

ASHP Guidelines on Outsourcing Sterile Compounding Services

Purpose

Health care organizations considering outsourcing sterile compounding services should have a clear understanding of what they want to accomplish. Consideration should include, at the least, an internal needs assessment, a cost analysis, and a careful review of prospective compounding pharmacies. The organization should examine the potential long-term consequences of outsourcing as well as the short-term outcomes expected during a contract's performance period.

The purpose of these guidelines is to provide an overview of factors and processes for health care organizations to consider when exploring outsourcing of pharmacy sterile compounding. The ideas presented in this document could be used for strategic planning with the organization's decision-makers, for drafting contract provisions, for comparing prospective compounding pharmacies, for preparing for contract negotiations, or for evaluating a compounding pharmacy's performance.

This document includes ideas about reasons for outsourcing and reasons for not outsourcing, services available from compounding pharmacies, the outsourcing process and outsourcing arrangements, and evaluation of a compounding pharmacy's performance. The appendix provides a topical list of contract provisions, some of which relate to practices that are the subject of other American Society of Health-System Pharmacy (ASHP) guidelines. Organizations should refer to pertinent ASHP guidelines for additional information on which to base their contract provisions, agreements, and decisions.¹⁻³ This document addresses representative outsourcing options and contract agreements and is not intended to cover all situations. Managers of pharmacy and health care organizations should use their professional judgment about applicability to their own needs and circumstances.

Environment

There are various environmental influences and market forces that may contribute to a facility's decision to consider outsourcing. A list of some of those considerations follows.

Organizational and Operational

- Limited available technological resources to provide the specific desired services.
- Re-engineering and downsizing initiatives.
- Consolidation and integration of health systems and departments within health systems.
- Elimination of or reduction in the size of traditional pharmacy departments.
- Reorganization around patient-focused care.
- Implementation of automated pharmacy systems and the attendant need to reorganize medication preparation and distribution functions.

Staffing

- Shortage of pharmacists, nurses, and other health care professionals.

- Shortage of pharmacy personnel with specific experience and capabilities.

Financial and Cost Control

- Restricted budgets.
- Increased operating costs.
- Increased drug costs.
- Increased emphasis on measuring performance in terms of staffing and costs.

Quality Assurance

- Increased expectations of and pressures from payers, accreditation organizations, and consumer groups to improve the quality of patient care, reduce the incidence of hospital infections, and demonstrate compliance with applicable standards and regulations.

Governmental and Regulatory

- Reductions of federal, state, and local government reimbursement for health care.
- Increased numbers of individuals dependent on federal, state, and local governments for health care.
- Increased federal and state interest in standards for sterile compounding (i.e., *United States Pharmacopeia [USP] chapter 797*⁴).

Competitive

- Increased competition among healthcare organizations.
- Increased competition among suppliers of pharmaceutical products and related services.

Purposes of Outsourcing

Health care organizations that conduct in-depth assessments may decide that outsourcing either is or is not a good option for meeting their needs. Reasons for their decision will vary according to a variety of factors.

Reasons Health Care Organizations Outsource Sterile Compounding Services. Organizations tend to outsource sterile compounding services when guided by a careful assessment of their capabilities of providing services themselves, when unsuccessful in using their own resources to provide those services, or, in some cases, upon advice from a consultant. Contracting with an outsourcing firm may produce one or more of the following results.

Organizational and Operational

- Ease the consolidation of pharmaceutical services in integrated health systems.

- Resolve operational inefficiencies (e.g., batch compounding, staff scheduling, high-demand periods).
- Provide compounded preparations outside the scope of preparations routinely provided (e.g., complex or rarely compounded preparations).
- Enable the organization to acquire additional resources and expertise to carry out other priorities (e.g., reallocation of existing staff to roles in patient care areas).

Staffing

- Help the organization to staff hard-to-fill pharmacy positions and address staffing vacancies.
- Allow the organization to reach optimal staffing levels for achieving productivity targets.

Financial and Cost Control

- Control or reduce the cost of the organization's services (e.g., by shifting costs associated with i.v. admixture production from fixed to variable).
- Control or reduce labor costs (e.g., by shifting responsibility for employees, benefits, and liabilities to a compounding pharmacy).
- Enable the organization to acquire a business partner to share the risks and other associated liability by defining the responsibilities associated with operating sterile compounding services.
- Minimize the cost of facility remodeling (e.g., to meet USP 797 requirements).

Quality Assurance

- Provide consistent pharmacy and sterile compounding services, including documented beyond-use dating.
- Enable the organization to maintain or improve the quality of patient care (e.g., by expanding clinical services or establishing new services).
- Provide support for the medical and nursing staffs and improve physician–nursing–pharmacy collaboration.
- Improve organizational procedures by learning from the compounding pharmacy's experience and knowledge, especially with new technologies (e.g., labeling, bar-coding, or tamper-evidence technologies).

Governmental and Regulatory

- Assist and ensure compliance with legal, regulatory, certification, and accreditation requirements.

Competitive

- Allow the organization to gain an edge on competitors through improvements in service, quality, or price.

Reasons Health Care Organizations Do Not Outsource Sterile Compounding Services. An organization's choice to continue providing its own sterile compounding services may be based on one or more of the following reasons.

Organizational and Operational

- The organization demonstrates that its sterile compounding services are cost-effective, well managed, and provided as efficiently as or better than they could be by a compounding pharmacy.
- Negative experiences with outsourcing pharmacy (or even nonpharmacy) services, or awareness of other organizations' negative experiences with such outsourcing.
- Concern about time delays in receiving compounded preparations, especially products that are needed urgently or have poor stability or short beyond-use times.
- Concern that the compounding pharmacy may experience interruptions in service, perhaps with little notice, due to quality-control issues not related to services provided to the organization.
- Concern that the decision to outsource sterile compounding services can be reversed only with great difficulty.
- Concern about losing short-term and long-term control over decisions regarding or expertise in sterile compounding services.

Staffing

- Concern that staff will be reduced to unacceptable levels.

Financial and Cost Control

- An assessment that outsourcing would increase rather than decrease costs.
- Concern that high-cost drugs might be excluded from contract agreements.
- Concern that the organization may not be able to re-capitalize sterile compounding services if outsourcing is unsuccessful.

Quality Assurance

- Concern that conflicting values and priorities of the compounding pharmacy and the organization will reduce quality.
- Concern about the qualifications or competencies of compounding pharmacy staff.

Professional Responsibility

- Concern that outsourcing sterile compounding will confuse or dilute the onsite pharmacists' ultimate professional and legal authority and responsibility for other medication-related activities and outcomes at the site.

Services Provided by Compounding Pharmacies

The needs of the health care organization should guide the identification of potential compounding pharmacies with the appropriate expertise and capabilities. Among the services that may be available from compounding pharmacies are

the preparation of implantable and external pump cartridges; total parenteral nutrition, dialysis, irrigation, or cardioplegia solutions; antibiotics; ophthalmic injectables and solutions; chemotherapy preparations; and analgesic preparations (patient-controlled analgesia, epidural, or regional nerve-block devices).

Compounding pharmacies are regulated in a number of ways. They may be registered as pharmacies and/or wholesalers in the states in which they dispense, as drug establishments and/or device manufacturers by the Food and Drug Administration (FDA), and/or as manufacturers by the Drug Enforcement Administration (DEA). FDA requires a device manufacturer registration for a compounding pharmacy to dispense devices such as dialysate solutions or heparin or citrate syringes. A compounding pharmacy registered as a drug establishment may apply for a labeler code that allows it to create National Drug Code (NDC) numbers for its products. These NDC numbers do not indicate FDA approval or that a New Drug Application has been filed, nor do they indicate a higher degree of quality (e.g., that terminal sterilization rather than an aseptic fill process has been used in compounding the preparation). Ascertaining that a preparation is labeled with an NDC number is therefore not a substitute for the due diligence required to verify a compounding pharmacy's quality processes (e.g., USP 797, current good manufacturing processes). Finally, compounding pharmacies are not permitted to prepare copies of commercial products. Dispensing of such products by compounding pharmacies will result in regulatory action, as FDA enforcement discretion does not apply to copies of commercial products.

Outsourcing Process

After the health care organization has completed an internal assessment of its needs and capabilities and decided to explore outsourcing, it should identify and contact reputable compounding pharmacies. Organizations that are part of a larger network (e.g., an integrated delivery network) may explore options that are available to them through the network or from other organizations in the network.

Some organizations simply identify prospective compounding pharmacies and ask them to submit a proposal. A more thorough approach is to require prospective compounding pharmacies to respond to a request for proposal (RFP). Although a formal RFP (and the compounding pharmacy's formal proposal based on the RFP) may not be necessary, the information found in typical RFPs and proposals may be helpful for making a decision about outsourcing.

Contents of RFPs. RFPs often include the following information:

- A description of the demographics of the organization making the RFP (e.g., number of hospitals, bed sizes, typical census).
- A description of the process the organization will use to select the compounding pharmacy.
- The organization's standard terms and conditions for contracting for services or, if available, a sample contract from the organization.
- The names and telephone numbers of individuals in the organization who are involved in the outsourcing decision (the organization's director of pharmacy should be included).
- A description of the specific services required of the compounding pharmacy (e.g., volume, intravenous admixture preparation, automated pharmacy systems, existing intravenous delivery systems and devices) and performance-measurement criteria or targets.
- The dates on which the organization's representatives can inspect the compounding pharmacy's facility, with reasonable notice.
- The number of copies of the proposal to submit.
- The name and address of the individual to whom the proposal is to be delivered.
- Acceptable methods for delivery of the proposal (e.g., e-mail, mail, delivery service, courier).
- A statement that the organization reserves the right to cancel its solicitation for services and reject any and all proposals.
- A deadline date and time for receipt of the proposal.
- The date on which the compounding pharmacy would be expected to initiate services.
- The date by which the selected compounding pharmacy must provide a written contract.
- Other requirements related to the proposal (e.g., that it be in a specific file format, include reference to an RFP number [if any], or be signed by an officer of the firm who is authorized to contract or his or her designee).

Contents of Proposals. RFPs should require prospective compounding pharmacies to submit the following information with their proposals:

- A brief history of the compounding pharmacy, including its mission, vision, and values.
- The location of the compounding pharmacy's offices and other facilities that would provide services to the organization.
- The compounding pharmacy's regular business hours or hours of operation and emergency and after-hours contact information.
- The names, addresses, telephone numbers, and résumés or background information on individuals who will provide the outsourced services.
- Assurance that all pharmacists employed at the compounding facility are licensed as required.
- Evidence of the following documentation regarding the compounding pharmacy:
 - Proof of current liability insurance.
 - Current accreditation or certification certificates, if applicable.
 - State pharmacy licensure and other appropriate licenses.
 - Licensure documents if the compounding pharmacy is registered with FDA as a drug establishment or device manufacturer.
 - Current DEA registration as a manufacturer or wholesaler.
 - Licensure of pharmacists employed and verification that they are in good standing on file and available for review.
 - Registration of pharmacy technicians employed and verification that they are in good standing on file and available for review, if applicable.

- Pharmacist and pharmacy technician notarized statements stating they have never been convicted of a drug-related misdemeanor or felony on file and available for review.
 - Standard operating procedures manual on file and available for review.
 - Pharmacist training manual on file and available for review.
 - Pharmacy technician training manual on file and available for review.
 - Policies and procedures for sterility testing on file and available for review.
 - Policies and procedures for pyrogen testing on file and available for review, if applicable.
 - Examples of batch reports for products being considered for outsourcing.
 - Examples of the quality-control reports.
 - Stability documents and clinical references, as well as any materials that are used to determine beyond-use dates.
 - A history of the results of all accreditation or regulatory surveys conducted of the compounding pharmacy's sites, including copies of significant regulatory actions.
 - Proof of professional liability, general liability, and workers' compensation insurance coverage (including the name, address, and telephone number of the insurance company).
 - Experience (e.g., years of experience in providing sterile compounding services, total number of clients served, current number of clients).
 - A list of the requested services that the compounding pharmacy can provide and the normal terms of service, including but not limited to normal delivery cycles, availability and cost of emergency preparation and delivery, remedies for failure to perform to the contract, specific goods and services to be provided, and the infrastructure available at the compounding pharmacy for electronic ordering.
 - A list of the requested sterile compounding services that the compounding pharmacy cannot provide and the reasons for its inability to provide them.
 - A copy of a standard or proposed contract.
 - A list of all fees and charges, including shipping, handling, and delivery charges, and any fees associated with order changes that would be billed under the contract and the billing methodology for their calculation.
 - A billing schedule and a copy of a sample bill for each of the preparations compounded by the compounding pharmacy.
 - A description of a routine delivery schedule (e.g., daily by a specified time) and options for nonroutine delivery (e.g., later the same day, after hours, weekends, holidays, during emergencies).
 - Examples of reports that the compounding pharmacy will be expected to submit to the organization.
 - Information relating to the compounding pharmacy's financial status and stability (e.g., balance sheets and audited financial statements for the past three years, bank references, lists of principal equity owners).
 - The process for requesting new preparations from the compounding pharmacy.
 - The names, addresses, and telephone numbers of
 - Current clients of a similar size or receiving similar types of compounded preparations, with written references and copies of annual performance-improvement reports, if possible.
 - Reference accounts served within the past two years and the reasons for all, if any, terminations of services.
- Additional information to obtain from the prospective compounding pharmacy but not necessarily contained in the proposal may include
- Whether the compounding pharmacy has had product liability lawsuits filed against it for preparations it compounded. If so, the compounding pharmacy should be asked to provide a description of the lawsuits filed, the file date of the lawsuits, and the outcome.
 - A description of the compounding pharmacy's formal procedures for conducting recalls and whether there have ever been recalls of any of its compounded preparations. If the compounding pharmacy has ever recalled any of its compounded preparations, it should be asked to provide the dates of recall, a description of the preparations recalled, and the reasons for the recall.
 - Information related to the delivery process (especially in the case of severe weather).
- Visits to Compounding Pharmacies and Their Clients.** Compounding pharmacies should allow the organization's representatives to visit their corporate offices and compounding facilities. The compounding pharmacy should provide ample opportunity for the organization's representatives to confer with the compounding pharmacy's corporate, pharmacy, and compounding staff.
- Evaluating Proposals.** A decision to outsource sterile compounding services should be collaborative and may involve, as appropriate, the governing board, the chief executive officer (CEO), the chief financial officer (CFO), the chief operating officer (COO), the chief of the medical staff, the chair of the pharmacy and therapeutics (P&T) committee, the director of nursing (DON), the director of pharmacy, legal counsel, and department heads, for example. The organization should scrutinize the following factors when evaluating proposals:
- Services offered versus services requested (including the compounding pharmacy's potential to enhance currently offered sterile compounding services).
 - Professional experience (e.g., years of service; number, size, and types of clients; knowledge of the organization's operations).
 - Quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment.
 - Financial stability (e.g., ability to absorb start-up expenses and to commit the resources needed to initiate service),
 - References and reputation.
 - Information systems and other technological infrastructure (e.g., the capability to interface with the organization's information and drug delivery systems, such

as infusion pumps or bar-coded medication administration systems).

- Demonstrated commitment to continually integrating technology and knowledge to improve patient safety.
- Education and training of compounding pharmacy's staff (e.g., internal and external continuing-education programs, educational allowances for professional and technical staff).
- The organization's and the compounding pharmacy's policies on specific compounding practices (e.g., references with real-time stability data supporting beyond-use dating, compliance with standards and regulations, use of USP–NF-grade ingredients or FDA-approved products in accordance with the organization's intended use).
- Risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities and that the medications dispensed are compatible with the client's medication administration devices (e.g., bar-code labeling, smart pumps).
- Knowledge of the regulatory requirements and accreditation standards that the customer must meet and willingness to assist customers in meeting these standards.
- Inventory and supply chain issues (e.g., the organization's and compounding pharmacy's back-order policies).
- Emergency-preparedness implications (e.g., the ability of the organization and the compounding pharmacy to deliver services in the event of a disaster).
- Additional qualities (e.g., high employee morale, confidentiality, creativity, dedication to the community, collaborative spirit).
- Cost aspects of services (e.g., cost-effectiveness, ability to achieve economies of scale).

The compounding pharmacy should, at a minimum, be able to

- Provide assurance that each compounded sterile preparation meets applicable state and federal labeling requirements and is sterile and free of pyrogens and unintended particulate matter, according to professionally established and accepted quality monitoring data.
- If the compounding pharmacy is compounding high-risk preparations, provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pyrogens and unintended particulate matter.
- Deliver appropriate compounded preparations in tamper-resistant packaging and in containers that will maintain proper storage temperature and (when required) protection from light during delivery and storage.
- Provide, upon request, batch records for any compounded sterile preparation.

The organization should assign an evaluation rating to each proposal. Ratings should be weighted appropriately with respect to services, experience, references, and cost. The organization should base its decision to outsource sterile compounding services on its assessment of the compounding facility's ability to meet the organization's needs and fulfill the terms of the contract.

Outsourcing Arrangement. The health care organization and the compounding facility should agree on the outsourcing arrangement that best meets their needs. The contract should clearly describe all aspects of the outsourcing arrangement. The health care organization's pharmacy should

- Ensure that the proper body of the health care organization (e.g., the organization's P&T committee) has developed a formal process to identify which preparations will (and which preparations will not) be prepared by the compounding pharmacy, based on the therapeutic needs of patients and logistical considerations associated with using a compounding pharmacy.
- Establish the components of the medication order or prescription.
- Determine whether patient consent must be obtained for use of preparations compounded outside the health care organization's pharmacy, consistent with state board of pharmacy regulations and prevailing law.
- Ensure that the agreement and the compounding pharmacy facility have been reviewed by all the necessary bodies in the pharmacy's health care organization (e.g., the organization's risk management team, legal counsel, P&T and infection control committees, epidemiology department staff).
- Determine how to handle situations in which a patient presents with a compounded medication that neither the health care organization's pharmacy nor the compounding pharmacy prepares under the existing agreement (e.g., medication in an implantable device, i.v. push medication, i.v. infusion) and that has not been previously considered by the P&T committee. Considerations include what the process will be for
 - Having the P&T committee consider outsourcing the compounding of such medications to a compounding pharmacy.
 - Acquiring such medications from a compounding pharmacy that the health care organization does not have an agreement with and how the associated liability risks will be addressed until the P&T committee decision is obtained regarding such medications.
 - Continuing to acquire such medications if the compounding pharmacy already under contract cannot or will not prepare them and how the associated liability risks will be addressed (e.g., whether the health care organization's pharmacy will negotiate an agreement with another compounding pharmacy that does compound the preparation) until the P&T committee decision is obtained regarding such medications.

Negotiating the Contract. The health care organization should carefully review the proposal and clarify the provisions of the contract. Active participation by the health care organization's risk management and legal counsel is highly recommended. Negotiations can ensure a contract that best meets the needs of the health care organization and the compounding pharmacy. ASHP believes that the health care organization's pharmacist-in-charge (e.g., a pharmacy director) must take complete responsibility for patient outcomes from all medication-related activities performed at or for the

organization's work sites, whether they are carried out by the organization's staff or by off-site contractors. This responsibility should be explicitly stated in all outsourcing contracts.

The signed contract between the parties should at a minimum

- Describe the term length of the agreement and the processes for the compounding pharmacy's billing to the health care organization, including methods of determining the charge for the compounded items, payment terms, and processes for resolution of disputed invoices.
- Contain a confidentiality clause and a Health Insurance Portability and Accountability Act business associate agreement, if applicable.
- Establish the pharmacy's right to inspect the premises of the compounding facility at any time with reasonable notice, including the right to inspect quality-control reports.
- Describe the method of communicating the medication order or prescription from the health care organization's pharmacy to the compounding pharmacy (e.g., telephone, fax, computer transmission, hard copy, electronic DEA form 222).
- Protect the health care organization from liabilities created by errors made by the compounding pharmacy and delineate the obligations of both parties.
- Establish preparation recall procedures that comply with hospital policy mandates and prevailing law should a preparation need to be recalled by the compounding pharmacy.
- Address documentation, regulatory and accreditation compliance, sterile compounding process, and compounded preparation considerations.
- Describe the pertinent situations and processes for the return of compounded preparations to the compounding pharmacy.
- Describe any requirements regarding the submission of quality reports by the compounding pharmacy.
- Describe the procedures for resolving preparation or delivery issues encountered by the organization or the compounding pharmacy.
- Describe the contents of ancillary agreements or addenda to the contract (e.g., the "expectations agreement" between the organization and the compounding pharmacy).

Organizations often find it convenient to outline expectations that are subject to frequent change in an addendum to the contract, because that allows the addendum to be updated rather than the entire contract. If such terms are not included in the contract, the expectation agreement should

- Delineate routine sterile compounding turnaround times (e.g., from receipt of the medication order or prescription by the compounding pharmacy to delivery to the health care organization) and describe acceptable deviations from the agreed-upon schedules (e.g., raw product availability problems, unique end-product testing requirements, compounded preparation stability characteristics, nonroutine and emergency requests).
- Describe the specific drugs provided, documentation flow, delivery methods, security considerations,

and time frames for the provision of controlled substances by the compounding pharmacy.

- Describe any special processes, documentation flow, delivery methods, security considerations, and time frames for the provision of hazardous drugs by the compounding pharmacy.

Signing the Contract. In some organizations the director of pharmacy may be authorized to sign contracts for outsourced services. If this is not the case, the director of pharmacy must be fully involved in negotiating the contract and advising the authorized signers.

Contract Provisions

A contract that meets the needs of the health care organization and of the compounding pharmacy is the foundation for a successful relationship. Contracts should specifically describe the respective responsibilities of the organization and the compounding pharmacy. See the appendix for examples of contract provisions.

Evaluation of Compounding Pharmacy's Performance

The health care organization should evaluate and document the compounding pharmacy's performance and assess the compounding pharmacy's compliance with the terms of the contract. The compounding pharmacy should regularly submit quality reports, and the organization should regularly perform objective and subjective evaluations (e.g., quarterly, annually). Evaluations should address all measurable standards of performance specified in the contract. Evaluations should be multidisciplinary and should involve, for example, the CEO, CFO, COO, DON, and medical staff representatives, as appropriate. An evaluation may include an assessment of how well the compounding pharmacy has

- Improved the quality of patient care.
- Responded to the organization's needs (e.g., invoicing, process adjustment).
- Helped the organization achieve its financial and patient-outcome goals.
- Improved the productivity and performance of pharmacy staff.
- Improved pharmacy processes (e.g., medication dispensing and delivery).
- Reduced and controlled pharmacy costs without compromising patient care.
- Worked and communicated effectively with the organization's staff and resolved problems.

Handling Performance or Quality Issues

The compounding pharmacy should provide the health care organization with information at least quarterly on its compliance with contract requirements and other information needed for the organization's quality-assurance programs. A mechanism should be in place for resolving preparation or delivery issues (e.g., delivery to the wrong location, late deliveries).

Conclusion

These guidelines offer an overview of factors and processes for health care organizations to consider when exploring the outsourcing of pharmacy sterile compounding. Such considerations include an internal needs assessment, a cost analysis, a careful review of prospective compounding pharmacies, and an examination of the potential long-term consequences of outsourcing as well as the short-term outcomes expected during a contract's performance period. The ideas presented can be used for strategic planning, drafting of initial contract provisions, comparing prospective compounding pharmacies, preparing for contract negotiations, or evaluating a compounding pharmacy's performance. These guidelines are intended to address representative outsourcing options and contract agreements and may not be applicable to all situations. Managers of pharmacy and health care organizations should exercise professional judgment about applicability to their own needs and circumstances.

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Suggested Readings

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Appendix—Contract Provisions

The following are examples of contract provisions that, among others, the organization and a compounding pharmacy might adapt as needed and include in a contract, depending on the scope of services being considered. In addition, a contract would include provisions about the specific compounding services to be provided by the compounding pharmacy. The language in contract provisions should always be adapted to meet the specific needs of the health care organization and to comply with the organization's contracting policies and applicable laws and regulations.

In reviewing the following list of suggested contract provisions, attention should be paid to the fact that listed provisions are not intended and should not be considered all-inclusive and do not constitute legal advice but rather are provided solely to convey general information related to legal issues commonly addressed in contracts for the outsourcing of sterile compounding services. The purpose of enumerating the following possible contract provisions is to provide a general understanding of the types of provisions that may be included in a contract. Because laws vary from jurisdiction to jurisdiction and are subject to varying interpretations, health care organizations considering outsourcing sterile compounding services should consult with professional legal counsel in their relevant jurisdictions regarding the drafting of contracts.

Accreditation and Certification. A contract should include a requirement that services meet or exceed applicable accreditation and certification standards. These include, but are not limited to, the standards (or requirements) of the following organizations.

- The Joint Commission
- American Osteopathic Association
- Center for Medicare and Medicaid Services
- Pharmacy Compounding Accreditation Board

After-Hours Access. This section describes the process and extent of access to off-site compounding pharmacy resources after normal business hours.

Choice of Law. The contract should state that the contract is governed by the laws of the state in which patient care is provided.

Compounding Pharmacy Indemnification. This section describes in detail the indemnities the compounding pharmacy owes the health care organization, such as

Contractor shall indemnify and defend Customer and its Affiliates, and each of their respective officers, directors, trustees, employees, agents, and representatives (collectively, the “Customer Indemnities”) and hold them harmless from and against any and all Losses on account of any Claims asserted by a third party in connection with, arising from, or related to (a) any of the

acts or omissions to this Agreement attached hereto, (b) breach of Contractor's representations, (c) injuries to persons, including death, or damage to property caused by Contractor's agents, servants, or employees, or in any way attributable to Contractor's performance and prosecution of this Agreement, and (d) any sexual harassment or other illegal sexual advances upon any of Customer's employees, contractors, agents, or other personnel by any of Contractor's employees, independent contractors, or other personnel.

Compounding Pharmacy Performance Responsibilities.

The off-site compounding center's responsibilities and commitments associated with proper federal and state licensure and regulatory requirements for all the preparations it compounds are outlined in this section (e.g., labeling). It further describes the compounding center's responsibilities to operate in accordance with applicable Good Manufacturing Practices, Drug Enforcement Agency (DEA) requirements (as applicable), *United States Pharmacopeia (USP) 797* requirements, and company standard operating procedures.

Compounding Pharmacy Reports. The content and regularity of performance reports that the compounding pharmacy will submit to the organization may be specified.

Confidential Information. This section describes what information is considered confidential and actions that are required to prevent unauthorized distribution of such information. Both parties must agree to safeguard access to computer databases and patient records to ensure that the patient's rights to privacy and confidentiality are protected. Use of the information should be limited solely to purposes specified in the contract.

Customer Responsibilities. This section describes the health-system pharmacy's responsibilities for affirming that it has all required state, local, and federal licenses associated with the receipt of services being provided by the off-site compounding pharmacy. It may also describe the health care organization's responsibilities for determining clinical appropriateness of any compounded preparation it purchases from an off-site compounding pharmacy as well as the procedures to be used to ensure the traceability of compounded preparations.

Extension of Period of Performance. Conditions for extending the period of performance should be included in the contract.

Force Majeure. This section describes when neither party shall be liable for nonperformance or delays related to causes that are beyond one's reasonable control.

Forms. Responsibilities for the design, approval, purchase, and storage of forms may be assigned.

General Provisions. This section outlines a myriad of other contractual items, such as contract assignment, process for adding or changing compounding services, reference to other agreements, and reference to other applicable terms outside of the services agreement.

Hazardous Drug Preparations. Responsibilities for ensuring the safety of the organization's staff and patients during delivery and distribution of hazardous drug preparations may be assigned. Either the organization or the compounding pharmacy should provide a hazardous materials handling program, including staff training,

that meets ASHP guidelines and Occupational Safety and Health Administration (OSHA) requirements.

Indemnification. This section describes specific conditions under which both parties will hold each other harmless for, and potentially defend, the actions of the other.

Information Transfer. This section describes the mechanisms by which the organization transfers orders and other information to the compounding pharmacy.

Laws, Rules, and Regulations. Requirements for services to meet or exceed federal, state, and local laws, rules, and regulations may be specified. These include but are not limited to those of FDA, DEA, OSHA, *USP*, and the state board of pharmacy. The compounding pharmacy should maintain (e.g., display, file) the appropriate licenses, permits, and records of equipment maintenance and certification. Any compounding pharmacy required to be licensed as a manufacturer must be so licensed.

Liability Insurance. This section describes the responsibility for maintaining liability insurance coverage. The contract might specify, for example, the specific level of liability insurance coverage that the health care organization and the compounding pharmacy must maintain.

Payment Terms. This section describes the agreed-upon number of days from receipt of an invoice by the health care organization's pharmacy until payment is due to the compounding pharmacy.

Period of Performance. This section specifies the period for which the compounding pharmacy will provide services to the organization.

Pricing. The price of each service the hospital pharmacy is interested in purchasing from the off-site compounding pharmacy along with conditions and methodology for price increases is described in this section. Shipping, handling, and delivery charges for both routine and non-routine deliveries should also be detailed.

Policies and Procedures. This section describes the required written policies and procedures covering the outsourced services, all of which should comply with applicable laws, regulations, and accreditation or certification standards. The contract should specify that the policies and procedures must not conflict with those of the organization.

Record Maintenance. The contract should specify that all pertinent records must be kept for the time required by law and by the organization and describe how, where, and by whom the record will be maintained.

Requirements. This section establishes a mutual understanding of annual purchase volume commitments between the health care organization's pharmacy and the compounding pharmacy.

Staff Education and Training. Responsibilities for required ongoing staff or compounding pharmacy education and training may be specified. For example, there might be an agreement that the compounding pharmacy's staff will participate in some of the organization's education and training programs. In addition, the compounding pharmacy may agree to provide specific training to ensure that all compounding pharmacy and health care organization personnel can perform the duties created by the compounding pharmacy's services.

Successors. The rights of each party in the event that the health care organization or compounding pharmacy merges or transfers its business or assets to a successor should be addressed in a contract.

Term of Agreement. This section communicates the length of time the agreement is in effect between the health care organization and the compounding pharmacy, including renewals.

Termination. This section describes how and when the contract will end or be terminated, including early termination. It should also address any penalties which may be appropriate or when the contract may be ended without penalty.

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