MITCHELL | HAMLINE
School of Law

March 31, 2021

(via cam@cpso.on.ca)

College of Physicians and Surgeons of Ontario
80 College Street
Toronto, Ontario M5G 2E2

Dear CPSO:

Re: Consultation on Complementary and Alternative Medicine (CAM) Policy

I am a law professor currently serving as the Fulbright Canada Research Chair in Health Law, Policy and Ethics at University of Ottawa. I appreciate the opportunity to participate in the consultation regarding the *Complementary and Alternative Medicine (CAM)* policy. Furthermore, I would be delighted to continue engagement with the CPSO as it revises the Policy. Such work fits the mission of my Fulbright award.

Informed Consent Provisions

My comments concern the informed consent provisions in the policy. Obviously, no physician should administer therapies that have zero clinical benefit for the patient. The policy rightly cautions against that. The more challenging situation is when the CAM therapy has some clinical benefit and conventional therapy also has some clinical benefit. This is a paradigm situation of preference sensitive medicine. The conventional therapy may have more effectiveness but also more side effects. The CAM therapy may have lower effectiveness but also lower side effects.

How should the benefits and risks in these options be balanced? This is a value-laden decision reserved for the patient. The Policy rightly focuses on assuring that the patient has complete and accurate information sufficient to make an informed decision between CAM and conventional therapy. But the current draft of the Policy misses an opportunity to help best assure this.

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Patient Decision Aids

Specifically, in 13(f), the Policy requires that physicians communicate "a clear and impartial description of how the treatment compares to . . . conventional treatment that could be offered." Given the special risk of inadequate informed consent in this context, the CPSO should strongly consider at least advising (even if not requiring) physicians to use a patient decision aid.[1] U.S. regulators are increasingly mandating the use of PDAs for preference sensitive interventions particularly vulnerable to under-informed patient choice.

Patient decision aids are evidence-based educational "tools" that help patients do three things. First, PDAs help patients understand the various treatment options available to them, including the risks and benefits of each choice. Second, they help patients communicate their beliefs and preferences related to their treatment options. Third, PDAs help patients decide with their clinicians what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences. PDAs do not replace the physician-patient discussion. They supplement and facilitate that discussion.

PDAs take various forms. They include educational literature with graphics, photographs, and diagrams. They also take the form of decision grids, videos, and website-based interactive programs such as sequential questions with feedback. No matter what form they take, the best PDAs provide an appropriate presentation of the condition and treatment options, benefits, and harms. They have three key advantages over the traditional informed consent process. First, the information in the PDA is accurate, complete, and up to date. Second, the PDA presents the information in a balanced manner. Third, the PDA conveys the information in a way that helps patients understand and use it. PDAs are truly patient-centered.

CAM Decision Aids

While PDAs have not been developed for all CAM therapies, there are PDAs for CAM in general. One is validated and available open access in the Ottawa Health Research Institute inventory.[2] More are being developed, tested, and certified.[3]

PDAs can help assure that patients get complete and accurate information presented in a balanced and unbiased manner. Indeed, growing evidence shows that most patients want an objective source like PDAs to inform them about the pros and cons of CAM therapies.[4] In short, PDAs can facilitate the goal of section 13(f), "clear and impartial description" of how CAM compares to conventional treatment.

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Conclusion

Section 13 of the Policy lists six separate elements (enumerated a to f) that physicians must communicate before providing complementary or alternative medicine. Seriously consider adding the following language to the end of section 13: "Physicians are advised to communicate this information with an evidence-based decision tool or patient decision aid when possible."

Sincerely,

Thaddeus Pope
Professor of Law

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[1] *See, e.g., Anaya-Burgos v. Lasalvia-Prisco,* 607 F.3d 269 (1st Cir. 2010).
[2] *Complementary Medicine: Should I Use Complementary Medicine?* https://decisionaid.ohri.ca/AZsumm.php?ID=1566.
[3] *See, e.g.,* Miek C. Jong et al., Development of an Evidence-Based Decision Aid on Complementary and Alternative Medicine (CAM) and Pain for Parents of Children with Cancer, 28 *Supportive Care in Cancer* 2415 (2020).
[4] *See. e.g.,* Trine Stub et al., Communication and Information Needs about Complementary and Alternative Medicine: A Qualitative Study of Parents of Children with Cancer, 21 *BMC Complement Med Therapies* 85 (2021).

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