to compound. Action required if the tests yield any garbing deficiencies, or if the sampling results are >0 colony-forming units (CFU)/plate on the three initial validations.*				Y	
130.00	Is there documentation that compounding personnel have passed an annual (every six months for those performing high risk compounding) observed gowning procedure and gloved fingertip sampling test? *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU/plate upon revalidation.*				N	Random testing
131.00	Is there documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that compound low or medium risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days.*				Y	
132.00	Is there documentation that a media fill test procedure is performed for each compounding employee at least semi-annually for individuals that compound high risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days.*				N	Annual at present
133.00	Do the media-fill testing procedures include media selection, fill volume, incubation time and temperature, inspection of filled units, documentation, interpretation of results, and action levels with the corrective actions required?				Y	
		Substantially Compliant	**X**	**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes: Somewhat Compliant					

	Environmental Monitoring *If any part of a question is no, answer the whole question "no" and explain the observation.*	**Y/N/?/NA**	**Note**
134.00	Sterile Compounding: Have all cleanrooms, laminar airflow workbenches, BSCs, CAIs, CACIs, and barrier isolators been certified?	Y	Due June 2015
135.00	Does the pharmacy have an ISO Class 5 shielded laminar workflow area built in to the room (not a hood) and is it certified?	N	
136.00	Is certification performed at least every six months and whenever a device or room is moved or major work is done to the space?	Y	
137.00	Are certification reports available? *Note the date of the last certification.* *Obtain copies the certification reports and use them to answer the following questions. Note any findings that are "fail" and any findings outside of guidelines that require action yet are indicated as "pass". Indicate what action was taken as a result.*	Y	12/29/14; Monitronics of Glendale CA
138.00	Is the PIC familiar with what testing is required and interpretation of results, have action levels have been identified, and are these further customized based on trended data of performance?	Y	
139.00	Is certification performed by a qualified certifier? (USP states "qualified individual" with no detail). Note the name of certifier, company, and contact information, and if the certifier is CETA National Board of Testing (CNBT) accredited.	Y	Jake Bell, Technician did the certification- did not find his credentials in the report; spoke by phone with Greg Page, VP (microbiologist) and he described the training and background of Mr. Bell
140.00	Is certification to the Controlled Environment Testing Association (CETA) standard (USP: CETA CAG-003-2006-11 Certification Guide for Sterile Compounding Facilities) and is it noted on the report? *If not, indicate the standards used as indicated on the report. (Environmental monitoring to CETA CAG-009-00 Viable Environmental Sampling and Gowning Evaluation may also be listed)*	N	Per Mr. Page of Monitronics- use USP-797 (complete) and ISO 14644-3
141.00	Has the equipment used by the certifier been calibrated to the manufacturer's recommended intervals at a minimum, and is that equipment identified in the report by model, SN, last calibration date (or date when next calibration is due)? *The certification report will typically include the calibration certificates for the equipment used.*	Y	
142.00	Does each test on the certification report have a clear indication of pass or fail?	Y	
143.00	**Are the HEPA filtered air changes per hour (ACPH) measured for the compounding rooms?**	Y	

144.00	• Is the ISO Class 7 non-hazardous sterile compounding room certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources? *No more than half the total ACPH are allowed from air recirculated through PECs.*	Y	
145.00	• Is the ISO class 7 ante-room certified as having a minimum of 30 ACPH?	NA	
146.00	• Is the ISO class 8 ante-room certified as having a minimum of 20 ACPH? *No criteria set - a minimum of 20 ACPH is commonly referred to by the FDA and others.*	Y	
147.00	• Is the ISO class 7 hazardous sterile compounding room certified as having a minimum of 30 ACPH? *Typically all of the air will be from outside.*	NA	
148.00	• If a CACI is used, is the room in which it is located certified to maintain a minimum of 12 ACPH?	NA	
149.00	**Was air pattern analysis using smoke testing performed?** ***And is the smoke flow described in the report for the various tests such as turbulent, sluggish, smooth, etc.?***	Y	
150.00	• Was air pattern analysis conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions?	Y	
151.00	• Was air pattern analysis conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs?	Y	
152.00	• Was air pattern analysis conducted around particle generating equipment *while the equipment was in operation* to confirm air flow?	NA	

153.00	**Was differential pressure or displacement airflow measured? *Will be one or the other for each room.***	Y	
154.00	• Was the differential pressure measured to be at least 0.02 water column positive from the cleanroom to the ante-room and between the ante-room and all adjacent spaces with the doors closed?	Y	
155.00	• Was the displacement airflow (for low and medium-risk non-hazardous rooms only) measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the ante-room. *Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.*	NA	
156.00	**Were particle counts measured? *Include particles of 0.5mm and larger.***	Y	
157.00	• Were all particle counts taken during dynamic conditions? *Verify by asking personnel present at the time of certification.*	N	
158.00	• Are ISO Class 5 areas and hoods certified as having less than 3,520 particles per cubic meter of air?	Y	
159.00	• Are ISO Class 7 areas certified as having less than 352,000 particles per cubic meter of air?	Y	
160.00	• Are ISO Class 8 areas certified as having less than 3,520,000 particles per cubic meter of air?	Y	
161.00	**Was HEPA filter testing performed?**	Y	
162.00	• Were all room HEPA filters leak tested?	Y	
163.00	• If leaks were identified were they fixed?	NA	None found; new equipment
164.00	• Were all hood HEPA filters leak tested and air flow velocity measured?	Y	
165.00	• If leaks were identified were they fixed?	NA	
166.00	**Were viable air and surface sampling tests conducted?**	Y	
167.00	• Is appropriate growth media used that supports both bacterial and fungal growth? *List media used in note.*	Y	
168.00	• Was viable air sampling by active impaction using a volumetric air sampling device? *NOTE: Passive air sampling is not compliant with USP Chapter <797>.*	Y	
169.00	• Was each air sample taken in the ISO Class 5 areas or hoods at least 1000 liters in volume *(not 500 liters for a bacterial plate and 500 liters for fungal/mold plate)? Note: recommendation is 1000 liters. Minimum is 400 liters.*	Y	1000
170.00	• Was each air sample taken in the ISO Class 7 or 8 areas at least 400 liters in volume?	Y	500

171.00	• Was viable surface sampling performed on all direct compounding areas (inside of ISO 5 rooms or hoods), in each room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc., performed?	Y	
172.00	• Did any of the viable samples exceed the USP recommended microbial action levels (or internal action levels if more restrictive)? Classification / Air Sample / Surface Sample ISO Class 5: >1 CFU/m3 / >3 CFU/plate ISO Class 7: >10 CFU/m3 / >5 CFU/plate ISO Class 8: >100 CFU/m3 / >100 CFU/plate *Note: CFUs are TOTAL of bacterial plus fungal/mold plates.* *Note: If less than 1000 liters (= one cubic meter) is used for the air sample, the number of CFUs found must be multiplied by the appropriate factor to equal one cubic meter of air.*	N	
173.00	• Were all CFUs detected analyzed to determine the organism down to the genus? *All CFUs detected must be identified even if the number of CFUs does not exceed an action level.*	N	Human source bacteria recovered per Mr. Bell
174.00	• Were any mold, yeast, coagulase positive staphylococcus, or gram negative rods detected? *If yes, immediate remediation and investigation into the cause must be conducted.*	N	
175.00	• Did the testing report indicate that it included growth promotion testing and sterility quality control testing of the media plates? *Positive and negative control tests important to validate results of viable testing.*	Y	
176.00	• Did the testing results report include media lot numbers and expiration dates and a signature of the laboratory analyst and/or reviewer?	Y	

		Substantially Compliant	**X**	**Somewhat Compliant**		**Substantially Non-Compliant**

Inspector Notes: Somewhat Compliant; several calls were placed to the certification company regarding the report and eventually spoke with a VP of the company; exact credentials of the certifier were not obtained and more detail about the standard used for the report would be helpful.

	Compounding equipment *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
177.00	Sterile Compounding: Appropriate equipment available and in good working order including appropriate equipment for handling hazardous materials. *View maintenance and calibration logs.*	Y	
178.00	Are scales, balances, and other equipment used for measuring or weighing calibrated at least annually? *Indicate by whom.*	Y	
179.00	Are any Automated Compounding Devices (ACDs) used? *Such as those used to compound parenteral nutrition and repeater pumps.*	N	
180.00	Are there written policies for the use, daily calibration and maintenance g of the ACD?	NA	
181.00	Is there documentation of the ACD tubing being changed every 24 hours?	NA	
182.00	Is the ACD used when performing media fill testing?	NA	
183.00	Does the pharmacy have a lyophilizer? *If so, note the volume or percent of products per week produced using the lyophilizer and if the lyophilizer is part of the viable air and surface sampling, media fill testing procedures, and cleaning schedules and procedures.*	N	

	X	**Substantially Compliant**		**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes: Substantially Compliant					

	Compounding Procedures *If any part of a question is no, enter "N" and explain the observation.*	Y/N/?/NA	Note
184.00	Are all procedures performed in a manner designed to minimize the risk of touch contamination and are gloves and critical sites sanitized with adequate frequency and with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA) spray and a nonlinting wipe?	Y	
185.00	Are objects that shed particles prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads)?	Y	
186.00	Are essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) wiped down with sterile 70% IPA before bring brought into the buffer or clean area?	Y	

187.00	Are supplies required for the scheduled operations of the shift prepared and decontaminated by wiping or spraying the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area (preferably) on one or more movable carts?	Y	
188.00	Are compounding employees using appropriate aseptic technique? Observe from outside. *May require inspector to garb and enter clean room. Inspector to record observations after exit from the clean room (may not bring in objects, pens, paper, etc.). Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA), etc.*	NA	No sterile compounding was taking place during the inspection; volume is very low and sterile compounding does not take place every day.
189.00	Are supplies required for back-up or general support of operations stored on the designated shelving in the buffer or clean area? *Look for excessive accumulation as all products will have to be re-cleaned upon monthly cleaning.*	N	Do not keep back-up supplies in the clean room
190.00	Do compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use?	Y	
191.00	Are all rubber stoppers of vials and bottles and the neck of ampules sanitized every time with sterile 70% IPA (and a wait of at least 10 seconds to dry) prior to the introduction of a needle or spike for the removal of product?	Y	
192.00	After the preparation of every admixture, are the contents of the container-thoroughly mixed and then inspected for the presence of particulate matter, evidence of incompatibility, or other issues?	Y	
193.00	Are opened or needle punctured single-dose containers (bags, bottles, syringes, or vials) that are opened or punctured in worse than ISO Class 5 air used within one (1) hour and the remaining contents discarded? *How are they marked?*	Y	
194.00	Are single-dose vials exposed to ISO Class 5 or cleaner air used within six (6) hours of the initial puncture and any remaining contents discarded? *How are they marked?*	Y	
195.00	Are the remaining contents of opened single-dose ampules discarded immediately? *May not be stored for any time period.*	NA	Don’t use ampules
196.00	Are multiple-dose vials that are formulated for removal of portions on multiple occasions (usually containing preservatives) assigned a BUD of 28 days or the manufacturer's specific BUD (whichever is less) after the initial entry or puncture?	NA	Don’t use these

197.00	Before being dispensed (and/or administered), are the clarity of solutions visually confirmed, the identity and amounts of ingredients, the procedures to prepare and sterilize CSPs, and the specific release criteria are reviewed to assure their accuracy and completeness?	Y	
197.90	Is the compounding record complete? *1. Official or assigned name, strength and dosage of the preparation* *2. Names, lot numbers and expiration dates of all components* *3. Total quantity or number of units compounded* *4. Person compounding the preparation* *5. Person performing the quality control procedures* *6. Person who approved the preparation* *7. Date of compounding* *8. Assigned internal identification number or prescription number* *9. Assigned BUD and reference if extended beyond USP guidelines* *10. Duplicate label* *11. Sterilization method (if applicable)* *12. Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if appropriate.*	Y	
198.00	Are procedure for in-process checks followed? *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product and documentation of the compounding accuracy is by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.*	Y	
199.00	Do labels on BATCH preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials?	Y	
200.00	Do labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include identifiers for the persons preparing and performing the final verification, stability or BUD, flow rate (if applicable), and appropriate packaging and labeling of hazardous materials?	Y	

201.00	Inspect several different finished products and look for any particulates. Do any of the finished products inspected show any evidence of particulates? *If so, list the products including lot and expiration date and obtain photos (if possible).* **REQUEST THE PRODUCT BE QUARANTINED AND NOTIFY NABP IMMEDIATELY.**	NA	No sterile compounding being done today- unable to examine any finished products ready for dispensing
202.00	Sterile Compounding: Are BUDs greater than 24 hours documented with justification based on USP guidelines, testing or literature. *Verify documentation.*	Y	USP-797, PCCA documentation, send testing to Eagle Analytical for testing before extending BUD
203.00	Are BUDs assigned that are longer than the USP Chapter 797 guidelines? **Low Risk** 48 hours room temp, 14 days refrigerated, 45 days frozen **Medium Risk** 30 hours room temp, 9 days refrigerated, 45 days frozen **High Risk** 24 hours room temp, 3 days refrigerated, 45 days frozen	Y	USP-797, PCCA documentation, send testing to Eagle Analytical for testing before extending BUD
204.00	Is there a process for determining and assigning a BUD that addresses single-dose containers, multiple-dose containers, and proprietary bag ad vial systems? *Multiple dose containers 28 days after initial opening or entry, six hours for single dose containers kept in ISO Class 5 air, and one hour for worse than ISO Class 5 air, 0 for opened ampules (not allowed) or other if by documentation from manufacturer.*	Y	USP-797, PCCA documentation, send testing to Eagle Analytical for testing before extending BUD
205.00	Are appropriate sterilization methods used and documented? *Ensure P&Ps in place that address determining the appropriate type of sterilization method, equipment to be used, documentation to be kept and testing to be performed.*	Y	Filters only
206.00	Does the pharmacy use non-sterile empty vials and vial stoppers or closures and terminally sterilize them with on on-site autoclave?	N	
207.00	**Filter sterilization:** Is there documentation that: 1. The 0.2 micron sterile microporous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP 2. That filtering is completed rapidly without filter replacement 3. That confirmation of filter integrity (bubble testing) is performed for each filter used with each batch sterilized by filtration? *View documentation on batch records of items sterilized by filtration to confirm.*	Y	

208.00	**Steam sterilization:** Is there documentation that: 1. The autoclave has been validated for the exposure time and mass of the items to be sterilized 2. Ensures live steam contacts all ingredients and surfaces to be sterilized 3. Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization 4. Heated filtered air is evenly distributed throughout the chamber with a blower 5. That the CSP will not be adversely affected by the steam and heat 6. The description of steam sterilization includes conditions and duration for specific CSPs				NA	
209.00	**Dry heat sterilization:** Is there documentation that: 1. Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture 2. Sufficient space is left between materials to allow for air circulation 3. The description of dry heat sterilization includes conditions and duration for specific CSPs 4. That the effectiveness of steam sterilization is verified each time using appropriate biological indicators 5. The oven is equipped with a system for controlling temperature and exposure period?				NA	
210.00	**Depyrogenation by dry heat:** Is there documentation that: 1. Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes 2. The description of the cycle and duration for specific load items 3. The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs) 4. Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a three log reduction in endotoxins				NA	
		Substantially Compliant	**X**	**Somewhat Compliant**		**Substantially Non-Compliant**
	Inspector Notes: Somewhat Compliant; no sterile compounding taking place on the day of inspection so observation not possible					

	Finished Preparation Release Checks and Tests *If any part of a question is no, answer the whole question "no" and explain the observation.*	Y/N/?/NA	Note
211.00	Sterile Compounding: Is there a process in place to sample prepared products for potency and/or contamination and recall actions to take if discrepancies are found? For suspensions, is the particle size measured?	Y	No suspensions
212.00	Are products checked for particulates or other foreign matter against both a light and a dark colored background?	Y	
213.00	Are there checks for container and closure integrity?	Y	
214.00	Is compounding accuracy documented by verification of steps?	Y	
215.00	Is verification of ingredient identity and quantity verified? *Is there a reconciliation of components?*	Y	Yes
216.00	Are labels verified as being correct and is a copy of the label included in the record? *Complies to regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route of administration.*	Y	Don't stick a label on the record- In PK Compounder all the information from the label is on the record
217.00	Sterility testing: Is sterility testing performed for each batch of CSPs that have extended BUDS, are prepared in batches of more than 25 identical containers, or are exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized?	Y	
218.00	Are the appropriate quantities of units for each batch tested? For parenterals, if the number if the number of units in the batch: 1. Less than 100, test 10% or four units, whichever is greater 2. 100 up to 500, test 10 units 3. More than 500, test 2% or 20 units, whichever is less For large volume parenterals: 2% or 10 containers, whichever is less. For non-parenterals (eye drops, inhalation, etc.): 1. Less than 200 containers, test 5% or 2 containers, whichever is greater 2. 200 or more containers, test 10 containers 3. If the product is packaged in unit doses, use the parenteral testing above. *View records to confirm appropriate number tested. View records of products failing tests including investigation and action taken.*	Y	

219.00	If items are dispensed or distributed prior to sterility testing completion, is there a written procedure requiring daily observation of the incubated media and requirement of an immediate recall if there is any evidence of microbial growth? *In addition, is the patient and the physician of the patient to whom a potentially contaminated CSP was administered notified of the potential risk?*				Y	If early released, this process is used (rare)	
220.00	Are all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials), or in multiple dose vials for administration to multiple patients, or exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized tested to ensure that they do not contain excessive bacterial endotoxins? *View results of testing and indicate number or percentage of units tested.*				Y	Use a Charles River Endotoxin machine (Endotest Safe Record is printed out)	
221.00	Are products tested for purity and potency? *How are the products selected for testing?*				Y	Potency testing is random for quality assurance-technique of the compounder; Sterility for all batches	
222.00	View testing records. Have products that failed sterility, endotoxin, purity or potency testing been dispensed or distributed and not recalled? *How are 'inconclusive' results handled?*				N		
223.00	Does the pharmacy have its own lab to perform testing? If so, what testing is performed in house?				Y	Endotoxins in-house	
224.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*				Y	Eagle Analytical for sterility	
	X	**Substantially Compliant**		**Somewhat Compliant**			**Substantially Non-Compliant**
	Inspector Notes: Substantially Compliant						

The information and comments obtained in the supplement sections are based on USP Chapters <795> and <797>. An inspection against current Good Manufacturing Practices (cGMPs) was not conducted.

Iowa Board of Pharmacy
ATTN: Sue Mears, RPh-Compliance Officer
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May 6, 2015

Dear Ms. Mears,

We are in receipt of your email letter dated May 4, 2015, and are providing the answers to the questions that you have posed in regards to our recent NABP-VPP survey on April 8, 2015.

1. ***Item 68: "Are there alarms or alerts when excursions are detected in the compounding area? Is there an action plan when an excursion occurs?"*** *The answer given was "N".*
    - YES to both questions. Any and all deviations or readings that are outside of the pre-programmed range will trigger an alert via a NIST-traceable calibrated system that measures ambient temperature and barometric pressure. We are immediately notified via telephone, email, and/or text message that a problem is present, and where/what the problem is; no less than two personnel are notified at the same time. These readings are transmitted and recorded into the Sterile Compounding Pharmacist's work station computer via Rx Unlimited's secure internal network, and readable via Wi-Fi transmission to a secured Web site. For example, in the case of a door that is not shut or has opened, the barometric pressure monitor drops to 'zero' after a specified time (approximately 5 minutes, to account for cleaning personnel that may be in transition between rooms while cleaning and sterilizing, or compounding personnel that may be transferring/transporting preparations), and we are alerted if the time limit has been exceeded.
        - To allay concerns or fears that unauthorized personnel enter and exit the Clean Room facility at random, all personnel have been instructed in the procedures required to enter any part of the Clean Room facility; no more than two Sterile compounding personnel are allowed in any part of the Clean Room facility, and one of them is the Sterile Compounding Pharmacist. No drugs or ingredients, with the exception of non-sterile refrigerated items, are stored within the Clean Room facility at any time, and all ingredients to be used in compound preparation are brought in under the supervision of the Sterile Compounding Pharmacist at all times.

2. ***Item 79: "Is the humidity monitored daily and in the range of 35%-60% in the sterile compounding area?"*** *The answer given was "N", and a note indicated that the humidity at the time of inspection was 27%.*
   - YES. The NABP surveyor requested and received the actual relative humidity (RH) monitoring unit in hand. He then noted the reading displayed on the unit itself, which read 27% RH. The unit, having been displaced from its environment, began to adjust itself according to the change of environment before finally pausing itself. Upon hearing this concern from the surveyor, the Sterile Compounding Pharmacist calibrated and installed a brand-new unit. After approximately one hour, at 4:45 pm, she retrieved the log results from the new unit, which showed that the RH was 37%, which is within the specified acceptable range (please see attached copy of RH log results). As an aside, in researching USP <797>, we have not found in any chapter or section where the specifications/allowable ranges defining humidity or even temperature is listed; we take into consideration the comfort of the personnel, as well as if there are any specific humidity requirements for a compound. On average, the humidity levels in any of the rooms hover in the 35%-45% range.

3. ***Item 103: "Does the cleaning of the ISO 5 PEC include cleaning with sterile water and sanitizing with sterile 70% IPA using a non-linting wipe?"*** *The answer given was "N".*
   - All ISO-Class 5 equipment/PEC used in the clean room (an LAFW and a BSC) are sterilized before use, between preparations, and after use, as well as regularly cleaned and sterilized. No water is used except as described above during a "hard" cleaning, as the metallic construction and electronic instrumentation contained within the units may induce corrosion; therefore, we use ***Decon-Ahol sterile 70% IPA*** purchased from Cleanroom Connection for use only within the Clean Room environment, and is also used in the ISO-Class 8 rooms where applicable. Decon-Ahol 70% IPA is both double-bagged and gamma-irradiated to guarantee sterility.
   - In actuality, cleaning and sterilizing of the LAFW and the BSC is carried out as described above using both Clean Room-only mops, mop covers, tacky rollers, and by using ***TruCare Biomedix 9" x 9" Sterile Lint-Free Wipes (45%/55% Poly/Cellulose composition)***, also ordered from Cleanroom Connection, and also double-bagged and gamma-irradiated for sterility.
   - All non-shedding wipes, cloths, and garb are considered one-time use only, and are discarded after use. One exception may possibly be the mop head covers that we are considering for purchase. These covers are able to be sterilized via autoclave and reused multiple times, thereby saving both the expense and the time necessary to procure one-time use covers. This is still being discussed at this time.
   - We clean and sterilize all ISO-Class 5 equipment/PEC in accordance with United States Pharmacopaeia (USP) <797>, which states the minimum frequency: "*At the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compound activities are occurring, after spills, and when surface contamination is known or suspected".* Additionally, Clean Room testing and certification exceeds USP <797> standards, with ISO 14644-1 and 14644-2 standards being the minimum.

4. ***Item 105: "Does daily cleaning include the floors starting from the clean room and working outwards?"*** *The answer given was "N", and inspector note indicates twice weekly.*
   - As outlined on page 56, Table 3 of USP <797> (02/2014), the cleaning of floors on a daily basis is applicable to rooms designated as ISO-Class 5; ISO-Class 5 PEC's/equipment cleaning is classified under a different regimen. Rx Unlimited's Preparation and Ante Rooms are both rated at ISO-8, which allows a maximum 100,000 particles of 0.5 µm and larger per cubic meter, while the Clean Room itself is rated ISO-Class 7, which allows a maximum 10,000 particles of 0.5 µm and larger per cubic meter; the LAFW and BSC in the Clean Room are both rated at ISO-Class 5 which allows a maximum 100 particles of 0.5 µm and larger per cubic meter, as

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required by USP <797> guidelines. All rooms and equipment do not deviate from these requirements, idicated by the certification documentation (please see attached). The cleaning of a Clean Room is also determined by its frequency of use as well. Higher-rated ISO-class rooms (ISO-Class 3-5), those rooms used more frequently, and high-risk only compounding would necessitate the more stringent level and frequency of cleaning and sanitization, as dictated by USP <797>; we do not normally utilize the Clean Room on a daily, nor even on a consistent, weekly basis. In some cases, the twice-weekly cleaning exceeds the actual use or time spent in either of the ISO-Class 8 rooms or the ISO-Class 7 room. As compounded preparations are custom-made for each patient on an as-prescribed basis, the actual use of the room is dictated solely by this. On average, we typically compound 90% non-sterile to 10% sterile; as such, the cleaning regimen we have established reflects this infrequency of actual Clean Room usage. The ceilings, walls, and floors are tacky roller'd and/or vacuumed, wiped down with sterile 70% IPA, and mopped with 70% IPA respectively, on every Tuesday and Thursday, in a specific pattern (please see attached for cleaning pattern illustration). This same pattern is used when performing a monthly (or as required) "hard" cleaning with a bleach-based disinfectant.

5. ***Item 130: "Is there documentation that compounding personnel have passed an annual (every six months for those performing high risk compounding) observed gowning procedure and gloved fingertip sampling test?"*** *The answer given was "N" and inspector note indicates random testing.*
   - At the time of inspection, we presented documentation indicating annual testing, but we were informed by the surveyor that it was recommended to test those personnel that performed high-risk sterile compounding biannually instead of annually. We test personnel on an annual basis, and were unaware that the annual testing was considered insufficient as it applies to high-risk compounding technicians. We immediately revised our SOP's to include the additional testing protocol; accordingly, the Sterile Compounding Pharmacist and the Pharmacist-in-charge felt that additional testing at the pharmacists' discretion, as well as unannounced random testing would further enhance both the highest quality assurance and quality control levels that we constantly strive to achieve. This procedure has been immediately implemented as of April 8 2015 (Please SOP attachment).

6. ***Item 132: Is there documentation that a media fill test procedure is performed for each compounding employee at least semi-annually for individuals that compound high-risk-level products?"*** *The answer given was "N", and the inspector note indicates annual testing.*
   - The NABP inspector advised us that it was recommended to perform this testing and documentation on at least a biannual basis, and not on an annual basis as we had been doing up to this point. We immediately informed both compounding technicians of this change in testing procedures, and our Compliance Manager immediately made the appropriate changes in our SOP's. This procedure has been immediately implemented as of April 8 2015 (Please see SOP attachment).

7. ***Item 173: Were all CFU's detected analyzed to determine the organism down to the genus?"*** *The answer given was "N" and inspector note says "Human source bacteria recovered per Mr. Bell"*
   - During the last inspection/certification by Monitronics on December 29 2014, technician Bell performed all testing without requiring any assistance from Rx Unlimited personnel. Insofar as observation, technician Bell explained in detail what tests he performs to determine whether a Clean Room Facility passes or fails inspection; technician Bell was observed by our Compliance Manager performing those tests that correlated with the detection of fungal, bacterial and sporicidal organisms, and whether or not those detections

exceeded the acceptable levels that ISO-Class 8 and ISO-Class 7 rooms are rated for. Since all rooms were certified as "passing" by Monitronics, and passing to ISO-14644-1 and ISO 14644-2 specifications, we were not offered, nor were we inclined to press, Monitronics for this information. As explained to the Compliance Manager and Pharmacist(s) later, the vast majority of potential contaminants that enter the Clean Room facility are from the personnel themselves, in the form of hair and skin cells, and possibly any fibers or material from the garb. Personnel who are sick, or exhibit signs and symptoms of a cold or flu, are prohibited from compounding entirely, and are sent home until the cold or flu has run its course completely. Positive pressure rooms such as ours, in conjunction with the 12 air changes per hour exchange rate and HEPA filtration, minimize particulate matter from settling on surfaces at all times. Finally, spectral or **c**hromatographic analysis of that which was detected is prohibitively expensive to conduct in all but the most concerning of cases; however, that does not mean that we would not request the most detailed analysis IF we were notified that there was a cause for concern after the initial detection and analysis. We of course want to know such things, and if there is the potential for any type of harm; nothing analyzed or detected at the time of certification exceeded the maximum levels as outlined in ISO-14644-1 or ISO-14644-2, nor was it classified as potentially dangerous or harmful, and especially not a potential hazard to public safety per technician Bell in his debrief with the Compliance Manager post-inspection/certification (Please see attached certification reports from Monitronics).

We trust that the answers provided above, as well as the documentation attached herein referencing the inquiries sent are to the Board's satisfaction. We conscientiously strive to meet or exceed compliance standards as outlined in USP <795>, USP <797>, ISO 14644-1, ISO 14644-2, and the Pharmacy Laws pertaining to California-based pharmacies.

Thank you in advance for your time regarding this matter.

Sincerely,

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ATTORNEY-CLIENT MEMO — CONFIDENTIAL

TO: The Iowa Board of Pharmacy

FROM: Meghan Gavin

RE: IPRN and the Takeaway Program

DATE: May 22, 2015

The Iowa Board of Pharmacy currently contracts with the Iowa Pharmaceutical Association to implement the Impaired Pharmacist Recovery Network and the Takeaway Program. Both of these contracts are set to expire on June 30, 2015. I was asked to prepare legal advice on whether the Board has the authority not to renew those contracts and run both programs in house.

Impaired Pharmacist Recovery Network

Iowa Code section 155A.39 establishes a program to aid impaired pharmacists, pharmacist-interns, or pharmacist technicians. The Code section allows the Board the option of running the program in-house or contracting with a "professional pharmaceutical association or society" to run the program. *See* Iowa Code § 155A.39 ("The Board may contract. . . .").

The question then becomes should the Board renew its contract with IPA? Our advice is not to renew the contract for the following reasons.

First, all other impaired recovery programs are run by the respective boards. For example, the Board of Medicine runs the Iowa Physician Health Program (IPHP) and the Bureau of Professional License runs Impaired Practitioner Review Committee (IPRC). The Board of Nursing is currently establishing its own program. None of these boards contracts with a private entity, let alone a trade association, to run the program.

Second, the Board already has the necessary administrative rules to run the program successfully.

Third, this is a function that the Board can and should do itself. The public and the State clearly have an interest in aiding impaired professionals. Delegating such an important function to a private organization does not adequately protect the public. Additionally, given the United States Supreme Court's recent case, *Federal Trade Commission v. North Carolina Dental Board*, licensing boards should be mindful of their connection with trade associations. Delegating a state function to the IPA creates at least the impression that the Board is impermissibly intertwined with IPA.

Most importantly, the Board can run the program more effectively and cost efficiently. Currently, all Board complaints concerning impaired practitioners are treated as discipline. This

is unique to the Board of Pharmacy. If the substance abuse concerns have not affected the licensee's practice or there was no harm to the public, other boards, including the Board of Medicine, refer the complaint/case to IPHP. There are several benefits of doing this. The primary benefit is that IPHP (like IPRN) is confidential. Impaired practitioners are given an opportunity at recovery before their license is publically censored. The public is not harmed by the referral because IPHP, IPRC, and the alike chemically screen participants. Moreover, if a licensee does not cooperate with the program (make daily calls, attend AA/NA meetings, etc.) or have a positive UA, he/she is referred back to the board for discipline. It seems unfair for pharmacists not to have the second chance offered to members of the other health professions in Iowa.

Currently the Board pays IPA approximately $115,000 to implement IPRN. We believe the Board could run this program more cost efficiently in house. We estimate it would cost the Board approximately one half FTE to get more services and more oversight than currently offered by IPRN.

It's important to note that IPA could continue to run an impaired program. Several trade associations for other professions have such volunteer programs. The difference is the Board would not fund the program.

Takeaway Program

Iowa Code section 155A.43 establishes a program to collect and dispose of unused pharmaceuticals. As with IPRN, the Code allows but does not require the Board to contract with "the Iowa pharmacy association" to carry out this program. *See* Iowa Code § 155A.43 ("The board of pharmacy may cooperate. . . .").

Currently the Board pays IPA $125,000 a year to implement the Takeaway Program. This is the maximum permitted by law. *Id.* In recent years, the Board has expressed its growing frustration that this program is 100% Board funded. Despite repeated Board warnings, the IPA has not secured either grant funding for the program or corporate sponsors.

Under these circumstances, and the need to separate ourselves from the IPA, it is our advice not to renew IPA's contract for the Takeaway Program on July 1, 2015. Like IPRN, the program can be run in house. Since the Board is and has always been the only sponsor of this program, it is unclear why the Board delegates this responsibility to a private entity. Keeping the program in house would further allow the Board to coordinate with other state agencies (Department of Public Safety, Board of Medicine, etc.) to collect and dispose of unused and expired pharmaceuticals.