Frequently Asked Member Questions

What are the rules and regulations regarding compounding for “office-use”?  

The compounding and dispensing of prescription drugs for in-office administration by a prescriber to his/her patients is governed by the individual state Boards of Pharmacy. Those regulations and rules vary greatly from state to state.

For example, New York specifically prohibits dispensing “office-use” prescriptions because their regulations require that a patient name appear on all prescriptions in order for it to be considered valid. In Texas, “office-use” dispensing is permitted and there are multiple sections in their laws that outline how and when this is allowed. In Oklahoma, “office-use” is permitted but there are limitations on the total amounts a pharmacy may dispense and there is a prohibition that the dispensed prescription may not be resold or redispensed to the patient by the physician.

IACP has a compilation of each state’s rules and regulations pertaining to “office-use” compounding and dispensing available for purchase as part of its IACP Law Library. An order form and additional information is available at our website – www.iacprx.org

Can controlled substances be compounded for “office-use”?  

No.

The federal Controlled Substances Act (CSA) only permits the transfer of a controlled substance prescription between Drug Enforcement Administration (DEA) registrants via a “sales” transaction and not a prescription.

No controlled substance prescription – compounded or manufactured finished drug product – may be dispensed on prescription to an authorized prescriber or his/her agent for “office-use.” The DEA provided IACP with a formal ruling on that issue in June 2012. A copy of the DEA’s response is available in the Member Center of the IACP website.
Can I send a controlled substance compound to a physician office for them to administer to a specific patient?

No. “Constructive transfer” of a controlled substance is deemed an illegal and prohibited act by the Drug Enforcement Administration (DEA).

Under current DEA interpretation, the dispensing and delivery of a controlled substance medication - either manufactured or compounded -- when that prescription is labeled for a specific patient, must only be to the patient themselves or their designated agent.

What's also important to understand is that the DEA holds that neither a DEA registrant nor his/her employees can serve as a designated "agent" of the patient. A DEA registrant’s spouse would also be considered an agent of the prescriber and therefore could also not receive or accept a patient-specific prescription for a controlled substance.

Here's the core section of the Controlled Substances Act upon which the agency makes that determination:


That's also referenced (dispensed to the "ultimate user") in the Pharmacists’ Manual.


Lastly, IACP has a formal letter from the DEA that clearly states that "office-use" is not permitted for controlled substances; that was in follow-up to a formal inquiry asking for clarification from the agency.


IACP and other professional pharmacy associations continue to work on changing this DEA policy.

How do I provide any controlled substance-containing preparation to a physician?

Pursuant to the DEA’s policies, you would have to obtain a DEA manufacturer/distributor permit in order to sell or distribute a controlled substance-containing compound to another DEA registrant. That’s different than the requirements imposed upon pharmacies by the DEA for the sale and transfer of finished manufactured drug products.
The DEA does not distinguish between registering as a manufacturer and registering as a supplier/distributor. They’re all categorized as one and the same together under a Form 225 registration.

Information about registering with the DEA as a “manufacturer” can be found here:


Some issues to consider when determining whether your pharmacy wishes to become a DEA registered manufacturer/distributor.

1) You may have to comply with cGMP standards.
2) You will be subject to regular inspections including all prescriptions, order forms, invoices, etc.
3) You must have a separate security system and have all products/materials used for the “manufacturing” side of your business kept apart from your regular inventory.
4) There are reporting requirements that are additional to what you currently report as a pharmacy.
5) Your pharmacy liability insurance may not cover your manufacturing activities because it is considered outside the scope of “traditional” practice. Evaluating your liability coverage is an essential part of the decision process.

I’ve given my compounded preparation a proprietary brand name. Is that permitted?

It depends upon your state’s law and regulations.

Some states prohibit the use of “coded” or “secret” formulas on prescriptions. Using a “brand name” for a compounded preparation which you promote to prescribers may unintentionally result in invalid prescriptions. Check with the state Board(s) of Pharmacy in which you are licensed to determine if the use of a proprietary brand name, for which ingredients and composition are not publicly available, would be considered a violation of any regulations or rules.

Can I prepare compounds in advance before I receive a prescription or prescriber order?

What you are asking about is anticipatory compounding. Anticipatory compounding is the preparation of compounded medications based upon historical prescriptions received by the pharmacy. It’s essentially a form of inventory management which enables the pharmacy and the pharmacist to prepare compounded preparations in amounts sufficient to meet the needs of patients and prescribers. Additionally, it provides for ample time for a pharmacist to submit a medication to a laboratory for potency and sterility testing.

Federal law as outlined in section 503(a) of the Food Drug & Cosmetic Act provides for anticipatory compounding. That section includes the following language:
(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between ---

(i) the licensed pharmacist or licensed physician; and

(ii) (I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

In addition to the federal law that specifically permits the preparation of compounded medications in advance and based upon historical business trends, many individual states also have similar language in their pharmacy practice acts.

One of the most important components of anticipatory compounding is assuring that whatever quantity you are preparing for subsequent dispensing is based upon the prescriptions and orders you have previously received. Having a retaining documentation to support that decision is essential to answer any questions by an inspector.

**Am I permitted to give samples of my compounded preparations to a prescriber?**

Assuming you mean providing a sample of a drug for the prescriber to give at no charge to a patient, then the general answer is “no.”

Almost every single state specifically requires that a pharmacist must have an order from an authorized prescriber before a prescription drug can be dispensed to anyone. Without such an order, a pharmacist or pharmacy that gives a “sample” of a medication to a prescriber – similar to how a pharmaceutical manufacturer representative provides complimentary drug samples to physicians – would be in violation of those laws since no prescription preceded the provision of the medication.

Complimentary drug samples provided by pharmaceutical manufacturer representatives are heavily regulated by the Food and Drug Administration (FDA) as well as individual state Boards of Pharmacy. The enactment of the Prescription Drug Marketing Act of 1987 (PDMA) mandated that the states establish regulatory oversight of manufacturers, wholesalers, and suppliers. Those state laws and regulations also affect who may provide a complimentary drug sample to a prescriber. That impacts pharmacists as well. Many states actually mandate licensure and/or reporting to the Board of Pharmacy by anyone intending to distribute drug samples.

IACP has a compilation of each state’s rules and regulations pertaining to sampling of medications by pharmacists available for purchase as part of its IACP Law Library. An order form and additional information is available at our website – www.iacprx.org
In addition to regulatory restrictions related to complimentary drug samples, a pharmacist and pharmacy must also address the underlying philosophical question – if compounding is the creation of a customized medication solution for a particular patient, how is it possible to have a standardized formula that can be sampled? More importantly, why would a pharmacy wish to be perceived as a manufacturer by performing the same activities and marketing behaviors as the pharmaceutical industry?

**What licensing is necessary to ship compounds into other states?**

Pharmacies which dispense and ship prescription medications to patients residing outside their state are required to obtain out-of-state pharmacy permits in all states except for Pennsylvania and Massachusetts. Georgia changed its law in April 2013 to require non-resident pharmacy permits. Massachusetts currently has legislation pending to do so as well; however, that law has not yet been enacted.

The legislation establishing out-of-state pharmacies to be licensed and subject to disciplinary action by a state Board was originally introduced in the early 1990’s with the proliferation of mail-order pharmacy services. As compounding pharmacists have expanded their geographical services, more and more are finding it necessary to obtain additional permits.

Some states provide exemptions for obtaining an out-of-state permit. For example, a pharmacy that ships a prescription drug to one of their regular patients who is on vacation in another state and needs an emergency refill may not need to register. State permitting requirements vary and can be found by calling the relevant Board or visiting their website for application instructions.

**Are you making treatment claims if you say your Bioidentical Hormone Replacement Therapy (BHRT) compounds address hot flashes?**

Yes.

According to the Food and Drug Administration, a health claim is an explicit or implied characterization of a relationship between a substance and a disease or a health-related condition. Stating that a particular BHRT compounded preparation will reduce or eliminate hot flashes is a claim.

Any statement indicating that a product cures or ameliorates a disease or symptom of a disease or affects the human body in a particular fashion is a “claim” of efficacy. Similarly, statements purporting to the safety of a particular compounded medication is also considered a “claim”.

Unless the compounded preparation has been submitted to the Food and Drug Administration for review and approval, you may not make any claims about safety, efficacy, or outcomes about a particular prescription drug. Doing so constitutes misbranding.
Note. This addresses claims made for marketing and promotional purposes. An inter-professional discussion between a pharmacist and a prescriber about a particular patient or group of patients may include anecdotal, empiric, or scientific information that reference appropriateness, efficacy and safety. That is not necessarily a “claim”. Similar conversations between a non-pharmacist marketing or sales person and a prescriber would be considered a “claim”.

**Can I provide information about treatment claims, efficacy or safety if I use a disclaimer?**

No, not if the claims are being made for marketing or promotional reasons outside of an inter-professional physician/pharmacist consultation or conversation.

A disclaimer similar to the ones used in dietary supplements (e.g., “these statements have not been evaluated by the Food and Drug Administration”) is not sufficient protection to allegations of making claims about a particular compounded preparation. The FDA disclaimer cannot be used for prescription drugs – only foods and dietary supplements. Additionally, state laws also include significant sections that mirror the federal FDCA and allegations of misbranding – false or misleading claims – may include state as well as federal action.

Note. This addresses claims made for marketing and promotional purposes. An inter-professional discussion between a pharmacist and a prescriber about a particular patient or group of patients may include anecdotal, empiric, or scientific information that reference appropriateness, efficacy and safety. That is not necessarily a “claim”. Similar conversations between a non-pharmacist marketing or sales person and a prescriber would be considered a “claim”.

**Are there any standards or guidelines for handling hazardous or potent pharmaceuticals?**

USP <797> addresses chemotherapeutic and other potentially hazardous sterile preparations. Additionally, USP’s Expert Committee on Compounding is in the process of developing formal standards for comment by the health care community on the handling of hazardous chemical use for both sterile and non-sterile compounding.

Pharmacies should also review OSHA (Occupational Safety and Health Administration) regulations at both the federal and state level. These regulations provide specific responsibilities for protecting workers from exposure to potentially hazardous chemicals including hormones, chemotherapeutics, and others.
What do I do if a drug is listed on the FDA "Negative Drug" List?

The enactment of the Food and Drug Administration Modernization Act (FDAMA) in 1997 included multiple changes and additions to the agency’s oversight of compounded medications. One of those was the establishment of a list of drugs which the FDA has formally stated should not be compounded by any U.S. pharmacy.

This list, commonly referred to as the “negative list,” is available at online at the FDA website. That link is: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=216.24

Almost all of these medications are products which have been removed from the market for safety reasons or known adverse effects. It is important to note that in some cases, the products on the list are specific to some salts of chemicals while other products are specific to certain dosage forms.

In a ruling called Western States, the Ninth Circuit Court of Appeals struck down entire sections of FDAMA that impact compounding pharmacists. That negated the federal requirement for compliance with the “negative list” for those pharmacies in Washington, Oregon, Idaho, Montana, Nevada, California, and Arizona.

Regulatory compliance is one issue to consider when asked to compound a medication that is on the FDA “negative list.” Professional communication with the prescriber is another. Pharmacists should always inform the prescriber who has issued a prescription if he or she has requested an ingredient that appears on the “negative list.”

Can I compound a drug that is not FDA approved and does not have a USP monograph?

There are many prescription medications in common use that are not FDA-approved finished drug products. These include more than 200 different products which predate the enactment of the 1938 Food Drug and Cosmetic Act (FDCA) that established the Food and Drug Administration’s authority to mandate demonstration of a drug’s safety before a manufacturer could market, distribute, and sell it. Those drugs include codeine, morphine, sodium bicarbonate, calcium gluconate, chloral hydrate, hydrocodone, and many others. Therefore, it is not at all unusual for a pharmacist to dispense or compound with a medication that is not “FDA approved.”

Some states, however, have included in their practice acts requirements that pharmacists must either compound using components of FDA-approved medications or which have a published United States Pharmacopeial Convention (USP) monograph. In such an instance, in order to comply with the state law, a USP monograph must exist before the compound would be considered legal within that state. Other states do not have such a requirement in their laws. Still others recognize official compendia monographs that are not included in the USP (e.g., the BP or British Pharmacopeia).

Prior to making a compounding and dispensing decision for a preparation that includes an ingredient which is neither FDA approved nor has a published monograph, the pharmacist should have a...
consultation with the prescriber to examine potential alternatives and to ensure that the patient is informed.

**Is there a special license required to ship scripts into Puerto Rico?**

It depends. Puerto Rico does not require out-of-territory pharmacies to obtain a pharmacy permit at this time. In general, if a pharmacy is preparing a patient-specific prescription and shipping it to Puerto Rico, no further pharmacy permits are required.

Puerto Rico does require a business license in order to sell or transact business within its borders. If a pharmacy is selling (e.g., for office-use) a non-patient specific prescription to a physician, clinic, hospital or other entity, consult an attorney to determine if the business license must be obtained prior to sending medicines into the territory. This license is distinct and separate from the Board of Pharmacy’s authority.

Information on obtaining a business license in Puerto Rico can be found here: [http://www.pfcpa.com/registration_and_licensing.html](http://www.pfcpa.com/registration_and_licensing.html)

Note also that shipping companies including UPS, FedEx, DHL and others have importation requirements which must be satisfied and forms that must be completed prior to their acceptance of a prescription drug for commerce to Puerto Rico. Check also with your shipper about their individual requirements.

**Can I provide practitioners with pre-printed prescription pads for their use for products I compound and dispense?**

In most states they are *not legal* if:

- They contain the name, address, phone number of other identifying information of a particular pharmacy.
- Are provided by the pharmacist, pharmacy or the pharmacy’s representatives to the physician.

Providing pre-printed prescription blanks to a prescriber is usually a prohibited act because it directly interferes with the patient’s freedom to choose their pharmacy.

A prescriber’s office may prepare their own prescription templates and pre-printed blanks if they contain all the required information as outlined in the state’s laws and regulations.

On the federal level, the DEA has taken the position that any prescription containing a controlled substance that is prepared by a DEA registrant pharmacy for signature/approval of a prescriber – including faxed refill authorization forms – cannot be filled legally by the pharmacy. The DEA’s interpretation is that by “writing” the prescription, the pharmacy is acting as the physician’s agent and is therefore excluded from subsequently filling and dispensing the medication.
IACP is compiling a summary of all state pharmacy practice act regulations pertaining to pre-printed prescription blanks and templates.

**We are shipping compounded preparations to other states. The doctors there have requested that we develop a faxable template of frequently prescribed compounds for them. Can we do that?**

In this instance, you would have to not only research your own state regulations but also the regulations in other states. Even if a pre-printed prescription template you created and provided is legal in your home state, it has to be legal in the other state as well. If it’s not legal in your home state but legal in the other state? Then it’s still illegal to do so.

**If compounding for hospital shortages, how can I legally do so as I would not be compounding by specific prescription for a specific patient?**

This would be equivalent to compounding and dispensing medications for “office-use.” Please see the section above for a more complete explanation.

One issue which compounding pharmacists encounter when meeting hospital drug shortage needs is the complexity of a health-system’s established purchasing process. Most hospital purchasing departments believe that a simple purchase order or invoice is sufficient to obtain a prescription drug. It is not.

Since a compounding pharmacy is neither a wholesaler nor manufacturer, a formal written prescription or medical order signed by an authorized prescriber must be received prior to the dispensing of that compound to the hospital. A purchase department employee or even a hospital pharmacist does not have the necessary authority to order a prescription medication from another pharmacy. That can only be done by a state authorized prescriber.

**I’ve been contacted by my Department of Corrections to provide a compounded drug for lethal injection. Is that something I can do?**

With more and more medications in drug shortage and “do not sell” policies by the manufacturers of some drugs like sodium pentothal, several state prison systems have reached out to compounding pharmacies to supply medications for lethal injections. While this is a rare and unusual situation, it is one that requires some thought and research.

Aside from the ethical decision which you would have to make personally, there are several other significant areas to consider before making a final decision on the compounding of medications for lethal injection or for use in executions.
• Definitely check with your state Board of Pharmacy to see if this is even permitted or not. There may be some specific laws related to the dispensing of a medication which you know is going to cause harm that may affect your license or pharmacy’s permit. This is a “must do” before proceeding any further.
• Assess the potential negative response from the media and groups opposed to capital punishment. You should consult with a public relations firm to handle press and others. You should also consider the need for additional security for your business, yourself personally, and for your staff who may be subject to unwanted verbal or even physical attacks by those who are opposed to the death penalty.
• Most importantly, you should contact your malpractice insurance company. Would compounding a drug for lethal injection be part of your policy’s coverage? What would happen in the event you are sued by the prisoner or the family of an executed prisoner for “cruel and unusual punishment”?

We want to create a commercial for both our local television station and our website that features a patient having a hot flash then using her compounded BHRT. Can we do that?

Probably not. There are extensive FDA, Federal Trade Commission (FTC), and state regulations that address the advertisement of both prescription and over-the-counter drugs. Many of them pertain to claims – making a statement of efficacy, safety, etc., that have not been formally proven through controlled studies. In addition, many states prohibit the use of patient testimonials in advertising for health care services and products.

You may be better off talking about the types of services and consults your pharmacy provides (e.g., “we work with women going through menopause to help deal with the discomfort of…” but make no mention of a product or combination of products). Depending on your state laws, you may be able to include a patient talking about how she feels in your pharmacy and staff taking care of her needs, how attentive and understanding they are, and other non-product related statements.

What if we use a disclaimer on our advertisements that says “this statement has not been evaluated by the FDA…” so we can talk about the compounds we prepare and what they do?

You cannot use that disclaimer for any OTC or prescription compounded medication.

We’ve all seen the disclaimers that run at the bottom of TV commercials or are printed on advertisements that say, This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease. Many pharmacists
believe they can make claims about a compounded medication’s efficacy, use, treatment purposes, etc., in advertising and use this disclaimer as a means to “make it legal.”

Title 21 of the Food Drug and Cosmetic Act, Chapter I, (b)(101)(F)(101.93) governs the labeling of foods and statements made for dietary supplements. This statement or "disclaimer" is required when a manufacturer makes a structure/function claim on a dietary supplement label. In general, these claims describe the role of a nutrient or dietary ingredient intended to affect the structure or function of the body. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not approved by the FDA. For this reason, the law says that if a dietary supplement label includes such a claim, it must state in a "disclaimer" that the FDA has not evaluated this claim. The disclaimer must also state that this product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim.

The disclaimer above is only permitted to be used by dietary supplements. It cannot be used by any producer or supplier of prescription or over-the-counter medications to excuse the listing of a drug claim or mention of efficacy that has not been officially approved by the FDA.

**Can I compound estriol?**

FDCA section 503(a) specifically provides for compounders to prepare medications which are either components of approved drugs or which have a USP monograph or are on a list promulgated by the Secretary.

Estriol is a drug product whose use predated the 1938 enactment of the federal Food Drug and Cosmetic Act (FDCA).

Estriol as a single chemical moiety or in combination with other agents was never submitted by a pharmaceutical manufacturer for formal review and approval by the FDA. Estriol was a component of several products manufactured in the 1950’s and 1960’s by Carnrick Laboratories; however, Carnrick never submitted a New Drug Application (NDC) nor had it reviewed. That was the subject of a major court case between the FDA and Carnrick in the late 1970’s. This is probably more than you care to know but here’s a link to the court decision in that case.


Estriol does have a USP monograph.

As with any compounded medication, your own clinical knowledge and decision making is paramount. Is this appropriate for this patient? Did you consult with the prescriber about the medication and medication plan for this patient? What is the physician’s reputation and knowledge base about Bio-identical Hormone Replacement (BHRT)? Is the prescriber aware of the Investigational New Drug (IND) requirement? Those intra-professional conversations coupled with good documentation on your part are some of the best defense you can have in case of an issue. And, of course, it is essential that you adequately counsel and advise any patient that their compounded...
medication is not FDA approved, has been selected and customized for them by their prescriber, and that they should be aware of and report any side-effects, adverse reactions, etc. to both you, their pharmacist, and their physician.

**Does a prescriber have to obtain an IND from the FDA to prescribe estriol?**

According to the FDA, yes, they do need to file for an Investigational New Drug application (IND) ([http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm183078.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm183078.htm)). That position has not changed or been updated since 2009. The pharmacy is not required to obtain an IND; however, if an FDA inspector finds estriol in a pharmacy, they may ask for documentation that the prescriber has a valid IND.

What isn’t clear is whether a state Board of Medicine requires a prescriber to comply with an FDA mandate – an issue of federal versus state jurisdictional authority. Nor is it clear whether or not a state Board of Pharmacy would take action against a pharmacist/pharmacy for compounding or dispensing estriol if an IND has not been filed.

**Does a pharmacy have to obtain an IND from the FDA to dispense estriol?**

No. It is the pharmacy’s responsibility, however, to assure that an IND exists prior to dispensing a medication if the FDA requires one.

Again, it is unclear what authority over a pharmacy or action the FDA can take against a pharmacy’s permit or pharmacist’s license if an IND is not followed. Consult with your Board of Pharmacy for direction.

**I’ve seen OTC and cosmetic products containing estriol. How is this permitted?**

Any over-the-counter medication containing estriol would be in clear violation of the FDA rules and should be reported to their offices immediately.

There are a number of estriol-containing cosmetics on the market and while IACP has pointed that out to the agency, the FDA has taken no action to our knowledge to cease the distribution or sale of those items.

It is indeed unfortunate that the agency takes active pursuit against healthcare practitioners directly involved in patient care yet leaves large corporations promoting and selling the same product largely untouched.
Can a pharmacist compound a non-FDA approved drug?

In general, the answer is “yes.” There are currently more than 200 different drugs which are legally manufactured, marketed and sold in the U.S. which pre-date the 1938 enactment of the Food, Drug and Cosmetic Act (FDCA) which required all new drugs to be submitted to the FDA for review and approval of safety. Included in the list are commonly used products like codeine, morphine, ASA, potassium chloride, sodium bicarbonate, etc. Many state practice acts address this in their laws by requiring that compounding should only be done if the product is either a component of an FDA approved drug or has a USP monograph. Estriol has a USP monograph that’s been in existence since the 1950’s.

Some states actually have a very narrow definition. For example, IACP has worked on an issue in Utah where the regulation mandates compounding only for those products which are a component of the FDA approved drug products. Theoretically, every pharmacy compounding with sodium bicarbonate in Utah – hospitals included – are violating the law. That was something unforeseen by the Utah Board when their regulation was enacted.

Many members of the public as well as healthcare professionals, who should know better, assume that all drugs sold in the U.S. are FDA approved. Compounding pharmacists can help educate physicians, nurses, and other pharmacists that there are many non-FDA -approved medications that are used every day to treat patients.

Is there a list of non-FDA- approved drugs that predate the 1938 Food Drug & Cosmetic Act?

The International Journal of Pharmaceutical Compounding's “Compounding Today” website has a list that can be downloaded, e-mailed and/or printed and distributed. To access that list, visit their website at: http://compoundingtoday.com/Unapproved/

Can I compound domperidone for gastroporesis? For lactation induction?

FDCA section 503(a) specifically provides for compounders to prepare medications which are either components of approved drugs or which have a USP monograph or are on a list promulgated by the Secretary.

Domperidone is a drug product that has never been approved by the FDA for marketing or use within the United States for humans. While available outside the U.S. for the treatment of gastroporesis, it does not have approval for treatment of lactation induction. A study is underway at the University of Texas for that specific use. Domperidone is approved in the U.S. for the treatment of lactation induction in mares; drugs approved for veterinary use cannot be used for the treatment of humans.

Domperidone does not have a USP monograph.
Several state Boards of Pharmacy have specifically instructed licensees that the compounding of domperidone is not permitted in their state. Such decisions apply to both in-state as well as non-resident pharmacy permit holders.

**Where can I obtain SOPs for my pharmacy's operations?**

One of the best sources for SOP (Standard Operating Procedure) templates is through the *International Journal of Pharmaceutical Compounding*. IJPC’s “Compounding Today” website has a library of these SOPs that are downloadable and customizable for a fee. IACP members receive a subscription discount to IJPC publications.

You can visit that site at: [http://compoundingtoday.com/](http://compoundingtoday.com/)

Additionally, you should contact your compounding equipment and material suppliers as many companies have SOPs available to their customers as part of their value-added services.

**Is it legal (illegal) to list the cost of my compounded preparations on my advertisements, websites, flyers, etc?**

IACP is not aware of any regulations in any state that says you cannot advertise or list the price of a medication… compounded or not. In some states, there are regulations that actually require you to either post or provide those prices to the public at any time.

While neither legal nor illegal, promoting prices for compounded preparations carries a different kind of risk. For example, a flyer that lists specific compounds with prices gives rise to concerns by both state and federal regulators that you are advertising a finished “manufactured” product. Here’s the rationale: *If a compound is based upon a prescription or prescriber order, and each of those preparations is theoretically unique with different strengths and quantities, how is it possible for you to have a “standard” price? You must be making batches of those and then going out and trying to sell them... and that’s what manufacturers do.*

Something to consider when promoting prices on your materials is to include a disclaimer. Wording you may want to think about in promotional materials to physicians and other prescribers is as follows:

“Because each compounded preparation is individualized to meet your or your patient’s needs, please contact XYZ Compounding Pharmacy to discuss medication prices with our pharmacy staff.”

**Since DQSA doesn't cover non-human patients, can I still do veterinary office use depending on one's state board?**
Sections 503A and 503B within the Drug Quality and Security Act of 2013 address compounding for humans. The law is silent on veterinary compounding. In May 2015, the FDA circulated a draft Guidance for Industry (GFI) that replaces their 2003 Compliance Policy Guideline for veterinary compounding. Within that document, FDA's position is that compounding for animals requires a patient-specific prescription (e.g., Fluffy the Cat, Racehorse #3, Rex the Dog). Referencing language within the AMDUCA (Animal Medicinal Drug Use Clarification Act of 1984), the FDA's position is that office-use compounding for veterinarians is not permitted regardless of state law. Although not finalized, the GFI if adopted with that language would take precedence over state law and office-use compounding for veterinarians would be prohibited.

**Can I compound for office-use with controlled substances?**

No. There is no such thing as an office-use prescription for a controlled substance for any person or animal. The Controlled Substances Act provides for the purchase of controlled substances from pharmacies using a medical order/invoice (Schedules III-V) or a Form 222 (Schedule II); those are not considered a prescription although many pharmacists and practitioners make the error of calling a medical order or invoice a "prescription".

**How do I handle a recall from a supplier of bulk ingredients?**

Handling of a recall from a supplier of bulk ingredients should be consistent with the same process that your pharmacy would use in the event of a finished product recall from a manufacturer.

- All products in the effective lot(s) should be removed immediately from the dispensing or compounding laboratory.
- All products in the effective lot(s) should be carefully quarantined and sealed to prevent accidental use by pharmacy staff.
- Returns of the recalled lot(s) should be handled in a manner consistent with information provided for pharmacies by the supplier.
- If required, disposal of the recalled lot(s) can be handled following the pharmacy's Standard Operating Procedure (SOPs) for discarding bulk ingredients including issues related to hazardous drugs and controlled substances.
- Communication to any patient who may be in possession of a medication which has been recalled should proceed in accordance with the pharmacy's internal SOPs.
- Individual state Boards of Pharmacy or other regulatory groups at the state level may have regulations specific to the handling of a recall by which the supplier must abide. Confirm with the supplier whether or not they have informed the regulatory agency in the impacted state(s).
- Individual state Boards of Pharmacy may have regulations specific to the handling of a recall by a compounding pharmacy that includes notification to the Board. IACP is reviewing state laws and will provide a summary of those for members in the near future; however, a...
member pharmacist should always be familiar with and ascertain their individual state Boards' policies and requirements.

Is reconstituting a medication or combining two medications (e.g., a sterile finished drug product added to a larger volume sterile IV bag) considered “compounding”?

If reconstitution or admixture preparation is done in full compliance with the FDA-approved labeling for a finished drug product, the FDA's position is that is not compounding. If, however, a pharmacist reconstitutes or combines a sterile drug(s) in a manner that is not consistent with or different from the approved labeling, that would be considered compounding.

It's important to note that the definition used by the FDA for reconstitution differs from that contained within USP <795> and <797>. The act of reconstitution or the combining of any medications is considered to be a compounding activity by USP.

Is repackaging a medication considered compounding?

The FDA considers repackaging of a finished manufactured drug product as something distinctly separate from compounding. There are several guidance documents from FDA that address the repackaging of finished drug products and a separate guidance document for repackaging of biologics (e.g., Avastin®).

It's important to note that the definition used by the FDA for repackaging differs from that contained within USP <795> and <797>. The act of repackaging is considered to be a compounding activity by USP.

What is the difference between office-use and anticipatory compounding?

The two terms are not interchangeable.

Office-use compounding or distribution is the provision of a medication to an authorized prescriber without a patient-specific name associated with the order. Office-use medications are frequently obtained from pharmacies to enable a practitioner to administer to or treat a patient with a particular medication within their practice setting.

Anticipatory compounding is the preparation of inventory within the pharmacy based upon a historic utilization rate within a defined period of time. Anticipatory compounding is no different than determining that within any given month, you would ordinarily dispense a certain quantity of a particular medicine and decide to order the entire expected amount from a wholesaler at one time.
**Can a 503B outsourcing facility compound and dispense non-sterile prescriptions? Do they have to have an individual patient prescription.**

There are no provisions within the *Drug Quality and Security Act* nor within the compliance guidelines issued by the FDA to date which would enable a 503B outsourcing facility to compound and distribute office-use non-sterile preparations. They would be required to obtain an individual patient specific prescription from an authorized prescriber.

In addition, they would have to compound that non-sterile preparation in full compliance with CGMP guidelines (the entire facility and all compounding activities must be CGMP compliant in order to be a 503B outsourcing facility) and they cannot prepare the prescription using an API unless the drug in question is in actual shortage as listed on the FDA's website. In other words, they would need to use FDA-approved finished manufactured drug products and not APIs to compound almost all non-sterile medications.

A draft guidance document regarding the activities of 503B outsourcing facilities was issued by the FDA in February 2015; although the comment period ended in May 2015, the document is still pending final adoption by the agency. You can read the draft document here:


**Do I have to be PCAB accredited?**

Becoming an accredited compounding pharmacy is a decision each individual practice should make. Accreditation is a process by which an independent organization reviews and determines whether a pharmacy is complying with a set of published standards developed to provide a quality measurement.

Some third-party payers and pharmacy network administrators are increasingly examining whether accreditation should be mandatory to maintain a contract with the payer or for continued participating in the network.

**Am I allowed to repackage Avastin® for office-use by a physician?**

The FDA issued a guidance document in February 2015 that addresses the repackaging and distribution of biologics including Avastin. Although the comment period for that guidance document ended in May 2015, the final recommendations and requirements have not yet been published.
What quality standards should FDA use when inspecting a compounding pharmacy?

FDA does not use “quality standards” for conducting an inspection. If they deem a pharmacy to be out-of-compliance with federal law, including the provisions of 503A that exempt a traditional compounder from being considered a manufacturer/distributor, they will apply CGMPs (Current Good Manufacturing Practices) which are based on regulations, rules and guidance documents. IACP believes that the inspection of any compounding pharmacy should occur using the nationally recognized standards published within USP General Chapters <795> and <797>.

Where can I find compounding training courses?

IACP has a number of Corporate Partners who provide extensive non-sterile and sterile compounding training courses. These include: Fagron Academy, Letco Medical, Medisca, , and PCCA. Additionally, the American College of Apothecaries (ACA) conducts compounding training courses at their offices in Memphis, TN. For additional information on when and where these courses are offered, please visit the Corporate Partners section of the IACP website at www.iacprx.org.

What are labeling requirements for Sustained Release and Extended Release formulations?

USP provides clear definitions for SR (sustained release) and ER (extended release) formulations. Those definitions also include requirements for certain types of studies and documentation. Unless a compounded preparation fully complies with the USP definitions, using SR or ER designations should be avoided. "Slow release" may be a preferable term; however, it should not be abbreviated as SR to minimize confusion or misinterpretation that the finished preparation is "sustained release".

If a facility is registered as a 503B outsourcing facility, and distributes/sells controlled substances such as testosterone without a patient specific prescription, does that facility have to register with the DEA as a manufacturer?

If the facility is not already registered with the DEA as a pharmacy, then they will definitely have to register with DEA as a manufacturer/distributor/supplier via a Form 225. If the 503B facility is also pharmacy and has a DEA registration for the same physical location, fulfilling patient-specific controlled substance prescriptions would not necessitate registering as a manufacturer/distributor/supplier. If the 503B outsourcing facility is a pharmacy with an existing DEA registration and distributes/sells controlled substances, it may need to also obtain a DEA registration as a manufacturer/distributor/supplier. Contact the DEA for additional instructions.
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