

Bureaucratic Autonomy in Decision-Making for Adding New Oncology Medications to Public Drug Benefit Plans in Canada

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Abstract

In Canada, prescription drugs go through a multi-stage process before they are paid for by provincial governments. For oncology drugs, among the most important of these steps are licensing for sale by Health Canada, a non-binding recommendation by the Pan Canadian Oncology Drug Review (PCODR) as to whether provinces should reimburse for the use(s) proposed for the medication, then each province makes a final decision through its own deliberation process. These final provincial deliberations vary in terms of the role granted to the bureaucrats involved. For example, in Alberta the minister of health has the final say on adding and removing drugs from the provincial formulary. In Ontario, the final say, rests with the bureaucrat in charge of the drug benefits programs, the Executive Officer of the Ontario Public Drug Programs. However, even though this bureaucrat formally has full decision-making authority, it will be seen that in fact, the steps leading up to the final decision substantially restrict the Executive Officer's autonomy and that the position of the Executive Officer's office within the state, also creates substantial ability for the Minister to indirectly influence him or her, so that there is not much difference between the decision-making structure of the two provinces. This helps to explain why, even though politicians in Ontario have used the delegation of final decision-making authority to the Executive Officer as a blame avoidance strategy, there is no statistically significant difference in the number of uses for oncology drugs receiving a negative evaluation from the PCODR rejected for public reimbursement by the two provinces. The reader should be cautioned that the research presented in this paper is somewhat speculative in nature. Confirming whether these speculations are accurate will require further research involving interviews with participants.

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1: Introduction

Under the Westminster system, ministers are supposed to be accountable to the legislature for all the actions of their ministries or departments. As a result, situations where public servants are granted the final say were relatively rare in Canada until the advent of the New Public Management (NPM). With the NPM's emphasis on the division of roles between policymaking and policy-implementation and emphasis on outcomes accountability over procedural accountability, more and more situations emerged where final-decision making authority was legislatively delegated to senior public servants at both the federal level and in the provinces (Doberstein 2022, 602).¹ A negative side effect of this delegation, is that it permits the creation of a blame avoidance screen for politicians anxious to separate themselves from the consequences of the neoliberal policies senior public servants were being asked to carry out via the NPM (Cohn 1997). Cohn (2016) compared the delegation of decision-making to public servants in two policy areas in Ontario, decision-making over contracts with private power companies for new electrical generating capacity and adding new medications to the provincial drug benefit formulary. The article found that it was easier for politicians to delegate authority both to improve governance, as well as to engage in blame avoidance, in the case of the provincial public drug programs and that politicians did actively use the delegation of authority to deflect blame for not adding new oncology drugs to the provincial benefit plan's formulary.

¹ However, care must be taken to distinguish between the greater autonomy accruing through agencification and other forms of delegation to senior public servants at the heads of agencies, boards and other organizations and the autonomy experienced by their subordinates. As Doberstein (2022) notes, they often experience a tightening of control over their work. A phenomenon also noted by Halligan (2020, 95) when he observes that decentralization of authority under managerialism is often accompanied by a centralization of rules within the units receiving the decentralized grant of authority.

A question that went unanswered by Cohn (2016) was what the consequences were of this use of delegation of decision-making authority for blame avoidance?

In Canada, oncology drugs go through a multi-stage process before they are paid for by provincial governments. The major steps are: Approval for sale by Health Canada; The establishment of a maximum price the drug can be sold for in Canada by the Patent Medicine Price Review Board; A non-binding recommendation as to whether provinces should reimburse for the use of the medication proposed by its manufacturer by the Canadian Agency for Drug and Technology in Health's (CADTH's) Pan-Canadian Oncology Drug Review (PCODR) Expert Review Committee; Since 2015 the provinces, acting as a collective through the Pan-Canadian Pharmaceutical Alliance (PCPA) then negotiate with the manufacturer on price; Finally, each province then reaches a final decision using its own internal process (Gotfrit et al. 2022; McPhail and Snow 2022: 2065).² The blame avoidance literature suggests that delegating decision-making to public servants can be an effective way for politicians to avoid blame for the consequences of difficult decisions and problems (Cohn 1997; Hood 2011, 72; Mortensen 2013; Weimer 2006). Therefore, it is plausible that a province which has instituted reforms to leave the final decision in the hands of bureaucrats, thereby creating a blame avoidance screen for the government, ought to be able to say no more often than a province where the health minister has the final say. Enjoying career employment, bureaucrats are not subject to electoral pressures and they work in an environment where they are supposed to apply their technical expertise to making decisions that follow the application of a known set of rules to

² Quebec does not participate in either the activities of the CDTHA (including the PCODR) or the PCPA.

empirical facts, to produce outcomes that are both efficient and fair. It was this sort of thinking that in part encouraged the creation of the NPM and the slogan “letting managers manage” (Cohn 1997, 585; Bezes and Jeannot 2017, 4-5). Using the list of recommendations issued by the CADTH’s Pan-Canadian Oncology Drug Review (PCODR) from 2011 to January 2023, Cohn (2023) conducted a comparative study between two Canadian provinces. He tested the hypothesis that Ontario, where legislation grants the power to make final decisions on adding medications to the provincial formulary to a senior public servant, would have adopted fewer of the drugs with negative PCODR recommendations than Alberta, where the final decision rests with the Minister of Health. The study looked at decisions involving 42 uses for oncology drugs that had received negative recommendations from the PCODR, between 2011 and 2023. It was found that there was no statistically significant difference between Alberta and Ontario and the hypothesis was rejected.

Table 1. Provincial Decisions to Reimburse for Uses of Oncology Drugs that Received a Negative PCODR Report 2011-2023^a

Count		Province		Total
		AB	ON	
Reimbursed	No	32	37	69
	Yes	10	5	15
Total		42	42	84

Chi Sq. Sig. Equal approx. 0.15

a. Source: Cohn (2023) Table 2.

The present paper seeks to provide an explanation for that result. The paper takes a closer look at the process leading up to final decision-making in the two provinces. It also seeks to assess the degree of autonomy granted to the public servant in Ontario responsible for final

decision-making over the formulary for the provincial drug programs by utilizing the typology of bureaucratic autonomy developed by Verhoest et al. (2004). The analysis shows that although the Executive Officer of the Ontario Public Drug Programs has final decision-making authority, the Executive Officer's autonomy is in fact somewhat limited due to the advisory process that leads up to their decisions, which unlike Alberta's involves patient representatives. This has the potential to expose the Executive Officer to the same public pressures as the health minister faces in Alberta. As well, the structure of the Executive Officer's office also must be noted. It is situated in a traditional bureaucratic hierarchy, what Verhoest et al. (2004, 110) describe as a "core government organization". This affords Ontario's health minister ample ability to indirectly steer the Executive Officer's decisions. Most notably, by constraining the time that the senior public servant serving as Executive Officer can devote to this role, the Executive Officer is likely to become even more dependent on the advice that they receive in the lead up to their decisions. Consequently, the result that there is no statistically significant difference in the number of drugs with a negative PCODR recommendation that Alberta and Ontario reject, is perhaps explainable.

The next section of the paper reviews some theoretical works on health technology assessment and the roles of advisory committees, specifically the role of patient representatives in the process. Then attention turns to the typology developed by Verhoest et al. (2004) for categorizing the various dimensions of bureaucratic autonomy. The fourth section reviews in greater detail the decision-making process for whether or not provinces will pay for oncology drugs and some of the key structures of Alberta and Ontario's drug plans, with a particular focus on Ontario, as it deviates from the Westminster system in granting a

bureaucrat final decision-making authority over adding medications to the provincial formulary. The fifth section provides a conclusion re-interpreting the results in light of Verhoest et al.'s categorization of bureaucratic autonomy and the advisory processes that lead up to decisions. Before proceeding, it should be noted that what will be attempted in this paper is to create a tentative explanation for the problem presented above. Confirming whether this explanation is accurate, will require further research in the form of interviews with participants.

2. Health Technology Assessment and the Role of Patient Representatives

The costs of new oncology medications are often very high, while their impacts in terms of increasing longevity and in terms of improving quality of life, are sometimes marginal when compared to existing treatments (Meyers et al. 2021). Therefore, becoming more selective in terms of which uses of oncology medications provinces reimburse for, began to appear as a legitimate avenue for cost control for Canada's provincial governments, which are constitutionally responsible for health care. However, there was also a recognition that maintaining public legitimacy required better coordination, so that different provinces less frequently came to different decisions on whether to add drugs to their public drug plan formularies. These pressures led to the creation of the Common Drug Review process in 2003 and the Interim Joint Oncology Drug Review in 2007 (Morgan et al. 2006, 346; Yong et al. 2013, 230). Subsequently, a decision was reached to provide a stronger institutional structure for Health Technology Assessment (HTA). This led to the creation of the CADTH, which took over the operation of the Common Drug Review and transformed the interim process for oncology

drugs into the PCODR (Gotfrit et al. 2022). According to Boothe (2021, 424), when applied to the evaluation of drugs in Canada:

HTA uses a range of clinical, economic, legal and ethical evidence to determine which new drugs should be publicly funded, based on their clinical and cost effectiveness. The methods are implemented by independent drug advisory committees made up of health care professionals, clinical epidemiologists, health economists and other technical experts, which make non-binding recommendations to public drug plans.

Morgan et al. (2006) in their study of centralized drug evaluations in four countries observed that such processes can help make “tough decisions” more acceptable through their transparency in terms of process and evidence considered and by following rigorously high standards in terms of the evidence they employ. In short, the PCODR process, followed by the further advisory committee evaluation which occurs in each province (whether the final say rests with a public servant or the province’s health minister) perform a legitimization function as well as the instrumental function of providing better evidence for the final decision-maker (Boothe 2019, 634).

An important question is what role the public and patient representatives ought to play in the HTA process (Boothe 2021; Boothe 2019). In short are the committees which carry out HTA advisory committees (committees with both lay and professional members) or expert advisory committees (committees restricted to professionals involved in health care delivery, health care management, economics, ethics and law)? Gagnon et al. (2021) conducted an international comparison of patient and public involvement in HTA. They found that it was more common to incorporate input from the public and from patient representatives into HTA through consultation, rather than through direct involvement as representatives serving on HTA committees. Consequently, the CADTH’s PCODR, as well as Ontario’s similar committee

are a bit outside the mainstream in that they have patient representatives sitting on the committees performing HTA (Boothe 2021, 424-425). Another important question is what the impact is when the public and patient representatives are included on committees performing HTA. Boothe (2019, 656) found that both technical experts and patient representatives were unsure what impact public and patient involvement had on HTA decision-making, but they did believe it had some. If it is unclear what impact public and patient representatives on HTA committees are having, it is more clear what patient advocacy groups want. Lexchin (2019) reviewed submissions made by groups representing patients to the Canadian Common Drug Review (for non-oncology medications) and the PCODR. 242 out of 268 submissions reviewed (approximately 90%) were positive endorsements for the use of the medication under review. Some have suggested this is not surprising given the large amounts of funding that drug companies benefiting from these decisions provide to patient groups (Grant 2018). However, that might be too simplistic. Abelson et al. (2016) notes there are several reasons to include patient input through consultations and patient representatives in HTA. These include the legitimization function already mentioned, as well as to improve the quality of decisions by ensuring decisions are made from a health conditions perspective. For example, by taking account of evidence that is difficult to capture through empirical research, such as the impact of a medication on the quality of life patients enjoy. As a result, it can be reasoned that the degree to which the process is opened up to patient representatives might increase the likelihood that a proposed use for a drug will receive a positive decision. As noted above, and as will be discussed further below, Ontario's provincial committee undertaking HTA of proposed uses for oncology medications and making recommendations on whether these

should be reimbursed, includes patient representatives. The similar committee in Alberta does not.

3: What do we mean when we say a public servant or public sector organization is autonomous?

If you carefully read the Canadian Constitution, you will notice that, as with the informal constitution of the UK, all final decision-making authority in terms of approving or rejecting laws approved by Parliament, the issuance of regulations under the laws, major appointments (including judges), and the command of Canada's military, security and police forces, are vested in the Crown. In the case of Canada the Crown delegates these powers to a vice-regal official known as the Governor General. In reality, the Governor General's formal right to have the final say on most matters, is tightly restricted by the fact that Canada is a parliamentary democracy and by the constitutional requirement for Parliament to approve all taxes and spending of public money. Therefore, as is the case in the UK, the Governor General asks the leader of the party most likely to command a majority in the Canadian House of Commons to become his or her Prime Minister and to "advise" him or her on what to do.³ This example was meant to illustrate that although the law may grant some one or some agency decision-making authority, they might not have much autonomy in how they use that power.

³ There have only been two cases in Canadian history of a Governor General rejecting the advice of their Prime Minister on a major issue. The last took place in 1926. At the provincial level there have only been a handful of cases where Lieutenant Governors have rejected the advice of provincial premiers on a significant matter.

This question of what it means to say some one or some agency is “autonomous” and how we can differentiate levels or categories of autonomy between different bureaucrats and different public sector organizations is the topic tackled by Verhoest et al. (2004). One major issue with using this taxonomy for the present paper is that it was specifically designed to distinguish levels of autonomy available to agencies outside of the traditional structure of bureaucratic government. However, in this case both the Alberta and Ontario public drug plans are run by public servants operating in traditional public sector organizations. Nevertheless, when it is applied to the discussion of the structure of the public drug plans and decision-making in section 4, it allows for a clearer understanding of what exactly the autonomy is that the Executive Officer of the Ontario Public Drug Programs possesses that his or her colleagues in Alberta do not and how this relates to the tools available to the minister in Ontario to indirectly steer the work of the Executive Officer. Verhoest et al. (2004) suggest that we can categorize government organizations into six types.

- Type 1: Core government organizations. In Canada that means traditional ministries and departments.
- Type 2: Internally autonomous public organizations without legal personality. In the Canadian context an example might be the various regulator agencies at arms-length from the minister that enjoy autonomy in their operation but whose final decisions can often be over-ridden by an order of the cabinet.
- Type 3: Funds with Public Law Legal Personality. An example here might be Export Development Canada (a special bank that makes loans and offers loan guarantees to spur exports)

- Type 4: Internally autonomous public organizations with public law legal personality.
Examples might include the various agencies established by the federal government that also operate on behalf of the provinces, such as the Canada Revenue Agency (the agency which collects income and sales taxes for Ottawa and 9 of the 10 provinces).
- Type 5: Externally autonomous public organizations with public law or hybrid legal personality, an example might be the Higher Education Quality Council of Ontario, which monitors the quality of academic programs and accredits these programs for Ontario's Colleges and Universities.
- Type 6: Externally autonomous public organizations with private law legal personalities.
In Canada good examples might be "crown corporations", private companies established to achieve a government objective by operating in a commercial manner, such as the post office. Their main difference from other large companies is that they have only one shareholder, the Crown.

To assess the autonomy these different types of government organizations have, Verhoest et al. (2004) developed a taxonomy of bureaucratic autonomy that groups six dimensions of autonomy under two major headings.

- Autonomy as decision-making competencies
 - o Managerial autonomy: How much autonomy does the organization or official have over the structure of the agency or inputs such as human resources or financial transactions? Or conversely how much control can the central government exercise over it through managing these? An example relevant to this project might be the question of expert advisory boards that are present in

the oncology drug approval process in each province. Who names the members of these boards, the Minister of Health or the senior public servant in charge of the province's drug plan?

- o Policy autonomy: How much autonomy does the organization or official have to make decisions and the rules that lead to decisions?
- Autonomy as the exemption of constraints on the actual use of the decision-making competencies
 - o Structural autonomy: How embedded in the bureaucratic hierarchy is the organization or official? How strong are the lines of accountability to the central government?
 - o Financial autonomy: How much autonomy does the organization or official have over its finances?
 - o Legal autonomy: Does the agency or official have a grounding for their agency's separate status in law and how secure is it? Here what is referred to is not any legislation which empowers decision-making but that provides the agency or official with a structural position outside of the central government, such as a separate legal identity.
 - o Interventional autonomy: What are the reporting requirements and can these be used to control the agency or official's direction?

They also provide criteria for evaluating whether the autonomy available for each dimension is minimum possible, low, medium, high or maximum possible. What they find is that the cases they look at generally correspond to their predictions, with Type 1 organizations having the

least autonomy on most dimensions. However, a number of Type 1 organizations are seen as having greater freedom under the policy autonomy dimension, which along with the managerial dimension, is part of the first major group Autonomy as decision-making competencies (Verhoest et al. 2004, 107 and 112). As the organizations dealt with here in the present paper are both traditional government ministries, it is therefore these two dimensions of autonomy that are of interest, managerial and policy autonomy. Following is an excerpt from Table 2 in Verhoest et al. (2004, 107-108) which describes how to measure different levels of autonomy on these two dimensions.

Table 2. Excerpt from Verhoest et al. (2004) Degrees of the Different Dimensions of Autonomy

Ontario	Alberta

	principle, the procedures and the transactions (high strategic managerial autonomy)	agency is authorized to issue general regulations (high strategic policy autonomy)
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As will be seen in the next section, although the Executive Officer of Ontario's Public Drug Programs has policy autonomy that fits partially into the low and high level categories, and some managerial autonomy, the Executive Officer is a traditional public sector executive and his or her Office is part of a traditional public sector ministry. As a result, it enjoys minimal levels of autonomy in the four dimensions grouped by Verhoest et al. (2004) under the heading "Autonomy as the exemption of constraints on the actual use of the decision-making competencies." Consequently, the ability of this senior public servant to have the final say, may well be the ability to come to same conclusion as the Minister of Health would have done, if he or she had the final say. Second, it will be seen that the advisory process leading up to decision-making on whether to say no to drugs that have negative PCODR reviews is similar to the process in Alberta, with one major difference beyond who makes the final decision. In Ontario the committee undertaking HTA for oncology drugs, The Ontario Steering Committee for Cancer Drug Programs, include representatives of patient groups.

3. Public Insurance for Pharmaceutical Products in Canada and Oncology, Why It is a Public Policy Problem and Differences between Alberta and Ontario

As noted above, the PCODR's recommendations are only that, recommendations to the various provinces. They still must come to their own decisions on whether to follow the PCODR's recommendations. The process which takes place so as to prepare a recommendation for the final decision-maker within the two provinces is fairly similar. In both provinces, the receipt of

a recommendation from the PCODR is not sufficient to begin consideration of a drug, there must be an application to the respective programs to publicly reimburse for the proposed use of the drug. Once an application is received, a recommendation as to whether reimbursement should be provided is prepared by an advisory committee. In Ontario the agency involved is the Ontario Steering Committee for Cancer Drugs and in Alberta the review is done by a panel of the Alberta Expert Committee on Drug Evaluation and Therapeutics (Alberta 2023a; Alberta 2021; Ontario 2023b; Ontario 2006). Significant differences between these two committees include the following, one is a specialized cancer committee the other undertakes HTA for all proposed drugs. Second, unlike Alberta, patient representatives have membership on Ontario's committee (Alberta 2021; Ontario 2013).

The summary of Ontario's Bill 102, which was prepared by the Ontario Legislature's staff makes it clear that the intent is to grant the Executive Officer all the managerial and policy autonomy he or she needs to manage Ontario's public drug programs on a day-to-day basis.

Part II [of the Bill] makes amendments to the *Ontario Drug Benefit Act* (ODBA). It includes principles pertaining to the public drug system. It creates the position of the executive officer of the Ontario public drug programs and sets out his or her functions and powers. Most of the functions and powers that previously rested with the Minister are transferred to the executive officer (Ontario 2006, ii).

The managerial powers that the Executive Officer enjoys, fit with the description given by Verhoest et al. of "low level" powers. For example, the Executive Officer can name the members of the HTA committees and publish guidelines for them to follow, but the need for such committees is established in legislation and in the case of the Ontario Steering Committee for Cancer Drug Programs, the Executive Officer must consult with the leadership of Cancer Care Ontario (the Ontario Health Ministry Agency that is responsible for funding and delivering

Cancer Care) before naming the Chair. Similarly, the Executive Officer can enter into financial negotiations and agreements in a limited range of areas with pharmacies and drug companies (Ontario 2006, Ontario 2013).

In terms of policy autonomy, the Executive Officer appears to sit half in Verhoest et al.'s (2004) low category and half in their high category. This is because although the Executive Officer cannot choose the policy instruments employed, he or she does make decisions on specific files, whether to add or remove uses for drugs from the provincial formulary and in some cases whether individual patients will receive oncology drugs at public expense. In granting the Executive Officer of the Ontario Public Drug Programs final decision-making authority over adding and removing medications from the formularies of Ontario's drug plans and delegating the Executive Officer all the powers necessary for the day-to-day management and operation of these programs, the provincial legislature chose to emphasize the importance that the Executive Officer ought to attach to the recommendations made by the HTA advisory committees (whether the Expert Committee on Drugs which deals with all non-cancer medications, or the specialized committee for Cancer drugs). The act required the creation of the predecessors of these committees. It also required the minister to establish a review process for the Executive Officer's decisions that can only be implemented if the Executive Officer's decisions differ from the recommendations he or she receives from the HTA advisory committees (Ontario 2006, Part II Section 7, 1.1 (5) a and b).

At this point it is worth pausing to recap what has been discussed so far. It has been noted that Cohn (2016) both argued that blame avoidance for not adding drugs to the provincial formulary was one reason why this authority was delegated to the Executive Officer

and that he found evidence of this occurring. Ministers facing questions in the legislature regarding the lack of funding for specific medications, have deflected blame and justified their refusal to get involved, by reminding fellow MLAs that the law delegated decision-making power over which medications to fund to a senior public servant, the Executive Officer of the Ontario Public Drug Programs (Cohn 2016, 72-73). A major source of this pressure ministers are seeking to avoid comes from groups representing patients (Lexchin 2019; Grant 2018). However, when delegating authority to the Executive Officer, the politicians also made it clear that he or she ought to pay close attention to the HTA advisory committees that prepare recommendations to inform his or her decisions. Committees that include representatives of patients, exposing the Executive Officer to some of the pressure that the politicians themselves sought to avoid.

As well as having final decision-making powers over whether to add uses for drugs to the provincial formulary, in some situations, the Executive Officer also has final decision-making power over whether individual patients will receive oncology drugs at public expense. This occurs through two special programs administered by his or her office. These are the Exceptional Access Program and the Compassionate Access Program. These programs reimburse for the cost of medications not generally paid for by Ontario's public drug programs. In the case of both programs, a patient's health care providers apply for access to the medications and a special committee of the Committee to Evaluate Drugs or the Ontario Steering Committee for Cancer Drug Programs then reviews the application and makes a recommendation to the Executive Officer (Ontario 2023a).

The present Executive Officer of the Ontario Public Drug Programs is an Assistant Deputy Minister, which is the third highest rank within the management ranks of the Ontario Public Service and is an ordinary executive within the Ministry of Health.⁴ The ordinary nature of the Executive Officer's position, in spite of the authority that has been delegated to that office, is confirmed when we look at the Ministry's present organizational chart, where the individual listed as the Executive Officer is also shown as being the head of the ministry's Health Programs and Delivery Branch and the General Manager the Ontario Health Insurance Plan, the province's program for paying doctors who provide care under the province's universal ,single-payer health care plan (Ontario 2023d). In the fiscal 2021-22 provincial budget, it was estimated that OHIP would account for roughly 23% of the Ontario Ministry of Health's \$CDN 74 Billion budget (or about \$CDN 17 Billion). Meanwhile the province's public drug programs were estimated to account for only about 7% or roughly \$CDN 5 Billion (Financial Accountability Office of Ontario 2021, 2-5).⁵ The multiple hats worn by the senior public servant serving as the Executive Officer of the Ontario Public Drug Programs, means that the time they can devote to that role will be constrained. It appears that when this official is acting as the Executive Officer, he or she is not expected to be a detail-oriented, micro-manager, but to be more of a strategic manager or supervisor of processes. In short, a manager who respects the judgement of their advisors and tends to follow the advice they provide.

⁴ In other countries with a Westminster-style form of government, this official would probably be styled as an assistant permanent secretary. The use of terms such as deputy minister, associate deputy minister and assistant deputy minister to refer to public servants being uniquely Canadian.

⁵ 1 Canadian Dollar has been equal to approximately 75 US cents for much of the last year.

As an ordinary public sector executive, the assistant deputy minister serving as Executive Officer for the Ontario Public Drug Programs enjoys the same job protections and has the same conditions of service as any other public sector executive. While his or her dismissal for anything but legitimate cause, would be wrongful dismissal, like any other public sector executive they can be moved from one office to another. They also lack final say in the budget available for the provincial drug programs, their eligibility requirements or the level that they reimburse patients at. The office also lacks legal autonomy and the legislation specifically requires the Executive Officer to report on the operation of the drug programs to the Minister (Ontario 2006, Part II Section 7, 1.1 (3)).

This inability to control the design of the province's drug programs (the policy instruments) is a significant issue. Unlike Alberta, where the province provides universal access to cancer medications listed in the provincial formulary at no charge to patients, whether the drugs are administered in hospitals or as take home drugs (Alberta 2003b), Ontario only pays for take home drugs through the Ontario Drug Benefit for those on social assistance, seniors, and those resident in long-term care facilities and other forms of social housing.⁶ Other Ontarians are supposed to pay for their medications themselves or with private insurance. However, given the high costs involved, even those with private insurance may find they cannot

⁶ The Canada Health Act, which provinces must comply with so as to receive subsidies from the federal government for their health systems, require all provinces to pay the full costs of all medications used to treat patients in hospitals. However, they are not required to pay the costs of prescription drugs used at home. Most Canadian families have some form of private insurance to help meet these costs and other costs not covered by Canada's system of provincial universal single payer health insurance plans (Marchildon et al. 2020, 74).

gain access to the needed medications.⁷ For those Ontarians who face high drug costs, there is a second plan called the Trillium Drug Benefit which helps covers the cost of medications for those whose drug costs exceed 4% of their annual income (Auditor General of Ontario 2017a and 2017b). In 2021 the Government of Ontario increased the copayments and deductibles associated with the Ontario Drug Benefit and the Trillium Drug Plan to require some patients to shoulder a greater share of the costs of their medications (Ontario 2023c). Some researchers suggest that this increasing cost will exacerbate financial hardship facing many cancer patients and that some may fail to receive timely care as a result (McPhail and Snow 2022; Abdel-Rahman and North 2021; Auditor General of Ontario 2017a and 2017b). That the Executive Officer lacks a say in this issue speaks clearly to the limited autonomy of their office.

5. Applying the Literature on HTA and patient representatives and Bureaucratic Autonomy, Something of a Conclusion.

This paper began with a surprising research result. The blame avoidance literature suggests that when decisions are delegated to public servants to create a blame avoidance screen for politicians, tough decisions become easier to make. However, when Cohn (2023) looked at the adoption of oncology medications into the formularies of the provincial drug benefit plans of two provinces, Ontario where a senior public servant makes the final decision, and Alberta where this power rests with the minister of health, there was no statistically significant

⁷ Kratzner et al. (2013, 39) found that the most common cost-sharing mechanism in the private health insurance plans they surveyed was a percentage co-payment per prescription (found in 61% of private drug plans in Canada). Given the cost of oncology medications, this could easily amount to a copayment equal to thousands of dollars for each prescription per month.

difference in the number of times they refused to adopt medications that had received negative evaluations from the PCODR. To explain this result, the present paper has suggested it is necessary to look more closely at the process that takes place in the lead up to decision-making in each province, especially Ontario, and at the situation of the senior public servant making formulary decisions in Ontario (the Executive Officer of the Ontario Public Drug Programs) within the provincial bureaucracy. It was noted that there was a significant difference in the process leading to final decisions between the provinces. After receiving recommendations from the PCODR and an application to include a proposed use for a medication in the provincial formulary, each province then subjects the application to its own internal evaluation process. The committee undertaking this task in Ontario (The Ontario Steering Committee for Cancer Drug Programs) has patient representatives on it, while the committee in Alberta (the Alberta Expert Committee on Drug Evaluation and Therapeutics) does not. The literature on the role of patients in HTA suggests that including patient representatives might well expose the Executive Officer in Ontario to the same pressures that the Minister sought to avoid by delegating decision-making to a public servant, thereby mitigating some of the ability to make tough decisions, that the delegation of authority to a public servant was supposed to provide. When looking at the situation of the Executive Officer within Ontario's public sector bureaucracy, Verhoest et al.'s (2004) typology of autonomy was used to better explore the nature of the freedom of action available to Executive Officer. It was found that this public servant enjoyed low levels of managerial autonomy and some elements of both their low level and high level category when it came to policy autonomy. However, in other ways, the Executive Officer is still an ordinary public

servant working in a core government agency, meaning there were a number of ways for the minister to constrain and indirectly steer the Executive Officer's actions. Whether intentionally or not, this power may have structured the Executive Officer's work to make them into a supervisory official, when it comes to decisions on the provincial drug programs formularies, rather than an active participant in most decisions. This is because serving as Executive Officer for the Ontario Public Drug Programs is only one of many duties assigned to the senior public servant filling the role. As a result, the fact that Ontario's internal evaluation process for cancer drugs includes patient representatives would take on even greater weight, as the Executive Officer is likely to be very dependent on the recommendations they receive through the province's internal evaluation process.

It should be noted that the research presented in this paper primarily involves applying the literature on role of patients in HTA and a typology of bureaucratic autonomy (Verhoest et al. 2004) to the features of the internal evaluation process in Ontario and Alberta that occurs before decisions are reached by these governments on whether or not to reimburse for proposed uses of oncology medications, and then speculating on what impact might result. These speculations suggest a possible solution for the problem that the paper began with. However, whether or not they actually explain the problem will require further evidence in the form of interviews with participants so as to confirm that these speculations are accurate or to reject them.

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