ASHP Guidelines on Outsourcing Sterile Compounding Services

Purpose

The purpose of these guidelines is to provide an overview of factors and processes for healthcare organizations to consider when contracting with compounding pharmacies or outsourcing facilities to obtain sterile compounding services. These guidelines describe services available from compounding pharmacies or outsourcing facilities, reasons for outsourcing and reasons for not outsourcing, the outsourcing process and outsourcing arrangements, and recommendations for evaluating a contractor'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] The concepts presented in this document could be used for strategic planning with the organization's decision-makers, assisting in assessing the quality of compounded sterile preparations or products, drafting contract provisions, comparing prospective contractors, preparing for contract negotiations, and evaluating contractor performance.

This document addresses representative outsourcing options and contract agreements and is not intended to cover all situations. Managers of pharmacy and healthcare organizations should use their professional judgment about applicability to their own needs and circumstances.

Developed through the ASHP Council on Pharmacy Management and approved by the ASHP Board of Directors on June 6, 2015. These guidelines supersede the ASHP Guidelines on Outsourcing Sterile Compounding Services dated January 14, 2010. These guidelines are currently in press at the *American Journal of Health-System Pharmacy*.

Services Provided by Vendors of Outsourced Sterile Compounding Services

The Drug Quality and Security Act (DQSA) of 2013[4] dramatically changed federal regulation of pharmacy compounding. The DQSA amended the federal Food, Drug, and Cosmetic (FD&C) Act, carving out a safe harbor for traditional, prescription-based compounding pharmacies (called "503A compounding pharmacies" for the section of the FD&C Act that regulates them, or more simply, "compounding pharmacies") and creating a new category of drug establishment, Human Drug Compounding Outsourcing Facilities. These facilities (frequently referred to as "registered 503B outsourcing facilities" for the section of the FD&C Act that regulates them, or more simply "outsourcing facilities") are permitted to engage in the manufacture and interstate shipment of larger quantities of compounded sterile drug products without prescriptions or medication orders. (For the purposes of these guidelines, both types of entities are referred to as "vendors of outsourced sterile compounding services," or simply "vendors.") The regulatory changes spawned by DQSA have significant implications for compounding pharmacies, outsourcing facilities, and their customers. Healthcare organizations considering outsourcing sterile compounding services need to have a clear understanding of how these two distinct types of entities are regulated (Table 1).

Compounding Pharmacies. Section 503A clarified the FD&C Act for activities described as traditional patient-specific compounding (sometimes now called "503A compounding"). Healthcare organization pharmacies fall into this category, as do other pharmacies that fill prescriptions or medication orders within a prescriber-pharmacist-patient professional relationship. All 503A compounding pharmacies, except those in federal facilities, are regulated

by state boards of pharmacy; however, they may also be subject to FDA inspection under the agency's authority to enforce Section 503A of the FD&C Act. The agency's expectations for compliance are specified in the *FDA Compliance Policy Guide* (CPG) *on Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*.[5] In addition to current regulatory requirements, such as prescriptions or medication orders for compounded preparations and compliance with applicable *United State Pharmacopeia* (*USP)* chapters on compounding (i.e., *USP* chapters 795[8] and 797[9]), inspectors may look for implementation of additional CPG recommendations. The services provided by compounding pharmacies are limited by the existing requirement for individual prescriptions or medication orders and may be further limited by forthcoming regulation of distribution across state lines,[7] state and federal restrictions on office-use preparations, and other limitations of section 503A.

Outsourcing Facilities. Section 503B outsourcing facilities are not required by federal regulation to be licensed pharmacies or fill prescriptions or medication orders; however, a licensed pharmacist must supervise compounding. Outsourcing facilities are federally regulated by the FDA, which has established guidance documents for the industry that will be updated as necessary. Outsourcing facilities must comply with applicable Current Good Manufacturing Practices (CGMPs) established under section 503B by the FDA,[6] which differ from those for manufacturers. States may establish additional requirements with which outsourcing facilities must comply. All outsourcing facilities are inspected by the FDA. The frequency of reinspections is determined by a risk-based schedule. Inspection findings are documented on a Form FDA-483, Inspectional Observations. A Form FDA-483 is used to notify the entity of any concerns or

potential violations and provide an opportunity for correction prior to enforcement action.[10] The establishment may work with inspectors to resolve issues during the inspection or respond in writing with a corrective action plan, usually within 15 days. Contents of these forms are publicly available.[11] However, findings in 483 reports do not represent a final determination of noncompliance, nor is information available indicating that findings have been satisfactorily resolved.

Healthcare organization pharmacy leaders must be aware of the quality standards that should be expected from outsourcing facilities.[12,13] In a letter sent to hospitals in January 2014, the FDA encouraged healthcare organizations to purchase compounded sterile drugs from FDA-registered outsourcing facilities.[14] Although the FDA usually inspects an outsourcing facility soon after registration (unless the facility has been inspected previously), pharmacy leaders should be aware that registration does not necessarily mean that a particular outsourcing facility has been inspected and found to meet FDA standards. The FDA website listing registered outsourcing (503B) facilities[15] provides dates of initial and most recent registration as an outsourcing facility; the end date of last FDA inspection related to compounding; whether a Form FDA-483 issued; FDA action taken, if any, based on the last inspection; and whether the outsourcing facility intends to compounds sterile drugs from nonsterile bulk active pharmaceutical ingredients (APIs). Leaders should bear in mind that FDA or state inspections only reflect conditions at one particular time and should consider a facility's history as well as its most recent results.

Environmental Influences Affecting Outsourcing Decision

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

Organizational and Operational

- Elimination of or reduction in the size of traditional pharmacy departments, re-engineering, and downsizing initiatives.
- Limited available physical or technological resources (e.g., sterile compounding area, inventory storage area, engineering controls) to provide the specific desired services.
- Consolidation and integration of health systems and departments within health systems, including pressure to provide pharmacy services to acquired entities (e.g., physician practices).
- Implementation of automated pharmacy systems and the attendant need to reorganize medication preparation and distribution functions.
- Inability to cost-effectively perform in-house testing to establish extended beyond-use dating for sterile preparations.
- Federal restriction under section 503A of the DQSA on the distribution of compounded sterile preparations from a central site in the healthcare organization to other campuses of the same system.*

* At the time of writing, the FDA had not issued final guidance on interstate distribution by 503A facilities.[7]

Staffing

- Shortage of pharmacy personnel with specific experience and capabilities, especially regarding sterile preparation.
- Lack of resources, experience, or investment to effectively train staff on sterile compounding and aseptic technique.

Financial and Cost Control

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

Drug Shortages

- Unavailability of medications or specific dosage forms.
- Conservation of limited supplies of available medications.

Quality Assurance

- Increased expectations of and pressures from payers, regulatory agencies, 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

- Increased federal and state interest in standards for sterile compounding (i.e., *United States Pharmacopeia* [*USP*] chapter 797[9]).

Competitive

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

Purposes of Outsourcing

Healthcare organizations should conduct an in-depth assessment to decide whether outsourcing is a good option for meeting their needs. Reasons for their decision will vary according to a variety of factors, some of which are outlined below. As with use of other contracted services, hospital leadership must be included in the decision-making process for outsourcing. 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 pharmacy, the director of nursing (DON), legal counsel, medication safety officer, risk management director, and department heads, for example.

Reasons Healthcare 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 qualified consultant. Contracting with a compounding pharmacy or outsourcing facility may produce one or more of the following results.

Organizational and Operational

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

Staffing

- Allow organizations to acquire quality compounded sterile preparations or products without hiring for hard-to-fill pharmacy positions and to concentrate on other staffing priorities.
- Allow the organization to reach optimal staffing levels for achieving quality and productivity targets.

Financial and Cost Control

- Control or reduce the cost of the organization's services (e.g., by shifting costs associated

with sterile compounding services from fixed to variable).

- Control or reduce labor costs (e.g., by shifting responsibility for employees, benefits, and liabilities to a compounding pharmacy or outsourcing facility).
- Enable the organization to acquire a business partner to share the risks and other associated liability by delineating and contracting for the responsibilities associated with operating sterile compounding services.
- Minimize the cost of facility remodeling or maintenance (e.g., to meet *USP* chapter 797[9] or 800[16] requirements).

Quality Assurance

- Provide consistent and high-quality pharmacy and sterile compounding services, including documented or extended beyond-use dating[†] and batch-level sterility, potency, and endotoxin testing.
- Enable the organization to maintain or improve the quality of patient care (e.g., by expanding clinical services or establishing new services).
- Enhance patient safety by providing more medications in dose-specific, ready-to-administer form.
- Provide support for the medical and nursing staffs and improve prescriber–nursing–pharmacy collaboration.

[†]Draft CGMP limits on beyond-use dates (BUDs) for 503B outsourcing facilities may present challenges to those purchasing them. For sterile preserved drugs, the longest permissible BUD is 30 days beyond completion of a sterility test. If a sterility test is completed before release, the BUD must not exceed 14 days (at USP controlled room temperature or refrigerated) beyond completion of the test (e.g., for a 14-day sterility test, the BUD could not exceed 28 days).For terminally sterilized products without a sterility test, the BUD cannot 14 days. And for aseptically processed products without a sterility test, the BUD cannot exceed 24 hours at USP controlled room temperature or 3 days refrigerated. BUDs for frozen products are considerably longer.[6]

- Improve organizational procedures by learning from contractors' experience and knowledge, especially with technologies used to improve safety (e.g., labeling, bar-coding, or tamper-evident technologies).

Governmental and Regulatory

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

Reasons Healthcare 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 meet the requirements and standards of *USP* chapter 797[9]; comply with applicable local, state, and federal regulations; are cost-effective, well managed, and provided as efficiently as or better than services that could be provided by a compounding pharmacy or an outsourcing facility.
- Negative experiences with outsourcing other clinical services, or awareness of other organizations' negative experiences with such outsourcing.
- Concern about time delays in receiving compounded sterile preparations or products, especially ones that are needed urgently or have poor stability or short beyond-use times.

- Concern that the contractor 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- 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 recapitalize sterile compounding services if outsourcing is unsuccessful.

Quality Assurance

- Concern that conflicting values and priorities of the contractor and the organization will reduce quality.
- Loss of direct control over quality assurance procedures for the compounding process.
- Concern about the qualifications or competencies of contractors' pharmacy staff.

Governmental and Regulatory

- Legal, regulatory, certification, and accreditation requirements may hinder operational efficiencies.

Outsourcing Process

The needs of the healthcare organization should guide the identification of potential vendors of outsourced sterile compounding services with the appropriate expertise and capabilities. Among the services that may be available from such vendors are the preparation of implantable and external pump cartridges; total parenteral nutrition; cardiovascular solutions; anesthesia syringes and solutions; dialysis, irrigation, or cardioplegia solutions; continuous renal replacement therapy, hydration, and oxytocin solutions; antibiotics; ophthalmic injectables and solutions; chemotherapy preparations; and analgesic preparations (patient-controlled analgesia, epidural, or regional nerve-block devices).

After the healthcare organization has completed an internal assessment of its needs and capabilities and decided to explore outsourcing, it should identify and contact vendors of outsourced sterile compounding services.

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. Health systems may be exempt from registering as a 503B entity if they compound medications for the health system's own patients in response to a prescription or medication order or in a "limited quantity" in anticipation of such prescriptions or orders, based on a history of such prescriptions or orders, as long as the pharmacy complies

with state laws.[5] This exemption is expected to be clarified by the FDA in the future.[13]

Many organizations begin to identify prospective contractors through a request for information (RFI). The RFI should provide:

- A short history of the prospective contractor, including number of years in business, number and location of facilities, approximate number of customers served, and approximate volume of compounded sterile products or preparations delivered per month or year.
- The prospective contractor's regulatory status (i.e., compounding pharmacy or registered outsourcing facility), and applicable licensure/registration information (e.g., pharmacy license number).
- Whether the prospective contractor compounds sterile preparations or products from nonsterile bulk APIs (for registered outsourcing facilities, this information is available on the FDA Registered Outsourcing Facilities website.[15]
- Description of products and services typically available (e.g., customer support, website), value-added services available (e.g., clinical support), and typical ordering process and turnaround times.
- Representative prices for specified compounded sterile products or preparations and services at an annual unit demand.
- Whether the prospective contractor has any contracts with group purchasing organizations.
- A description of the prospective contractor's backup facility capabilities and business continuity/disaster recovery plans.

- Whether the prospective contractor has ever been the subject of an enforcement or accreditation action.

After prospective contractors have been identified through RFIs, many organizations require them to respond to a more detailed request for proposal (RFP). Although a formal RFP (and the contractor's formal proposal based on the RFP) may not always be necessary, the information found in typical RFPs and prospective contractor responses or proposals is often helpful in making a systematic 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 contractor.
- 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 contractor (e.g., desired drugs, strengths, concentrations, diluents, container systems, and annual demand) and performance-measurement criteria or targets. Special packaging, handling, and delivery procedures for hazardous drugs should be included.
- A request for documentation of follow-up and correction of any enforcement or

accreditation findings.

- The dates on which the organization's representatives can inspect the contractor's facility, with reasonable notice. (Inspections by the organization's representatives will be more important when contracting with vendors that are not regularly inspected by the FDA or state inspectors.)
- 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 for any reason or for no reason.
- A deadline date and time for receipt of the proposal.
- The date on which the contractor would be expected to initiate services.
- The date by which the selected contractor 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 Responses or Proposals. RFPs should require prospective contractors to submit the following information with their responses or proposals:

- A brief history of the contractor, including its mission, vision, and values.
- A history of the results of all regulatory or accreditation surveys conducted of the

contractor's sites, including copies of significant regulatory actions.

- The location of the contractor's offices and other facilities that would provide services to the organization.
- The contractor'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 services.
- Assurance that all pharmacists employed at the compounding facility are licensed as required and all technicians involved in the compounding process are registered (if required by the state or by the healthcare organization's policy).
- Evidence of the following documentation regarding the contractor:
    - Proof and description of coverage of current liability insurance.
    - Current accreditation or certification certificates, if applicable.
    - State pharmacy licensure or other appropriate licenses.
    - Registration with the FDA as an outsourcing facility, which can be obtained on the FDA registered outsourcing facilities webpage.[15]
    - Proof of FDA registration as a device manufacturer, if applicable.
    - Current DEA registration, consistent with federal and state regulations.
    - 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 or proof of background check on file and available for review.
  - Pharmacist and pharmacy technician training manual on file and available for review.
  - Standard operating procedures manual on file and available for review.
  - Certificates of analysis for nonsterile ingredients used in compounding on file and available for review, if applicable.
  - Policies and procedures for stability testing on file and available for review.
  - Policies and procedures for sterility assurance 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 on file and available for review.
  - Examples of the quality-control and quality assurance reports.
  - Stability documents and clinical references, as well as any materials that are used to determine beyond-use dates on file and available for review. (Because studies used to establish beyond-use dates are sometimes considered proprietary, compounding service providers may require a nondisclosure agreement.)
- 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 contractor 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 site for electronic ordering.
- A list of the requested sterile compounding services that the contractor cannot provide and the reasons for its inability to provide them.
- Expectation statements to assist in meeting Centers for Medicare & Medicaid Services (CMS) requirements[17] and accreditation organization standards[18-23] related to contracted services, if applicable.
- 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 contractor.
- 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 contractor will be expected to submit to the organization.
- The process for requesting new preparations from the contractor.

- The contractor's policy on unannounced inspections by its customers.
- The names, addresses, and telephone numbers of:
  - Current clients of a similar size or receiving similar types of compounded preparations or products, with written references and copies of annual performance-improvement reports, if possible.
  - Reference accounts currently served.

Additional information to obtain from the prospective contractor but not necessarily contained in the proposal may include:

- Whether the contractor has had product liability lawsuits filed against it for preparations it compounded. If so, the contractor should be asked to provide a description of the lawsuits filed, the file date of the lawsuits, and the outcome, although such information is sometimes sealed as part of a settlement or decision and may not be disclosable.
- A description of the contractor's formal procedures for conducting recalls and whether there have ever been recalls of any of its compounded preparations. If the contractor 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. Outsourcing facilities must comply with the specific requirements of the FDA for 503B entities, which include having procedures for putting into place corrective and preventive actions.[6]
- Information related to the delivery process and backup planning when severe or catastrophic events happen (e.g., severe weather).

Visits to Contractors and Their Clients. Outsourcing facilities and compounding pharmacies should allow the organization's representatives to visit their corporate offices and compounding facilities. The contractor should provide ample opportunity for the organization's representatives to confer with the contractor's corporate, pharmacy, and compounding staff. During the evaluation phase, the organization's representative should expect to give notice of a visit, but after a contract has been signed the contractor should allow unannounced inspections provided that the visit will be conducted in a manner that does not interfere with daily activity or compromise the microbial state of control.

For outsourcing facilities, the FDA inspection report and documentation of follow-up and correction of any enforcement or accreditation findings should be reviewed in advance of the visit. For compounding pharmacies, the healthcare organization should, in addition to requesting any FDA or state inspection reports and any applicable accreditation reports, assess the contractor's compliance with *USP* chapter 797 using a standard tool, such as the ASHP Foundation Contractor Assessment Tool for Outsourcing Sterile Products Preparation.[24]

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 pharmacy, the director of nursing (DON), legal counsel, medication safety officer, risk management director, and department heads, for example. The organization should scrutinize the following factors when evaluating proposals:

- Services offered versus services requested (including the contractor's potential to enhance currently offered sterile compounding services or customize to the organization's needs).
- 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, environmental monitoring, 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 the contractor's staff (e.g., internal and external continuing-education programs, educational allowances for professional and technical staff).
- The organization's and the contractor'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., automated distribution devices, barcode labeling, smart pumps).

- Knowledge of the regulatory requirements and accreditation standards that the organization must meet and willingness to assist the organization in meeting these standards.
- Inventory and supply chain issues (e.g., the organization's and contractor's back-order policies, the contractor's ability to produce drug products in shortage through validated compounding procedures).
- Emergency-preparedness implications (e.g., the ability of the organization and the contractor 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 contractor should, at a minimum, be able to:

- Provide assurance that each compounded sterile preparation or product meets applicable state and federal labeling requirements and is sterile and free of endotoxins (when required) and unintended particulate matter, according to professionally established and accepted quality monitoring data.
- If the contractor is extending beyond-use dates longer than defined in *USP* chapter 797,[9] confirm the validity of those beyond-use dates with stability and strength,[25] sterility, and

endotoxin testing that is available for review.

- If the contractor is compounding high-risk preparations or products, provide documentation of the end product testing processes used to determine that the preparations or products are sterile, free of endotoxins and unintended particulate matter, and (for preparations or products made from bulk APIs) meet the strength requirements of the drug.
- Deliver appropriate preparations or products in tamper-resistant packaging and in containers that will maintain the sterility and stability of the drugs. All products must be shipped under proper storage temperatures and (when required) protection from light.

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 contractor's ability to meet the organization's needs and fulfill the terms of the contract.

Outsourcing Arrangement. The healthcare organization and the contractor should agree on the outsourcing arrangement that best meets their needs. The contract should clearly describe all aspects of the outsourcing arrangement. The healthcare organization's pharmacy should:

- Ensure that the proper body of the healthcare 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 contractor, based on the organization's

assessment of the therapeutic needs of patients and logistical considerations associated with outsourcing.

- Establish the components of the medication order or prescription.
- Determine whether patient consent must be obtained for use of preparations compounded outside the healthcare organization's pharmacy, consistent with state board of pharmacy regulations and prevailing law.
- Determine a method for identifying patients receiving the contractor's preparations or products.
- Ensure that the contract and the contractor's facility have been reviewed by all the necessary bodies in the pharmacy's healthcare 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 is not available from the healthcare organization's pharmacy or the contractor under the existing contract (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 another contractor with which the healthcare organization has an agreement.
    - Acquiring certain compounded medications if the contractor already under contract cannot or will not prepare them and how the associated liability risks will be

addressed (e.g., how the healthcare organization's pharmacy will negotiate an agreement with another contractor from which the preparation or product is available) until the P&T committee decision is obtained regarding such medications.

Negotiating the Contract. The healthcare organization should carefully review the proposal and clarify the provisions of the contract. Active participation by the healthcare organization's risk management and legal counsel is highly recommended. Negotiations can ensure a contract that best meets the needs of the healthcare organization and the contractor. ASHP believes that the healthcare organization's pharmacist-in-charge (e.g., a pharmacy director) must take 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 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 contract and the processes for the contractor's billing to the healthcare 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 unannounced inspections of the premises where compounding occurs, including the right to inspect quality-control reports, provided that the visit will be conducted in a manner that does not interfere with daily activity or compromise the microbial state of control.

- Describe the method of communicating the medication order or prescription from the healthcare organization's pharmacy to the contractor (e.g., telephone, fax, computer transmission, hard copy, controlled substance ordering system.
- Protect both parties from liabilities created by errors made by the other party and delineate the obligations of both parties.[26]
- Establish recall procedures that comply with hospital policy mandates and prevailing law should a preparation or product need to be recalled by the contractor.
- Address documentation, regulatory and accreditation compliance, sterile compounding process, and compounded preparation or product considerations.
- Describe the pertinent situations and processes for the return, credit, or destruction of compounded preparations or products with the contractor.
- Describe any requirements regarding the submission of quality reports by the contractor.
- Describe the procedures for resolving preparation or delivery issues encountered by the organization or the contractor.
- Describe the expectations to be met by the contractor. These expectations must comply with CMS Hospital Conditions of Participation for Contracted Services requirements,[17] which state (in part) that "The governing body must ensure that a contractor of services … furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services." Hospital accreditation organizations (The Joint Commission,[18] DNV GL Healthcare,[19] Healthcare Facilities Accreditation Program,[20] and the Center for Improvement in Healthcare Quality[21]) and other accreditation organizations (e.g., the Accreditation Commission for Health Care's

Pharmacy Compounding Accreditation Board,[22] National Association of Boards of Pharmacy Verified Pharmacy Program[23]) have additional standards that must be addressed.

Both operational and quality expectations should be defined by the organization, such as expectations that:

- Delineate routine sterile compounding turnaround times (e.g., from receipt of the request, medication order, or prescription by the contractor to delivery to the healthcare 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 delivery requests).
- Describe the specific drugs provided, documentation flow, delivery methods, security considerations, and time frames for the provision of controlled substances by the contractor.
- Describe any special processes, documentation flow, delivery methods, security considerations, and time frames for the provision of hazardous drugs by the contractor.
- Describe the frequency of quality statements provided to the healthcare organization, such as quarterly summaries of facility, personnel, and environmental monitoring.

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 healthcare organization and of the contractor is the foundation for a successful relationship. Contracts should specifically describe the respective responsibilities of the organization and the contractor. See the appendix for examples of contract provisions.

Evaluation of the Contractor's Performance

The healthcare organization must evaluate and document the contractor's performance and assess the contractor's compliance with the terms of the contract. The contractor should regularly submit quality reports, and the organization must 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 led by the Director of Pharmacy, 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 contractor has:

- Helped improve the quality of patient care.
- Responded to the organization's needs (e.g., invoicing, process adjustment).
- Met their contractual obligations, including timely and complete deliveries of products.
- Provided clear and concise quality metric data ensuring compliance with state and federal regulations and patient-safety standards.

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

Handling Performance or Quality Issues

The contractor should provide the healthcare 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 healthcare 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 outsourcing facilities and 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 contractors, preparing for contract negotiations, or evaluating a contractor'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 healthcare organizations should exercise professional judgment about applicability to their own needs and circumstances.

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Appendix—Contract Provisions

The following are examples of contract provisions that, among others, the organization and a contractor 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 contractor. The language in contract provisions should always be adapted to meet the specific needs of the healthcare 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, healthcare 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.

- Centers for Medicare & Medicaid Services[17]
- The Joint Commission[18]
- DNV-GL Healthcare[19]
- American Osteopathic Association[20]
- Center for Improvement of Healthcare Quality[21]
- Pharmacy Compounding Accreditation Board[22]
- National Association of Boards of Pharmacy Verified Pharmacy Program[23]

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

Choice of Law. The contract should state by which state law the contract is governed.

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.

Contractor. The outsourcing facility or compounding pharmacy contracted by the healthcare organization to provide sterile compounding services.

Contractor Indemnification. This section describes in detail the indemnities the contractor owes the healthcare 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 related to the services and/or products provided pursuant to this Contract attached hereto, (b) breach of Contractor's representations and warranties, (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 of this Contract, and (d) any breach of any laws or regulations in connection with Contractor's performance of services or provision of products pursuant to the Contract.

Contractor Reports. The content and regularity of performance reports that the contractor will submit to the organization may be specified.

Contractor's Performance Responsibilities. The contractor's responsibilities and commitments associated with proper federal (if necessary) and state licensure and regulatory requirements for all the preparations or products it compounds are outlined in this section (e.g., labeling). It further describes the contractor's responsibilities to operate in accordance with applicable Current Good Manufacturing Practices, United States Pharmacopeia (USP) compounding standards, Drug Enforcement Agency (DEA) requirements (as applicable), and company standard operating procedures.

Customer Responsibilities. This section describes the healthcare organization 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 contractor. It may also describe the healthcare organization's responsibilities for determining clinical appropriateness of any compounded preparation or product it purchases from the contractor as well as the procedures to be used to ensure the traceability of compounded preparations or products.

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 the services agreement.

Hazardous Drug Preparations or Products. Responsibilities for ensuring the safety of the organization's staff and patients during delivery and distribution of hazardous drug preparations or products may be assigned. Either the organization or the contractor must provide a hazardous materials handling program, including staff training, that meets ASHP guidelines, Occupational Safety and Health Administration (OSHA) requirements, and United States Pharmacopeia (USP) compounding standards.

Indemnification. This section describes specific conditions under which, and responsibilities for 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 contractor.

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 contractor should maintain (e.g., display, file) the appropriate licenses, permits, and records of equipment maintenance and certification. Any contractor required to be registered as an outsourcing facility must be so registered.

Liability Insurance. This section describes the responsibility for maintaining liability insurance coverage. The contract might specify, for example, the specific level and types of liability insurance coverage that the healthcare organization and the contractor must maintain.

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

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

Pricing. The price of each service the hospital pharmacy is interested in purchasing from the contractor along with conditions and methodology for price increases is described in this section, which may be an addendum to the contract. 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.

Purchase Volume Requirements. This section establishes a mutual understanding of annual purchase volume commitments between the healthcare organization's pharmacy and the contractor.

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 records will be maintained.

Staff Education and Training. Responsibilities for required ongoing staff training may be specified. For example, there might be a clause in the contract that the contractor's staff will participate in some of the organization's education and training programs. In addition, the contractor may agree to provide specific training to ensure that all contractor and healthcare organization personnel can perform the duties created by the contractor's services.

Successors. The rights of each party in the event that the healthcare organization or contractor merges or transfers its business or assets to a successor are described in this section.

Term of Agreement. This section communicates the length of time the agreement is in effect between the healthcare organization and the contractor, 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.

Table 1. Differences between compounding pharmacies and outsourcing facilities.

	503A Compounding Pharmacies	**503B Registered Outsourcing Facilities**
Regulatory authority	State boards of pharmacy	FDA, according to guidelines established by federal legislation; states may add requirements
Applicable standards	USP compounding standards; FDA Compliance Policy Guide on Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act[5]	Applicable 503B-specific FDA Current Good Manufacturing Practices[6] (CGMPs); subject to additional state requirements
FDA inspection	Subject to FDA inspection under authority to enforce Section 503A	Subject to risk-based FDA inspection and enforcement procedures
State inspection	Subject to state board of pharmacy inspection	May be subject to state inspection if state law imposes additional requirements
Limitations on services	• May only dispense pursuant to an individual prescription or medication order for an identified patient • Anticipatory compounding of "limited quantities" is permitted, but a prescription or medication order is required prior to dispensing[5] • FDA limitations on interstate distribution, either 5% or 30%, depending on whether state has entered into an MOU with FDA* • May *not* compound: ○ Drugs that present demonstrable difficulties for compounding ○ Copies of FDA-approved products ○ Drugs using certain prohibited bulk substances	• Not required to be a licensed pharmacy or obtain prescriptions for specific patients • May compound and maintain inventory of compounded products in anticipation of customer orders • No federal limit on interstate commerce; some state regulations may apply • Compounding from bulk API only allowed for drugs on approved list • May compound copies of FDA-approved products from bulk substances if on FDA shortage list
Office Use Compounding	Not yet addressed in FDA guidance[5]	Permitted; resale prohibited but "resale" does not include administration or dispensing by the purchaser[4]
Labeling Requirements	As mandated by state law and regulation	Must include "Office Use", "This is a compounded drug", "Not for Resale"

*At the time of writing, the FDA had not issued final guidance on interstate distribution by 503A facilities but had proposed a 30% limit on interstate distribution of compounded sterile preparations by 503A compounding pharmacies in states that had entered into a memorandum of understanding (MOU) with FDA and a 5% limit in states which had not entered into an MOU.[7]

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