July 10, 2017

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852


Via Electronic Submission (https://www.regulations.gov)

The American Society of Clinical Oncology (ASCO) is pleased to submit comments on the Food and Drug Administration’s (FDA) draft revisions to the “FDA Blueprint for Prescriber Education for Extended-Release and Long-Acting (ER/LA) Opioids,” which lays out the required elements of health care provider education under the FDA’s Risk Evaluation and Mitigation Strategy (REMS) authority, and on possible changes to the FDA’s ER/LA REMS.

ASCO is the national organization representing more than 42,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes and are committed to ensuring that evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans.

Background

In July 2012, FDA approved an Extended-Release and Long-Acting (ER/LA) Opioid Analgesics REMS, including an FDA-created “Blueprint for Prescriber Education for Extended Release and Long-Acting (ER/LA) Opioid Analgesics” (the “FDA Blueprint”). The ER/LA Opioid Analgesics REMS requires that training in the form of accredited continuing education be made available to health care providers who prescribe ER/LA opioid analgesics; currently, this education is optional for prescribers. The accredited continuing education must include all elements of the FDA Blueprint, which includes a basic outline and the core messages related to ER/LA opioid analgesics.
In May 2016, FDA convened a joint meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee to discuss whether this REMS assures safe use of these products; whether or not it is unduly burdensome to patient access to these drugs; and whether it (to the extent practicable) minimizes the burden to the health care delivery system. FDA also sought input on possible modifications to the ER/LA Opioid Analgesic REMS, including expansion of the scope and content of prescriber training and expansion of the REMS program to include immediate release (IR) opioid analgesics. Advisory Committee members were in favor of modifying the REMS program to include the IR opioid analgesics as well as broadening the training program to include pain management. The majority of the members were in favor of a requirement for all prescribers to complete training. Many of the members recommended that the required training program be implemented through mechanisms outside the FDA REMS authority. The majority of members also stated that other health care providers involved in the management of pain should be included as a target audience for education, though they did not specify that the training should be mandatory for non-prescribing health care providers.

FDA is considering modifications to the existing Blueprint based on recommendations from the May 2016 Advisory Committee meeting. The original 2012 Blueprint did not discuss pain management and was limited to discussion of ER/LA opioids. The draft revisions to the Blueprint would broaden the Blueprint and include information on the following: pain management, including the principles of acute and chronic pain management; nonpharmacologic treatments for pain; pharmacologic treatments for pain (both non-opioid analgesic and opioid analgesic); and basic elements of addiction medicine and opioid use disorders. It would also extend training to other health care providers involved in the management of patients with pain (pharmacists, nurses).

Most recently, in May 2017, FDA held a public meeting to “seek input on issues and challenges associated with Federal efforts to support training on pain management and the safe prescribing, dispensing, and patient use of opioids (safe use of opioids) for health care providers.” The FDA is considering the input from this meeting concurrently with its draft revisions to the FDA Blueprint, and intends to consider public input as it considers modifications to the ER/LA Opioid Analgesics REMS.

**ASCO Comments on the Revised Blueprint and Modifications to the ER/LA Opioid Analgesics REMS**

Among the issues FDA is considering as it reviews the ER/LA REMS program and revises the FDA Blueprint is whether to extend education to non-prescribers, whether education should be mandatory, and what elements health provider education should include. It has also been recommended to FDA by stakeholders that any mandatory education be provided by an alternative mechanism (i.e. not through the REMS program).

The basis for mandatory prescriber education is the expectation that such education will lead to more appropriate prescribing, likely more limited prescribing, and heightened awareness of the
risk for patient misuse and abuse, ultimately resulting in a decrease in overdose and overdose deaths. Therefore, in assessing the impact of provider education, the most relevant and valuable endpoint would be overdose and overdose death statistics; intermediate outcomes could include patient awareness of risks and benefits, maintenance of access for appropriate patients, and provider prescribing patterns. As FDA considers a requirement for mandatory education, we urge the agency to identify and monitor these appropriate endpoints for consideration in further revisions to the REMS.

Additionally, as ASCO has stated previously, providers should have a choice of sources and materials for education in opioid prescribing, and mandated education in particular should be provided by entities other than manufacturers. The current ER/LA REMS relies on grants from manufacturers to accredited continuing education providers; given the FDA’s proposal to expand significantly the Blueprint to include all forms of pharmacologic and non-pharmacologic management for pain, we remain concerned about manufacturer involvement under the REMS mechanism. Further, given the ever-growing sub-specialization of medicine, provider education should be tailored to the special needs of professionals practicing in those areas. We believe this education is best provided by medical professional societies or other organizations that understand the specific needs of their audience. For example, ASCO’s education programs are developed by professionals, undergo peer-review, and are carefully tailored to meet the needs of oncology professionals. ASCO faculty developing these materials provide published conflict of interest statements (see Appendix 1 for a selection of ASCO-developed educational modules and guidelines). In addition to didactic forms of education, ASCO has long offered quality improvement programs to its members; our Quality Oncology Practice Initiative (QOPI®) offers a platform for members to measure their performance based on oncologist-developed quality measures, many of which relate to pain management (see Appendix 2 for a listing of ASCO’s pain-related quality measures).

As FDA considers expanding opioid education to other prescribers and non-prescribers, FDA should ensure that such education is geared towards and takes into account the roles of each of these groups of professionals. Additionally, we would note that healthcare professional opioid education needs to be offered via a variety of platforms (e.g. online, class or conference setting, or other mechanisms).

As stakeholders across the country have attempted to grapple with the opioid epidemic, many programs have been put into place both at individual institutions and at the state level. At the local level, many institutions already provide training in pain management and opioid prescribing. Many states, through legislation and regulation, have already or are now considering putting into place required training for healthcare professionals. We would ask that the FDA factor in new and existing state requirements as it reviews its own educational program, in order to avoid duplicative efforts and burdens, and that a process be established to recognize existing pain management programs at the institutional level.

Any mandated provider education should not present an additional administrative hurdle to those who prescribe opioids, but should be associated with existing requirements such as
renewal of DEA licensure, Board examinations, or state licensure. Mandated provider education should help to fulfill existing requirements for state licensing, state medical board requirements, maintenance of certification, and the like, and not present a new set of unrelated requirements. We are concerned with statements made at the 2017 FDA public meeting suggesting that prescribers who do not obtained the required education be prohibited from prescribing all Schedule 2 substances, as this could decrease patient access to other needed treatments. Finally, as stated above, any mandated education should be associated with evidence of outcomes.

We thank the FDA for the opportunity to submit these comments, and welcome the opportunity to further discuss proposed revisions to the FDA Blueprint and ER/LA REMS.

Sincerely,

Bruce E. Johnson, MD, FASCO
President, American Society of Clinical Oncology
Appendix 1: Select ASCO Educational Modules and Guidelines

Position Statement:
ASCO Policy Statement on Opioid Therapy: Protecting Access to Treatment for Cancer-Related Pain

Guidelines:
Management of Chronic Pain in Survivors of Adult Cancers

Online Sessions:
Pain Management
Developed by ASCO University
Faculty:
   Eduardo Bruera, MD
   Kimberly Chow, NP
   Judith Paice, PhD, RN
http://university.asco.org/pain-management-program

ASCO Annual Meeting Sessions:
Monday, June 5, 2017 from 11:30 AM-12:45 PM
Pain and Opioids in Cancer Care
Session Type: Education Session
Location: S100a
11:30 AM - 12:45 PM
Judith A. Paice, PhD, RN - Chair
Northwestern University
Opioids in Cancer Survivors: Risks, Benefits, and Challenges.
11:30 AM - 11:50 AM
Michael Bennett, MD, FRCP, FFPMRCA
University of Leeds School of Medicine
Opioids in Advanced Cancer: Access, Efficacy, and Outcomes
11:50 AM - 12:10 PM
Mark S. Wallace, MD
University of California, San Diego
Cannabis: An Alternative to Opioids?
12:10 PM - 12:25 PM
Panel Discussion
Panel Question and Answer

Palliative and Supportive Care in Oncology Symposium:
Saturday October 28, 2017 (8:10-9:45 am)
General Session 4: Tough Issues in Opioid Management
Methadone Challenges
My Patient Needs Opiates and Benzodiazepines: What Should I Do?
Opioid Use Disorders
Risk Tools and Opioid Contracts in Clinical Practice
Panel Question and Answer
### Appendix 2: ASCO QOPI® Measures Related to Pain Management

<table>
<thead>
<tr>
<th>MODULE</th>
<th>MEASURE#</th>
<th>MEASURES</th>
<th>NQF Endorsed Measure</th>
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<tr>
<td>CORE</td>
<td>CORE3</td>
<td>Pain assessed by second office visit</td>
<td>NQF Endorsed #0383/#0384 (adapted)</td>
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<tr>
<td>CORE</td>
<td>CORE4a</td>
<td>Pain intensity quantified by second office visit</td>
<td>NQF Endorsed #0384 (adapted)</td>
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<tr>
<td>CORE</td>
<td>CORE5</td>
<td>Plan of care for moderate/severe pain documented</td>
<td>NQF Endorsed #0383/#0384 (adapted)</td>
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<td>CORE</td>
<td>CORE6</td>
<td>Pain addressed appropriately (defect-free measure, CORE3, CORE4a, and CORE5)*</td>
<td>NQF Endorsed #0383 (adapted)</td>
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<tr>
<td>CORE</td>
<td>CORE6a</td>
<td>Pain assessed on either of the two most recent office visits</td>
<td>NQF Endorsed #0383/#0384 (adapted)</td>
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<tr>
<td>CORE</td>
<td>CORE6b</td>
<td>Pain intensity quantified on either of the two most recent office visits</td>
<td>NQF Endorsed #0383/#0384 (adapted)</td>
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<tr>
<td>CORE</td>
<td>CORE6c</td>
<td>Plan of care for moderate/severe pain documented on either of the two most recent office visits</td>
<td>NQF Endorsed #0383/#0384 (adapted)</td>
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<td>CORE</td>
<td>CORE6d</td>
<td>Pain addressed appropriately on either of the two most recent office visits (defect-free measure, CORE6a, CORE6b, and CORE6c)</td>
<td>NQF Endorsed #0383/#0384 (adapted)</td>
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<td>CORE</td>
<td>CORE6e</td>
<td>Pain addressed appropriately by second office visit and during most recent office visits (defect-free measure, CORE6 and CORE6d)</td>
<td>NQF Endorsed #0383/#0384 (adapted)</td>
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<td>CORE</td>
<td>CORE7</td>
<td>Effectiveness of narcotic assessed on visit following prescription</td>
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<td>CORE</td>
<td>CORE8</td>
<td>Constipation assessed at time of narcotic prescription or following visit</td>
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<td>EOL</td>
<td>EOL35</td>
<td>Pain assessed on either of the last two visits before death</td>
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<td>EOL</td>
<td>EOL36a</td>
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<td>EOL37</td>
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<td>EOL</td>
<td>EOL38</td>
<td>Pain addressed appropriately (defect-free measure, EOL35, EOL36a, and EOL37)*</td>
<td>NQF Endorsed #0383/#0384 (adapted)</td>
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<td>PC</td>
<td>PC98</td>
<td>Pain quantified using a standardized instrument at every clinical encounter in the past 3 months for patients with advanced/metastatic lung, pancreatic and colorectal cancer</td>
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<td>PC</td>
<td>PC99</td>
<td>Plan of care for pain when moderate/severe pain present in the past 3 months for patients with advanced/metastatic lung, pancreatic and colorectal cancer</td>
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<td>PALLIATIVE CARE</td>
<td>PC100</td>
<td>Constipation, fatigue, and nausea assessed at the clinic visit following a new prescription or increasing opioid regimen for patients with advanced/metastatic lung, pancreatic and colorectal cancer</td>
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<td>PALLIATIVE CARE</td>
<td>PC108</td>
<td>Documented substance abuse history, including tobacco, alcohol and illicit drug use within the first 3 visits after diagnosis with advanced/metastatic lung, pancreatic and colorectal cancer (<em>Test Measure</em>)</td>
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