

EXECUTIVE SUMMARY

# The Value of Specialty Pharmacy Services to the Healthcare System

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Neighbourhood  
Pharmacy  
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## EXECUTIVE SUMMARY

# The Value of Specialty Pharmacy Services to the Healthcare System

Specialty medications are sophisticated, high-value, high-touch drugs used to treat chronic, rare, genetic or complex conditions.<sup>[1]</sup> They are often characterized by complicated manufacturing and specialized distribution and require customized therapy management services for patients.

Pharmacies provide a wide range of services to support patients taking specialty medications, *The Value of Specialty Pharmacy Services to the Healthcare System* report defines, describes and quantifies the value to the healthcare system of six major categories of specialty pharmacy services, including:

1. Upfront and ongoing investment in infrastructure and facilities to manage high-cost, complex medication inventory
2. Reimbursement navigation to help patients access appropriate financial coverage
3. Intravenous (IV) infusion administration and coordination
4. Enhanced dispensing-related services to protect the integrity of complex medications
5. Enhanced medication management to optimize therapy outcomes
6. Enhanced clinical monitoring to ensure effectiveness and safety of specialty medications

A formal funding mechanism does not exist for many of these specialty services. As medication prices and markups face mounting pressure to cut back, the sustainability of these services is in jeopardy.

This Executive Summary is a synopsis of the key findings from the full report, which explores each of these categories in depth to illustrate the value of pharmacy's contributions for patient care and the healthcare system. In so doing, the report demonstrates how pharmacies are filling gaps through the provision of specialty services that would otherwise have to be provided, and paid for, by the public healthcare system.

## Methodology

In March 2023, the Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) collaborated with its members and partners and IQVIA Canada to conduct an analysis of some of the key specialty services offered by pharmacies. The analysis utilized IQVIA's internal databases, data from Neighborhood Pharmacies, including information from member pharmacies that provide specialty services, data from pharmacy partners, and a secondary literature search.

## The Specialty Pharmacy Services Landscape

- Specialty medications are sophisticated, high-value, high-touch drugs used to treat chronic, rare, genetic or complex conditions.<sup>[1]</sup> They are often characterized by complicated manufacturing and specialized distribution and require customized therapy management services for patients. Specialty medications are a growing part of the Canadian pharmaceutical landscape.<sup>[1,2]</sup>
- Specialty medications have revolutionized patient treatments and/or cured complex and debilitating diseases such as cancer, hepatitis C, HIV and psoriasis. In Canada, approximately 1.9 million patients receive specialty medications every year to treat and manage their chronic or complex conditions.<sup>[3]</sup>
- 11,549 pharmacies of all types (e.g., chain, independent, etc.) support the dispensing of specialty medications, of which 388 are non-traditional pharmacies (including pharmacies dedicated to providing services for specialty drugs, pharmacies in long term care facilities and hospitals, mail order services, and hospital/dispensing clinics) that dispensed approximately \$7 billion worth of specialty prescriptions in 2022 (52 per cent of the sales volume of all specialty prescriptions).<sup>[4,5]</sup>
- Specialty medications cost significantly more than other medications. They represent just 1.7 per cent of prescription medications dispensed yet account for 44 per cent of the dollar value.<sup>[5]</sup>
- Biologics (including originator biologics and biosimilars) constitute approximately 67 per cent of the specialty market and grew by nine per cent in 2021.<sup>[4]</sup> Biosimilars alone grew by 51 per cent from March 2021 to March 2022.<sup>[4]</sup> Higher uptake is expected in the next few years with expanded biosimilar transition programs across Canada.<sup>[6]</sup>
- The complex nature of specialty medications necessitates specialized handling, administration and monitoring, as well as additional clinical services to ensure stability, safety and effectiveness. Pharmacies play a critical role in providing such services to ensure therapy appropriateness and to optimize patient outcomes, thereby creating cost-savings for the healthcare system. Some pharmacies and pharmacy distributors have adapted their operations, facilities and practices to focus primarily on serving the specialized needs of patients taking complex medications.
- A formal funding mechanism does not exist for many services associated with specialty therapies that are provided to patients. Pharmacies and pharmacy distributors rely mostly on revenue from markups that are tied to the cost of the medication to support the delivery of these services. As medication prices and markups face mounting pressure, the sustainability of these services is in jeopardy under the current model.

## VALUE CATEGORY 1:

# Upfront and ongoing investment in infrastructure and facilities to manage high-cost, complex inventory

While all pharmacies dispense at least one medication that meets the definition of a specialty medication, some have invested significantly in customizing their facilities to meet the unique and complicated requirements for the distribution, storage and handling of complex, high-cost, fragile medications that are potentially susceptible to damage.

Canadian pharmacies providing specialty services estimate it costs upwards of **\$10 million** to establish a specialty pharmacy facility, plus ongoing annual expenses of approximately **\$1.2 million**. Pharmacies in Canada providing specialty services have invested nearly **\$700 million in infrastructure**, and continue to invest **\$100 to \$200 million in yearly maintenance**.<sup>[4,8,30]</sup>

The protection of specialty medications during transportation and storage requires a sizeable investment in cold-chain technology. The global market value of cold chain protection of biologic drugs exceeds **\$21 billion US**.<sup>[31]</sup>

In Canada, forty-two per cent of the **13 million** prescriptions dispensed annually by pharmacies require cold chain protection. Pharmacies protect the integrity of specialty pharmaceuticals worth an estimated **\$13.3 billion** each year.<sup>[5]</sup>

Canadian pharmacies providing specialty services estimate that the maintenance of on-site cold chain integrity costs between **\$400,000 and \$2 million** per pharmacy per year; or between **\$27.2 million and \$136 million** for the sector.<sup>[4,8]</sup>

Specialty medications that require cold chain management are often shipped directly from the pharmacy to infusion clinics, patients' homes or other medical facilities. Each cold chain shipment, including seasonally appropriate packaging, costs **\$25 to \$50** for packaging and five to 15 minutes for preparation time.<sup>[4,8,9]</sup>

Financial risks due to cold chain failure are high, with the global pharmaceutical industry losing approximately **\$35 billion US** annually due to temperature related issues.<sup>[32]</sup> Without cold chain protection, up to 90 per cent of specialty medications—or **\$12 billion**—would be wasted or spoiled.<sup>[5, 33]</sup> Despite investments in cold chain integrity and packaging to withstand Canada's climate challenges, pharmacies providing specialty services estimated they each absorb up to **\$300,000** a year in unavoidable spoilage or wastage of specialty medications.<sup>[8]</sup>

## VALUE CATEGORY 2:

# Reimbursement navigation to help patients access appropriate financial coverage

Most specialty medications are costly. An average annual cost of **\$10,000** is not unusual and a growing number cost more than **\$100,000** annually.<sup>[3]</sup> It is imperative that the out-of-pocket financial burden for patients does not prevent, curtail or interrupt access to these life-changing therapies.

Accessing insurance coverage can be very complex and time-consuming since almost all prescriptions for specialty medications must go through a prior authorization process. For instance, **more than 70 per cent** of non-oncology drugs approved from 2010 to 2022 require a special authorization in at least one Canadian province.<sup>[34]</sup>

This process is even more complex for children since many specialty medications do not have pediatric indications. Such off-label use requires additional steps to justify that the medication is medically necessary.

Reimbursement navigators are immersed in the complex world of insurance coverage and connect patients to public and private sources of coverage they may not know they already have. They demystify industry jargon and guide patients through enrollment, the exploration of options, applications and appeals. They coordinate with patient support programs for additional financial assistance, if warranted.

In Canada, many patients are simply unaware they are eligible for insurance coverage.<sup>[35,36]</sup> Reimbursement navigation support is essential, and a key offering of Canadian pharmacies that provide specialty services. Patients benefit from more timely access to their specialty medications and can focus on their health rather than worry about their financial future.

Reimbursement navigation services can improve patient outcomes and create savings to the healthcare system. Canadian studies with oncology patients found that reimbursement navigation services reduced time to treatment initiation by **60 to 71 per cent (six to 25 days)**.<sup>[10,11]</sup> A one-month delay in cancer treatment can lead to a **six to 13 per cent** higher risk of death, and a one-day delay in treatment to a non-small cell lung cancer specialty drug can cost the Canadian economy more than **\$112.2 million** in lost quality-adjusted life years (QALYs).<sup>[37,38]</sup>

Reimbursement and care navigation services have also been found to help improve medication adherence. A Canadian study found that adherence could be improved by **83 per cent** with these services.<sup>[20]</sup> In addition, patients who received support from navigators were **69 per cent** less likely to stop treatment and **20 per cent** more likely to be in remission compared to those who did not.<sup>[39,40]</sup>

Reimbursement demands consistent and ongoing effort. Canadian pharmacies providing specialty services estimate that reimbursement navigation requires **30 to 120 minutes** per patient per encounter.<sup>[9]</sup> A single reimbursement navigator may support up to **600 patients** a year, providing **20 hours** of support per patient annually. Initial training costs approximately **\$18,000**.<sup>[8]</sup>

### VALUE CATEGORY 3:

## Intravenous (IV) infusion administration and coordination

More than a third of specialty medications require administration by intravenous (IV) infusion. Patients must go to infusion clinics staffed by trained healthcare providers.<sup>[12]</sup>

More than **430 infusion clinics** operate across Canada.<sup>[8,13]</sup> Almost all (**98 per cent**) were established and are managed or operated by pharmacies dedicated to providing specialty services, outside of the publicly funded healthcare system.<sup>[13]</sup>

Clinic staff administered approximately **500,000 specialty IV infusions** worth over **\$2.2 billion** to more than **130,000 patients** across Canada in 2022.<sup>[3,13,14,41]</sup>

These clinics are vital to increasing patient access to administration and delivery of specialty medications, particularly in remote areas. There are **147 pharmacy-operated infusion clinics** serving patients living in rural and remote cities with populations of less than 50,000.<sup>[13]</sup> Without these infusion clinics, patients living in rural areas (as many as one-in-three) would face hours of additional time per infusion to travel to a clinic in a major city, often relying on family or friends for transport. This extra time, as well as the added transportation costs, can negatively impact adherence to therapy and overall physical and mental well-being.<sup>[42]</sup>

Specialty pharmacy-run infusion clinics fill a gap in timely and equitable access to care for Canadians requiring infusions of specialty medications. They provide patient convenience and increase satisfaction by operating during weekends and outside of work hours (for example, In one study, patient perception of IV infusion experience improved by **42 per cent** after receiving services offered by pharmacy-operated IV infusion clinics.)<sup>[43]</sup>

More importantly, they increase healthcare capacity by adding an estimated **1 to 2.5 million hours of essential infusion capacity** to the healthcare system.<sup>[3,34]</sup> They do not receive government funding yet, without them, the Canadian public healthcare system would have to take on significant costs to match their volume and level of service.



## VALUE CATEGORY 4:

# Enhanced dispensing-related services to protect the integrity of complex medications

The fragile and potentially sensitive nature of specialty medications, as well as their unique administration requirements (e.g., infusion), necessitates enhanced dispensing-related services such as compounding and specialized delivery coordination.

## COMPOUNDING

Compounding services may be required to alter the strength or formulation of a medication, or to combine medications. Canadian pharmacies providing specialty services estimate **that 10 to 20 per cent** of all specialty medications involve compounding.<sup>[8]</sup> Between **1.3 million and 2.6 million specialty prescriptions** are compounded annually.<sup>[5,8]</sup>

A “clean room” is mandatory to compound sterile medications and work safely with hazardous materials. Canadian pharmacies providing specialty services report an upfront investment of approximately **\$680,000** to install a clean room and **\$300,000** annually for maintenance, including testing, cleaning, supplies, and staff training.<sup>[8]</sup>

## COORDINATION OF DELIVERIES

Many pharmacies providing specialty services deliver specialty medications directly to patients’ homes to remove the risks associated with vulnerable, frail or immunocompromised patients leaving their homes. These medications are primarily self-injectable as well as oral.

Additionally, many specialty prescriptions require IV infusion administration. Some oral specialty medications also must be administered in combination with IV products. Pharmacies must coordinate the delivery of these medications to infusion clinics, ensuring they arrive on time. Close to **one-third of specialty medications** require this service.<sup>[8]</sup>

Ensuring that medications arrive in the right place at the right time for the right patient necessitates coordination of packaging, delivery, patient medication dosing regimens and appointments at clinics. Pharmacies providing specialty services estimate that pharmacy staff spend more **125,000 hours annually** on infusion coordination services alone, and that each coordination takes **10 to 15 minutes**. The average cost per shipment ranges from **\$15 to \$50**.<sup>[8,12]</sup>



## VALUE CATEGORY 5:

# Enhanced medication management to optimize therapy outcomes

Patients taking specialty medications require significant clinical support from their pharmacy teams. Specialty drugs are more complex than most other prescription medications. This complexity may be due to the drug itself, the way it must be administered, the management of adverse events (i.e., side effects) or the nature of the disease or condition treated. It could be a combination of some or all of these factors.

Standard clinical services such as patient education, counseling and medication assessment may be more frequent and involve more time and therapeutic expertise than are typical for non-specialty medications. In addition, the pharmacy team may need to provide unique clinical services for testing and monitoring.

These services are essential for optimal health outcomes. Without them, the risk is much higher for avoidable healthcare costs due to sub-optimal therapeutic effect, treatment delays and disease progression.

Overall, pharmacies providing specialty services contribute an estimated **8.9 million** hours of clinical medication management services annually.<sup>[3,8,9]</sup> The value-add in such clinical support alleviates a substantial burden on the public health system, potentially offsetting up to **\$790 million** in incremental costs if these services were provided by physicians.<sup>[3,8,9,23]</sup>

## EDUCATION AND COUNSELLING

Canadian pharmacies providing specialty services estimate that general education for patients can take up to one hour per consultation. General counselling on disease states and related health concerns, or answering patients' own questions, can take up to **one hour**.<sup>[8]</sup>

Many specialty medications must be administered by subcutaneous injection. In many cases, patients are trained to self-inject these medications. In 2022, Canadian pharmacies dispensed more than **1.9 million prescriptions** for self-injectable specialty medications.<sup>[12]</sup> Canadian pharmacies providing specialty services train an estimated **3,000 to 4,000 patients** per pharmacy per year, on average. This training is critical to ensure proper technique and prevent errors, and to support better therapeutic outcomes and improve adherence.<sup>[8,12]</sup>

Patients taking specialty medications value the education and training from their pharmacy teams. For example, **86 per cent** of cancer patients agree it is important to talk to a pharmacist about their initial specialty treatment and **76 per cent** want a pharmacy follow-up during future visits.<sup>[15]</sup>

## MEDICATION ASSESSMENT

Specialty medications carry risks of serious adverse events. Pharmacies providing specialty services devote extensive time and expertise ensuring that the specialty medication is safe, effective and appropriate for the patient. This includes identifying and preventing potential drug-drug interactions. These assessments are generally more time-intensive than comparable activities for patients on traditional therapies. For example, Canadian pharmacies providing specialty services estimate that taking a medication history, an important first step for an assessment, can take between **30 minutes and 2.5 hours**, compared to 10 minutes on average for patients taking traditional medications.<sup>[8,16]</sup>

Pharmacy teams conduct medication assessments before, during and after consultations with patients. It may be necessary to communicate with other members of the patient's healthcare team. All told, Canadian pharmacies providing specialty services report each assessment takes **one to four hours** and occurs at least several times a year per patient, or with each refill of their medication.<sup>[8]</sup>

Medication assessments and resulting interventions have direct economic benefits resulting from improved health, faster recovery and reduced absences from work or school. One landmark study demonstrated how these services in community pharmacies reduced visits to emergency rooms by **17 per cent**, to walk-in clinics by **29 per cent** and to family physicians by **15 per cent**.<sup>[17]</sup> When these numbers are extrapolated to patients taking specialty medications, who may be more fragile, have more comorbidities and may suffer more serious consequences due to adverse events or drug interactions, the savings can be significant.

## MEDICATION ADHERENCE

Adherence to a drug therapy for certain disease states can be a matter of life or death. Many factors can negatively impact adherence, especially for patients taking specialty medications. They often live with multiple chronic conditions or co-morbidities, such as pain and depression, which can affect mood, functionality and energy levels. They often need to take multiple medications, each with its own regimen, which can be difficult to coordinate.

An estimated **50 per cent** of all medications for chronic disease are not taken as prescribed. **Twenty to 30 per cent** of prescriptions are never filled.<sup>[18]</sup> And where there is no adherence support, **30 per cent** of patients simply stop taking their medication before consulting a specialist.<sup>[19]</sup>

Canadian pharmacies providing specialty services support adherence in multiple ways. They spend, on average, **30 minutes** per adherence activity, which include refill reminders, adherence monitoring, compliance packaging and conversations with patients during follow-up interventions.<sup>[9]</sup>

One study of patients taking specialty medications found that adherence support increased prescription refill rates by **10 to 20 per cent**, reduced the risk of discontinuations by **72 per cent** and increased the likelihood of adherence by **83 per cent**. Studies have further demonstrated that adherence support services for complex therapies lead to many positive clinical and cost-utilization outcomes.<sup>[20,44]</sup>

Nonadherence can result in lapses in therapy. This not only jeopardizes health outcomes and may speed the progression of disease, but it also wastes valuable medications and healthcare services. In Canada, nonadherence is the cause of **five per cent** of hospital admissions and **five per cent** of physician visits, resulting in **\$4 billion** in avoidable annual costs to the healthcare system.<sup>[21]</sup>

## SERVICES FOR PATIENTS ON BIOSIMILAR MEDICATIONS

Biologics (including brand biologics and biosimilars) constitute approximately **two-thirds** of the specialty market in Canada and the global market is forecast to grow by **nine per cent** from 2022 to 2023.<sup>[4,22]</sup>

In recent years, as patents for originator biologics expire, biosimilar biologics have come to market and have become a focus for cost-containment efforts by public and private payors. In Canada from March 2021 to March 2022, biosimilars saw a **51 per cent** growth in sales.<sup>[4]</sup> Higher uptake of biosimilars in the Canadian market will continue apace as "biosimilar switch" initiatives roll out across provincial drug programs and are subsequently adopted by some private payors.

Of note, biosimilars cost significantly less than originator biologics but require the same level of services. Patients switching from a familiar biologic to an unfamiliar biosimilar require additional transition assistance from their pharmacy team. These biosimilar-specific services aim to ensure that patients are comfortable with the new medication and understand its benefits, potential side effects and dosing requirements. They also typically involve counselling from trained pharmacists in response to patients' specific questions or concerns, which can prove vital for medication adherence and treatment outcomes.

Despite requiring the same or greater level of service as originator biologics, biosimilars generate less funding for pharmacies due to the lower markups resulting from their lower price points.<sup>[45]</sup> This discrepancy puts the sustainability of specialty services at risk, which in turn threatens patient care and therapeutic outcomes. While some provinces have implemented a small one-time fee for pharmacies to support patients transitioning to biosimilars, it compensates but a fraction of the time required to support patients in their transition to a biosimilar.

## VALUE CATEGORY 6:

# Enhanced clinical monitoring to ensure effectiveness and safety of specialty medications

Unlike most other drugs, specialty medications often have a much smaller “window” between the dose needed for therapeutic effect and the dose that can lead to severe adverse effects. As well, the complexity of the drug may lead to variable responses in patients. Specialty pharmacies or their associated infusion clinics provide or support a range of monitoring services, including patient assessment, sample testing (via laboratories, point of care or home-based tests) and multiple therapy adjustments.<sup>[27]</sup>

## THERAPEUTIC DRUG MONITORING

Many specialty patients require therapeutic drug monitoring (TDM). The laboratory-based service measures drug concentrations in the patient’s blood, which enables healthcare providers to adjust doses with a high degree of precision for the individual patient. Biologics in particular require TDM.

TDM provides proven value to patient outcomes and the healthcare system. In patients with immune-mediated inflammatory disease, TDM was **22.3 per cent** more effective at sustaining disease control and delaying disease progression, while creating cost-savings for the healthcare system (e.g., health expenditures dropped by more than 50 per cent as a result of reactive TDM of infliximab that focused on managing levels of anti-drug antibodies).<sup>[24,25]</sup>

## THERAPY ADJUSTMENT

Dosage adjustments are very common in a specialty patient’s journey due to the progression of the disease and other health issues or life events. For example, **31 per cent** of people with Crohn’s disease need dose intensification at 12 months.<sup>[26]</sup> Global studies identified a therapy adjustment rate of **up to 67 per cent** for specialty biologics, demonstrating the indispensable role of pharmacies in therapy and dosing adjustment.<sup>[27]</sup>

Pharmacy teams are the last line of defense before patients receive and initiate therapies. Pharmacists providing specialty services become experts in the pathophysiology and progression of complex diseases. They use evidence-based treatment decision-making algorithms to determine when adjustments in therapy are required, and spend **up to 20 minutes** per drug interaction assessments and **up to 15 minutes** per therapy adjustment.<sup>[8,9]</sup>

## PREVENTION AND REPORTING OF ADVERSE EVENTS

Adverse drug events (ADEs), or side effects, are responsible for almost **three per cent** of hospital admissions in Canada.<sup>[28]</sup>

Canadian pharmacies providing specialty services spend, on average, **2.5 hours per patient** on services to prevent ADEs, including up-to-date medication histories, assessments of therapeutic appropriateness and checking for drug interactions. Some patients require these services several times a year.<sup>[8,9]</sup>

When an ADE does occur, pharmacies must gather and submit a detailed ADE report to Health Canada. Such pharmacovigilance is critical to help monitor the safety and effectiveness of medications and prevent similar occurrences. Canadian pharmacies providing specialty services estimate each ADE report requires an average of **30 minutes**.<sup>[8]</sup> Biologics, radiopharmaceuticals and genetic therapies, three types of specialty medications, accounted for more than **60,000 ADEs** in 2019.<sup>[29]</sup>

## Conclusion

Canadian pharmacies and their teams play an increasingly essential role in supporting the health and wellness of patients who require complex and expensive specialty medications. In Canada, a network of more than **47,000 pharmacists** in more than **11,500 pharmacies** contribute to the rapidly burgeoning specialty drug market. They collectively dispense over **13 million specialty prescriptions** to **1.9 million patients** annually.

Pharmacies safeguard the distribution and preserve the integrity of **\$13 billion** worth of specialty drugs every year and this figure continues to grow at an approximate rate of **10 per cent** annually.

Pharmacies take on substantial costs to provide specialty services. Pharmacies dedicated to services for specialty drugs have invested nearly **\$700 million** in upfront costs and spend **\$100 to \$200 million** annually to maintain the necessary infrastructure and facilities for dispensing and providing specialized services that are often unique to these medications.


Pharmacies providing specialty services contribute an estimated **8.9 million hours** of clinical services per year to optimize health outcomes of patients on specialty drugs. Without the enhanced services of pharmacies that dispense specialty medications, the negative impact on patients' health and well-being could be devastating. Patients would be vulnerable to limited access to the medications, increased out-of-pocket costs and reduced access to professional advice. Their risk of adverse drug events, interrupted therapy and poorer health outcomes would be higher. Drug spoilage and wastage would increase.

Canadian pharmacies that provide specialty services fill gaps in the public healthcare system in the areas of reimbursement navigation, infusion, patient education, monitoring and adherence support and, more recently, the transition of patients from originator biologics to biosimilar biologics. The current public system simply does not have the capacity to provide these services. For example:

- Specialty pharmacies' more than **400 infusion clinics** administer approximately **500,000 infusions** for over **130,000 patients** every year, adding an estimated 1 million to **2.5 million hours** of essential infusion capacity to the healthcare system.
- Pharmacy-led clinical support services potentially offset up to **\$790 million** in incremental costs if these services were provided by physicians.

In total, pharmacies that provide specialty services directly invest and offset an estimated **\$1 billion**, at minimum, in economic value for the **1.9 million patients** who are otherwise unsupported by the current public health system.

Despite the value of specialty pharmacy services, a formal funding mechanism does not exist for many of them. Pharmacies must rely mostly on revenue from markups that are tied to the cost of the medication. As medication prices and markups face mounting pressure to cut back, the sustainability of these services is in jeopardy.

At the same time, the pipeline for specialty medications continuously evolves, with increasingly complex, highly volatile medications for small numbers of patients on the one hand, and more readily available, self-administered medications for relatively large patient populations on the other hand. New models of remuneration for services are essential for pharmacies to resource appropriately so that patients, and the healthcare system, can benefit fully from these life-changing, and at times revolutionary, medications. 



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