NEWS RELEASE

NEWFOUNDLAND AND LABRADOR
MEDICAL ASSOCIATION

Doctors fear Prescription Monitoring legislation may have unintended consequences for patients

For immediate release – November 15, 2017

St. John's, NL – The Newfoundland and Labrador Medical Association (NLMA) supports the creation of the *Prescription Monitoring Act*; however, the NLMA is concerned about the inadequate consultation and many unanswered questions surrounding the new legislation. Some provisions outlined in the legislation could have the unintended effect of driving physicians away from the prescribing of opioids and related medication. This could have serious consequences for patients who legitimately need these medications.

"The NLMA applauds the goal of reducing inappropriate prescribing of opioids and other monitored drugs," said NLMA President Dr. Lynn Dwyer. "Our concern is that the Medical Association was given less than 24 hours to review the draft legislation before the *Act* was released. The House of Assembly can still improve the legislation by making amendments and we encourage them to do so."

The proposed *Act* needs more focus on delivering data to physicians about their prescribing patterns in comparison to their peers, as well as continuing medical education, which all physicians would welcome and could result in positive changes in prescribing behavior. At present, the legislation is mainly focused on inspection and enforcement rather than education and behavior change.

The NLMA is also concerned about the power of an inspector to enter a physician's office and copy sensitive personal health information without reasonable grounds. The government has not justified the need for this power, given that all the requirements that the *Act* places on physicians can be verified without entry to a physician's office. The NLMA would not have a concern if this new power had a good rationale, but the government has not provided one. At the very least, the *Act* needs to be adjusted to incorporate the need for reasonable grounds.

The NLMA is also concerned there is no plan for implementing the HEALTHeNL Viewer across all physician offices and places of work and the associated changes in work flow. An important part of the new legislation requires physicians to check the medication profile of the patient on HEALTHeNL Viewer before prescribing a monitored drug. Currently, most doctors do not yet have the network available in their offices.

Issues identified by the NLMA were submitted to the Department of Health and Community Services last night and are included as an attachment to this release.

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Newfoundland and Labrador Medical Association – Assessment of the Bill to Enact the Prescription Monitoring Act

November 14, 2017

The NLMA supports the establishment of a prescription monitoring program. The Department provided a conceptual briefing on the legislation on October 5, 2017, and provided a copy of the Bill for review on November 14, 2017. The Bill will be tabled in the House of Assembly on November 15, along with a media briefing and a press conference.

The NLMA is disappointed in the lack of opportunity to review the Bill in detail and discuss potential changes with the Department before it being tabled in the House. The following points are provided for Departmental consideration and further dialogue. We acknowledge that some of the opinions expressed below may change after dialogue and more complete understanding of the Department's goals. Similarly, additional concerns or recommendations may arise as we consult further with members and have additional feedback from the Department.

1. Object of the Program

The object of the program is to "educate, support and assist" a) individuals in the safe and appropriate use of monitored drugs (by identifying and reducing instances of abuse and misuse of monitored drugs), and b) prescribers and dispensers in appropriately prescribing and dispensing monitored drugs.

Comment: the emphasis in this section is enabling and supportive, rather than an emphasis on control and compliance. Yet the Bill focuses substantially on the role of an inspector and the intrusive power to enter premises for the collection of information. A clearer statement of the object would be helpful, such as the one in the Ontario Act, which states:

> *The purpose of this Act is to seek to improve the health and safety of Ontarian by permitting the monitoring, analyzing and reporting of information, including personal information, related to the prescribing and dispensing of monitored drugs, in order to,*
>
> *(a) contribute to and promote appropriate prescribing and dispensing practices for monitored drugs in order to support access to monitored drugs for medically appropriate treatment, including treatment for pain and addiction;*
>
> *(b) identify and reduce the abuse, misuse and diversion of monitored drugs; and*
>
> *(c) reduce the risk of addiction and death resulting from the abuse or misuse of monitored drugs.*

The NLMA agrees with the phrase: "educate, support and assist", and we hope it can be retained in an amended clause.

2. Educational Purpose

While an object of the Act is to support education, the only follow-up reference in the Bill is section 4(f) as follows:

- *The Minister shall…educate prescribers and dispensers regarding appropriate prescribing and dispensing of monitored drugs….*

Comment: The NLMA wishes to see the data in the pharmacy network used for professional development purposes and peer comparison. Tools and products can be created out of the data to help self-assess one's prescribing behaviour. When combined with appropriate education materials or CME opportunities, behaviour change will be encouraged. This approach underlies the Choosing Wisely program and should be promoted in this legislation. To reinforce the use of data and educational tools, and to give substance to the "object" of the Act related to education, the Bill could be improved by including the following, or similar words, in section 4:

- The Minister shall…cause the development of a prescriber portal that allows prescribers to perform peer comparisons and to access education and professional development materials or services.

Also, with respect to the current 4(f), we wonder if this should be modified to focus on providing access to educational tools, information, and other services related to appropriate prescribing and dispensing. As currently written, a reader could make an inference that the Department is taking on a primary role, similar to the College, the Faculty, and other professional bodies that currently take a leading role in education related to prescribing.

3. Prescription Information Requirements

Section 7 states that prescribers "shall record the information prescribed in the regulations on the prescription. By way of comparison, the Ontario and PEI Acts specifically include the following requirements:

> The registration number on the certificate of registration issued to the prescriber by the College, 2. The name of the person for whom the monitored drug is prescribed. 3. The name, strength (where applicable) and quantity of the monitored drug. 4. The directions for use of the monitored drug. 5. The name and address of the prescriber. 6. The date on which the monitored drug is prescribed. 7. Any other information, including personal information, required by the regulations.

The benefit of being specific in the Act is that it is transparent and gives greater certainty to physicians about the kinds of information to be captured. The ability to ask for additional information by way of regulation remains.

4. Consulting the EHR (HealtheNL)

The Bill requires prescribers to review the medication profile on the EHR and "record in the manner prescribed in the regulations that the patient medication profile" was reviewed before the prescription was issued. This means that every doctor who prescribes controlled substances (initially opioids) must include a review of the EHR in their routine before providing the prescription to the patient. Previously we were told by the Department that this requirement would be deferred until mid-2019. We were informed today that it will come into effect in mid-2018.

Comment: 1) We have previously asked for a work flow assessment of this requirement to ensure we understand the amount of time per patient that may be required, any impact on patient wait times, and any specific workplaces where special arrangements may be needed (e.g., post-operative clinics, hospital bedside, ERs, locums). The Department has not responded to this request, and now the requirement will be legislated before the analysis is complete. We are seeking a commitment to undertake this analysis right away so that it can inform planning. 2) An implementation plan is needed to estimate the number of physicians not currently using the EHR, the capacity of NLCHI to train and activate more users, and the costs associated with same. The NLMA asks to be involved in the development of this plan.

It is critical that this implementation process does not have the unintended consequence of some physicians exiting the prescribing of monitored drugs. Patient access to these drugs is an essential medical service and we should avoid creating shortages of physicians willing to prescribe because of a perception of new barriers or risks. Doctors have informed us, for example, that the EHR can sometimes "go down" during the day, or doctors will be dropped temporarily without explanation, and will take an hour or more to resume. What will doctors do with patients who require prescriptions during that time? Will patients who need renewals go home without the necessary prescription? These are technical problems, but they are examples of the careful planning and quality assurance that will be needed in advance of the start date to ensure patient access to appropriate medications. We ask the Department to consider these points in relation to the proclamation date for this section of the Act.

5. College Provides Notice to Minister

Section 9 requires the College to notify the Minister when it restricts the licence of a doctor related to prescribing of a monitored drug, suspends the licence of a doctor, or revokes the licence of a doctor.

Question: What are the requirements of the College regarding such notices under current legislation?

6. Informing Law Enforcement Authorities and Colleges

Section 10 allows the Minister, if he or she "believes on reasonable grounds" that an offence under this Act, the Criminal Code, or the Controlled Drugs and Substances Act, has been committed, to disclose this information to the authorities. Similarly, if the Minister believes that the physician is acting "in a manner inconsistent with the objects of the program", such information may be disclosed to the College. Finally, if there is reason to believe an individual is abusing or misusing drugs, this information may be passed on to the doctor or pharmacist.

Comment: The Ontario Act, which is the model for the inspection power below, does not contain a reference to disclosing information to law enforcement authorities or to Colleges. More information is required on why this is the case. Why does this jurisdiction (also, PEI and New Brunswick) not permit disclosure of information to law enforcement authorities?

The Nova Scotia Act does contain the power to disclose information to law enforcement authorities, but it does not contain the inspection power of entry to premises (see below).

Therefore, the NL Act will have the largest collection of disclosure and inspection powers in the country. This status is not inappropriate if the requirement for such a powerful statute are justifiable in the circumstances, but this is not clear. See below.

The phrase, "in a manner inconsistent with the objects of the program" is too broad. Doctors will never be able to discern the many ways they can be inconsistent with the objects of the Act. It is preferable to focus on non-compliance, where the rules will be clear and well-defined. The Bill should be amended to say "in a manner not in compliance with this Act" or similar wording.

7. The Inspection Power

The Inspector may "at all reasonable times, <u>for a purpose related to the administration or enforcement of this Act or the regulations</u>, inspect or examine the premises, processes, books and the records of a person that the inspector may consider relevant for the purpose of determining compliance with this Act or the regulations…." Furthermore, the inspector, "without a warrant" may enter any premises (e.g., a practice location) to make copies of documents, etc., and may require the owner/staff to provide reasonable assistance, etc., but may not enter a private dwelling.

Comment: It is unclear what aspect of a physician's duties under the Act requires entry to a physician's office to determine compliance. There are only two compliance requirements of physicians: 1) to provide correct information on prescriptions (which will be filed and stored in pharmacist premises); and 2) to review the EHR (for which there is an electronic fingerprint at NLCHI). In both cases, compliance can be fully determined with records and data outside a physician's office. In our dialogue to date, the Department has not provided an example of why an inspector would need to enter a physician's premises to determine compliance. The analogous province is Ontario (as no other province except new legislation in PEI has such a provision) and we understand the Ontario Government has not been consulted to determine the relevance of this provision for doctors. Given the lack of justifiable need for this provision, at least based on present information, it would be advisable to remove this section (as it pertains to doctors, as we only represent the views of doctors). Our advice in this regard is premised on the notion that creating an intrusive legislative authority must be based on a clear understanding of the necessary circumstances under which the power is to be used, and that the power is the least intrusive necessary to fully accomplish the purpose of the Act. In this regard we note that personal health information exists in all the relevant records, and should only be subject to copying by someone outside the circle of care when there is a justifiable requirement.

If the government is unwilling to change this section, then it should be amended to require the inspector to have reasonable grounds for believing that non-compliance is occurring. Such grounds are the same

as those required of the Minister under section 10 and they are consistent with the requirement for "reasonable purposes" under section 22 of the Medical Care and Hospital Insurance Act.

The inspection power also gives rise to questions about what medical advice the inspector will receive prior to exercising this power, and what training inspectors must have to: a) discern what records are appropriate to copy, b) avoid infringement of other legislation such as the PHIA, and c) to implement proper procedures and communications when executing the function. We wish to return to these matters during the drafting of the regulations.

8. Advisory Committees

The Minister may create one or more committees to advise on "matters relating to the administration and enforcement of this Act that are referred to them by the minister." Composition and terms of reference of committees will be established in regulations. Each committee shall have at least one prescriber and one dispenser.

Comment: Given the preponderance of physicians in the prescribing of monitored drugs, the Act should require that all committees have at least two physicians (probably a family physician and a specialist) with relevant training and experience, and who are independent of the government, RHAs and the College. We acknowledge and welcome the fact that other prescribers may be present on such committees as well.

It is particularly important that the committee which provides advice on the interpretation of pharmacy network data, and the appropriate timing to escalate compliance inspections, contains two physicians.

Section 14.1 limits the advice and recommendations of committees to matters referred to them by the minister. This limitation is inappropriate. The committees should be able to advise on any matter related to the administration and enforcement of the Act, including future amendments that may enable the legislation and regulations to better achieve its purposes.

9. Ministerial Regulations

There are 15 areas in which the Minister can make regulations without reference to the Cabinet. This extensive set of regulatory powers is also quite broad in scope. For example, the Minister may make new rules "respecting the additional requirements that are required to be met before a prescriber may prescribe or a dispenser may dispense a monitored drug" and "generally, to give effect to the purpose of the Act".

Comment: Ministerial regulations should be narrowly focused, such as the setting of fees, the specification of boundaries, or prescribing time periods for the filing of documents. Instead, this list is too broad and should be reconstituted. In particular, the requirements for prescribing are set by the College of Physicians and Surgeons and an unlimited power in this regard should not be within the power of the Minister. It is difficult to understand how such a regulation fits within the ambit of this Act.