DRAFT ASHP Guidelines on Selecting Pharmaceutical Manufacturers and Suppliers

Pharmacists are responsible for selecting, from hundreds of manufacturers and suppliers, those that will enable them to fulfill an important obligation: ensuring that patients receive pharmaceuticals and related supplies of the highest quality and at the lowest cost, even during times of market shortages. (For purposes of these guidelines, *pharmaceutical* refers to a drug product or preparation.) Pharmacists are also responsible for ensuring manufacturers and suppliers can meet regulatory requirements, such as Drug Supply Chain Security Act (DSCSA).[1]

The purpose of these guidelines is to provide criteria pharmacists should consider when purchasing products from suppliers, including criteria regarding

- product specifications and quality;
- supply integrity, consistency, and recalls;
- regulatory compliance (e.g., with the DSCSA, compounding requirements, 503A and 503A facility guidance, and 340B Drug Pricing Program and orphan drug program requirements);
- product safety;
- product distribution;
- marketing and sales policies; and
- contracting and billing procedures.

The guidelines also provide recommendations to optimize the purchasing process, including

recommendations regarding business partnerships and practices, the role of the chief pharmacy officer (CPO), the role of group purchasing organizations (GPOs), bidding procedures, and supplier access.

The recommendations in these guidelines represent a consensus of professional judgment, expert opinion, and documented evidence. They are written to establish reasonable goals, to be progressive and challenging, yet attainable as best practices in applicable settings. They do not represent minimum levels of practice, and pharmacy professionals are encouraged to exercise their professional judgment in assessing and adapting these recommendations to meet the specific needs of their healthcare organizations.

Obligations of the supplier

Pharmacists should consider the criteria presented below when purchasing products from suppliers. Other factors (e.g., payment terms, credit policies, delivery times, and the breadth of a supplier's product line) will also need to be considered when selecting a supplier.

Product specifications and quality

Suppliers should make available to the purchasing organization all information related to the product design, testing, and quality and safety standards.[2] In addition, suppliers must follow regulatory guidelines and laws associated with the manufacturing and packaging of pharmaceuticals.

1. On request of the pharmacist, the supplier should furnish
    a. Analytical control data.

b. Sterility testing data.

c. Bioavailability data.

d. Bioequivalency data.

e. Descriptions of testing procedures for raw materials and finished products.

f. Any other information that may be indicative of the quality of a given finished drug product.

Testing data developed by independent laboratories should be identified by the supplier. All information should be supplied at no charge.

2. All drug products should conform to the current requirements of *The United States Pharmacopeia–The National Formulary (USP–NF)*,[3] unless otherwise specified by the pharmacist. Items not recognized by *USP–NF* should meet the specifications set forth by the pharmacist.
3. Therapeutic, biopharmaceutic, and toxicologic information should be available to the pharmacist on request; toxicity information should be available at all times.
4. Patient and staff educational materials that are important for proper use of the product should be routinely available.
5. On request, the supplier should furnish proof of any claims made with respect to the efficacy, safety, and superiority of its products.
6. On request, the supplier should furnish, at no charge, a reasonable quantity of its products to enable the pharmacist to evaluate the products' physical traits, including pharmaceutical elegance (appearance and absence of physical deterioration or flaws), packaging, and labeling.

Supply integrity, consistency, and recalls

Purchasing organizations face many challenges related to pharmaceutical procurement. Obtaining pharmaceuticals in a safe and efficient manner is more challenging in the setting of frequent shortages and recalls. Changing suppliers on a frequent basis can lead to patient safety concerns and can divert limited resources from patient care to procurement. Purchasing organizations should assess a supplier's ability to provide quality products and escalate production to meet demand. Purchasers are also responsible for assessing the integrity of suppliers and pharmaceuticals during times of market shortage to ensure product quality.[4]

Purchasers should consider the history of supplier performance regarding to recalls and shortages, including but not limited to the following.

1. There should be no history of recurring product recalls indicative of deficient quality control procedures.
2. A supplier should have a network of reliable and quality back-up suppliers during times of shortage.
3. Suppliers who manage product on consignment should have a plan in place to clearly define the distribution process during times of market shortage.
4. The supplier should permit visits (during normal business hours) by the pharmacist to inspect its manufacturing and control procedures.
5. The supplier should be willing to provide clear and complete information about production sites, manufacturing redundancies, and disaster plan management.
6. Performance metrics (e.g., purchasing discrepancies, controlled substance management, Drug Enforcement Administration [DEA] inspection results) should be readily accessible

and shared with the purchasing organization regularly and upon request.

7. The supplier should have FDA inspection reports and corresponding corrective action plans readily accessible and share them with the purchasing organization at the time of engagement and following any inspection thereafter.
8. Supplier reputation and capacity for managing supply should be considered. Suppliers that engage in excessive price increases should be avoided, and purchasing organizations should look for alternative products or suppliers if possible.
9. The supplier should have a process for the purchasing organization to report defective products and receive a replacement product. The supplier should also have a quality program in place to prevent defective products from being shipped to the purchasing organization.
10. The purchasing organization should consider the following factors when purchasing pharmaceuticals that have been repackaged: (1) Pharmaceuticals are properly labeled and packaged. (2) The supplier follows current good manufacturer practices. (3) Products are labeled to allow for traceability.[5]
11. Purchasing organizations should use strict supplier vetting policies to prevent sales from nonreputable or gray market suppliers. Purchasing organizations should also confirm that the supplier has a license within the state, complies with DSCSA requirements, and has stored the product properly. Purchasing organizations should exercise caution when purchasing pharmaceuticals from suppliers when the primary wholesalers are out of product. Having one point of contact within the purchasing organization can be helpful in mitigating adverse exposure from conducting business with nonreputable suppliers.

12. Methods to identify gray market suppliers could include the following: (1) Supplier has ample product when the primary wholesalers are out of stock. (2) Supplier has marked up products over 100% compared to products purchased directly from primary wholesaler. (3) Supplier will not offer additional pedigree for product purchased.

Regulatory compliance

The pharmaceutical supply chain is governed by a number of regulatory bodies that protect key stakeholders in the supply chain. The DSCSA defines requirements to trace illegitimate drugs in the supply chain. Suppliers should meet all the requirements of DSCSA and should recognize that government agencies will conduct studies to identify compliance with these policies. In addition, oversight agencies, such as the Office of the Inspector General, may provide guidance and standards that need to be considered by stakeholders in the supply chain. The FDA 503A and 503B guidances provide directions for pharmacies and outsourcing facilities on sterile compounding compliance.[6-8] The FDA takes action on compounders that are noncompliant and pose a safety risk to the public. Similarly, compliance with the 340B program ensures covered entities are utilizing savings in the spirit of the law and that manufacturers are treated fairly. Finally, regulation of alternative supply chains is not well established but will be an emerging trend as site-of-care implications direct patient care to outpatient settings.

DSCSA. All aspects of compliance with DSCSA requirements is beyond the scope of these guidelines. Some important elements of DSCSA compliance to consider in selecting pharmaceutical manufacturers and suppliers include but are not limited to the following.

1. Suppliers are defined as various types of trading partners under DSCSA and must be

authorized to conduct such activities.[1]

2. Manufacturers and repackagers must have a valid registration with the FDA, which can be validated on the FDA's Drug Establishment Current Registration Site database (DECRS).[9]
3. Wholesaler distributors and third-party logistics carriers must have a valid state or federal license, which can be validated on the FDA's wholesaler and third-party logistics providers reporting database.[10]
4. DSCSA requires trading partners to provide transaction information for all products when change of ownership occurs. Prescription drugs must be accompanied by appropriate tracing information, including the transaction information (TI), transaction history (TH), and transaction statement (TS).[1]
5. When evaluating compliance, purchasers will need assurance that proper exchange of tracing information occurs. Health systems should consider the operational efficiency associated with electronic storage and retrieval of data.[1]
6. DSCSA provides guidance on the standardization of TI, TH, and TS data and instances in which it is acceptable to omit data (e.g., patient-specific dispenser-to-dispenser sales, grandfathered products).[1]
7. Trading partners should have the IT infrastructure to support electronic data exchange. They should also be capable of interfacing with third-party vendor software that collects and stores TI, TH, and TS data for dispensers.[1]
8. Suppliers and patient care providers need to be vigilant and continuously evaluate requirements of DSCSA to ensure full compliance.[1]

9. Purchasing organizations need to routinely monitor FDA and Office of Inspector General reports for guidance on DSCSA compliance.[1]

Compliance with compounding requirements. In the setting of drug shortages, 503B outsourcing facilities play a critical role in ensuring the production of safe and quality pharmaceuticals. Due to supply chain disruptions, some health systems are engaging in 503A compounding to support their own patient care needs. While 503A compounding does not engage with an external supplier, organizations must ensure compliance with all relevant regulations. In situations in which there is a need to engage in compounding to provide patient care, certain standards need to be ensured to develop the supplier relationship. Organizations that enter into supplier arrangements with 503B facilities need to ensure that certain core principles are maintained. Although this is not an exhaustive list, below are the some core elements compounding facilities must maintain. For more information, refer to the ASHP Guidelines on Outsourcing Sterile Compounding Services.[11]

503A facilities. Some important elements of 503A compliance to consider in selecting pharmaceutical manufacturers and suppliers include but are not limited to the following.

1. 503A pharmacies are considered traditional compounding pharmacies by the FDA and are permitted to compound patient-specific drug products. 503A pharmacies are required to comply with USP chapters 795 and 797 and state board of pharmacy regulations.[6,12-14]
2. 503A pharmacies must register with their state board of pharmacy and the DEA.
3. Sterile drug products must be dispensed as patient specific. Environmental monitoring is required every 6 months.

4. All drug products should be labelled with patient information, drug information, company information, and adequate directions for use of the product.
5. Beyond-use dating must be assigned in accordance with internal and external scientific literature on stability.
6. Compounding may be done from category 1 bulk drug substances, bulk drug substances with a USP or NF monograph, or drug components that are components of drugs approved by the Secretary of Health and Human Services (HHS).

503B facilities. Some important elements of 503B compliance to consider in selecting pharmaceutical manufacturers and suppliers include but are not limited to the following.

1. 503B facilities are considered outsourcing facilities that may produce large batches of product with or without prescriptions to be sold to healthcare facilities for office use.
2. Sterile products are not required to be but may be dispensed on a patient-specific basis.
3. 503B facilities must comply with current good manufacturing practices and, in some cases, state board of pharmacy regulations.[7]
4. Development of a robust environmental monitoring program is required and must be performed, at a minimum, per production shift in the ISO 5 primary compounding areas and weekly in the ISO 7 and ISO 8 secondary compounding areas.
5. Products must be labelled in accordance with the Drug Quality and Security Act (DQSA).[15]
6. A quality department that is independent of the operations and sales department must be in place and have complete autonomy for investigations and releasing products.
7. A robust stability program must also be put in place to scientifically confirm the stability

of a medication when subjected to degradation variables.

8. 503B facilities may only compound from Category 1 bulk drug substances.
9. 503B facilities must register with the DEA and FDA. Registration with the state board of pharmacy may also be required by state pharmacy law. 503B facilities have an additional requirement to report their product list to FDA biannually.

340B and Orphan Drug programs. Congress mandates that manufacturers participating in Medicaid or Medicare Part B programs enter into a pricing agreement with the federal government (the 340B Drug Pricing Program), which allows safety net providers to receive drug products for outpatient use at discounted prices.[16,17] Any noncompliance by participating manufacturers should be reported to the Health Services & Resources Agency (HRSA).

For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, drugs designated by the Secretary of HHS under section 526 of the Federal Food, Drug, and Cosmetic Act as orphan drugs for rare diseases are not included in the 340B program, so manufacturers are not required to provide 340B program discounts.[18] A manufacturer may, at its sole discretion, offer discounts on orphan drugs. Health systems should contact such manufacturers for a system-based contract with discounts.

Nontraditional pharmaceutical supply chain. The acquisition of pharmaceuticals in a manner that maintains supply chain integrity is a cornerstone of pharmacy procurement. Alternative, nontraditional supply chains have the potential to threaten the integrity of a health system's procurement practices. These alternative methods may also increase the operational costs to the purchasing organization.

Pharmaceuticals acquired outside standard processes, such as through brown, white, or

clear bagging, carry significant patient safety implications, and organizations are responsible for ensuring that patient safety and the integrity of the product are maintained.[19] Policies on drug acquisition should be in place to ensure compliance with regulatory and accreditation standards. “Brown bagging” is the process of a patient bringing a personally acquired pharmaceutical into a healthcare setting for administration. It carries significant patient safety implications due to the absence of pharmacy oversight of medication storage. “White bagging” is the practice of an outside outpatient pharmacy billing a patient’s prescription on a pharmacy benefit, then coordinating the delivery and administration of the drug in an outpatient setting. “Clear bagging” is the process of a health system using its own outpatient pharmacy to bill a patient’s prescription on the pharmacy benefit for administration in a clinic owned by the health system; control of product storage is in place and product integrity is maintained.

Product safety

Safety in the pharmaceutical supply chain stems from regulatory guidance that defines how suppliers should package medications. Unit dose packaging of medications has long been considered the safest and most effective way to administer medications in an acute care setting. Manufacturers should provide drug products in unit dose packages. If unit dose packaged products are not available, health systems will need to engage in unit dose repackaging, abiding by FDA guidance. Products should be labeled in a way that is clear to the end user and compliant with labeling requirements. For products with special storage requirements, suppliers are responsible for ensuring proper storage conditions throughout the production, shipping, and delivery process. Some important steps to ensure product safety

include the following.

1. To the extent possible, all products should be available in single unit or unit dose packages. These packages should conform to the ASHP Technical Assistance Bulletin on Single Unit and Unit Dose Packages of Drugs.[20]
2. When single unit or unit dose packages are not available from suppliers, health systems may conduct unit dose repackaging themselves or engage a supplier that can provide these services. The FDA's Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities guidance document provides detailed information for repackagers.[21] Prior to engaging a supplier in conducting unit dose repackaging, health systems should evaluate the package insert of a product in question and refer to section 16, How Supplied/Storage and Handling, for unique packaging requirements. If a manufacturer does not provide clear guidance in the package insert, they should provide stability and degradation data to a repackager. Purchasers should ensure repackaging vendors meet all regulatory and labeling guidelines.
3. To ensure product integrity and the ability to identify the product manufacturer during drug recall or shortage, the name and address of the manufacturer and repackager or distributor should be included on the final dosage form.
4. Expiration dates should be clearly indicated on the package label. USP General Chapter <7> recommends that expiration dating not exceed 6 months from the date of repackaging, or the manufacturer's expiration date, or 25% of the time between the date of the repackaging and the expiration date shown on the manufacturer's bulk article container of the drug being repackaged, whichever is earlier.[22]

5. Products should also be embedded with a two-dimensional data matrix barcode that consists of serialization data: national drug code, serial number, lot number, and expiration date.
6. Purchaser should consider reviewing FDA warning letters sent to suppliers to identify whether suppliers have violated FDA standards. These warning letters should be carefully evaluated to consider the risk a supplier's product adds to the pharmaceutical supply chain. FDA 483 forms detail specific, objectionable conditions associated with an FDA inspection that violate the Food Drug and Cosmetic Act.[23]
7. Purchaser should include in supplier contracts a requirement for suppliers to provide the purchaser notice if an FDA 483 citation has been received, along with the corrective action plan to fix the issues in the citation.
8. Purchaser should receive product from the supplier well before its beyond-use date. The supplier should be able to supply a sufficient amount of product that will not expire before use to meet the purchaser's established usage patterns.

Product distribution

Relationships between organizations and product distributors, including manufacturers, wholesalers, and other direct suppliers, should be clearly defined so that product quality is maintained and the product is ordered and delivered within defined time frames to meet patient needs. Some important aspects of product distribution include the following.

1. Manufacturers should distribute their product using an open distribution method, allowing health-system pharmacies access to product through their preferred

wholesaler or through direct or drop-ship relationships.

2. Unless otherwise specified or required by stability considerations, the interval between a product's time of delivery and its expiration date should not be less than 12 months.
3. If the supplier's supply of the product is inadequate to meet market demand, the process by which the supplier determines allocations for each customer should be transparent to the customers. Although suppliers may prefer to prioritize contracted customers over other customers when products are in short supply, such prioritization should be avoided for medically necessary products when alternative suppliers or equivalent therapeutic options are unavailable.
4. Manufacturers and wholesalers must comply with all applicable regulations.
5. Suppliers should ship all goods in a timely manner, freight prepaid, and enclose a packing list with each shipment. All out-of-stock items should be noted, and the anticipated availability of those items should be clearly indicated. There should be no extensive recurrence of back orders.
6. The process for handling credits, returns, and notifications regarding the issuances and handling of recalls should be transparent to both parties.
7. Suppliers should have a clear process and policy for handling of short-dated product, including how to process returns if the purchaser receives short-dated product unexpectedly.
8. Suppliers should have a process for accepting liability and return for shipment of damaged goods.
9. Suppliers should accept for full credit (based on purchase price), without prior

authorization, any unopened packages of goods returned up to 12 months of their expiration date. Credits should be in cash or applied to the institution's account. Suppliers should have a clear process and policy for handling of short-dated product, including return if the purchaser receives short-dated product unexpectedly.

10. Purchasers may consider working with a reverse distributor to handle return of short-dated, expired, and recalled products. Suppliers should maintain policies to facilitate credit for products returned in their original packaging near or shortly after the labeled beyond-use date.
11. All manufacturers, wholesalers, and distributors must comply with the requirements of DSCSA. A pedigree must be provided or made accessible for each purchased product, documenting the origin of the product at the manufacturer and each purchase and resale.
12. The supplier should warrant title to commodities supplied, warrant them to be free from defects and imperfections and fit for any rational use of the product, and indemnify and hold the purchaser harmless against any and all suits, claims, and expenses, including attorneys' fees, damages, and injuries or any claims by third parties relating to the products.

Restricted drug distribution systems. Restricted drug distribution systems (e.g., specialty pharmacy distribution systems, risk evaluation and mitigation strategies) should only be used when there are patient safety, limited supply, or special storage issues that require special handling or consolidation of inventory to a few sites. Restricted drug distribution systems can

negatively affect patient care by delaying access to products or preventing access by the patient's preferred pharmacy or location of care. Although restricted distribution channels are typically exempt from the negotiated cost-of-goods-sold discounts negotiated by wholesalers and health systems, they should not be used solely to avoid the distribution fees that are involved when using a wholesaler. When used, the manufacturer should supply details of distribution procedures, the decision process for assignment of limited distribution status, and criteria of assigning distribution authority. Certain specialty or high-cost medications may require special considerations; however, suppliers should follow, where possible, established processes on the distribution of these products.

Restricted drug distribution systems should be supported by publicly available evidence that they are the least restrictive means to improve patient safety and should not (1) limit patient access to medications; (2) undermine continuity of care; (3) impede population health management; (4) adversely impact patient outcomes; (5) erode patients' relationships with their healthcare providers, including pharmacists; (6) interfere with the professional practice of healthcare providers; or (7) be created for any reason other than patient safety.[24]

Marketing and sales policies

Interactions with suppliers can support the mission and goals of an organization and should work in concert with the organization. These partnerships must not compromise patient confidentiality or interfere with patient care. When conducted ethically and transparently, interactions with suppliers can result in benefits to patients and trainees. Appropriate contacts with supplier sales representatives or medical liaisons can provide learning opportunities about

new therapies or new research.[25]

1. The supplier should follow the organization's vendor policy regarding appointments, sales, marketing, education, and contracting activities within the organization.
2. The supplier should honor formulary decisions made by the organization's pharmacy and therapeutics committee, and the supplier's sales representatives should comply with the organization's regulations governing their activities.
3. The supplier should not offer cash, equipment, or merchandise to the organization or its staff.
4. The supplier should not, without the organization's written consent, use any specific pharmacist or organization name in any advertising or other promotional materials or activities.
5. The supplier should always discuss pharmaceutical pricing and contract proposals with the pharmacy department leadership prior to discussions with any other health professionals within the organization.
6. The supplier should not distribute, post, or leave any type of printed or handwritten materials, advertisements, signs, or other such promotional materials, unless specifically requested in writing by the organization.
7. All parties to the bidding process should respect the integrity of the process and the contracts awarded thereby.

Contracting and billing

It is imperative that organizations have clear and transparent contracts with their

suppliers. All contracts should contain certain core elements. Spending time to develop a set of standard terms and conditions for an organization's contracts can increase reliability and efficiency of the contracting process and outcome. Health systems should verify pricing on all accounts on a quarterly basis, either internally or through a vendor. Manufacturers and wholesalers should promptly correct and credit any pricing errors. Important elements of a sound contract and billing process include the following.

1. Purchasers should collaborate with their strategic sourcing and legal teams to develop and implement standard contract terms and conditions that can serve as a template for new or proposed agreements.
2. GPOs can facilitate the development and review of terms and conditions. Many organizations accept GPO base agreements as written, with negotiation only required for terms such as specific pricing or volume commitments.
3. Core elements and components of a contract should include the following:
    a. *Statement of work:* provides a description of intent and key deliverables of the agreement between supplier and purchaser, such as
        i. Shipment terms
        ii. Product returns
        iii. Delivery
        iv. Recalls
    b. *Duration:* describes the length of the contract, with renewal terms. Some contracts contain an "evergreen" clause, which automatically renews the contract unless a

termination notice is provided within a certain period of time in advance of the termination date.

c. *Exclusivity:* specifies whether an agreement is exclusive for a product, product line, or supplier, or what the expectations are for the agreement to continue.

d. *Payment terms:* describes the agreed-upon terms for providing payment, which may include incentives or rebates if certain performance thresholds are met. Late fee structures should be straightforward and in alignment with the organization's accounts payable guidelines.

e. *Termination:* specifies terms for terminating the agreement outside of the specified duration of the contract; such terms may include:

    i. *Termination for cause:* if, for example, there is a material breach of the contract.

    ii. *Termination for convenience:* if one party fails to meet the payment terms (right to cure) or delivery terms (failure to supply).

    iii. *Immediate termination:* if, for example, a party declares bankruptcy or does not meet other terms of the contract such as maintaining insurance.

f. *Mutual indemnification:* specifies that both parties agree to compensate the other for losses arising from the other's breach of the contract.

g. *Confidentiality/HIPAA:* describes the obligations of each party regarding confidentiality of shared information, including information governed by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

h. *Insurance requirements of both parties:* specifies the types and levels of insurance required by each party to the contract.

i. *Governing law:* defines which laws govern the contract, should disagreements about the contract rise.

4. Other contract considerations include the following.

a. *Payment methods:* an organization may require or prefer specific payment methods, such as electronic data interchange or wire, which should be considered with direct suppliers.

b. *Price changes:* purchasers may prefer or require notice of any price changes, and could include a requirement in the contract terms; such terms may include limits on annual changes to prices outside of pre-specified terms (e.g., significant changes to raw material costs).

c. *Late fees:* purchasers should scrutinize complex late fee structures.

d. *Bundling of services or products:* consideration may be given to combining some or all services or products provided by a company to negotiate additional benefits, including cost of goods decreases, rebates, or other value-add services, such as education or consultation.

e. Contracts may come with certain formulary or access requirements. Decisions on formulary status should be deferred to the organization's pharmacy and therapeutics committee, with consideration of applicability or governance in nonhospital settings (e.g., physician clinics, infusion centers, home infusion,

ambulatory care centers, retail pharmacies). Where applicable, alternative sites of care or classes of trade should be addressed in the contract terms.

Responsibilities of the purchaser

The responsibilities of the purchaser, in which the chief pharmacy officer (CPO) has an important role, include promoting beneficial business partnerships and practices, ensuring sound bidding procedures, defining the role of GPOs, and establishing vendor access policies.

Role of the CPO. Pharmacy leadership should ensure that the pharmacy department serves as the primary conduit for information on distributors, medications, and best practices. The CPO must be an active member of discussions regarding the pharmaceutical industry. The CPO should encourage alignment of purchasing practices across a health system to attain cost savings and formulary consistency. The pharmacy executive should engage with the health-system government relations division to advocate on behalf of the pharmacy department and ensure strong supplier representative policies exist.[25]

Pharmacy leadership should build and maintain relationships with internal health-system stakeholders, including staff responsible for informatics, finance, legal matters, and the supply chain. These relationships are crucial to ensuring the existence of bi-directional communication of supplier data for compliance with DSCSA, financial implications and legality of vendor contracts, and ensuring the integrity of the nonpharmaceutical supply chain. The CPO should also partner with informatics and data analytics professionals to conduct supply chain market trend monitoring to maintain a competitive advantage and improve decision-making on strategic initiatives.

Business partnerships and practices. Suppliers and health systems can become valued partners. It is important that these relationships be purposeful and beneficial to both parties, and that business practices like those outlined below are put in place to maximize these relationships.

1. The purchaser should ensure the supplier is supporting health-system goals across all sites of care when creating a partnership with a supplier.
2. Purchasers should work to become a "customer of choice" by creating an environment that welcomes and encourages partnerships with high-performing suppliers.
3. Purchasers should select appropriate outsourcing facilities that meet the safety and efficiency goals of the health system.
4. Purchasers should encourage purposeful supplier diversity and partnerships to manage risk, and should choose suppliers with sound sustainability practices.
5. Purchasers should review the manufacturer's emergency management and mitigation strategy policies in evaluating a partnership.
6. Purchasers should work with suppliers to establish quarterly business reviews for important partners. Suppliers should come prepared to talk about how they can help the purchaser achieve their goals through value-added products or services.
7. Purchasers should practice strategic sourcing and opportunistic buying, working with the partner to identify these opportunities as well as mitigating for anticipated supply stressors.
8. Purchasers should consider developing a strategic sourcing committee. This group

would be responsible for identifying systemwide savings opportunities through contracting and negotiation, through GPO and/or direct supplier and manufacturer relationships, and track realized savings to demonstrate value.

9. Purchasers should leverage their internal resources and expertise (e.g., supply chain, sourcing, legal, risk management) to support supplier evaluation and contract management. In addition, partnering with the purchasing and contracting departments is key to building an optimized contracting model. Ideally, a purchaser should develop a centrally managed, structured contracting process, with performance metrics to improve quality.
10. Suppliers should work to provide a transparent and supportive sales process that meets the needs of the purchaser while supporting the business goals of the organization.
11. Suppliers should follow through on commitments and be responsive to the needs of the purchaser.

Bidding procedures. It may be desirable to purchase drugs or other commodities on a competitive bid basis. The purchaser should ensure that competitive bidding procedures conform to the guidelines below.

1. Invitations to bid should be mailed to the suppliers' home offices, with copies to their local representatives (if any), unless suppliers specify otherwise.
2. Potential bidders should be given no less than 3 weeks to submit a bid.
3. The opening date for bids should be specified and honored by the purchaser.
4. The language of the invitation to bid should be clear and should indicate the person

(and organization address and telephone number) the bidder should contact in the event of questions or problems. Specifications should be complete with respect to products, packaging, presentations, and quantities desired.

5. The invitation to bid should specify whether a specific form should be used, or if the supplier's template can be used to complete the bid. If bidding forms are used, they should contain adequate space for the bidder to enter the information requested.
6. The winning bidder should be notified in writing. Unsuccessful bidders should also be informed.
7. The quantities specified in the invitation to bid should be a reasonable estimate of requirements.
8. If the invitation to bid is offered on behalf of a group of purchasers, the individual members of the group should not engage in bidding procedures of their own and should purchase the goods in question from the winning bidder.

Role of GPOs. GPOs can be important partners in helping to maintain, evaluate, and maximize the efficiency of the procurement process. GPOs have matured to offer many value-added services beyond purchasing. These services may include drug information, networking, professional development, consulting, and many other services.[26]

1. The purchaser's leadership should leverage their GPO to help monitor any outsourced organizations, pharmacies, and suppliers.
2. In multi-hospital systems, one GPO should be used across all sites to drive purchasing power and achieve volume-based discounts. Pharmacy leadership should play an active role in the recommendation and selection of the GPO.

3. The GPO should be able to monitor and evaluate pricing, contract compliance, purchasing habits, and shifts in the marketplace.
4. Pharmacy leadership should maximize the value of their GPO by participating in various networking, professional development, and consulting arrangements that are offered.
5. Pharmacy leaders should be aware of shareback fees, rebates, and other financial drivers associated with GPO membership.

Vendor access. Purchasers should have consistent vendor accessibility practices across the organization. A vendor liaison office (VLO) should be established either within the department of pharmacy or the supply chain team with the purpose of managing vendor representatives for the organization.[27] The VLO should be in charge of registering and badging vendors, maintaining a database of vendors and monitoring their activities, and ensuring that vendor representatives have an appropriate amount of access to patient care areas.

Conclusion

These guidelines provide criteria pharmacists should consider when purchasing pharmaceutical products from suppliers, recommendations to optimize the purchasing process, and a description of the responsibilities of suppliers and purchasers. The recommendations in these guidelines are written to establish reasonable goals, to be progressive and challenging, yet attainable as best practices in applicable settings, and do not represent minimum levels of practice. Readers are encouraged to exercise their professional judgment in assessing and adapting these recommendations to meet their specific needs.

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When approved, these guidelines will supersede the ASHP Guidelines for Selecting Pharmaceutical Manufacturers and Suppliers dated November 14, 1990.