

# A Remedy for Canada's Drug Shortage Dilemma

## Opportunities and Recommendations

January 2021



*OMA Thoughts*

This white paper was produced by staff of the Economics, Policy and Research Department at the Ontario Medical Association (OMA) with input from key informants, stakeholders and other partners.

Authors: Fahey-Walsh, J., Oentoro, N., Laxer, D., Wright, Dr. J. (2021). A Remedy for Canada's Drug Shortage Dilemma: Opportunities and Recommendations.

Please address requests about the publication to:  
Ontario Medical Association, 150 Bloor St. West, Suite 900, Toronto, ON, M5S 3C1

© Ontario Medical Association 2021

## Table of Contents

<b>Section 1: Executive Summary .....</b>	<b>4</b>
<b>Section 2: Introduction and Purpose .....</b>	<b>9</b>
<b>Section 3: National Opportunities .....</b>	<b>12</b>
<b>Section 4: Front-Line Delivery .....</b>	<b>14</b>
Mitigating Drug Shortages .....	14
Limiting Waste and Conserving Drugs .....	14
Redistributing or Reallocating Unused Medications.....	16
Managing Drug Shortages.....	20
Substitutions and Alternatives.....	20
Using an Ethical Decision-Making Framework.....	22
Enhancing Communication .....	22
Temporarily Expanding Drug Programs .....	23
Developing and Implementing a Comprehensive Drug-Monitoring System .....	23
<b>Section 5: Summary and Next Steps .....</b>	<b>25</b>
<b>Section 6: Appendices .....</b>	<b>26</b>
<b>Section 7: References.....</b>	<b>29</b>

## Section 1: Executive Summary

An adequate drug supply is critical for high-quality health care. Although drug shortages in Canada are not new,<sup>1</sup> the COVID-19 pandemic has amplified the issue and placed additional strain on the supply and distribution of drugs, in particular those required in palliative and critical care settings.

Drug shortages can occur at the national, provincial, regional, institutional, hospital and pharmacy level. Their impact can be catastrophic for patients and can lead to difficult decisions for health-care providers.

### Purpose and Framing

The Ontario Medical Association (OMA) and the physicians it represents are concerned about ongoing drug shortages and the additional burden the pandemic has placed on drug supply and distribution. The OMA developed this white paper to:

- Summarize best practices and resources on drug shortages.
- Highlight opportunities for improvement to better support health-care providers dealing with limited access to essential drugs.
- Identify potential actionable and innovative solutions and recommendations to promote drug access and alleviate future shortages in Ontario.

This paper's focus on solutions and recommendations is particularly important given the ongoing second wave of COVID-19 in Canada, not to mention potential subsequent waves. To provide guidance in the development of this paper and its recommendations, the OMA undertook an extensive review of relevant Canadian and international resources and reports (developed before and during the pandemic) that identify ways to manage and mitigate drug shortages. In addition, the OMA consulted with provincial and national stakeholders, including physicians, pharmacists, associations and regulators and other key informants to inform the preparation of this document.

The national multi-stakeholder toolkit<sup>2</sup> for *Improved Understanding and Transparency of Drug Shortage Response in Canada*<sup>i</sup> was used to help frame this paper. The toolkit provides an overview of the four phases of Canada's drug supply chain: drug approvals, manufacturing, procurement/distribution and front-line delivery. Disruption at any of these phases can significantly affect drug supply across the country. The paper focuses primarily on provincial strategies and recommendations at the front-line delivery phase to mitigate and manage drug shortages. Recommendations are also included to address opportunities at the national/federal level.

---

<sup>1</sup> For example, shortages of numerous drugs were projected in 2012 because of a fire at the Sandoz drug manufacturing factory in Quebec.

<sup>2</sup> The Multi-Stakeholder Steering Committee on Drug Shortages (MSSC) was assembled in 2012. It includes representatives from industry associations, health professional associations and federal, provincial and territorial governments working together to address drug shortages.

The recommendations are outlined below. They are categorized by time frame based on whether they are meant for immediate consideration and action (short-term recommendations) or for further planning and discussion (long-term recommendations).

## National/Federal Recommendations

### **Short-Term Recommendation:**

- The federal, provincial and territorial governments should work with hospital and community stakeholders to continue developing and monitoring Canada’s essential medication list and ensure a sufficient supply of drugs in the National Emergency Strategic Stockpile.

### **Long-Term Recommendation:**

- The federal government should empower and strengthen the domestic drug manufacturing sector to increase the production of essential drugs within Canada.

## Provincial Recommendations<sup>3</sup>

### **A) Mitigating Drug Shortages**

Limiting waste and conserving drugs

#### **Short-Term Recommendation:**

- To address drug shortages, the Ontario College of Pharmacists (OCP) should explore options to enhance access to medications used at end of life prepared by community pharmacists (such as pre-filled syringes).

## Redistributing or Reallocating unused drugs

### **Long-Term Recommendations:**

- The Ministry of Health (including Ontario Health), in collaboration with pharmacy regulators, professional associations and key stakeholders (such as hospice and palliative care physicians), should change legislation (including Section 32(19) of the regulations under the *Drug and Pharmacies Regulation Act*) and policies to support the safe return and redistribution of high-demand unused medications in hospital and community settings, where appropriate (for example, Medical Assistance in Dying [MAiD] kits, Symptom Relief/Response Kits [SRKs] and so on). The ministry will need to work with Health Canada to ensure compliance with Canada’s *Controlled Drugs and Substances Act* and *Food and Drugs Act*.
- Practitioners should develop criteria based on principles set by pharmacy regulators to ensure the safety, integrity and stability of returned drugs. Criteria will need to be adjusted based on patient populations and the types and purposes of drugs (MAiD kits, SRKs and so on), the

---

<sup>3</sup> See Appendix A for a complete list of acronyms used in this paper

personnel dispensing and administering the drugs and the settings where the drugs may be used.<sup>4</sup>

- To enable the reuse of unused drugs, the Ministry of Health<sup>5</sup> (including Ontario Health) should work with key stakeholders—such as the OMA, OCP, Ontario Pharmacists Association (OPA), Ontario Long-Term Care Association (OLTCA), Registered Nurses Association of Ontario (RNAO), Ontario Palliative Care Network (OPCN), College of Physicians and Surgeons of Ontario (CPSO) and College of Nurses of Ontario—to identify required changes to legislation, regulations and policies (such as those related to the medication management system under the *Long-Term Care Homes Act*) in settings where there is high use of medications, such as long-term care (LTC) homes, retirement homes and hospices. Supportive policy to guide the reuse should be developed to ensure the drugs' quality and integrity before they are re-dispensed.
- The Ministry of Health (including Ontario Health) should work with key stakeholders—such as the OMA, physicians, pharmacists and other prescribers and patients—to minimize medication waste and support vulnerable populations who have difficulty accessing needed medications by examining existing programs and expanding them to other parts of Ontario based on need. [Ottawa Inner City Health](#) is a good example.

## **B) Managing Drug Shortages**

### Using substitutions and alternatives

#### ***Short-Term Recommendations:***

- In collaboration with system stakeholders such as Ontario Health, the OPA, the RNAO, the NPAO and the OMA, the Ministry of Health should create a dedicated website (or other online platforms) focused on resources and supports for drug substitutions and therapeutic alternatives and ensure it is accessible to prescribers, nurse practitioners and pharmacists to support informed decision-making and safe practices when considering drug substitutions and therapeutic alternatives.
- The Ministry of Health should determine if substitutions and alternatives exist for all clinical situations, and work with clinicians to address gaps and errors by creating multiple contingency plans for situations where alternatives or substitutions are also in short supply.

---

<sup>4</sup> Relevant legislation, policies and procedures established in other jurisdictions—such as British Columbia, Nova Scotia and the National Health Service—may be used to help guide the development of the principles and criteria for redistribution.

<sup>5</sup> The Ministry will need to work with Health Canada to ensure compliance with relevant federal legislation.

## Using an ethical decision-making framework

### **Short-Term Recommendation:**

- The OMA should work with physicians and other partners—such as the Ontario Hospital Association (OHA), OPA, RNAO and Joint Centre for Bioethics—to promote the adoption of an ethical decision-making framework in all settings across the province of Ontario. This would help guide decision-making regarding the allocation of drugs to patients during the COVID-19 pandemic and beyond.

## Enhancing communications

### **Short-Term Recommendation:**

- The federal and provincial/territorial governments should enhance their communication efforts by providing regular, timely updates on drug shortages to all system stakeholders, health-care providers and patients to allow optimal time for preparation and related activities. To further support health-care providers, the Ministry of Health should increase its information-sharing on best practices and educational resources to help manage drug shortages.

## Temporarily expanding drug programs

### **Short-Term Recommendation:**

- Although it has taken proactive measures to temporarily expand drug coverage in response to shortages, the Ontario government—in partnership with key stakeholders—should continue to monitor and identify additional essential medications and ensure that adequate temporary coverage for them is available so patients continue to receive and access appropriate treatment and care.

## Developing and implementing a comprehensive drug-monitoring system

### **Long-Term Recommendation:**

- The federal, provincial and territorial government should work with key stakeholders and health-care providers (that is, the OMA, OPA, OHA, Canadian Association of Pharmaceutical Distribution, Group Purchasing Organizations, Innovative Medicine Canada and the Canadian Generic Pharmaceutical Association) to develop and implement a centralized drug supply-monitoring system that provides real-time updates on community drug supply and distribution. This should include specifying reasons for shortages and the anticipated durations of shortages, and making this information accessible to community pharmacists, physicians and other prescribers.
- The Ontario government should expedite the inclusion of all community pharmacies into the Digital Health Drug Repository and link them with ConnectingOntario and ClinicalConnect to enable real-time electronic communications with prescribers through their electronic medical records.

## Summary and Next Steps

Drug shortages and their impacts on patients and health-care providers are a chronic, long-standing issue that has worsened during the pandemic. The OMA and its member physicians are important partners in helping to solve ongoing and challenging issues related to drug shortages. This paper seeks to build on ongoing work in this area. It identifies new opportunities and actionable solutions at the national and provincial level.

Pre-pandemic and ongoing experiences in other jurisdictions have highlighted the need in Ontario to consider and implement bold and innovative solutions to address the complex issue of drug shortages comprehensively. Success will require the full partnership, attention and commitment of multiple organizations.

Going forward, the OMA—with the help of its partners and key stakeholders at the provincial and national level and in collaboration with the governments—will prioritize and potentially expand on these recommendations and determine next steps to facilitate their implementation. In addition, in this rapidly evolving pandemic environment, the OMA will continue to assess, adapt and revise these recommendations as needed to help address chronic drug shortages.



## Section 2: Introduction and Purpose

An adequate drug supply is critical for high-quality health care. Drug shortages can be systemic or local. Systemic drug shortages can be caused by a variety of factors, such as natural disasters, manufacturer recalls and infectious disease outbreaks, among others.<sup>ii</sup> Although drug shortages in Canada are not new,<sup>6</sup> the COVID-19 pandemic has amplified the issue and placed additional strain on the supply and distribution of drugs in the system, in particular those required in palliative and critical care settings.

Drug shortages resulting from COVID-19 can happen at the national, provincial, regional, institutional, hospital and pharmacy level. The impact of drug shortages can be catastrophic for patients and is also challenging for health-care providers, who may have to make difficult choices. To ensure continuity of care for patients, substitute therapies may be the only recourse. Initiating them requires additional due diligence by prescribers and/or pharmacists to ensure therapeutic outcomes are maintained and to mitigate against errors. [Table 1](#) lists examples of the possible impacts on patients and providers.<sup>iii,iv</sup>

**Table 1 - How Drug Shortages Affect Patients and Providers**

Patients	Providers
<ul style="list-style-type: none"><li>• Outcomes (disease trajectories/symptoms/suffering)</li><li>• Potential financial burden</li><li>• Issues with adherence to medication</li><li>• Requirement to adjust to substitutions/alternatives adverse effects/drug interactions</li><li>• Potential treatment delays</li><li>• Risk of overdose or underdose</li><li>• Potential for misunderstanding, confusion</li></ul>	<ul style="list-style-type: none"><li>• Additional complexity and opportunities for errors in prescribing, preparing, administering and monitoring medications</li><li>• Additional workload (including time to educate staff), potentially causing stress, fatigue and decreased time for patient care</li><li>• Ethical considerations for drug allocations during shortages</li></ul>

The health-care system and providers must proactively plan for and consider drug alternatives, given that shortages may continue into the foreseeable future. The Ontario Medical Association (OMA) developed this paper to summarize best practices and resources on drug shortages, highlight opportunities for improvement, better support health-care providers when dealing with limited access to essential drugs, and identify potential actionable solutions and recommendations to promote drug access and alleviate future shortages in Ontario.

This focus on solutions and recommendations is particularly important given the second wave (and potential subsequent waves) of COVID-19 in Canada, which many other places and countries have experienced or are now experiencing, such as Europe, Hong Kong, Australia and Japan.<sup>v</sup> Countries that experience exponential increases in COVID-19 cases, such as the United States (U.S.), put additional strain on the global supply of essential drugs, directly affecting Canada's ability to access them.

To guide the development of this paper and its recommendations, the OMA undertook an extensive review of relevant Canadian and international resources and reports (developed before and during the pandemic) that identify ways to manage and mitigate drug shortages. In addition, the OMA consulted

---

<sup>6</sup> For example, shortages of numerous drugs were projected in 2012 as a result of a fire at the Sandoz drug manufacturing factory in Quebec.

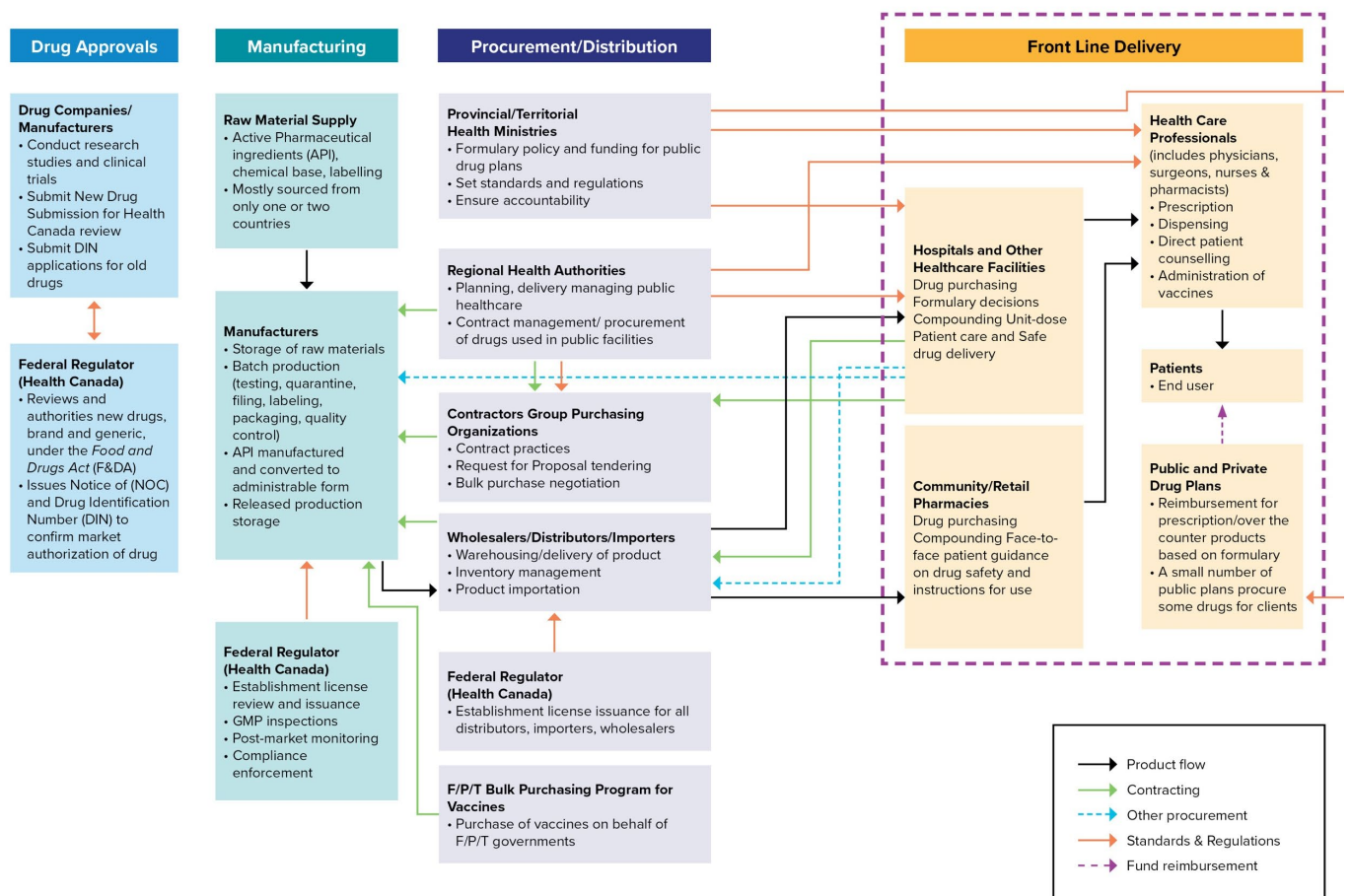
with provincial and national stakeholders, including physicians, pharmacists, associations and regulators, experts and government.

### Framing

The multi-stakeholder toolkit for *Improved Understanding and Transparency of Drug Shortage Response in Canada*<sup>vi</sup> provided an overview of Canada’s drug supply chain. The chain can be broken down into four phases: drug approvals, manufacturing, procurement/distribution and front-line delivery.

Disruptions during any of these phases can significantly affect drug supply across the country. While the paper focuses primarily on provincial strategies and recommendations at the front-line delivery phase to mitigate and manage drug shortages, recommendations have been included to address opportunities at the national/federal level. Please refer to [Figure 1](#)<sup>vii</sup> for Canada’s drug supply chain and the identified area of focus for this paper, and to [Figure 2](#) for the framework for this paper.

**Figure 1 – Drug Supply Chain in Canada. This paper focuses on the areas identified in purple.**



**Figure 2 – Framework: Navigating Ontario’s Chronic Drug Shortage**



## Section 3: National Opportunities

As previously mentioned, while this paper focuses primarily on provincial strategies to manage and mitigate drug shortages, it would be an oversight to not identify national issues that affect the supply and distribution of drugs across the country. While the OMA recognizes that much is occurring at the federal level, national action is key to Canada’s supply chain. Since the start of the pandemic, Health Canada has signed an [Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19](#) (IO). The IO gives the Minister of Health the authority to add products to a list of drugs for exceptional importation and sale that are not approved in Canada but are manufactured with similar standards, subject to certain requirements. The Tier Assignment Committee, which existed before the pandemic, recommends “designated Tier 3 drugs” that would be eligible under the IO to ensure an adequate supply of essential drugs<sup>7</sup> is maintained and that the drugs are distributed in Canada. Unfortunately, despite these efforts, supplies remain limited. While many of these drugs experienced shortages prior to the pandemic (such as propylthiouracil), COVID-19 has highlighted the ongoing issue of drug shortages in the country. Disruption during any phase of Canada’s drug supply chain can have a huge impact on drug availability across the country. For example, at the onset of the pandemic, there were concerns about securing sufficient supplies of imported active pharmaceutical ingredients (APIs) from countries such as China and India. The potential threat of limited API supply could have resulted in major disruptions in the manufacturing and distribution of drugs across Canada and the U.S. As COVID-19 continues to be a global issue with the potential to affect API procurement, Health Canada—including provincial/territorial governments and stakeholders—must look at solutions to mitigate supply disruptions and explore solutions to strengthen the domestic drug manufacturing sector. This can help ensure an adequate supply of essential medicines in the health-care system.

**“Essential medicines,”** as defined by the World Health Organization, are those that satisfy the priority health-care needs of the population. They are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.

As well, in anticipation of the current second wave (and potential subsequent waves) of COVID-19, recommended proactive measures have been put in place that Health Canada can implement in partnership with provinces and territories to ensure essential drugs are available. As noted by the [Critical Drugs Coalition](#) and supported by the OMA, it is recommended that the federal, provincial and territorial governments work closely with hospital and community stakeholders to establish a Canadian essential medication list. The government should also commit to monitoring and ensuring a sufficient supply of drugs in the National Emergency Strategic Stockpile.<sup>viii</sup> This will ensure that an adequate supply of essential medication remains available during and after the pandemic.

### **Short-Term Recommendation:**

- The federal, provincial and territorial governments should work with hospital and community stakeholders to continue developing and monitoring Canada’s essential medication list and ensure a sufficient supply of drugs in the National Emergency Strategic Stockpile.

---

<sup>7</sup> [WHO essential drugs definition.](#)

***Long-Term Recommendation:***

- The federal government should empower and strengthen the domestic drug-manufacturing sector to increase the production of essential drugs in Canada.

## Section 4: Front-Line Delivery

If the supply chain is interrupted and/or demand exceeds supply, front-line delivery will need to be addressed. Various strategies have been employed in Canada and other countries to help address drug shortages, mitigate drug waste and reduce the impact on patients. Many of these strategies include regulatory changes that are being implemented on a temporary basis in response to the pandemic. Other strategies and programs have been in place for some time to help alleviate drug shortages, increase access and decrease costs and are typically used for certain populations and settings. These programs may involve redistributing unused drugs within or across sectors (for example, from a hospital to a community setting or vice versa). This section of the paper describes those strategies and identifies areas where improvements can be made during the front-line delivery phase. It also describes solutions aimed at enhancing the management and mitigation of drug shortages in Ontario and beyond in seven key areas.

### Mitigating Drug Shortages

1. Limiting waste and conserving drugs
2. Redistributing or reallocating unused drugs

### Managing Drug Shortages

3. Using substitutions and alternatives
4. Using an ethical decision-making framework
5. Enhancing communications
6. Temporarily expanding drug program coverage
7. Developing and implementing a comprehensive drug-monitoring program

### Mitigating Drug Shortages

#### Limiting Waste and Conserving Drugs

Compounding<sup>8</sup> drugs is one strategy that has been used to limit waste and conserve drugs. There are many ways to compound drugs. Simpler methods include repackaging, which involves transferring a drug from an original container into smaller ones (for example, pre-filling syringes) or combining or pooling drugs. Diluting drugs is another approach. There are also more complex methods of compounding, such as creating new formulations.<sup>ix</sup> In response to the pandemic, many countries, including Canada, the U.S. and the United Kingdom (U.K.), are using strategies related to sterile compounding and issuing temporary guidelines to increase supply and conserve drugs.<sup>9</sup> For example, in the U.S., the Food and Drug Administration (FDA) modified rules and issued guidance regarding who may compound certain drugs for hospitalized patients during the pandemic.<sup>x</sup> In the U.K., the National Health Service (NHS) developed guidance documents that are valid only for the duration of the current pandemic to help reduce the wastage of critical medications that are in high demand.<sup>xi</sup>

#### Risks and Implications

There are implications and risks related to the stability and sterility of compounded drugs. For instance, there are stability risks associated with placing drugs in new containers (such as plastic syringes) and

---

<sup>8</sup> Compounding is the act of creating a pharmaceutical preparation to transform it into a usable state. The term “compound” can also refer to the material that has been prepared (e.g., a chemical or pharmaceutical preparation). [NAPRA Standards](#), p. 64.

<sup>9</sup> Appendix B contains a list of resources, supports and strategies that have been developed in Canada and other jurisdictions regarding how to minimize drug waste using sterile compounding.

there is sterility risk for microbial contamination when compounding a drug. In 2016, the National Association of Pharmacy Regulatory Authorities (NAPRA) updated compliance standards for compounded medications that address these risks.<sup>xii</sup> These standards for non-hazardous sterile preparations come into effect once they are adopted by pharmacists' provincial or territorial regulators.

The standards provide the following guidance regarding beyond-use dates (BUDs)<sup>10</sup> for compounded sterile medications, based on risk of microbial contamination:

- Low risk of contamination: 48 hours at room temperature or up to 14 days refrigerated.
- Medium risk of contamination: 30 hours at room temperature or up to nine days refrigerated.
- High risk of contamination: 24 hours at room temperature or up to three days refrigerated.<sup>xiii</sup>

Although these BUDs have been provided by NAPRA, provincial or territorial regulators can make adaptations. Quebec has its own (similar) BUD standards for non-hazardous preparations. In April 2020, the Ordre des Pharmaciens du Québec (OPQ) temporarily extended the BUD to nine days from three for injectable palliative care medications because of drug shortages.<sup>xiv</sup> At this time, no other province or territory has temporarily extended the BUD for injectable palliative care medication.

In the U.S., the American Society of Anaesthesiologists (ASA) and the American Society of Health-System Pharmacists (ASHP) issued a joint call to extend BUDs.<sup>xv</sup> In addition to sterile compounding and the consideration of extending BUDs at room temperature, the joint statement recommended that regulators consider and adopt policies permitting the use of drugs based on stability data and literature that supports extended dating beyond the FDA-approved manufacturer labelling. The need to minimize waste and strike a “balance between the preservation of scarce resources with the possible risk of exposure from possible sources of contamination” is critical to helping to address these shortages.<sup>xvi</sup>

For palliative care drugs, there are concerns about drug supply because of the increased demand for medications used for multiple purposes in multiple settings. In addition, the Canadian Society of Palliative Care Physicians (CSPCP) has expressed concerns about the ability to meet NAPRA standards in the community, as many providers have “little or no capacity” to meet them.<sup>xvii</sup> The standards are intended to protect patients from microbial infections when they receive certain drugs—for example, long-term chemotherapy or antibiotic therapy at home. For patients with palliative care needs, medications are meant to provide comfort and manage pain. Palliative care medications for patients who choose to be at home during their end-of-life care are typically drawn up by community pharmacists or nurses, or in some cases by lay caregivers or family members. These pre-filled syringes have BUDs of only 24 hours, as per NAPRA standards.<sup>xviii</sup> Patients with limited access to community nurses or pharmacists may have problems accessing needed medications with such short BUD windows. Further, according to CSPCP, “...evidence for requirements of maintaining high sterility standards in drawing up pre-filled syringes for patients near end of life is lacking” in Canada, “with no reported adverse outcomes related to either drug stability or microbial contamination. At end of life, “comfort should be the highest priority” especially because “more people want to die at home because of the pandemic (due to) fear of hospital and prefer own home where visitors are allowed.”<sup>xix</sup>

The CSPCP recommended to provincial pharmacy regulators that palliative care teams rely on medications pre-filled by nurses or pharmacists to reduce the risk of errors and exempt these medications from the 24-hour BUD requirements in order to meet palliative patients' needs. To promote

---

<sup>10</sup> The beyond-use date, or BUD, is the “Date and time after which a compounded sterile preparation cannot be used and must be discarded (because of a risk of loss of sterility). For the purposes of these Model Standards, administration of the compounded sterile preparation must begin before the BUD has passed.” [NAPRA Standards](#), p. 67.

timely access to necessary medications for good symptom control, reduce the risk of drug errors and minimize the risk of health-care provider exposure to COVID-19 in patients' homes, the OMA supports this CSPCP recommendation. The OMA also recognizes that there might be increased risks associated with this practice, necessitating patient/family consent. Efforts to reduce the risk of Schedule 1 drugs being diverted should continue.

**Short-Term Recommendation:**

- To address drug shortages, the Ontario College of Pharmacists (OCP) should explore options to enhance access to medications used at end of life prepared by community pharmacists (such as pre-filled syringes).

To carry out this recommendation, the OCP should work with the OMA, the Ministry of Health, the Ontario Pharmacists Association (OPA), NAPRA and other stakeholders, given the potential impact that adapting the standards may have on provincial practices and patients (for example, risks related to possibilities of contamination). These organizations should also collaborate to determine what constitutes a drug shortage and who decides. It is also important to consider if others might be involved in the preparation of these medications (such as nurses) and to involve appropriate stakeholders.

**Redistributing or Reallocating Unused Medications**

The redistribution or reallocation of unused medication has also been identified as a mechanism to conserve drug supply, particularly for drugs that are in high demand because of the pandemic. Outside of Ontario, several different programs and policies enable the recycling of drugs. Some were established on an urgent and short-term basis in response to the pandemic and related drug shortages. For example, in British Columbia (B.C.), the College of Pharmacists has enabled a temporary exemption for the dispensing of Medical Assistance in Dying (MAiD) drugs deemed to be in short supply by permitting unused drugs to be returned to inventory if certain conditions are met.<sup>xx</sup>

In the U.K., the NHS developed guidance to enable the redistribution of medications in care homes and hospice settings during the pandemic.<sup>xxi</sup> Other programs to redistribute unused medications have existed for a much longer period. Many were put in place to address the significant and costly wastage of unused medications and help populations in need, such as those with no insurance or limited access to prescribed medications. Approximately 38 U.S. states have had some form of medication recycling program since 1997, such as Iowa's "SafeNetRx" program, established in 2001.<sup>xxii</sup> In Canada, very few programs exist to serve populations in need. One is [Ottawa Inner City Health](#), which serves individuals who are homeless.<sup>xxiii</sup> While some programs in the U.S. and Europe accept medications from the public, researchers examining the redistribution of medications have found that in general, medications donated from health-care facilities are in better condition and more likely to be reusable because their safety and integrity can be determined. Unused drugs recycled from hospitals, care homes and other similar locations where the drug has never been in a patient's possession are more dependable because of the "unbroken chain of accountability for the medicine."<sup>xxiv</sup>

In Canada, the ability to redistribute unused drugs easily and readily often depends on enabling legislation, regulations and policies. For example, in Nova Scotia (N.S.), pharmacists may return previously dispensed medications to inventory in accordance with specified eligibility criteria,<sup>11</sup> such as drugs used for the purposes of MAiD or in other settings according to legislation (under the *Homes for Special Care Act*) and regulatory policy.<sup>xxv</sup> In B.C., standards of practice enable pharmacists to reuse

---

<sup>11</sup> Appendix C – Nova Scotia – Pharmacy Practice Policy – Return of Medication



medications in residential care homes<sup>xxvi</sup> and hospitals<sup>xxvii</sup> if certain conditions (similar to those in N.S.) are met.

For example, in B.C., previously dispensed drugs must not be re-dispensed unless, in the case of community pharmacies:

- They have been returned to the pharmacy in a single-drug, sealed-dosage unit or container as originally dispensed.
- The labelling is intact and includes a legible drug lot number and expiry date.
- The integrity of the product can be verified.

In both N.S. and B.C., the drug must not have been in a patient's possession (for example, it may have been kept in a medication cart or other secure area). That way, a pharmacist can more readily verify the drug's safety and integrity.

### Ontario Context

In Ontario, some reuse of medications returned to inventory is permitted in both hospital and community pharmacy settings under the *Drug and Pharmacies Regulation Act*.<sup>xxviii</sup> Hospital-accredited and community pharmacies are permitted to return to stock, resell or re-dispense a drug that was previously sold or dispensed if certain conditions are met. In hospital pharmacies, those requirements are:

- The drug is returned to the pharmacy in a sealed-dosage unit or container as originally dispensed.
- The drug is returned with the labelling intact, and the label includes a legible drug lot number and expiry date.
- The integrity of the drug can be verified.<sup>12</sup>

Further, drugs must have remained under the control of regulated health professionals and not been in a patient's possession.

In community pharmacies, the requirements are:

- The drug is listed in Schedule II or III,<sup>13</sup> does not require refrigeration and is in its original, unopened packaging.
- Or, the purpose is to repackage and re-dispense the drug to the same patient. In this case, the drug must still be suitable for repackaging and be repackaged and re-dispensed to that patient only.

Despite the ability to redistribute or reallocate drugs in Ontario, especially within hospitals, the inability to reuse Schedule I drugs in community pharmacies is problematic. For example, under the current law, community pharmacies cannot re-dispense unused injectable medications in palliative care Symptom

---

<sup>12</sup> It is through this exemption and a contractual agreement that hospital pharmacists can re-dispense unused drugs to Ottawa Inner City Health.

<sup>13</sup> Schedule II drugs are over-the-counter and non-prescription drugs that are located behind-the-counter. Schedule III drugs are over-the-counter and non-prescription drugs that are located in front of the counter. Source: [NAPRA, Outline of the Schedules](#).

Relief/Response Kits (SRKs)<sup>14</sup> or MAiD kits that have been under the control of a regulated health professional. These drugs are in high demand as a result of the pandemic. Unless there are changes to the regulations, community pharmacies will continue to be unable to recycle these drugs.

### Other Considerations

There are risks involved in accepting unused drugs previously dispensed into the community for return to stock and reuse. Unopened drugs that have been dispensed to consumers may have been subject to tampering and/or improper storage, such as storage at incorrect temperatures. If an unused drug that is being returned has been in a patient's possession, it is difficult for a pharmacist to verify its safety and integrity. These are significant considerations in developing any program that involves re-dispensing returned drugs. Programs in the U.S. and other countries, such as the Netherlands and Singapore, can provide best practices on how to do this for high-demand medications with acceptable risks to the medications' safety, quality and integrity.<sup>xxix,xxx,xxxi</sup>

Additionally, some community pharmacies may not accept drugs for return during the COVID-19 pandemic to reduce the risk of spreading the virus from consumers to pharmacy staff.<sup>xxxii</sup> Health Canada has issued guidance on the return of controlled substances during the pandemic.<sup>xxxiii</sup> Many pharmacies already have procedures in place to support mandatory returns. For drugs in short supply, it is important for health-care providers to consider other conservation approaches, including options for isolation, disinfection and segregation when drugs may have been contaminated. There are mechanisms and processes that can help reduce contamination and the spread of COVID-19.<sup>xxxiv</sup>

Despite these issues, the need to minimize drug wastage—particularly for drugs in high demand, such as injectable medications in SRKs<sup>xxxv</sup>—is critical, especially during a pandemic. For example, to address SRK shortages, the CSPCP recommended that palliative care medications used at end of life be exempt from the disposal requirement and that a medication reuse system be put in place to ensure access for patients in need.

As discussed earlier, the wastage of unused drugs comes at a significant cost to the health-care system. For example, in 2013, it was estimated that more than \$8 billion worth of drugs go unused annually and are wasted in Canada.<sup>xxxvi</sup> Drug wastage can occur when prescriptions are changed or patients stop requiring a medication. Recycling of unused drugs in settings such as LTC homes does happen in other provinces. In Ontario, residents of LTC and retirement homes were among the hardest hit by the pandemic; to date, more than 63 per cent of all deaths in Ontario occurred in LTC.<sup>xxxvii</sup> Drug shortages occurred in all settings, including residential care homes that treat residents at end of life (a shortage of midazolam is one example). Yet currently, unused drugs cannot be reused in these Ontario settings. When a resident no longer needs a medication, the drug must be disposed of according to the rules that govern care homes and the pharmacists who dispense the medications.

Given the drug shortages that occurred during the first wave of COVID-19 across all settings, now is the time to consider opportunities to update regulations as required and to adopt policies within these settings to ensure residents have timely access to essential drugs. Further, considering the significant wastage of unused drugs in Canada—including in settings where high medication use occurs, such as residential care homes—considerations should also be made to establish rules that would permit the reuse of drugs for certain populations, as has been done in B.C. and N.S..

---

<sup>14</sup> For the purposes of this paper, the terms symptom relief kits and symptom response kits (SRKs) are interchangeable. These terms are specific to the jurisdictions in which the kits are used or dispensed.

To determine whether a medication should be reused and help ensure the safety and integrity of medications, various policies and procedures should be applied. As noted previously, the NHS established a guide to facilitate the reuse of medications in hospices and care homes during the pandemic.<sup>xxxviii</sup> The guide includes the need for the care home to determine whether a specific medication should be redistributed based on a risk assessment. Conditions include:

- There is no other stock of the medication available.
- There is an immediate need.
- No suitable alternative is available in a timely way.
- The benefits of using another patient’s medication (that is no longer needed) outweigh the risks of use.

The drug must also be assessed for its suitability for redistribution by a regulated health professional. That person must make this assessment against specific criteria, including whether the medication remains unopened, has not expired, is licensed and has been stored appropriately. While not appropriate for the Ontario context at this time, the NHS has gone one step further in its policy to enable the return of unused drugs that have been in a patient’s possession or room as long as certain criteria are met. For example, the policy states that the drug packaging must be assessed for potential COVID-19 contamination and decontaminated, and that permission for the redistribution must be obtained from the patient or substitute decision-maker.

**Long-Term Recommendations:**

- The Ministry of Health (including Ontario Health), in collaboration with pharmacy regulators, professional associations and key stakeholders (such as hospice and palliative care physicians), should change legislation (including Section 32(19) of the regulations under the *Drug and Pharmacies Regulation Act*) and policies to support the safe return and redistribution of high-demand unused medications in hospital and community settings where appropriate (for example, those in MAiD kits, SRKs and so on). The ministry will need to work with Health Canada to ensure compliance with Canada’s *Controlled Drugs and Substances Act* and the *Food and Drugs Act*.
- Practitioners should develop criteria based on principles set by pharmacy regulators to ensure the safety, integrity and stability of returned drugs. Criteria will need to be adjusted based on patient populations and the types and purposes of drugs (MAiD kits, SRKs and so on), the personnel dispensing and administering the drugs, and the settings where the drugs may be used.<sup>15</sup>
- To enable the reuse of unused drugs, the Ministry of Health<sup>16</sup> (including Ontario Health) should work with key stakeholders—such as the OMA, OCP, OPA, Ontario Long-Term Care Association (OLTCA), Registered Nurses Association of Ontario (RNAO), Ontario Palliative Care Network (OPCN), College of Physicians and Surgeons of Ontario (CPSO) and College of Nurses of Ontario—to identify required changes to legislation, regulations and policies (such as those related to the medication management system under the *Long-Term Care Homes Act*) in settings where there is high use of medications, such as LTC homes, retirement homes and

---

<sup>15</sup> Relevant legislation, policies and procedures established in other jurisdictions, such as B.C., N.S. and the NHS, may be used to help guide development of the principles and criteria for redistribution.

<sup>16</sup> The ministry will need to work with Health Canada to ensure compliance with relevant federal legislation.

hospices. Supportive policy to guide the reuse should be developed to ensure the drugs' quality and integrity before they are re-dispensed.

- The Ministry of Health (including Ontario Health) should work with key stakeholders—such as the OMA, physicians, pharmacists and other prescribers, and patients—to minimize medication waste and support vulnerable populations who have difficulty accessing needed medications by examining existing programs and expanding them to other parts of Ontario based on need. [Ottawa Inner City Health](#) is a good example.

## Managing Drug Shortages

### Substitutions and Alternatives

Determining appropriate drug substitutions and therapeutic alternatives for patients can be daunting and time-consuming for prescribers and pharmacists. To ensure patients receive appropriate and timely medications, prescribers and pharmacists should collaborate. They should account for any important considerations before prescribing substitutions or alternatives to ensure patients do not suffer from adverse effects when switching medications. Other considerations may include:

- **Education** on available products, concentrations and dosage forms that are less familiar to prescribers to ensure they prescribe, administer, monitor and prepare alternatives and substitutions appropriately. Prescribers can also consult pharmacists to gain more knowledge around these drugs.
- **Open communication and consultation** with pharmacists working together with patients to ensure safe transitions to new medications. This could include referrals for medication reviews or best possible medication histories to determine whether a patient had already tried the alternative medication(s) being considered with no or suboptimal results.
- **Additional resources and supplies.** The province experienced severe shortages of personal protective equipment and health human resources during COVID-19. Prescribers may need to consider whether the suggested drug substitution and therapeutic alternative requires additional resources and supplies to administer and/or monitor, and assess accordingly, in order to safely transition patients to new treatments/medications.
- **Access to treatment.** Switching medications can pose a financial burden for patients and hinder their adherence to treatment plans. When prescribing an alternative/substitution, consider if the new drug will be covered under the patient's private insurance plan or, if applicable, the Ontario Drug Benefit program.
- **Safety.** The Institute for Safe Medication Practices found that using alternative medications and/or substitutions introduces complexities and opportunities for errors.<sup>xxxix</sup> Additional measures should be in place to reduce the likelihood of errors, such as special patient monitoring, appropriate labelling and clear directives.

### Resources and Supports

To assist with prescribing substitutions and alternatives, the chart below includes a variety of resources, including recently developed strategies on the selection of therapeutic alternatives for drugs whose supply has been affected by COVID-19.

**Table 2 - Substitutions and Alternatives Resources**

Title	Description
<a href="#"><u>Therapeutic alternatives and strategies for drug conservation in the intensive care unit during times of drug shortage: a report of the Ontario COVID-19 ICU Drug Task Force</u></a>	The Ontario COVID-19 ICU Drug Task Force was directed to recommend drug conservation strategies and therapeutic alternatives for essential drugs at risk of shortage in intensive care units during the COVID-19 pandemic.
<a href="#"><u>Strategies for Potential Shortages in Medications Relevant to Palliative Care during the COVID-19 Pandemic</u></a>	To establish policies and procedures in the face of shortages, the OPCN developed this guidance for system planners, clinicians who make decisions about medication choices in the face of shortages, and pharmacists who service the palliative care sector.
<a href="#"><u>Managing potential palliative care medication shortages during the COVID-19 pandemic: A Guide provided by Pallium Canada</u></a>	This six-page guide from Pallium Canada sets out strategies to manage drug shortages during COVID-19.
<a href="#"><u>Drug Shortages: A Guide for Assessment and Patient Management</u></a>	The Canadian Pharmacists Association created a practical guide that pharmacists, physicians and other prescribers can use in any drug shortage situation.
<a href="#"><u>Drug Shortages Continue to Compromise Patient Care</u></a>	This article published by the Institute for Safe Medication Practices provides general advice on medication safety issues caused by shortages.
<a href="#"><u>Drug Shortages Canada</u></a>	Drug Shortages Canada’s website reports on drug shortages and discontinuations in Canada.
<a href="#"><u>Multi-Stakeholder Toolkit – A Toolkit for Improved Understanding and Transparency of Drug Shortage Response in Canada</u></a>	This toolkit describes the Canadian drug supply chain (including pharmaceuticals, biologic drugs and vaccines), clarifies the roles and responsibilities of key players, and identifies the tools and strategies available to address drug shortages at specific stages of the supply chain.

**Short-Term Recommendations:**

- In collaboration with system stakeholders such as Ontario Health, the OPA, the RNAO, the NPAO and the OMA, the Ministry of Health should create a dedicated website (or other online platforms) focused on resources and supports for drug substitutions and therapeutic alternatives and ensure it is accessible to prescribers, nurse practitioners and pharmacists to support informed decision-making and safe practices when considering drug substitutions and therapeutic alternatives.
- The Ministry of Health should determine if substitutions and alternatives exist for all clinical situations, and work with clinicians to address gaps and errors by creating multiple contingency plans for situations where alternatives or substitutions are also in short supply.

## Using an Ethical Decision-Making Framework

Applying an ethical framework when responding to drug shortages is one way to enable the equitable allocation of drugs during a shortage. In response to the COVID-19 pandemic, the Joint Centre for Bioethics and other experts developed an ethical framework for drug shortages (May 7, 2020).<sup>xi</sup> The framework is based on the [existing provincial Ethical Framework for Resource Allocation during the Drug Supply Shortage](#) (2012)<sup>xii</sup> and is intended to capture new issues related to the current pandemic, including the efficacy of existing and experimental drugs to treat COVID-19, emerging ancillary drug shortages, and collateral drug shortages related to demand for essential medicines.

The document includes guidance related to ethical principles and strategies to help guide decision-making during provincial drug shortages. The document will evolve based on its use by physicians, other health-care providers and policy decision-makers in the province.

### ***Short-Term Recommendation:***

- The OMA should work with physicians and other partners—such as the Ontario Hospital Association (OHA), OPA, RAO and Joint Centre for Bioethics—to promote the adoption of an ethical decision-making framework in all settings across the province of Ontario. This would help guide decision-making regarding the allocation of drugs to patients during the COVID-19 pandemic and beyond.

## Enhancing Communication

Ongoing communication and information-sharing among manufacturers, distributors, government, health-care providers and system stakeholders are key when managing critical shortages in the province (Multi-Stakeholder Steering Committee on Drug Shortages Toolkit).<sup>xiii</sup> The pandemic exposed the need for better and more timely and comprehensive communication to reach community pharmacies, hospitals, LTC homes, health-care professionals and patients with information about drugs that are at risk of critical shortages.

For providers, the lack of timely and reliable information not only prevented proactive planning to minimize the impact of shortages on treatment and care but caused additional stress related to the need to find immediate solutions to conserve drugs, limit waste and prescribe substitutions and therapeutic alternatives to ensure patients received appropriate and timely care as well as continuity of care.

Health-care professionals would also benefit from regular interprofessional engagement and sharing of best practices, such as guidelines for the use of products that are in short supply and information about recommended alternatives, including dosing, preparation, administration and monitoring. This would further support prescribers and promote safe practices.

Although measures were put in place to prevent stockpiling (such as the 30-day dispensing policy for chronic medications), the public should be informed about the current status of drug supplies and reassured to avoid panic and stockpiling of medications. The Ontario government also needs to act quickly to address and mitigate patient concerns about increased out-of-pocket costs that may result from temporary restrictions on dispensed quantities.

### ***Short-Term Recommendation:***

- The federal and provincial/territorial governments should enhance their communication efforts by providing regular, timely updates on drug shortages to all system stakeholders, health-care providers and patients to allow optimal time for preparation and related activities. To further support health-care providers, the Ministry of Health should increase its information-sharing on best practices and educational resources to help manage drug shortages.

### Temporarily Expanding Drug Programs

Drugs that are dispensed and administered in hospitals are covered by the provincial government, but those dispensed in the community setting are paid for by public drug programs, private insurance plans, individual insurance plans or out-of-pocket payments.

During drug shortages, health-care providers will often prescribe substitutions and/or therapeutic alternatives to ensure patients continue to receive appropriate treatment and care. In some cases, this may result in patients being provided cutting-edge treatments that are not covered under public drug programs or private insurance plans.

Studies have indicated that when patients must pay out-of-pocket for prescription drug costs, their treatment adherence declines.<sup>xliii</sup> They may neglect to fill or renew a prescription, or split doses to make a prescription last longer. Behaviours like these directly affect patient outcomes.<sup>xliiv</sup>

#### **Short-Term Recommendation:**

- Although it has taken proactive measures to temporarily expand drug coverage in response to shortages, the Ontario government—in partnership with key stakeholders—should continue to monitor and identify additional essential medications and ensure that adequate temporary coverage for them is available so patients continue to receive and access appropriate treatment and care.

### Developing and Implementing a Comprehensive Drug-Monitoring System

A critical gap that has emerged around managing drug shortages in the province concerns the lack of available, accurate, real-time information on community supply and distribution. The [Drug Shortages Canada](#) website provides updates on reported drug shortages across the country. However, experts, system stakeholders and other providers report that they find the website to be too vague and impractical for community use and lacking in detail on the reasons behind shortages. For example, it lacks information about inventory remaining in the system.

To understand the scope of the problem and allow optimal time for planning, pharmacists, physicians and other prescribers need reliable, accessible information on drug inventories, shortages and alternatives.

For physicians and pharmacists, access to reliable data on community supply can reduce delays in providing medications to patients. Typically, when physicians or other prescribers are unaware of shortages, pharmacists must contact them to discuss alternatives/substitutions so a new prescription can be issued. This back and forth often leads to significant delays and added stress and frustration for both patients and providers.

#### **Long-Term Recommendations:**

- The federal, provincial and territorial governments should work with key stakeholders and health-care providers (that is, the OMA, OPA, OHA, Canadian Association of Pharmaceutical Distribution, Group Purchasing Organizations, Innovative Medicine Canada and the Canadian Generic Pharmaceutical Association) to develop and implement a centralized drug-supply monitoring system that provides real-time updates on community drug supply and distribution. This should include specifying reasons for shortages and the anticipated durations of shortages, and making this information accessible to community pharmacists, physicians and other prescribers.
- The Ontario government should expedite the inclusion of all community pharmacies in the Digital Health Drug Repository and link them with ConnectingOntario and ClinicalConnect to enable real-time electronic communications with prescribers through their electronic medical records.



## Section 5: Summary and Next Steps

Drug shortages can occur at the national, provincial, regional, institutional and hospital and pharmacy level, and are not a new issue in Canada. Their impact can be catastrophic for patients when they do not get timely access to drugs that are essential for their treatments. The COVID-19 pandemic has exacerbated these shortages, particularly for palliative and critical care drugs.

The OMA and the physicians it represents are concerned about these ongoing drug shortages, given the burden the pandemic has placed on drug supply and distribution. This paper was developed to summarize best practices and resources on drug shortages, highlight opportunities for improvement, and identify potential actionable solutions and/or recommendations to promote drug access and alleviate future shortages in Ontario.

The recommendations included are short- and long-term, national and provincial in scope and include regulatory as well as significant policy changes. For an overview of the recommendations, refer to the Executive Summary. Learnings from other jurisdictions (pre-pandemic and during the pandemic) to address drug shortages highlight the need in Ontario to consider and implement bold, innovative solutions that require full partnership, attention and commitment from multiple organizations. Addressing drug shortages is a complex issue. Success will require ensuring that the recommendations presented in this paper are enacted in as timely a way as possible through provincial and national collaborations or partnerships.

Going forward, with the help of its partners and key stakeholders at the provincial and national level, and in collaboration with governments, the OMA will prioritize and potentially expand upon these recommendations and determine next steps to facilitate their implementation. In addition, in this rapidly evolving pandemic environment, the OMA will continue to assess, adapt and revise the recommendations as needed to help achieve the goal of addressing chronic drug shortages.

## Section 6: Appendices

### Appendix A – Glossary of Terms/Acronyms

#### **A**

ASA – American Society of Anesthesiologists  
ASHP – American Society of Health-System Pharmacists  
API – Active Pharmaceutical Ingredient

#### **B**

BUD – Beyond Use Date

#### **C**

CPSO – College of Physicians and Surgeons of Ontario  
CSPCP – Canadian Society of Palliative Care Physicians

#### **F**

FDA – Food and Drug Administration

#### **I**

IO – Interim Order

#### **M**

MAiD – Medical Assistance in Dying  
MSSC – Multi-Stakeholder Steering Committee on Drug Shortages in Canada

#### **N**

NAPRA – National Association of Pharmacy Regulatory Authorities  
NHS – National Health Service

#### **O**

OCP – Ontario College of Pharmacists  
OHA – Ontario Hospital Association  
OLTCA – Ontario Long-term Care Association  
OMA – Ontario Medical Association  
OPA – Ontario Pharmacists Association  
OPCN – Ontario Palliative Care Network  
OPQ – Ordre des Pharmaciens du Québec

#### **R**

RNAO – Registered Nurses Association of Ontario

#### **S**

SRK – Symptom Relief Kit/Symptom Response Kit

**Table 3 - Examples of Sterile Compounding Guidelines**

Title	Description
<p><a href="#">COVID-19 Guidance: Minimising Wastage of Critical Injectable Medicines: Advice to Pharmacy Aseptic Units operating under Section 10 of the Medicines Act</a></p> <p><a href="#">COVID-19 Guidance: Minimising Wastage of Critical Injectable Medicines: Advice to healthcare professionals preparing doses in clinical areas</a></p>	<p>The U.K.’s National Health Service has developed guidance for health-care professionals preparing drugs in the clinical setting to help reduce wastage of injectable medications.</p> <p>During COVID-19 emergency periods, it is essential to minimize wastage of critical medicines. These guides provide advice to staff in pharmacy aseptic units and clinical areas on how to safely provide a supply of injectable medicines to meet the increased demand while minimizing wastage.</p> <p><b>Scope</b></p> <ul style="list-style-type: none"> <li>• The guidance contained in these documents applies to injectable medicines used in the treatment and supportive care of COVID-19 patients when U.K.-wide supply of these medicines is severely constrained.</li> <li>• The guidance is valid only for the duration of the current COVID-19 emergency.</li> </ul>
<p><a href="#">Minimizing Medication Waste during the Coronavirus-19 Global Pandemic: Joint Statement by the American Society of Anesthesiologists® and American Society of Health-System Pharmacists</a></p>	<p>The American Society of Anesthesiologists and the American Society of Health-System Pharmacists developed a joint statement with recommendations to help to minimize waste with a focus on three key areas:</p> <ul style="list-style-type: none"> <li>• Infection prevention and control</li> <li>• Medication storage policies</li> <li>• Beyond use dating and compounding medications</li> </ul>
<p><a href="#">Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations</a></p>	<p>The National Association of Pharmacy Regulatory Authorities’ suite of model standards for pharmacy compounding comprises three model standards: one pertaining to non-hazardous sterile preparations, one to hazardous sterile preparations and one to non-sterile preparations.</p> <p>The implementation of the model standards is under the authority of the respective provincial, territorial or Canadian Armed Forces pharmacy regulatory bodies. These bodies each establish their own process for implementing the standards in their jurisdictions.</p>

## Appendix C – Nova Scotia – Pharmacy Practice Policy – Return of Medication

Table 4 - NS Pharmacy Practice Policy: Return of Medication

<b>The Nova Scotia College of Pharmacists</b> <b>Pharmacy Practice Policy – Return of Medication</b>	
Setting/ Context	Criteria
<p>Under the <a href="#">Homes for Special Care Act</a> (for example, LTC homes)</p>	<p>From the Nova Scotia College of Pharmacists Pharmacy Practice: Policy Return of Medication</p> <p>A pharmacist may accept, for disposal only, medication previously dispensed and removed from a pharmacy.</p> <p>A pharmacist may accept, for return to inventory, medication previously dispensed to a facility licensed pursuant to the <i>Homes for Special Care Act</i> where, in the exercise of professional judgment, it is appropriate to do so and where all the following conditions are met:</p> <ul style="list-style-type: none"> <li>• The patient has not been in possession of the medication.</li> <li>• The lot numbers and expiry dates (where applicable) of the medication are directly attached to the dispensed container.</li> <li>• The medication has not been packaged with other medications within the same blister, envelope or other container.</li> <li>• Each dose of the medication is individually sealed, and the seal is intact at the time of the return to the pharmacy.</li> <li>• The pharmacist has sufficient knowledge of the medication administration and storage conditions/policies of the facility registered under the <i>Homes for Special Care Act</i> to permit the exercise of professional judgment.</li> <li>• The medication returned is stored in a separate container from the manufacturer’s container and is labelled with the name of the medication (including the manufacturer, if appropriate), the DIN #, lot #, and expiry date.</li> </ul>
<p>For the purpose of providing Medical Assistance in Dying</p>	<p>A pharmacist may accept, for return to inventory, injectable medication previously dispensed for the purpose of providing Medical Assistance in Dying if they are satisfied that:</p> <ul style="list-style-type: none"> <li>• The medication has not left the possession of the physician or nurse practitioner, or a licensed health-care professional designated by the physician or nurse practitioner.</li> <li>• Each dose (vial, ampoule, etc.) is full and has not been used (i.e., has an intact seal or other evidence of being tamper-proof).</li> <li>• The medication has been stored in accordance with the manufacturer’s required storage conditions.</li> </ul>

## Section 7: References

- 
- <sup>i</sup> [https://www.drugshortagescanada.ca/files/MSSC\\_Toolkit\\_2017.pdf](https://www.drugshortagescanada.ca/files/MSSC_Toolkit_2017.pdf)
- <sup>ii</sup> <https://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/DrugShortagesGuide.pdf>
- <sup>iii</sup> [https://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-03\\_Drug\\_Shortages.pdf](https://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-03_Drug_Shortages.pdf)
- <sup>iv</sup> [https://www.ismp-canada.org/download/PharmacyConnection/PC2013Fall\\_DrugShortagePatientSafety.pdf](https://www.ismp-canada.org/download/PharmacyConnection/PC2013Fall_DrugShortagePatientSafety.pdf)
- <sup>v</sup> <https://www.wsj.com/articles/coronavirus-is-back-with-a-vengeance-in-places-where-it-had-all-but-vanished-11595842202>
- <sup>vi</sup> [https://www.drugshortagescanada.ca/files/MSSC\\_Toolkit\\_2017.pdf](https://www.drugshortagescanada.ca/files/MSSC_Toolkit_2017.pdf)
- <sup>vii</sup> [https://www.drugshortagescanada.ca/files/MSSC\\_Toolkit\\_2017.pdf](https://www.drugshortagescanada.ca/files/MSSC_Toolkit_2017.pdf)
- <sup>viii</sup> <https://www.canada.ca/en/public-health/services/emergency-preparedness-response/national-emergency-strategic-stockpile.html>
- <sup>ix</sup> Lee VT. (April 21, 2020) Conserving Drugs with Sterile Compounding During the COVID-19 Pandemic. Canadian Society of Hospital Pharmacists, webinar series
- <sup>x</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-compounding-certain-drugs-hospitalized-patients-pharmacy-compounders-not-registered>
- <sup>xi</sup> <https://www.sps.nhs.uk/articles/minimising-wastage-of-critical-medicines-during-covid-19-2/>
- <sup>xii</sup> [https://napra.ca/sites/default/files/2017-09/Mdl\\_Stnds\\_Pharmacy\\_Compounding\\_NonHazardous\\_Sterile\\_Preparations\\_Nov2016\\_Revised\\_b.pdf](https://napra.ca/sites/default/files/2017-09/Mdl_Stnds_Pharmacy_Compounding_NonHazardous_Sterile_Preparations_Nov2016_Revised_b.pdf)
- <sup>xiii</sup> [https://napra.ca/sites/default/files/2017-09/Mdl\\_Stnds\\_Pharmacy\\_Compounding\\_NonHazardous\\_Sterile\\_Preparations\\_Nov2016\\_Revised\\_b.pdf](https://napra.ca/sites/default/files/2017-09/Mdl_Stnds_Pharmacy_Compounding_NonHazardous_Sterile_Preparations_Nov2016_Revised_b.pdf)
- <sup>xiv</sup> [https://www.opq.org/CMS/Media/5302\\_38\\_fr-CA\\_0\\_Express\\_2020\\_04\\_03\\_covid.html](https://www.opq.org/CMS/Media/5302_38_fr-CA_0_Express_2020_04_03_covid.html)
- <sup>xv</sup> <https://www.asahq.org/-/media/files/spotlight/joint-ashp-asa-statement-on-minimizing-medication-waste42320.pdf?la=en&hash=B3DD6E6C829B7924284ADEF4259DF712D05CE9BB>
- <sup>xvi</sup> <https://www.asahq.org/-/media/files/spotlight/joint-ashp-asa-statement-on-minimizing-medication-waste42320.pdf?la=en&hash=B3DD6E6C829B7924284ADEF4259DF712D05CE9BB>
- <sup>xvii</sup> Canadian Society of Palliative Care Physicians (CSPCP), Urgent Request to Provincial Pharmacy Regulators, May 11, 2020.
- <sup>xviii</sup> <sup>xviii</sup> [https://napra.ca/sites/default/files/2017-09/Mdl\\_Stnds\\_Pharmacy\\_Compounding\\_NonHazardous\\_Sterile\\_Preparations\\_Nov2016\\_Revised\\_b.pdf](https://napra.ca/sites/default/files/2017-09/Mdl_Stnds_Pharmacy_Compounding_NonHazardous_Sterile_Preparations_Nov2016_Revised_b.pdf)
- <sup>xix</sup> Canadian Society of Palliative Care Physicians (CSPCP), Urgent Request to Provincial Pharmacy Regulators, May 11, 2020.
- <sup>xx</sup> <https://www.bcpharmacists.org/medical-assistance-dying>
- <sup>xxi</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/881838/medicines-reuse-in-care-homes.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/881838/medicines-reuse-in-care-homes.pdf)
- <sup>xxii</sup> <https://safenetrx.org/about/>
- <sup>xxiii</sup> <https://www.cmaj.ca/content/182/4/E197>
- <sup>xxiv</sup> <https://doi.org/10.1177/0269216316639798>
- <sup>xxv</sup> [http://www.nspharmacists.ca/wp-content/uploads/2018/10/Policy\\_ReturnOfMedication.pdf](http://www.nspharmacists.ca/wp-content/uploads/2018/10/Policy_ReturnOfMedication.pdf)
- <sup>xxvi</sup> [http://library.bcpharmacists.org/6\\_Resources/6-1\\_Provincial\\_Legislation/5080-HPA\\_Bylaws\\_Residential\\_Care.pdf](http://library.bcpharmacists.org/6_Resources/6-1_Provincial_Legislation/5080-HPA_Bylaws_Residential_Care.pdf)
- <sup>xxvii</sup> [http://library.bcpharmacists.org/6\\_Resources/6-1\\_Provincial\\_Legislation/5079-HPA\\_Bylaws\\_Hospital.pdf](http://library.bcpharmacists.org/6_Resources/6-1_Provincial_Legislation/5079-HPA_Bylaws_Hospital.pdf)
- <sup>xxviii</sup> <https://www.ontario.ca/laws/regulation/160264#BK40>
- <sup>xxix</sup> <https://doi.org/10.1177/0269216316639798>
- <sup>xxx</sup> <https://bmjopen.bmj.com/content/9/5/e024767>
-

- 
- xxxvi <https://link.springer.com/article/10.1007/s11096-018-0642-8>
- xxxvii [https://www.ocpinfo.com/wp-content/uploads/2020/04/Post-consumer-returns-bulletin\\_revised.pdf](https://www.ocpinfo.com/wp-content/uploads/2020/04/Post-consumer-returns-bulletin_revised.pdf)
- xxxviii [https://www.ocpinfo.com/wp-content/uploads/2020/04/Post-consumer-returns-bulletin\\_revised.pdf](https://www.ocpinfo.com/wp-content/uploads/2020/04/Post-consumer-returns-bulletin_revised.pdf)
- xxxix <https://www.asahq.org/-/media/files/spotlight/joint-ashp-asa-statement-on-minimizing-medication-waste42320.pdf?la=en&hash=B3DD6E6C829B7924284ADEF4259DF712D05CE9BB>
- xl <https://med-fom-fpit.sites.olt.ubc.ca/files/2020/03/End-of-Life-Symptom-Management-COVID-19.pdf>
- xli <https://journals.sagepub.com/doi/10.1177/1715163513490654>
- xlii <https://www.publichealthontario.ca/-/media/documents/ncov/epi/2020/covid-19-daily-epi-summary-report.pdf?la=en>
- xliiii [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/881838/medicines-reuse-in-care-homes.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/881838/medicines-reuse-in-care-homes.pdf)
- xliiii [https://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-03\\_Drug\\_Shortages.pdf](https://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-03_Drug_Shortages.pdf)
- xli <http://jcb.utoronto.ca/news/documents/Ethical-Framework-for-Drug-Shortages-during-COVID-Pandemic.pdf>
- xli [http://www.health.gov.on.ca/en/pro/programs/drugs/supply/docs/ethical\\_framework.pdf](http://www.health.gov.on.ca/en/pro/programs/drugs/supply/docs/ethical_framework.pdf)
- xlii [https://www.drugshortagescanada.ca/files/MSSC\\_Toolkit\\_2017.pdf](https://www.drugshortagescanada.ca/files/MSSC_Toolkit_2017.pdf)
- xliiii <http://angusreid.org/prescription-drugs-canada/>
- xliiv <http://angusreid.org/prescription-drugs-canada/>