Introduction

Chapter <797> of the United States Pharmacopeia (USP) was initially introduced on January 1, 2004, in an effort to provide a new standard for compounded sterile preparations (CSPs). It was the first enforceable guideline of its kind that specifically addressed pharmacy-prepared compounds (as opposed to manufacturers’ premixes). In essence, this regulation was established to increase the rigor of sterile drug compounding procedures taking place in health care settings.

The Joint Commission considers the requirements established in the revised USP Chapter <797>, released in December 2007 and published in June 2008, to be best practice, and the regulations may require compounding facilities to begin the renovations and upgrades necessary for compliance with completion by June 1, 2008, depending on the state. Enforcement, however, will be left up to each individual state. Hospital pharmacies unable to meet the requirements may have to make alternative arrangements for their compounding services, and some have opted for outsourcing. Additionally, even those facilities that meet the revised Chapter <797> requirements may choose to reduce their on-site admixture compounding volume and burden through outsourcing. This review discusses the benefits of outsourcing and provides an overview of what hospital pharmacists should look for in compounding service providers.

USP Chapter <797>: A Brief Overview

In order to mandate consistently accurate compounded medications, the recently revised USP Chapter <797> enlists quality controls for technique, method, and validation, with the goal of building quality and safety into the entire compounding process—from compounding to the labeling, transport, and storage of compounded sterile preparations.

The chapter recognizes 5 risk levels (low, medium, and high, plus low risk level with 12
performing compounding to meet the new standard.\textsuperscript{4} Indeed, to lance, and consistency for both pharmacists and technicians
• poorly designed and operated compounding facilities.
• failure of the pharmacy to establish procedures for the valida-
• poor-quality aseptic technique and environmental controls
• poorly articulated procedures for in-house compounding;
• poorly trained pharmacy staff;

The USP developed the Chapter <797> regulations in response to reports of patient illnesses and deaths resulting from contaminated compounded drug solutions in the 1990s and early 2000s, most of which originated from retail compounding pharmacies. The resulting court cases from these incidents made it clear that the responsibility for the quality of a drug solution lies squarely on the shoulders of the dispensing pharmacy and the medical staff that administers it.

Common factors in retail and hospital pharmacies that led to these issues were the following:\textsuperscript{2}:
• poorly trained pharmacy staff;
• poorly articulated procedures for in-house compounding;
• poor-quality aseptic technique and environmental controls on the part of the compounding pharmacists;
• failure of the pharmacy to establish procedures for the valida-
tion of sterile methods; and
• poorly designed and operated compounding facilities.

To address these issues, experts advocate leadership, vigilance, and consistency for both pharmacists and technicians performing compounding to meet the new standard.\textsuperscript{4} Indeed, to comply with the requirements of USP Chapter <797>, hospital pharmacies must ensure that the compounded preparations they dispense are prepared appropriately (in a sterile environment) by well-trained staff and are tested and verified prior to dispensing, and that documentation of these processes is in place in the event of a problem. To safeguard the hospital pharmacy from liability, procedures and facilities must be monitored and/or maintained to ensure that they continue to meet currently accepted standards. Ultimately, compliance with Chapter <797> can be challenging for hospital pharmacies because of the time, costs, and resources required (Tables 1 and 2).\textsuperscript{6} Because USP Chapter <797> places more stringent requirements on compounded drugs that start with nonsterile ingredients, a survey performed in 2006 suggested that a large percentage of facilities plan to reduce such compounding (Table 3).\textsuperscript{5}

### Outsourcing Compounding Services

For these reasons, many hospital pharmacies have opted to use private contractors for compounding preparations rather than establish in-house procedures for producing every CSP they dispense. Outsourcing among hospital pharmacies is becoming more prevalent, in part because it can be a viable alternative to the cost-prohibitive installation of an on-site clean room (the revised USP Chapter <797> requires all compounding facilities to meet International Organization for Standardization standards) and the labor-intensive aspects of staff training, performance evaluation, and quality control. Recent surveys of pharmacy practice in hospital settings showed that 30% of all hospitals and 55% of hospitals with 400 or more beds outsourced some preparation activities (Table 4, Figure 1).\textsuperscript{1} Among the more commonly outsourced preparations were analgesics, total parenteral nutrition solutions, solutions used in labor and delivery, antibiotics, and other I.V. admixtures.

Outsourcing the compounding of sterile I.V. preparations enables hospital pharmacies to reallocate resources to other areas by lowering costs and reducing the burden on dedicated compounding facilities. The purchase price of an outsourced preparation may offer savings over the expenses of in-house compounding, especially when factors such as equipment costs, quality testing, waste, and labor offsets are considered. Outsourcing may also enable hospital pharmacies to allocate more staffing resources to patient care. However, hospital pharmacies selecting this option must still establish policies for outsourcing that ensure quality and compliance with USP Chapter <797> requirements.

There are many different ways a hospital pharmacy can verify that compounding providers are meeting the requirements of USP Chapter <797>. A number of organizations and agencies—

### Table 1. Effect of USP Chapter <797> on Resource Allocation

<table>
<thead>
<tr>
<th>Budgeted Resource</th>
<th>Hospitals That Have Increased Allocation, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.V. room supplies or equipment</td>
<td>87.2</td>
</tr>
<tr>
<td>I.V. clean room floors sanitized on a daily basis (similar to how operating room suites are sanitized)</td>
<td>69.9</td>
</tr>
<tr>
<td>Manufacturer-premade or frozen CSPs</td>
<td>51.0</td>
</tr>
<tr>
<td>Point-of-care–activated devices (eg, Add-Vantage, Mini-Bag Plus)</td>
<td>44.8</td>
</tr>
<tr>
<td>Pharmacy technician FTEs</td>
<td>31.9</td>
</tr>
<tr>
<td>Pharmacist FTEs</td>
<td>20.8</td>
</tr>
</tbody>
</table>

\textsuperscript{FTEs, full-time equivalents; CSPs, compounded sterile preparations,}
including the American Society of Health-System Pharmacists, The Joint Commission, and the Drug Enforcement Agency (DEA)—publish rules, regulations, and standards for compounding. A compounding pharmacy should be compliant with these standards, as well as all state, federal, and municipal laws. Outsourcing pharmacies that register with the FDA as drug establishments undergo periodic and intense federal inspection. In addition, the Pharmacy Compounding Accreditation Board (PCAB) regularly inspects many off-site compounding facilities and awards a seal of approval to companies meeting its standards. This accreditation is voluntary. The PCAB is made up of a variety of organizations, including the USP.7

Selecting a Compounding Company

Several companies offer outsourcing of compounding services, including national providers, such as PharMEDium and B. Braun Medical (Central Admixture Pharmacy Services, CAPS), as well as regional and local providers. These companies can vary significantly in the size and scope of the services they offer. Hospital pharmacy directors should conduct their own evaluation of the provider’s facilities in terms of regulatory compliance and sterile preparation competencies. The USP explicitly defines compounded medications as being the practice of pharmacy as opposed to a manufactured product. As a result, CSPs remain under the purview of state agencies and professional standards. However, no company should be used based on name, FDA registration, or PCAB accreditation alone. In selecting a provider for outsourcing, hospital pharmacy administrators should consider the following factors:

Customer Base

A provider’s customer base can be a telling factor. Pharmacy directors may feel more comfortable knowing a particular compounding company is being used by similar facilities or similarly sized hospitals. Colleagues may provide frank and honest opinions of service and preparation quality, and their opinions often carry a great deal of weight in the decision-making process.

Preparations To Outsource

Ideal CSPs to outsource include stable I.V. solutions—provided the beyond-use dating offered meets institutional needs—as
Table 3. Respondents’ Opinions About USP Chapter <797>

<table>
<thead>
<tr>
<th>Survey Questions</th>
<th>Mean (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate the effect that USP Chapter &lt;797&gt; will have on the following:</td>
<td></td>
</tr>
<tr>
<td>Workload of pharmacy technicians (n=251)</td>
<td>2.10 (1.99-2.21)</td>
</tr>
<tr>
<td>Workload of pharmacists (n=251)</td>
<td>2.14 (2.02-2.25)</td>
</tr>
<tr>
<td>Overall efficiency of operations (n=249)</td>
<td>2.08 (1.96-2.19)</td>
</tr>
<tr>
<td>Pharmacy’s ability to provide CSPs in a timely manner (n=251)</td>
<td>2.11 (1.99-2.24)</td>
</tr>
<tr>
<td>Pharmacy’s ability to provide excellent customer service (ie, nursing satisfaction) (n=251)</td>
<td>2.41 (2.28-2.54)</td>
</tr>
<tr>
<td>Quality of care provided to your hospital’s patients (n=251)</td>
<td>3.57 (3.44-3.70)</td>
</tr>
<tr>
<td>Rate your agreement with the following statement*:</td>
<td></td>
</tr>
<tr>
<td>The rigor of USP Chapter &lt;797&gt; exceeds what is necessary for hospital pharmacy practice. (n=250)</td>
<td>3.86 (3.69-4.03)</td>
</tr>
</tbody>
</table>

*a 1, very negative or restrictive effect; 2, somewhat negative effect; 3, neutral or no effect; 4, somewhat positive effect; 5, very positive or helpful effect.

Adapted from reference 5.

well as high-volume items in standardized dosage forms (ie, magnesium sulfate, oxytocin, and calcium gluconate; Table 5). Other items to consider include patient-controlled analgesia cartridges and epidural solutions, such as fentanyl, hydromorphone, and bupivacaine.8

Vendor Capabilities

Compounding pharmacies should be licensed by a state board of pharmacy and ideally registered with the FDA. These facilities should allow site visits and reviews of their licenses and certifications. Environmental quality can be assessed by an examination of clean room certifications and maintenance records. The facility should provide copies of all licensures and certifications, as well as proof of applicable liability insurance.

Pharmacy directors and staff pharmacists with expertise in compounding should also consider site visits at all potential outsourcing vendors’ facilities to evaluate them in terms of regulatory compliance and sterile preparation competencies, as well as their approach to preparation. Visits should include tours of the clean room facilities as well as thorough reviews of all licenses, certifications, and training and performance assessment programs for staff. Pharmacies should also carefully review the integrity of the compounding process flow and aseptic control.

Any outsourced admixture provider should readily make available a detailed monthly or quarterly quality report that summarizes key areas, such as environmental testing, media-fill results, equipment validation, and any other indicators that would normally be monitored if the compounding were not being outsourced.

Pyrogen and bacterial endotoxin testing is required for high-risk compounds, and the method and procedures for such testing should be clearly documented. Hospital pharmacies should also review batch records for the preparations to be outsourced for stability, sterility, and pyrogenicity testing.8 The outsourcing vendor selected should have beyond-use dating and compounding policies and procedures that match those of the client pharmacy; if different, they should be substantiated by documented evidence. A copy of this evidence should be kept on site for reference purposes. In addition, the compounding pharmacy should possess adequate liability coverage in the event a contamination occurs.

In judging the quality of an outsourced compounder, it is helpful to understand how it meets or exceeds various industry standards or regulations with regard to preparation processes and how these processes ultimately affect patient care. This can be a good indicator of how highly it prioritizes quality activities over competing business priorities. For example, do environmental controls exceed those required by USP Chapter <797>?7

Bar Coding and Labeling

All compounding pharmacies must be able to provide preparation labels that meet the needs of the individual hospital pharmacy and nursing staff. Quality labeling is a primary benefit and consideration when compounding services are outsourced. An important factor to consider is that many serious medication errors occur at the point of administration because of improper labeling.8 Standardized bar codes applied in a highly controlled compounding pharmacy have been shown to be more accurate than those applied outside a formal quality process. PharMEDi-um, for example, has been very aggressive in developing labeling that meets not only USP Chapter <797> standards but also many of the published recommendations of industry safety experts. Hospital pharmacies may consult the Institute for Safe Medication Practices website to view suggested labeling practices for compounded I.V. preparations.10
For facilities that use bar-coded medication administration (BCMA), the vendor’s bar-coding capabilities are especially important. According to survey results published by Pedersen et al., the use of BCMA is rising, 9% of all hospitals and 16% of hospitals with more than 100 beds reported using it in 2005. If the labels contain bar codes, their readability must be tested for compatibility with the hospital’s scanners. The vendor should also be willing to match its warning labels with those of the client hospital pharmacy. Some companies can produce a variety of bar codes and will even customize those bar codes to meet specific needs by including data such as lot numbers, expiration dates, and preparation identification numbers in 2-dimensional bar codes. Outsourced vendors should also incorporate other label safety features, such as TALLman lettering and bar codes and configurations and warnings that most hospital pharmacies may not be able to easily reproduce (Figure 2).

Bar codes are changed, even by major I.V. admixture manufacturers, for many reasons, ranging from revisions in company procedures to changes in FDA requirements. Even a simple deviation in the ink used can affect how a bar code is read. In the face of such alterations, the most important thing a company can do is ensure excellent communication with its customers, the hospital, and the hospital staff, who may rely on bar codes for record keeping and patient charting. A reputable outsourced provider will scan to validate each and every bar-coded admixture it sends out to a customer. This can reduce potentially time-consuming delays that inadvertently create “wrong time” medication errors or other scanning difficulties at the point of care. In addition, admixtures coming into the pharmacy should be scanned to ensure they can be read properly. This step should be completed before the compounded drug is given to a nurse, who will need to scan it before administering it to the patient.

In terms of working with outside providers of CSPs, high-quality, consistent labeling is crucial. For example, when a preparation with a “smart” infusion device that relies on an integrated bar-code scanner is used, it is important that the outsourced compounding pharmacist has worked directly with the infusion device manufacturer to validate that the barcode works correctly. This is an added step to ensure safe patient care and that the preparation will interface correctly with the infusion device.

**Monitoring, Management, and Documentation**

Once an off-site compounding provider has been selected, it is necessary to regularly review data to ensure the ongoing quality of the preparations the company is providing. As previously mentioned, outsourced vendors should provide monthly or quarterly quality reports that include preparation-specific data: records on sterility testing, batch certifications, competency assessment and training results, environmental monitoring, and certification for clean rooms and laminar airflow workstations. The information provided in these reports must be consistent and equivalent to documentation that would be required (by the state board of pharmacy, for example) if the admixture were prepared on site. Reviewing a sample report in advance with the vendor can be helpful.

**A quality report must address all of the elements required by USP Chapter <797>: environmental testing, employee performance testing, and individual preparation testing. Specific details for each of these elements should be included.**

### Table 4. Current Compounding Practices of Hospitals, by Staffed Bed Size

<table>
<thead>
<tr>
<th>Current Practice</th>
<th>&lt;50 Beds</th>
<th>50-99 Beds (n= 54)</th>
<th>100-199 Beds (n = 43)</th>
<th>200-299 Beds (n = 41)</th>
<th>300-399 Beds (n = 43)</th>
<th>&gt;400 Beds (n = 42)</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSPs are in satellite pharmacies.</td>
<td>7.1</td>
<td>5.6</td>
<td>16.3</td>
<td>22.0</td>
<td>61.2</td>
<td>76.2</td>
<td>19.9</td>
</tr>
<tr>
<td>Hospital pharmacy has a clean room in the central pharmacy area that meets Chapter &lt;797&gt; standards.</td>
<td>28.6</td>
<td>35.2</td>
<td>34.9</td>
<td>36.6</td>
<td>48.9</td>
<td>45.2</td>
<td>35.2</td>
</tr>
<tr>
<td>Of those with a central pharmacy clean room, the hospital pharmacy’s clean room meets ISO class 7 standards.</td>
<td>85.7</td>
<td>76.5</td>
<td>57.1</td>
<td>78.6</td>
<td>80.0</td>
<td>57.9</td>
<td>72.5</td>
</tr>
<tr>
<td>The hospital pharmacy compounds high-risk preparations.</td>
<td>10.7</td>
<td>5.6</td>
<td>14.0</td>
<td>20.0</td>
<td>30.2</td>
<td>54.8</td>
<td>16.9</td>
</tr>
<tr>
<td>The hospital has performed a gap analysis to identify any deficiencies in complying with Chapter &lt;797&gt;.</td>
<td>64.3</td>
<td>72.2</td>
<td>83.7</td>
<td>97.5</td>
<td>93.0</td>
<td>95.2</td>
<td>78.3</td>
</tr>
<tr>
<td>The hospital uses Chapter &lt;797&gt; to evaluate nursing practice in preparing sterile doses in patient care areas.</td>
<td>39.3</td>
<td>35.2</td>
<td>51.2</td>
<td>55.0</td>
<td>55.8</td>
<td>57.1</td>
<td>46.2</td>
</tr>
</tbody>
</table>

CSPs, compounded sterile preparations; ISO, International Organization for Standardization

Adapted from reference 5.
environmental testing, it is important to know how regularly it is performed. For example, the report should summarize how often the hoods are checked, when the high-efficiency particulate air (HEPA) filters are changed, and the results of air quality samples. In addition to listing the education and experience of staff members, employee testing should report glove tip testing and other checks to make sure that employees are following good aseptic technique.4,8 The quality reports provided should be reviewed regularly for accuracy, anomalies, and any other possible trends.

Compounding vendors should be able to provide documentation describing their compounding processes, specifically for methodologies used to establish beyond-use dating, to validate sterility of sterile preparations compounded, for pyrogen testing (high-risk category CSPs), and, if not, provide certificate of analysis and potency of the bulk ingredient at the time of dispensing. Potency testing is limited as it typically only measures the concentration of drug in a compounded preparation at the time of compounding. Also, depending on the method of potency testing used, degradants or excipients may go undetected, meaning that the true drug concentration could change before the beyond-use date has been reached. Conversely, real-time stability testing can be used to accurately determine the beyond-use date because it essentially involves re-creating a facility’s entire compounding and shipping process to ensure accuracy and quality aseptic technique (ie, method development and method validation). Effective stability tests separate the drug from any degradants and excipients, usually via heat or ultraviolet radiation.11

For individual preparations, paperwork such as batch records and data on stability, sterility, and pyrogenicity should be available. Pharmacy directors can request historical reports, inspection results, and background information on their preparations as a way to review the company’s track record.12 For example, if a pharmacy is considering purchasing a controlled substance, it is entirely appropriate to ask to see the record keeping and reports for those preparations for the past year, as well as any batch-related problems or unusual events. Obtaining answers to questions like these before a business relationship is started may also contribute to that ever-crucial issue of trust. Any qualified vendor should be more than willing to provide the requested data.8

Quality assurance is an important factor in determining a suitable outsourcing partner. Ask vendors for specifics of the inspection process and determine if there are quality mechanisms in place to reduce the potential for human error. As has been well documented in the hospital setting, bar-code scanning systems (both in the pharmacy and at the bedside) can be effective in reducing medication errors. Similarly, outsourced compounders using a process similar to that used in manufacturing have found automated bar-code verification systems to be a way to improve quality without sacrificing efficiency in the preparation process. Some companies have developed proprietary systems that use a bar-code verification process in addition to detailed inspection of all critical steps in the compounding process.

### Delivery

In selecting an off-site service provider for compounding needs, one must also consider logistics. For example, does the compounding facility’s location allow the timely delivery of compounded preparations? Are the hours of operation sufficient to meet the needs of the department? The frequency of deliveries available will determine the inventory for each preparation that is required and may also affect preparation waste. Finally, does the company have the capability to forward orders to another compounding center location in the event the primary facility has to close because of an emergency?

Additionally, hospital pharmacies that plan to outsource controlled substances must assess whether vendors use electronic processing of DEA 222 forms. A manual process can add to the

<table>
<thead>
<tr>
<th>Table 5. Commonly Outsourced I.V. Admixtures</th>
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<tbody>
<tr>
<td>Cardioplegic solutions</td>
</tr>
<tr>
<td>CRRT admixtures</td>
</tr>
<tr>
<td>Total parenteral nutrition</td>
</tr>
<tr>
<td>Oxytocin in various diluents</td>
</tr>
<tr>
<td>Magnesium sulfate in various diluents</td>
</tr>
<tr>
<td>Controlled substances in PCA syringes</td>
</tr>
<tr>
<td>Epidural admixtures</td>
</tr>
<tr>
<td>Various antibiotics as piggybacks</td>
</tr>
<tr>
<td>Flush solutions</td>
</tr>
<tr>
<td>Other small-volume admixtures</td>
</tr>
</tbody>
</table>

CRRT, continuous renal replacement therapy; PCA, patient-controlled analgesia.
time it takes to receive an order.\textsuperscript{8} It is possible for electronic processing of the form 222 to reduce the time it takes to obtain a preparation by as much as 2 days. Also, compounders offering online ordering capabilities can reduce the turnaround time on outsourced compounding orders.

**Additional Benefits of I.V. Outsourcing**

Nurse preparation of I.V. doses without pharmacist involvement increases the opportunity for medication errors. This is a consequence of the lack of a controlled preparation environment and the potential for contamination caused by poor aseptic technique. The desire to prevent these errors may account for the relative decrease in compounding by nursing staff, yet in 2002, 19\% of hospitals still reported that nurses compounded I.V. solutions. By 2005, that number had dropped to 15\%. However, it should be noted that the rate remains higher in smaller hospitals (<100 beds); in all, 29\% of these hospitals reported that nurses continue to compound I.V. solutions.\textsuperscript{6} In facilities where nurse compounding is common practice, outsourcing may relieve nurses of this duty and provide additional patient safety benefits.

Labels with a Reduced Space Symbology composite bar code, including the National Drug Code number, lot, and expiration date, may allow hospitals to better track and reconcile controlled substances or high-risk drugs, improve inventory control, and reduce unused or wasted drug admixtures in addition to the obvious benefit of improved readability.\textsuperscript{13} For example, in May 2008, PharMEDium announced the availability of a new label design, developed based on extensive surveys of labeling practices in the hospital market (Figure 2).

Compounded, ready-to-use preparations can also address a host of operating room risk factors, such as “look-alike” vials, syringes, and high-risk medications that lack labels and bar codes, all of which contribute to medication errors. To enhance drug recognition, certain outsource compounders have developed color-coded syringe preparations by class (eg, orange for sedatives, red for neuromuscular blocking agents, blue for narcotics, etc) consistent with American Society for Testing and Materials (ASTM) standards.\textsuperscript{14} This standard is widely accepted and endorsed by the American Society of Anesthesiologists (ASA). Drug names are color-coded and dual-banded (so the drug name on a syringe can be seen from any orientation), and shapes on labels assist in distinguishing different concentrations within drug families (Figure 3).

Similarly, common sense dictates the value of having emergency medications available in ready-to-use form; however, this practice can lead to waste when they are not used. If ready-to-use preparations with beyond-use dates longer than what is specified by USP are employed, a tamper-evident seal should be considered to ensure that a noncommercially available preparation has not been previously opened and potentially contaminated. Non-commercial tamper seals, such as a shrink band, are the best means to thwart the potential for diversion because an easy-to-obtain device may be removed and then replaced without any indication of drug tampering.\textsuperscript{15}

Beyond-use dating can also be exceeded if evidence in the literature or actual real-time studies supports stability. The main advantage of extended dating for hospital pharmacies is that it...
reduces waste. It is essential that hospital pharmacy directors perform due diligence to ensure that the off-site compounding facility, whether a local pharmacy or a national company, is meeting or exceeding all of the requirements. Prerequisites for local compounding vendors require careful consideration, given the recent history of major adverse events that resulted from contaminated products coming from such pharmacies.

Ready-to-use and point-of-care—activated I.V. admixtures often allow an extended shelf life. For example, many point-of-care products allow at least 30-day beyond-use dating once the product is assembled, but not activated, according to the manufacturer's package insert. If compounded by pharmacy staff in a clean room, these same medications would generally be subject to a 14-day refrigerated beyond-use date—or 48 hours at room temperature. By extending beyond-use dating, hospital pharmacies can reduce waste and eliminate the staff time necessary to recompound expired medications.

Conclusion

The decision to purchase CSPs from an off-site vendor cannot be taken lightly. Before entering into a business relationship, pharmacy leadership must carefully examine a vendor’s sterile preparation portfolio, quality standards, service capabilities, customization opportunities, delivery methods, and pricing, as well as the company's ability and willingness to provide comprehensive quality data. It is critical to ensure that the off-site vendor is following or exceeding all the same quality control and quality assurance steps required by USP Chapter <797> or pharmacy practice guidelines that would be enacted during on-site compounding.

When considering outsourcing CSP admixtures, pharmacists must take into account reliability, quality assurance, supply and demand, labeling, cost, and time savings, as well as safeguards against medication errors. Company reputation and reliability will also influence the choice of a particular service provider, or the decision of whether to enter into a contract with the service provider at all.

Pharmacists can take many routes to achieve the desired outcome of accurate and sterile compounded preparations. Such flexibility allows pharmacies of different sizes and types to choose an outsourced vendor to assist with Chapter <797> compliance, but pharmacists must hold outsource partners to the same or higher levels of accountability for the preparations they purchase.

References