# Chapter 10
# Saskatchewan Cancer Agency—Cancer Drug Supply Management

## 1.0 Main Points

The Saskatchewan Cancer Agency is responsible for delivering effective and sustainable research, education, prevention, early detection, treatment, and supportive care programs for the control of cancer in Saskatchewan. It provides cancer drug treatments to more than 10,000 patients each year.

To appropriately treat cancer patients, the Agency must manage its supply of cancer drugs to have the right type of cancer drugs available for patients at the right time. In 2021-22, the Agency spent over $120 million on cancer drugs.

At June 30, 2022, our audit found the Agency had effective processes to manage its supply of cancer drugs, except it needs to formally document:

- Processes for updating the approved list of cancer drugs available on its drug formulary. This mitigates delays in updating the drug formulary in the event of staff turnover and makes new cancer drug treatments available to patients as soon as possible.

- Timeframes for making decisions on physician requests for exception cancer drugs. Our testing identified two cases where the Agency did not make timely decisions on requests for exception cancer drugs; one decision took 64 days. Timely decisions can help patients have access to the cancer drugs needed to support their treatment.

- Relevant factors (e.g., pricing, clinical reasons) considered when deciding to purchase cancer drugs directly rather than using group purchasing methods to help the Agency appropriately assess whether it is making appropriate purchasing decisions. Group purchasing enables the Agency to realize the benefits of nationally-negotiated prices for cancer drugs.

- Rationale, and approvals, when purchasing drugs using the single or sole source purchasing methods. This helps the Agency to reduce the risk of not facilitating fair and equitable treatment of suppliers, and not obtaining the best value when making purchasing decisions. During 2021–22, the Agency purchased about $10 million of cancer drugs through single or sole source purchasing.

- When and who completed supplier evaluations when tendering for cancer drug purchases to protect the Agency in the event of possible conflicts of interest and provide evidence of its supplier decisions before entering into purchasing contracts.

Failure to purchase safe and effective cancer drugs in the right quantities may put patients at risk of not receiving the most appropriate treatment when needed. Ineffective purchasing processes increases the risk of the Agency not receiving best value for cancer drugs.

# 2.0 INTRODUCTION

This chapter outlines the results of our audit of the Saskatchewan Cancer Agency's processes to manage its supply of cancer drugs for the 12-month period ended June 30, 2022.

Our audit did not involve assessing healthcare providers' decisions to provide treatment or to administer cancer drugs to patients.

## 2.1 Cancer Treatment in Saskatchewan

The Saskatchewan Cancer Agency is responsible to deliver effective and sustainable research, education, prevention, early detection, treatment, and supportive care programs for the control of cancer in Saskatchewan.[1]

The Agency maintains a list of approved cancer drugs for cancer patients in Saskatchewan through its drug formulary. It uses three main methods for acquiring these drugs:

- Contracts originating from terms negotiated by the pan-Canadian Pharmaceutical Alliance (pCPA). The pCPA uses the combined negotiating power of its members (i.e., provincial, territorial and federal governments) to conduct joint negotiations for brand name and generic drugs in Canada, and obtain greater value for publicly funded drug programs and for patients.[2] In 2021–22, the Agency purchased almost $89 million of cancer drugs under this method.

- Contract established by Health Shared Services Saskatchewan (3sHealth) with a national group purchasing organization (i.e., HealthPRO) for most generic cancer drugs and support medications (e.g., anti-nausea).[3,4] In 2021–22, the Agency purchased over $4.5 million of cancer drugs under this method.

- Contracts negotiated directly by the Agency. In 2021–22, the Agency purchased over $27.7 million of cancer drugs under this method.[5]

The Agency administers most cancer (i.e., oncology) treatments at its two main centres—the Allan Blair Cancer Centre in Regina and the Saskatoon Cancer Centre.[6] The Agency pays for the costs of approved cancer drugs administered to patients—it provides treatment at no cost to the patient.

As shown in **Figure 1**, the Agency provides chemotherapy (i.e., drug) treatments to over 3,000 cancer patients annually at its two centres.

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[1] *The Cancer Agency Act*, s. 9.
[2] www.pcpacanada.ca/about (26 September 2022).
[3] 3sHealth is responsible for facilitating the purchase of goods and services on behalf of its member agencies (i.e., shared procurement), including the Saskatchewan Cancer Agency, and the Saskatchewan Health Authority and its affiliates. Our Office audited 3sHealth's shared procurement processes in our *2015 Report – Volume 2*, Chapter 34, pp. 185–203.
[4] HealthPRO brings together the national buying power and expertise of 1,300 member organizations to deliver contracts for high-quality products and services, saving both time and money for healthcare institutions across Canada. www.healthpro canada.com/about-us (21 September 2022).
[5] Information provided by the Saskatchewan Cancer Agency.
[6] The Allan Blair Cancer Centre is located at the Pasqua Hospital, and the Saskatoon Cancer Centre is located at the Royal University Hospital.

**Figure 1—Number of Patients and Chemotherapy Treatment Visits Provided at the Saskatchewan Cancer Centres in Regina and Saskatoon**

| Centre | 2018–19 | 2019–20 | 2020–21 | 2021–22 |
|---|---|---|---|---|
| **Allan Blair Cancer Centre** | | | | |
| Chemotherapy treatment visits | 10,641 | 11,357 | 11,010 | 11,881 |
| Number of patients | 1,410 | 1,542 | 1,490 | 1,539 |
| **Saskatoon Cancer Centre** | | | | |
| Chemotherapy treatment visits [A] | 12,044 | 12,568 | 11,900 | 13,007 |
| Number of patients [A] | 1,652 | 1,718 | 1,594 | 1,752 |
| **Total chemotherapy treatment visits** | **22,685** | **23,925** | **22,910** | **24,888** |
| **Total number of patients** | **3,062** | **3,260** | **3,084** | **3,291** |

Source: Adapted from the Saskatchewan Cancer Agency *Annual Report 2021–22*, p. 16.
[A] Pediatric oncology moved to the Saskatchewan Health Authority Jim Pattison Children's Hospital in 2019–20.

The Agency also uses 17 Community Oncology Program of Saskatchewan (COPS) sites across the province to allow patients to receive certain treatment closer to their home.[7] The Agency maintains a list of drugs eligible for administration at the COPS sites; not all cancer drugs on the Agency's cancer drug formulary are provided at COPS sites.

As shown in **Figure 2**, the number of patients receiving chemotherapy treatment at COPS sites continues to rise, with over 2,400 cancer patients receiving treatment in 2021–22.

**Figure 2—Number of Patients and Chemotherapy Treatment Visits Provided at Community Oncology Program of Saskatchewan (COPS) Sites**

| | 2018–19 | 2019–20 | 2020–21 | 2021–22 |
|---|---|---|---|---|
| Chemotherapy treatment visits | 13,514 | 13,869 | 14,391 | 15,018 |
| Number of patients | 2,008 | 2,057 | 2,128 | 2,405 |

Source: Adapted from the Saskatchewan Cancer Agency *Annual Report 2021–22*, p. 17.

## 2.2 Importance of Effectively Managing the Supply of Cancer Drugs

Cancer is the leading cause of death in Canada.[8] It poses an enormous burden on both the health of Canadians and on the Canadian healthcare system.

The Canadian Cancer Society estimates 43% of Canadians will be diagnosed with cancer in their lifetime.[9] In 2021, it expected 229,200 new cancer cases, with Saskatchewan residents representing 6,000 of those cases.[10] It also estimates by 2028–32, the average annual number of new cancer cases will increase 79% compared to 2003–07 driven by an aging and growing population.[11]

[7] COPS sites are located in Estevan, Melville, Moose Jaw, Moosomin, Swift Current, Weyburn, Yorkton, Humboldt, Kindersley, Lloydminster, Meadow Lake, Melfort, Nipawin, North Battleford, Prince Albert, Tisdale, and Flin Flon (for Saskatchewan residents only).
[8] Canadian Cancer Society, *Canadian Cancer Statistics 2021*, (2021), p. 67.
[9] Ibid., p. 22.
[10] Ibid., p. 15.
[11] Ibid., p. 72.

To properly treat cancer patients, cancer organizations must have the right type of cancer drugs available at the right time. Purchasing cancer drugs is a complex process involving agencies, committees, and individuals—on both a national and provincial level. It is important that fair access is provided to drugs in a way that is affordable for the health system.[12] The World Health Organization notes good pharmaceutical purchasing practices are based on four strategic objectives:

- Purchase the most cost-effective drugs in the right quantities
- Select reliable suppliers of high-quality products
- Ensure timely delivery
- Achieve the lowest possible cost[13]

Effective processes to manage cancer drugs contribute to the safety and well-being of cancer patients in Saskatchewan. Failure to purchase safe and effective cancer drugs in the right quantities may put patients at risk of not receiving the most appropriate treatment when needed. This may lead to irreparable mental and physical health damage and, in extreme cases, avoidable loss of life. Ineffective purchasing processes increases the risk of the Agency not receiving best value for cancer drugs and may result in excessive waste and increased costs to the healthcare system.

## 3.0 Audit Conclusion

**We concluded, for the 12-month period ended June 30, 2022, the Saskatchewan Cancer Agency had, other than the following areas, effective processes to manage its supply of cancer drugs.**

**The Agency needs to formally document:**

- **Processes for updating the approved list of cancer drugs available on its drug formulary to treat cancer patients**
- **A timeframe for making decisions on physician requests for exception cancer drugs**
- **Relevant factors considered when deciding to purchase cancer drugs directly rather than using group purchasing methods**
- **Rationale, and approvals, when purchasing drugs using the single or sole source purchasing methods**
- **When and who completed supplier evaluations when tendering for cancer drug purchases**

[12] McMaster Health Forum & Canadian Centre for Applied Research in Cancer Control, *Making Fair and Sustainable Decisions about Funding for Cancer Drugs in Canada*, (2016), p. 16.
[13] Adapted from World Health Organization, (1999), *Operational principles for good pharmaceutical procurement* (Essential Drugs and Medicines Policy Interagency Pharmaceutical Coordination Group). www.apps.who.int/iris/bitstream/handle/10665/66251/WHO_EDM_PAR_99.5.pdf? (10 May 2022).

**Figure 3—Audit Objective, Criteria, and Approach**

**Audit Objective:**

To assess whether the Saskatchewan Cancer Agency had effective processes to manage its supply of cancer drugs for the 12-month period ended June 30, 2022.

Our audit did not involve assessing healthcare providers' decisions to provide treatment or to administer cancer drugs to patients.

**Audit Criteria:**

Processes to:

1. **Approve list of cancer drugs supplied, at no cost, to patients**
   - Review list of cancer drugs regularly
   - Approve changes (i.e., additions/deletions) to list of cancer drugs
   - Assess requests for use of cancer drugs not on the list
2. **Determine appropriate cancer drug suppliers**
   - Determine which drugs are subject to group purchasing
   - Define roles for various purchasing methods (e.g., direct, group)
   - Evaluate potential suppliers for best value
   - Track performance of key suppliers
3. **Maintain an adequate supply of cancer drugs**
   - Regularly assess need for cancer drugs
   - Appropriately distribute and store cancer drugs
   - Analyze key performance information (e.g., shortages, cancer drug wastage, dispensing patterns)
   - Regularly report to key stakeholders (e.g., senior management, Board, Ministry of Health)

**Audit Approach:**

To conduct this audit, we followed the standards for assurance engagements published in the *CPA Canada Handbook—Assurance* (CSAE 3001). To evaluate the Agency's processes, we used the above criteria based on our related work, review of literature including reports of other auditors, and consultations with management. The Agency's management agreed with the above criteria.

We examined the Agency's policies and procedures relating to managing its supply of cancer drugs. We interviewed key staff responsible for managing the Agency's supply of cancer drugs. We tested samples of changes to the cancer drug formulary, exception drug requests, and drug purchases. In addition, we observed the Agency's processes to manage its supply of cancer drugs in one of its main cancer centres and two COPS sites. We also used an independent consultant with subject matter expertise in the area to help us identify good practice and assess the Agency's processes.

# 4.0 KEY FINDINGS AND RECOMMENDATIONS

## 4.1 Process for Maintaining Cancer Drug Formulary Not Documented

The Saskatchewan Cancer Agency regularly reviews and updates its cancer drug formulary (i.e., list of approved cancer drugs); however, the process to do so is not formally documented.

The Agency maintains a list of cancer drugs funded by the Ministry of Health on its website.[14] At September 2022, the Agency had over 180 cancer drugs on its list. It provides these drugs, at no cost to patients, for cancer treatment.[15] See **Figure 4** for a summary of content within the cancer drug formulary.

[14] www.saskcancer.ca/health-professionals-article/drug-formulary?highlight (13 September 2022).

[15] In some cases, cancer treatment in another province or country may be desired or necessary (i.e., certain procedures or treatments may not be available in Saskatchewan). The Ministry of Health provides prior approval for payment in such cases. Patients are responsible for the costs of related travel, meals, and accommodations. www.saskcancer.ca/patients-and-families-articles/receiving-treatment-out-of-province (27 September 2022).

**Figure 4—Cancer Drug Formulary Content Summary**

- Drug name (under its generic or chemical name)
- Dosage form (e.g., tablet, vial)
- Strength (e.g., 250 mg, 500 mg)
- Disease site group (e.g., gastrointestinal)
- Cancer site (e.g., pancreas, colon)
- Funded indications and eligibility requirements (i.e., criteria for use in specific cancers, specific treatment settings, in combination with other drugs)

Source: Saskatchewan Cancer Agency Drug Formulary, September 2022.

The Agency makes its Pharmacy and Therapeutics Committee responsible for the oversight and management of the cancer drug formulary.[16] However, we found the terms of reference for this Committee is outdated (last updated in 2008), and did not align with current practices (e.g., terminology, membership, subcommittees).

A national drug expert review committee assesses the clinical evidence of drug trials (e.g., efficacy, safety, patient impact) and cost-effectiveness (e.g., versus available comparators in Canada) of new cancer drugs on the market.[17] It makes recommendations to all the federal, provincial, and territorial publicly-funded drug plans to help guide their drug funding decisions. In addition, upon the committee's recommendations for acceptance of new cancer drugs, the pan-Canadian Pharmaceutical Alliance (pCPA) negotiates nationally with the drug manufacturers and sign letters of intent.[18]

Each month, the Agency's Pharmacy and Therapeutics Committee reviews the new drug recommendations from the national committee. It also considers the epidemiology information from the manufacturer, the Canadian market's expected acceptance of the drug, and budget impact.[19]

Once a pCPA letter of intent for a new cancer drug or indication (i.e., using a certain drug for treating a specific cancer) is in place, the Agency submits a request for approval of the drug in its quarterly drug funding submission to the Ministry of Health. Upon receiving Ministry approval, the Agency adds the new cancer drug or indication to its approved drug formulary. The Agency indicated the Ministry has yet to deny the Agency's requests for adding new cancer drugs to its approved drug formulary.

As of September 2022, management indicated pCPA had letters of intent for 180 brand name cancer drugs and associated indications, and the Agency had all but five of them on its drug formulary. The Agency expects to add these five drugs and associated indications on its formulary before the end of 2022.

For cancer drugs already in use, physicians may request a change to drug eligibility requirements set out in the approved drug formulary. For example, a physician may request

[16] The Pharmacy and Therapeutics Committee is chaired by the Director of Oncology Pharmacy Services and includes various executives (i.e., Vice-President of Care Services, Vice-President of Population Health, Quality, and Research) and senior medical staff (e.g., medical directors, hematologist, medical oncologists).
[17] Canada's Drug and Health Technology Agency (CADTH) has a national drug expert review committee to bring consistency and clarity to the assessment of drugs in Canada. The committee's membership includes a chair, three patient representatives, one ethicist, and 12 expert members (e.g., physicians, pharmacists, health economists). CADTH was established by Canada's federal, provincial, and territorial governments to be a trusted source of independent information and advice for the country's publicly funded healthcare systems. www.strategicplan.cadth.ca/about/ (26 September 2022).
[18] As of April 30, 2022, the pan-Canadian Pharmaceutical Alliance (pCPA) estimates it has, through collective negotiations, realized overall savings of $2.67 billion annually for brand name drugs (across all types of drugs, including cancer drugs). www.pcpacanada.ca/about (26 September 2022).
[19] Epidemiology is the method used to find the causes of health outcomes and diseases in populations. www.cdc.gov/ career paths/k12teacherroadmap/epidemiology.html (29 September 2022).

the expansion of the use of a drug beyond a specific cancer. The Agency's Pharmacy and Therapeutics Committee reviews and approves such requests prior to the Agency changing the cancer drug formulary. In addition, if the Agency continues to see multiple requests for a particular exception (i.e., cancer drugs not on the formulary, or use of a drug on the formulary but outside of the eligibility criteria), the Committee also considers adding those particular exceptions to the formulary. The Agency added one additional indication for an approved drug to its formulary in 2021–22.

In 2021–22, the Agency made 21 changes to its cancer drug formulary. We tested four changes and found the Agency followed its established process (e.g., reviewed national committee recommendations, requested Ministry of Health's approval) and made timely updates to its formulary. We found the Agency added these new drugs to its approved drug formulary within two or three months of pCPA signing a letter of intent with the applicable drug manufacturers (and about a year after the national committee's initial recommendations).

While we found the Agency's processes to modify its cancer drug formulary aligned with good practice, the Agency has not formally documented its processes. For example, it has not documented the various roles and responsibilities, frequency of updates, evaluation criteria, or approval process. Good practice recommends it should.

Without formally documenting its processes to update its cancer drug formulary, those involved in the process may not be aware of, or fully understand, the process and the desired results—especially in the event of staff turnover. As a result, this may increase the risk of delays in cancer drugs available for patient treatments.

1. **We recommend the Saskatchewan Cancer Agency formally document its processes for updating the approved list of cancer drugs (i.e., formulary) available to treat cancer patients.**

## 4.2 Timeframe for Decisions on Exception Cancer Drugs Needed

The Saskatchewan Cancer Agency has a formalized process to approve exception drug requests. However, it does not have an established timeframe for deciding on requests.

The Agency maintains a case-by-case review program for exception drug requests (i.e., on an individual patient basis). The program is intended for a small group of patients with rare types of cancer. It provides a standardized and transparent process for Agency staff to follow when physicians request cancer medications outside of the Agency's approved list of cancer drugs or approved indications (i.e., using a certain drug for treating a specific cancer) in the formulary.

The Agency's Case-By-Case Review Program Policy requires physicians to apply for an exception drug by completing an electronic form that includes information and evidence (e.g., estimated median survival with and without treatment, other anticipated clinical benefit, research/papers) to support the request. The Director of Oncology Pharmacy Services and the disease/tumor site leader evaluate all applications to either approve or deny the requests.[20] We found the Case-By-Case Review Program Policy for exception drug requests aligns with good practice.

[20] A disease/tumor site leader is a physician specialist with expertise in the relevant disease site (e.g., breast).

Between July 1, 2021 and May 31, 2022, the Agency received 175 requests for exception drugs. Of those requests, 131 were approved, 39 denied, and 5 withdrawn.

For all 17 exception drug requests we tested (i.e., 10 approved, 7 denied), we found physicians submitted complete applications and the Agency used standardized criteria to evaluate the requests. We also found the documentation maintained (e.g., discussion points between the Director of Oncology Pharmacy Services and disease/tumor site leader) supported the decision.

We found the Agency has not established a timeframe (e.g., within one week) for making decisions on physician requests. We found in two cases, the decision was not timely—it took 9 and 64 days respectively for the Agency to make a decision. We found the Agency denied these two requests.

Management indicated the Agency is working on developing a timeframe for making decisions on physician requests for exception drugs within its Case-By-Case Review Program Policy. It expects to complete this work by March 2023.

Delays in making decisions on physician requests for exception drugs may affect a patient's future treatment plans. Having a timely case-by-case review program for exception drug requests helps to ensure all patients have access to the cancer drugs needed to support their treatment.

**2. We recommend the Saskatchewan Cancer Agency establish a timeframe for making decisions on physician requests for exception cancer drugs.**

## 4.3 Need to Consider Relevant Factors When Deciding on Direct Purchasing

The Saskatchewan Cancer Agency does not set relevant factors it expects staff to consider when deciding to purchase cancer drugs directly rather than using group purchasing methods.

As noted in **Section 2.1**, the Agency uses three main methods for acquiring cancer drugs:

- Contracts originating from terms negotiated by the pan-Canadian Pharmaceutical Alliance (pCPA)—used mainly for brand name drugs still under patent protection (78 contracts during 2021–22)
- Contract established by 3sHealth with a national group purchasing organization (i.e., HealthPRO)—used for most generic cancer drugs and support medications (e.g., anti-nausea) (84 contracts during 2021–22)
- Contracts negotiated directly by the Agency—used for tenders and single/sole source drug purchases (5 tendered contracts and 24 single/sole sourced contracts in 2021–22)[21]

[21] Single source is purposely choosing a single supplier even though others are available (typically for small purchases or emergency purchases). Sole source is when only one supplier for the required item is available. These are non-competitive procurement methods.

For drugs acquired through group purchasing methods (i.e., pCPA, HealthPRO), the Agency remains aware of new cancer drugs and negotiations through its participation on group purchasing committees. For example, Agency staff participate in pCPA's weekly Oncology Operations Committee meetings. The pCPA expects each of its members (provincial, territorial and federal governments) to lead pCPA negotiations with some manufacturers, along with providing advice on negotiations led by other members. The Agency is Saskatchewan's representative on the pCPA and leads some negotiations with manufacturers as required.

Upon completion of negotiations, pCPA enters into a letter of intent with the manufacturer. Each member has the option of participating in the letter of intent which sets out the material terms of the agreement (e.g., reimbursements under public drugs plans, pricing, rebates) between the participating members and the manufacturer. Each member also enters into their own agreement with the manufacturer for a specific period (e.g., three years) establishing the net price of the cancer drug to the member and any product rebates.[22] In addition, we found the pCPA letter of intent acknowledges that members (including Saskatchewan) may re-negotiate the terms of the agreement if there are significant market changes.

The Agency has procurement-related policies and procedures to help guide the Agency's purchases, including drug purchases. Its delegation of authority policy sets out required approvals for drug purchase contracts. In addition, the Agency's contract management policy includes the contract process for tendering purchases and single/sole source purchases.

However, the Agency's contract management policy does not consider certain factors when deciding to purchase cancer drugs directly and not using group purchasing (e.g., through contracts established by pCPA and HealthPRO). We think it should because the decision to negotiate contracts directly rather than participate in group purchasing is an important purchasing decision. Group purchasing enables the Agency to realize the benefits of nationally-negotiated prices for cancer drugs. As such, the Agency should formally establish relevant factors (e.g., pricing, clinical reasons) staff must consider and document when deciding to negotiate drug purchase contracts directly.

**Figure 5** highlights key requirements within the Agency's policies and procedures.

**Figure 5—Analysis of Key Requirements for Cancer Drug Purchases Compared to Current Policies and Procedures**

| Requirement | Part of Saskatchewan Cancer Agency's Policies and Procedures? |
|---|---|
| Outlines key principles when making purchasing decisions (e.g., achieve best value, conduct purchasing in an equitable manner) | Yes |
| Sets out available purchasing methods: | |
| Group purchasing (i.e., through HealthPRO and pCPA), including process for participating in group letters of intent with manufacturers and factors (e.g., pricing, clinical reasons) to justify not using these purchasing methods | No |

[22] Within its agreements with drug manufacturers, the Agency may negotiate product rebates based on the Agency's purchases or utilization of the drugs. Rebates can take the form of monetary rebates or access to additional quantities of drugs at no cost to the Agency.

| Requirement | Part of Saskatchewan Cancer Agency's Policies and Procedures? |
|---|---|
| Non-competitive such as single or sole source purchases | Yes—however, does not set requirements for staff to document sufficient rationale, nor seek approval, for the use of these purchasing methods. See **Section 4.4** |
| Competitive requests for public tenders | Yes |
| Sets out guidance for evaluating potential suppliers when staff use competitive purchasing methods (i.e., public tenders) | Yes—Agency uses an evaluation matrix to evaluate tenders for cancer drug purchases. See **Section 4.5** |
| Outlines signing authorities for specific positions and types of purchases | Yes |

Source: Developed by the Office of the Provincial Auditor of Saskatchewan.

Without establishing relevant factors to consider when deciding between purchasing cancer drugs directly rather than using group purchasing methods, there is increased risk the Agency may not use the most appropriate method to purchase cancer drugs. This can result in the Agency not obtaining the best value when making purchasing decisions.

3. **We recommend the Saskatchewan Cancer Agency set out, in writing, relevant factors it expects staff to consider when deciding to purchase cancer drugs directly rather than using group purchasing methods.**

We tested 31 drug purchases and found the Agency selected a reasonable purchase method for all items, as follows:

- For the 11 group purchases in our sample, we found the Agency appropriately participated in a letter of intent with a manufacturer (i.e., pCPA purchases) or committed to purchasing drugs from HealthPRO.
- For three tendered items and 17 single/sole source items in our sample, the Agency provided sufficient verbal rationale for use of these methods (e.g., clinical reason, only one manufacturer available). We found no indications the Agency did not obtain best value in these circumstances.
- For all drug purchases tested, the Agency appropriately approved the drug purchase contracts (e.g., approval given by the President and Chief Executive Officer, and the Director of Oncology Pharmacy Services).

Using an appropriate purchasing method is necessary for the Agency to obtain best value when purchasing cancer drugs.

## 4.4 Rationale for Use of Single or Sole Source Purchasing Not Documented

The Saskatchewan Cancer Agency does not document rationale, nor seek approval, for the use of single and sole source purchases of cancer drugs.

As noted in **Section 4.3**, the Agency has a policy guiding its use of single or sole source purchasing. However, contrary to good practice, we found the policy does not set

requirements on what staff must consider and document when using these purchasing methods, and what approvals are necessary.

During 2021–22, the Agency purchased about $10 million of cancer drugs through single or sole source purchasing. This represents about 40% of drug purchases directly negotiated by the Agency.

We tested 17 single or sole source purchases made by the Agency and found it did not document its rationale, or seek approval (e.g., management independent from Oncology Pharmacy Services), for using these purchase methods. While the Agency did not maintain the documentation and approval, we found the rationale (verbally provided by management) reasonable for each purchase. In most cases, only one manufacturer existed from which the Agency could purchase the drugs (i.e., sole source); in other cases, the Agency provided clinical reasons (e.g., patients experienced adverse reactions to other drugs) for purchasing drugs from a specific manufacturer (i.e., single source).

Not documenting the rationale for its use of single or sole source purchasing increases the risk of the Agency not facilitating fair and equitable treatment of suppliers, and not obtaining the best value when making purchasing decisions.

4. **We recommend the Saskatchewan Cancer Agency document its rationale, and seek approval, when purchasing cancer drugs using the single or sole source purchasing methods.**

## 4.5 Supplier Tender Evaluations Completed, But More Documentation Required

The Saskatchewan Cancer Agency evaluated suppliers when tendering for the purchase of cancer drugs; however, improvements in the process are needed.

The Agency uses an evaluation matrix to score each bid received on a tender. Members of the Agency's pharmacy team (i.e., Director, Manager, and Financial Consultant) complete the evaluations and provide an overall score for each proposal. See **Figure 6** for the criteria used in evaluating proposals. We found the criteria set out in the evaluation matrix aligned with good practice.

**Figure 6—Criteria for Evaluating Cancer Drug Proposals**

- Financial considerations (e.g., price, value additions [such as doses at no charge])
- Proponent relations (e.g., service and support; return policy/expiry date; distribution/shipping; backorder, allocation and supply history; rebate payments)
- Product particulars (e.g., labeling, packaging, dosage, storage conditions, and stability)

Source: Information provided by the Saskatchewan Cancer Agency.

We tested three tenders and found the Agency evaluated the proposals using the evaluation matrix and selected the supplier with the highest score.

However, we found the Agency does not record who was involved in the evaluation process and/or have them sign-off on the completed evaluation.

Lack of evidence of those involved in evaluations increases the risk associated with defending purchasing decisions if there are conflict of interest allegations. In addition, formal sign-offs on completed evaluations provide evidence of the Agency finalizing its supplier decisions prior to entering into contracts with chosen suppliers.

5. **We recommend the Saskatchewan Cancer Agency formally document when and who completed potential supplier evaluations when tendering for cancer drug purchases.**

## 4.6 Supplier Performance Issues Addressed

The Saskatchewan Cancer Agency uses an ad hoc approach to address supplier performance issues.

Only a few individuals are responsible for making a large portion of the Agency's cancer drug purchasing decisions. As such, the Agency can more easily identify significant supplier performance issues.

We found the Agency handles supplier performance issues on an ad hoc basis through direct communication (e.g., emails) with the manufacturer, distributor, or with the involvement of HealthPRO (where applicable). Through our discussions with management, we identified two supplier performance issues. We found the Agency appropriately handled and communicated these performance issues. For example, the Agency:

- Directly communicated with HealthPRO and a drug manufacturer over a nine-month period between December 2019 and August 2020 in relation to issues with a drug crystalizing (i.e., the drug is no longer usable). The issues persisted and the Agency subsequently purchased from an alternate manufacturer.

- Directly communicated with a distributor in July 2022 about delivery issues, resulting in the Agency receiving a credit for the drugs purchased.

Proactively identifying and addressing supplier performance issues helps to ensure the Agency receives cancer drugs as expected.

## 4.7 Need for Cancer Drugs Regularly Assessed

The Saskatchewan Cancer Agency regularly assesses its need for cancer drugs.

The Agency generally maintains a minimum six-week and maximum eight-week supply of cancer drugs; however, there are exceptions. For example, some drugs that need refrigeration may have a lower supply maintained due to limitations in storage space. The Agency also maintains inventories of some drugs regardless of expected utilization, as they deem these "life-saving" drugs.

Each quarter, the Agency reviews its minimum and maximum levels of cancer drugs in its inventory management IT system. It reviews utilization reports from the previous three months to help assess and adjust the minimum and maximum inventory levels at its two main centres. We found the Agency's process to maintain its cancer drug inventory levels aligns with good practice.

For eight cancer drugs tested at each main centre, we found the Agency followed its process (i.e., consideration of drug utilization for the previous three months) when setting its minimum and maximum inventory levels.

Our analysis found, as at July 2022, the Agency had 191 drugs (of varying doses) where the quantity on hand exceeded the maximum level by more than 10% and 29 drugs where it was below the minimum level by more than 10%. In instances where the Agency established a minimum level for a drug, our analysis did not identify any instances where the Agency did not have a specific drug available for cancer patients.

We tested 10 drugs with variances from the Agency's established minimum and maximum inventory levels and found the Agency provided reasonable explanations for the differences. For example, our testing found a drug with inventory below the established minimum level due to a supply shortage. This specific drug was on backorder from the manufacturer and the Agency instead sourced it from the Saskatchewan Health Authority on an as needed basis.

See **Figure 7** for common reasons why the Agency does not always maintain the minimum and maximum levels of cancer drugs as planned.

**Figure 7—Common Reasons for Not Maintaining Minimum and Maximum Levels of Cancer Drugs**

- The Agency becomes aware of an upcoming backorder/supply shortage issue and may order more than required, if allowed by the vendor, of a frequently used drug
- Package size limits the ability to order precisely to the maximum level noted
- The agreement with the manufacturer limits the number of drug orders
- Some drugs are purchased only on an as needed basis, as the cost per unit may be high and the number of patients expected to receive the drug may be very low, or the drug may have a short shelf-life

Source: Information provided by the Saskatchewan Cancer Agency.

Each month, the Agency reviews expiry dates for cancer drugs at its main centres in Saskatoon and Regina. Expired cancers drugs do not represent a significant loss to the Agency. In 2021–22, the Agency had approximately $170,000 of cancer drugs expire but obtained manufacturers' credits (as per the agreements) for almost 90% of these drugs.

Regularly assessing the need for cancer drugs helps to ensure the Agency maintains an appropriate supply of cancer drugs and reduces the risk of patients not receiving the most appropriate treatment when needed.

## 4.8 Community Oncology Centres Used To Deliver Certain Cancer Treatments

The Saskatchewan Cancer Agency uses 17 community oncology centres (i.e., COPS) across the province to deliver cancer treatment to patients closer to their home.[23]

The Agency maintains a list of approved drugs that staff can administer at each site. It determines which cancer drugs/treatment regimens that community oncology centres

[23] The Community Oncology Program of Saskatchewan (COPS) has sites located in Estevan, Melville, Moose Jaw, Moosomin, Swift Current, Weyburn, Yorkton, Humboldt, Kindersley, Lloydminster, Meadow Lake, Melfort, Nipawin, North Battleford, Prince Albert, Tisdale, and Flin Flon (for Saskatchewan residents only).

can safely deliver by using criteria, with a scoring system, to assess the cancer drug/treatment regimens. See **Figure 8** for the safety and practical factors used in determining which cancer drugs/treatment regimens that community oncology centres can safely deliver. We found this process comprehensive and systematic.

**Figure 8—Safety and Practical Factors Used in Assessing Cancer Drugs Delivered at Community Oncology Program of Saskatchewan (COPS) Centres**

**Safety Factors:**

- Drug/treatment regimen toxicity (e.g., risk associated with administration)
- Complexity of drug/treatment regimen
- Community oncology centre staff education requirements
- Agency physician support for request

**Practical Factors:**

- Cost factors (e.g., high cost/dose)
- Drug wastage
- Transportation factors (e.g., difficult and/or hazardous drug to transport)
- Preparation factors (e.g., complex and/or difficult drug preparation)
- Time capacity of community oncology centre to provide service (e.g., requires extended delivery time)
- Staff capacity required by community oncology centre to provide service (e.g., requires extensive staff participation)
- Agency staff capacity to provide service (e.g., requires extensive Agency staff participation)

Source: Saskatchewan Cancer Agency, *Approval for a Cancer Drug/Treatment Regimen in COPS Policy*.

The Agency also maintains a secure website that contains key documents supporting cancer drug distribution, and safe storage and handling for community oncology centre staff reference. For example, the secure website includes:

- Preparation guideline chart—provides guidance on storage, mixing, and dispensing of cancer drugs

- Specific work standards for rare or more complex drugs—provides additional guidance on how to prepare the cancer drug for administration to patients

- COPS "Do Not Make Ahead Lists"—drugs which must not be made until the patient has been assessed by nurses as ready for treatment to ensure drug stability and to minimize wastage

Each community oncology centre maintains a small inventory of cancer drugs. The Agency's Senior Oncology Pharmacy Technicians work with the centres to determine their needs and to set the minimum and maximum levels of inventory required.

We observed the processes used at two community oncology centres. We found each site had a reasonable process to order cancer drugs to manage minimum and maximum levels. For example, at one centre, staff used cards placed on shelves amongst the drug inventory as reminders for when to order more of a specific drug. We also found the centres properly stored drugs (e.g., on shelves, in refrigerators).

During our observations, we selected nine drugs from the centres' available inventory and found the drugs were three months to two years away from expiry (i.e., not at risk of expiry).

Having community oncology centres with an adequate supply of cancer drugs allows patients to receive treatment closer to home, which contributes to the safety and well-being of cancer patients.

## 4.9 Cancer Drug Shortages Monitored

The Saskatchewan Cancer Agency regularly monitors cancer drug shortages.

The Agency identifies cancer drug supply shortages through communication with manufacturers and colleagues (including those in other jurisdictions), and through its participation on group purchasing committees (i.e., HealthPRO's Pharmacy Specialties Oncology Committee).

Each month, the Agency's Pharmacy and Therapeutics Committee monitors drug shortages and planned actions to address the shortages.

We found, at June 2022, the Agency monitored three cancer drug shortages, compared to five shortages in August 2021. The Agency monitors whether it has sufficient supply for patients currently scheduled for treatment and considers alternate drugs prior to expected shortages occurring. For example, the Committee noted the dosage for a particular drug may be temporarily unavailable in early 2023. In response, the Committee anticipates considering alternate drugs (based on a report provided by Canada's Drug and Health Technology Agency) prior to the possible shortage.[24]

We also found the Agency appropriately includes a clause in its drug contracts with suppliers as a protection measure in the event of a shortage. In such circumstances, the supplier and/or the Agency identify an alternate supplier (mutually agreed upon) from which the Agency can purchase cancer drugs and a force majeure may take effect, if necessary.[25]

Regularly monitoring cancer drug shortages helps the Agency to assess its existing inventory levels and consider alternate courses of action in preparation for a shortage. Doing so helps the Agency to maintain uninterrupted treatments for cancer patients.

## 4.10 Key Cancer Drug Information Analyzed and Reported

The Saskatchewan Cancer Agency analyzes key cancer drug information and reports the results to senior management, its Board of Directors, and the Ministry of Health.

Each month, the Agency analyzes and reports to senior management, its Board of Directors, and the Ministry of Health in three key areas:

- Drug utilization—information detailed by drug category (e.g., hormone therapy, supportive care) and administration route (e.g., take home, intravenous)
- Rebates—tracked by each type of drug, as consideration of drug rebates is an important factor in the Agency's total net cost of cancer drugs
- Financial information—the annual budget, year-to-date spending, estimates to year-end, and an expected variance from budget for the top 70 cancer drugs budgeted for the year

[24] Canada's Drug and Health Technology Agency (CADTH) was established by Canada's federal, provincial, and territorial governments to be a trusted source of independent information and advice for the country's publicly funded healthcare systems. www.strategicplan.cadth.ca/about/ (26 September 2022).

[25] Force majeure clauses in contracts free both parties from liability or obligation when uncontrollable events (e.g., labour stoppages, epidemic) prevents one or both parties from fulfilling their obligations under the contract.

For a sample of two months, we found the Agency provided the Ministry with an accurate financial package including the prior year and current year-to-date drug expenses and rebate information, along with a comparison to budget and variance explanations. The Agency provides the same information to its Board on a quarterly basis.

We found the Agency also tracks cancer drug wastage that can occur under various circumstances (e.g., vial punctured and/or partially utilized, prepared wrong concentration of drug, improper storage conditions). We found cancer drug wastage is not a significant issue for the Agency as it amounted to less than 1% of the total cancer drug expenses in 2021–22.

We also found the Agency periodically provides ad hoc information to the Ministry. For example, in January 2022, the Agency presented the 2022–23 drug and financial forecast to the Ministry. The presentation contained information on items such as cancer drug expenditures before and after rebates, annual unique patients receiving particular drug treatments (i.e., 2020–21: 10,314 patients; 2019–20: 10,072 patients), and savings from using generic and biosimilar cancer drugs (total estimated savings of over $17 million in 2021–22).[26,27]

Each year, the Agency publicly reports numerous statistics in its annual report for the previous four years, including trend information on the number of patients receiving treatment at its two main centres and at its community oncology centres (see **Section 2.1**). **Figure 9** provides further examples of the statistics the Agency publicly reports. Overall, we found the Agency provides comparable statistics to other jurisdictions, and in some cases more.

**Figure 9—Examples of Further Statistics Publicly Reported**

| Statistics | 2018–19 | 2019–20 | 2020–21 | 2021–22 |
|---|---|---|---|---|
| New patient appointments | 7,412 | 8,006 | 7,725 | 7,914 |
| Oral prescriptions processed | 57,913 | 63,560 | 64,244 | 65,246 |
| Intravenous medications – inpatient | 4,754 | 4,472 | 4,660 | 5,126 |
| Intravenous medications – outpatient | 46,602 | 51,908 | 49,377 | 49,361 |
| Community oncology centres' orders dispensed | 13,167 | 16,245 | 16,905 | 16,328 |

Source: Adapted from the Saskatchewan Cancer Agency's *Annual Report 2021–22*, p. 16.

Periodic analysis and reporting of information about cancer drugs provides decision makers with information necessary to understand the effectiveness of the Agency's processes to manage its supply of cancer drugs.

[26] Unique (distinct) patients is the total number of patients receiving at least one cancer drug prescription dispensed by the Agency's pharmacy. The Agency only counts patients once even if they received more than one prescription during the fiscal year.

[27] A generic drug is an exact copy of a brand name drug. Biosimilar drugs are very close in structure and function to a biologic drug (drugs made in a living system such as yeast, bacteria, or animal cells). A biosimilar drug behaves in much the same way, so that there are "no meaningful differences" between it and its brand name biologic drug. www.cancer.org/treatment/treatments-and-side-effects/treatment-types/biosimilar-drugs/what-are-biosimilars.html (22 September 2022).

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