February 23, 2017

Mr. Thomas Leet
Comprehensive Health Planner II
MaineCare Services
242 State St.
11 State House Station
Augusta, Maine 04333-0011

RE: 14-118 C.M.R. Chapter 11, Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications

Dear Mr. Leet,

The American Society of Clinical Oncology (ASCO) and the Northern New England Clinical Oncology Society (NNECOS) appreciate the opportunity to comment on the Maine Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications.

ASCO is the world's leading professional society representing physicians who care for people with cancer. With more than 40,000 members, our core mission is to ensure that cancer patients have meaningful access to high quality cancer care. NNECOS is a professional society whose mission is "to assure the availability of and access to high quality oncology care in our region." NNECOS represents more than 500 oncology professional members in Vermont, New Hampshire and Maine.

ASCO and NNECOS are concerned about the epidemic of opioid use disorder and support efforts to address the widespread problems, while ensuring that policies do not have the unintended consequence of limiting patient access to treatment of pain for cancer patients and survivors.

<u>Cancer Patients: A Special Population</u>

Opioid therapies are an essential component of treating cancer patients and are used during all phases of treatment. From the clinical perspective, there is broad agreement that opioid therapy is generally the first-line approach for moderate to severe chronic pain associated with active cancer, whether or not the patient is receiving anti-neoplastic therapy.

Cancer survivors often suffer recognized post-cancer or treatment syndromes, and others present with less common, potentially unique, but nevertheless very real post-treatment pain syndromes. More commonly recognized post-cancer pain syndromes may include chemotherapy induced peripheral

neuropathy, lymphedema, post-surgical pain syndromes such as phantom limb pain, graft versus host disease after transplant, or post-radiation therapy syndromes.

Across the country, many of the new policies that limit or otherwise affect opioid prescribing specifically exempt patients who have cancer-related pain. This reflects the recognition that cancer patients are special, often requiring access to medically necessary opioid therapies to alleviate the pain related to disease, the treatments, and the related aftereffects.

Prescription Limits

There is broad agreement that patients with cancer and cancer survivors should not be subject to prescription limits that artificially limit access to medically necessary treatment. ASCO and NNECOS appreciate that the rule includes "exemption codes" for aggregate daily limits that cover many aspects of cancer care. However, we are concerned that the current exemptions leave gaps where legitimate scenarios involving the care of cancer patients may not be covered. For example, there is no clinical rationale justifying any arbitrary timeframe for cancer-related pain to end after the active treatment of the cancer or after remission of the cancer. For instance, a patient who is in remission may have long-term pain related to radiation therapy or other cancer treatments administered in the past. As a result, we urge the State to clarify and revise Exemptions A or B for acute cancer treatment or palliative care to confirm that individuals with pain resulting from their cancer or cancer treatments will qualify for an exemption that continues beyond six-months or any other arbitrary timeframe.

Prescription Monitoring Program

The rule requires prescribers to query the Prescription Monitoring Program system for records related to the person for whom the medication is being prescribed. We urge you to include a provision explicitly exempting opioid prescriptions for cancer-related pain from the database query requirement.

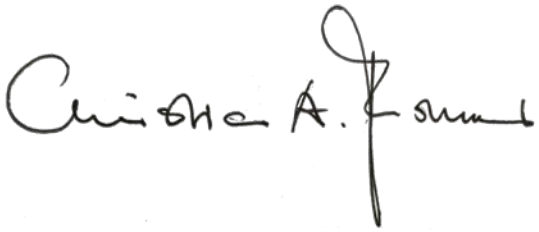
Additionally, we believe the rule language must be clarified to expressly state that a prescriber in a physician office can rely on staff to perform the clerical task of accessing the database to satisfy the requirement for the prescribing physician. Elective or mandated queries of these databases should not be limited only to prescribers. As the checking of these databases is largely an administrative activity, it is appropriate for a clinician to delegate authority for such activities to other practice staff or clinicians, while the treating clinician is responsible for interpreting the results contextually for each patient.

We also urge you to take into account the special needs of cancer patients in the context of reviewing and reporting information from the prescription monitoring program. We urge the State to provide explicit language noting that the plan to identify outliers will be tempered by the specialty and patient population of the provider, including recognition that oncologists treating cancer pain are legitimately expected to prescribe a higher volume of opioids compared to many other specialties. It is not unusual for cancer patients to require high doses of opioids to provide medically appropriate control their cancer pain.

Conclusion

We appreciate you considering our views as you work to finalize the Maine Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications. ASCO and NNECOS offer the "ASCO Policy Statement on Opioid Therapy: Protecting Access to Treatment for Cancer-Related Pain" as a resource to you. If you have questions or would like assistance from ASCO on any issue involving the care of individuals with cancer, please contact Jennifer Brunelle at jennifer.brunelle@asco.org.

Sincerely,



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

Christian A. Thomas, MD
President-Elect
Northern New England Clinical Oncology Society