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February 16, 2018

The Honorable Orrin Hatch
Chair
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden,

The American Society of Clinical Oncology (ASCO) appreciates the opportunity to provide input on questions raised in your February 2 letter regarding efforts to improve the Medicare, Medicaid and human services programs' responses to the opioid epidemic. ASCO is the national organization representing nearly 45,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis, and prevention.

Along with you, we are deeply concerned about the epidemic of opioid use disorder and its devastating impact on many of our citizens. We support efforts to address the opioid epidemic, while ensuring initiatives do not have the unintended consequence of limiting access to appropriate medical opioid therapy for our patients with cancer.

ASCO provides numerous educational resources for its members on pain control and opioid prescribing, and participates in the American Medical Association's Opioid Task Force, which seeks to provide further education and resources for providers to assist them in appropriate prescribing and in raising awareness of the critical role that healthcare professionals play in stemming this crisis.

Opioid therapies are often an essential component of treating cancer patients and may be used during all phases of treatment, including palliative care with no active anti-cancer therapy. We have made advances in cancer treatment, and many of our survivors cope for months and years with the delayed side effects of curative as well as life prolonging cancer therapies. There is broad agreement from the clinical perspective that opioid therapy is generally the first-line approach for moderate to severe pain control, alone or in combination with other medications in patients with active cancer, whether or not they are 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 include inflammation of peripheral nerves from chemotherapy (peripheral neuropathy), painful swollen limbs (lymphedema), post-surgical pain syndromes such as phantom limb pain, pain from rejection of normal tissues (graft versus host disease after transplant), or post-radiation therapy nerve syndromes.

Are there changes to Medicare and Medicaid prescription drug program rules that can minimize the risk of developing OUD and SUDs while promoting efficient access to appropriate prescriptions?

ASCO is a strong supporter of the policies within the *Comprehensive Addiction and Recovery Act* intended to address the opioid addiction epidemic. As the Centers for Medicare and Medicaid Services (CMS) continues implementing CARA's directives, ASCO has encouraged the agency to consider the unique needs of specific populations to prevent any unintended gaps in patient access to medically necessary pain medication, including the cancer patient population.

ASCO supports the Agency's proposal that exempts cancer patients from CARA's new drug management program for at-risk beneficiaries. The proposed policy acknowledges that oncologists are specially trained to help patients cope with pain that cancer patients may encounter throughout their cancer treatments. Prescription medications with addictive potential are widely used in palliative care and to treat pain associated with cancer and both chemotherapy and radiation therapy treatments. The Agency's decision to exempt cancer patients from the program recognizes their unique needs and alleviates efforts impede immediate and timely access to medically necessary pain relief during all stages of treatment.

How can Medicare or Medicaid better prevent, identify and educate health professionals who have high prescribing patterns of opioids?

ASCO cautions that any efforts to identify "aberrant" patterns of prescribing for any individual provider must consider the provider specialty and any further sub-specialization, population of patients treated, and other factors that may legitimately influence prescribing patterns. Those who treat cancer pain may prescribe opioids to relatively large numbers of patients and may provide some with multiple controlled drugs at relatively high doses. These providers should not repeatedly trigger review by regulators or law enforcement.

Provider education should be tailored to the special needs of professionals practicing in those areas, given the ever-growing sub-specialization of medicine. ASCO believes bodies such as medical professional societies, or other organizations that understand the specific needs of their audience, can best provide such education. Education provided by ASCO is developed by professionals, peer-reviewed, and carefully tailored to meet the needs of oncology professionals; the ASCO faculty developing these materials additionally provide published conflicts of interest statements.

Any mandated provider education should not present an additional hurdle to those who prescribe opioids and have already been effectively trained in opioid prescribing. Rather it should be associated with existing requirements such as renewal of DEA licensure, Board examinations, or state licensure. Additionally, any mandated education should be associated with evidence of improved outcomes.

What can be done to improve data sharing and coordination between Medicare, Medicaid, and state initiatives, such as Prescription Drug Monitoring Programs?

Prescription drug monitoring programs (PDMPs) contain electronically transmitted prescribing and dispensing data submitted by pharmacies and dispensing practitioners. Currently, PDMP programs exist in 49 states and the District of Columbia; Missouri lacks a statewide PDMP but some counties in the state are standing up their own PDMPs.

PDMPs can provide valuable information to prescribers and dispensers regarding the prior or current use of opioids by individual patients. Policymakers also find the aggregate information useful to track overall opioid prescriptions and patterns of use.

There must be a high priority put on making PDMPs accessible through a single portal or interoperable in a way that is seamless to the end-user, as many physicians see patients from multiple states and must therefore review several separate databases for each patient. Policymakers should consider removing any state-level barriers to e-prescribing of controlled substances (EPCS), to deter the theft of prescription note pads and subsequent fraudulent prescriptions. More “real-time” reporting into PDMPs would make them more useful to practicing physicians, and a more proactive system of “alerts” from the PDMP to the physician could also be helpful.

To further help ensure PDMPs work seamlessly in oncology practice, clinicians should be able to delegate authority for such activities to other practice staff/clinicians. The clinician should be responsible for interpreting the results contextually for each patient. Additionally, physician practices should be allowed to “batch” check patients at the front end. A delegated practice staff member would check each day’s patients in a “batch” at the beginning of the day or up to 24 hours in advance, depending on what the practice knows about the needs of these patients in advance.

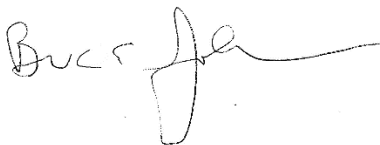
What best practices employed by states through innovative Medicaid policies or the private sector can be enhanced through federal efforts or incorporated into Medicare?

Many of the new laws, guidelines, and regulations restricting access or limiting doses of prescription opioids specifically exempt patients with cancer-related pain. This recognizes the unique nature of their disease, and potentially life-long adverse health effects from having had cancer.

CMS recently proposed a “hard edit” of 90 MME (morphine milligram equivalents; approximately equal to 60mg of oxycodone) per day to be implemented by Medicare Part D plans. This would mean that patients requiring over 90 MME per day would need to be approved for such treatment through a special exceptions process. CMS specifically exempted patients with cancer and patients in hospice from these requirements, however, in recognition of the special needs of these populations. ASCO asks that you also consider these special needs as you propose initiatives aimed at curbing this devastating epidemic.

We offer the [ASCO Policy Statement on Opioid Therapy: Protecting Access to Treatment for Cancer-Related Pain](#) for more information. If you have questions or would like assistance on any issue related to providing care of individuals with cancer, please contact Jennifer Brunelle at Jennifer.brunelle@asco.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce E. Johnson". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Bruce E. Johnson, MD, FASCO
President, American Society of Clinical Oncology