Operational Review of the *Prescription Monitoring Act*

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New Nouveau Brunswick

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Province of New Brunswick
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Message from the Minister of Health

I am pleased to present a report on the operational review of the *Prescription Monitoring Act*.

The *Prescription Monitoring Act* was reviewed to ensure that it remains current and effective and that it is administered in a way that continues to serve its original purpose. The Act received Royal Assent on December 18, 2009 and was proclaimed on August 1, 2014.

The *Prescription Monitoring Act* enables the Prescription Monitoring Program (PMP) to support the safe use of monitored drugs in New Brunswick, prevent and reduce associated harms, and identify individuals at risk for addiction. Monitored drugs include opioids such as Dilaudid, benzodiazepines such as Ativan, and stimulants such as Ritalin.

The importance of the PMP has increased over the last few years with the challenges associated with the misuse of medications for pain management. The PMP allows New Brunswick prescribers and pharmacists to view a patient's monitored drug prescriptions and promotes the appropriate use of monitored drugs with the potential for abuse, misuse and diversion for nonmedical purposes.

The PMP relies on real-time prescription information submitted by community pharmacies to the Drug Information System (DIS), housed within the provincial Electronic Health Record (EHR). The PMP shows authorized healthcare professionals a patient's most up-to-date prescription information to help them make safe, informed decisions about patient care.

Over the past year, the Department of Health has engaged with multiple health sector stakeholder groups and professionals. The following report is largely inspired from the feedback received. The report presents the most common themes heard during these consultations. We believe that the challenges identified can largely be addressed through policies, procedures as well as changes to legislation. An action plan to address the identified challenges and opportunities has been developed and is included in this document.

As Minister responsible for the *Prescription Monitoring Act*, I want to thank all the participants for their thoughtful submissions. The actions resulting from the feedback received will greatly benefit our healthcare system.

Hon. Hugh J. Flemming, Q.C.
Minister

Summary of the Review Process

The operational review of the *Prescription Monitoring Act* began in early 2019 with a comprehensive examination of the issues that the Department of Health identified since the Act came into force in 2014. Generally, these items were matters that required clarification to make the administration of the Act more efficient or effective.

This information was then used in the development of a discussion paper that was released in April 2019 for public and stakeholder feedback and comment. The document highlighted several discussion topics and questions that have arisen over the years with respect to PMP users, data quality, and governance.

Stakeholders and members of the public who wished to provide feedback on any matter pertaining to the Act were asked to provide their input by May 24, 2019. Through this process, the Department received 10 briefs from various stakeholder groups and 12 individual responses.

All the feedback received was compiled for use in the development of this final report.

Stakeholder Input: What we heard

Prescription Monitoring Program users

Currently, section 6 of the *Prescription Monitoring Act* allows prescribers of monitored drugs (physicians, dentists and nurse practitioners) as well as dispensers of monitored drugs (pharmacists) to register with the PMP and thus access PMP information. It was suggested that access to the PMP by other healthcare providers or delegates could support workflows, aid decision-making and make the PMP more effective.

All stakeholders agreed that nurses and pharmacy technicians should be authorized to access the PMP, if they have delegated status. However, opinion was mixed with respect to granting access to PMP to other delegates such as office medical assistants and students in the health professions. Stakeholders raised several concerns, including privacy issues, the appropriate level of access, and the fact that some delegated professions did not have a regulatory body.

Further, some stakeholders suggested that other health professions should be granted access to the PMP, namely midwives, optometrists, podiatrists, and dental hygienists.

Requiring all prescribers and dispensers to register with the PMP

Currently, registration of prescribers or dispensers with the PMP under the *Prescription Monitoring Act* is done on a voluntary basis. There are no obligations for prescribers or pharmacists to participate in the PMP.

All stakeholders support mandatory PMP registration. Most stakeholders support a short transition period to mandatory registration (six to twelve months) to allow prescribers and dispensers enough time to meet this new requirement should the *Prescription Monitoring Act* be amended.

Adding the Nurses Association of New Brunswick and the Midwifery Council of New Brunswick as licensing authorities under the *Prescription Monitoring Act*

Currently, the *Prescription Monitoring Act* requires that licensing authorities listed in the legislation have duties regarding PMP, namely to notify the PMP if one of their member's privileges to prescribe or dispense is revoked, suspended or otherwise altered. The list of licensing authorities that are subject to the Act is currently limited to the bodies that regulate physicians, dentists and pharmacists. The Act provides regulation-making authority to add additional bodies to the list of licensing authorities defined in the legislation.

All stakeholders support the suggestion of adding additional bodies as licensing authorities under the Act. Licensing bodies for recognized prescribers, such as nurse practitioners and midwives, should have the same duties and responsibilities under the Act as those for existing prescribers. Some commented that this should be in effect immediately.

Adding the Nurses Association of New Brunswick as a licensing authority would align New Brunswick with other jurisdictions such as Newfoundland and Labrador, Nova Scotia, British Columbia, Alberta, Saskatchewan and Manitoba. British Columbia is the only Canadian jurisdiction which names the midwifery council as a licensing authority.

Requiring pharmacies to submit information about compounded drugs that contain active ingredients from the monitored drug list

Compounding is a practice in which a licensed pharmacist combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Currently, pharmacies are not required to submit information regarding compounded drugs that include a monitored drug.

Opinions from stakeholders were mixed with respect to compounded drugs. While various stakeholders support the idea of requiring the submission of compounded drugs, several concerns were raised. Without a drug information number, the documentation of compounded products is complicated. Potential software issues might make it difficult to properly and uniformly enter compounds that contain monitored drugs so that they are properly identified for reporting. It was also noted that compounded drugs for topical use are less likely to have a risk for diversion. Some compounded drugs might include a very weak concentration of a controlled drug, which would not result in the same concern with misuse of the drug or addiction. Finally, these constraints with respect to compounded drugs would likely lead to additional work for pharmacists.

British Columbia, Alberta and Manitoba require that information about compounded drugs be submitted to their drug monitoring programs.

Including non-traditional dispensing locations in the definition of "pharmacy" in the Act

Currently, the *Prescription Monitoring Act* defines "pharmacies" who must participate in the PMP as pharmacies that have been issued a valid certificate of accreditation under the Pharmacy Act. However, there are some dispensing locations that do not have such certificates that dispense drugs, including monitored drugs, to patients.

Most stakeholders would support an amendment that would require all dispensed monitored drugs be reported to the PMP, regardless of location. Acceptable exceptions might include circumstances where this requirement creates a barrier to urgent access to such drugs in a timely fashion. Of note, some raised the concern of additional regulatory burden causing dispensing physicians to cease operations, which may have the unintended consequence of removing a necessary service from a rural community.

Several jurisdictions, namely Ontario, Newfoundland and Labrador, Prince Edward Island and Alberta refer to "dispensers" in their legislation, which means a "person authorized under a health profession act to dispense drugs". In these jurisdictions, the program does not only apply to pharmacies or pharmacists.

Establishing a Prescription Monitoring Program Advisory Committee

Section 9 of the *Prescription Monitoring Act* mandates that an advisory committee known as the Prescription Monitoring Program Advisory Committee be established to make recommendations and advise the Minister of Health on matters related to the Act and the PMP.

The Department of Health established a PMP Working Group to inform the initial focus for PMP and get certain elements of the Program firmly established. The Department now intends to proceed with the establishment of the Prescription Monitoring Program Advisory Committee.

The stakeholders identified some gaps in the membership of the Committee. Some argued that more licensing authorities should be represented, while others maintained that the composition is quite large and recommended that there be more representation from those who are using the system regularly, specifically physicians and pharmacists. It was also suggested that the sections in the Act dealing with membership are vague and need clarity.

Other suggestions for consideration

Stakeholders made several other suggestions to be explored by the Department of Health. It was noted that regulatory bodies should be aware of the prescribing activity of their members. Some were interested in the linkage of the PMP to other electronic systems and the possibility of integrating the EHR with pharmacy prescription-filling programs. Stakeholders commented that the use of the PMP is not quick or intuitive and many find the use of the EHR challenging. It was also suggested that there be a requirement for prescribers and dispensers to check PMP for patients they do not know. Other comments raised included the perceived inconsistencies between the English and French language versions of the Act and some terminology questions, which could be resolved with a thorough editorial review of the legislation.

Moving Forward: An Action Plan

The environment in which front-line health care providers deliver care to New Brunswickers has changed significantly since the legislation was first developed. Additionally, addressing the challenges associated with the misuse of opioids requires a concerted and multi-pronged approach, involving up-to-date and robust legislation, improved monitoring and analysis, and an enhanced adaptability to reflect a rapidly changing environment. These challenges underscore the need to both update the legislation to more accurately reflect current practice, and to close gaps that have been identified.

There is also a compelling case for the need to not only provide access to information at the point of care, but also to prevent harm with monitoring and surveillance activities. To provide the needed information in a consistent and timely capacity, a stronger PMP is needed as it must not only electronically store monitored drug dispensing information, but also monitor and analyze it. Moving forward, our Action Plan will result in the modernization of the PMP to adapt and respond to its dynamic environment.

Our vision for the PMP is to evolve the way health professionals access and use drug information. By seamlessly connecting clinical decision makers to real-time, clear information, we will create communities of healthcare providers that share health information and collectively advance patient care to prevent the harms of problematic drug use. For the PMP to support the safe use of monitored prescriptions drugs in New Brunswick, prevent and reduce associated harms, and identify high-risk individuals, we envision the PMP to have four essential characteristics:

- Adaptive to its environment
- Effective in conveying drug information
- Robust to provide high-quality data
- Intelligent to support clinical decisions, without increasing workload burden

Importantly, this also involves a balanced approach that does not cause more harm than good. The approach must be mindful of unintended consequences of exacting too much force and creating a landscape where pain management is diminished by overly restrictive activities.

We plan to achieve this vision by engaging in an Action Plan that focuses on four key objectives, which are to:

1. Strengthen governance of monitored drug prescribing and dispensing practices
2. Expand access to the PMP to support its use through all levels of care
3. Improve reporting and data quality
4. Enhance the functionality of the PMP

This Action Plan was developed with consideration of the many views expressed earlier in this report. Its implementation will require continuing partnerships and collaboration among key players in our health care system including communities, health care providers, citizens, and government.

Strengthen governance of monitored drug prescribing and dispensing practices

Since the PMP's implementation, a lack of governance has diminished its effectiveness. New Brunswick should align with the best practices followed in other provinces and address the variable and low registration of PMP users by various health professional groups. Evidence suggests that mandating registration and query of the PMP prior to prescribing or dispensing increases use through forced compliance and results in reduced prescriptions of monitored drugs.

It is important to not only use policy to shape or influence clinical practice but to also ensure the competency of practitioners and provide them with the tools necessary to optimize patient care. Regulatory bodies play a key role in this and in reporting or investigating individuals who may be intentionally or unintentionally harming patients or placing them at risk with their prescribing or dispensing practices.

Such initiatives require the continued collaboration of important partners such as regulatory bodies, health professional associations and clinician champions, and are expected to address gaps in the oversight of the PMP and allow it to be adaptive to its environment.

To accomplish these goals, the Department of Health will undertake the following actions:

Legislative and regulatory framework:

1. We propose to amend the *Prescription Monitoring Act* and the *General Regulation-Prescription Monitoring Act* to:
   - Mandate participation in and use of the PMP;
   - Add the Nurses Association of New Brunswick and the Midwifery Council of New Brunswick as licensing authorities.

Other actions:

2. We will establish the Prescription Monitoring Program Advisory Committee as provided for in the Act and regulation and review the committee composition within a year of its inception.
3. We will initiate discussions on the education and training of prescribers of monitored drugs with stakeholders such as regulatory bodies, regional health authorities, and health professional associations.
4. We will support new and continuing education of prescribers and dispensers on monitored drug practices.

Expand access to the PMP to support its use through all levels of care

The expansion of access to PMP to others involved in a patient's circle of care is generally supported but requires further study of the criteria for permitting access to different types of users and evaluating the management or auditing of PMP access.

Critically, the potential impact on patient care is that health professionals are not limited by a lack of access to relevant patient information, and health care providers – regardless of profession – have access to the same important information. Concerns of inappropriate use of PMP may be addressed by enhancing the capacity to audit the use of PMP information.

Moreover, expanding access to the future health professionals such as students, residents, and interns, will increase adoption of health technology and establish using such technologies effectively and consistently early in their careers.

A challenge that we will need to address is access management. The PMP can only be effective in providing information if it is being used; providing access to early career professionals will help advance future prescribing and dispensing practices in New Brunswick.

To accomplish these goals, the Department of Health will undertake the following actions:

Legislative and regulatory framework

5. We propose to amend the *Prescription Monitoring Act* and the *General Regulation-Prescription Monitoring Act* to:
   - Expand access to PMP to others involved in a patient's circle of care, e.g. delegates, students, and other health care professions.

Other actions:

6. We will review the criteria for permitting access to the PMP to ensure appropriate access to different types of users.
7. We will evaluate the management of auditing PMP access and enhance the capacity to perform audits to ensure appropriate use and access.

Improve data quality and reporting

Decisions made by clinicians and by government require robust data quality to ensure informed decision making. Data quality is the foundational requirement for a strong PMP, and the current PMP data quality is inadequate. The challenges with PMP data quality have limited the extent of reporting by the PMP. It does not provide any reporting publicly and only recently has provided ad hoc reporting to regulatory bodies.

In addition to the action to enhance governance through collaboration with key stakeholders, accountability also requires the collection, analysis, and evaluation of data that the PMP is indeed a beneficial tool to reduce patient harms and risks.

One of the most significant challenges the PMP faces in moving forward with this Action Plan is the limited capacity to maintain the program. The PMP lacks dedicated staffing that PMPs in other jurisdictions rely on for continued monitoring and surveillance of monitored drugs.

We plan to release publicly available data so that New Brunswickers can be informed and aware of the state of the opioid crisis within the province and have crucial conversations with their health care providers on drug therapy used to address pain.

Additionally, the government plans to use the data to detect trends and take a more proactive approach in combatting the opioid crisis. The reporting and surveillance activities being pursued not only include provincial reports, but also prescriber feedback reports to help individual prescribers reflect on their own practices. By doing so, the province would align to

leading practices followed by other provinces. Furthermore, by sharing information, we hope to reduce the stigma associated with the use of monitored drugs. This would allow for the recognition, acceptance, and action to be taken to address these issues.

As highlighted and supported by what we heard, the data quality of compounded monitored drugs is variable and incomplete. There are gaps in the data submitted into the provincial drug database, in terms of the sources and the content of drug information. The inclusion of dispensed monitored drugs from non-traditional dispensing locations (e.g. dispensing physicians) would give a more accurate patient record for clinical decision-making.

Enhancing the data quality and sharing data would help to anticipate unintended consequences of combatting the challenges associated with the excessive use of opioids. In particular, and as seen by other jurisdictions, this includes the rapid tapering of opioid prescriptions, refusal to care for patients with opioid-related issues, further stigmatization of patients, and the shift towards illicit sources of pain medications.

To accomplish these goals, the Department of Health will undertake the following actions:

Legislative and regulatory framework:

8. We propose to amend the *Prescription Monitoring Act* and the *General Regulation-Prescription Monitoring Act* to:
   - Require pharmacies to include the drug identification number of a monitored drug when submitting compounded drugs that contain active ingredients from the monitored drug list.
   - Include non-traditional dispensing locations in the definition of "pharmacy".
   - Require the dispenser to submit the prescriber identification number when dispensing prescriptions of monitored drugs and prohibit the use of default prescriber codes when dispensing monitored drug prescriptions.

Other actions:

9. We will develop and provide standard reporting on prescribing practices at aggregate and individual prescriber levels.
10. We will analyze PMP data to detect trends and use the information proactively to combat the challenges associated with the misuse of opioids.
11. We will create public provincial reports on monitored drug use.
12. We will provide prescriber feedback reports directly to individual prescribers to help them reflect on their practice.

Enhance the functionality of the PMP

In addition to monitoring and surveillance, we also aim to improve the PMP as a point-of-care tool. The PMP requires updates to its functionality to allow for streamlined applications within health care settings. The expectation that health care providers query the PMP must be followed with technology that is sufficiently intelligent to effectively support clinical decision making without increasing workload burden. In short, it must fit into today's health system.

To achieve this action, the Department of Health plans to continue engaging with key stakeholders to provide insights into improving functionality.

The Department of Health will undertake the following actions:

Legislative and regulatory framework:

13. We will review and make proposals to update the legislation to reflect changes in the PMP point-of-care tool functionality.

Other actions:

14. We will continue consultations with key stakeholders during the development of new functionality of the PMP point-of-care tool to improve its user friendliness and effectiveness.
15. We will evaluate the connectivity and integration of the PMP point-of-care tool with other health technologies.
16. We will evaluate the risk of unintended consequences in the PMP and redesign the point-of-care tool to minimize them.

Conclusion

This Action Plan outlines the path forward in transforming the PMP into an effective, adaptive, robust, and resourceful tool. It is the hope that the changes we propose will lead to better care and less harm to New Brunswickers. We look forward to the continued engagement and support of all stakeholders in implementing the Action Plan.