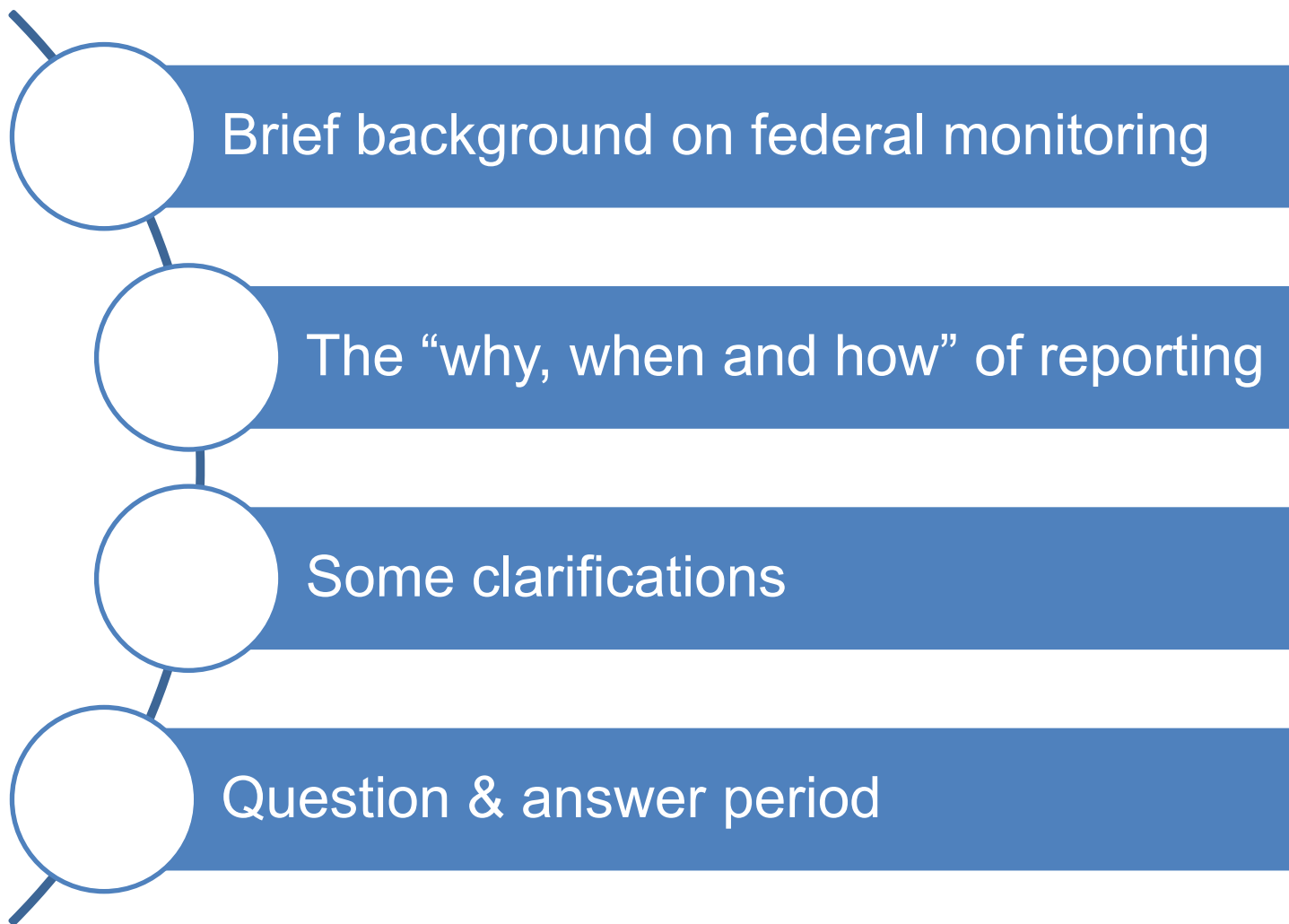


Medical Assistance in Dying (MAID) Federal Monitoring Regulations

Technical Briefing
October 17, 2018



AGENDA



BACKGROUND

June 2016: *An Act to amend the Criminal Code (medical assistance in dying)*

- Physicians and nurse practitioners may provide MAID to eligible patients. A pharmacist may dispense a substance for MAID.
- The federal Minister of Health must make regulations to monitor MAID.
- Practitioners and pharmacists must provide information for the purpose of monitoring.

August 2018: *Regulations for the Monitoring of Medical Assistance in Dying*

- Identify who must report, what information is required, timelines for reporting, and to whom information must be provided.
- Require the federal Minister of Health to publish a monitoring report at least once a year and stipulate the minimum type of information to be included.
- Provide information on other uses of the information.

Regulations will come into force on November 1, 2018

WHY MONITOR?

- A robust, pan-Canadian monitoring system was identified as an essential part of a MAID regime by:
 - Supreme Court of Canada in *Carter vs Canada (Attorney General)*
 - Parliament's Special Joint Committee on Physician-Assisted Dying
 - Provincial/Territorial Expert Advisory Group on Physician-Assisted Dying
 - Many stakeholders who testified before Parliamentary committees

- Federal monitoring will support:
 - Public accountability and transparency
 - Reporting on the application of the eligibility criteria and safeguards
 - Identification of trends in requests for, and the provision of, MAID
 - Insight into whether the legislation is meeting its objectives
 - Access to data by researchers for independent analysis and research

USES OF THE INFORMATION

Federal Monitoring Reports

The federal Minister of Health will publish a monitoring report at least once a year that provides a national picture of MAID in Canada.

Provincial / Territorial Monitoring

Information may be provided to provincial or territorial governments for their own monitoring purposes.

Research

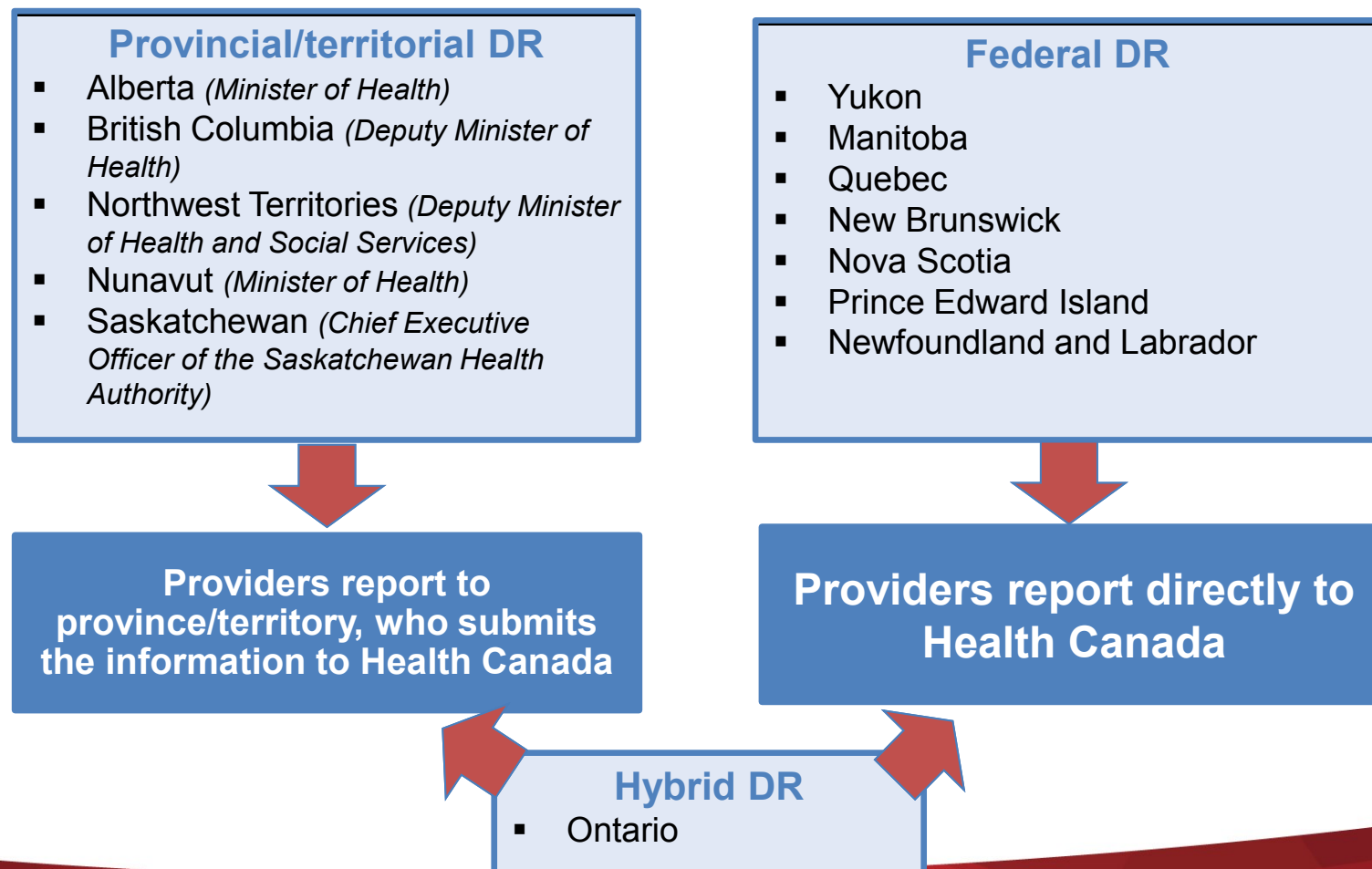
Information (excluding names) may be disclosed to independent researchers to enable research and statistical analysis, subject to conditions.

Protection of the information:

The federal government is subject to the *Privacy Act* with respect to the collection, retention, use and disposal of personal information. A Privacy Impact Assessment of federal monitoring activities is underway.

THE DESIGNATED RECIPIENT

- To minimize the reporting burden for jurisdictions with data collection systems already established, provinces and territories could choose to be a “designated recipient” (DR) of the information collected under the regulations.



WHO NEEDS TO REPORT?

- A written request was identified as the trigger to report as a means of balancing the need for information for the purposes of monitoring against the reporting burdening on providers.

Physicians and nurse practitioners:

- Receiving a written request for MAID triggers a requirement to report in most cases. Any written request asking for the provision of MAID can trigger reporting, as long as it:
 - is in writing, in any form;
 - is an explicit request for MAID; and
 - originates with a patient.

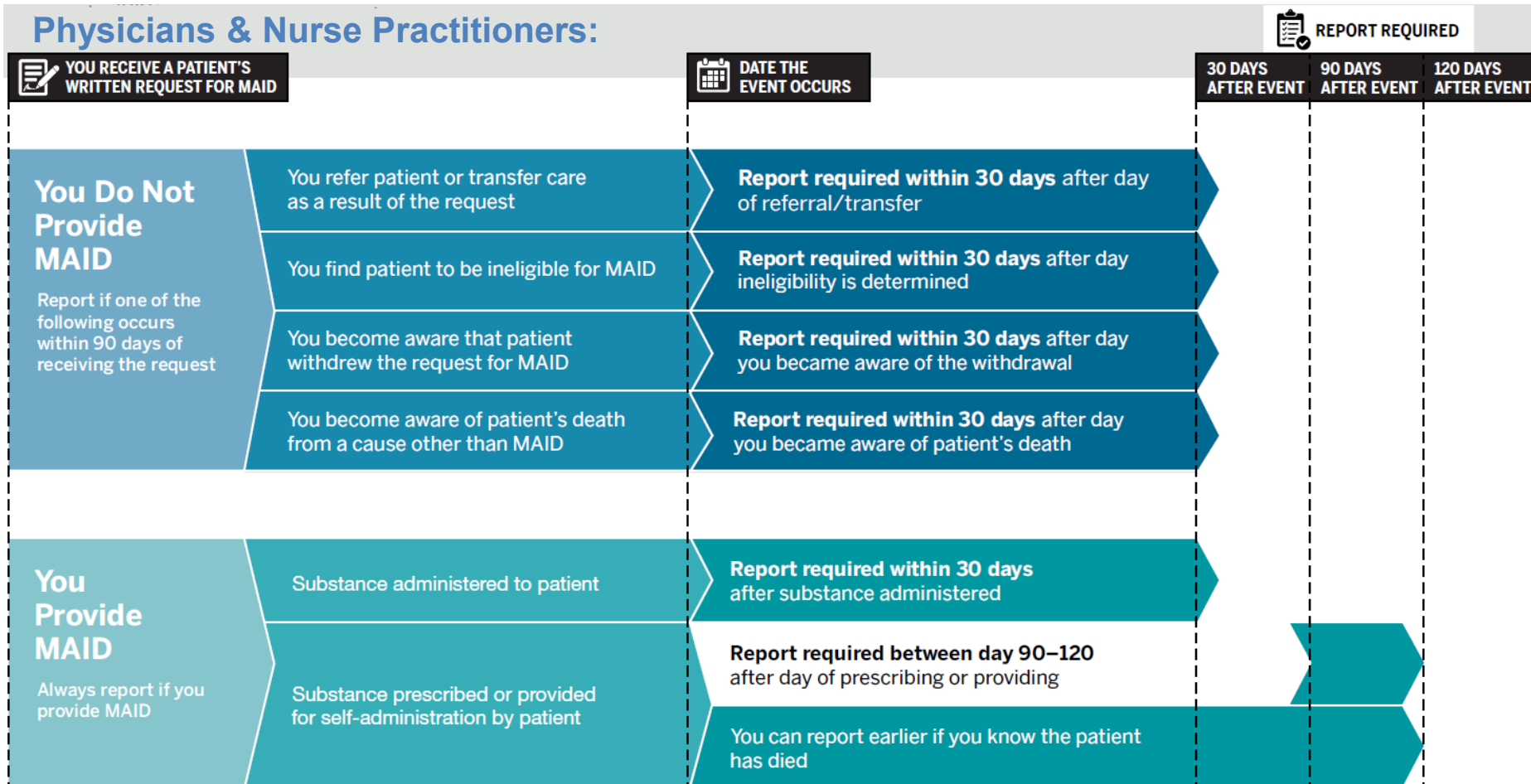
Pharmacists:

- Dispensing a substance for the purpose of MAID always triggers the requirement to report.

The written request: is a report needed?

- ✓ A practitioner receives a patient's written request through a care coordination service or a referral. **YES**
- ✓ A practitioner receives an unsigned request from a patient through email or text message. **YES**
- × A patient meets with a practitioner and asks for MAID but does not put their request in writing. **NO**
- × A patient emails a practitioner a list of questions about MAID to understand what is required to qualify. **NO**

TIMELINES FOR REPORTING TO FEDERAL DR

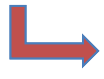


Pharmacists: Must always report within 30 days after the day on which the substance was dispensed.

Note: providers in jurisdictions with a provincial/territorial designated recipient may have shorter reporting timelines.

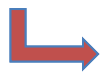
HOW TO REPORT

Practitioners and Pharmacists with a Federal Designated Recipient

 Report through the Canadian MAID Data Collection Portal

- The portal is an electronic filing system developed by Health Canada and Statistics Canada.
- No log in is required - simply follow the link posted on Health Canada's website to begin filing. All information entered is secure and the validity of filings will be verified upon receipt.
- Providers will be guided through a series of screening questions related to their involvement with a MAID request.
- The portal will present only the questions that need to be answered, based on the scenario selected during the screening.
- In the event that someone cannot access the Portal, they may contact Health Canada to request a PDF version of the reporting form to submit by fax or mail.

Practitioners and Pharmacists with a Provincial/Territorial Designated Recipient

 Follow the system established by that jurisdiction for submitting information

Tips for using the portal

- At this time, **you cannot save your work and return to complete a report later.** A checklist has been created to help providers make sure that they have all the information required before filing a report.
- Previous answers may be reviewed and changed up until the report is submitted.
- A confirmation number is provided upon submission. This will be used to help identify a filing if follow up is required.
- Providers may print the final report for their records
- Technical assistance will be available Monday to Friday from 8:00 a.m. to 7:00pm Eastern Standard Time.

EXAMPLE: REPORTING SCENARIO #1

A physician administers MAID in a hospital using drugs dispensed for that patient by a pharmacist in the hospital pharmacy.

The physician and pharmacist practice in a province where the federal Minister of Health is the designated recipient for MAID information.

	Physician/Nurse Practitioner	Pharmacist
Is reporting required?	Yes. The physician provided MAID by administering a substance	Yes. The pharmacist dispensed a substance for the purpose of providing MAID
Who to report to?	Canadian MAID Data Collection Portal	
What to report?	Information outlined in Schedules 1,3,4 & 6	Information outlined in Schedule 7
How to report?	Through the federal portal	
When to report?	Within 30 days of administering the substance	Within 30 days of dispensing the substance

EXAMPLE: REPORTING SCENARIO #2

A nurse practitioner (NP) has written the prescription and picked up the medication from a community pharmacy on the way to provide clinician-administered MAID in the patient's home. Upon the NP's arrival, the patient indicates that he has decided to withdraw his request. The NP had originally received the request six weeks earlier.

The NP and the pharmacist practice in a province where there is a provincial designated recipient for MAID information.

	Physician/Nurse Practitioner	Pharmacist
Is reporting required?	Yes. The NP became aware of the patient's withdrawal of the request within 90 days of having received it	Yes. The pharmacist dispensed a substance in connection with the provision of MAID
Who to report to?	Provincial designated recipient named in the regulations	
What to report?	Information outlined in Schedules 1,3 & 4, and 7 information about circumstances of the withdrawal	Information outlined in Schedule 7
How to report?	Using a process developed and communicated by the provincial designated recipient	
When to report?	Within 30 days of becoming aware of the withdrawal of the request	Within 30 days of dispensing the substance

EXAMPLE: REPORTING SCENARIO #3

A physician prescribes a substance for self-administration by a patient. The physician is not aware of subsequent events.

The physician practices in a territory where the federal Minister of Health is the designated recipient for MAID information. The patient did not fill the prescription.

	Physician/Nurse Practitioner	Pharmacist
Is reporting required?	Yes. The physician provided MAID by prescribing a substance for self-administration	No
Who to report to?	Canadian MAID Data Collection Portal	N/A
What to report?	Information outlined in Schedules 1,3,4 & 5	N/A
How to report?	Using an online form available through the federal portal for information collection	N/A
When to report?	Between 90 and 120 days after prescribing the substance	N/A

FOLLOW UP ON SUBMITTED REPORTS

- Practitioners and pharmacists are required under the *Criminal Code* to file the information required in the regulations within the specified timeframes.
- A practitioner or pharmacist who *knowingly* fails to comply with this requirement could face a maximum term of imprisonment of two years.
- Health Canada or a provincial/territorial designated recipient may follow up with practitioners or pharmacists if the information provided is unclear or incomplete, or to find out why a report has not been made.

Note: Oversight is different from monitoring and refers to the review of individual cases to determine whether applicable eligibility criteria and safeguards have been complied with. This remains a provincial/territorial responsibility.

To CLARIFY...

- **Delegates:** Practitioners and pharmacists are responsible under the *Criminal Code* for providing the required information directly to the designated recipient. A delegate (e.g. administrative staff; care coordination centre) may not submit a report on their behalf.
- **Referrals:** For the purposes of the federal regulations, if a practitioner's response to a written request for MAID is simply to provide the patient with contact information for another practitioner or a care coordination service, a referral has not taken place and reporting is not required.
 - The regulations seek to capture circumstances where a written request is referred to another practitioner or care coordination service, or where a patient's care is fully transferred in response to their request for MAID.
- **Start date:** Reporting in the Portal is required for written requests for MAID received on or after November 1, 2018. Pharmacists must report dispensing a substance for MAID on or after November 1, 2018.

Tools and resources

Online resources: The following resources will be available on Health Canada's webpage by November 1:

- Guidance Document – *A detailed guide to reporting requirements and timelines, as well as definitions and clarifications of selected terms*
- Reporting Timelines At a Glance – *A one-page snapshot of when to report*
- Reporting Checklists – *A comprehensive list of requirements for practitioners and pharmacists to review prior to filing a report*
- Provincial/Territorial Links – *Links to relevant information for practitioners and pharmacists reporting to a provincial/territorial DR*

Contact us: Still have questions about the regulations or reporting requirements?

Email: hc.maid.report-rapport.amm.sc@canada.ca

Phone: 1-833-219-5528

Questions?