



Massachusetts Society of  
Clinical Oncologists



May 19, 2017

Eileen Prebensen  
Senior Policy Counsel  
Board of Registration in Medicine  
200 Harvard Mills Square, Suite 330  
Wakefield, MA 01880

Re: Proposed Regulations 243 CMR 2.07, General Provisions Governing the Practice of Medicine

Dear Ms. Prebensen,

The Massachusetts Society of Clinical Oncologists (MSCO) and the American Society of Clinical Oncology (ASCO) appreciate the opportunity to provide comments on the Massachusetts Board of Registration in Medicine proposed regulation 243 CMR 2.07 (14), entitled “Providing Cancer Patients with Treatment Information.”

MSCO represents oncology providers across the Commonwealth, who are dedicated to improving cancer care and treatment. ASCO is the world’s leading professional society representing physicians and other health care professionals who care for people with cancer. With more than 42,000 members, our core mission is to ensure access to high quality cancer care.

MSCO and ASCO are deeply concerned by the proposed regulation and ask that it be reconsidered. It would impose disruptive and counterproductive requirements for physicians to discuss a specified list of treatment alternatives to a patient with cancer – this whether or not such treatments are relevant or appropriate. This mandated, robotic approach would interfere significantly with the physician-patient relationship and communications.

An oncologist routinely presents available treatment options, tailored to the patient’s cancer diagnosis and circumstances. This proposed regulation strays from this already complex process and adds risk by overloading the patient with unnecessary information that detracts from the focus and proper learning of the ultimately proposed treatment.

As proposed regimens are often dangerous and fraught with potential toxicities, oncologists must routinely be experts in educating and informing their patients, based on their unique circumstances. In the course of cancer management, patients receive treatment according to established pathway protocols. These protocols are becoming increasingly diverse as we leverage newer technologies that further personalize treatment. These technologies facilitate

the off-label use of anticancer agents or enrolment in a clinical trial, provided eligibility criteria are met. Regardless of the chosen pathway for treatment, informed consent is a critical and required first step in obtaining access to any proposed anti-cancer agent.

Oncologists routinely tailor options for treatment by taking into account the patient's performance status, comorbidities, emotional wellbeing, and ability and willingness to manage logistics. The overarching goal is to optimize safety and reduce risk while undergoing treatment. Given the risks and potential toxicities of treatment (known and unknown), each patient is educated to become an active member of the team before selecting or starting treatment. Therefore, for oncologists, educating and supporting patients to make informed decisions is the center of gravity from which all else emanates in the physician-patient relationship.

Under the Board's proposal, the physician would be required to present and discuss a series of specific alternatives with the patient, unless the patient states that he/she does not want to discuss anything further. The conversation is either over-inclusive or non-existent. This would interfere in many instances with the ability of the treating physician to focus on the information that is most important for an individual patient to hear - this during a very emotional and challenging time.

Informed consent entails going over the risk ratios for benefit and harm and the potential side effects for each treatment modality. The proposal would compel physicians to discuss theoretical options that may be unreasonable or a poor fit for the patient. It is already challenging to inform the patient in a manner that the specific patient can understand, retain, and internalize.

In many patients, the insertion of even a bit of excess non-tailored information would cause confusion and, more ominously, diffusion of the message.

Even before treatment options multiplied over the past 5 to 10 years, it was already known that:

- a. 40-80% of medical information provided by healthcare practitioners is forgotten immediately.
- b. The greater the amount of information presented, the lower the proportion correctly recalled
- c. almost half of the information that is remembered is incorrect.
- d. In the elderly, who have the highest incidence of cancer, the accurate retention of complex medical data is much worse.

The proposed regulation also would compel physicians to speak about options that may be better discussed by other experts. For example, the regulation may be interpreted by radiation oncologists to describe and prioritize chemotherapy options, while medical oncologists would feel obligated to present and recommend radiation therapy algorithms — neither have optimal capacity to do so and this would be redundant if the two specialists are consulted on the same case.

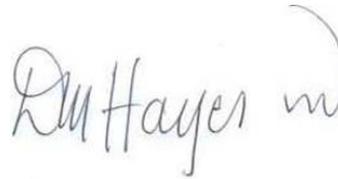
Existing professional ethics and standards of care already govern physicians' duty to their patients. That duty includes the need to provide relevant information to a patient regarding their condition and their treatment options. The Board already has the authority to discipline a physician and to respond to complaints whenever a physician's actions do not meet the standard of care. New regulations specific to informed consent for cancer care are unnecessary in light of the Board's existing authority, and the Board should not create this new requirement.

MSCO and ASCO urge the Board to eliminate the proposed clause (14) of section 2.07. Please contact Jennifer Brunelle at ASCO at [jennifer.brunelle@asco.org](mailto:jennifer.brunelle@asco.org) or Patrick Gagnon, M.D. at [MSCO@mms.org](mailto:MSCO@mms.org) if you have any questions or if we can be of assistance.

Sincerely,



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Daniel F. Hayes, MD, FACP, FASCO  
President  
American Society of Clinical Oncology



Omar Eton, MD  
Past President  
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