MINISTRY OF HEALTH
INFORMATION BRIEFING NOTE

Cliff # 962577

PREPARED FOR: Honourable Margaret MacDiarmid - **FOR INFORMATION**

TITLE: Investigation 2012-0601 Costs

PURPOSE: To provide information of the year to date and estimated costs to the government for Investigation 2012-0601.

BACKGROUND:

The Office of the Auditor General contacted the Assistant Deputy Minister of Financial and Corporate Services, Ministry of Health (MOH) on March 28, 2012, to advise that an allegation report was received by their office concerning inappropriate procurement, contracting irregularities, inappropriate data access arrangements, intellectual property infringement and code of conducts conflicts. MOH immediately launched an internal investigation and recommended a formal investigation be undertaken which began June 1, 2012.

DISCUSSION:

An investigation team was established with members from the Office of the Chief Information Officer (OCIO), Public Service Agency (PSA) and the MOH. The first phase of the investigation focussed on MOH staff and resulted in the termination of . Sect 22

Sect 22

Sect 22

Sect 13

Sec: 17

Sect 14, Sect 22

The investigation team has determined that there has been inappropriate personally identifiable information released/lost resulting in notification being provided to at least 38,000 British Columbia residents. A contract has been established to handle phone inquiries for the notification for up to $1.5M. In addition a contract has been established to review the ministry data practices making recommendations for improvement to reduce risk for $.6M.

A summary of the costs include:

Cost Type	Year to Date	Future	Total
PSA	$55,000	$7,000	$62,000

Sect 14

MOH	1,014,000	1,688,000	$2,702,000

Sect 14

Sect 14 of the total investigation costs are considered to be incremental costs.

Costs for the Ministry executive involved in this investigation are not included in the costs.

ADVICE:

- To date investigation 2012-061 has co: Sect 14

Sect 13, Sect 17

- A more detailed breakdown of costs is attached as Appendix A

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File Name with Path: G:\Admin\BriefingNotes\2012-2013

APPENDIX A
Ministry of Health
Investigation 2012-0601 Costs
June 1, 2012 - April 30, 2013

PSA	YTD	Estimated Future	Total	Portion Incremental	Portion Reassigned	Comments
Salaries & Benefits						
Sect 19	33,210	1,476	34,686		34,686	
	1,476	-	1,476		1,476	
	5,000	500	5,500		5,500	All estimated
	5,000	500	5,500		5,500	All estimated
	5,000	500	5,500		5,500	All estimated
	2,460	1,230	3,690		3,690	
Total Salaries	52,146	4,206	56,352			
Transcription Costs	3,375	2,500	5,875	5,875		
Total PSA Costs	55,521	6,706	62,227			
Ministry of Health						
Salaries & Benefits						
Sect 19	60,470	1,693	62,163		62,163	100% June to Aug 31, 60% Sept 1 - Jan 15
	87,959	37,316	125,274		125,274	100% Since June 1
	52,060	11,661	63,721		63,721	100% June to Aug 31, 60% Sept 1 - Jan 15, 50% Jan 16-April 30
	43,614	18,503	62,117		62,117	100% Since June 1
	45,233	25,331	70,564		70,564	100% Aug 1 - April 30
	7,970	-	7,970		7,970	2 months 50%
	39,129	21,912	61,042		61,042	100% Aug 1 - April 30
	52,921	29,636	82,556		82,556	100% Aug 1 - April 30
Total Salaries	389,356	146,052	535,408			
Deloitte Touche	611,000	-	611,000	611,000	-	Contract ends Jan 31, 2013
HSBC - 38000 letters (note1)	-	1,500,000	1,500,000	1,500,000	-	Help support for 38K letters
Postage/print/fold/stuff	-	31,000	31,000	31,000	-	Mail out for data loss - BC Mail Plus
Data Extractions	11,400	11,000	22,400	22,400	-	Charged back from Sect 19
Blackberry Sect 19	800	400	1,200	1,200	-	Charged back from
Other office supplies	800	-	800	800	-	Charged back from

Sect 14

Notes

1) Assumes no further notifications required.

The amount for the contact centre of $1.5M may be less - currently the number of calls is minor, but still will be at least $1M

Sect 14

MINISTRY OF HEALTH
INFORMATION BRIEFING NOTE

Cliff # 970485

PREPARED FOR: Honourable Dr. Margaret MacDiarmid - **FOR INFORMATION**

TITLE: Possible conflict of interest of Provincial Health Services Authority (PHSA) Board Member

PURPOSE: To provide an update on action taken to address the concerns expressed in the February 24th letter to the Minister of Health regarding the possible conflict of interest of PHSA Board member, Mary McDougall.

BACKGROUND:

In the fall of 2012, Fraser Health Authority (FHA) approached Health Shared Services BC (HSSBC) to support them with a procurement process for residential complex care services and mental health and substance use licensed facility care. The goal of this procurement was to establish contracts with organizations that have a proven capability to design, construct, and operate complex care facilities to a high standard of service.

With this goal, it was decided that a two-step procurement process was the most appropriate: the capability of interested organizations would first be identified through a Request for Pre-Qualification (RFPQ); those companies identified as capable would then be asked to submit competitive proposals through a Request for Proposal (RFP). Recognizing the complex and sensitive nature of this procurement, a Fairness Monitor was engaged to provide independent oversight of the procurement process.

HSSBC posted HSSBC RFPQ 00770 on November 2, 2012, and completed the RFPQ process by issuing notice to qualified proponents in early February 2013. In late February 2013, the Minister of Health received a letter expressing concern that Buron Healthcare Ltd. (Buron) had qualified as a proponent to participate in the RFP phase. The letter identified the role of Mary McDougall as both a principal of Buron and a Board member of PHSA. PHSA is one of the six BC Health Authorities that funds and uses the services of HSSBC. Although the operations of HSSBC are directed by a separate Management Board, it operates as a Division of PHSA for administrative purposes (legal, fiduciary/financial reporting).

DISCUSSION:

- Acquisition of the types of services being procured by Fraser Health in this procurement are outside of HSSBC's mandate. However, as part of HSSBC's service agreement with Fraser Health, HSSBC Supply Chain supports Fraser Health in these types of acquisitions through the provision of "professional procurement" services. As a result, HSSBC's involvement in this procurement was limited to the facilitation of the procurement process as well as the provision of RFPQ, RFP and contract templates. HSSBC Supply Chain was not involved in determining evaluation criteria or in the evaluation of the RFPQ responses. The

criteria were set by Fraser Health staff and the evaluation was conducted by Fraser Health staff alone. In addition, HSSBC will not be involved in negotiation of the resulting contract(s).

- HSSBC's RFPQ process and template do not require proponents to provide a statement of disclosure. HSSBC's standard process is to require qualified proponents to submit a statement of disclosure prior to their receipt of RFP documents during the second stage. If a submitted statement of disclosure identifies a conflict of interest or unfair advantage or potential for a perceived conflict of interest or unfair advantage, then, at the direction of the Evaluation Committee, a proponent would be disqualified if the conflict or advantage could not be adequately mitigated.

- Both Ms. McDougall and Buron were completely transparent about Ms. McDougall's relationship with Buron and PHSA. Buron disclosed Ms. McDougall's relationship with Buron and PHSA in their proposal, even though not required to do so by the terms of the RFPQ. Ms. McDougall also made a statement of disclosure to the PHSA Board Chair.

- Although a Division of PHSA for legal/administrative purposes, HSSBC affairs are managed by an independent Management Board comprised of the CEOs of all six Health Authorities, a representative of the Ministry of Health, and two outside directors. This structure is designed to ensure that no Health Authority Board (including PHSA) could have an undue influence on the affairs of HSSBC.

- In reviewing the concerns expressed in the letter, the Fairness Monitor noted that the language in HSSBC's RFPQ pre-amble which describes the relationship between HSSBC and the Health Authorities, could lead a proponent to believe that the relationship between PHSA and HSSBC is more direct than the actual structure. The Fairness Monitor concluded that this could lead to a perception of bias and unfair advantage over other qualified proponents in HSSBC 00770.

- The Fairness Monitor further noted that because of the legal/administrative relationship between HSSBC and PHSA, there may have ben an actual conflict of interest.

- HSSBC has identified that changes to the RFPQ language and HSSBC's standard processes could prevent this perception of a conflict of interest and could also highlight potential conflicts of interest earlier in the procurement process.

- The Fairness Monitor has recommended that to ensure the next stage of the procurement process is perceived to be fair; Buron Healthcare Ltd must be disqualified. This recommendation is based on the Fairness Monitor's belief that the language in the RFPQ preamble could be taken to indicate a direct relationship between PHSA and HSSBC and the public identification of a perceived relationship between HSSBC and Buron Healthcare Ltd. It is unlikely that a change in Ms McDougall's status on the PHSA Board (i.e. if she resigned) would change the perception of unfairness with other proponents.

- Although Fraser Health could cancel the RFPQ and start the whole process over again, this would impose a delay on the Fraser Health clinical program and could further aggravate the situation as successful proponents would see that they are being asked to incur further costs to accommodate an organization they may see as having an unfair advantage due to its current or past relationship.

- HSSBC RFPQ language provides Fraser Health with the right to disqualify any proponent at its sole discretion. Fraser Health has indicated to the Fairness Monitor that Buron will be disqualified.

- Given the fact that Buron has already been notified that it is a qualified proponent, it is possible that Buron will not accept disqualification from the next stage without some form of redress (e.g. judicial review).

SUMMARY:

The Fairness Monitor engaged to provide independent oversight of HSSBC's RFPQ 00770 indicated that a perception of conflict of interest exists due to the apparent lack of clarity in the RFPQ preamble. He further indicated an actual conflict of interest may also exist. For this procurement process to proceed, it is essential that the integrity of the procurement process, specifically the perception of fairness, be maintained.

The Fairness Monitor has indicated that Fraser Health has provided him, through email, the assurance they will disqualify Buron. To further minimize the potential for a similar perception of conflict of interest, in future HSSBC Supply Chain will:

- Clarify the relationship of PHSA and HSSBC in the preamble of its RFPQ and RFP templates.
- Adopt the same Statements of Disclosure language and process in the RFPQ as utilized with the RFP, where disclosure is required prior to the submission of proposals by proponents.
- At the launch of a procurement process, educate the Evaluation Committee on the relationship between HSSBC and PHSA, as well as the other Health Authorities.
- Ensure that the tests for a conflict of interest are well-defined and that all Evaluation Committees are educated on these tests at the launch of a procurement process.
- When a Fairness Monitor is engaged to support a procurement process, ensure that the Fairness Monitor is oriented to the governance relationship between HSSBC and PHSA as well as the other Health Authorities.

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File Name with Path: L:\Shared\Financial & Corporate Services\BRIEFING NOTES\2013\970485 - Possible conflict of Interest of PHSA Board Member.doc

MINISTRY OF HEALTH
INFORMATION BRIEFING DOCUMENT

Cliff # 964361

PREPARED FOR: Honourable Dr. Margaret MacDiarmid, Minister of Health
FOR INFORMATION

TITLE: Emergency Department Wait Times at Vancouver General Hospital

PURPOSE: To provide information regarding Emergency Department wait times at Vancouver General Hospital

BACKGROUND:
The Vancouver General Hospital (VGH) Emergency Department (ED) is projected to receive approximately 82,000 ED visits in the current fiscal year, of which approximately 23 percent will be admitted as inpatients. VGH is projected to see a 13 percent increase in ED visits between 2008 and the end of the current year, while total admissions from the ED will have increased by 15 percent in the same period.

Beginning April 1st, 2012 the province began collecting detailed information on ED wait times at 20 sites across the province (including VGH) with the implementation of the National Ambulatory Care Reporting System (NACRS). NACRS data provides 4 primary measures of ED wait times including time to: physician assessment, disposition decision, waiting for an inpatient bed and overall length of stay.

Previous to the collection of NACRS data the primary ED wait time measure (that was monitored by the Ministry) was percent of patients who waited 10 hours or less to access an inpatient bed from the time of decision to admit (10 Hour Indicator). The current target for the 10 hour indicator is 85 percent in Vancouver Coastal Health Authority.

Despite increasing numbers of patients being admitted from the ED, the 10 Hour Indicator at VGH improved from 81 percent in 2008/09 to 88 percent in 2010/11 and 2011/12, (as a result of significant attention being placed on patient flow in the organization – see discussion section) and has continued to be maintained at this level. Notably, this is the best performance of any large hospital in BC.

VGH currently has among the shortest wait times to physician care in Canada for similar sized institutions. According to CIHI NACRS data, the 90th percentile time to physician initial assessment in 2012/13 (year to date) for Canada is 3.18 hours -- VGH is 2.1 hours.

In addition, Appendix 1 contains more detailed data regarding ED wait times at VGH and seven other large EDs in the lower mainland (over 45,000 visits/year) for reference.

DISCUSSION:
In fiscal year 2010/11 VGH underwent a transformation throughout the hospital that resulted in significant improvements in ED wait times. Sect 13

Sect 13

Sect 13 What ensued has been the topic of many public presentations by the leadership team at VGH on, "Engaging the organization around patient flow."

The transformation at VGH began through daily senior leader engagement with frontline staff and physicians to get to the root of the patient flow problems. It quickly became apparent to the senior leadership team that to optimize patient flow they needed to reduce processing time in the ED and create sufficient bed capacity in the hospital. In order to achieve this they undertook a three pronged approach that included: setting a clear and strategically aligned course of action, leveraging and investing in tools and technology and creating a culture of visible and engaged leaders at the senior level.

While there has been much work done at the site to improve operations and patient flow, there is further work to be done to continue to reduce pressure on the ED at the front end by smoothing volume coming through the door. As such, VCHA has embarked on a project to develop three separate dashboards to track and communicate emergency ED operational activity and wait times regionally for BC Ambulance Service (BCAS), ED staff and the public. The public dashboard is expected to go live March 16th, 2013.

The public dashboard will use live data on relative waits to physician initial assessment at alternate facilities to help patients decide which ED may best suit their health need and provide information on alternatives (e.g. nearby walk in clinics, 8-1-1.) This dashboard is a tool to help patients choose between alternate facilities within a geographic area and smooth out patient volumes. In addition to the public tool, the BCAS dashboard will be used as a decision support tool to help smooth regional flow by bringing patients to the most appropriate and timely location in VCH.

CONCLUSION: VGH is a seen as a leader in BC in regards to ED wait times and patient flow. While they face challenges to meet increasing demand, they continue to seek ways to improve quality of care for patients in the ED.

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Appendix 1

There are currently 4 primary measures of ED wait times collected through NACRS at VGH that are collected by the Ministry. These include:

1. Time to physician initial assessment (TPIA)
2. Time to Disposition (TtoD)
3. Time Waiting for an Inpatient Bed (TWIB)
4. ED Length of stay (admitted and not admitted LOS)

Year to Date (Period 10) 2012/13 Wait Times at VGH and Seven Other Large Lower Mainland Hospitals[1]

Health Authority	Hospital	90th Percentile Wait Times (hours)					
		Admitted Visits				Non-Admitted Visits	
		TPIA	TtoD	TWIB	LOS	TPIA	TtoD/LOS
VCHA	Vancouver General Hospital	2.1	11.0	12.8	20.6	2.3	6.9
VCHA	St. Paul's Hospital	1.1	11.9	12.8	21.9	1.3	6.5
VCHA	Lions Gate Hospital	2.2	8.3	32.7	38.3	2.0	6.2
VCHA	Richmond Hospital	2.3	10.1	22.1	28.6	2.6	5.7
FHA	Royal Columbian Hospital	2.7	9.7	21.8	27.8	2.3	5.6
FHA	Surrey Memorial Hospital	3.8	8.6	23.0	28.4	3.3	5.8
FHA	Burnaby Hospital	1.5	6.3	19.9	23.7	1.9	4.6
FHA	Abbotsford Regional Hospital and Cancer Centre	2.5	8.4	42.7	48.6	2.5	5.7

10 Hour Indicator Fiscal 2008/09-2011/12[2]

Hospital	% of ED Patients admitted within 10 hours of the decision to admit			
	2008/09	2009/10	2010/11	2011/12
Vancouver General Hospital	81%	80%	88%	88%
St. Paul's Hospital	75%	75%	74%	84%
Lions Gate Hospital	58%	60%	53%	58%
Richmond Hospital	83%	76%	68%	67%
Royal Columbian Hospital	50%	69%	65%	69%
Surrey Memorial Hospital	45%	60%	55%	50%
Burnaby Hospital	60%	70%	71%	70%
Abbotsford Regional Hospital and Cancer Centre	55%	62%	54%	52%

[1] NACRS, CIHI refresh 16 Jan 2013, data extracted 24 Jan 2013

[2] Discharge Abstract Database, Priority Project Branch, Planning and Innovation Division, Ministry of Health. Info pulled from MoH Measurement Sharepoint February 5th, 2013

MEETING MATERIAL

Cliff #: 966644

PREPARED FOR: The Honourable Dr. Margaret MacDiarmid, Minister of Health, for a meeting with her constituent, Kent Chan-Kent and Marie Little, Chair of the Trans Alliance Society (TAS), on March 15, 2013.

TITLE: Minister MacDiarmid is meeting with Kent Chan-Kent and Marie Little to discuss transgender rights.

MEETING REQUEST/ISSUE: This meeting was requested Kent Chan-Kent to discuss transgender rights and funding for transgender people outside of the Vancouver area. Mr. Chan-Kent has also requested that Mary Little also attend the meeting.

Sect 13

BACKGROUND:

The Minister's Office has requested information on the TAS and the role of the Trans Health Collective.

- The TAS is a province-wide coalition, bringing individuals and groups together to inform and work on transgender issues. Work of the coalition includes:
  - forums and resources to assist in the personal development, growth, and contact of its members within the transgendered community;
  - promoting knowledge and understanding of the transgender culture;
  - building a sense of community through contact with other organizations or individuals sharing similar objectives; and
  - working towards removing all forms of barriers that negatively impact the transgendered community.

- Staff in the Health Authorities Division (HAD) have had discussions with Marie Little to address questions and concerns regarding the Transgender Health Program (THP) operated and funded through the Vancouver Coastal Health Authority (VCHA). HAD has also prepared an Information Briefing Document regarding the release of the VCHA internal review of the THP to its advisory group. Copies of the briefing document, internal review and related correspondence are enclosed for reference

- The THP provides the following services and supports:
  - a resource hub that provides information to anyone in BC with a transgender health question;
  - provides health care professionals who specialize part of their practice in transgender health care to build capacity in the local communities;

- provides primary care access for transgendered persons living in the Vancouver Coastal Health (VCH) Region (Vancouver, Richmond, North Shore, and Coastal/Rural) requiring diagnosis, hormone readiness assessment, and related health care services;
- these services are provided to those living in the VCH Region out of three sites: Three Bridges Clinic, Raven Song, and Pender Clinic; and,
- youth (under the age of 25), refugee claimants, those with complex mental health diagnoses, and individuals with post-operative complications, who *live outside the VCH Region* are given special consideration regarding access on a case by case basis. This may include referral to another health care provider or organization.

- The Medical Services Plan (MSP) insures and pays for physician services for BC residents. This includes services related to sex reassignment surgery (SRS) such as psychiatric assessments, family physician visits, specialist visits (e.g.endocrinologists), surgeon's fees, surgical assistant fees, anesthetic fees, and physician-requisitioned laboratory services.

- Currently MSP insures the following SRS services, on a pre-approval basis: female to male services include bilateral subcutaneous mastectomy (with contouring), hysterectomy, oophorectomy, and phalloplasty/metaioplasty. Male to female services include vaginoplasty (penectomy, orchidectomy) and breast augmentation (under specific conditions).

- SRS is a highly specialized field, with a very small number of qualified specialists who perform these complex procedures.

- The Ministry of Health (the Ministry) is currently working to increase access to qualified assessors for patients and clients requesting SRS in BC. The Ministry's goal is to decentralize access to assessments and have assessors in all health authorities, thus ensuring increased patient care by decreasing patient wait times.

- Currently the Ministry has no outstanding issues or working relationship with the Trans Health Collective.

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File Name with Path: K:\CRU - MSP\2013\Green Folder\Meeting Material 2 - Transgender Health 966644.docx

MINISTRY OF HEALTH
INFORMATION BRIEFING NOTE

Cliff # 959155

PREPARED FOR: Honourable Dr. Margaret MacDiarmid, Minister of Health – **FOR INFORMATION**

TITLE: Background information on the BC Patient Safety and Quality Council

PURPOSE: To provide information on the BC Patient Safety and Quality Council's (the Council) mandate, funding and recent accomplishments.

BACKGROUND:

- The Council was established in 2008 to provide system-wide leadership and bring a provincial perspective to patient safety and quality improvement activities in British Columbia.
- At the time of the establishment of the Council an advisory committee model was recommended in BC to support greater flexibility in the Council's organizational development. A commitment was made to review the Council's mandate at a later date and determine the need to legislate the Council. In a recent cross jurisdictional review it was identified that similar organization in other provinces such as Alberta, Saskatchewan, and Ontario have legislated Quality Councils.
- The role of the Council is to provide advice and make recommendations to the Ministry of Health (the Ministry) on matters related to patient safety and quality of care in all health care sectors, and to bring health system stakeholders together in a collaborative partnership, working toward a provincially coordinated, innovative, and patient-centred approach to quality improvements.
- The Council consists of a Chair and three members, as well as two ex-officio members. The Chair and members are selected based on their expertise and experience as it relates to patient safety and quality improvement. The Chair of the Council is Dr. Douglas Cochrane.
- Dr. Cochrane assumes full responsibility for the management of Council operations, and is accountable in this role to the Minister through the Deputy Minister.
- The Minister appoints one member to the position of the Patient Safety & Quality Officer. In 2008, Dr. Cochrane was appointed as the Patient and Safety Quality Officer and as part of his role leads independent investigations at the request of the Minister.
- Recent investigations conducted by Dr. Cochrane include a review of the quality of medical scans in BC and a review of Burnaby Hospital infection rates. As a result of Dr. Cochrane's recommendations a number of improvements are being implemented in BC.
- All other Council members are appointed by the Minister on the advice of the Officer. The Council selects a Vice-Chair from its membership.
- In the fall of 2010, the Council was renewed for a second three year term (2011/12 to 2013/14). The Council's revised Terms of Reference and Operational Plan for this new term are directly aligned with the strategic goals of BC's health care system.

DISCUSSION:

The Council's accomplishments include:

- Launching the BC Health Quality Network, a province-wide community of practice for sharing information to enhance patient safety and improve quality of care.
- Developing the BC Health Quality Matrix, a framework for defining the quality of health through four areas of care, using seven quality dimensions.
- Developing a provincial quality and patient safety education strategy, as well as the Quality Academy, a six month professional development program that provides participants with the capability to effectively lead quality and safety initiatives.
- Building support for the province-wide use of Global Trigger Tools, which help hospitals identify adverse events and track quality improvement efforts.
- Providing support for health quality organizations and initiatives such as the Western Node of *Safer Healthcare Now! Safer Healthcare Now!* is the largest well-defined and nationally endorsed patient safety and quality improvement project in Canada.
- Launching public engagement programs such as *It's Good to Ask*, a program designed to encourage patients to talk with their care providers about their own health.
- The Council created the Surgical Quality Action Network to support the National Surgical Quality Improvement Program, which is a key measurement tool to improve surgical quality. The Surgical Quality Action Network also supports the implementation of surgical improvements as well as the clinical care management improvement.

FINANCIAL IMPLICATIONS:

- The Council receives $3 million per year in each year of its renewed three year term (2011/12 to 2013/14).
- The Council received $1.75 million per year in each year of its first three-year term (2008/09 to 2010/11). The increase of $1.25 million per year is required to allow the Council sufficient resources to provide implementation support for the provincial Clinical Care Management initiative.

CONCLUSION:

- The Council has successfully provided leadership in patient safety through collaborative partnerships with health authorities and other health care providers to support system wide improvements.

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MINISTRY OF HEALTH
INFORMATION BRIEFING NOTE

Cliff #: 969177

PREPARED FOR: Honourable Dr. Margaret MacDiarmid, Minister of Heatlh – **FOR INFORMATION**

TITLE: Air Ambulance Audit

PURPOSE: To provide a summary of audit findings regarding the British Columbia Ambulance Service's air ambulance program in advance of the release of a report by the Office of the Auditor General of BC.

BACKGROUND:
In April 2012, the Office of the Auditor General (OAG) began an audit of the air ambulance services provided by the BC Ambulance Service (BCAS) Critical Care Transport (CCT) Program.

The defined scope of the audit was to determine whether the BCAS air ambulance program is providing timely, safe, and quality patient care. More specifically, this involved assessing whether BCAS:

- has and is meeting relevant service standards for quality of care, timeliness, and patient safety; and
- is providing paramedics and aircraft based on an assessment of patient needs.

A final draft of the audit findings were provided by the OAG to BCAS on February 25, 2013. BCAS submitted its formal response to the OAG on Monday, March 4, 2013, and is anticipating release of the audit report by mid-March.

DISCUSSION:
Summary of Audit Findings

The February 25, 2013 draft audit concludes that BCAS is unable to demonstrate whether it is providing timely, quality, and safe patient care through its air ambulance services.

The report notes that, while BCAS has introduced various processes to improve aspects of its service, it has not clearly defined its objectives or tracked relevant standard for quality of care, timeliness, or patient safety. In addition, while BCAS does provide paramedics and aircraft based on its understanding of patient needs, it has not fully assessed whether it has the right paramedics in the right locations to meet patient needs, nor does it adequately review air ambulance dispatch decisions.

The report therefore recommends that BCAS:

- Actively manage the performance of its air ambulance services to achieve desired service standards;
- Periodically review whether the distribution of staff and aircraft is optimal; and,
- Regularly identify and review a sample of air ambulance dispatch decisions to ensure resources are being allocated effectively and efficiently.

BCAS Response

BCAS has accepted the recommendations of the OAG. In its formal response, BCAS highlights that it is working to develop service standards and to improve data collection in order to better monitor performance and make evidence-based changes when required.

BCAS also highlights that it already has a strong foundation to support quality of patient care in its Critical Care Transport Program. This includes:

- A robust medical oversight system which provides critical care paramedics with regular access to critical care intensivist physicians;
- A Patient Care Quality Committee which reviews identified patient safety issues, monitors trends, and recommends changes;
- Opportunities to leverage PHSA infrastructure to support patient safety and quality care, such as the Patient Safety Learning System; and,
- An audit process to review the safety of contracted aircraft providers.

In addition to implementing the OAG's specific recommendations, BCAS is making additional improvements, such as:

- Working with the Air Medical Physicians Association (AMPA) to develop industry-wide quality metrics which will form the basis of a new BCAS performance management system to be implemented in Fall 2013;
- Pursing accreditation by the Canadian Medical Association (CMA) of its Critical Care Transport paramedic training program;
- Further expansion of the Early Fixed Wing Activation Program which provides early notification of an air ambulance aircraft by responding ground paramedics; and,
- Closer integration between BC Bedline and the BCAS Patient Transport Coordination Centre.

ADVICE:
The OAG audit findings focus on enhancements which could be made to the performance monitoring and reporting processes within the BCAS air ambulance program.

BCAS has accepted the OAG recommendations and has been actively working to improve its performance management systems and processes.

Recently introduced legislative amendments will also support BCAS and the Emergency and Health Services Commission in their efforts to improve their performance management system and further embed their philosophy of continuous improvement.

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MINISTRY OF HEALTH
DECISION BRIEFING NOTE

Cliff # 962967 xref 959368

PREPARED FOR: Honourable Dr. Margaret MacDiarmid, Minister of Health
- FOR DECISION

TITLE: Marihuana for Medical Purposes Regulations Briefing

PURPOSE: To brief the Minister on a draft response to proposed regulation changes to the federal marihuana medical access program (date TBD).

BACKGROUND:
Health Canada's current Marihuana Medical Access Program (the Program) and accompanying regulations were implemented in 2001 following court decisions that there must be a constitutionally viable medical exemption to the prohibition against the possession and cultivation of marihuana. As of December 31, 2012, British Columbia had the most federally authorized medical cannabis patients (13,362; 48 percent of Canada; 9,369 for personal use production, 2,232 for designated production, and 1,761 for simple authorizations to possess[1]).

Following consultations to update the Program that began on June 17, 2011, Health Canada published details of its proposed Marihuana for Medical Purposes Regulations on December 15, 2012, with a deadline for feedback due by February 28, 2013 (see http://www.gazette.gc.ca/rp-pr/p1/2012/2012-12-15/html/reg4-eng.html).

The proposed changes are intended to address concerns about the Program such as risk of exploitation by criminal elements; complexity, length and administrative burden of the application process; need for more current medical information for physicians; and public health and safety risks associated with home cannabis cultivation.

Under the proposed changes, planned to take effect on March 31, 2014:

- patients would obtain a document from their health care practitioner (physician, or nurse if provincially authorized), then submit it to a licensed producer to purchase cannabis (or through a pharmacist if provincially authorized);
- patients would no longer be permitted to grow their own cannabis or designate others to grow it, and existing authorizations to produce would be phased out, as the market is expected to provide competitive prices;
- categories of conditions or symptoms needed for authorization, and the specialist consultation requirement that some people had to obtain would be eliminated;
- health care practitioners would no longer be required to make specific declarations with respect to use of cannabis for medical purposes, the effectiveness or appropriateness of other therapies, or the regulatory status of cannabis;
- improved information for health care practitioners would be developed;
- a new secure supply and distribution system for cannabis that uses only licensed commercial producers subject to quality standards would be instituted; and
- health care practitioners would be able to sell cannabis for therapeutic purposes.

[1] Client Services, Bureau of Medical Cannabis, Health Canada, personal communication, email January 23, 2013.

A working group within the Ministry of Health and with other ministries (Justice; Social Development; Community, Sport and Cultural Development; Agriculture; Environment - Climate Action Secretariat) reviewed the proposals and provided feedback.

DISCUSSION:
The consolidated feedback from the inter-ministry working group, which contains many concerns, questions, and recommendations (see Appendices 1-3), is reflective of the very limited federal/provincial/territorial engagement as part of this process. In particular, the proposal for health practitioners to be able to sell cannabis, which is new and was not part of the consultation, is very concerning because of the potential to put practitioners in a conflict of interest position due to the financial incentive of selling. No rationale for this was provided and, as the plan is for patients to be able to obtain their cannabis directly by mail, or through their health care practitioner's office, this seems to be unnecessary. To preserve clinical objectivity and avoid conflict of interest, it is of fundamental importance to separate the selling of "dried marihuana" from the authorization to obtain "dried marihuana", which is given by a medical document provided by a health care practitioner. This concern is shared by the College of Physicians and Surgeons, the College of Registered Nurses, and other provinces and territories.

OPTIONS:

Sect 13

FINANCIAL IMPLICATIONS: Uncertain

RECOMMENDATION: Sect 13

Margaret

Approved / ~~Not Approved~~
Margaret MacDiarmid
Minister of Health

Feb. 25, 2013
Date Signed

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British Columbia response to Health Canada's proposed Marijuana for Medical Purposes Regulation – General Comments

Comments from British Columbia are below, with recommendations indicated by *italics*. A number of these comments have been expressed in the past and some are also mentioned in the "Section Specific Comments" feedback document. We are iterating them here as we feel they have not yet been fully addressed.

Consultation/Collaboration Process

There should be ongoing consultation with provinces and territories regarding further development, implementation, and evaluation of this program.

Program Planning Framework

The program should be described using a program planning framework. This would include articulating the program vision, principles, goals, objectives, and indicators of success, as these elements are foundational to good health care program planning and evaluation. This description is important so that the program aims can be understood, monitored and evaluated. Additional comments related to this recommendation are in the "Performance Measurement and Evaluation Plan Comments" feedback document.

Supports for Health Care Practitioners

The removal of categories of conditions or symptoms will need to be supported with clear information about the indications, contraindications, adverse effects, and interactions, etc., for use of cannabis for therapeutic purposes.

Health Canada has an important role to play in providing health care practitioners with effective and appropriate education and support.

As there are many professional, scientific, and health policy issues being raised by this program we are interested in the work of Expert Advisory Committee that will be providing advice, and whether they will be creating guidelines for health care providers. Outputs of this committee could have important influences on how this program relates to the provincial health care system. *Strong links should be established with national and provincial health care guideline making bodies to support development and dissemination of this information.*

Health Care Practitioners as Gatekeepers

Requiring health care practitioners to act as the gatekeeper imposes a regulatory function on them, which results in them having the responsibility to authorize possession of what is otherwise a prohibited, unregulated substance of variable quality and potency, and with modes of consumption that have not been scientifically evaluated for safety and efficacy. As Health Canada is aware, physicians have many concerns about this role and responsibility which has been and may continue to be rejected by physicians for a variety of reasons, thus impairing access. This role and responsibility could lead to health care practitioners/patient conflicts and health care practitioner conflicts with Health Canada and other regulatory bodies. *We recommend that the appropriate role for physicians with respect to cannabis for therapeutic purposes is as patient advisors rather than as surrogates for regulatory gatekeepers.*

In addition, imposing a role on health care practitioners as the gatekeeper potentially opens their practices to Health Canada scrutiny, which could be a potential additional intrusion in to health care practice.

In summary, Health Canada should not be abdicating their regulatory role in favour of health care practitioners picking up the responsibility to determine access to medical cannabis.

Therefore, we recommend a collaborative exploration of other options to allow access that does not involve imposing requirements on health care practitioners to act as the gatekeepers.

Health Care Practitioners Selling "Dried Marihuana"

We note the proposal that health care practitioners will be authorized, pursuant to sections 124, 126, and 127 of the proposed Marihuana for Medical Purposes Regulation to sell "dried marihuana" for therapeutic purposes. This proposal was not mentioned in the consultation document published June 17, 2011, nor was it mentioned in the only two consultation sessions that Health Canada held with BC.

We have very serious concerns about this authorization to sell due to the potential for putting health care practitioners in a conflict of interest, because practitioner judgement can be influenced by the monetary incentive of both providing the authorization for the product, and then selling the product based on that authorization. To preserve clinical objectivity and avoid conflict of interest it is of fundamental importance to separate the selling of dried marihuana from the authorization to obtain dried marihuana, which is given by a medical document provided by a health care practitioner. Further, as the plan is for patients to be able to obtain their cannabis directly by mail, or through their health care practitioner's office, it seems to be unnecessary to include this option.

Therefore, we are hereby registering our objection to this authorization for health care practitioners to sell "dried marihuana" in the strongest of terms, and we request that this be deleted from the regulation prior to it being finalized.

Product Promotion

We note that "advertising" appears to be allowed in the proposed regulation, yet according to page 14 of the Health Canada impact analysis, "Advertising any narcotic to the general public is prohibited under the NCR." We are concerned about the opportunities for advertising and request clarification on how the regulatory impact analysis statement and the mention of advertising in the regulations are to be reconciled.

One of the most important lessons learned from the commercialization of tobacco and alcohol, and the promotion of opioids for treating non-chronic cancer pain, is that product promotion is a significant driver of consumption and consequent increases in population harms. Therefore, all promotion of cannabis for therapeutic purposes should be prohibited.

Promotion comes in many forms and includes advertising, branding/naming, sponsorship, gifting, product association with film, leading personality recruitment, associating use with attractive activities such as sporting, socialization, sex, and vacations; pricing reductions (i.e. loss leaders); labelling suggestive of pleasure, enhanced performance, over stated benefits; creating similar products for children (i.e. chocolate cigarettes) or youth attractive products (e.g. alcopops, flavoured cigarettes and cigars); and other information presentations suggestive of performance enhancement. *The regulations should be much more explicit about prohibitions on all forms of product promotion.*

Branding is critical to promotion, and once branding is allowed promotion is very difficult to prevent. *Therefore, to prevent promotional activities, branding should not be allowed, and products should only be available in generic packaging.*

Patients Needs/Demands and Related Issues

A description is needed about how patients will receive advice and guidance e.g. indications, contraindications, how to use, options for use, different strains, different preparations, cautions, side effects to watch for and how to manage them. Provision of this level of detailed information will likely be beyond what could be expected to be provided by physicians and may have to be met by other intermediate service providers. *Including intermediate service providers in the regulatory scheme, such as dispensaries with appropriate expertise to meet patient needs, warrants serious consideration.*

Product

We note the lack of access to cannabis in non-smokable forms, i.e., oral mists, liquids, baked products, etc., for patients that prefer alternatives to smoking cannabis. *This program should include production of non-smoked product options to allow of reducing potential harms of smoked products, and to meet patient needs.*

Accommodation for People with Accessibility Challenges

Measures are needed to ensure that this program is accessible for people who have difficulty in accessing public programs, e.g., people with disabilities, disabling medical conditions, communication challenges, low literacy, and geographically isolated people.

Health and Social Services

Guidance documents and other educational resources for health care facilities need to be developed i.e. to address facilities management of requests for smoking cannabis on-site, issues related to home care use (worker exposure - safety and comfort), risk and liability of a facility or worker if they store/handle/administer cannabis.

Conflict of Interest

In order to prevent conflict of interest there should be rules about having financial interest in production operations for those who provide authorization, i.e. health care practitioners. It will be important that those who provide authorizations do not have such a conflict.

General Public and School Based Education

Information about this program developed to meet literacy levels of the general public, and tailored for school communities, should be developed.

Cost Pressures

There is a potentially large unmet demand that could result in increased provincial costs due to paying physicians for medical cannabis-related visits. Although visits to fill out forms are not billable, in practice there could be increased visits to review symptoms which would be billable.

There will be potential pressure for the Ministry of Health to pay physicians for filling out forms.

There will be potential pressure on the Ministry of Health or other ministries to subsidize/cover the costs of cannabis or related drug-delivery products (e.g., vaporizers).

Supply and Distribution Control

The proposed direct producer/retailer to consumer relationship raises the possibility of producers/retailers providing incentives and promoting their products to retain their customers, which could lead to inappropriate practices and promotions of use. This could be mitigated by using an impartial third party as a distributor, as is used for liquor distribution. See also our comments regarding "Product Promotion" and comments regarding the United Nations convention requirements below.

Direct producer/retailer to consumer relationship could also bring up a variety of consumer protection issues and complaints such as false advertising/poor service or product. How will these be resolved or addressed?

Specifically, regarding "pharmacy distribution", BC is not supportive of pharmacists dispensing dried marihuana for medical purposes. Pharmacists dispense drug products that have received a Notice of Compliance (NOC) from Health Canada and that have a product monograph. The NOC indicates that the manufacturer has met Health Canada's regulatory requirements for the safety, efficacy and quality of a product, and the product monograph is intended to provide the necessary information for the safe and effective use of a new drug. Marihuana has not received a NOC and does not have a product monograph. Therefore, pharmacists are unable to provide the necessary information for the safe and effective use of marihuana, and furthermore, pharmacists do not have knowledge and experience in dispensing marihuana.

Addressing Diversion and Security Concerns

The known contributors of criminal abuses of the current Medical Marihuana Access Program are not sufficiently addressed. The security clearance required for licensing does not seem sufficient to address the known possibility of licensed producers being controlled by organized crime. Similarly, the conditions for transportation of the product are not tethered to licensing, and the physical security requirements of the production operations are not clearly delineated thereby creating an opportunity for diversion.

Therefore we recommended the requirement for all employees of production facilities to undergo criminal reference checks by the producer/employer (in addition to key production staff being subject to security clearance by Health Canada – already proposed). Recommendations have also been made for more specific requirements around the transportation of marijuana and the security of growing operations.

Personal and Designated Production Phased Out

Leaving the market to set the price without a personal production option could lead to prices that are too high for some patients, i.e., for low income people or those on disability, and could potentially limit product options. *Addressing the needs of patients with limited financial means warrants consideration.*

Patients could put pressure on BC ministries to pay for marijuana if the market sets the price higher than what they can afford.

Some patients will continue to grow for their own use, which leads to the possibility of criminal sanctions for these people. The combination of removal of personal production and the recent introduction of mandatory minimum sentences related to cannabis could result in increasing the rate of incarceration for people growing cannabis for personal use, and coincidently increased costs and risks to health consequent to incarceration. *We recommend that careful consideration be given to developing measures to mitigate the potential adverse impacts of these changes on patients who are growing their own supply or who are having it grown for them.*

Safety and Security

There are outstanding safety concerns regarding the sites used for commercial production. Consideration for local public safety issues also seem to be underemphasized. More information is needed, particularly with regard to personnel and to safety and security requirements.

Regular audits and inspections by Health Canada (i.e., not just when one applies for or attempts to renew a production license), a schedule of audits/inspections, and clear information on what may be included in an audit/inspection (i.e., physical security of the location, compliance with local bylaw and building codes, access to client and personnel records, access to inventory records) are recommended.

Indoor Production Requirement

This limitation may result in unnecessary greenhouse gas production due to increased energy requirements. *There should be incentives or support for new licensed producers to utilize energy efficient equipment and use clean or renewable energy where possible and to undertake energy efficiency measures in their building. There should be consideration of outdoor growing with appropriate security that meets the program objectives while enabling use of sun energy for product production.*

Any growing facility should be required to maintain (and be regularly inspected against) local building, safety and electrical standards and/or zoning and other bylaws. As well, restrictions should be placed on pesticide use and the facilities should be subject to regular environmental inspections.

Transition Plan

More details are needed about the transition plan, specifically regarding the transition plan for phasing out personal production licenses, i.e., How will existing producers be informed? What may be done to ensure producers are aware of the illegality of continuing to produce marijuana without license? What is the plan to inspect license properties to ensure discontinuation after the license expires? What is the plan to deal with potentially unsafe properties formerly used for medical marijuana production?

Compliance and Enforcement

Legal Possession

As identification of eligible users relies on the possession of a marked container, there is a potential lack of clarity around proof of legal possession for enforcement purposes: once the product is taken from the marked container or the labelling and security of packaging is compromised there is a difficulty with proving a client's legal possession.

The development of a central repository or database in which commercial production facilities would be required to register their clients is recommended. With a 24-hour contact line, this database could be used by law enforcement to confirm legal possession of marijuana. This database can also be checked by producers upon receipt of a new medical document to prevent multiple dispensing to one individual (similar to how PharmaNet can be used by pharmacists).

Information Sharing

Despite the requirement to notify local government, police, and fire of the intention to establish a commercial grow operation at the time of application, the proposed regulation does not give ongoing consideration of these groups in compliance and enforcement activities.

Two-way information sharing between Health Canada and local governments, fire, and police to ensure that any criminal or safety concerns uncovered during inspection are communicated to the relevant body for follow-up is recommended. Additionally, there should be a requirement for producers to show proof of local government permit(s) to Health Canada prior to being given a production license as this would ensure that the production facility is in accordance with local building, safety and electrical standards, and/or zoning or other bylaws would be appropriate.

Compliance with the United Nations Single Convention on Narcotic Drugs

As we understand the *UN Single Convention on Narcotic Drugs* (Articles 28 and 23 2 d. - see below) governments which allow cultivation of cannabis must establish "one or more government agencies...to carry out the functions required under this article.", that "All cultivators of [cannabis] shall be required to deliver their total crops of [cannabis] to the Agency.", that "The Agency shall purchase and take physical possession of such crops...", and that the Agency "shall... have the exclusive right of wholesale trading."

In other words, it appears that the Convention requires that countries which permit cultivation of cannabis must establish a system to manage the cannabis supply that operates in a similar manner to the way provincial alcohol monopolies operate. For example in BC the Liquor Distribution Act mandates the Liquor Distribution Branch to manage the distribution of all BC manufactured and imported liquor, as is similar to other provincial alcohol monopolies.

Our interest in this is that the alcohol regulation evidence indicates that alcohol monopolies help to protect public health from alcohol related harms by inserting additional government control into the relationship between producers, retailers and consumers. We are aware that some tobacco control experts advocate for placing tobacco under a government monopoly type of system (see references below) to protect public health. The Single Conventions requirement for a government cannabis distribution agency does seem to be important from a public health protection point of view, and seems to be required by the UN convention.

As the proposed program does not include an intermediate agency as mandated in the Single Convention Article 23 , we request that Health Canada clearly articulate how it interprets the requirements of the Single Convention, in particular the requirement for a central agency to take possession of the crop prior to distribution, and for it to control cannabis production and distribution, with respect to the Health Canada proposal to license commercial producers that provide cannabis directly to consumers. If the International Narcotics Control Board has commented on the proposed Health Canada model we would request a copy of their comments.

THE SINGLE CONVENTION ON NARCOTIC DRUGS, 1961
(http://www.incb.org/pdf/e/conv/convention_1961_en.pdf)

Article 28
CONTROL OF CANNABIS
1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy.

2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.

3. The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.

Article 23
NATIONAL OPIUM AGENCIES
1. A Party that permits the cultivation of the opium poppy for the production of opium shall establish, if it has not already done so, and maintain, one or more government agencies (hereafter in this article referred to as the Agency) to carry out the functions required under this article.

2. Each such Party shall apply the following provisions to the cultivation of the opium poppy for the production of opium and to opium:

a) The Agency shall designate the areas in which, and the plots of land on which, cultivation of the opium poppy for the purpose of producing opium shall be permitted.

b) Only cultivators licensed by the Agency shall be authorized to engage in such cultivation.

c) Each licence shall specify the extent of the land on which the cultivation is permitted.

d) All cultivators of the opium poppy shall be required to deliver their total crops of opium to the Agency. The Agency shall purchase and take physical possession of such crops as soon as possible, but not later than four months after the end of the harvest.

e) The Agency shall, in respect of opium, have the exclusive right of importing, exporting, wholesale trading and maintaining stocks other than those held by manufacturers of opium alkaloids, medicinal opium or opium preparations. Parties need not extend this exclusive right to medicinal opium and opium preparations.

3. The governmental functions referred to in paragraph 2 shall be discharged by a single government agency if the constitution of the Party concerned permits it.

Tobacco Control Monopoly References

Borland R. A strategy for controlling the marketing of tobacco products: a regulated market model. Tobacco Control 2003;12:374-82.

Callard C, Thompson D, Collishaw N. Curing the addiction to profits: a supply-side approach to phasing out tobacco. Ottawa: Canadian Centre for Policy Alternatives; 2005.

British Columbia response to Health Canada's proposed Marijuana for Medical Purposes Regulation – Section Specific Comments

Note to Health Canada – there are many questions included here to which we request a response.

DEFINITIONS

1. (1) The following definitions apply in these Regulations.

- "brand name" means, with reference to cannabis, the name, in English or French,

  (*a*) that is assigned to it;

  (*b*) that is used to distinguish it; and

  (*c*) under which it is sold or advertised.

- Packaging should be of a generic nature, and branding should not be permitted, as branding enables many forms of product promotion, including advertising. All product promotion should be prohibited. See additional comments in the "Product Promotions" section of the BC "General Comments" document.

POSSESSION

3 (1) (a) and (b) Obtaining dried marijuana and cannabis

- Is this how those transporting marijuana from the producer to the user are able to be in possession of it? If not, how are these individuals legally able to be in possession of it?

3 (2) (b) Possession – Dried Marijuana

A person who requires dried marijuana for their profession

- This section makes it sound as if their job makes them need to use marijuana. Perhaps this could be worded as 'is required to have marijuana in their possession by virtue of their profession and their role in dispersing it.'

3 (2) (b) (ii) Possession – Dried Marijuana

The following persons may possess dried marihuana: a health care practitioner who is registered and entitled to practice in the province in which they have that possession.

- Health care practitioner needs to be defined. Perhaps reference a definition found in another act?
- Will health care practitioners be audited to ensure that marijuana is not being diverted to the illegal market?

3 (3) (b) Possession – Cannabis

- Is possession for individuals in these jobs not already exempt somewhere else? If not, how does this new allowance for legal possession fit with the *Criminal Code of Canada* and the *Controlled Drugs and Substances Act*?

3 (4) and (5) – Employee, Agent or Mandatary

- Mandatary needs to be defined with examples included.

GENERAL PROVISIONS

8 Inspection of Site

- Can licensed producers be inspected at any time? Or only when they are applying, amending or renewing their licence? Will Health Canada be creating a schedule of audits? There need to be regular inspections to ensure ongoing compliance and inspectors should be able to conduct these inspections at any time.
- Will inspections only be conducted based on information reported by the licensee in the information they are required to keep?
- What will a site inspection entail? Can records be inspected (i.e., including client lists, financial records, employee records, etc.)?

PART 1 - LICENSED PRODUCERS

DIVISION 1 - PERMITTED ACTIVITIES AND GENERAL OBLIGATIONS

12 Dwelling Place

- What will be done to inform MMAR production licence holders of the illegality of continuing to produce marijuana?
- What measures will be put in place to deal with those who continue to produce as if their MMAR licences were still valid?
- Will inspections be conducted to ensure discontinuation of production after the licence expires and to establish the safety of the premises that is no longer to be used for production?
- Additionally, regulations should specify that a licenced production facility cannot be located in close proximity to a school, daycare or playground.

15 Identification of Licensed Producer

"A licensed producer must include their name, as set out in their licence, on all the means by which the producer identifies themself in relation to cannabis, including advertising, product labels, orders, shipping documents and invoices."

- "Themself" should say "themselves".
- This section refers to "advertising". According to the *"Packaging and Labelling"* section of the Health Canada Regulatory Impact Analysis Statement, "Advertising any narcotic to the general public is prohibited under the NCR." BC recommends that all advertising be prohibited. See our more detailed comments in the Product Promotion section of our General Comments document.

18 Safekeeping during Transportation

- If the producer is liable for the safety of the shipments how liable is the company that is transporting the marijuana? How liable is the producer if the shipment is lost or stolen?
- When they say "a licenced producer must, when transporting" does it mean that the licenced producer transports the marijuana themselves. If so, what if the marijuana is transported by another company?
- The licensee should be accountable for the care and control of the drug for as long as possible and/or appropriate. This accountability should be tied to the licence and infractions in this regard should have sanctions – it would be far too easy to allow diversion of the product while in transit.

19 Report of loss or theft

- This relies on self reporting. If a licensee chooses to not report the loss, how will Health Canada know?
- What are the consequences to the licensee if cannabis is lost or stolen? Is there a reason the licensee may choose to not report the loss?

20 (3) (a) Witness to destruction

- Who is the senior person in charge? Will it be a person working for the producer? The producer themselves?

DIVISION 2 - LICENSING

21 Eligible persons

- Does it matter that the age of "adult" varies from province to province?

23 Notice to local authorities

- Health Canada will receive a copy of the letter, but how will they ensure that the letter has been sent and received by the local authority? Local authorities should be contacted by Health Canada to ensure that not only are they aware of the application but also that they approve of the presence of that business and its location within their community.
- Licensees should be required to show permits from local authorities proving compliance with local requirements before they are granted a licence. For example, there could be a two step process: (1) applicants apply to Health Canada and are given tentative approval to begin setting up a commercial production facility and then (2) applicants conform to Health Canada and local authority requirements, are inspected for compliance, and then have their licence issued.
- Local authorities should be informed by Health Canada when licence infractions are found during an inspection so that the local authorities may conduct additional inspections as they see fit.
- How does Health Canada plan to respond to concerns voiced by local authorities about specific licenced production operations?

24 (1) (a) (i) Application for licence

"To apply for a producer's licence, a person must submit to the Minister an application that contains the following information: if the applicant is an individual, the individual's name, date of birth and gender and any other name registered with a province, under which the individual intends to identify themself or conduct the activities for which the licence is sought (referred to in this section as "the proposed activities")".

- "Themself" should say "themselves".

24 (5) Method of keeping records

- Additional information needs to be given (e.g., how often audits may occur, what the scope of the audit may include? (i.e., site inspections and access to records).

25 Security clearance required

- •All staff of the licenced producer should be subject to records checks by the employer and the "key personnel" should be subject to a more in-depth security clearance by Health Canada.
- Are these clearances sufficient to address the possibility of licenced production operation being controlled by organized crime?

26 (h) and (i) Issuance of licence

- When would it be applicable to place a maximum quantity produced, sold, and/or provided on a licence and when would it not? Presumably the maximum quantity would be tied to the security requirements for the facility and therefore a maximum amount should be specified on all licences.

27 (1) (f) and (i) Grounds for refusal

The Minister must refuse to issue, renew or amend a producer's licence in the following cases: the applicant does not have in place the security measures set out in the Security Directive and Division 3 in respect of an activity for which the licence is requested and any of the following persons does not hold a security clearance.

- The Security Directive only mentions cannabis sativa, its preparations, derivatives, and similar synthetic preparations. What about Marijuana?
- Considerations for electrical safety and ground water contamination may be regulated by other levels of government, but perhaps there should be recognition that these other considerations should be met?
- "following persons does not" should say "following persons do not."

27 (2) Grounds for refusal

- How will an individual be expected to correct having contravened an act or regulation?

29 (1) Application for renewal

- Would it be appropriate to suggest that licenses be issued with conditions on them and that the conditions could be added to if certain breaches were observed. This would offer more flexible governance and would also require Health Canada to monitor the process between issuance and cancellation or expiry of licenses. It seems that a licensee can apply for an amended license but can the Minister impose conditions after a license is issued on his/her own accord? I.e., can the Minister amend a license based on interim/spot inspection (if those may be conducted)?

33 (1) (c) Notice to Minister – various changes

- Changes to site security should be approved first: producers may not be sufficiently knowledgeable about physical security to determine whether or not their change affects the security level of the production facility.

37 (1) (e) Revocation – other grounds

Subject to subsection (2), the Minister must revoke a producer's licence in the following circumstances: information received from a peace officer, a competent authority or the United Nations raises

reasonable grounds to believe that the licensed producer has been involved in the diversion of a controlled substance or precursor to an illicit market or use.

- This is a fundamental section for law enforcement. Will this be elaborated on in policy or procedure? For example, what will constitute "reasonable grounds"? Is this a potential link to enforcement under *the Controlled Drugs and Substances Act* and where individuals use this legislation to circumvent the *Controlled Drugs and Substances Act*?
- Can the Minister amend a license (for example, a producer may be required to let go of certain staff members if organized crime links are found or otherwise face suspension of the licence)?

37 (2) Revocation – exceptions

- How is an individual expected to correct having contravened an act or regulation?

38 (1) Suspension

- Are there circumstances (e.g., lack of compliance with some administrative requirements) that should also lead to the suspension of a licence?
- Do individuals have an opportunity to make corrections based on the outcome of audits or is their licence suspended immediately before they can make changes?
- What does suspension entail? Does it mean licensees don't ship marijuana to their clients? Do they keep growing? Do they continue to have access to the facility? Presumably they cannot continue to function as normal. If this causes an interruption in the supply, what happens to the clients who are expecting their next shipment and don't receive it? Do those clients have to get another medical document and find another producer and get set up and wait for it to be shipped before they could get their prescribed amount of marijuana? This seems contrary to HC's intended outcome of ensuring access.

38 (3) Opportunity to be heard

- Once a licence is suspended, what happens to the plants? Does the licensee have to stop tending them? If so, what happens if their licence is given back but their plants died from lack of care?

DIVISION 3 - SECURITY MEASURES

This section is too light on safety issues related to production. Could another section be added to cover the physical safety hazards of production facilities? MMPR should specifically require that applicants ensure that production facilities comply with all federal, provincial and municipal legislation, regulation and bylaw relating to building safety, health, fire, electrical, environmental and air quality standards.

41 (1) and (2) Restricted Access

- What activities must occur in "restricted areas"?

DIVISION 4 - GOOD PRODUCTION PRACTICES

48 Microbial and chemical content

- Set restrictions on pesticide and fertilizer usage and require regular environmental inspections.

53 Recall

- This is broad and could be interpreted in many ways. Will there be policy outlining what this entails?

57 Adverse Reactions

- This should include a provision that any information obtained by the Minister pursuant to this section may be shared with a provincial or territorial government and health care practitioner regulatory licensing body of the jurisdiction in which the adverse reaction happened.

DIVISION 5 - PACKAGING, LABELLING AND SHIPPING

61 (a) Client label

- Is there any concern that without the packaging law enforcement may not be able to confirm whether or not an individual is a registered user? What will happen if police stop an individual for using their prescription and that individual – though legally allowed to possess – is unable to prove they are in legal possession?

63 Department of Health Document

- To save on paper, printing, and associated costs and consumption of environmental resources perhaps recipients should be given the option of receiving the information electronically, or waiving the requirement to receive the document with every shipment.

64 Presentation of information — label

- Is forgery of labels a concern?

66 Reference to Act or regulations

- This section refers to "advertisements". According to the *"Packaging and Labelling"* section of the Health Canada Regulatory Impact Analysis Statement, "Advertising any narcotic to the general public is prohibited under the NCR." BC recommends that all advertising be prohibited. See our more detailed comments in the "Product Promotion" section of the BC "General Comments" document.

67 Shipping

- Is there a concern that the contents of the packages could still be identified because the return address of the licensee will be on the package and all licensee addresses will be published on the internet? Safekeeping needs to be defined. What would be considered "safekeeping" and who will be responsible for the shipment during transit?
- The licensee should be accountable for the care and control of the drug for as long as possible and/or appropriate. This accountability should be tied to the licence and infractions in this regard

should have sanctions – it would be far too easy to allow diversion of the product after it leaves the facility in which it is produced.

DIVISION 7 - SECURITY CLEARANCES

- Greater clarity needs to be given on what security clearances entail. Is this only a criminal record check? If so, that is only a criminal record check and not a security clearance. Will background checks also be conducted?
- All staff of the licenced producer should be subject to records checks by the employer with "key personnel" subject to more in-depth security clearance by Health Canada.

84 Checks and verifications

- This may be a significant power for police agencies to influence the licensing process where it is determined that an applicant may pose a security risk through direct or indirect links to organized crime. Will the role of law enforcement agencies need to be clarified under this section?

85 (c) Minister's decisions

- Would an individual's financial state possibly factor into an assessment of "whether there are reasonable grounds to suspect that the applicant is in a position in which there is a risk that they be induced to commit an act or to assist or abet any person to commit an act that might constitute a risk to the integrity of the control of the production and distribution of cannabis"? If so, should a financial check of key personnel be conducted?

DIVISION 8 - COMMUNICATION OF INFORMATION

94 Information concerning registered clients

- If this is not a 24/7 service provided by licensees, how will law enforcement be able to confirm whether or not an individual is legally allowed to be in possession of marijuana if they need to make the inquiry outside of business hours?

94 (3) Use of information

- This assumes that police have a degree of authority under this Act. If so, where are the provisions outlining their authority?

96 Information concerning licensed producers

- Would contraventions here move the case into the realm of the *Controlled Drugs and Substances Act*?

98 Providing information to foreign organizations

- Is this akin to providing information to the DEA, FBI, or Homeland Security? Will this compromise the security or ability of producers to travel internationally?

101 Security clearance – law enforcement agency

- The information needs to flow both ways between Health Canada and law enforcement, not just from law enforcement to Health Canada (i.e., for relevant infractions found during inspections or any other time).

- Will the Minister be able to act on information from other local authorities (i.e., fire or local government)? Also, Health Canada should inform local government/fire if inspections suggest that a production facility may not be compliant with building codes.

PART 2 - REGISTRATION AND ORDERING REGISTRATION

103 Registration application

- Will there be a central repository for this information that will be used by all licensees to coordinate service and to track clients' prescriptions? This would assist police in requesting information on who is legally entitled to possess marijuana as well as provide a method to prevent individuals from "double dipping" as PharmaNet currently does for prescription drugs.

103 (1) (b) (ii) Registration application

If the applicant ordinarily resides in Canada but has no dwelling-place, the address, as well as, if applicable, the telephone number, facsimile number and email address of a t;

- In the case that a package is delivered to a shelter, hostel or similar institution that provides food, lodging or other social services to the applicant, who will ensure the security of the package as it waits to be picked up? These are not secure locations and the possibility that there is more than one person having their marijuana stored at a particular location makes it a more likely target for theft.

103 (1) (f) (iii) Registration application

- If Health Canada no longer reviews use applications what is to stop someone from ordering the marijuana and selling it? In this instance the medical document is written by and the marijuana is shipped to the same person.

103 (5) Homeless applicant

- What prevents shelters, hostels or similar institutions from becoming illegal selling/distribution points? Individuals with no security clearance would be in possession of the substance and there are no security requirements at these locations. Additionally, individuals keeping the marijuana for the user would not have a maximum amount that they are allowed to possess at one time.

105. Verification of medical document

- If Health Canada is not keeping track of individual users, what is to stop individuals from going to different doctors and getting multiple medical authorizations and then going to different producers and thus obtaining more than the legally allowed amount of marijuana? There should be a database of information used by all licensees so that applications can be cross-referenced.
- This verification process could result in significant requirements for paper work for health care practitioners. We request additional details on how this process is anticipated to work in order to minimize administrative burden on health care practitioners.

118 Shipping

- This seems to preclude shipments to pharmacists or other intermediaries for provision to the client? Does this section preclude shipping to pharmacies?

119 (1) (d) Refusal

A licensed producer must refuse to fill an order referred to in section 117 if the order has been previously filled in whole or in part.

- This seems to mean that a registered client can't receive the rest of their prescription if they've received part of it earlier?
- What would happen if the user lost their prescribed quantity of marijuana?

PART 3 - REGISTERED CLIENTS AND OTHER AUTHORIZED USERS

122 Prohibition — obtaining from more than one source

- What are the sanctions related to this prohibition?
- If it is not prohibited or unusual for an individual to have more than one medical document, what prevents individuals from obtaining multiple documents and then getting more than they would otherwise be allowed?

123 (3) Return to licensed producer

- Who is responsible for the security of the package when a registered client returns dried marijuana to the licenced producer?

PART 4 - HEALTH CARE PRACTITIONERS

124 Authorized activities

- BC objects to the authorization for health care practitioners to sell "dried marihuana" in this section, as well as sections 126 and 127 in the strongest of terms, and we request that this authorization to sell be deleted from the regulation. See our more detailed comments in the BC "General Comments" document.
- If a medical practitioner can provide a medical document, obtain marijuana from an authorized source, and sell, provide or administer dried marijuana, are medical practitioners audited to ensure marijuana is not diverted.
- If Health Canada no longer reviews applications, what is to prevent a medical practitioner from ordering marijuana for fictitious persons and then selling it?

126 Labelling of dried marihuana

- Is there any concern regarding the use of discarded or stolen medical marijuana packages to hide illegal marijuana possession?

PART 5 - SALE OR PROVISION BY A LICENSED PRODUCER TO A PERSON OTHER THAN A REGISTERED CLIENT

128 (2) (a) Order required — dried marihuana

- Are hospitals, pharmacists and health care practitioners that distribute marijuana to users subject to audits? If so, where in the MMPR does it say that individuals and organizations (other than licensed producers) that distribute marijuana to users can be audited by Health Canada?

128 (4) Signature

"A licensed producer must verify in a reasonable manner the identity of the person who placed the order if the signature on the order is not known to the producer."

- The signature for comparison is provided as part of the application (per 103 (3)), but how qualified is the licenced producer to do a signature comparison? And if the signature doesn't match, what is a "reasonable manner" to verify identity?

PART 6 - RECORD KEEPING BY LICENSED PRODUCERS

- Are these records to be stored in a secure location to prevent alteration?
- What does the licensed producer do with the records? Do they send the records to Health Canada? Can they be required to show records to Health Canada, if requested, during inspections? Are they required to report out on any of this information?

PRODUCTION AND INVENTORY

141 (2) Destroyed Cannabis

"A licensed producer must keep, for each instance in which they destroy cannabis, a statement signed and dated by each of the witnesses referred to in paragraph 20(2) (b) stating that they have witnessed the destruction and that the cannabis was destroyed in accordance with section 20."

- This should say "witnessed the destruction of x weight" so that it is clear in the records that the witness saw destroyed all the marijuana that was reported as destroyed.

GENERAL OBLIGATIONS

144 Information required by Minister

- Who will ensure that the licenced producer is not growing too many plants? How does Health Canada plan to ensure compliance?
- This should include a provision that any information obtained by the Minister pursuant to this section may be shared with a provincial or territorial government.

British Columbia Response to Health Canada's proposed Marijuana for Medical Purposes Regulation

Performance Measurement and Evaluation Plan Comments

The lack of a program planning framework mentioned in our General Comments document has resulted in some important gaps in the evaluation plan. To reiterate, a comprehensive program planning framework would include clear articulation the program vision, principles, all of the goals, objectives, and indicators of success. Describing these elements is foundational to good health care program planning and evaluation. This description is important so that the program aims can be understood, monitored and evaluated.

For example, there is a lack of objectives with regards to creating access to cannabis for patients, including no definition of access, no assessment of the current level of access, and no objectives with respect to how the proposed changes are designed to improve patients' access.

Other program areas needing goals, objectives and outcomes include:

- Effects on patients' health of e.g. What health improvements are anticipated as outcomes of the program? What adverse health events for patients are of concern? How are the benefits and adverse events being monitored?
- Patient satisfaction
- Affordability for patients
- Health care provider knowledge, attitudes, competency and behaviours with respect to advising and recommending cannabis for therapeutic purposes
- Health care provider participation in the program
- Public knowledge about the risks and benefits of cannabis for therapeutic purposes
- How well the commercial supply meets patient needs
- Unintended benefits of the program such as reduced prescription medication use or reduced health care utilization.

Surveys of the authorized patients and authorizing providers should be done to monitor the implementation of the program with respect to the issue mentioned above.

We note that the evaluation plan does not include indicators to help understand the population for which this program is intended e.g. regular population based surveys should be done to measure populations rates of use of cannabis for therapeutic purposes, with collection of information such that analysis could be done by age, gender, geography, reason for use, duration of use, and beneficial and adverse effects.

We note that there are no plans to evaluate the health and social impacts of the changes on patients who rely on growing their own supply, or having their supply grown for them, the undesirable consequences of prior license holders continuing to grow such as justice system encounters for previously licensed growers who continue to grow, and consequences such as fines and incarceration of patients who continue to grow.

As part of the evaluation plan we would have expected to see dedicated funding for research as this is a substantially new and untested program.

We recommend that Health Canada report annually with regards to the implementation of this new program.

Expected Result / Output	Performance Indicator	Data Source	Frequency of Data Collection	Target*	Date to Achieve Target**	Responsible for data collection
Outputs						
O1. Information e.g guides, fact sheets, web content; responses to enquiries via telephone, fax, mail, email, etc.	-Number of information/ publication materials produced / year	Clients services and internal administrative data	Quarterly	Target number to be set after base year	Target to be achieved by Year V	OCS
O2.New/renewed/amended Licences; Import/Export permits; licence refusal , notices, etc.	-Number of licences and permits issued/renewed / amended per year; -Percent of applications processed within Service Standard per year	Internal Health Canada records/ operational data	Annually	Target to be set after Service Standard determined in base year	Target to be achieved by Year V	OCS
O3. Inspection/ audit reports, follow-up letters, suspension and revocation notices, events, etc.	-Percent of inspection/ audit reports completed/year out of total planned	internal Health Canada records/ operational data	Annually	Target completion rates to be set after base year	Target to be achieved by Year V	OCS
Immediate Outcomes						

Comment [A1]: How does the number of materials produced say anything about how effective these materials are? Perhaps how many individuals/organizations took these materials and how many they took? But even then it doesn't really speak to how helpful they are.

Comment [t2]: How many information publications are they planning to have each year? Once the initial information sheets are made, are more necessary each year? This is only relevant to 1st year. Timeliness to public inquiries should be tracked in 1st and future years.

Comment [t3]: This is just an output measure that does not indicate success. Suggest collecting number of users served by license holders in addition to this.

S1. Stakeholders are aware of regulatory provisions for access	-Level of stakeholder awareness of access provisions -Number of web hits/month -Number of enquiries (calls, emails) for information per year	-Proxy data (e.g. licence application, licence producer records); -HC website statistics	Annually	Targets to be set with reference to base year levels	Target to be achieved by Year V	OCS/OPSP
S2. Licensed producers set up, produce and distribute marihuana	-Number of active licensed producers /month -Percent of licensed producers licensed to grow / distribute per year	Internal HC administrative data; Inspection reports;	Quarterly	Target to be set after base year	Target to be achieved by Year V	OCS

Comment [b4]: There should be objectives about provider knowledge, attitudes, behaviour and participation rates with respect to advising and recommending medical documents.

Comment [A5]: Is a large number of enquiries a good thing because it shows many people were educated this way? Or is a large number bad because it shows that many people didn't understand and needed to phone in for information?

Expected Result / Output	**Performance Indicator**	**Data Source**	**Frequency of Data Collection**	**Target***	**Date to Achieve Target****	**Responsible for data collection**
S3. Licensed Producers aware of and comply with regulatory requirements	-Proportion of licence producers compliant with health/safety and security requirements/year -Number of licences suspended or revoked/year -Number of product recalls/ year reported to Health Canada by licensed producers	Inspection and audit reports; Other internal administrative internal data;	Annual	95% compliance with health and safety requirements.	Target to be achieved by Year V	OCS/RAPB
Intermediate Outcomes						

Comment [t6]: What would this be audited against? Relevant building/electrical code? Where are they health and safety requirements compiled and maintained?

Comment [A7]: Numbers should be included on: (1) how many licensees fix things and become compliant after an audit and (2) what kind of things licensees lose their licence for and how many of each kind of thing

M1. Regulated market has adequate capacity to maintain reasonable access to legal supply of marihuana	- Trend in volume of products (by weight) sold by licensed producers/quarter - Trend in registered licensed producers' clientele/quarter -Trend in number of active licensed producers; participating authorized health care practitioner/year	Licence producer records; Inspection/ audit reports Other internal Health Canada administrative data	Annual	Trend in products sold consistent with trend in registered clientele	Target to be achieved by Year V	OCS
M2. Quality-controlled marihuana produced in Health Canada-licensed and inspected facilities	- Trend in proportion of licence producers compliant with health/safety and security requirements/year - Trend in number of product recalls reported to Health Canada/ year by licensed producers	In-house reports and internal administrative data	Annual	See Target under S3	Target to be achieved by Year V	OCS
M3. Marihuana for medical purposes securely produced and distributed	- Proportion (and trend) of licence revocations/suspensions related to security	Internal Health Canada administrative data	Annual	See Target under S3	Target to be achieved by Year V	OCS

Comment [b8]: Reasonable access needs to be defined. Objectives with regards to access should be established.

Comment [A9]: Will anyone be keeping track of what amount of marijuana people are being prescribed?

Comment [A10]: Data should be collected on theft. E.g., at what stage in the process it occurs, how it occurs, quantities stolen.

Pages 43 through 44 redacted for the following reasons:
- -
Sect 13

MINISTRY OF HEALTH
DECISION BRIEFING NOTE

Cliff # 950039

PREPARED FOR: Honourable Dr. Margaret MacDiarmid, Minister of Health
- FOR DECISION

TITLE: Preventing Fetal Alcohol Spectrum Disorder Through Alcohol Warning Labeling

PURPOSE: To decide a course of action for funds currently available for Alcohol Warning Labeling for Fetal Alcohol Spectrum Disorder (FASD) prevention in British Columbia.

BACKGROUND:
Prenatal alcohol exposure presents a risk to the fetus resulting in FASD, the most common preventable developmental disability in Canada, affecting approximately 9 in every 1,000 infants[1]. The annual cost of FASD to Canada is estimated at $7.6 billion[2]. The total direct lifetime cost per person is estimated at $1.8 million.

As part of the *Next Wave of Prevention*, the previous Minister of Health, Honourable Michael de Jong, QC, allocated $450,000 for implementation of Alcohol Warning Labeling (labeling) as one component of a comprehensive approach to FASD prevention.

The subject of warning labeling on alcoholic beverages has been debated nationally and internationally. In Canada, labeling on alcohol beverages by the manufacturer (pre-market) requires federal approval (*Canada Food and Drug Act*). Several past attempts at legislating labeling were rejected amid pressure from the alcohol industry. After-market (point of sale) labeling requiring liquor stores to include warning labels on wine, spirits and packaged beers falls under provincial jurisdiction. In 1991, Yukon and the Northwest Territories implemented after-market labeling, but they have not evaluated it to determine the impact on consumption behaviour.

Recently, the National Alcohol Strategy Advisory Committee, a multi-sector group which includes the alcohol industry and Health Canada, agreed to explore standard drink labeling in Canada. This would enable consumers to understand the quantity of alcohol contained in a standard drink container and to make informed choices regarding abstaining from or reducing their drinking based on the Canadian Low-Risk Alcohol Drinking Guidelines.

DISCUSSION:
A jurisdictional scan and evidence review was commissioned to determine the impact of labeling on alcohol consumption. The review found that while labeling increases knowledge and awareness, it does not decrease alcohol consumption among moderate to high-risk drinkers (Appendix A).

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[1] Thanh NX., & Jonsson E. (Winter 2009). Costs of fetal alcohol spectrum disorder in Alberta, Canada. *Canadian Journal Clinical Pharmacology. 16*(1): e80-90. Epub 2009 Jan 16.

Other potential options include building upon existing provincial initiatives to ensure a more comprehensive approach to FASD prevention. This could include enhancing primary care providers' and other health and social service professionals' capacity to counsel girls and women on responsible alcohol use and alcohol related harms, including FASD.

The development of age- and gender-appropriate messages to engage clients, promotion of existing screening tools and resources, and brief intervention training, all of which have been shown to decrease alcohol consumption, would be included (Appendix B). A third option is to enhance First Nations and Aboriginal FASD services and supports for prenatal, perinatal, and postnatal women and their families.

OPTIONS:

OPTION 1: Sect 13

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OPTION 2: Enhance primary care providers' and other health and social service professionals' capacity to counsel girls and women on the responsible use of alcohol and alcohol related harms.

Pros:

- Brief Intervention therapy counseling by health care providers is an effective strategy for reducing alcohol consumption.
- Maximizes the uptake of existing tools and resources including alcohol screening tools for physicians and other providers.
- Short term work, consistent with one-time funding.

Cons:

- Is not consistent with the previous Minister of Health's direction.

OPTION 3: Sect 13

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FINANCIAL IMPLICATIONS:

One-time funds of $450,000 is available for FASD initiatives. Sect 17 has been used to complete a jurisdictional scan and evidence review on labeling.

RECOMMENDATION:

OPTION 2: Enhance primary care providers' and other health and social service professionals' capacity to counsel girls and women on the responsible use of alcohol and alcohol related harms. In addition, we have included a culturally appropriate First Nations/Aboriginal component.

Margaret

Approved/~~Not Approved~~
Margaret MacDiarmid
Minister

25. Feb. 2013
Date Signed

Program ADM/Division:	Arlene Paton, Population and Public Health
Telephone:	250 952-1731
Program Contact (for content):	Joan Geber, Executive Director, Healthy Women, Children and Youth Secretariat, 250 952-3678
Drafter:	Teresa Chiesa
Date:	December 7, 2012
File Name with Path:	S

Appendix A -Environmental Scan on Alcohol Warning Labels and FASD Prevention

A. How is alcohol use in pregnancy prevented?

FASD is reduced when multilevel approaches that mutually reinforce each other are in place. Multilevel approaches include alcohol policy strategies and awareness campaigns, but also include strategies that assist women at various levels of risk of drinking in pregnancy and postpartum with tailored and targeted assistance.

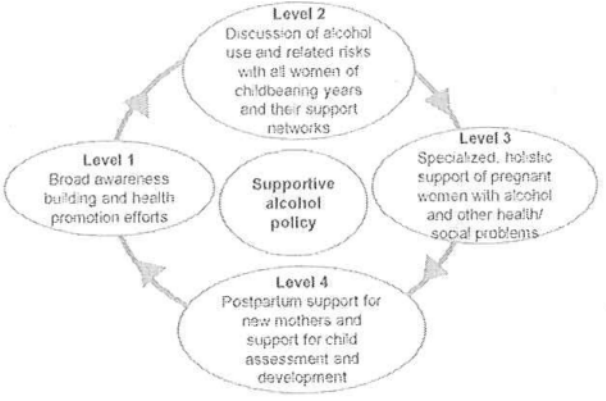

Diagram of multilevel approaches based on Poole, N. (2008). *Fetal Alcohol Spectrum Disorder (FASD) Prevention: Canadian Perspectives*. Ottawa, ON: Public Health Agency of Canada

B. Who is at risk of drinking alcohol in pregnancy?

Three age-related groups of women of childbearing years (underage, 19-24 years and 25-34 years) are drinking at risky levels and are at risk of drinking in pregnancy, either prior to realizing they are pregnant or throughout pregnancy. There is a statistically significant ($p > 0.05$) increase in rates of drinking 5+ drinks/sitting *once a month or more* since 2003 for **underage girls** and **women ages 25-34**. Rates of monthly or more often risky drinking are highest among **young adult women** peaking at just under 35 percent for women in this age group. The total percent of women drinking at **moderate and high risk levels** is 58 percent for young adults and 45 percent for women ages 25-34, and these women account for approximately 80 percent of all live births in Canada.

C. The evidence for labeling

There is little or no evidence that alcohol warning labeling (labeling) alone is able to significantly change consumer judgments and values about the risks of alcohol. In a meta-analysis of health warning labels, Argo and Main concluded that while the labels on most products were easy to read and understand, the majority of consumers did not read them[1]. Several studies suggest that awareness of labeling is not necessarily associated with shifts in alcohol consumption. In one of the best designed studies of the effects of labeling on behaviour, Greenfield, Graves and Kaskutas failed to find associations between increased awareness of warning labels and changes in drinking behaviour in repeated large-scale, cross-sectional national surveys of the US[2]. A study by Hankin et al found that exposure to warning messages by heavy drinking pregnant women attending an antenatal clinic had no significant effect[3].

Although universal interventions such as public service messages and alcohol warning labels on their own have not been shown to reduce the risky consumption of alcohol by pregnant women,

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[1] Argo, J. & Main, K. (2004), "Meta-Analyses of the effectiveness of warning labels," *Journal of public policy & marketing, 23*(2):193-208.

[2] Greenfield, T., Graves, K., & Kaskutas, L. (1999). Long-term effects of alcohol warning labels: Findings from a comparison of the United States and Ontario, Canada. *Psychology & marketing, 16*(3):261-261.

[3] Hankin, J., Firestone, I., Sloan, J., Ager, J., et al. (1993). The impact of the alcohol warning label on drinking during pregnancy. *Journal of public policy & marketing, 12*(1):10-10.

research suggests that when combined and integrated with other educational, policy and programmatic initiatives, labeling can help shift social norms to reduce risks[4].

[4] Babor, T., Caetano, R., Casswell, S., Edwards, G., Giesbrecht, N., Graham, K., et al. (2010). *Alcohol: No ordinary commodity, Research and public policy,* (2nd edition). New York: Oxford University Press.

Appendix B - Brief intervention therapy: Enhancing primary care providers and other health and social service professionals' capacity to counsel girls and women on the responsible use of alcohol and alcohol related harms.

BACKGROUND:

FASD is reduced when mutually reinforcing multilevel approaches and strategies that assist women at various levels of risk of drinking in pregnancy and postpartum are provided with tailored and targeted assistance. Research has shown that brief intervention therapy by primary care providers has a significant influence on behaviour change. Brief intervention therapy is an early intervention and prevention approach used by primary care providers and other health and social service professionals.

A study by Chang et al found that brief intervention was significantly related to decreased alcohol use during pregnancy, particularly among women who consumed more alcohol[1]. In 2010, a BC Ministry of Health survey found that less than two percent of the total female population reported that their health care provider talked to them about the effect of alcohol use on conception and/or pregnancy[2].

Building the capacity and confidence of primary care providers and other health and social service professionals to counsel girls and women on the impacts of alcohol across the lifespan, through brief intervention therapy and provision of consistent, targeted messaging, is an effective strategy to impact behaviour change. Brief Intervention Therapy enables them to support girls and women through a holistic and engaging approach, using a solution focused model while setting achievable goals with the girls and women, enabling them to recognise the strengths and resources they already have. These approaches help girls and women to change their behaviour regarding alcohol use across the lifespan thereby offering a significant cost savings to BC's health care system, not only through prevention of FASD, but also through prevention of alcohol-linked long term problems, such as cardiovascular disease and some cancers.

Gender-specific, culturally-sensitive and evidence-based tools available to public and primary care providers to counsel girls and women include:

1. the BC Medical Association and Ministry of Health problem drinking guidelines;
2. the Screening, Brief Intervention and Referral resource produced by the Canadian Centre on Substance Abuse and the College of Family Physicians of Canada;
3. the Society of Obstetricians and Gynecologist Alcohol Use and Pregnancy Consensus Clinical Guidelines;
4. the *Healthy Choices in Pregnancy* Women and alcohol resources; and the Low Risk Alcohol Drinking Guidelines; and
5. the Canadian Low Risk Alcohol Drinking Guidelines.

As part of the BC Healthy Families, Healthy Eating program, a new tool that creates fact sheets is being developed. This functionality can be leveraged for the creation of fact sheets for care providers to tailor "alcohol and your health" messaging specific to the target population and provide a handout based on the client's needs. Messages would be evidence-informed and built on existing messages from other jurisdictions across Canada, for use with girls and women, including First Nations and Aboriginal women. Messages would span across the reproductive lifetime to ensure that public and primary care providers provide consistent messaging to help girls and women understand the effect of alcohol on their health.

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[1] Chang, G., McNamara, T., Orav, E.J., Koby, D., Lavigne, A., Ludman, B., Vincitorio, N.A., & Wilkins-Haug, L. (2005). Brief intervention for prenatal alcohol use: A randomized trial. *American Journal of Obstetrics and Gynecology*, 105(5-1), 991-998.

[2] Healthy Choices in Pregnancy: results from the Community Health Education and Social Services Omnibus Survey in British Columbia, April 2008 to March 2009 Final Report.

Finally, resources could be set aside to allow for an evaluation of these FASD prevention interventions. Evaluation allows the Ministry of Health to understand the uptake and effectiveness of the FASD initiatives.

The project was originally provided $450,000. An initial investment [redacted] was spent preparing a review to inform decision making. It is proposed that the remainin[redacted] funding augment FASD prevention by enhancing primary care providers' and other health and social service professionals' capacity to counsel girls and women on the effects of alcohol. The proposed budget is as follows:

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1	Jurisdicational Scan & Evidence Review: a contract to conduct a jurisdictional scan and evidence review paper on labeling was prepared to ensure MoH direction in this area is evidence-informed. (Deliverable received)
2	Targeted message development: developing "alcohol and your health" evidence-informed messaging built on existing messages in other jurisdictions across Canada for use with girls and women, including First Nations and Aboriginal women, in BC. Messages would span across a woman's lifetime to ensure that primary care providers and other health and social service professionals ensure consistent messaging to help women understand the effects of alcohol on their health.
3	Fact sheet development for target populations based on "alcohol and your health" messages (refer to #2): This initiative leverages the Healthy Families, Healthy Eating program fact sheet functionality which allows care providers to tailor the messaging to specific target populations and provide a handout to individuals or groups based on the client's needs.
4	Best Practice Review for First Nations/Aboriginal (FNA) women: establishing best practices with FNA women will include a jurisdictional scan of current evidence-informed messaging and resources available in Canada and the US, and best practices for primary care providers and other health and social service professionals working on FASD prevention with FNA women across Canada and the US. Community consultations with First Nations and Aboriginal women will assist to validate findings, messages and methodologies for FASD prevention.
5	Accredited brief intervention therapy training for primary care providers and other health and social service professionals: all primary care providers and other health and social service professionals in BC will be offered accredited online BIT training program to assist girls and women in understanding their health, the impact of alcohol on women in childbearing years and the fetus, and to make positive behaviour changes necessary for health improvement. Fundamental to this role is building their confidence and capacity to counsel girls and women across the lifespan regarding alcohol related harms.
6	Implementation and Evaluation: This includes three key components. 1. An implementation plan for the FASD prevention interventions undertaken. 2. An evaluation framework and monitoring plan to understand the utilization and practice changes as a result of the initiatives and to evaluate the broader progress in the area of FASD prevention (based on the related objectives in the

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	FASD 10 year plan). 3. A report on progress in the area of FASD prevention against the 10 year plan.	
	Total	$450,000

MINISTRY OF HEALTH
INFORMATION BRIEFING NOTE

Cliff #: 959418

PREPARED FOR - Honourable Dr. Margaret MacDiarmid, Minister of Health **-**
FOR INFORMATION

TITLE: Tobacco Sales in Stores that Contain Pharmacies

PURPOSE: To discuss issues regarding tobacco sales in stores that contain pharmacies.

BACKGROUND:

British Columbia bans the display and promotion of tobacco where youth have access, so customers entering stores that allow youth to enter will not see any tobacco. However, BC is the only province that does not ban the sale of tobacco in stores that contain a pharmacy.

Most pharmacies are located in a retail venue, comprised of the front of the store, where a variety of products are sold, and has a separate dispensary area. Examples are:

- A small retail pharmacy that has a dispensary and sells products like toothpaste and bandages (e.g. Medicine Shoppe);
- A larger retail pharmacy that has a dispensary and sells products like toothpaste, and bandages, as well as computers and appliances (e.g. London Drugs); and
- A supermarket or warehouse that sells groceries, furniture, garden supplies, and contains a dispensary (e.g. Costco, Safeway).

Health organizations[1] are calling for a ban on tobacco sales in all parts of a store with a dispensary, stating tobacco sales are contrary to a pharmacy's mission to promote health and that it is a conflict of interest for pharmacists, as health care providers, to profit from a harmful product. The College of Pharmacists (the College) says tobacco sales are inconsistent with a pharmacist's professional standards. On the other side, the BC Pharmacy Association, the Canadian Association of Chain Drug Stores, and the Canadian Council for Grocery Distributors strongly oppose bans – with the BC Pharmacy Association stating:

> "…the choice to sell tobacco products, or not, is a business decision made in the context of the business operations that do not involve the health care setting (i.e. the dispensary), and do not involve the pharmacy professional staff. The trend towards inclusion of pharmacies within very large retail operations means that the sale of tobacco products and the dispensary may be physically well-removed from each other within the store…"

There is no evidence that a ban had a negative retail impact in any province where a ban is in force.[2] There is also no evidence that it lowers smoking rates. In provinces with a ban, stores with pharmacies simply moved tobacco sales to a side location (such as a kiosk in the mall or to a gas bar) and customers walked a bit further to buy tobacco.

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[1] Heart and Stroke Foundation, BC Lung Association, BC Medical Association, College of Pharmacists of BC
[2] *The Case for Creating Tobacco-Free Pharmacies in British Columbia,* The College of Pharmacists of British Columbia, June 2011, page 21

Government's approach has been to let pharmacies decide whether they sell tobacco, noting that customers in a pharmacy no longer see tobacco promoted. Pharmacies are the only retail site with health professionals knowledgeable about cessation medication and who can encourage customers to quit. Fifty-five percent of BC pharmacies do not sell tobacco.

DISCUSSION:

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Considerations:

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ADVICE:

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Program ADM/Division: Arlene Paton, ADM, Population and Public Health
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Drafter: Shelley Canitz
Date: January 11, 2012
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MINISTRY OF HEALTH
INFORMATION BRIEFING NOTE

Cliff: 960097

PREPARED FOR: Honourable Dr. Margaret MacDiarmid, Minister of Health
- FOR INFORMATION

TITLE: Concussion Prevention and Management

PURPOSE: To provide an update on the Ministry of Health's (the Ministry) approach to the development and implementation of concussion prevention, diagnosis and management training and resources including funding recently allocated to the British Columbia Injury Research and Prevention Unit (the Injury Unit) through LIFT Philanthropy Partners.

BACKGROUND:

Concussions have received enormous attention in recent years, both in lay and scientific literature, especially in the areas of football and hockey. Evidence suggests that children and youth are at greater risk of concussions and more serious head injury than the general population, take longer than adults to recover following a concussion, and that concussions can permanently change the way a child or youth talks, walks, learns, works, and interacts with others. If an individual returns to activity too soon and a second concussion is sustained before recovering from the first, a condition known as second-impact syndrome may occur: a swelling of the brain that can result in brain damage causing severe disability or even death. An individual is three times more likely to sustain a second concussion while in recovery from a concussion.

In British Columbia, there were 45,401 hospitalizations resulting from head injuries from 2001 to 2010, 22.6 percent of which occurred in children and youth ages 1-19 years[1]. Concussions accounted for 12.9 percent of all head injury hospitalizations[2]. Concussions are the most common form of head injury, yet it is believed that they are underreported owing to both a lack of consensus on the minimum requirements of the definition of a concussion and the presence of misconceptions among the general public regarding concussions.

Ministry of Health (the Ministry) staff have identified the need to increase prevention, consistent diagnosis and management protocols for concussion in BC. This has resulted in the Ministry developing resources and programs to prevent concussions and working closely with the BC Medical Association (BCMA) and provincial sports organizations to establish standardized concussion management protocols and guidelines. The Ministry collaborates closely with the Ministry of Community, Sport and Cultural Development, which has a role to support education on the issue through partnerships with SportMed BC and provincial sports organizations.

On November 17, 2011, to raise awareness of the need to better support concussion management in BC, Honourable Moira Stilwell, Minister of Social Development, introduced a private member's bill (Bill M206) calling for "Return to Play" legislation (Appendix A). Bill M206 called for youth "high risk" sport organizations to develop and adopt concussion guidelines, educational forms to be signed by athletes and parents/guardians, and licensed health care providers to evaluate and provide clearance to return to play. The proposed legislation

[1] Discharge Abstract Database

[2] *ibid*

contained within Bill M206 is aligned to similar legislation that has been implemented recently in several states in the United States.

On November 22, 2012, Honourable Stilwell met with the BC Concussion Advisory Network (the Network), chaired by Dr. Shelina Babul of the Injury Unit with members from the BCMA, University of BC Division of Sports Medicine, SportMed BC, BC Children's Hospital, Football BC and BC Hockey among others, to discuss her proposed approach on concussion prevention and management.

During this discussion, the Network provided feedback to Honourable Stilwell regarding existing gaps in concussion prevention and management in health care, school, community, and sport settings, as well as recommended next steps and actions. Particular recommendations from the Network included the need to develop targeted educational tools and resources for parents, coaches and trainers, as well as to work with the Ministry of Education to explore the development of "Return to Learn" and "Return to Play" protocols for a student's return to academics and athletics after a concussion.

DISCUSSION:

On December 3, 2012, LIFT Philanthropy Partners granted $150,000 to the Injury Unit to fund the development and provincial implementation of concussion prevention and management training and resources. This funding will be used to enhance development, implementation and promotion of a new Concussion Awareness Training Tool for health professionals which is currently being developed by the Injury Unit through funding from ChildHealth BC.

The grant will also fund the development of an educational training tool for parents, coaches, trainers, and athletes. Engagement with the not-for-profit organization, Community Against Preventable Injuries, and Preventable.ca, is being explored to leverage their expertise in social marketing to raise the awareness of concussions as well as the need for proper management and prevention. The development of an educational tool for parents, coaches, trainers, and athletes will build on materials that are currently being developed through a $1.5 million Public Health Agency of Canada "Active and Safe" grant by Think First Canada, Hockey Canada, the Coaching Association of Canada, and the Canadian Centre for Ethics in Sport.

In response to the recommendations from the Network's November 22, 2012 meeting, the funds will also be used to modify tools and resources produced by the Centres for Disease Control and Prevention in the United States, such as their recently released *Heads Up to Schools: Know your Concussion ABC's* resources which offer information regarding concussions to teachers, counsellors and school professionals.

The coordination, development and implementation of the above mentioned resources and protocols are based on recommendations out of the *2009 Zurich Consensus Statement on Concussion in Sport* (Appendix B), recognized as the global standard, which the Network has adopted to guide the work around concussions in BC.

CONCLUSION:

The outlined approach will result in better standardized concussion prevention, diagnosis and management in BC specific to children and youth.

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2011 Legislative Session: 4th Session, 39th Parliament
FIRST READING

DR. MOIRA STILWELL

BILL M 206 — 2011
CONCUSSIONS IN YOUTH SPORT SAFETY ACT

Explanatory Note

HER MAJESTY, by and with the advice and consent of the Legislative Assembly of the Province of British Columbia, enacts as follows:

1 In this Act:

"Health Care Professional" means a person licensed to provide health care under one of the following Acts:

(a) a person registered as a member of a college established or continued under the *Health Professions Act*, or

(b) a member of another organization that is designated by regulation of the Lieutenant Governor in Council.

"high risk sport" means a sport in which participants may be subjected to concussion as designated by regulation.

"youth athlete" means a person under the age of 19 who participates in a high risk sport.

"youth sports organization" means an organization providing a high risk sport program participated in by youth athletes.

2 Youth sports organizations must develop and adopt guidelines and other pertinent information and forms to inform and educate coaches, youth athletes, and their parents and/or guardians of the nature and risk of concussion and head injury including continuing to play after concussion or head injury.

3 On a yearly basis, a concussion and head injury information sheet must be signed and returned by a youth athlete and the athlete's parent and/or guardian prior to the youth athlete's initiating practice or competition in a high risk sport.

4 A youth athlete who is suspected of sustaining a concussion or head injury in a practice or game shall be removed from competition at that time.

5 A youth athlete who has been removed from play may not return to play until the athlete is evaluated by a licensed health care professional trained in the evaluation and management of concussion and receives clearance to return to play from that health care professional. The health care professional may be a volunteer. A volunteer who authorizes a youth athlete to return to play is not liable for civil damages resulting from any act or omission in the rendering of such care, other than acts or omissions constituting gross negligence or willful or wanton misconduct.

6 This Act comes into force by regulation of the Lieutenant Governor in Council.

Explanatory Note

The most common brain injury is a concussion. Most concussions occur without loss of consciousness and often are overlooked, with potentially serious consequence. Young athletes are particularly susceptible to concussions; in fact, according to the Canadian Paediatric Society, the majority of sport-related head injuries occur in individuals younger than 20 years old. Young athletes, their parents and coaches need to be aware of the risks that a second concussion can have if a previous concussion has yet to heal, and not feel pressured to hide their injuries or return to

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MINISTRY OF HEALTH
INFORMATION BRIEFING NOTE

Cliff # 958124

PREPARED FOR: Honourable Dr. Margaret MacDiarmid, Minister
– FOR INFORMATION

TITLE: College of Pharmacists of British Columbia proposed bylaw - Prohibition of Inducements

PURPOSE: To provide background information on the Ministry of Health's policy restricting pharmacy inducements and the College of Pharmacists of British Columbia's proposed bylaw that would prohibit all inducements.

BACKGROUND:

The purpose of the PharmaCare program is to assist British Columbians, particularly those with lower incomes, with the cost of eligible prescription drugs and designated medical supplies.

Incentive programs encourage people to shop at a particular pharmacy or pharmacy chain by enticing them with such things as loyalty points, coupons, discounts, goods, rewards and similar schemes rather than with lower prices. Incentive programs cost retailers money, which they build into the price they charge consumers. Rather than offering loyalty rewards, if a pharmacy sets its drug price or dispensing fee at a lower amount to attract customers, then customers, PharmaCare, and all taxpayers will save money.

In July 2011, the Ministry of Health (the Ministry) introduced a policy that prohibits pharmacies from providing loyalty points or other inducements to customers for the portion of their prescription covered by PharmaCare only. The prohibition was put in place based on the inappropriateness of using government money to subsidize customer rewards.

The policy was implemented after consultation with stakeholders such as the British Columbia Pharmacy Association and the Canadian Association of Chain Drug Stores, and respects the right of pharmacies to offer loyalty programs but believes that BC taxpayers should not have to subsidize such programs.

DISCUSSION:

This fall, the College of Pharmacists of British Columbia (the College) provided formal notice of its intention to introduce a bylaw to prohibit the use of loyalty points or inducements on the purchase of all pharmacy products in BC, regardless of the payer.

The College is the regulatory body for pharmacy in BC and is responsible for setting standards of practice. The College's mandate is to protect the public by ensuring pharmacists and pharmacy technicians provide safe and effective care to help people achieve better health.

In addition to supporting the rationale of the Ministry's policy, the College has cited issues of professionalism (physicians do not try to induce patients to their offices with customer rewards), and concerns over patient safety (such as patients filling prescriptions they may no longer need in order gain loyalty points), amongst its reasons for the proposed bylaw.

The College has the authority to make bylaws, consistent with the duties and objects of a College as set out under the *Health Professionals Act*. In making this bylaw, the College has undertaken a public consultation process ending December 28, 2012, to solicit input prior to requesting that it be brought into force.

Some pharmacies, particularly Canada Safeway, have voiced strong objections to the proposed bylaw stating that restricting customer rewards is unfair to customers. Safeway has instigated a letter writing campaign. Since the consultation period began in September 2012, the College and the Ministry have received over 10,000 responses in opposition to the prohibition.

Under the *Health Professions Act*, in order for a College bylaw to have effect, it must be filed with the Minister. If necessary and advisable, the Minister has the authority to disallow a College bylaw if it is not consistent with the College's specific duties and object, but instances of this occurring are rare as Colleges are recognized as being self-regulating entities.

ADVICE:

The Ministry should reserve taking a position on the proposed bylaw until the main points from these comments can be summarized and addressed by the College.

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