Vulnerable Persons Standard | Norme sur la protection des personnes vulnérables

February 13th, 2018

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Ref: Regulations for Monitoring of Medical Assistance in Dying

To Whom It May Concern:

The Vulnerable Persons Standard (VPS) is a series of evidence-based safeguards designed to protect the lives of vulnerable Canadians. The VPS is a vital policy instrument for safeguarding vulnerable Canadians, especially those with disabilities, from direct and indirect forms of coercion, abuse, and inducement to suicide.

The VPS has been developed by leading Canadian physicians, health professionals, lawyers, ethicists, public policy experts, and advocates. It is rooted in the Supreme Court of Canada's conclusion that a "properly administered regulatory regime is capable of protecting the vulnerable from abuse and error."

We respectfully submit the attached input on the proposed regulations for the monitoring of medical assistance in dying on behalf of the VPS community. VPS advisors and supporting organizations welcome the opportunity to provide input and would be happy to meet or correspond with the Ministry at any time, to clarify or collaborate on our recommendations, and to provide background research in support of our approach.

The submission has been prepared collaboratively by a working group of 10 VPS Advisors, bringing together expertise from medicine, palliative care, law, ethics, public policy, research and disability studies.

Yours sincerely,

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http://www.vps-npv.ca/

Towards a More Robust Monitoring Regime for Medical Assistance in Dying

Recommended Changes to the Draft Monitoring of Medical Assistance in Dying Regulations for:

The Act to amend the Criminal Code and to make related amendments to other Acts (medical assistance in dying)

Submitted to:

The Federal Minister of Health

Prepared by:

Advisors to the Vulnerable Persons Standard

February 2018

About the Vulnerable Persons Standard

The Vulnerable Person Standard (VPS) was created in early 2016 to support the development of Canada's response to the Carter decision and to assist policymakers now working to regulate the practice of medical assistance in dying.

The Standard incorporates five evidence-based safeguards intended to protect the lives of Canadians. These safeguards aim to ensure that Canadians requesting assistance from physicians to end their life can do so without jeopardizing the lives of persons in circumstances that make them vulnerable to abuse, coercion, and inducement to suicide.

The Vulnerable Persons Standard was developed in collaboration with a large group of Advisors with expertise in law, medicine, ethics, public policy and disability studies. The Standard has been endorsed and is supported by more than 50 national and local organizations representing the voices of people with disabilities, faith communities, health professionals and socially marginalized groups. Our shared purpose is threefold:

- to promote robust safeguards to protect persons whose life circumstances or socially devalued status may render them vulnerable to being induced or coerced to request and consent to MAiD;
- to guard against the perpetuation of prejudice, stigma and harmful stereotypes in our social and cultural ethos; and
- to support lawmakers, regulators, educators and policymakers and journalists with sound analysis and reliable evidence on issues related to vulnerability and inducement in the context of MAiD.

More information about the Vulnerable Persons Standard, VPS Advisors, supporting organizations and research resources can be found online at www.vps-npv.ca.

"My review of the evidence… leads me to conclude that the risks inherent in permitting physician-assisted death can be identified and very substantially minimized through a carefully-designed system imposing stringent limits that are scrupulously monitored and enforced."

Justice Lynn Smith, Supreme Court of British Columbia
Carter v. Canada, June 15, 2012

"We agree with the trial judge that the risks associated with physician-assisted death can be limited through a carefully designed and monitored system of safeguards."

Supreme Court of Canada
Carter v. Canada, February 6, 2015

"It is essential for a properly functioning regulatory framework that there is robust and independent oversight to: monitor compliance with relevant laws, policies and standards; to inform continuing development of policies and practices; and to ensure public confidence in the integrity of the system."

Provincial-Territorial Expert Advisory Group on Physician-Assisted Dying
Final Report, November 30, 2015

"Almost every group and individual to appear before the Panel agreed about the need for adequate oversight. Advocacy groups, medical regulators, supporters and opponents all recognized that mechanisms must be in place to ensure that physician-assisted dying occurs in a transparent, safe and respectful manner. Dying with Dignity Canada argued that "every single case of assisted dying needs to be reported" and each case should be reviewed after death occurs. It also called for systemic review: "this is a matter of public interest. We need to know what's going on."

External Panel on Options for a Legislative Response to *Carter v. Canada*
Final Report, December 15, 2015

Table of Contents

INTRODUCTION

The proposed Regulations for Monitoring of Medical Assistance in Dying ("MAiD"[1]) are inadequate for creating a monitoring regime that will meet its main policy Objectives as detailed in the "Regulatory Impact Analysis Statement" published with the proposed regulatory text[2]:

- Support public accountability and transparency in relation to medical assistance in dying;
- Support the protection of vulnerable individuals by monitoring the application of the eligibility criteria and safeguards required by the legislation;
- Identify and monitor trends in requests for, and the provision of, medical assistance in dying;
- Help determine whether the legislation is meeting its objectives; and
- Make data available to qualified researchers for the purpose of enabling independent analysis and research.

This submission presents an analysis of the gaps in reporting requirements in the proposed Regulations, and presents recommendations to address them. Our fundamental concern arises from a disjuncture between the explicit legislative objectives of *An Act to amend the Criminal Code and to make related amendments to other Acts (medical assistance in dying) (*the *"Act")*[3] and the means proposed in the Regulations to monitor whether these objectives are being met. It is our submission that the proposed Regulations are insufficient to meet their own policy objectives, and further that without amendment, they will fail to meet the Act's important legislative objectives.

Priority attention is given in this submission to the issue of MAiD monitoring (provision and collection of information), although the authors note that the related issues of the use of that information, safeguard compliance and enforcement should be given equal attention and clarity in the MAiD regulatory framework. We will address this latter issue briefly in our recommendations but will focus here primarily on information needs for the purpose of effective monitoring according to the objectives outlined above.

[1] *Monitoring of Medical Assistance in Dying Regulations* , Volume 151, No. 50 (December 16, 2017).
[2] Government of Canada, "Regulatory Impact Analysis Statement" in *Monitoring of Medical Assistance in Dying Regulations* Volume 151, No. 50 (December 16, 2017).
[3] *An Act to amend the Criminal Code and to make related amendments to other Acts (medical assistance in dying)* S.C. 2016, c. 3

The submission has three principal components, with supplementary tables:

1. The **key spheres of responsibility** for medical or nurse practitioners as required by the legislative objectives for MAiD.
2. **Reporting gaps** in the proposed Regulations to meet these information needs.
3. **Recommendations** to address the gaps in the proposed Regulations.

Medical assistance in dying is authorized under the *Act,* which amends the *Criminal Code* to permit MAiD, as defined in section 241.1:

a. the administering by a medical practitioner or nurse practitioner of a substance to a person, at their request, that causes their death; or
b. the prescribing or providing by a medical practitioner or nurse practitioner of a substance to a person, at their request, so that they may self-administer the substance and in doing so cause their own death.

The *Act* sets out detailed requirements for practitioners to assess patient eligibility for MAiD, and identifies multiple safeguards and reporting requirements with which practitioners must comply before and after providing a medically assisted death. Provided that a practitioner meets all of these requirements, they will have provided lawful medical assistance in dying in accordance with the *Criminal Code* exemption for MAiD.

Framing the *Act* is its *Preamble*, which sets out the overarching legislative objectives for the *Act* and is reproduced in full in Table 1. These objectives provide clear guidance for MAiD practitioners by giving context and meaning to their duties and obligations under the *Act*. They also provide a crucial starting point for the design of a regulatory scheme to effectively monitor medical assistance in dying. At a minimum, determining whether the legislation is meeting its objectives will require reporting and review of information that practitioners are best positioned to provide. This provision of information by practitioners must go beyond a minimal self-reporting of whether they are dutifully complying with each of the safeguards prescribed in the law. Instead, a robust monitoring system must engage regulators, practitioners and the public in a wide-ranging dialogue about whether the practice of MAiD is achieving the objectives of the legislation.

For this reason, our submission proceeds from a framing of practitioner spheres of responsibility and from this starting point, works outward to a series of recommendations that implicate not only clinical practice and regulatory enforcement, but broader realms of policymaking and public engagement.

1. PRACTITIONER SPHERES OF RESPONSIBILITY

The specific legislative objectives articulated in the Act's *Preamble* inform all aspects of the legislative and regulatory regime for MAiD. The Government of Canada, Provincial/Territorial governments and other actors in our health and social service system all bear responsibilities in relation to these legislative objectives. This submission points to four main spheres of responsibility for practitioners who determine eligibility for or provide MAiD. These responsibilities arise from the specific legislative objectives as follows:

Protection of autonomy

- The overarching legislative objective of Canada's MAiD law requires both practitioners and regulators to "strike the most appropriate balance between the autonomy of persons who seek medical assistance in dying, on one hand, and the interests of vulnerable persons in need of protection and those of society, on the other". Fundamentally, this requires practitioners to respect patient autonomy, and to recognize when autonomy is compromised by conditions of vulnerability, pressure or inducement.
- Practitioners are directly responsible for complying with the legislative objective of "robust safeguards, reflecting the irrevocable nature of ending a life, to prevent errors and abuse in the provision of medical assistance in dying". This objective sets a high standard requiring a level of engagement greater than that of perfunctory compliance with patient safeguards embedded in the legislation.
- Similarly, in the assessment and treatment of any patient who requests MAiD, practitioners are directly responsible for protecting "vulnerable persons from being induced, in moments of weakness, to end their lives". This underscores the necessity for practitioners to consider the circumstances of a patient's life and living conditions, to pay particular attention to vulnerabilities arising from those circumstances and conditions and to provide patients with options to ease their suffering.

Understanding suffering

- In order to respect the autonomy of persons who have a grievous and irremediable medical condition, practitioners must engage in a serious exploration of a patient's experience of "enduring" and "intolerable" suffering. Before advising a patient of their options, for example, a practitioner, working in dialogue with a patient's primary care team, may need to unpack from a global assertion of intolerable suffering, unmet needs for particular kinds of care, support and assistive services. These clinical evaluations necessarily require that practitioners recognize and understand the roots of a patient's

suffering in order to respond appropriately.

- In order to comply with the legislative objective of recognizing that "suicide is a significant public health issue that can have lasting and harmful effects on individuals, families and communities", practitioners must be vigilant to detect suicidal ideation in the context of a patient's request for MAiD, and to respond appropriately where suicide prevention is warranted.

Non-discriminatory practice

- In order to "affirm the inherent and equal value of every person's life", practitioners must recognize that MAiD should be an option of last resort for any patient. This will require practitioner diligence in working with every patient to identify alternative courses of action.
- In order to support the legislative objective of avoiding "encouraging negative perceptions of the quality of life of persons who are elderly, ill or disabled", practitioners must be vigilant to ensure that stereotypes about disability, age and other immutable characteristics do not negatively shape their own judgments of a patient's quality of life and do not factor in their determination of appropriate treatment options.

Provision of Options

- Consistent with the legislative objective of recognizing "that in the living conditions of Canadians, there are diverse circumstances and that different groups have unique needs", practitioners must consider every request for MAiD in the context of a patient's full circumstances and unique needs. Responding appropriately to a patient's suffering therefore requires understanding the patient's life and living conditions, and being attentive to unmet needs that may contribute to their suffering.
- Practitioners have a key role to play in furthering the legislative objective of facilitating "access to palliative and end-of-life care, care and services for individuals living with Alzheimer's and dementia, appropriate mental health supports and services, and culturally and spiritually appropriate end-of-life care for Indigenous patients".

2. GAPS IN REPORTING REQUIREMENTS UNDER THE DRAFT REGULATION

Given the extensive spheres of responsibility with which MAiD practitioners are charged, only a comparably extensive system of reporting will suffice to build public confidence and trust that the system is working as it should. However, the regulations as currently drafted would fail to collect data sufficient to meet the criterion of determining "whether the legislation is meeting its objectives". In particular:

Protection of autonomy

- Information is lacking about whether practitioners who assess eligibility for or provide MAiD are striking the appropriate balance between protecting autonomy and protecting persons who may be vulnerable. Particular gaps in this information include:
    - practitioner recognition of the patient's suffering and factors that may be causing or compounding it;
    - practitioner identification of any factors affecting consent, and evaluation of possible coercion or inducement to request or receive MAiD beyond a broad assurance that the request was not made as a result of "external pressure";
    - practitioner assessment of factors motivating a patient's request;
    - the means practitioners make available to patients to relieve their suffering, or would have recommended if these means were accessible to the patient or available in Canada; and
    - practitioner reasons for concluding that a patient did <u>not</u> meet certain eligibility criteria. (Currently, with very limited exceptions, the proposed Regulations only require the reporting of practitioner reasons for concluding that a patient <u>does</u> meet the MAiD eligibility criteria.)

Understanding Suffering

- *Recognizing the complexity of suffering.* In many cases it will be impracticable for a single practitioner to arrive at an informed opinion that a patient meets all of the eligibility criteria under sections 241.2 (1) and (2) of the Act. Arriving at this opinion is the first "safeguard" under subsection (3) and requires a full understanding of the interplay of factors and conditions at the root of a patient's suffering. Other members of the patient's health care team will have insights to contribute to this process, and should be engaged in the monitoring regime to ensure fulsome and diligent compliance with the safeguard. At a minimum, other attending

physicians and primary health care providers who have provided care to the patient in the 6 months preceding a request for MAiD must be invited to contribute information that will help to identify life circumstances that may affect eligibility, including factors that compound patient suffering and point toward means available to relieve that suffering.

- *Psychosocial and socio-economic factors:* The supplementary patient information to be reported under Schedule 3 of the Regulations fails to recognize the complexity of human suffering and the many factors that contribute negatively to patient health and well-being. The Social Determinants of Health are well documented in medical and social science literature, pointing to a wide range of psychosocial and socio-economic factors that can all give rise to enduring and intolerable suffering.[4]
- *Patient circumstances and living conditions:* Under the proposed Regulations, practitioners are not required to report their observations about the circumstances and living conditions of patients who request MAiD. This implies that practitioners are passive witnesses to a patient's existential decline, whereas in fact they must play an active role in identifying factors extrinsic to an illness, disease or disability that may be causing or compounding the patient's suffering. Such active engagement by practitioners is necessary to enable them to respond appropriately to patient's suffering and to inform patients who seek MAiD of other means available to alleviate their suffering.
- *Means offered to relieve suffering:* Nor are practitioners required by the proposed Regulations to report on information about the specific means they offered to relieve the patient's suffering, as required in the course of obtaining informed consent. If this deficiency in the reporting system is not addressed, we will be unable to monitor for error and abuse with the degree of vigilance commensurate with "the irrevocable nature of ending a life". Moreover, we will miss a crucial opportunity to develop our understanding of the interventions that may reduce vulnerability and alleviate suffering by addressing their root causes directly.
- *Practitioner accounts of patient suffering:* Under the proposed Regulations, the monitoring regime appears to invite practitioners to paraphrase the patient's description of their suffering, rather than inviting patients to give their own account. This may ultimately skew the insights to be gleaned from the monitoring system by blurring the line between practitioner and patient reporting. Practitioners should report their analysis of the patient's suffering, and patients should be invited to

[4] WHO. (2008). Closing the gap in a generation: Health equity through action on the social determinants of health. See also: What Makes Us Sick? (2013, July 2013). Paper presented at the CMA Town Hall Report.

report their own narrative account of their suffering.

- *Patient first-person description of suffering:* First-person description, to the extent that patients wish to provide it, is a vital element missing from the draft regulations. Reporting directly from patients will help to confirm that practitioners are interpreting and describing patient suffering validly, reliably and comprehensively, and that they have offered a range of means to relieve the suffering. The information will also help to reveal any interpretive inconsistency between practitioner and patient descriptions of suffering that may undermine MAiD safeguards. Reporting instruments for patients should provide ample opportunity for free-form, qualitative expression and should not be restricted to predetermined drop-down lists.
- *Identification of vulnerability factors and detecting trends:* Without considerably more robust information about patients requesting and receiving MAiD, the monitoring regime will be unable to report on psychosocial and socio-economic factors, circumstances and living conditions which may be making patients vulnerable to inducement. Neither will we have the capacity to detect significant public health "trends in requests for, and the provision of, medical assistance in dying", one of the important policy objectives of the monitoring regime identified in the proposed Regulations.

Non-discriminatory practice

- Confronting ableism, ageism and other forms of social devaluation and discrimination is at the heart of the legislative objective of avoiding policy and practice that would encourage "negative perceptions of the quality of life of persons who are elderly, ill or disabled". In this context, it is of critical importance that the monitoring system collect information from both patient and practitioner perspectives about how an illness, disease or disability impacts, is expected to impact or is perceived to impact quality of life. This information must be collected in order to permit effective identification and tracking of trends highly relevant to the legislative objective of avoiding "encouraging negative stereotypes". Such data must be collected in order to inform a broad range of future federal and provincial policies aimed at promoting equality and inclusion.

Provision of options

- Under Schedule 4 of the current draft regulations, practitioners are only required to provide information that:
    - They are of the opinion that the patient gave informed consent having been informed of the means available to relieve suffering,

including palliative care. *No information is required on what means other than palliative care were considered.*
    - They are of the opinion that the patient's suffering could not be relieved "under conditions that they consider acceptable", and the practitioner's reasons for that opinion. *No information is required on what alternative courses of action were made available to the patient.*
    - Whether or not the patient accessed palliative care, and if it was accessible.
- These are significant gaps in information that will substantially hamper Canada's capacity to monitor for errors and abuse, and to determine if patients are vulnerable to ending their lives because of a lack of reasonable options. Nor will the monitoring regime have the capacity to assess trends in requests for and provision of MAiD in relation to the range of options being provided in different jurisdictions and communities, or in relation to different medical conditions and life circumstances and conditions.

In addition, the regulations as drafted are deficient in ways that undermine the responsible administration of MAiD monitoring. In particular:

- The Draft Regulations make inadequate provision for appropriate communication in the event that a designated Recipient of information[5] receives practitioner information suggesting a possible breach of the Act's safeguards. They contain no indication of thresholds, criteria or process for Recipient disclosure of possible violations to law enforcement authorities. This absence of compliance protocols will undermine the cornerstone principles of transparency and public accountability.
- Provisions in Schedule 4 could be read to indicate that the practitioner has discretion about whether or not to assess if a patient meets the MAiD eligibility criteria. The regulation must be clear that all eligibility criteria must be assessed by the practitioner, and that reasons for each assessment must be reported.
- The proposed Regulation exempts practitioners regulated under 241.2(3)(e) of the Criminal Code from providing certain information. To the extent that any practitioner has collected information required by the Regulation, they should be required to report it.

[5] Government of Canada, *Monitoring of Medical Assistance in Dying Regulations* Volume 151, No. 50, section 2, (December 16, 2017).

3. RECOMMENDATIONS TO ADDRESS INFORMATION GAPS

The following amendments and additions to the Draft Regulations, if implemented, would ensure that Canada's MAiD monitoring regime meets its stated objectives.

1. **Expand Schedule 3 to require practitioners to provide information about factors that may cause or contribute to the patient's suffering**.

   Specifically, these include:

   a) Social Determinants affecting a person's experience of enduring and intolerable suffering, including those determinants identified by the World Health Organization (WHO), and endorsed by the Canadian Medical Association[6]. These Determinants are defined by the WHO as "the circumstances in which people are born, develop, live and age"[7] and must be reported to the best of the practitioner's knowledge. In particular, the WHO criteria include:
      - income
      - early life (e.g. trauma)
      - education
      - housing
      - food security
      - employment and working conditions
      - unemployment and job security
      - social safety net
      - social inclusion and exclusion
      - health services

      Ideally, questions related to each of these criteria should be added to Schedule 3. If this is not practicable however, at a minimum, in a single open ended question, practitioners should be required to situate each MAiD patient within the context of the Social Determinants of Health.

   b) Given extensive evidence of the health implications of loneliness, and early indications that loneliness plays a significant role in the lives of persons who have pursued an assisted death in other jurisdictions[8], it is critically important that practitioners report their assessment of whether a patient is socially isolated.

   c) access to needed disability-related supports, including personal care, in-home supports, communication assistance and assistive technology.

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[6] Canadian Medical Association, *Health equity and the social determinants of health*, online: https://www.cma.ca/En/Pages/health-equity.aspx

[7] WHO, "The determinants of health", online: http://www.who.int/hia/evidence/doh/en/

[8] Kim, S., Vries, R. D., & Peteet, J. (2016). *Euthanasia and Assisted Suicide of Patients with Psychiatric Disorders in the Netherlands 2011 to 2014*. JAMA Psychiatry. doi:10.1001/jamapsychiatry.2015.2887,

d) assessment of family/ caregiver burden of care.

e) discrimination that may have been experienced by the person and the immutable characteristic(s) linked to such experience (for example, race, gender identity, indigenous heritage).

f) stability of patient's residential status (i.e., is the patient in transition, in need of or awaiting alternate residential accommodation?)

g) Section 1 should be amended to include other residential options, such as hospice, hospital, prison and homeless status.

2. **Include an additional instrument for voluntary reporting by patients or their representatives.**

This instrument should permit reporting of a patient's basic and supplementary information, modelled after Schedules 1 & 3, as extended by recommendation #1 above. In addition, the following additional questions should be included:

- Apart from health care practitioners, have you discussed your decision to seek MAiD with any other person? If so, how many different persons? Have any of these discussions lasted more than 30 minutes?
- Under what conditions would you find it acceptable to continue living, even temporarily?

This would provide an important opportunity for patients to self-report their experiences and circumstances, in a manner respectful of their autonomy and privacy. The information collected would:

a) be provided by the patient, or a representative designated by the patient, on a completely voluntary basis;
b) enable both narrative and structured responses to minimize the risk of predictive bias;
c) be provided confidentially to the Recipient, without direct access or review by any practitioner or their health facility or regulatory body;
d) be subject to the same privacy requirements as information provided by practitioners under the regulations;
e) be available for research about and assessment of the system, with analysis of this source of information included in public reporting.

Practitioners would be required to advise patients of the availability of this reporting mechanism at the time a MAiD request is received. Schedule 4 would also require revision to include practitioner confirmation that a patient was made aware of the option for MAiD self-reporting.

In order to make participation minimally burdensome for patients, creativity and flexibility will be essential as the reporting process is designed. So too, will be a commitment to communication access which meets individual patient needs. Within the VPS community there is both the willingness and the talent to lead or assist in the development of appropriate tools and processes for this purpose.

3. **Provide an opportunity for voluntary reporting by the patient's primary health care providers.**
   Practitioners should be required to identify to the Recipient the patient's primary care physician/family physician/nurse practitioner, as well as other attending physicians who have cared for the patient in the six months preceding a request for MAiD. These physicians should then be invited to report their understanding of any unique circumstances in the patient's life that might have compounded their suffering or undermined their autonomy, as well as means available to relieve the patient's suffering.

4. **Amend Schedule 4, section 2(h) to explicitly require practitioners to report their own description of the patient's suffering.**
   The proposed Regulations require practitioners to report the patient's description of their suffering. However, practitioners may have insights informed by clinical judgment that would differ from the patient's report, and that would take into account all of the practitioner's assessment of the patient's life circumstances and living conditions. Accordingly, these observations should be reported directly by practitioners speaking from their own perspectives.

5. **Require practitioners to complete an additional "Schedule of Motivating Factors".**
   This Schedule should be modelled on an expanded version of the "Follow-up Form" required for physician reporting under the *Oregon Dying with Dignity Act*[9]. Practitioners would be required to report their informed judgment about the extent to which the patient's request is motivated by a number of factors. This should include the following specific factors, with an accompanying indication for each factor about whether this is an actual experience, or a feared future expectation:
   - the financial cost of treating or prolonging their medical condition;
   - the physical or emotional burden on family, friends, or caregivers;
   - loss of autonomy arising from their medical condition;
   - a decreasing ability to participate in activities that made life enjoyable;
   - loss of control of bodily functions, such as incontinence and vomiting;
   - inadequate pain control;
   - loss of dignity;
   - social isolation or loneliness;

[9] Oregon Death with Dignity Act, Attending Physician Follow-up Form, Online: http://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EVALUATIONRESEARCH/DEATHWITHDIGNITYACT/Documents/mdintdat.pdf

- intolerable living conditions, for example incarceration, institutionalization, confinement in hospital or long-term care facility;

In addition, the Schedule should include factors, other than fear or immediate distress, that may describe a patient's motivations, including the following option:

- a lifelong pattern of concern with issues of control, autonomy and self-sufficiency. [10]

The Schedule should also include the opportunity for free-form entry of factors not on the above list.

This *Schedule of Motivating Factors* would also be included in the instruments made available for voluntary patient reporting and for extended care team reporting.

6. **Amend Schedule 4 to require practitioners to identify alternative means (other than MAiD) that were available to relieve a patient's suffering.**
Schedule 4, section 2(e) requires that practitioners confirm that a patient has given their consent after being informed of "the means that are available to relieve their suffering, including palliative care". Beyond this simple declaration, however practitioners should be required to report on:
   a) all means the practitioner offered to the patient to relieve their suffering, and whether, to the best of the practitioner's knowledge or belief, these means were accessible to the patient; and
   b) any means that could have relieved the patient's suffering but were not, to the best of the practitioner's knowledge or belief, accessible or readily available to the patient.

7. **Delete Section 3 of the draft regulations, which exempts practitioners in some circumstances from the necessity to report.**
There is still relevant information to be gleaned from practitioners for purposes of system monitoring, even if a patient withdraws their request, is found to be ineligible, or dies from a cause other than MAiD.

8. **Amend the Draft Regulations to provide clear lines of responsibility for Recipient disclosure of possible breaches of the Act for appropriate criminal investigation.**
The Regulations cannot be silent on issues of compliance and enforcement. Instead, consistent with other international jurisdictions where some form of medically assisted death is authorized,[11] there must be some clear provision

[10] Oldham, R., Dobscha, S., Goy, E., & Ganzini, L. (2011). Attachment styles of Oregonians who request physician-assisted death. Cambridge Core: Palliative and Supportive Care, 9(2), 123-128.
[11] See, for example, section 93 of Victoria, Australia's Voluntary Assisted Dying Act, 2017, available at http://www.legislation.vic.gov.au/Domino/Web_Notes/LDMS/PubStatbook.nsf/f932b66241ecf1b7ca256e92000e23be/B320E209775D253CCA2581ED00114C60/$FILE/17-061aa%20authorised.pdf

detailing when and how investigative and prosecutorial interventions will be triggered.

9. **Amend Section 13 (2) to require annual publication of incidents of safeguard non-compliance.**
   Consistent with the regulatory goals of transparency and accountability, the proposed Regulations in Section 13(2) should be amended to include in the Minister of Health Report, information related to Recipient notification and/or disclosure to the relevant prosecutorial authorities, regarding possible practitioner non-compliance with safeguards.

Conclusion

When the state takes a path, it has the obligation to track the nation's progress along that path.[12] The proposed Monitoring of Medical Assistance in Dying Regulations are an important first step toward the fulfilment of that obligation. We applaud this step, and the commitment to a process of public consultation as the Regulations progress toward revision, refinement and final approval by the Minister of Health.

In their final form, the regulations will serve to monitor the practice of MAiD, to ensure compliance with the Act and to support research consistent with the public interest goals of protecting the health and well-being of Canadians. It is with these three functions in mind that we have reviewed the proposed Regulations and prepared this response to the government's call for input.

Our submission is centred on the role that these regulations must play in relation to the legislative objectives of Canada's 2016 law permitting medical assistance in dying. These obligations, expressed clearly in the *Preamble* to the Act, demand of practitioners and administrators, researchers and policymakers alike, a nuanced understanding of the delicate balance required between respecting individual patient autonomy and protecting the rights of persons in vulnerable circumstances.

While the proposed Regulations currently fall short of compliance with MAiD's legislative objectives, it is our belief that the revisions and additions recommended in this submission would close this gap in accountability and ensure that both in day-to-day practice and in broader social consequence, Canada's MAiD regime lives up to its promise of fairness and compassion.

[12] Reference to "Physician-Assisted Death: Scanning the Landscape and Potential Approaches -- A Workshop", February 13, 2018. Online at http://nationalacademies.org/hmd/Activities/HealthServices/PADworkshop/2018-FEB-12.aspx

TABLE 1: LEGISLATIVE OBJECTIVES FOR MAiD

AN ACT TO AMEND THE CRIMINAL CODE AND TO MAKE RELATED AMENDMENTS TO OTHER ACTS (MEDICAL ASSISTANCE IN DYING)

PREAMBLE

Whereas the Parliament of Canada recognizes the autonomy of persons who have a grievous and irremediable medical condition that causes them enduring and intolerable suffering and who wish to seek medical assistance in dying;

Whereas robust safeguards, reflecting the irrevocable nature of ending a life, are essential to prevent errors and abuse in the provision of medical assistance in dying;

Whereas it is important to affirm the inherent and equal value of every person's life and to avoid encouraging negative perceptions of the quality of life of persons who are elderly, ill or disabled;

Whereas vulnerable persons must be protected from being induced, in moments of weakness, to end their lives;

Whereas suicide is a significant public health issue that can have lasting and harmful effects on individuals, families and communities;

Whereas, in light of the above considerations, permitting access to medical assistance in dying for competent adults whose deaths are reasonably foreseeable strikes the most appropriate balance between the autonomy of persons who seek medical assistance in dying, on one hand, and the interests of vulnerable persons in need of protection and those of society, on the other;

Whereas it is desirable to have a consistent approach to medical assistance in dying across Canada, while recognizing the provinces' jurisdiction over various matters related to medical assistance in dying, including the delivery of health care services and the regulation of health care professionals, as well as insurance contracts and coroners and medical examiners;

Whereas persons who avail themselves of medical assistance in dying should be able to do so without adverse legal consequences for their families — including the loss of eligibility for benefits — that would result from their death;

Whereas the Government of Canada has committed to uphold the principles set out in the Canada Health Act — public administration, comprehensiveness, universality, portability and accessibility — with respect to medical assistance in dying;

Whereas everyone has freedom of conscience and religion under section 2 of the Canadian Charter of Rights and Freedoms;

Whereas nothing in this Act affects the guarantee of freedom of conscience and religion;

Whereas the Government of Canada recognizes that in the living conditions of Canadians, there are diverse circumstances and that different groups have unique needs, and it commits to working with provinces, territories and civil society to facilitate access to palliative and end-of-life care, care and services for individuals living with Alzheimer's and dementia, appropriate mental health supports and services and culturally and spiritually appropriate end-of-life care for Indigenous patients;

And whereas the Government of Canada has committed to develop non-legislative measures that would support the improvement of a full range of options for end-of-life care, respect the personal convictions of health care providers and explore other situations — each having unique implications — in which a person may seek access to medical assistance in dying, namely situations giving rise to requests by mature minors, advance requests and requests where mental illness is the sole underlying medical condition;

Now, therefore, Her Majesty, by and with the advice and consent of the Senate and House of Commons of Canada, enacts as follows:

TABLE 2: SUMMARY OF RECOMMENDATIONS AND ANALYSIS

REGULATORY PROVISION	RECOMMENDED AMENDMENTS	RATIONALE
Schedule 3 – Supplementary Information about Patient	Expand Schedule 3 to require practitioners to provide information about a critical range of factors that may cause or contribute to patient suffering.	In order to respond appropriately to suffering, practitioners will necessarily have to cultivate an understanding of the complex factors that produce or compound patient suffering. Success in meeting MAiD's objectives of respecting autonomy, and protecting against the vulnerability that results when autonomy is compromised, can only be measured in relation to the diverse and unique circumstances of patient's lives. The public health outcomes of Canada's MAiD regime require careful tracking of how this practice intersects with the Social Determinants of Health, and careful monitoring for systemic and discriminatory impacts.
No existing regulatory provision.	Include an additional instrument for voluntary reporting by patients or their representatives	Hearing from patients directly provides the greatest possible assurance that MAiD is provided without abuse, inducement, coercion or external pressure. Including persons who are directly served (or imperilled) by MAiD conforms with a human rights based approach to monitoring. Only in this way will patients at the end of life have access to being heard, to participating in the oversight of MAiD, and to "counting" in future social policy determinations.
No existing regulatory provision.	Provide an opportunity for voluntary reporting by the patient's primary health care providers.	Responsibility for the well-being of patients who request MAiD is not limited to "practitioners" as defined by the Act. Other members of the patient's health care team have valuable insights about patient suffering and the means available to relieve that suffering. The legislative objective of vigilance commensurate with "the irrevocable nature of ending a life" calls for a monitoring system that draws from all available sources of relevant and reliable input.

REGULATORY PROVISION	RECOMMENDED AMENDMENTS	RATIONALE
Schedule 4, section 2(h) 2 An indication of which of the following eligibility criteria were assessed by the practitioner and whether the practitioner was of the opinion that the patient met or did not meet each of those criteria: (h) the illness, disease or disability or state of decline caused the patient enduring physical or psychological suffering that was intolerable to them and that could not be relieved under conditions that they considered acceptable and, if the practitioner assessed this criterion and was of the opinion that the patient met it, the reasons why the practitioner was of that opinion, including the patient's description of the suffering;	Amend Schedule 4, section 2(h) to explicitly require practitioners to report their own description of the patient's suffering	Practitioners will have informed insights about the roots of suffering and the interplay of living conditions and personal circumstances that underlie a patient's request for MAiD. There is no reason to exclude these insights in collecting information that may help to identify policy priorities for end-of-life care in Canada, and to help shape social programming aimed at reducing suffering and mitigating conditions of vulnerability. Such an approach would support the legislative objectives related to suicide prevention, end-of-life care and respect for the personal convictions of health care providers.
No existing regulatory provision.	Require practitioners to complete an additional "Schedule of Motivating Factors"	Confronting ableism, ageism and other forms of social devaluation and discrimination is at the heart of the legislative objective of avoiding policy and practice that would encourage "negative perceptions of the quality of life of persons who are elderly, ill or disabled". Developing a detailed aggregate analysis of factors that motivate Canadians to seek MAiD will provide invaluable insights about the degree to which this important legislative objective is being met, and will point the way toward remedial programming in other domains.
Schedule 4, section 2 (e) 2 An indication of which of the following eligibility criteria were assessed by the practitioner and whether the practitioner was of the opinion that the patient met or did not meet each of those criteria: (e) the patient gave informed consent to receive medical assistance in dying after having been informed of the means that are available to relieve their suffering, including palliative care;	Amend Schedule 4 to require practitioners to identify what alternative means (other than MAiD) were available to relieve a patient's suffering, beyond simply asserting that the patient has been informed of such measures.	An essential MAiD safeguard within the informed consent process is the identification of alternative courses of action for patient consideration. Beyond a broad assurance that a patient's request was not made as a result of "external pressure" a more detailed account of the decision-making process permits greater assurance that the consent process was free of coercion or inducement. This information is central to ensuring MAiD compliance and fidelity to the legislative objective of "protecting vulnerable persons from being induced… to end their lives"

Regulatory Provision	Recommended Amendments	Rationale
3 A practitioner who has received a patient's written request for medical assistance in dying from the patient directly or from another practitioner, a care coordination service or another person on the patient's behalf in order to obtain the practitioner's written opinion, for the purposes of paragraph 241.2(3)(e) of the Code, regarding whether the patient meets all of the eligibility criteria, is not required, in respect of the request, to provide information under sections 5, 6, and 9.	Delete Section 3 of the draft regulations, which exempts practitioners in some circumstances from the necessity to report.	There is still relevant information to be gleaned from practitioners for purposes consistent with the legislative objectives, even if a patient withdraws their request, is found to be ineligible, or dies from a cause other than MAiD.
No existing regulatory provision.	Amend the Draft Regulations to provide clear lines of responsibility for Recipient disclosure of possible breaches of the Act for appropriate criminal investigation	Compliance and enforcement are one of the primary uses for regulatory standards. Clarity about enforcement of the Act will be critical to its success in protecting Canadians, and Canadian society, from harm.
13 (1) The Minister of Health must cause to be published, at least once a year, on the website of the Government of Canada a report that is based on information that the Minister obtained under these Regulations. (2) The report must contain information relating to written requests for medical assistance in dying received by practitioners and the provision of medical assistance in dying during the period covered by the report, including:	Amend Section 13 to require annual publication of incidents of safeguard non-compliance.	Required for consistency with the regulatory goals of transparency and public accountability.