

IN BRIEF

Drug coverage in Canada is a patchwork of provincial, territorial and federal public plans, private drug insurance and out-of-pocket payments. Millions of Canadians cannot afford the drugs they have been prescribed. But there is an opportunity to change this. The federal Liberal government has signed a supply-and-confidence agreement with the New Democratic Party that includes a commitment to introduce a national pharmacare plan. There are several models the government could use to implement such a plan. This paper calls for a fiscally prudent staged approach, starting with a federal reinsurance program for high-cost medications for rare diseases, which would lay the groundwork for moving toward a comprehensive, universal drug-coverage plan.

EN BREF

Au Canada, l'assurance médicaments est une mosaïque de régimes publics provinciaux, territoriaux et fédéraux, d'assurances privées et de paiements directs. Des millions de Canadiens n'ont pas les moyens d'acheter les médicaments qui leur ont été prescrits. Mais nous avons l'occasion de changer cette situation. Le gouvernement libéral fédéral a signé un accord de soutien et de confiance avec le Nouveau Parti démocratique qui comprend l'engagement d'introduire un régime national d'assurance médicaments. Il existe plusieurs modèles que le gouvernement pourrait utiliser pour mettre en œuvre un tel régime. Le présent document préconise une approche par étapes, prudente sur le plan financier, en commençant par un programme fédéral de réassurance pour les médicaments coûteux destinés au traitement des maladies rares, qui jetterait les bases d'un régime d'assurance médicaments complet et universel.



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Michael Law is a professor and Canada Research Chair in Access to Medicines at the University of British Columbia.

Fiona Clement is a professor and department head at the University of Calgary.

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CONTENTS

Key Findings	3
Faits saillants	5
Introduction	7
Overarching Goals	8
Implementation Principles	9
National Reinsurance for Prescription Drugs	10
Linking to Goals and Implementation Principles	12
Other Benefits of this Approach	13
Design and Implementation Considerations	14
Discussion of Critiques	15
Conclusion	16
References	17

KEY FINDINGS

Pharmacare has risen on the policy agenda many times in Canada. Virtually every commission on health since the 1960s has called for some form of standard coverage for a comprehensive list of medicines. Yet drug coverage in Canada remains a patchwork of different provincial, territorial and federal public plans, private drug insurance and out-of-pocket payments by households. This results in different levels of coverage, both within and across jurisdictions. Millions of Canadians cannot afford the drugs they have been prescribed by a physician.

There is a window of opportunity to change this situation for the better. The federal government took some initial steps toward national pharmacare in its 2019 budget. It announced the creation of the Canadian Drug Agency, which among other things would create a national list of drugs to be covered, assess their effectiveness and negotiate their prices with pharmaceutical companies. The government also said it would create a national strategy on high-cost drugs for rare diseases. It allocated more than \$1 billion to develop the strategy and the agency. Momentum increased in March 2022 when the governing Liberals signed a supply-and-confidence agreement with the New Democratic Party that included a commitment to pass a Canada Pharmacare Act by the end of 2023. That did not happen, but the parties recently agreed to a new deadline of March 1, 2024.

A key factor in the national pharmacare debate is the public cost, which the Parliamentary Budget Office estimated would be \$11.2 billion in 2024-25 if the national list of drugs was the same as the list used by the Quebec provincial plan. There are, however, many models that policymakers could follow to transition to a national plan. These include limiting coverage to a small number of essential medicines or establishing a plan that would focus on providing coverage for drugs that are expensive relative to household incomes.

A successful plan must make prescription drugs more affordable and accessible for all Canadians, removing barriers related to cost and reducing inequities between the sexes, among income levels, among provinces, between those who have private insurance and those who do not, and for First Nations communities. It should improve how medicines are prescribed and used. And it must be practical. It should target areas of highest need first, minimize disruptions to existing coverage and drug use, fit within available budgets and be designed to eventually cover all Canadians. Acknowledging this and the need for a financially sustainable approach to national pharmacare, we propose and recommend a reinsurance plan run by the federal government that would start with high-cost medications.

We recommend that the reinsurance plan include the following features:

A value-based formulary or list of drugs: The formulary would start with a small list of expensive drugs for rare diseases to fit within available federal funding. It would expand over time, maximizing the overlap with existing public lists. Costs would be

- controlled through measures such as mandatory generic substitution. It could be designed to target people who do not fill prescriptions, delay refilling them or skip or reduce doses because of costs.
- First payer: The federal plan would be first payer on all drug claims, meaning that it would pay for eligible prescriptions before all other insurance plans. It would pay for all prescriptions for those without a deductible, as well as before private insurance plans for higher-income households who have exceeded their deductible. By taking on the role of first payer, the federal plan would essentially act as a reinsurer for existing plans in Canada, both public and private.
- Copayments: The plan could be designed to include or exclude copayments for prescriptions over the reinsurance threshold, depending on the available budget. If used, copayments should direct patients to lower-cost drugs, when they are available. They could do this by making generic drugs free at the point of use and by using reference-based pricing policies.
- Full coverage for lower-income groups and higher thresholds for higher-income groups: The plan would provide generous exemptions to cost-sharing for low-income groups but set a higher threshold for those with higher incomes. Several provinces base the thresholds for their public plans on household income.
- Coverage escalator: The threshold above which drug costs are reimbursed would increase over time, eventually reaching 100 per cent. To encourage the provinces and territories to participate, the federal government could commit to funding a portion of these increases over time.

There are many advantages to this proposal beyond improving access to medicines, increasing equity in the system and improving how drugs are prescribed and used in Canada. It could be comparatively inexpensive to introduce. Future spending by governments would be adaptable and predictable. It works well with existing coverage plans in the provinces and territories. A federal reinsurance plan could build on existing co-operation between the federal, provincial and territorial governments to assess new drugs and negotiate prices. And it would bring the federal government to the table, outline its financial contributions and create a viable pathway to more comprehensive and co-ordinated universal coverage.

Canadian policymakers have talked about national pharmacare for more than half a century. We have an opportunity to take a decisive step toward that goal. Let's not waste it.

FAITS SAILLANTS

L'assurance médicaments a été inscrite à de nombreuses reprises à l'ordre du jour des politiques au Canada. Pratiquement toutes les commissions sur la santé depuis les années 1960 ont demandé une certaine forme de couverture standard pour une liste complète de médicaments. Pourtant, la couverture des médicaments au Canada reste une mosaïque de régimes publics provinciaux, territoriaux et fédéraux, d'assurances privées et de dépenses à même la poche des ménages. Il en résulte des niveaux de couverture différents, tant à l'intérieur d'une même juridiction qu'entre les différentes juridictions. Des millions de Canadiens n'ont pas les moyens d'acheter les médicaments qui leur ont été prescrits par un médecin.

Il existe une fenêtre d'opportunité pour améliorer cette situation. Le gouvernement fédéral a pris des mesures initiales en faveur d'un régime national d'assurance médicaments dans son budget 2019. Il a annoncé la création de l'Agence canadienne des médicaments, qui serait notamment chargée de dresser une liste nationale des médicaments à couvrir, d'évaluer leur efficacité et de négocier leurs prix avec les compagnies pharmaceutiques. Le gouvernement a également déclaré qu'il créerait une stratégie nationale sur les médicaments à coût élevé pour les maladies rares. Il a alloué plus d'un milliard de dollars à l'élaboration de cette stratégie et à la création de l'agence. L'élan s'est renforcé en mars 2022 lorsque les libéraux au pouvoir ont signé une entente de soutien et de confiance avec le Nouveau Parti démocratique qui comprenait l'engagement d'adopter une loi sur le régime d'assurance médicaments du Canada avant la fin de l'année 2023. Cela ne s'est pas produit, mais les partis ont récemment convenu d'un nouveau délai, fixé au 1er mars 2024.

Un facteur clé dans le débat sur le régime national d'assurance médicaments est le coût public, que le Bureau parlementaire du budget a estimé à 11,2 milliards de dollars en 2024-2025 si la liste nationale des médicaments était la même que celle utilisée par le régime provincial du Québec. Il existe cependant de nombreux modèles que les décideurs politiques pourraient suivre pour passer à un régime national. Il s'agit notamment de limiter la couverture à un petit nombre de médicaments essentiels ou d'établir un plan qui se concentrerait sur la couverture des médicaments coûteux par rapport aux revenus des ménages.

Un plan efficace doit rendre les médicaments sur ordonnance plus abordables et plus accessibles pour tous les Canadiens, en supprimant les obstacles liés au coût et en réduisant les inégalités entre les sexes, entre les niveaux de revenus, entre les provinces, entre ceux qui ont une assurance privée et ceux qui n'en ont pas, ainsi qu'entre les communautés des Premières Nations. Il doit améliorer la manière dont les médicaments sont prescrits et utilisés. Enfin, il doit être pratique. Il devrait d'abord cibler les domaines où les besoins sont les plus importants, minimiser les perturbations de la couverture existante et de l'utilisation des médicaments, s'inscrire dans le cadre des budgets disponibles et être conçu pour couvrir, à terme, tous les Canadiens. Compte tenu de ces éléments et de la nécessité d'adopter une approche financièrement viable en matière d'assurance médicaments nationale, nous proposons et recommandons un régime de réassurance géré par le gouvernement fédéral qui commencerait par les médicaments coûteux.

Nous recommandons que le plan de réassurance comporte les caractéristiques suivantes :

- Un formulaire ou une liste de médicaments fondés sur la valeur: Le formulaire commencerait par une liste restreinte de médicaments coûteux pour les maladies rares, dans la limite des fonds fédéraux disponibles. Il s'étofferait au fil du temps, en maximisant le chevauchement avec les listes publiques existantes. Les coûts seraient contrôlés par des mesures telles que la substitution obligatoire par des médicaments génériques. Il pourrait être conçu pour cibler les personnes qui ne remplissent pas leurs prescriptions, tardent à les renouveler, sautent des doses ou les réduisent en raison des coûts.
- Premier payeur: Le régime fédéral serait le premier payeur pour toutes les demandes de remboursement de médicaments, ce qui signifie qu'il paierait les prescriptions admissibles avant tous les autres régimes d'assurance. Il prendrait en charge toutes les prescriptions pour les personnes ne bénéficiant pas d'une franchise, ainsi que les régimes d'assurance privés pour les ménages à revenu élevé ayant dépassé leur franchise. En assumant le rôle de premier payeur, le régime fédéral agirait essentiellement comme un réassureur pour les régimes existants au Canada, qu'ils soient publics ou privés.
- Copaiements: Le régime pourrait être conçu de manière à inclure ou à exclure les copaiements pour les prescriptions dépassant le seuil de réassurance, en fonction du budget disponible. S'ils sont utilisés, les copaiements doivent orienter les patients vers des médicaments moins coûteux, lorsqu'ils sont disponibles. Pour ce faire, les médicaments génériques pourraient être gratuits au point d'utilisation et des politiques de prix basées sur des références pourraient être utilisées.
- Une couverture complète pour les groupes à faibles revenus et des seuils plus élevés pour les groupes à revenus élevés : Le plan prévoirait de généreuses exemptions de participation aux coûts pour les groupes à faible revenu, mais fixerait un seuil plus élevé pour les groupes à revenu élevé. Plusieurs provinces fixent présentement les seuils de leurs régimes publics en fonction du revenu du ménage.
- Augmentation graduelle de la couverture: Le seuil à partir duquel les coûts des médicaments sont remboursés augmenterait au fil du temps, pour finalement atteindre 100 %. Pour encourager les provinces et les territoires à participer, le gouvernement fédéral pourrait s'engager à financer une partie de ces augmentations au fil du temps.

Cette proposition présente de nombreux avantages, au-delà de l'amélioration de l'accès aux médicaments, du renforcement de l'équité du système et de l'amélioration de la manière dont les médicaments sont prescrits et utilisés au Canada. Son introduction pourrait être relativement peu coûteuse. Les dépenses futures des gouvernements seraient adaptables et prévisibles. Il fonctionnerait bien avec les régimes de couverture existants dans les provinces et les territoires. Un régime fédéral de réassurance pourrait s'appuyer sur la coopération existante entre les gouvernements fédéral, provinciaux et territoriaux pour évaluer les nouveaux médicaments et négocier les prix. Enfin, il permettrait au gouvernement fédéral de s'asseoir à la table des négociations, de préciser sa contribution financière et de créer une voie viable vers une couverture universelle plus complète et mieux coordonnée.

Cela fait plus d'un demi-siècle que les responsables politiques canadiens parlent d'un régime national d'assurance médicaments. Nous avons l'occasion de faire un pas décisif vers cet objectif. Ne la gâchons pas.

INTRODUCTION

Pharmacare has risen on the policy agenda many times in Canada. Virtually every commission on health since the 1960s has called for some form of national pharmacare, meaning a plan that includes standard coverage across Canada for a comprehensive list of medicines. They included the Royal Commission on Health Services (1964), also known as the Hall Commission; the National Forum on Health (1997); the Commission on the Future of Health Care in Canada (2002), also known as the Romanow commission; the Study on the State of the Health Care System in Canada (2003), also known as the Kirby commission; and, most recently, the Advisory Council on the Implementation of National Pharmacare (2019). Despite these repeated calls, drug coverage in Canada remains a patchwork of different provincial, territorial and federal public plans, private drug insurance and out-of-pocket payments by households (Daw & Morgan, 2012). This has resulted in different levels of coverage, both within and across jurisdictions. Millions of Canadians cannot afford the drugs they have been prescribed by a physician (Holbrook et al., 2021).

The federal government announced three pharmacare initiatives in its 2019 budget: the creation of the Canadian Drug Agency to assess the effectiveness of new prescription drugs and negotiate prices on behalf of Canadians, the development of a national list of covered drugs (a formulary) and the creation of a national strategy for high-cost drugs for rare diseases. Health Canada received \$35 million to spend over four years on the Canadian Drug Agency and the national formulary. The government committed up to \$1 billion in funding over two years, starting in 2022, and up to \$500 million a year afterwards on the strategy for high-cost drugs for rare diseases (Government of Canada, 2019). It said these steps toward a national pharmacare program would increase affordability and access.

Movement on pharmacare accelerated in March 2022 when the Liberals and the New Democratic Party struck a deal they called *Delivering for Canadians Now, a Supply and Confidence Agreement*. In it they agreed to continue "progress towards a universal national pharmacare program by passing a Canada Pharmacare Act by the end of 2023" (Liberal Party of Canada and the New Democratic Party, 2022). The details of the program have not been stated publicly, aside from having the Canadian Drug Agency develop a national formulary and a bulk purchasing plan. The parties were still negotiating when the 2023 deadline passed without the introduction of new legislation. Recently, a new deadline of March 1, 2024, was agreed upon.

All prior windows of opportunity for pharmacare reform closed with limited progress toward a national approach with a defined role for the federal government. However, a number of bodies and initiatives have emerged to fill some of this void. For example, public drug plans now do a centralized assessment of new brand medicines through Canada's Drug and Health Technology Agency, an independent, not-for-profit body set up by the federal, provincial and territorial governments. The drug plans collectively negotiate drug prices through the pan-Canadian Pharmaceutical Alliance, an independent organization whose members include the federal, provincial and territorial

governments. These initiatives have led to significant convergence in the formularies across the public plans but have not had a major impact on how the different plans are designed (Patented Medicine Prices Review Board, 2017). As a result, there is still significant variation across the country in who is covered by public plans and under what terms. Improving coverage and co-ordination remains a significant imperative, and a place where the federal government has a potential role to play.

In March 2023, the federal government announced further specifics on how the funding for expensive drugs for rare diseases would be used (Health Canada, 2023). A significant portion of the funding allocated over a three-year period, \$1.4 billion, was earmarked for bilateral agreements with the provinces and territories to improve access to new and emerging drugs for Canadians with rare diseases. The agreements will target a specific set of new and emerging drugs that will be covered across the country. The list of drugs and the nature of the cost sharing required of the provinces, territories and patients has not yet been disclosed. The 2023 federal budget contained no additional financial commitments for drug coverage (Government of Canada, 2023).

One impediment to change is the potential cost to the public of a national pharmacare plan. The Office of the Parliamentary Budget Officer (PBO), which provides economic and financial analysis to Parliament, estimated in 2023 that national pharmacare would save money at a societal level, reducing drug expenditures by \$1.4 billion in 2024-25 (Office of the Parliamentary Budget Officer, 2023). However, it would significantly increase public spending as the government assumed responsibility for payments currently made through private insurance or by households. The PBO estimated that public expenditures would increase by \$11.2 billion in 2024-25 if the national plan was based on the Quebec drug list.

It is critical that another window of opportunity does not pass without progress toward more co-ordinated and comprehensive drug coverage in Canada. In this paper, we outline how to leverage the existing commitments for expensive drugs for rare diseases and lay the groundwork for national pharmacare in a way that is consistent with fiscal prudence, universality and public administration. Our plan focuses on the feasible first step of implementing a federal reinsurance program for high-cost medications. It builds on the funding for high-cost drugs for rare diseases that has already been committed and creates a platform for staged expansion that could eventually achieve a full and comprehensive program of consistent universal public drug coverage across Canada.

OVERARCHING GOALS

This proposal builds on the following key goals:

- Improved affordability: Canadians should have better access to the prescription medicines they need. Cost-related barriers should be minimized for everyone.
- Improved equity in access: Access to prescription drugs should be more equitable. Inequities exist between the sexes, between those who have private

- health insurance and those who do not, among provinces, among different income levels and for First Nations communities.
- Improve how medicines are prescribed and used: National pharmacare should aim to optimize the quality of prescribing. It should also encourage patients to use the most cost-effective medicines.

IMPLEMENTATION PRINCIPLES

Policy change in this area is contentious. We address this concern by proposing the following principles for implementation:

- Target areas of highest need first: An incremental approach to national pharmacare should first attempt to make medication more affordable for vulnerable populations with higher rates of medication-affordability problems.
- Minimize disruptions in coverage and drug use: Any change should be made in a manner that limits short-term disruption to existing public and private coverage and allows for a gradual transition to occur. This is to both ensure continuity of care and to increase the feasibility of the proposed approach.
- Immediate feasibility: Where possible, the approach should build on existing money and momentum. In particular, the approach should have the flexibility to fit within available budgets.
- Plan for the future: The approach should have a built-in mechanism to achieve the eventual coverage of the entire Canadian population. In the current context, this would mean that the approach for using the rare disease funds should not reinforce the existing model of siloed coverage.

Working from the above goals and principles, it is possible to assess the various options available to policymakers for developing a universal approach to national pharmacare. There are several potential models for transitioning to a more comprehensive program (Law et al., 2018). Recent debates have largely focused on two main options. The first would start with coverage of a small number of medicines that are deemed essential because they cover the priority needs of the population. The second is a reinsurance program that would focus on providing coverage for drugs that are expensive relative to household incomes. It is critical to assess which model would work best with the current funding for expensive drugs for rare diseases, as this dedicated funding provides a potential launchpad for a more comprehensive approach.

The Advisory Council on the Implementation of National Pharmacare advocated using the first model to transition to national pharmacare in its 2019 report. Lists of essential medicines have been used in other countries. The World Health Organization publishes a model list of essential medicines and updates it every two years (World Health Organization, 2021). The advisory council recommended that the federal government introduce coverage for a list of essential medicines and expand it over five years to include a more comprehensive list of covered drugs.

From the standpoint of feasibility, this approach is highly incompatible with the existing funding for drugs for rare diseases. While there is nothing inherent in an essential medicines list that would exclude expensive drugs, none of the current lists are composed entirely of expensive medications. The majority of the drugs on existing lists of essential medicines are lower-cost medicines, largely generics, which would not qualify for funding under the recently announced funds. In addition, the estimated cost of covering essential medicines far exceeds the funding allocated through the expensive drugs for rare diseases envelope. It may well exceed what the government is currently willing to spend. Therefore, it is difficult to see how this approach to starting national coverage would be consistent with the current funding. There are more general drawbacks that merit consideration (Health Canada, 2023). For example, the majority of Canadians already have coverage for many essential medicines. That means that new public funding would largely displace existing coverage.

NATIONAL REINSURANCE FOR PRESCRIPTION DRUGS

The model that can feasibly adhere to the goals and principles outlined above is a reinsurance plan run by the federal government. It would share many principles with catastrophic coverage plans, whereby the cost of a list of drugs would be covered beyond a set threshold. This approach would provide public plans with financial support for Canadians with particularly high drug expenditures. Such an approach could target those with the highest need first, build on the existing funding for expensive drugs for rare diseases and develop the platform and infrastructure for a more comprehensive and co-ordinated approach to drug coverage across Canada.

It would include the use of a defined national formulary, coupled with price negotiations at the national level for inclusion on the federal list. To align with the above principles, such a plan would need to cover the entire population but be designed at the outset to include generous coverage for low-income households. To achieve this, the plan should have two avenues for expansion: a coverage escalator to lower the reinsurance thresholds to achieve comprehensive public coverage, and a method to increase over time the formulary of drugs beyond those for rare diseases.

This model would include the following features:

■ Value-based formulary: The formulary would be designed to cover a small selection of expensive drugs for rare diseases to fit with the available funding from the federal government. Over time, this would be expanded to a more comprehensive formulary with treatments for multiple diseases and non-rare conditions. This eventual list would aim to maximize overlap with existing public formularies. It should include cost-control measures with a proven track record, such as reference-based pricing and mandatory generic substitution (Acosta et al., 2014). Reference-based pricing is when all effective drugs in a reference class, such as arthritis control, are compared and only the most cost-effective are approved (IRPP Task Force on Health Pollicy, 2000). Some parts of the formulary could be designed to target specific groups with higher rates of cost-related non-adherence.

- Cost-related non-adherence is when people do not fill prescriptions, delay refilling them or skip or reduce doses because of costs.
- First payer: The federal plan would be first payer on all drug claims, meaning that it would pay for eligible prescriptions before all other insurance plans. It would pay for all prescriptions for those without a deductible, as well as before private insurance plans for higher-income households who have exceeded their deductible. By taking on the role of first payer, the federal plan would essentially act as a reinsurer for existing plans in Canada, both public and private.
- Copayments: The plan could be designed to include or exclude copayments for prescriptions over the reinsurance threshold, depending on the available budget. If used, copayments should direct patients to lower-cost drugs, when they are available. They could do this by making generic drugs free at the point of use and by using reference-based pricing policies.
- Full coverage for lower-income groups: There should be generous coverage for lower-income groups, with a limited role for patient charges. This could be done by providing generous exemptions to cost-sharing requirements for low-income households. Additional considerations for how this could be done are outlined in the section below on setting the low-income threshold.
- Higher threshold for higher-income households: The remainder of the population would be insured for the cost of drugs on the formulary above a particular threshold. This could be set as either a fixed dollar amount or as a percentage of household income. Fixed dollar amounts have been proposed in the past, for example by the Kirby and Romanow commissions. Several provinces base their thresholds on household income. For example, the current threshold for some public coverage plans is 4 per cent of household income in British Columbia and Ontario.

Time

Existing coverage

National And Separation of the Control of

Figure 1. Design of the coverage escalator

Source: Law and Clement.

Coverage escalator: The plan should include an escalator clause that would increase the deductible-free threshold over time, as shown in figure 1. This could increase to 100 per cent coverage over a defined period for either a fixed dollar amount or an income-based threshold. To encourage the provinces and territories to participate, the federal government could commit to funding a portion of these increases over time.

LINKING TO GOALS AND IMPLEMENTATION PRINCIPLES

With these features, the model would achieve the key principles stated above:

- Equity in access: At first, this model would help improve equity in access to expensive drugs for rare diseases across income levels and jurisdictions. As the escalator and size of the formulary increase, the eventual comprehensive public plan would cover all Canadians with an equitable approach that is more consistent with existing medicare coverage of hospital and physician services.
- Improve how medicines are prescribed and used: By using evidence-based tools such as reference-based pricing and mandatory generic substitution, the plan would help improve the quality of prescribing. Physicians would eventually become familiar with the resulting national formulary. The use of academic detailing on a national basis would help reinforce these approaches. Academic detailing is when a trained health care provider meets face to face with a doctor or nurse to provide information about the drug being prescribed. Finally, as data collection is necessary to track progress toward deductibles, this system would open possibilities for nationwide research on the use and safety of prescription drugs.
- Target areas of highest need first: We know from existing research that deductibles do not impact drug use in some populations with low levels of affordability problems. Thus, this approach would target the area of highest needs first. It would provide an exemption from cost-sharing for households with incomes under \$60,000. This would cover about 35 per cent of the population and more than 50 per cent of the reported cases of cost-related non-adherence in Canada (Law et al., 2018). This could also be designed to mesh with the existing threshold of \$90,000 being used in the new Canada Dental Benefit program.
- Minimize disruptions in coverage and drug use: This approach would also avoid covering the vast majority of Canadians who already hold private insurance. Just 18.6 per cent of those currently reporting private coverage have household incomes under \$60,000 (about 2.9 million people) (Bolatova & Law, 2019). The remaining 12.8 million people covered by private insurance have incomes over \$60,000. The disruption to existing private insurance markets would be limited in the short term.
- Immediate feasibility: This approach would be much quicker to implement than other options because it would build on and fulfil the intent of the already dedicated federal funding for expensive drugs for rare diseases. Notably, the overall budget for the plan would have a great deal of flexibility, as the

- financial commitment from the federal government would be determined by the initial size of the formulary and the reinsurance threshold. That said, the plan would likely have to be generous enough to entice provincial collaboration.
- Plan for the future: A coverage escalator would ensure that the more comprehensive segment of coverage would grow steadily across income bands until it covered the entire Canadian population.

OTHER BENEFITS OF THIS APPROACH

Along with achieving the above principles, this model would have several other positive impacts:

- Comparatively low and predictable expenditure: This model would be comparatively inexpensive in the early stages in terms of the public purse. Growth over time could be predicted based on the addition of new drugs. This would fit with the funding that is currently allocated, as \$1.4 billion over three years represents a very small portion of total prescription drug expenditure in Canada. In the early stages, the formulary, cost-sharing with the provinces and territories, and income thresholds could be set to cover expensive drugs for rare diseases within the current allocated budget. The cost of subsequent expansions would need to be modelled and would depend on design factors such as the size of the eventual comprehensive formulary, whether copayments would be required, any cost-sharing with provinces and the initial reinsurance threshold set for higher-income beneficiaries.
- Works well with existing coverage plans: This approach respects the multiplicity of public drug plans across Canada and would allow provinces and territories to retain existing coverage. It would be compatible with plans that currently use deductibles. It would also work with plans that have different designs. The national plan would act as a reinsurer for existing public plans that are more generous for certain populations, providing budget relief for the province or territory in question. This model is also flexible. It would not preclude any particular mix of federal versus provincial contributions. Further, it respects the jurisdictional boundaries traditionally drawn between the federal, provincial and territorial governments with respect to health care operations. Provinces and territories could continue to operate their existing public plans while receiving reinsurance coverage from the federal government.
- Reduces the cost of private insurance plans: By acting as first payer, the national plan would provide a reinsurance function for private insurers for drugs in the formulary. This would, in turn, lower the cost of private insurance across the country. The impact of this reinsurance benefit is already apparent in Canada. The three western provinces with income-based models have monthly private insurance costs per covered member of \$78, compared to \$110 in Ontario, \$129 in Quebec and \$126 in the Atlantic provinces (Telus Health, 2023). This benefit could be returned to employees as additional wages or benefits, or the provinces and territories could impose rules to limit the out-of-pocket cost

- for prescriptions in private insurance plans. The latter option would help address the existing affordability problems faced by more than 600,000 Canadians with private insurance (Law et al., 2018).
- Assumes centralized control over high-cost drugs: As the first payer, the national program would be responsible for paying for high-cost and orphan drugs in the formulary. This would allow Canadian public plans to act in concert with one another. It would also remove the incentive for pharmaceutical companies to give a large discount to one province to pressure others to list.

DESIGN AND IMPLEMENTATION CONSIDERATIONS

How much a federal reinsurance plan will cost depends on several key decisions made during its design. They include:

Constructing the formulary

The development of a national formulary would be required for this plan to be enacted. To leverage the committed funding for expensive drugs for rare diseases, with perhaps some additional funding, the formulary would have to be a comparatively small list of high-cost medicines at the start. This list could be expanded over time to include more commonly used medications, while overlapping with public plan formularies to the maximum extent possible. This eventual overlap would be quite substantial in terms of the drugs that people use. For example, the Canadian Institute for Health Information, a research and advisory body funded by the federal, provincial and territorial governments, has estimated that drug classes found on 12 of the public drug program formularies constituted 89.9 per cent of all claims by seniors in 2016 (Canadian Institute for Health Information, 2016).

Setting the low-income threshold

There is an empiric rationale to support an initial threshold around \$60,000 of household income, as noted above. Alternatively, it could be set at \$90,000, the same threshold used in the new federal dental benefit. The relationship between household income and cost-related non-adherence is reasonably linear up to approximately \$100,000. Reductions in the threshold would result in proportionate declines in the amount of cost-related non-adherence that could be addressed (Law et al., 2018). Increases in the threshold through the escalator would expand the plan to cover more, and eventually all, Canadians.

Funding split with the provinces and territories

The provinces and territories have public drug programs that cover a significant number of the medicines that would be included in a federal reinsurance plan. Its creation would offset some existing provincial and territorial spending and free up resources. Whether these offset amounts continued to be or are required to be spent on drug coverage will have important implications for the number of drugs that could be included on the formulary.

Required data infrastructure

Consistent, comprehensive data will be required to support the implementation of this approach. This data collection would build upon the momentum already established by some large investments in robust pan-Canadian data, such as funding for the Health Data Research Network Canada. Its members include federal, provincial and territorial governments and organizations that have a national health mandate or hold national data. The network is helping standardize the data collected by provinces and territories (Health Data Research Network Canada, 2023). Universal capture of prescription drug use would have obvious benefits for managing the reinsurance plan. It would also enable research and evidence-informed decision-making about which drugs to cover.

DISCUSSION OF CRITIQUES

We have existing public plans elsewhere in Canada that are similar to this approach. Yet cost-related non-adherence continues to persist. This raises the question of why the proposed approach might work at the federal level. We view our proposed plan as the thin end of the wedge. It capitalizes on the current context to lay the groundwork for national pharmacare. Importantly, our approach will bring the federal government to the table, outline its financial contributions and create a viable pathway to more comprehensive and co-ordinated universal coverage.

One common argument against national pharmacare is that it will not cover new and/ or high-cost drugs. There is nothing inherent in this model, nor indeed the broader vision of comprehensive national pharmacare, that would preclude the listing of high-cost and newer medications. In fact, they would be included if the program started with the existing funding for expensive drugs for rare diseases. Formulary design at the national level would ensure a more consistent and fair application of rules across the country to determine what we should pay for, given a particular budget. Decisions about listing particular drugs could be driven by value (among other factors). The ultimate size of the formulary would depend on the level of funding provided to the program and how much of the cost is charged to patients. Finally, this plan would provide a backstop for the funding of many high-cost drugs, an increasing problem for small- and medium-sized employers with private benefits plans (Telus Health, 2023).

There would, of course, be a requirement to maintain and update the formulary. It requires significant human resources to assess drugs for addition to the list and to identify those that should be de-listed because of concerns about their safety, effectiveness or value. By consolidating the current formularies of public and private plans, the work of formulary management would also be consolidated, reducing duplication of work. This component builds on the momentum created by the establishment of the Canadian Drug Agency, whose role is to develop, maintain and update a national formulary.

Critics of this proposal may argue that drug purchasing will remain fragmented, diminishing possible bargaining power with pharmaceutical companies. However, the pan-Canadian Pharmaceutical Alliance already negotiates with pharmaceutical companies on behalf of all the public plans, seeking lower prices for Canadians. It is worth noting that, while complete consolidation of the sector to create a bargaining block may increase negotiating power, Canada remains a small component of the global market. Its influence is dwarfed by that of Europe and the United States. In addition, Canada has signalled through multiple other avenues, such as abandoning recently proposed changes to the Patented Medicine Prices Review Board, that the government has little appetite for new approaches in the current policy environment.

One concern with any stepped approach to national pharmacare is that the next steps will not be taken. In our model, the argument would translate to the coverage escalator not being implemented, leaving us with just a federal reinsurance system. There are two responses to this critique. First, the federal government could enshrine the escalator in any funding agreements signed with the provinces and territories. This would force future governments to honour this commitment. There would also be continued political pressure for additional support, as there is for the federal funding that contributes to physician and hospital services in provincial medicare programs. Second, even absent the coverage escalator, the reinsurance plan would improve access to expensive drugs for rare diseases and lay the groundwork for improved coordination of coverage in Canada.

CONCLUSION

We believe it is crucial to take a meaningful step toward national pharmacare and not lose this opportunity for progress. The approach laid out above would achieve the stated goals once it is fully in place. It would improve access to medicines, increase equity in the system and improve how drugs are prescribed and used. Importantly, it would be consistent with the implementation principles outlined above. It is the most practical approach that maintains universality as a core principle. This proposal advances coverage for those with the highest need, builds on existing momentum and will create a platform from which further progress could be made.

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