Abbreviated Sample Summary of OBP Prescriber Compounding Inspection Guide Elements for Medical Practices				
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Topic			**Noted OBP Inspector Reviews**	**Comments**
Applicability				
	Are you a terminal drug distributor licensed by the OBP?		If Yes – the inspection guide applies, licensees are subject to an onsite inspection without notice If No – the inspection guide does not apply.	There are exemptions (4729:7-3-02) - have you determined if they apply to you?
	Do you quality for exemptions from OBP inspections and regulations? No, if you handle any drugs classified as hazardous			
Responsible Person				

	There shall be a designated responsible person for the license, and a responsible person(s) assigned to the direct responsibilities for developing and implementing appropriate proceduresfor compliant sterile and non-sterile hazardous and non-hazardous compounding, overseeing facility compliance, ensuring training and compentency of staff, maintaining appropriate and compliant records, proper maintenance, cleanliness and use of all equipment, and ensuring aseptic technique for the preparation of all sterile compounded drugs.	Inspectors will review for the designation of responsible persons and for their compliant exection of their responsibilities.	There are software that can speed the process of policies and procedures, SOPS, and the other tracking and monitoring indicated in these responsibilities. We can help find the right one for you.
Compounding			
	Do you "compound"? "Compounding" means the preparation, mixing, assembling, packaging, and labeling of one or more drugs. Compounding includes the combining, admixing, mixing, diluting, reconstituting, or otherwise altering of a drug or bulk drug substance.	Inspectors will review all licensed prescribers considered to be compounding dangerous drugs for compliance. There are exemptions to compounding rules uner certain circumsantces for mixing of sterile or nonsterile NON-HAZARDOUS drugs	There may be potential to pushback on the definition of compounding vs preparation, dilution and reconstitution in accordance with direct manufacturer labeling based upon other state activity,given the direction in which USP was going with new rules for <797>.
	Do you follow and label beyond use dates for dangerous drugs under manufacturer recommendations, or 6 hours if no published manufacturer recommendations? Do you dilute or draw dangerous drugs into a syringe not more than 6 hours prior to administration?	Inspectors will review all licensed prescribers considered to be compounding dangerous drugs for compliance.	You may think that you are exempt from the inspections due to the wording of "dangerous drugs" in 4729:7-03-02, but 4729:7-03-02 presents a compliance standard for all hazardous drugs (a subset of "dangerous drugs" as defined by the OBP) which is likely to be applied

	Prescribers must inspect and approve the compounding processes, policies and procedures.	Inspectors will look for such provider approval. Page 30 of the PCIGuide.	This was highlighted on Page 30 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
Immediate Use for non-hazardous drugs			
	Do you store and mix sterile non-hazardous drugs in a contained room separate from hazardous drug mixing and storage?	Inspectors will look for aseptic technique, separation of storage and mixing from hazardous drugs, labeling, and careful attention to beyond use dates, a dedicated contained clean medical drug preparation area, and no compounding for anticipated needs.	Sterile, non-hazardous drugs may be mixed outside of the full hazardous mixing storage and preparation area requirements, but in a separate contained room, subject to tight parameters, and aseptic technique. This may mean a facility needing to designate a new space that is compliant.
Aseptic technique			

	The drug handling regulations refer to use of aseptic technique when mixing dangerous drugs. Do you have a formal process and policy for executing and following aseptic technique? Prescriber must maintain sufficient supplies, reference materials and environment for sterile products and aseptic technique where required. Do you have supplies and environment for suitable aseptic preparation of sterile products?	Inspectors will review for, at a minimum: Using barriers to prevent the transfer of microorganisms from health care personnel and the environment to the patient. This may include gloves, gowns, masks, etc. Sterile instruments (syringes, equipment, devices) used for drug preparation. Antiseptic skin preparation for patient administration. Environmental controls: Keeping doors closed, minimizing traffic, limiting unnecessary people in compounding areas. Only sterile to sterile contact is allowed. Non-sterile to sterile contact must be avoided.	While not defined in the regulation definitions page, thse details are found on Page 14 of the PCIGuide. Formal, written documenation of a facility process, training, monitoring, and surveillance of aseptic technique will be important for compliance. Proper aspectic technique is noted as including hand-hygiene (which is not defined in the supporting regulations, but is defined on Page 16 of the PCIGuide.
Labeling	There are specific labeling requiremnts for each drug	Inspectors will be looking for detailed compliancefor labeling requirements that vary with the time between mixing and administration	Medical practices labeling systems may not be currently compliant with OBP labeling requirements and should review current systems for compliance.
Needles	needles used for compounding will NEVER be the needle used for patient adminstration.	Inspectors will be looking for policy and execution that needles used for compounding will NEVER be the needle used for patient adminstration.	This was highlighted on Page 18 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?

	Hazardous drugs shall be administered, when dosage forms allow, using closed-system transfer devices or other protective techniques Page 42 of the PCIGuide	Inspectors will be looking for policy and execution that Hazardous drugs shall be administered, when dosage forms allow, using closed-system transfer devices or other protective techniques Page 42 of the PCIGuide.	This was highlighted on Page 42 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
	Syringes and needles are NOT crushed or clipped prior to disposal in appropriate hazardous waste containers. Page 50 of the PCIGuide.	Inspectors will be looking for policy and execution that Syringes and needles are NOT crushed or clipped prior to disposal in appropriate hazardous waste containers.	This was highlighted on Page 50 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
Medical validation/Poitive Identification			
	Appropriate medical validation of compounding must be done whether compounding is performed by nurses, but especially when compounding is done by other staff than nurses. Positive identification must be required and documented as part of the validation process.	Inspectors will be reviewing for medical validation and positive identification of validators.	The documentation of medical validation, and positive idenfication of validators in the drug recordkeeping will be a hot button for inspectors.
Staff Training and Competency			

	Staff must be fully trained on their job functions before independently handling hazardous drugs. All training and competency assessments must be documented with staff confirmation in writing that they understand the risks of handling hazardous drugs. Recommendations are required to be made to staff for annual medical examinations. Staff competency must be reassessed every 12 months or when a new hazardous drug or new equipment is used, or a new or significant change in process or SOP occurs and documented.	Inspecdtors will review training records for compliance. Pages 43,44 and 45 of the PCIGuide.	This was highlighted on Pages 43,44 and 45 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
Policies and Procedures			
	Do you have a policy and procedures manual and standard operating procedures (SOPs) that includes quality assurance program (monitoring personnel qualifications, training and performance, product integrity, equipment, facilities, and guidelines regarding patient education)? Are they actively and readily integrated into the management, education, training and assessment of staff, facilities, and operations?	At every step of the compounding oversight, management and actual process, inspectors will be reviewing for the presence, accessibility, active maintenance, staff knowledge of and use of the policies and procedures and SOPs, and continuous monitoring and updating of the same.	A few good software systems exist that share templates for SOPs, to be adapted and individualized by practices. At least one can also track staff training and competency assessments, and monitoring, with training options. We can help you find one that is right for
	A licensed healthcare provider discusses with the patient or caregiver the drug dosage and form, route of administration, duration of therapy, special directions/precautions for administration, and stability and/or incompatibilities of the medication. Page 50 of the PCIGuide.	Inspectors will review training records for compliance.	This was highlighted on Page 50 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?

	A written quality assurance program must address initial personnel skills assessment and examination, as well as annual assessments. Assessments must include personal cleansing, proper PPE, aseptic technique, proper cleanroom conduct, cleanroom disinfecting policies and procedures Pages 50 and 51 of the pCIGuide.	Inspecdtors will review training records for compliance.	This was highlighted on Pages 50 and of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
	A written, documented quality assurance program must address verification of compounding processes, including: continued verification of compounding accuracy, continued verification of automated compounding devices, and review of end-product testing. Page 51 of the PCIGuide.	Inspecdtors will review training records for compliance.	This was highlighted on Page 51 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
	Written documented SOPs to ensure that transport of hazardous drugs within a healthcare settings or externally must use packing materials that maintain the physical integrity, stability and sterility of the drugs while protecting healthcare workers doing the transportation. Transported hazardous drugs must be labeled, stored and handled in accordance with applicable federal, state, and local regulations. Page 52 of the PCIGuide.	Inspectors will review for compliance.	This was highlighted on Page 52 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?

	Written, documented policies, training and procedures must reflect compliance with labeling requirements for hazardous drugs prepared and personally furnished by the prescriber. Pages 52 and 53 of the PCIGuide.	Inspectors will review for compliance.	This was highlighted on Pages 52 and 53 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
	Written and documented policies, training and procedures that ensure prescribers shall perform medication validation for any compounded drug prior to medication administration if the drug was compounded by anyone other than a nurse or the prescriber themselves (i.e. a pharmacy technician). Validation requirement for drugs prepared by a nurse without the final check of the prescriber shall be for two nurses to comply with the verification requirements. Positive identification of those person (s) performing medication verification must be documented in the compounding record. Pages 53 and 54 of the PCIGuide	Inspectors will review for compliance.	This was highlighted on Pages 53 and 54 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
Recordkeeping			
	Record keeping must be kept and documented for maintenance, access, completeness, and compliance – required to be on-site for 3 years unless otherwise documented and noted to the Board Pages 23, 24, 25, 26, and 27 of the PCIGuide	Inspectors will review for compliance.	This was highlighted on Page 23, 24 and 25 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?

Facilities	Separate equipment and contained rooms for hazardous and non-hazardous drugs, to include storage and preparation. The separate compounding rooms are expected to be in low traffic areas, with no unauthrozed staff entry. oAreas where hazardous drugs are unpacked, stored, and prepared shall be restricted to persons with authorized access, located away from break rooms and refreshment areas, and with prominent signage warning of a hazardous drug area. Page 45	Inspectors will review for compliance. The PCIGuide notes specifically that inspectors will review spaces for privacy, sealed activity and low traffic areas.	Hazardous drugs C-PEC and C-SEC shall **not** be used for non-hazardous drugs - requiring separate contained space for handling, mixing and storage. Non compounding personnel shall not enter the contained mixing areas for hazardous and non-hazardous drugs - consider mixed use areas and cleaning staff for non-compliance.
	Do you compound within a Containment Primary Engineering Control (C-PEC) that meets all of the requirements, including these requirements and more:	Inspectors will review for compliance, including calibration, inspection, and documented records. Environmental controls of compounding areas should include monitoring every 6 months, via viable air and surface sampling. Page 30 PCIGuide.	
	ISO class 5 or better, Class II BSC types A2, B1 or B2 are acceptable	Inspectors will review to ensure compliance.	Often referred to as a "hood" in medical practice, but must meet named specifications
	HEPA filter for exhaust from C-PEC	Inspectors will review to ensure compliance.	

		C-PEC shall be externally vented away from HVAC or points of entry to building (Extension to this requirement may be possible)	Inspectors will review for compliance. Page 35, PCIGuide. There is no mention of waiver options if facility changes cannot be made.	This requirement may prove a physical challenge for medical offices
		Separate C-PEC for sterile hazardous and non-sterile hazardous drug preparations. o If preparing hazardous drugs with a BUD of less than 12 hours, the PEC may be located in a C-SCA, but needs to be isolated from traffic and disturbances, large enough to hold PEC as well as storage, with sink and wash station availability. o Hazardous and non-hazardous drugs must be compounded and stored in separate designated areas, each being a C-SCA as long as BUD is below 12 hours, each with containment and isolation, and room for storage and compounding	Inspectors will review to ensure compliance.	This will require two separate rooms, large enough to support drug storage and preparation/mixing, plus needed supplies and surfaces for process.
		C-PEC for hazardous drugs shall be located in a containment secondary engineering control (C-SEC)	Inspectors will review to ensure compliance.	This will require two separate rooms, large enough to support drug storage and preparation/mixing, plus needed supplies and surfaces for process.
	A containment segregated compounding area (C-SCA) may be used for **non-sterile hazardous and sterile hazardous drugs with a beyond use date of twelve hours or less that meets all of the following:**		Inspectors will review to ensure compliance.	These would still need to be 2 isolated, contained areas

		Isolated from other areas and traffic and airflow disturbances	Inspectors will review to ensure compliance.	This requirement may prove a physical challenge for medical offices
		Of a size to hold the C-PEC and proper drug storage	Inspectors will review to ensure compliance.	This requirement may prove a physical challenge for medical offices
		A C-PEC for sterile and another for non-sterile compounding may be in one C-SCA at least 3 feet apart	Inspectors will review to ensure compliance.	This requirement may prove a physical challenge for medical offices
		Must contain a sink and emergency access to water for removal of substances from eyes and skin	Inspectors will review to ensure compliance.	This requirement may prove a physical challenge for medical offices
	A written documented quality assurance plan if the clean room and other primary engineering controls fail. **Page 52** of the PCIGuide.		Inspectors will review to ensure compliance.	This was highlighted on Page 52 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
Cleaning				

	There are specific approved cleaning agents for aseptic, hazardous and non-hazardous areas. Cleaning is specified as before each compound is mixed, not once per day on Page 19 of the PCIGuide. oCleaning is not to be done with sterile alcohol or bleach, only with a product that is a surfactant, cleaning and disinfecting shall be followed by wiping with a residue-free disinfecting agent, such as 70% (required level) sterile isopropyl alcohol and allowed to dry before compounding begins. – Pages 20 and 21 of the PCIGuide.	Inspectors will look for brands, ingredients, and what is used where. The PCIGuide lists specific parameters on Page 20, a likely hot button for inspection. Inspectors will review: is the compounding area and equipment clean and appropriate? Are cleaning processes performed between compounding? Is specialized equipment maintained and calibrated?	This was highlighted on Page 19, 20 and 21 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
	Environmental wipe sampling is not required, but a recommended best practice **If wipe sampling is done, deactivation, decontamination and cleaning is required. Page 38** of the PCIGuide	Inspectors will ensure that training and documentation reflect compliance.	This was highlighted on Page 38 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
	Areas and equipment where hazardous drugs are handled are routinely deactivated, decontaminated and cleaned. Reusable cleaning tools must be used only for hazardous drug areas, never other areas of the practice. Page 45 and 46	Inspectors will review documentation to validate cleaning has occurred at the minimum requirements, using the correct agents, for the correct dwell times.	Cleaning crews for the rest of the practice should 1) ideally not enter the contained mixing rooms, and 2) policies and practices of the prescriber facility should have completely uniqe cleaning tools and supplies for each contained area.

	Hazardous waste is properly disposed of in a compliant manner, and personnel involved in routine custodial waste removal and cleaning are documented and compliant in processes and training. Page 49 of the PCIGuide	Inspectors will ensure that training and documentation reflect compliance.	This was highlighted on Page 49 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
	Personnel cleaning facilities must wear appropriate PPE and have documented appropriate training for compliance in handling linens, feces or urine from patients who have received hazardous drugs within the last 48 hours. Page 50 of the PCIGuide	Inspectors will ensure that training and documentation reflect compliance.	This was highlighted on Page 50 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
	Documented environmental monitoring of all clean rooms and primary engineering devices at least every six months, with records maintained for at least three years and be readily retrievable. Page 51 of the PCIGuide.	Inspectors will review certification records for compliance.	This was highlighted on Page 51 of the PCIGuide, so it must be a hot button for the inspectors, perhaps an expected violation?
Personal Protective Equipment (PPE)			

	Specific requirements for PPE for hazardous and non hazardous drugs for gloves, gown, head, hair and shoe covers. Gowns cannot be worn in other areas, requiring degowning and regowning every time the C-SCA is entered or left. Pages 39 and 40 of the PCIGuide		Inspectors will review PPE policy and SOPs for compliance for wearing and disposal. Inspectors will review for handwashing before and after gloves used Pages 41 and 43 of the PCIGuide	If nurses are mixing drugs, how will the PPE separation process inside and outside the containment area work for your staff flow? Your supply costs? Will you need to change staffing models to a single person respondible for mixing for a period of time? What challenges or delays in compliance might the combination of separate space and PPE requirements cause for the timing of your compliance?
Waste and cleaning				
			Inspectors will review hazardous waste sealing, container cleaning and wiping, and transport away Page 41 and 42 of the PCIGuide	
		Appropriately individually fitted N95 respirators are required to be worn when there is a spill, or a risk of inhalation of hazardous drug particles. Page 42 and 43 of the PCIGuide	Inspectors will review training records to see if proper fit testing has been completed and that there is proper access to N95 respirators	

		Spills are contained and cleaned immediately by qualified trained personnel using appropriate PPE and that exposed staff is immediately evaluated by a healthcare professional. Page 47, 48 and 49 of the PCI Guide	Inspectors will review documentation to ensure cleaning and staff medical followup was done in a compliant manner with appropriately trained and documented personnel.	

Estimated Compliance Preparedness Score for the Group (the sum of all estimated preparedness rankings on a scale of 1 to 5). Score

44 at the least prepared and 220 for Fully prepared With 1 being Not al all Compliant Currently, and 5 Being Fully Comp

Links	**Practice Compliance Self Evaluation: Readiness on a scale of 1 to 5, with 1 not ready at all for compliance, and 5 being fully compliant currently**
4729:7-3-02 - Exemptions 12/16/2020, Terminal Distributor Requirements for Prescribers Possessing Compounded Drugs or Engaging in Drug Compounding (2/11/2017)	
4729:7-3-02 - Exemptions 12/16/2020	

4729:7-3-04 Immediate-Use, Sterile **also** Non-Hazardous Drugs Compounded by a Prescriber 12/16/2020 **also** 4729:7-3-05 Hazardous drugs compounded by a prescriber 12/16/2020 **also** 4729:7-3-06 Recordkeeping 12/16/2020 **also** PCIGuide – Prescriber Compounding Inspection Guide (Rev. 12/17/2020)	
4729:7-3-03 Non-Hazardous Drugs Compounded by a Prescriber 12/16/2020 also Terminal Distributor Requirements for Prescribers Possessing Compounded Drugs or Engaging in Drug Compounding (2/11/2017)	
4729:7-3-02 - Exemptions 12/16/2020 **also** 4729:7-3-05 Hazardous drugs compounded by a prescriber 12/16/2020	

PCIGuide – Prescriber Compounding Inspection Guide (Rev. 12/17/2020)	
4729:7-3-04 Immediate-Use, Sterile, Non-Hazardous Drugs Compounded by a Prescriber 12/16/2020	

PCIGuide – Prescriber Compounding Inspection Guide (Rev. 12/17/2020) **also** Terminal Distributor Requirements for Prescribers Possessing Compounded Drugs or Engaging in Drug Compounding (2/11/2017) **also** 4729:7-3-03 Non-Hazardous Drugs Compounded by a Prescriber 12/16/2020 **also** 4729:7-3-05 Hazardous drugs compounded by a prescriber 12/16/2020	
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