

ASHP Guidelines on Outsourcing Pharmaceutical Services

Purpose

Health-system pharmacy, as an essential component in health care organizations, is challenged by changes in the structure and financing of health care to reduce costs and improve performance. One option being used to achieve these goals is outsourcing. Outsourcing is a formal arrangement by which a health care organization contracts with an outside company to obtain selected pharmaceutical services or comprehensive management of the organization's pharmacy. Through this arrangement, the organization negotiates a contract with a company to access its expertise, technologies, and resources.

ASHP believes that the 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 or contractor's onsite staff or by the contractor off site. This responsibility should be explicitly stated in all outsourcing contracts.

Health care organizations considering outsourcing pharmaceutical 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 possible contractors. 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. 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 contractors, for preparing for contract negotiations, or for evaluating a contractor's performance. These guidelines may be applied, for example, to independent and networked acute care hospitals, ambulatory care clinics, and home care providers.

This document includes ideas about reasons for outsourcing and reasons for not outsourcing, services available from contractors, the outsourcing process and outsourcing arrangements, and evaluation of contractor performance. The appendix provides a topical list of contract provisions, some of which relate to specific pharmaceutical services, pharmacy practices, or administrative functions that may be the subject of other ASHP practice standards. Organizations should refer to pertinent ASHP practice standards for additional information on which to base their contract provisions, agreements, and decisions. 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

Various environmental influences and market forces that may contribute to outsourcing being considered as an option include the following.

Organizational and Operational

- 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 departments
- Reorganization around patient-focused care
- Implementation of automated pharmacy systems and the attendant need to reorganize medication distribution functions

Staffing

- Shortage of nurses and other health care professionals
- Shortage of pharmacists 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 instead of clinical outcomes

Quality

- Increased expectations of and pressures from accreditation organizations and consumer groups to improve the quality of patient care

Governmental and Regulatory

- Increased numbers of individuals dependent on federal, state, and local governments for health care
- Reduced ability of federal, state, and local governments to finance health care
- Increased government controls on reimbursement for health care

Competitive

- Increased competition among health care 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 Pharmaceutical Services. Organizations tend to outsource pharmaceutical services when guided by a careful assessment of their capabilities of providing services themselves, when unsuccessful in

using their own resources to provide services, or, in some cases, when influenced by 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., by improving medication distribution systems, designing new pharmacy workspaces, reducing medication dispensing and administration errors, and improving computer and information systems)
 - Enable the organization to acquire additional resources and expertise to carry out other changes (e.g., reallocation of existing staff to pharmaceutical care roles in patient care areas)
 - Provide educational programs for patients and their families and for health care staff

Staffing

- Help the organization to staff hard-to-fill pharmacy positions
- 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
- Control or reduce labor costs (e.g., by shifting the cost of employees, benefits, and liabilities to a contractor)
- Enable the organization to acquire a contractor who will share the risks associated with operating the pharmaceutical services
- Avoid the cost of purchasing and maintaining pharmacy equipment
- Avoid the cost of physical remodeling (e.g., by using an offsite contractor to provide specific services for which remodeling would be required)
- Increase the organization's financial operating margin (e.g., by allowing the organization to purchase drugs in bulk quantities, use group purchasing contracts, decrease lost charges, improve billing accuracy, decrease drug diversion and pilferage, improve drug formularies, and transfer drug inventory, equipment, and supply activities to a contractor)

Quality

- Enable the organization to maintain or improve the quality of patient care (e.g., by expanding clinical services and pharmaceutical care, establishing new services, and obtaining specialized expertise in pharmaceutical care)
- Provide support for the medical and nursing staffs and improve physician–nursing–pharmacy collaboration

Governmental and regulatory

- Correct regulatory and accreditation problems relating to pharmaceutical services
- Ensure continuing compliance with accreditation and certification standards

Competitive

- Enhance the organization's image
- Allow the organization to gain an edge on competitors through improvements in service, quality, or price

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

Organizational and operational

- A belief that pharmaceutical services are well managed and are provided as effectively as or better than they could be by a contractor
- Negative experiences with outsourcing contractors (pharmacy or nonpharmacy) or awareness of other organizations' negative experiences with such contractors
- Concern that the decision to outsource pharmaceutical services can be reversed only with great difficulty
- A belief that the organization's needs are currently met cost-effectively and that changes are therefore unnecessary
- Concern about losing short-term and long-term control over decisions about pharmaceutical services
- Concern about reduced involvement of pharmacy leadership in organizationwide initiatives (e.g., development and implementation of information systems, clinical care plans or pathways, and disease management)

Staffing

- Concern that staff will be reduced to unacceptable levels
- Concern about potentially alienating relationships between pharmacists and other health care staff

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 pharmaceutical services if outsourcing is unsuccessful

Quality

- Concern that conflicting values and priorities of the outsourcing contractor and the organization will reduce quality
- Concern that clinical quality could be reduced as a result of a loss of continuity of pharmacy staffing and relationships with medical and nursing staffs

Professional responsibility

- Concern that outsourcing will confuse or dilute the on-site pharmacists' ultimate professional authority and responsibility for all medication-related activities and outcomes at the site

Pharmaceutical Services Provided by Contractors

Some contractors manage and provide comprehensive pharmaceutical services. Other contractors focus more on providing specialty services or carrying out specific tasks (e.g., drug information services, offsite preparation of sterile products). The needs of the health care organization should guide the identification of potential contractors

with the appropriate expertise and capabilities. Examples of services that may be available from contractors follow. (This list is likely to grow over time.)

Organizational and Operational

- Development of pharmacy policies, procedures, and processes
- Pharmacy record-keeping systems
- Productivity reviews
- Feasibility studies on expanding services (e.g., outpatient dispensing and home infusion)
- Unit dose medication distribution
- Pharmacy-based or offsite preparation of sterile products
- Pharmacokinetic monitoring and dosage determinations
- Medication therapy monitoring (e.g., for appropriate and effective use)
- Investigational drug programs
- Patient profile reviews
- Medication therapy-related consultation with physicians, nurses, and other health care professionals
- Assessment of patients' nutritional needs
- Guidance in purchasing and implementing automated pharmacy equipment
- Educational programs for patients, families, and caregivers
- Drug information services
- Packaging and repackaging of pharmaceuticals

Staffing

- Competency assessment and performance review
- Management, operational, and clinical training
- Recruitment and retention assistance

Financial and Cost-Control

- Billing
- Inventory control
- Formulary management

Quality

- Performance improvement (including improvement of medication use and reduction of medication errors)
- Quality assurance

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 and experienced contractors. Some organizations simply identify prospective contractors and ask them to submit a proposal. A more thorough approach is to require prospective contractors to respond to a request for proposals (RFP). Although a formal RFP (and the contractor'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 organization (including statistical information)

- The organization's financial status (e.g., a current balance sheet and audited financial statement, the pharmacy's financial status)
- A description of the process the organization will use to select the contractor
- The organization's standard terms and conditions for contracting for services
- The names and telephone numbers of individuals in the organization who are involved in the outsourcing decision (the director of pharmacy should be included)
- A description of the specific outsourced services required of the contractor (e.g., pharmacy workspace design, intravenous admixture preparation, and implementation of an automated pharmacy system) and performance-measurement criteria or targets
- The date(s) on which the contractor can inspect the facility and the pharmacy
- 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 method(s) for delivery of the proposal (e.g., 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 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 typewritten, that it include reference to an RFP number [if any], that it be signed by an officer of the firm who is authorized to contract)

Contents of Proposals. RFPs often require contractors to submit the following information with their proposals.

- A brief history of the contractor, including its mission, vision, and values
- The location of the contractor's offices and other facilities that would provide services to the organization
- The names, addresses, telephone numbers, and résumés or background information on the individual(s) who will provide the services
- Evidence that the contractor can provide qualified staff who are licensed or eligible for licensure by federal, state, and local agencies and a history of turnover in management, pharmacist, and support staff
- A history of the results of Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Health Care Financing Administration, National Committee for Quality Assurance, state, or other accreditation or regulatory surveys conducted in the contractor's sites
- Proof of professional liability, general liability, and workers'-compensation insurance coverage (including the name, address, and telephone number of the insurance company) and a history of claims filed against the contractor
- Minimum-experience requirements (e.g., years of experience in providing outsourced pharmacy-management services, total number of clients served, current number of clients)

- A list of the requested services that the contractor can provide
- A list of the requested services that the contractor cannot provide and the reasons for the contractor's inability to provide them
- Evidence of organizational and staff experience and competence (including nature and extent) in the services the contractor can provide (e.g., pharmaceutical care, specialty clinical practice, antineoplastic medication preparation, enteral and parenteral nutrition solution preparation), as pertinent
- A copy of a standard or proposed contract
- A list of all fees and charges that would be billed under the contract and the detailed methods for their calculation, as well as a billing schedule
- A description of reports that the contractor will be expected to submit to the organization
- Information relating to the contractor'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 names, addresses, and telephone numbers of current clients receiving similar services
- The names, addresses, and telephone numbers of other clients served within the past two years and the reasons for all, if any, terminations of services
- Written references and copies of annual performance-improvement reports from clients of a similar size with similar types of patients

Visits to Contractors and Their Clients. Contractors should allow the organization's representatives to visit their corporate offices and production facilities and to tour pharmacies in the facilities of other clients. The contractor should provide ample opportunity for the organization's representatives to confer with the contractor's corporate and pharmacy staff.

Evaluating Proposals. A decision to outsource pharmaceutical services should be collaborative and should 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 committee, the director of nursing (DON), the director of pharmacy, and department heads, for example. The organization should scrutinize the following factors when evaluating proposals.

- Services offered versus services requested (including the contractor's ability to enhance current services)
- Professional experience (e.g., years of service; number, size, and types of clients; knowledge of the client's business)
- Financial stability (e.g., ability to absorb start-up expenses and to commit the resources needed to effect change)
- References and reputation (e.g., client-satisfaction reports, reputation in the health care industry, commitment to improving patient care)
- Technology or automated pharmacy systems (e.g., up-to-date hardware, proprietary software, the capability to interface with the organization's information systems)
- Education and training (e.g., internal and external continuing-education programs, educational allowances for professional and technical staff)

- Additional qualities (e.g., high employee morale, confidentiality, creativity, sensitivity to minorities and the community, willingness to share risks and rewards)
- Cost aspects of services (e.g., cost-effectiveness, ability to affect economies of scale)

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

Negotiating the Contract. The organization should carefully review the proposal and clarify the provisions of the contract. Assistance from the organization's risk-management and legal counsel may be necessary. Negotiations can ensure a contract that best meets the needs of the organization and the contractor.

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 should be fully involved in negotiating the contract and advising the authorized signer(s).

Outsourcing Arrangement

The health care organization and the contractor should agree on the outsourcing arrangement that best meets their needs. Several outsourcing options are available to health care organizations. Variations and combinations of these options are common. The contract should clearly describe the outsourcing arrangement. Examples of outsourcing arrangements include the following.

Consulting. The contractor acts as a pharmacy consultant to the organization. Some consulting arrangements are limited to an assessment of all pharmaceutical services or to specific aspects of pharmaceutical services (e.g., clinical pharmacy services, productivity, compliance with JCAHO standards). Other consulting arrangements may include advising the pharmacy and helping it to improve its services.

Onsite Advisor. The contractor provides a full-time onsite advisor to the organization's director of pharmacy. The advisor works with the director of pharmacy and others, as needed, to carry out programs that will fulfill the contract provisions.

Management of Specific Pharmaceutical Services. The contractor provides one or more specific services (e.g., i.v. admixture preparation, drug information, stock replenishment, medication distribution). Services may be provided onsite or at an offsite location.

Comprehensive Management. The contractor assumes complete responsibility for operating the pharmacy and may provide some or all of the pharmacy staff.

Contract Provisions

A contract that meets the needs of the health care organization and of the contractor is the foundation for a successful

relationship. Contracts should include provisions of the outsourcing arrangement that describe agreements between the organization and the contractor concerning their respective responsibilities. These provisions will vary depending on the kind and scope of services outsourced. For example, contractors who prepare sterile products at an offsite location will not require onsite pharmacy space and utilities. Also, the assignment of responsibilities may vary. A contract may specify that the organization will purchase all drugs. Conversely, another contract may assign this responsibility to the contractor. See the appendix for examples of contract provisions.

Evaluation of Contractor's Performance

Health care organizations should evaluate and document their contractor's performance and assess their contractor's compliance with the terms of the contract. Objective and subjective evaluations should be regular (e.g., quarterly or annually). Evaluations should address all measurable standards of performance that are 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 contractor performed the following functions.

- Improved the quality of patient care
- Responded to the organization's needs
- Helped the organization to achieve its financial and patient-outcome goals
- Evaluated the productivity and performance of pharmacy staff
- Provided continuing education for pharmacy staff
- Implemented and improved pharmacy clinical programs
- 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 interdepartmental problems
- Participated effectively in the organization's performance-improvement program

Suggested Reading

1. Curtis FR, Stai HC. Contract pharmacy services. In: Brown TR, ed. Handbook of institutional pharmacy practice, 3rd ed. Bethesda, MD: American Society of Hospital Pharmacists; 1992: 299–306.
2. Talley CR. Outsourcing drug distribution. *Am J Health-Syst Pharm.* 1997; 54:37. Editorial.
3. Schneider PJ. Outsourcing: a key to professional survival. *Am J Health-Syst Pharm.* 1997; 54:41–3.
4. Lazarus HL. Outsourcing: a success story. *Am J Health-Syst Pharm.* 1997; 54:43–4.
5. Puckett WH. Outsourcing: taking the first step. *Am J Health-Syst Pharm.* 1997; 54:45–8.
6. Kolar GR. Outsourcing: route to a new pharmacy practice model. *Am J Health-Syst Pharm.* 1997; 54:48–52.
7. Eckel FM. Outsourcing: at odds with pharmacy's professional foundation. *Am J Health-Syst Pharm.* 1997; 54:52–5.

8. Gates DM, Smolarek RT, Stevenson JG. Outsourcing the preparation of parenteral nutrient solutions. *Am J Health-Syst Pharm.* 1996; 53:2176–8.
9. Burruss RA, Carroll NV, Schraa C, et al. Outsourcing inpatient IV compounding: expense and medication error implications. *Pharm Pract Manage Q.* 1996; 16(3):52–9.
10. McAllister JC III. Collaborating with re-engineering consultants: maintaining resources for the future. *Am J Health-Syst Pharm.* 1995; 52:2676–80.
11. Anderson RJ. Clinical service contracts between hospital pharmacy departments and colleges of pharmacy. *Am J Hosp Pharm.* 1991; 48:1994–7.
12. Murphy JE, Ward ES, Job ML. Implementing and maintaining a private pharmacokinetics practice. *Am J Hosp Pharm.* 1990; 47:591–7.
13. Souhrada L. Contract management. *Hospitals.* 1990; 64(8):66–8.
14. Wagner M. Basic pitfalls can undermine hospital–service firm relationship. *Mod Healthc.* 1993; 23(8):32.
15. Wagner M. Contract-managed pharmacy departments are just the prescription at some hospitals. *Mod Healthc.* 1988; 18(8):36–40.

Appendix—Contract Provisions

The following are examples of contract provisions that, among others, the organization and 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 pharmaceutical services to be provided by the contractor. The language in contract provisions should be adapted to meet the needs of the health care organization and to comply with the organization's contracting policies and applicable laws and regulations.

Accreditation and Certification: A contract may 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.

- Joint Commission on Accreditation of Health-care Organizations
- American Osteopathic Association
- Health Care Financing Administration
- National Committee for Quality Assurance

After-Hours Pharmaceutical Services when 24-Hour Services Are Not Provided: The contractor may agree, for example, to provide an after-hours stock of drug products for authorized staff to use in filling urgent medication orders. In addition, the contractor may agree to ensure that a pharmacist is on call or available to return to the facility to provide pharmaceutical services.

Automation: A contract may outline responsibilities for the purchase or lease and the use of automated medication storage and distribution equipment and software associated with the equipment.

Choice of Law: There may be a statement that the contract is governed by the laws of the state in which patient care is provided.

Compensation for Contractor's Services: There may be compensation arrangements, which vary greatly but are often based on one or more of the following principles.

- Management fee(s)
- Fee per item dispensed or service performed
- Fixed fee per patient per patient day, admission, discharge, adjusted patient day, adjusted admission, or adjusted discharge

Besides agreeing on a compensation arrangement, the organization and the contractor may agree on ways for the contractor to share the financial risk of contract performance with the organization; these might include guarantees or incentives for meeting targets and penalties for underperformance.

Computer Equipment and Information Systems: A contract may outline responsibilities for the purchase, ownership, and maintenance of computer equipment and related software. Agreements might extend to personal computers used by pharmacy staff. There should be clear agreement about access to and use of data generated by the information system.

Confidentiality: There may be a requirement that information not generally available to the public (e.g., financial statements, medical records, market information) be kept confidential. Both parties must agree to safeguard access to computer databases and patient records to ensure that the patient's rights to privacy and confidentiality is protected. Use of the information should be limited solely to purposes specified in the contract.

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

Controlled Substances: Responsibilities may be assigned for the procurement and security of controlled substances in compliance with Drug Enforcement Administration (DEA) and state regulations. For example, the organization may be required to

- Register with the DEA and any state equivalent for each site involved
- Assume complete responsibility for record keeping and security of controlled substances throughout the facility
- Ask the contractor to maintain proper records and provide adequate security for controlled substances as required by federal, state, and local laws and regulations and
- Verify that the contractor maintains proper records and provides adequate security for controlled substances

It may be necessary for the organization to grant power of attorney to the contractor to order and purchase controlled substances.

Similarly, the contractor may be required to

- Ensure that all registrations are current
- Order and maintain an adequate stock of controlled substances
- Ensure compliance with record-keeping and security requirements
- Inform the organization of problems with compliance

Cost Control: A contract may include objectives, methods, and performance measures for controlling costs.

Cytotoxic and Hazardous Drug Products: Responsibilities for ensuring the safety of the organization's staff and patients during the preparation and distribution of cytotoxic and hazardous drug products may be assigned. Either the organization or the contractor should pro-

vide a hazardous-materials handling program, including staff training, that meets Occupational Safety and Health Administration (OSHA) requirements.

Drug Inventory Disposition upon Termination of the Contract: A provision for the disposition of the drug inventory is based on inventory ownership. In cases in which the drug inventory may be purchased by either party, a mutually acceptable, independent appraiser could decide the purchase price. Legal advice may be needed to ensure that purchases comply with the Prescription Drug Marketing Act and other applicable laws and regulations.

Drug Inventory Ownership: If the contractor purchases the organization's inventory, a mutually acceptable, independent appraiser could decide the purchase price. Expired and other unusable drugs should be excluded from the purchase. The contractor could agree to obtain credit for the organization for expired and other unusable drugs if credit is obtainable. Legal advice may be needed to ensure that purchases comply with the Prescription Drug Marketing Act and other applicable laws and regulations.

Drug Ordering: A contract may assign responsibilities for selecting vendors and purchasing drug supplies for the organization. The contract should specify that all drugs used must be subject to approval by the organization's pharmacy and therapeutics (P&T) committee or its equivalent. The organization should understand how purchasing discounts are accounted for, recorded, and distributed. The impact of removing pharmacy items from group purchasing programs should be clear also.

Early Termination: There may be conditions for early termination of the contract.

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

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

Formulary System: A contract may assign responsibilities for evaluation of medications, collaboration with the P&T committee, and provision of formulary-related information services.

Hours of Pharmacy Operation: A contract may specify hours of operation that meet or exceed legal requirements and that are sufficient to serve patients' needs.

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, and the state board of pharmacy. The pharmacy should maintain (e.g., display, file) the appropriate licenses, permits, and records of equipment maintenance and certification. Any contractor required to be licensed as a manufacturer must be so licensed. The organization may agree to allow the contractor to act on the organization's behalf in communicating with the state board of pharmacy and other regulatory agencies.

Liability Insurance: Responsibilities for maintaining liability insurance coverage for the acts of employees may be assigned. The contract might specify, for example, that the contractor must maintain adequate liability insurance coverage for the acts of its employees.

Nondiscrimination: There might be a requirement that the contractor abide by all laws and regulations relating to discrimination in appointments, promotions, and terminations.

Ownership of Equipment, Fixtures, and Supplies: A contract may specify ownership of equipment, fixtures, and supplies and responsibilities for ensuring that equipment is maintained and certified according to applicable practice standards, laws, and regulations.

Performance Improvement: Responsibilities for establishing any performance-improvement programs and integrating them with the organization's performance-improvement activities may be included. Performance-improvement programs might be appropriate, for example, for the ordering, dispensing, and administering of medications and for the monitoring of medication effects and misadventures, including adverse drug reactions and adverse drug events.

Period of Performance: The contract might specify the period for which the contractor will provide services to the organization.

Pharmacy Staff Education and Training: Responsibilities for required ongoing staff education and training may be specified. For example, there might be an agreement that the contractor's staff will participate in the organization's education and training programs. In addition, the contractor may agree to provide specific training to ensure that all pharmacy personnel can perform any duties imposed by contractor-implemented functions.

Pharmacy Staff Employment: There may be a provision for the employment of pharmacists and technical and support personnel; this may specify those who will be employed by the organization and those who will be employed by the contractor. Whether employed by the organization or by the contractor, all staff should be competent and legally qualified. The organization should retain the right to assess, accept, or reject the performance of any of the contractor's staff who are used at the organization's work sites.

Pharmacy Staff Expenses: Responsibilities for any personnel expenses may be assigned. A contract might specify, for example, that the organization will be responsible for the salary, wages, and benefits of its employees whereas the contractor will be responsible for such expenses for its own employees. The contract might also allocate expenses for parking, meal discounts, and similar privileges for employees.

Pharmacy Staff Levels: There may be a requirement that the staffing levels for the contracted services be sufficient to meet the organization's needs.

Pharmacy Staff Orientation: A contract may assign responsibilities for orientation of all new pharmacy staff members to the organization and to the pharmacy, according to the organization's requirements.

Pharmacy Staff Performance: Responsibilities for pharmacy staff competency assessments and performance evaluations and for ensuring that assessments and evaluations are based on criteria in the individual's job description may be assigned.

Policies and Procedures: Responsibilities may be assigned for developing 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.

Purchasing and Accounts Payable: Responsibilities for maintaining the pharmacy's purchasing and accounts-payable functions, including ordering drugs, monitoring costs, and authorizing payment to vendors, might be specified.

Record Maintenance: A contract may assign responsibilities for maintaining and storing records. The contract should specify that all pertinent records must be kept for the time required by law and by the organization.

Space: Responsibilities for space required by the contractor to provide onsite services might be outlined. The organization should agree to provide space for the provision of onsite contractor services that is acceptable to the contractor and within the guidelines of the agencies that regulate the practice of pharmacy. Organizations might agree to provide the following facilities, depending on the contract's scope of services.

- Adequate square footage
- Space for preparing, compounding, packaging, and storing drugs under proper conditions
- Space for receiving and storing intravenous fluids and supplies
- Refrigerators and freezers
- Adequate space for maintaining and storing pharmacy records
- Laminar-airflow hoods and biological safety cabinets (if needed)

Sterile Products: A contract might include requirements for the quality of sterile products provided by the contractor. The contractor should ensure that sterile products (e.g., large-volume intravenous admixtures, total parenteral nutrient solutions) are prepared and labeled in a suitable environment by trained and competent employees. The contractor should provide quality-control information periodically and on demand. For services that involve deliveries, the contract should specify order cutoff and delivery times, any penalties for late deliveries, and arrangements for after-hours or emergency services and deliveries.

Successors: The rights of each party in the event that the organization or contractor merges or transfers its business or assets to a successor may be included in a contract.

Utilities: A contract may assign responsibility for utilities required by the contractor to provide onsite services. These utilities may include the following, as appropriate.

- Electrical service
- Water
- Heating and air conditioning
- Plumbing
- Janitorial services
- Internal and external telephone services (allowance might be made for a private external telephone line for the contractor)
- Security
- Waste disposal

These guidelines were reviewed in 2013 by the Council on Pharmacy Management and by the Board of Directors and were found to still be appropriate.

Approved by the ASHP Board of Directors, April 22, 1998.
Developed through the Council on Administrative Affairs.

Copyright © 1998, American Society of Health-System Pharmacists, Inc. All rights reserved.

The bibliographic citation for this document is as follows: American Society of Health-System Pharmacists. ASHP guidelines on outsourcing pharmaceutical services. *Am J Health-Syst Pharm.* 1998; 55:1611–7.