## **Central Fill Inspection Form**

| 40-43-83(F) & (D)         | Permit Displayed   |
|---------------------------|--|
| 40-43-84(B)               | Intern certificate displayed   |
| 40-43-86(A)(1)            | Sufficient space for safe & proper storage and compounding   |
| 40-43-86(A)(2)            | Area designated for patient counseling   |
| 40-43-86(A)(3)            | Current drug reference materials   |
| 40-43-86(A)(7)(8)         |  |
|                           | Equivalent Drug Product Evaluation Reference-internet access and pharmacists demonstrate ability to locate resources   |
| 40-43-86(A)(9)            | Patient oriented reference materials list patient references   |
| 40-43-86(A)(10)           | Storage areas temperature adequate-what is temperature in the facility   |
| 40-43-86(A)(11) & (16)(i) | Sink with hot and cold running water used in connection with compounding and dispensing  |
| 40-43-86(A)(12)           | Pharmacist responsible for security of pharmacy department   |
| 40-43-86(A)(13)           | Physical or electronic barrier to pharmacy testing of alarm; documentation of last alarm testing   |
| 40-43-86(A)(15)           | Equipment and supplies maintained according to manufacturer's specs-list equipment and supplies reviewed   |
| 40-43-86(A)(16)(a)(b)     | Prescription Area clean and orderly/Free of contamination  |
| 40-43-86(A)(16)(c)        | Outdated, damaged, unlabeled drugs removed from active stock   |
| 40-43-86(A)(16)(d)        | Refrigerator Temperature (36-46 degrees F) is refrigerator monitored? Freezer?   |
| 40-43-86(A)(16)(e)        | Stock and material for compounding labeled   |
| 40-43-86(A)(16)(h)        | Instruments, etc. clean and free from all foreign substances   |
| 40-43-86(B)(2)            | Directed by a pharmacist who is Pharmacist in Charge   |
| 40-43-86(B)               | Pharmacist in Charge is on site a sufficient amount of time to provide supervision and control of pharmacy (50%)   |
| 40-43-86(B)(3)(b)         | Pharmacist in Charge ensures Interns and technicians wear proper identification  |
| 40-43-86(B)(4)(b)         | Written Policies and Procedures on technician duties   |
| 40-43-86(B)(4)(b)         | Technician to pharmacist ratio   |
| 40-43-86(B)(5)            | Policy & procedures for management of recalls-date and subject of last recall documented   |
| 40-43-86(Q)               | Policy and procedure for providing pharmacy services in event of disaster; reviewed by staff annually and  |
|                           | documented   |
| 40-43-86(H)(5)            | Brand name or generic manufacturer on Rx copy or in computer   |
| 40-43-86(H)(5)            | Generic name and manufacturer and 'substituted for' brand name   |
| 40-43-86(I)(1)(b)         | Re-packing log   |
| 40-43-86(I)(8)            | Multi-dose packaging as per USP guidelines   |
| 40-43-86(CC)(6)           | Compounding log for each ingredient and formulas   |
| 40-43-195(E)(1)(a)        | CF label contains: name & address or name and license number of the pharmacy filling the prescription  |
| 40-43-86(I)(4)(b)         | Label contains name of patient   |
| 40-43-86(I)(4)(c)         | Label contains name of prescribing practitioner  |
| 40-43-86(I)(4)(d)         | Label contains directions for use  |
| 40-43-86(I)(4)(e)         | Label contains date of dispensing  |
| 40-43-86(I)(4)(f)         | Label contains any cautions required by federal or state laws  |
| 40-43-86(I)(4)(g)         | Label contains serial number   |
| 40-43-86(I)(4)(h)         | Label contains the name or initials of the dispensing pharmacist   |
| 40-43-86(I)(4)(i)         | Label contains the proprietary or generic name and strength  |
| 40-43-86(I)(4)(j)         | Label contains generic manufacturer  |
| 40-43-86(I)(4)(k)         | Label contains generic name first followed by brand name   |
| 40-43-86(I)(8)            | Labeling of multidrug packages complies with USP requirements  |
| 39-24-30                  | Substitution of therapeutically equivalent drugs   |
| Regulation 99-15          | Pharmacists annual renewal certificate displayed   |
| 40-43-82(A)(3)            | Pharmacy Technician shall display registration   |
| 40-43-60(F)               | No Drug or Device deemed adulterated   |
| 40-43-60(F)               | No Drug or Device deemed misbranded  |
| Reg 99-43(G)              | Primary and secondary wholesalers are permitted (list wholesalers)   |
| 40-43-86(B)(3)(c)         | Pharmacy only ships to states where licensed (list states licensed and review shipping/dispensing logs)  |
| 40-43-86(DD)(7)           | Shall Maintain complete and accurate records of all drugs received, dispensed or disposed-review invoices  |
| 40-43-86(B)(4)            | The pharmacist-in-charge must be assisted by a sufficient number of licensed pharmacists and registered pharmacy technicians as may be required to competently and safely provide pharmacy services. |
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|                           | Central Fill   |
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| 40-43-195(F)        | Maintains and uses adequate storage or shipment containers and shipping processes to ensure drug stability and   |
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|                     | potency. Must include the use of appropriate packaging material or devices or both to insure that the drug is  |
|                     | maintained at an appropriate temperature range to maintain the integrity of the  |
|                     | medication throughout the deliver process.   |
| 40-43-195(A)(2)(a)  | Prescriptions are shipped in containers that are sealed and tamper proof   |
| 40-43-195(B)(3)     | Controlled substance prescriptions filled by a central fill pharmacy must comply with both state and federal statutes and regulations. DHEC#   |
| 40-43-195(B)(4)(a)  | Must not fill prescriptions for controlled substances in Schedule II   |
| 40-43-195(B)(4)(b)  | Must not fill prescriptions provided directly by a patient or an individual practitioner.  |
| 40-43-195(B)(4)(c)  | Must not mail or otherwise deliver a prescription directly to a patient of an individual practitioner  |
| 40-43-195((D)(1)    | Must provide written information regarding the prescription with the filled prescription and a toll-free phone number for patient questions. The following statement must be provided with the prescription delivery to the patient. "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions." |
|                     | The central fill pharmacy is only required to maintain those portions of the policy that relates to that pharmacy's operations   |
| 40-43-195(F)(1)(a)  | Policies in place for patient notification of CF processing  |
| 40-43-195(F)(1)(b)  | Policies in place maintaining confidentiality and integrity of patient information   |
| 40-43-195(F)(1)(c)  | Policies in place for drug utilization review  |
| 40-43-195(F))(1)(d) | Policies in place for record keeping and logs, including a list of the names, addresses, phone numbers, and license or   |
|                     | registration numbers of the pharmacies, pharmacists, and pharmacy technicians at the central fill pharmacy and at the originating pharmacy;  |
| 40-43-195(F)(1)(e)  | Policies in place regarding counseling responsibilities;   |
|                     |  |
| 40-43-195(F)(1)(f)  | Policies in place procedures for return of prescriptions not delivered to a patient and procedures for invoicing medication transfers;   |
| 40-43-195(F)(1)(g)  | Policies in place for operating a continuous quality improvement program for pharmacy services designed to   |
|                     | objectively and systematically monitor and   |
|                     | evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve  |
|                     | identified problems;   |
| 40-43-195(F)(1)(h)  | Policies in place safe delivery of prescriptions to patients;  |
| 40-43-195(F)(1)(i)  | Policies in place to ensure stability and potency of medication;   |
| 40-43-195(F)(1)(j)  | Policies in place requirements for storage and shipment of prescription medication;  |
| 40-43-195(F)        | Policies are reviewed annually and documentation of review is available  |
| 40-43-195(F)        | Policies in place for a continuous quality improvement program   |
|                     | Facility has current list of all originating pharmacies  |
|                     | Facility has the ability to provide dispensing records   |
| 40-43-195(E)(1)(b)  | Label contains name and address of the originating pharmacy which received the filled prescription for delivery to the patient or the patient's agent  |
| 40-43-195(E)(1)(c)  | Label clearly indicates which pharmacy filled the prescription   |
|                     |  |