



American Academy of
Hospice and Palliative Medicine

December 7, 2011

Leslie Kux, JD
Acting Assistant Commissioner for Policy
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Division of Dockets Management (HFA-305)

Submitted electronically to <http://www.regulations.gov>

Re: FDA-2011-D-0771; Draft Blueprint for Prescriber Education for Long-Acting/Extended-Release Opioid Class-Wide Risk Evaluation and Mitigation Strategy; Availability; Request for Comments

Dear Assistant Commissioner Kux,

On behalf of the more than 4,200 members of American Academy of Hospice and Palliative Medicine (AAHPM), I am pleased to offer this response to the call for public comment regarding the core messages intended for use by continuing education providers to develop educational materials to train prescribers of long-acting (LA) and extended-release (ER) opioids under the required risk evaluation and mitigation strategy (REMS) for these products, as published in the November 7, 2011, Federal Register. We appreciate the opportunity to work with the FDA to ensure the safe and responsible use of opioid pain medications.

AAHPM is the professional organization for physicians specializing in hospice and palliative medicine, and our membership also includes nurses and other health and spiritual care providers deeply committed to improving quality of life for patients facing life-threatening or serious conditions through the provision of palliative care. Palliative care often requires the delivery of timely and effective management of pain and other distressing symptoms.

Overall, we find the provisions in the draft blueprint to be balanced and useful in terms of outlining risk-reducing practices. However, AAHPM suggests the following additions and/or modifications to the proposed core competencies:

Advancing the Science of Comfort Affirming the Art of Caring

❖ **ADD TO CORE COMPETENCIES: Indications for Treatment with ER/LA Opioid Therapy**

Prescribers should be familiar with the approved indications for any LA/ER opioid they prescribe.

❖ **Under “Initiating Therapy, Modifying Dosing, and Discontinuing Use of ER/LA Opioids”:**

ADD: Prescribers should be knowledgeable about differences in the care required for special populations.

Over 1.5 million Americans receive hospice services annually. A similar number of others reside in long-term care, a majority of whom are cognitively impaired. Both of these patient populations have chronic medical problems and are likely to face increased risks of side effects when they receive treatment with LA/ER opioids.

While AAHPM acknowledges the diversity of the learner population and its educational needs, and further recognizes the need for simplification of the prescriber education to fit within limited time resources, it is still important to ensure that any curriculum addresses differences in approach to the care of special populations, including:

- *Patients with limited prognosis, as often encountered in hospice*
- *Patients with very severe or escalating acute pain requiring rapid titration of opioids (including LA/ER formulations in combination with normal-release products),*
- *Patients with chronic pain residing in long term care facilities, and*
- *Patients with chronic pain who have cognitive impairment.*

Underestimating the needs of these special populations would be a disservice to them and may create unintended barriers to legitimate opioid access for these patients, especially they are frequently managed by practitioners who do not possess specialist-level training in palliative care.

❖ **Under “Managing Therapy with ER/LA Opioids”**

ADD: Prescribers should be able to identify indications for appropriate specialty referrals.

❖ **Under “Counseling Patients and Caregivers About the Safe Use of ER/LA Opioids”**

ADD: Prescribers should discuss the value and effectiveness of opioids when prescribed and used appropriately and responsibly.

❖ **Under “Specific Drug Information for ER/LA Opioid Products”**

ADD: Prescribers should be knowledgeable about product-specific disposal for any ER/LA opioid product they prescribe.

Thank you for the opportunity to comment on the proposed blueprint for prescriber education. AAHPM recognizes the public health imperative to diminish abuse, misuse and diversion of opioids and applauds the FDA's efforts to stem this tide. We are committed to partnering with the FDA in efforts designed to enhance prescribers' knowledge and skills to improve care and outcomes for patients and improve public health and safety. At the same time, we want to protect our patients' continued, legitimate access to medications essential to their care. Towards this end, our Academy leaders would welcome any opportunity to provide additional information or comment regarding this or any other agency initiatives, particularly with regard to the unique and important needs of patients with serious or life-threatening conditions.

Please address questions regarding AAHPM's comments to Jacqueline M. Kocinski, AAHPM Director of Health Policy and Government Relations, at jkocinski@aahtm.org or 847-375-4841.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Crossno". The signature is fluid and cursive, with a large initial "R" and a long, sweeping underline.

Ronald J. Crossno, MD CMD FAAFP FAAHPM
President