AMERICAN ACADEMY OF
HOSPICE AND PALLIATIVE MEDICINE

April 6, 2026

The Honorable Martin A. Makary, MD, MPH
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Developing Specifications for In-Home Disposal Systems that May Be Made Available Through the Opioid Analgesic Risk Evaluation and Mitigation Strategy for Opioid Analgesics Dispensed in an Outpatient Setting; Establishment of a Public Docket; Request for Comments [FDA-2026-N-1001]

Dear Commissioner Makary:

On behalf of the more than 5,000 members of the American Academy of Hospice and Palliative Medicine (AAHPM), we would like to thank the U.S. Food and Drug Administration (FDA) for the opportunity to comment on the public docket referenced above. AAHPM is the professional organization for physicians specializing in Hospice and Palliative Medicine (HPM). Our membership also includes nurses, social workers, spiritual care providers, pharmacists, and other health professionals deeply committed to improving quality of life for the expanding population of patients facing serious illness as well as their families and caregivers. Together, we strive to advance the field and ensure that patients across all communities and geographies have access to high-quality palliative and hospice care.

AAHPM appreciates FDA's goals when considering whether to require application holders of opioid analgesics (OA) dispensed in outpatient settings to make in-home disposal systems available under the OA Risk Evaluation and Mitigation Strategy (REMS). We recognize the toll that opioid misuse and abuse have taken on our nation, including tragically high rates of opioid-related overdose and death. We therefore understand FDA's consideration of efforts to minimize risks of inappropriate access to unused opioid medications and generally support more robust safe disposal guidance.

1061 American Lane, Suite 310, Schaumburg, IL 60173-4973 • 847.375.4712 • Fax 847.375.6475
aahpm.org • palliativedoctors.org • info@aahpm.org

At the same time, we underscore that the timely and effective management of pain and other distressing symptoms is central to providing high-quality palliative care to patients with serious illness, and that opioid analgesics are critical tools in alleviating their suffering. We believe a balanced approach to policymaking is necessary to manage the challenges and risks of opioid use, while maintaining access to appropriate pain medications for patients with serious or complex chronic illness, including those at the end of life.

We therefore urge FDA to keep this vulnerable population in mind and ensure that any modifications to the REMS for OA dispensed in an outpatient setting do not place harmful barriers to access to these medications for these patients.

We offer more detailed comments and recommendations below in response to FDA's questions.

Questions 1, 2, and 3

FDA asks about the percentage of an opioid product's active ingredient that an in-home disposal system would need to render unavailable, and over what course of time. FDA also asks about potential susceptibility of in-home disposal systems to manipulation after they are used. ***AAHPM strongly recommends any standards or requirements that FDA establishes based on these variables be grounded in robust evidence and specified in a manner that is proportionate to actual risk.*** We are particularly concerned that setting thresholds that are not meaningful or too high may drive up the cost and complexity of these systems in a way that would ultimately create friction for patients and dispensers, with little actual benefit. We also note that FDA may need to test in-home disposal systems separately for extended-release formulations – which are commonly used by patients with serious illness – and/or set separate standards relative to immediate-release formulations.

Question 4

FDA seeks additional information on potential specifications for in-home disposal systems, including information on potential user error such as overfilling, incorrect water temperature, and insufficient shaking. AAHPM believes there is significant risk that patients will have difficulty using in-home disposal systems, particularly for patients with serious illness and/or their family members and caregivers. These could include individuals like a frail 80-year-old with advanced heart failure, a caregiver who has just lost their spouse, or a family member managing a home death, among others. Keeping these patients in mind, ***AAHPM stresses the need for these in-home systems to be simple enough for these types of individuals, who may be seriously ill, frail, grieving, stressed, and/or exhausted, to use correctly. To ensure such an outcome, FDA should require human factors testing that includes older adults with functional limitations and bereaved caregivers. Additionally, FDA should ensure that instructions for disposal systems be very easy to use, with clear instructions, and that systems are safe to use around children and pets.***

Question 5

FDA broadly asks for additional information on system specifications FDA should require or other actions FDA could take in addition to, or in support of, an in-home disposal system REMS requirement to increase safe disposal of unused opioid analgesics. In response, ***AAHPM urges the FDA to better understand and assess the risks versus benefits of imposing new requirements for in-home disposal systems under the OA REMS, and to ensure that policies are proportionate to actual risks.*** For example, better information on the following questions would help to assess the need for changes to the REMS and the extent to which such changes should apply to patients with serious illness:

- What proportion of unused medications are diverted for improper use?

- What proportion of opioid-involved overdose deaths comes from excess medications that were not disposed properly? How does that compare to risks from illicit fentalogues?
- What added benefit would new requirements for in-home disposal systems offer relative to existing options for drug disposal? How would costs and burden associated with new requirements compare to efforts to expand availability of existing disposal options?

For patients with serious illness, reliable access to pain medications is much more of a challenge than disposing of leftover medications. Therefore, ***we underscore that disposal system requirements should never become a barrier to appropriate prescribing or dispensing.***

To the extent that evidence supports requirements for in-home disposal systems under the OA REMS, ***AAHPM urges FDA to ensure that in-home disposal system specifications and other requirements account for the unique circumstances of patients with serious illness, including those in hospice and at the end of life.***

To that end, AAHPM highlights special considerations for patients enrolled in hospice and the hospices who care for them. Hospice patients are a discrete and unique subset of patients who require opioids and other controlled substances to manage intractable pain and other distressing symptoms of serious illness – and they often present with urgent needs. Hospice patients must be certified to be "terminally ill" by two physicians who each attest the patient has an estimated life expectancy of 6 months or less. Typically, however, patients receive hospice care for much shorter periods, with the median length of stay in hospice only 21 days and 31 percent of hospice patients enrolled in hospice for 7 days or less.[1] Timely management of pain and other symptoms is crucial at the end of life, and it is particularly urgent when patients present with pain crises. Barriers to pain relief during this period deprive patients of the peace and dignity they deserve.

Hospice care also offers numerous protections to mitigate the risk of medication misuse or abuse. All hospice care is supervised by a hospice physician, with much of the day-to-day care provided by interdisciplinary hospice team members, which include advance practice registered nurses, physician assistants, nurses, social workers, chaplains, and others based on these. These team members are in regular face-to-face contact with patients, making frequent home visits, providing extensive education and supervision, and making themselves available 24/7 – all of which increases their ability to detect and address questionable drug behavior and safety concerns with both patients and their caregivers. Hospice nurses also work to prevent diversion through activities such as pill counts and use of locked medication boxes when risks of diversion or abuse are identified, and hospice staff help families manage medications and ensure appropriate disposal when the medications are no longer needed or after a patient dies.

Given all of the above, AAHPM recommends that FDA carefully consider how in-home disposal system specifications would be implemented in the context of opioid analgesics dispensed to patients enrolled in hospice, and we offer the following questions for consideration.

- Will hospice patients be required to obtain in-home disposal systems in order to be able to access opioids? We question whether such a requirement is necessary, given that hospice teams already work to ensure appropriate disposal. If such requirements are established, how will they work with existing hospice processes?
- Who will be required to pay for these systems when opioids are dispensed to hospice patients? Financial demands may serve as barriers for patients accessing these systems if they are required

[1] https://allianceforcareathome.org/wp-content/uploads/Facts-and-Figures-2025.pdf

to pay. Likewise, hospices may also have difficulty absorbing the cost of these systems for their patients, given that hospices are paid a fixed daily rate.

- What documentation requirements will apply if hospices are expected to distribute or track these systems? Clear guidance will be needed to ensure compliance.

Finally, for all patients with serious illness – whether enrolled in hospice or not – ***AAHPM recommends that FDA ensure appropriate education such that materials do not pressure patients or families to rush disposal of medications when they are still needed for symptom control or when caregivers are in the aftermath of a patient's death. AAHPM also recommends that FDA take steps to ensure access to in-home disposal systems in rural areas, where pharmacy access or delivery may be limited.***

Conclusion

Thank you for your consideration of our comments in response to the above-referenced request for comments. If you have any questions, please feel free to reach out to Wendy Chill, Senior Director, Health Policy and Government Relations, with any questions at wchill@aahpm.org or (847) 375-6733.

Sincerely,

Kimberly Curseen, MD, FAAHPM
President, American Academy of Hospice and Palliative Medicine