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## **Outsourcing: Guidelines for Pharmacy Practice (2011)**



Canadian Society of Hospital Pharmacists  
Société canadienne des pharmaciens d'hôpitaux

## **Outsourcing: Guidelines for Pharmacy Practice**

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# Outsourcing: Guidelines for Pharmacy Practice

## INTRODUCTION

This is the original edition (2011) of the Canadian Society of Hospital Pharmacists (CSHP) document “Outsourcing: Guidelines for Pharmacy Practice.”

CSHP endorses the Pharmaceutical Inspection Convention Co-operation Scheme (PIC/S) *Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments* (2008).<sup>1</sup> CSHP’s “Outsourcing: Guidelines for Pharmacy Practice” is intended to be read and used in conjunction with that guide, as well as with the relevant codes of ethics, standards, and legislation forming the legislative framework for the practice of pharmacy.

Many sections of this guideline most notably those that address the outsourcing phases related to tendering, contract negotiations, and contract management draw on collections of publications published by the Australian Government and the United Kingdom's Office of Government Commerce. Both organizations have authorized CSHP to use and adapt their respective publications for this set of guidelines.

## 1. SCOPE

These guidelines were prepared to assist pharmacies in managing the outsourcing of any aspect of their operations and also to guide pharmacists who provide pharmacy services through contractual arrangements.

These guidelines apply to the outsourcing of pharmacy operations in all service sectors, including hospitals, ambulatory care clinics, and long-term care facilities. They provide broad guidance on the key steps in the outsourcing process and include recommendations on the elements to be included in a contract.

The guidelines are intended to augment but not replace relevant legislation nor the policies and procedures of the hospital or the pharmacy department. Similarly, they are not a substitute for legal, financial, or other professional counsel when outsourcing is being considered or is undertaken.

CSHP Mission:

CSHP is the national voice of pharmacists committed to the advancement of safe, effective medication use and patient care in hospitals and related healthcare settings.



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### 2. GLOSSARY OF TERMS, ABBREVIATIONS, AND SYMBOLS

The following definitions apply for terms used in these guidelines. They may have different meanings in other contexts.

<b>Contract management</b>	“The process of administering a contract from its award to close-out. It includes the monitoring of time, cost, performance, enforcement of contractual terms, final reconciliation of payments, and evaluation of contractor performance and method of supply.” <sup>2</sup>
<b>Contract management team</b>	The person or people who are “responsible for managing the contract after signing.” (In some cases contract management and negotiation may be done by the same person.) <sup>3</sup>
<b>Expression of interest</b>	A document that is completed by persons or companies who are interested in submitting a proposal in response to a request for proposal.
<b>Hospital</b>	An institution providing acute or long-term care, which may include corporately-related healthcare facilities that are served by the institution's pharmacy service.
<b>Negotiation team</b>	“The person or people who develop the contract and negotiate the contract through to contract signing.” (In some cases contract management and negotiation may be done by the same person.) <sup>3</sup>
<b>Outsource</b>	To obtain a good or service by contract from a source that is outside of the healthcare facility's corporate structure.
<b>Outsourcing process</b>	A set of activities undertaken by an organization to outsource a good or service. The process typically includes the following activities: <ol style="list-style-type: none"> <li>1. Deciding to outsource</li> <li>2. Planning to outsource</li> <li>3. Undertaking the tendering process</li> <li>4. Finalizing the contract</li> <li>5. Managing the contract</li> <li>6. Terminating the contract</li> </ol>
<b>Purchaser</b>	A legal entity that agrees to enter into a contractual relationship with a vendor. Term is synonymous to “Contract giver” in <i>PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments</i> . <sup>1</sup>
<b>Request for proposal</b>	An invitation to potential bidders to submit a proposal for the provision of a good or service
<b>“Shall”</b>	Indicates a requirement set forth in these guidelines.
<b>“Should”</b>	Indicates a recommendation, something that is advised but not mandatory.
<b>Vendor</b>	A legal entity that offers a contract. Term is synonymous to “Contract acceptor” in <i>PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments</i> . <sup>1</sup>

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### 3. OUTSOURCING PHARMACY SERVICES

Refer to section 7, “Work Contracted Out”, of the PIC/S *Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments*.<sup>1</sup>

Many aspects of pharmacy services may be outsourced. Outsourcing can arise through 1 of the following 2 ways<sup>4</sup>

- a) Substitution – replacing the existing internal production of a good or service and acquiring the good or service from the outside market;
- b) Abstention – acquiring from the outside market a good or service that was not previously provided through the organization’s in-house processes.

The limits of arrangements for such outsourcing may be determined by federal, provincial, or territorial legislation, as well as by hospital policy. The purchaser shall ensure that all contracted services comply with the relevant federal, provincial, or territorial legislation.

The following are some examples of work that might be outsourced:

- a) preparation, packaging, and sterilization of products used or supplied by the pharmacy;<sup>5,6</sup>
- b) pharmacist services (e.g., consultations, review of medication orders, provision of drug information, therapeutic drug monitoring);
- c) drug distribution<sup>7</sup> and transportation services (e.g., between facilities);
- d) quality control programs;
- e) training and education;
- f) certification of equipment;<sup>6</sup>
- g) maintenance of equipment;
- h) maintenance of facilities (e.g., heating, ventilation, and air conditioning systems);
- i) waste management;
- j) pest control;
- k) monitoring of vendor compliance;<sup>8</sup>
- l) environmental monitoring;
- m) drug information services;<sup>7</sup>

- n) remote order-entry services;<sup>6,9</sup>
- o) drug stocking programs;<sup>5</sup>
- p) inventory stock-taking;<sup>6</sup>
- q) home care services;<sup>5</sup>
- r) outpatient prescription services;<sup>5</sup>
- s) purchasing services;
- t) pharmacy management;<sup>6</sup>
- u) quality assessment, and
- v) operational reviews.

### 4. DECIDING TO OUTSOURCE

If a pharmacy is unable to provide a service according to required specifications or standards, the pharmacy’s managers, in collaboration with other internal stakeholders, may consider purchasing the service through a contractual agreement with a third party. This option should be exercised only if it complies with applicable legislation and with the organization’s internal policies.

The managers of the hospital pharmacy shall be involved in all decisions to outsource any aspect of the medication-use process within the hospital.

When a decision is made to outsource, it is prudent to consider the results of various analyses, including cost–benefit analyses, and to avoid sacrificing the quality of the good or service as a means of saving money.

The purchaser’s decision to outsource should take into account many factors, such as the following:

- a) the costs of in-house provision of the good or service relative to the costs of outsourcing;<sup>10</sup>
- b) alignment with strategic goals and objectives;
- c) ways in which outsourced activities could be controlled and integrated into the organization’s processes;<sup>11</sup>
- d) effect on the organization’s long-term performance and innovation;<sup>4,11</sup>
- e) potential of outsourcing to increase the capabilities and other highly valued assets of the organization;<sup>12</sup>

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- f) availability of potential vendors to meet the specifications of the good or service to be outsourced;<sup>12</sup>
- g) ability of the organization to effectively manage the contract;<sup>13</sup> (refer to section 12 of this document);
- h) security considerations that might impede outsourcing;<sup>10</sup>
- i) likelihood of a collaborative, cooperative relationship with the vendor;<sup>12</sup>
- j) the organization's cultural readiness to work in a new, different way with an outside provider;
- k) the political, social, and economic environment and related implications of the decision;<sup>14</sup>
- l) purchaser's willingness to accept that it cannot transfer its business risk to the vendor, nor can it transfer its obligations to deliver key outcomes.<sup>13</sup>

The reasons to outsource will vary within a single organization and between different organizations. It is recommended that the reasons for outsourcing be formally documented. A business case, minutes of meetings, and records of management decisions are examples of documented deliberations and justification for outsourcing.

### 5. IDENTIFYING PEOPLE TO BE INVOLVED IN THE OUTSOURCING PROCESS

The purchaser shall identify the team of persons within the organization who are sufficiently experienced and knowledgeable to be responsible for developing, managing, and terminating contracts. It may be necessary to create a committee to oversee a particular contract or group of contracts. The roles, responsibilities, and expectations of the responsible personnel should be clearly stated and understood by those involved in activities related to the contract. If the person or team does not possess expertise in a particular area, additional team members should be invited to join the team as needed.

It is recommended that the support and involvement of senior management be sought and obtained at key stages (e.g., request for proposal, contract development) in the outsourcing process.<sup>3,15</sup>

#### 5.1 Involvement of internal stakeholders

Representatives of all key internal stakeholders should participate in the outsourcing process to help ensure that the specifications of the final contract will meet their needs. In addition, the person (or team) responsible for managing the final contract should be involved in the related tendering and contract-awarding processes.<sup>16</sup>

#### 5.2 Responsibility of pharmacy service

A contract to outsource any function related to pharmacy services does not negate the responsibility of the hospital pharmacy to ensure that its products and services are safe, meeting or exceeding current standards of hospital pharmacy practice, and that the provided contract good or service meets operational specifications.<sup>17</sup>

#### 5.3 Involvement of other stakeholders

The outsourcing process should involve stakeholders from other departments of the purchasing organization, especially if they share with the pharmacy department the responsibility for the good or service to be outsourced. For example, responsibility for maintaining air quality standards in the pharmacy may be shared between the pharmacy and facilities' management departments.

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### 6. PLANNING TO OUTSOURCE

Before the tendering process begins, the team should agree on approaches regarding the following topics:

- a) managing conflicts of interest;
- b) determining the minimum requirements to be included in the request for proposal;
- c) issuing the invitation to tender (tendering process);
- d) determining the criteria and process to evaluate bids; and
- e) handling appeals.

#### 6.1 Managing conflicts of interest

To protect the interests of the purchaser, all perceived and actual conflicts of interests should be monitored throughout the outsourcing process.

At a minimum, the purchaser should adopt the following practices to help manage conflicts of interest.<sup>15</sup>

- a) require all persons (including external contractors, experts, and advisors) involved in any process related to outsourcing to declare and document all perceived and actual conflicts of interest before tendering begins and to update that information whenever circumstances change;
- b) re-assess the risk of conflicts of interests at pre-established milestones in the outsourcing process;
- c) check for “embedded” conflicts of interests that might arise (such as a conflict of interest with a subcontractor);
- d) clearly define the roles and responsibilities of all parties involved in the outsourcing process, segregating incompatible duties and ensuring that one person is not solely responsible for the process from start to finish;
- e) forbid the acceptance of gifts or hospitality from potential bidders; and

prohibit potential and successful bidders and vendors from soliciting the purchaser’s employees for a defined period and instruct all employees to notify their respective supervisors if a bidder offers employment (this prohibition should be mentioned in both the request for proposal and the contract).

#### 6.2 Determining the minimum requirements to be included in the request for proposal

To aid potential vendors in preparing their proposals, the request for proposal should include relevant information about the purchaser and appropriate specification of the good or service to be outsourced.

The following topics should be included in every proposal, along with others specified by the purchaser:

- a) qualifications of the potential vendor and its staff or providers;
- b) the potential vendor’s mission, vision, and goal statements;<sup>18</sup>
- c) the potential vendor’s service record, including evidence of ability to provide service in a timely manner;
- d) description of the products or services that the potential vendor proposes to provide under the contract;
- e) estimated cost or budget, with justification;
- f) copies of the potential vendor’s policies and procedures that are relevant to the proposal;
- g) description of the potential vendor’s programs to manage and improve the quality of its goods and services (e.g., quality assurance program, quality improvement program, quality control processes);
- h) description of the potential vendor’s human resource capacity to meet the required specifications (e.g., list of staff members relevant to the proposal; description of hiring, training, and retention practices);

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- i) description of how the potential vendor proposes to integrate the outsourced good or service into the existing operations of the purchaser;
- j) audited financial statements of the potential vendor for a specified period, to demonstrate long-term financial viability (e.g., 3 years);
- k) provisions to prevent the potential vendor from soliciting the purchaser's employees for a defined period, although former employees of the purchaser should not be unreasonably or unfairly prevented from seeking employment with a potential vendor;<sup>15</sup>
- l) disclosure and documentation of all relevant conflicts of interest, real or perceived; and
- m) list of current references or testimonials from previous or current clients.

Where appropriate and relevant, the potential vendors should be asked to supplement their submissions with activities such as interviews with or presentations to the purchaser, tours of facilities,<sup>18</sup> or provision of samples.

### 6.3 Issuing the invitation to tender

In situations where multiple service providers or vendors are available and the value of the contract is considered significant, the process of tendering a contract should begin with the distribution of a request for proposal to potential vendors, as a means of inviting those who might be suitable as vendors to submit formal proposals.

#### 6.3.1 Exceptions to the requirement for tendering

The purchaser may approve certain exceptions to the requirement for tendering. Examples of such circumstances include emergency situations (where the protection of life or property or the continuity of essential services is necessary), the use of a sole source for reasons of compatibility (e.g., with existing equipment), or expansion of a relationship with an existing service provider.

#### 6.3.2 Approaches to issuing the invitation to tender

The invitation to bid may occur via either of the following approaches:

- a) Closed (restricted or selected) invitation: An invitation to submit a bid is sent to individuals or organizations that have been selected by the purchaser according to predetermined inclusion and exclusion criteria.
- b) Open invitation: An invitation to submit a bid is distributed publicly (e.g., by advertisement) or to all relevant vendors known to the hospital organization. Either of these approaches can include the option to submit an expression of interest, which will help the purchaser to identify individuals or organizations that meet any qualifying criteria. The request for proposal is then issued to those individuals or organizations that meet the criteria.

### 6.4 Determining the criteria and process to evaluate bids

The purchaser, via its team of key stakeholders, should determine the process to evaluate the bids received using the following general approach:

- a) establish an evaluation team comprising representatives of the purchaser's stakeholders; and
- b) determine the roles and responsibilities of the team and its individual members.

Depending on the resources available, the evaluation team may consist of the same people as those participating in the contracting team (refer to section 5 of this document) or a subset of that team.

#### 6.4.1 Evaluation criteria

The roles and responsibilities of the evaluation team should include the establishment of evaluation criteria and the development of a process to evaluate each bid according to the criteria.

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The evaluation criteria should have the following characteristics:<sup>15</sup>

- a) helpful in eliminating bids that do not meet the mandatory requirements;
- b) clearly articulated;
- c) comprehensive, including all of the factors (both quantitative and qualitative) that the purchaser will consider when evaluating the bids.

Each criterion should be assigned a weight according to its classification as either mandatory or desirable and its relative importance.

### 6.4.2 Process to evaluate the bids

The process to evaluate the bids should facilitate fair application of the evaluation criteria using the following approach:

- a) Each member of the evaluation team should:
  - i) eliminate bids that do not meet the mandatory requirements;
  - ii) evaluate each bid against the criteria, according to the weights assigned to each element of the proposal;
  - iii) compare the results of the evaluations; and
  - iv) compare the results of the evaluations; and forward his or her individual results to the evaluation team.
- b) The evaluation team as a whole should:
  - i) compile and compare the results submitted by the individual members of the team; and
  - ii) evaluate select the successful bidder.

### 6.5 Handling appeals

The purchaser, via its stakeholders, should establish a procedure for responding to appeals related to the outsourcing process or the decisions arising from that process. The procedure should specify the conditions under which an appeal will be accepted (e.g., within a specified number of days).

## 7. UNDERTAKING THE TENDERING (BIDDING) PROCESS

The request for proposal should invite each potential vendor to submit a proposal expressing interest in the contract and including information about the potential vendor's ability to meet the purchaser's needs.

### 7.1 Content of the invitation

At a minimum, the invitation should include the following information:<sup>15</sup>

- a) the name of the purchasing entity;
- b) a brief description of the purpose of the specific proposal;
- c) contact information (including name, telephone number, email address, fax number);
- d) acceptable methods to submit the proposal (e.g., by paper, email, or Web-based tool); and
- e) closing date and time (specifying the time zone) for submissions.

In addition, the following information should be provided, either in the invitation itself or during a briefing session:<sup>15</sup>

- a) relevant background information that would be helpful to the potential vendor in preparing a bid; and
- b) estimated timeframes for milestones in the outsourcing process (e.g., dates for notifying bidders and awarding the contract, duration of contract).

### 7.2 Responses to queries

The purchaser, through a designated contact person, should handle any queries from potential bidders promptly and consistently. Any information released to one bidder that might give that bidder an unfair advantage over the other bidders should be disclosed to all bidders. The contact person should

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record all requests for information and the responses provided.<sup>15</sup>

### 7.3 Receipt of bids

To protect the integrity and confidentiality of all proposals and to promote fairness in the outsourcing process, procedures should be established to securely receive and store the bids, regardless of how they are transmitted (e.g., in paper or electronic form).

The following provisions should be employed<sup>15</sup>

- a) The details (e.g. date and time of receipt) of each bid received should be noted as it arrives.
- b) All submissions should remain unopened and should be stored securely until the closing date has passed.
- c) Any bid received after the closing date should be excluded from the evaluation unless the delay was caused by the purchaser.
- d) Access to all documents related to the outsourcing process should be restricted to authorized personnel (as determined by a direct need to know).
- e) Each bidder's requests for anonymity should be respected.
- f) In the case of proposals sent electronically, controls over the transmission and storage of proposals shall be used to protect the data.

### 7.4 Assessment of bids

The team of key stakeholders should assess the bids promptly, according to the agreed-upon method (refer to section 6.4 of this document), examining all of the information supplied by the bidders. Every effort should be made to prevent avoidable and unnecessary delays.

#### 7.4.1 Clarification of a bid

When clarification of a bid is needed, the bidder should be asked to supply the necessary information. The purchaser should document any communications in this regard. Any such clarification should not substantially alter the proposal as originally submitted.<sup>15</sup>

#### 7.4.2 Non-acceptance of any bid

The purchaser should not be obliged to accept a bid that does not meet the criteria to the full satisfaction of the team that is managing the outsourcing process. It may be necessary to review and possibly revise the request for proposal and then re-issue the proposal.

#### 7.4.3 Notification to successful bidder

Once a decision has been reached, the purchaser should immediately notify the successful bidder that contract negotiations will begin within a specified time period. However, until both the purchaser and the vendor have agreed to the contract, the purchaser should avoid implying to the successful bidder that it has been awarded the contract.<sup>3</sup>

## 8. DEVELOPING THE CONTRACTUAL AGREEMENT

Refer to section 7, "Work Contracted Out," of the *PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments*.<sup>1</sup>

All parties involved in the development of the contract should agree on the final contract specifications.<sup>3</sup>

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### 8.1 Complying with provincial pharmacy regulatory authority

The contract shall comply with all relevant requirements set forth by the provincial pharmacy regulatory authority.

The regulatory authority may have requirements addressing one or more of the following matters related to contracts:

- a) the pharmacy's authority to enter into the contract (e.g., to provide or receive services beyond provincial borders, if that is part of the proposed outsourcing contract);
- b) mandatory elements of the contract; and
- c) mandatory reporting requirements associated with the contract.

### 8.2 Soliciting legal and financial counsel

It is recommended that the vendor and the purchaser each retain legal and financial counsel before entering into a contract as a means of protecting their individual interests.

### 8.3 Identifying risks

The purchaser should identify the risks inherent in each phase of the contract's life cycle and should specify how those risks are to be managed, either within the contract or by other methods, such as through operational or financial means. The following aspects of the contract, among others, represent sources of risk:<sup>3</sup>

- a) capacity to manage the contract (e.g., lack of adequately skilled persons to manage the contract);
- b) resources (e.g., lack of organizational support in terms of financial resources, skills, or time required to manage the contract)
- c) the deliverables (e.g., vague or unrealistic description of deliverables);

- d) measures of contract performance (e.g., inability to effectively assess performance);
- e) negotiations with the vendor (e.g., failure to act fairly and in good faith);
- f) relationships with stakeholders (e.g., differences of opinion among stakeholders);
- g) relationships with vendor (e.g., inability to resolve disputes); and
- h) changes in the purchaser's circumstances or requirements (e.g., lack of formal documentation of changes to the contract).<sup>3</sup>

## 9. NEGOTIATING THE CONTRACT

Refer to section 7, "Work Contracted Out", of the *PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments*.<sup>1</sup>

The purchaser and the vendor should each determine the most suitable approach for negotiating the terms and conditions of the contract with the other party. Careful consideration should be given to how contract negotiations are undertaken as it can influence the nature of the relationship after the contract comes into effect. Factors that may influence the selected style include the organizational culture, the context of the contract, and any prior relationship between the parties.

Regardless of the style used, the resulting contract should identify the obligations of both the purchaser and the vendor within a legal construct, while enabling a productive, cooperative relationship between the 2 parties.<sup>13</sup> Ethical and fair approaches to negotiation,<sup>3</sup> along with mutual trust and good communication<sup>13</sup> should be the basis for the negotiations.

The following factors will likely influence the negotiating style that is used:<sup>3</sup>

- a) resources available;
- b) skills and experience;

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- c) complexity of issues to be negotiated; and
- d) timeframe.

### 9.1 Creating a negotiating team

It may be necessary to establish a negotiating team. All persons involved in negotiations should have the relevant skills and experience to fulfill their responsibilities. The team should include the person or team who will manage the final contract.<sup>16</sup> It may be necessary to include a professional advisor (e.g., legal counsel, accountant).

### 9.2 Planning for negotiations

Plans to negotiate should establish the following:<sup>3</sup>

- a) items in the draft contract that are subject to negotiation;
- b) objectives and restrictions of the negotiation process;
- c) roles and responsibilities of the negotiating team;
- d) assignment of persons to the negotiating team with the legal authority to act on behalf of their respective organizations;
- e) approaches to barriers or opportunities;
- f) resources (time, money, expertise) required by the negotiating team; and
- g) policy parameters (as defined by senior management).

Together, the purchaser and the vendor should agree to the terms and conditions for the negotiations, including the following aspects:<sup>3</sup>

- a) composition of the negotiating teams;
- b) location and agenda for each negotiation meeting;
- c) timeframes for negotiation;
- d) procedure for keeping formal minutes of negotiation meetings;
- e) procedure for minimizing non-negotiable items;
- f) acceptance of trade-offs for low-priority items; and
- g) knowledge about any relationships between specific issues or provisions such as volume of

service or good provided and the price of the contract.

### 9.3 Adhering to principles of contract law

At all times, the negotiating teams should adhere to the principles of contract law. If there is any doubt about any matter with potential legal ramifications, the teams should seek legal counsel.<sup>3</sup> The teams should also have realistic expectations of what can be delivered under the proposed contract.<sup>13</sup>

### 9.4 Communicating with the stakeholders

The negotiating teams should debrief the stakeholders of their respective organizations on the progress and outcome of the negotiations.<sup>3</sup>

### 9.5 Defining the output specifications of the contract

The output specifications of the contract should be described in writing as clearly as possible,<sup>10</sup> since poorly written specifications frequently lead to unfulfilled expectations and poor relationships between the purchaser and the vendor.<sup>10, 13, 19</sup> The contract should be correctly stated, agreed on, and managed to avoid misunderstandings that could result in a product, work, or analysis of unsatisfactory quality.<sup>19</sup>

Attention should be given to ensuring that the control and integration of the outsourced activities do not hinder the organization's long-term productivity and innovation.<sup>11</sup>

The contract shall be written to meet all applicable legal and policy requirements. The elements of each individual contract will vary with the nature and scope of the goods and services to be provided.

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At a minimum, the following topics should be covered by the contract.

### 9.5.1 Governing laws

The contract should state the laws which will govern the contract.

### 9.5.2 Responsibilities

The contract should state all responsibilities of the purchaser and the vendor related to the services to be covered by the contract. The contract should also state that the purchaser retains ultimate responsibility for the quality of the services provided under the contract.

### 9.5.3 Specification of the good or service to be provided

The contract should specify the expected standards of performance, quality, and volume of the good or service to be provided by the vendor, the required timeline, and the terms under which the good or service is to be provided.<sup>13</sup>

### 9.5.4 Necessary qualifications

The contract should state that the vendor will ensure that all persons directly providing the good or service have the necessary qualifications (i.e., credentials, training, and experience) to fulfill the responsibilities and carry out the duties to which the vendor has agreed. The vendor should demonstrate to the purchaser that all persons providing the service have the required education, training, and experience by providing references from other clients (past or present), statements of professional qualifications and experience, and (when applicable) evidence of the vendor's policies and procedures.

### 9.5.5 Necessary resources

The contract should state that the vendor has access to the resources that will be required to safely produce the good or provide the service to fulfill the requirements of the contract. Depending on the purpose of the contract, such resources may include suitably skilled human resources, appropriate facilities, access to ingredients, and access to information resources and technology. Any resources that are to be provided by the purchaser should be clearly described in the contract. (Refer to section 9.5.22 of this document for more information regarding ownership and custody.)

### 9.5.6 Access to hospital personnel and other resources

The contract should specify the conditions under which the vendor (or its agents) is permitted to have access to hospital personnel and other resources.

For example, if the vendor is expected to interact with hospital personnel, the contract should state the purpose of any such interactions and the conditions under which they should occur and be approved.

### 9.5.7 Communications

The contract should specify how communications should occur between the parties to the contract.

It is recommended that communications occur in a peer-to-peer manner where possible, to avoid imbalances in governance arrangements and that contract managers of both parties meet on a regular basis to ensure that any issues arising are addressed promptly.<sup>13</sup> (Refer to section 12 of this document for more information about communications between the parties.)

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### 9.5.8 Indemnification and insurance

The contract should include an indemnification clause appropriate to the level of risk that the purchaser is willing to assume. The contract should also declare the required type and amount of insurance coverage required by both parties. To protect their interests, both parties to the contract should ensure that their respective insurance plans cover situations that might arise in the course of outsourcing or providing a good or service via contractual agreements.

### 9.5.9 Notice regarding inability to fulfill responsibilities

The contract should require the vendor to inform the purchaser, within a suitable and clearly specified timeframe, if the vendor is unable to fulfill the responsibilities agreed to in the contract. This will allow the purchaser to make alternative arrangements.

### 9.5.10 Compliance with legal requirements

The purchaser and the vendor shall adhere to federal, provincial or territorial, and municipal legislative requirements, accreditation standards, professional standards, and generally accepted national standards or guidelines relevant to the scope of the contract.

The contract should specify the legislation governing the contract. Both parties to the contract should familiarize themselves with that legislation.

### 9.5.11 Compliance visits to the vendor's facilities

If applicable in the context of the good or service to be provided (e.g., outsourcing of some aspect of drug distribution), the contract should specify that the purchaser may conduct unannounced visits to the vendor's production facilities to gauge compliance with the contract. Such visits may

include interviews with personnel; reviews of policies, procedures, licenses, education and training manuals, and other documents; and tours of the facilities.<sup>18</sup>

### 9.5.12 Reports of noncompliance

The contract should state that both the purchaser and the vendor will formally notify the other party, within a specified period after discovery, if the good or service provided does not comply with the contract specifications. The contract should include options for action on the part of the purchaser in case of the vendor's noncompliance.

### 9.5.13 Performance management

The contract should state that the purchaser will, at defined intervals (e.g., quarterly), review operational issues related to the contract and the vendor's performance in adhering to the requirements of the contract.<sup>16</sup> The contract should also outline all measurable standards of performance that will form the basis of the evaluation, as well as the stakeholders who will be involved in the performance review.<sup>9</sup> The metrics used to assess the vendor's performance should be clear, objective, and meaningful.<sup>16</sup>

A requirement that the vendor continually improve its performance should be included in the contract, along with incentives encouraging the desired behaviour or penalties in response to substandard performance.<sup>3,20</sup> Targets set as part of an improvement program should be realistic.<sup>13</sup>

### 9.5.14 Response to an error

The contract should state that if the vendor discovers an error affecting the quality of a good or service provided under the contract, the vendor will immediately inform the purchaser of the error and of all facts known about the error.

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Similarly, the contract should state that if the purchaser discovers an error related to a good or service provided by the vendor, the purchaser will immediately notify the vendor of the error and of all facts known about the error.

For both situations, the contract should state that the process and the content of the disclosure will be consistent with the purchaser's disclosure policies and procedures.

### 9.5.15 Reporting of errors

The contract should state that the vendor will provide to the purchaser all reports of errors, including any investigation and follow-up actions. The contract should also state who will approve or lead the internal investigations arising from such reports.

### 9.5.16 Business continuity plan

The contract should state the requirement that both the purchaser and the vendor have a plan to respond to interruptions in the delivery of the good or service, such as interruptions attributable to a natural disaster.

### 9.5.17 Records management

The contract should specify the following information about the records that the vendor will create and maintain:

- a) the form and content of the records;
- b) the retention period;
- c) the storage location; and
- d) the need to back up electronically stored records at specified intervals.

### 9.5.18 Progress Reports

The contract should describe the reports that the vendor is expected to submit to the purchaser or its agent and the reports that the purchaser is expected

to submit to the vendor. The contract should also state that each party to the contract (the purchaser and the vendor) will formally review and acknowledge the reports provided by the other party.

### 9.5.19 Access to records and reports

The contract should state that any records relevant to assessing the quality of the good or service provided by the vendor will be made accessible to the purchaser for a specified period.<sup>19</sup>

### 9.5.20 Subcontracting

Refer to subsection 7.4.3 in section 7.4. "Contract Acceptor" of the PIC/S *Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments*.<sup>1</sup>

In addition to the requirements set out in the PIC/S guide, the contract should also state that any work subcontracted by the vendor does not reduce the responsibilities or obligations of the vendor to fulfill its obligations under the contract.

### 9.5.21 Enticement of employees

The contract should prevent the vendor from offering employment to the purchaser's current employees for a defined period.<sup>15</sup>

### 9.5.22 Ownership and custody

In some instances, it may be necessary for the purchaser to supply goods to the vendor to allow fulfillment of the vendor's responsibilities. To protect the interests of the rightful owner in such circumstances, the contract should address issues related to the ownership and custody of goods and other assets, including intellectual property.

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### 9.5.23 Use of confidential information

The contract should describe acceptable and unacceptable uses of confidential information provided by either of the parties.

### 9.5.24 Payment for goods and services rendered

The contract should list all fees and appropriate taxes (e.g., Harmonized Sales Tax, Goods and Services Tax) that are to be paid by the purchaser to the vendor for fulfilling the obligations described in the contract.

The contract should also state the following elements related to payment:<sup>3</sup>

- a) the billing regime (e.g., fixed price, variable price, cost reimbursement, variable quantity, performance based payments, incentive payments);
- b) the schedule according to which the payments will be made;
- c) the dependencies on key deliverables or milestones (e.g., payment will be made upon 50% completion of the work or every 3 months);
- d) the acceptable invoicing method; and
- e) the time after a correctly completed invoice is submitted that the vendor should expect payment.

Consideration may be given to adding an incentive or penalty structure to the payment.<sup>16</sup> (Refer to section 9.5.13.)

### 9.5.25 Transitioning in the contract

The contract should identify processes to facilitate the introduction of the vendor's good or service into the purchaser's operations.<sup>3</sup>

### 9.5.26 Process for resolving disputes

The contract should specify the procedures and responsibilities of the purchaser and the vendor to resolve disputes that may arise during the life of the contract<sup>3, 16</sup> (e.g., arbitration, mediation, adjudication).

### 9.5.27 Amendments

The contract should specify the process by which minor and major changes to the contract will be handled.<sup>16</sup>

The contract should specify the procedures that will be followed when there are changes to services, procedures, or other contracts that affect the delivery of the good or service under the contract. The procedures should identify the respective roles and responsibilities of both parties and should include how requests for changes will be handled and approved.<sup>13</sup>

If changes are made to any elements of the contract, they should be documented as one or more formal, written amendments, to keep the contract up to date.<sup>16</sup>

### 9.5.28 Acceptance of the contract

The contract should specify the individuals who are authorized to sign the contract on behalf of the purchaser and the vendor.

### 9.5.29 Termination of the contract

The contract should state the terms and conditions related to terminating the contract, including the conditions under which the contract may be terminated early.

The contract should also specify the exit strategy and responsibilities of both parties when the contract is nearing termination or has been terminated. The exit strategy should be designed to ease the

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departure of the vendor from the operations of the purchaser.<sup>3</sup>

### 9.5.30 Other elements

The contract should include other elements, such as disclosures of competing interests, requirements for confidentiality and privacy, and responsibilities for provision of equipment required for on-site services, as determined by the nature of the good or service to be provided.

## 9.6 Re-issuing the invitation to bid

If the negotiations result in a major revision to the original requirements set out in the tendering process, it may be necessary to invite all of the bidders to resubmit their proposals for evaluation on the basis of the new requirements.<sup>3</sup>

## 10. FINALIZING THE CONTRACT

Before a contract can be finalized, both parties should undertake the following activities:<sup>3</sup>

- a) obtain all required authorizations to comply with organizational and legislative requirements; and
- b) review the contract to ensure that it accurately reflects the full agreement between the 2 parties.

The persons who sign the contract must have the authority to do so and should be fully aware of their obligations under the contract.

### 10.1 Declining a contract

The purchaser and the vendor should not be obliged to accept a draft contract that does not meet their respective criteria to the full satisfaction of the negotiating teams and the committee managing the outsourcing process. The decision to decline a contract should not be taken lightly and should take into account the potential legal and managerial

risks.<sup>3</sup> In this situation, it may be necessary to review and possibly revise the request for proposal and re-issue the proposal.

## 10.2 Notifying unsuccessful bidders

According to the principles of fair practice, the purchaser should promptly notify all unsuccessful bidders of the decision to award the contract.

If feedback is requested by an unsuccessful bidder, the purchaser should document all such communication.<sup>15</sup>

All appeals received from unsuccessful bidders should be handled according to the process established in section 6.5 of this document.

## 11. PLANNING THE TRANSITION FROM TENDERING PHASE TO CONTRACT MANAGEMENT PHASE

The purchaser should plan the transition from the tendering phase to the contract management phase.<sup>16</sup> The arrangements should facilitate the provision of the contract deliverables, establish systems, procedures and relationships applicable to the contract, and complete the transfer of resources to the vendor, as needed under the contract.<sup>3</sup>

The transition plan should include the following elements:

- a) clear ownership of the contract and contract management processes;<sup>16</sup>
- b) clear contract management processes, which align with the broader governance processes, operations, and risk structures of the organization;<sup>16</sup>
- c) defined approaches to monitor performance according to the contract;<sup>3</sup> and
- d) clear description of a reporting mechanism to inform senior management of contract management performance and related issues.<sup>16</sup>

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The amount of detail provided in the plan is usually proportional to the complexity of the contract.<sup>3</sup>

### 12. MANAGING THE CONTRACT

Both parties to the contract should have a formal process for contract management to ensure that they fulfill their obligations under the contract, to ensure that the contract produces desirable value for money,<sup>13</sup> and to allow them to be prepared for managing the risks and taking advantage of opportunities presented by the contract.<sup>13,16,20</sup>

Contract management includes activities in 3 specific areas:<sup>13,20</sup>

- a) service delivery— ensuring that the agreed-upon levels and quality of service are maintained throughout the contract;
- b) relationships – building trust and understanding, fostering open and excellent communication at the operational, business and strategic levels, and developing a cooperative approach to managing delivery and improving performance under the contract; and
- c) contract administration – developing processes to manage records related to the contract and ensure that the administrative components of the contract are fulfilled, identifying who is responsible for what, at what times, and by what means (e.g., payment procedures, cost monitoring, management reporting, contract termination).

The effectiveness of the contract management processes will be influenced by the following factors:<sup>2</sup>

- a) legislative framework;
- b) staff expertise;
- c) size and complexity of the organization;
- d) nature of the organization’s business; and
- e) scope and complexity of the contract management process.

### 12.1 Determining the extent of contract management activities

The extent of activities undertaken for contract management and the level of resources assigned to support those activities should be determined in consideration of the expected benefits by managing the risks inherent in the contract; and the expected added value that might arise from contract management.<sup>16</sup>

Under any contract, the purchaser and the vendor may be exposed to 3 categories of risk:<sup>16</sup>

- a) service failure (e.g., business interruptions, failure to deliver good or service);
- b) tarnished reputation (e.g., illegal actions undertaken by the other party); and
- c) additional expenses (unexpected cost overruns).

It is good practice to identify the key risks under the contract, estimate the probability that the risk will occur, and predict the consequences if the risk does occur. The results of this exercise should inform the purchaser and the vendor of ways to mitigate or manage those risks.

The purchaser or vendor should capitalize on any added value outside of but related to the contract. Such added value may occur through improved reputation, reduced costs in providing the good or service, or higher-than-specified service levels in providing the good or service, at no extra cost.<sup>16</sup>

Values can arise in any of the following categories:<sup>13</sup>

- a) business benefit (e.g., creation of new opportunities for the business);
- b) capacity or capability (new skill in service delivery); and
- c) economy (efficient services through economies of scale).

### 12.2 Assigning responsibilities

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A contract management team should be given responsibility for managing the contract in the areas listed in section 12. The team should know who is responsible for what, when, and how. To effectively and efficiently fulfill this responsibility the team should have the necessary knowledge and skills to effectively and efficiently fulfill this responsibility.<sup>20</sup> Such capacity includes having a full understanding of the following areas:<sup>13</sup>

- a) the business related to the contract; and
- b) the content, context, complexities, and dependencies of the contract.<sup>13</sup>

### 12.3 Responding to change

Both parties should be prepared to adapt the terms of the contract in response to any change in the environment that introduces problems not anticipated when the contract was awarded. It is recommended that each party attempt to understand the implications of such changes from the perspective of the other party.<sup>13</sup>

## 13. MANAGING THE RECORDS

All records arising from the outsourcing process should be systematically maintained, in either paper or electronic form, in accordance with federal, provincial, or territorial legislation, and with each organization's policies and procedures

The records should provide evidence of the outsourcing process that was followed (including the rationale to deviate from previously established processes), as well as key decisions made and the reasoning behind those decisions.<sup>3</sup>

### 13.1 Information maintained by purchaser

The following list highlights the types of information that should be maintained by the purchaser (for any

items referring to the contract itself, see also section 9.5 of this document):<sup>3,13</sup>

- a) risk assessments;
- b) declarations of conflicts of interest;
- c) minutes of meetings with stakeholders;
- d) business case;
- e) tendering process;
- f) request for proposal (including invitation);
- g) evaluation criteria;
- h) responses to the request for proposal;
- i) responses to queries regarding the proposal (including appeals);
- j) final assessments of bids;
- k) drafts of the contract;
- l) professional advice received;
- m) records of negotiations (discussions, agreements);
- n) contract, including all schedules, attachments, and amendments;
- o) evidence that each party has fulfilled its obligations under the contract;
- p) transition plans;
- q) records of contract performance;
- r) records of problems and complaints (oral or written) and responses given;
- s) substantive communications related to the contract;
- t) payment records;
- u) evaluation plan; and
- v) lessons learned.

### 13.2 Information maintained by vendor

The following list highlights the types of information that should be maintained by the vendor (for any items referring to the contract itself, see also section 9.5 of this document):

- a) risk assessments;
- b) declarations of conflicts of interest;
- c) minutes of meetings;

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- d) bid submitted in response to the request for proposal;
- e) records of communications with the purchaser;
- f) responses to queries regarding the proposal;
- g) records of negotiations (discussions, agreements);
- h) contract, including all schedules, attachments, and amendments;
- i) evidence that each party has fulfilled its obligations under the contract;
- j) records of contract performance;
- k) records of problems and complaints (oral or written) and responses given;
- l) payment records;
- m) evaluation plan; and
- n) lessons learned.

The preceding lists are not all inclusive, and the parties to the contract shall consult with personnel within their respective organizations who have expertise and responsibilities relating to legal aspects, risk management, and financial and operational matters relevant to the contract to ensure that all appropriate and requisite records are maintained.

### 14. TERMINATING THE CONTRACT

When a contract ends, the purchaser should ensure that the contract is appropriately discharged according to the exit strategy agreed to within the contract. Such activities include ensuring that all materials loaned to the vendor are returned to the purchaser, that all access privileges given to the vendor (e.g., to the purchaser's premises or to the purchaser's information systems) are terminated within the agreed-upon timeframe, that payment for services or goods received under the contract has been made, and that arrangements are made to transition out of the contract relationship.<sup>3</sup>

#### 14.1 Obtaining professional advice

A contract may be terminated for any of a variety of reasons, such as delivery of all goods and services under the contract, by mutual agreement, or because of breach of contract or frustration. If an unusual or complex situation arises that causes either the vendor or the purchaser to consider terminating the contract before all obligations have been fulfilled, the party is cautioned to obtain suitable professional advice before terminating the contract.<sup>3</sup>

### 14.2 Evaluating the contract

When the contract ends, the vendor and the purchaser should evaluate the performance of both parties.<sup>13</sup> The evaluation should include an assessment of the purchaser's organizational structure and processes used during the outsourcing. Refer to section 15 of this document for more information.

## 15. MANAGING THE QUALITY OF CONTRACTED GOODS AND SERVICES

The purchaser should periodically review its organizational structure and processes for awarding contracts and for managing outsourced activities to ensure that it obtains the desired value in exchange for payments rendered. Consideration should be given to identifying ways to improve the management of contracts. The review should occur during the life of and upon termination of every contract.

### 15.1 Conducting the evaluation

The following questions should be answered when reviewing the structure, processes, and outcomes of the outsourcing to obtain or provide a good or service:

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- a) Was the process fair and transparent? Did it align with the organization's strategic approach to outsourcing? Were the individuals involved adequately prepared to fulfill their responsibilities?<sup>2</sup>
- b) Were appropriate monitoring and reporting processes used to provide the information that managers needed to effectively and efficiently manage the outsourcing process?<sup>2</sup>
- c) Does the contract meet the needs of the business? Are there other options for delivering the service in-house or obtaining the service through outsourcing?<sup>16</sup>
- d) How does the vendor's performance compare with benchmarked performance?<sup>13</sup>
- e) Were the objectives of the contract met? Did the good or service satisfy the purchaser's requirements? How could the provision of the good or service be improved under future contracts? Did the contract result in the benefits that were expected for the costs incurred? How was the care that patients received affected by the contract? Were risks understood and managed throughout the outsourcing process?
- f) Was the process well managed in terms of time and money? Did the good or service cost more than anticipated? Did delivery of the good or service take more time than anticipated?
- g) Were responsibilities regarding the development and management of the outsourcing process stated clearly and understood correctly by the parties involved, at every key stage in the process?
- h) Did the purchaser and the vendor agree to the interpretation of the terms of the contract, or were there disputes related to interpretation?
- i) Were mechanisms used to entice the purchaser and the vendor to improve their respective performance?
- j) Were revisions to the agreement documented as amendments to the contract?

Both parties to the contract should have an opportunity to provide evidence pertinent to issues under dispute and to participate in discussions

leading to remedial action, if any such remedial actions are warranted.<sup>3</sup>

### 15.2 Reporting to stakeholders

A report summarizing the key findings and action plan arising from the evaluation should be provided to the relevant stakeholders.<sup>3</sup> This information may be used to inform future decisions about contract management and any future relationships between the vendor and purchaser.

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