AGENDA

Florida Board of Pharmacy
Compounding Committee Meeting
October 2, 2018 – 11:30 a.m.

Embassy Suites Ft. Lauderdale
1100 SE 17th Street
Ft. Lauderdale, FL 33316
954-315-1326

Committee Members:
Mark Mikhael, PharmD
Richard Montgomery, BPharm, MBA
Blanca Rivera, BPharm, MBA
David Wright, BPharm

Board Staff
C. Erica White, MBA, JD - Executive Director
Shay Marcelus, JD – Prog. Operations Admin.

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Note: Participants in this public meeting should be aware that these proceedings are being recorded.

1. **Call to Order**
2. **Student Compounding** – *Dr. Scott Kjelson, Director Student Transitions/ Asst. Professor NSU College of Pharmacy*
3. **Discussion: Rule 64B16-27.700, F.A.C. - Definition of Compounding**
4. **Revised MOU – Compounding**
5. **Old Business**
6. **New Business**
7. **Public Comment**
8. **Adjourn**

TAB #2

797 REQUIRMENTS

Minimum Requirements (Based on USP 797 Proposed Requirements)			
	Item	Frequency	Competency Assessment Method
Core Competencies	Hand Hygiene	Initially and then at least every 6 months	Visually observed (by qualified person)
	Garbing	Initially and then at least every 6 months	Visually observed (by qualified person)
	Cleaning & Disinfection		
	Calculations		
	Measuring		
	Mixing		
	Aseptic Technique		
	Achieving and/or maintaining sterility and apyrogenicity		
	Use of Equipment		
	Documentation of compounding process (MFR, CR)		
	Principals of HEPA- filtered unidirectional airflow within ISO 5		
	Proper use of PEC		
	Principals of movement of materials within the compounding area		
	INITIAL-Gloved fingertip and	Initial testing (3 times)	Initially done 3 separate times. Each time must be done after performing a

	thumb sampling		separate and complete hand hygiene and full garbing procedure. Successful completion is defined as zero CFU for initial. Must be performed on donned sterile gloves in a ISO 7 buffer room or segregated compounding area.
	*** SUBSEQUENT - Gloved fingertip and thumb sampling	After initial, every 6 months in conjunction with media-fill testing	Must be done after media fill test. Successful completion is defined as ≤ 3 CFU (total from both hands). Must be performed on donned sterile gloves inside an ISO 5 PEC.
	Media fill test	Initial qualification, and then every 6 months in conjunction with gloved fingertip and thumb sampling.	Use the most difficult and challenging compounding procedures and processing conditions encountered by the person during a work shift. (most manipulations, most complex flow of materials, longest time to compound, size of batch). Replace all components with soybean-casein digest media. Failure is indicated by visible turbidity or other visual manifestations of growth in one or more container-closure units on or before the end of incubation period.

- Each compounding facility must develop a written training program that describes the required training, frequency of training, and process for evaluating the performance of individuals involved in preparing CSPs.
- Any other personnel handling CSPs and/or accessing the compounding area must complete training and demonstrate competency in maintaining the quality of the environment in which they are performing their assigned task…this can be students observing in the compounding area
- USP states before being allowed to independently compound, all compounders must successfully complete an initial competency evaluation, including visual observation and gloved fingertip and thumb sampling, no fewer than 3 separate times.
- After pausing in compounding, personnel who have not compounded CSPs in more than 6 months must be requalified in all core competencies before they may resume compounding duties

***

The highlighted area represents the items outside of the didactic training and options for the following:

- Students may cover Media Fill Testing (Initial)/ Subsequent Gloved Fingertip Testing requirement outside the institution in which they have an accredited APPE rotation site. The

required items highlighted could be fulfilled in either the College of Pharmacy or outsourced to certified programs in partnership with the college (ie. LP3 Network), with agreed upon policy and procedures that describes and outlines the exact setting in which it shall mimic the most extreme environment deemed at institutional. Institutions shall work with the college of pharmacy to create agreed upon settings and update every 6 months.

- The second option would be to have the student fulfill the above highlighted sections by working directly with the institutions within a year of and no later than two weeks before the accredited APPE rotation site.

TAB #3

White, Erica

From: D. Ty Jackson <Ty.Jackson@gray-robinson.com>
Sent: Monday, September 17, 2018 4:00 PM
To: White, Erica
Cc: David Flynn; 'Lawrence Harris'; Jason.unger@gray-robinson.com
Subject: RE: Telephone Message - Rules Committee (proposed changes to sterile compounding rule)

Erica,

Thank you for your response. Our request is to have an item on the agenda to discuss amending the Florida Rules governing compounding found in Chapter 64B16-27 of the Florida Administrative Code to specifically incorporate the requirements of section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a). Section 503B of the Act is currently incorporated into the Rules. *See* Fla. Admin. Code R. 64B16-27.700(3)(g). We believe 503A applies to compounding in Florida, and for purposes of clarification, would like to discuss amendment of the Rules governing compounding to specifically reflect that requirement.

If you need any additional information from us to get this item on the agenda for discussion, please let me know.

Thank you,

Ty

D. Ty Jackson | Shareholder
GRAY | ROBINSON

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Facebook | LinkedIn | Twitter

From: White, Erica [mailto:Erica.White@flhealth.gov]
Sent: Saturday, September 15, 2018 9:25 AM
To: D. Ty Jackson
Cc: David Flynn; 'Lawrence Harris'
Subject: Telephone Message - Rules Committee (proposed changes to sterile compounding rule)

Good Morning Mr. Jackson:

I received your voicemail from Friday, September 14th regarding the deadline to submit changes to the sterile compounding rule for discussion by the Rules Committee at the next Florida Board of Pharmacy meeting in October. I am forwarding your question to our Board attorneys by copying them on this e-mail,

so that they may respond to you directly regarding your inquiry.

Please let me know if you need any additional information.

Sincerely,

C. Erica White, MBA, JD
Executive Director | Florida Boards of Pharmacy,
Orthotists & Prosthetists, and Podiatric Medicine
Department of Health | Division of Medical Quality Assurance
4042 Bald Cypress Way, Bin C-04| Tallahassee, Florida 32399
Phone: (850) 245-4197 | Fax: (850) 413-6982
Erica.White@flhealth.gov

MISSION: To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.
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VISION: Healthiest State in the Nation
~~~~~~
VALUES: (ICARE)
Innovation: We search for creative solutions and manage resources wisely.
Collaboration: We use teamwork to achieve common goals & solve problems.
Accountability: We perform with integrity & respect.
Responsiveness: We achieve our mission by serving our customers & engaging our partners.
Excellence: We promote quality outcomes through learning & continuous performance improvement.
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64B16-27.700 Definition of Compounding.

"Compounding" is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent; and shall specifically include the professional act of preparing a unique finished product containing any ingredient or device defined by Sections 465.003(7) and (8), F.S. The term also includes the preparation of nuclear pharmaceuticals and diagnostic kits incident to use of such nuclear pharmaceuticals. The term "commercially available products," as used in this section, means any medicinal product as defined by Sections 465.003(7) and (8), F.S., that are legally distributed in the State of Florida by a drug manufacturer or wholesaler.

(1) Compounding includes:

(a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.

(b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.

(c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner.

(2) The preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities for purposes of dispensing or distribution is not compounding and is not within the practice of the profession of pharmacy, except that the supply of patient specific compounded prescriptions to another pharmacy under the provisions of Section 465.0265, F.S., and Rule 64B16-28.450, F.A.C., is authorized.

(3) Office use compounding, "Office use" means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy. A pharmacist may dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner in accordance with this section provided:

(a) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration date of the drug;

(b) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;

(c) The quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

(d) The pharmacy and the practitioner enter into a written agreement. The agreement shall specifically provide:

1. That the compounded drug may only be administered to the patient and may not be dispensed to the patient or sold to any other person or entity,

2. That the practitioner shall include on the patient's chart, medication order, or medication administration record the lot number and the beyond-use-date of any compounded drug administered to the patient that was provided by the pharmacy,

3. That the practitioner will provide notification to the patient for the reporting of any adverse reaction or complaint in order to facilitate any recall of batches of compounded drugs.

(e) The pharmacy shall maintain readily retrievable records of all compounded drugs ordered by practitioners for office use. The records must be maintained for a minimum of four (4) years and shall include:

1. The name, address and phone number of the practitioner ordering the compounded drug for office use and the date of the order,

2. The name, strength, and quantity of the compounded drug provided, including the number of containers and quantity in each,

3. The date the drug was compounded,

4. The date the compounded drug was provided to the practitioner,

5. The lot number and beyond use date.

(f) The pharmacy shall affix a label to any compounded drug that is provided for office use. The label shall include:

1. The name, address, and phone number of the compounding pharmacy,

2. The name and strength of the preparation of a list of active ingredients and strengths,

3. The pharmacy's lot number and beyond-use-date,

4. The quantity or amount in the container,

5. The appropriate ancillary instructions such as storage instructions, cautionary statements, or hazardous drug warning labels were appropriate; and,

6. The statement "For Institutional or Office Use Only – Not for Resale," or if the drug is provided to a veterinarian the statement "Compounded Drug."

(g) In the case of compounded products intended for human use, the pharmacy must be in full compliance with 21 U.S.C. §353b, including being registered as an Outsourcing Facility. 21 U.S.C. §353b (eff. Nov. 27, 2013) is hereby adopted and incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-04180.

Rulemaking Authority 465.005 FS. Law Implemented 465.003, 465.0155, 465.0265 FS. History–New 10-1-92, Formerly 21S-27.700, 61F10-27.700, 59X-27.700, Amended 11-2-03, 10-7-08, 3-21-13, 6-22-14, 1-28-18.

TAB #4

DRAFT MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED DRUG PRODUCTS BETWEEN THE STATE OF [insert STATE] AND THE U.S. FOOD AND DRUG ADMINISTRATION

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the State of [insert State] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate and the appropriate investigation by the State of [insert State] of complaints relating to human drug products compounded in such State and distributed outside such State. This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities.

II. BACKGROUND

a. Section 503A of the FD&C Act describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act requiring:

   1. Compliance with current good manufacturing practice (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));

   2. Labeling with adequate directions for use (section 502(f)(1) (21 U.S.C. 352(f)(1)); and

   3. FDA approval prior to marketing (section 505 (21 U.S.C. 355)).

b. To qualify for these exemptions, among other things, a compounded drug product must meet the conditions in section 503A(b)(3)(B) of the FD&C Act, under which the drug product is compounded in a State that:

   1. Has entered into an MOU with FDA that addresses the distribution of inordinate amounts[1] of compounded drug products interstate and

[1]The definition of *inordinate amounts* in this MOU is separate and distinct from and should not be used in relation to the term *inordinate amounts* as it is used in section 503A(b)(1)(D) of the FD&C Act (pertaining to compounding a drug product that is essentially a copy of a commercially available drug product). The interpretation of this term in each instance necessarily is based on the particular context of the distinct provisions within 503A in which the term appears.

provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State (section 503A(b)(3)(B)(i)); or

2. Has not entered into an MOU with FDA and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (section 503A(b)(3)(B)(ii)).

c. Section 503A(b)(3) of the FD&C Act directs FDA to develop a standard MOU for use by the States in complying with section 503A(b)(3)(B)(i). The content of this MOU conforms to the standard MOU developed by FDA for this purpose.

III. SUBSTANCE OF AGREEMENT

a. Investigation of Complaints Relating to Compounded Drug Products Distributed Outside the State

1. Appropriate agencies of the State of [insert State] will investigate complaints received relating to drug products compounded by a pharmacist and distributed outside the State by a pharmacy. Primary responsibility for investigating complaints involving drug products compounded by a pharmacist will generally lie with the [insert State Board of Pharmacy or other appropriate State agency].

2. Complaints relating to compounded drug products distributed outside the State that will be investigated include reports received by the State concerning adverse drug experiences or product quality issues associated with drugs compounded by a pharmacist. See Appendix A for definitions of *adverse drug experiences* and *product quality issues*.

3. Any investigations performed by the State of [insert State] under this MOU will include, but are not limited to, taking steps to assess (1) whether there is a public health risk associated with the compounded drug product; and (2) whether any public health risk associated with the product is adequately contained.

4. Based on findings from an investigation of a complaint about drug products compounded by a pharmacist and distributed outside the State, if the complaint is found to be valid, the State of [insert State], in accordance with and as permitted by State law, will take the action that the State considers to be appropriate and warranted to ensure that the relevant compounding pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient

corrective action to address any identified public health risk relating to the complaint, including the risk that future similar complaints may occur.

5. The State of [insert State] will notify FDA by sending an email to StateMOU@fda.hhs.gov with the information described in section III.c.1.a of this MOU as soon as possible, but no later than 3 business days after receiving any complaint relating to a drug product compounded by a pharmacist and distributed outside the State involving a serious adverse drug experience or serious product quality issue. After this notification, the State will share with FDA the results of the investigation that it conducted. See Appendix A for definitions of *serious adverse drug experience* and *serious product quality issue*.

6. If the State of [insert State] receives a complaint involving an adverse experience or product quality issue relating to a drug compounded by a physician and distributed outside the State, the State will notify the appropriate regulator of physician compounding within the State. If the complaint involves a serious adverse drug experience or serious product quality issue, the State will also notify FDA by sending an email to StateMOU@fda.hhs.gov with the information in section III.c.1.a of this MOU as soon as possible, but no later than 3 business days, after receiving the complaint.

7. The State of [insert State] will maintain records of the complaint, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the State receives notice of the complaint. The State will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.

b. Distribution of Inordinate Amounts of Compounded Drug Products Interstate

1. For purposes of this MOU, a pharmacy or physician has distributed an inordinate amount of compounded drug products interstate if the number of prescription orders for compounded drug products distributed interstate during any calendar month is greater than 50 percent of the number of prescription orders for compounded drug products distributed or dispensed both intrastate and interstate by such pharmacy or physician during that month.

2. On an annual basis (at minimum), the State of [insert State] will identify, using surveys, reviews of records during inspections, or other mechanisms available to the State, compounding pharmacies that distribute inordinate amounts of compounded drug products interstate by collecting information regarding the total number of prescription orders for compounded drug products distributed or dispensed

intrastate and the total number of prescription orders for compounded drug products distributed interstate.

3. If the State of [insert State] becomes aware of a physician who is distributing compounded drug products interstate, the State will coordinate with the appropriate regulator of physician compounding within the State to determine, using surveys, reviews of records during inspections, or other mechanisms available to the State, whether the physician distributes inordinate amounts of compounded drug products interstate by collecting information regarding the total number of prescription orders for compounded drug products distributed or dispensed intrastate and the total number of prescription orders for compounded drug products distributed interstate.

4. For pharmacies or physicians that have been identified as distributing inordinate amounts of compounded drug products interstate, the State also will collect information regarding the total number of prescription orders for sterile compounded drugs distributed outside the State; the number of States in which the compounding pharmacy or physician is licensed or number of States into which the compounding pharmacy or physician distributes compounded drug products; and whether the State inspected for and found during its most recent inspection that the compounding pharmacy or physician distributed compounded drug products without valid prescription orders for individually identified patients.

5. The State will notify FDA by sending an email to StateMOU@fda.hhs.gov within 30 days of identifying a pharmacy or physician within its jurisdiction that has distributed inordinate amounts of compounded drug products interstate and will include the information described in section III.c.1.b of this MOU.

c. Submission and Disclosure of Information

1. When submitting information to StateMOU@fda.hhs.gov regarding complaints relating to compounded drug products distributed outside the State or regarding distribution of inordinate amounts of drugs interstate, the following minimum information will be included:

a. Complaints:

i. Name and contact information of the complainant;

ii. Name and address of the pharmacy/physician that is the subject of the complaint;

iii. Description of the complaint, including a description of any compounded drug product that is the subject of the complaint;

iv. State's initial assessment of the validity of the complaint relating to a compounded drug product distributed outside the State, if available; and

v. Description and date of any actions the State has taken to address the complaint.

b. Inordinate Amounts:

i. Name and address of the pharmacy/physician that distributed inordinate amounts of compounded drug products interstate;

ii. The total number of prescription orders for compounded drug products distributed or dispensed intrastate;

iii. The total number of prescription orders for compounded drug products distributed interstate;

iv. The total number of prescription orders for sterile compounded drug products distributed interstate;

v. The number of States in which the compounding pharmacy or physician is licensed or into which the pharmacy or physician distributes compounded drug products, and

vi. Whether the State inspected for and found during its most recent inspection that the compounding pharmacy or physician distributed compounded human drug products without valid prescription orders for individually identified patients.

2. The parties to this MOU will share information consistent with applicable statutes and regulations. The parties recognize that a separate agreement under 21 CFR 20.88 or commissioning of officials under 21 CFR 20.84 may be necessary before FDA can share information that is protected from public disclosure. Such an agreement, or commissioning terms, will govern FDA's sharing of the following types of information:

- Confidential commercial information, such as information that would be protected from public disclosure under Exemption 4

of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4));

- Personal privacy information, such as information that would be protected from public disclosure under Exemption 6 or 7(C) of the FOIA (5 U.S.C. 552(b)(6) and(7)(C)); or

- Information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), the Health Insurance Portability and Accountability Act (Public Law 104-191), and FDA's regulations in parts 20 and 21 (21 CFR parts 20 and 21)).

FDA agrees that information provided to FDA by the State of [insert State] will only be disclosed consistent with applicable Federal law and regulations governing the disclosure of such information, including, but not limited to, the FOIA (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), 21 U.S.C. 331(j), 21 U.S.C. 360j(c), the Trade Secrets Act (18 U.S.C. 1905), FDA's regulations in 21 CFR parts 20 and 21, and other pertinent laws and regulations.

IV. ENFORCEMENT AUTHORITIES AND LEGAL STATUS OF AGREEMENT

The parties to this MOU recognize that FDA and the State of [insert State] retain the statutory and regulatory authorities provided by the FD&C Act, other Federal statutes and attendant regulations, and State statutes and regulations. The parties also recognize that this agreement does not restrict FDA or any other Federal agency from taking enforcement action, when appropriate, to ensure compliance with Federal statutes, including the FD&C Act and attendant regulations, or prevent the State of [insert State] from taking enforcement action, as appropriate, to ensure compliance with applicable State statutes and regulations. This MOU does not create or confer any rights for or on any person. By signing this MOU, the [insert name of State agency] affirms that it now possesses and will maintain, at the discretion of the State legislature, the legal authority (under State statutes and/or regulations) and the resources necessary to effectively carry out all aspects of this MOU. If State law changes such that the State no longer has the legal authority or resources necessary to effectively carry out all aspects of this MOU, the State will notify FDA.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

U.S. Food and Drug Administration
Center for Drug Evaluation and Research

Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
Bldg. 51, Suite 5100
Silver Spring, MD 20993-0002
Telephone: (301) 796-3110
Email: StateMOU@fda.hhs.gov

[State]
TBD

Upon signing the MOU, each party must designate one or more liaisons to act as points of contact. Each party may designate new liaisons at any time by notifying the other party's liaison(s) in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the parties will name a new liaison within 2 weeks and notify the other party's liaison(s).

VI. PERIOD OF AGREEMENT

a. When accepted by both parties, this MOU will be effective from the date of the last signature and will continue until terminated by either party. It may be terminated in writing by either party, upon a 30-day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.

b. If the State does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded drug products distributed outside the State, the MOU may be terminated upon 30-days' notice of termination.

In case of termination, FDA will post a notice of the termination on its Web site and the State will notify all licensed pharmacists, pharmacies, and physicians within the State of the termination and advise them that as of 30 days from the date of the posting of the termination notice, compounded drug products may be distributed (or caused to be distributed) out of the State only in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by the licensed pharmacy or physician (section 503A(b)(3)(B)(ii) of the FD&C Act).

VII. APPROVALS

APPROVED AND ACCEPTED FOR THE U.S. FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR THE STATE OF [insert State]
By (Type Name)	By (Type Name)
Title	Title

Date	Date

Appendix A. Definition of Terms Used in the MOU

- **Adverse Drug Experience**: Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).

- **Distribution:** *Distribution* means that a compounder has sent a drug product out of the facility in which the drug was compounded. Such distribution may include, but is not limited to, delivery or shipment to a physician's office, hospital, or other health care setting for administration, and dispensing the drug product by sending it to a patient for the patient's own use.

  Note: To qualify for the exemptions under section 503A, a compounder must obtain a prescription for an individually identified patient (section 503A(a) of the FD&C Act). This MOU will not alter this condition.

- **Product Quality Issue**: Information concerning (1) any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or (2) any bacteriological contamination; any significant chemical, physical, or other change or deterioration in the distributed drug product; or any failure of one or more distributed batches of the drug product to meet the applicable specifications (21 CFR 314.81(b)(1)). Contamination in general, including but not limited to mold, fungal, bacterial, or particulate contamination, is a product quality issue.

- **Serious Adverse Drug Experience**: Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 310.305(b)).

- **Serious Product Quality Issue**: Any product quality issue that may have the potential to cause a serious adverse drug experience (e.g., possible contamination, superpotent product).