American Society of Anesthesiologists®

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February 9, 2021

The Honorable Janet Woodcock, MD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: [Docket No. FDA-2020-N-1561]: Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes–Exploring the Path Forward for Assessment; Public Workshop; Issues Paper; Request for Comments

Dear Dr. Woodcock:

On behalf of the American Society of Anesthesiologists (ASA) and our more than 54,000 members, we are pleased to provide comments in response to the Food and Drug Administration's (FDA) request for comments; *Evaluating the Effect of the Opioid Analgesics Risk Evaluation and Mitigation Strategy Education Program on Prescribing Behaviors and Patient Outcomes–Exploring the Path Forward for Assessment*. As the medical specialty society representing the largest number of practicing physician anesthesiologists, ASA has significant interest in reducing the misuse, abuse, and diversion of opioid medications that have led to unintended deaths. We commend the FDA for implementing a voluntary continuing education (CE) program with no cost to physicians.

As the nation continues to confront the opioid epidemic, physicians play a key role in ensuring the responsible prescribing of opioid medications. Physician anesthesiologists have an important role in the delivery of care that makes these specialists uniquely positioned to help reduce inappropriate use and abuse of opioids throughout the perioperative period and upon discharge. ASA supports efforts that reduce opioid overdose deaths but still preserve patient access to pain management therapies. Given the ongoing opioid crisis and new challenges that have arrived throughout the COVID-19 pandemic, ASA supports the continuation of the Risk Evaluation and Mitigation Strategy (REMS) program and believes it could be a part of the solution to address the ongoing opioid crisis.

ASA recommends REMS education should follow traditional Accreditation Council for Continuing Medical Education (ACCME) standards for accredited CME providers.

ASA understands the FDA is interested in specific, measurable outcomes that might demonstrate the REMS program is effective in educating prescribers and other health care providers involved in the treatment and monitoring of patients in pain, and appropriate opioid prescribing. ASA recommends that REMS education should follow traditional ACCME standards for accredited CME providers; the goal should be to measure changes in competence, performance, or patient outcomes. ASA suggests analyzing those changes by providing pre and post-tests, as well as a 90-day follow up to ensure implementation of changes the physician committed to because of the educational activity. If providers encounter barriers to making that change, they should also be asked what those barriers are and, subsequently, modifications that can be made to develop educational interventions to minimize those barriers.

In 2019, ASA received a REMS grant from the FDA and administered education through four on-demand interactive modules and four live meetings. There were 3,257 participants, and 3,101 of those participants

completed the training. We found there was significant growth in the number of learners who demonstrated levels of correctness combined with high levels of confidence in their knowledge and competence in treating patients with chronic pain; a 92 percent average relative increase in knowledge gained across all learning objectives; a 51 percent change in incorporating non-pharmacologic treatment options; and a 51 percent change in incorporating an individualized approach to pain relief. However, we still identified persistent learning gaps/needs, such as 35 percent of participants continued to have low confidence regarding their knowledge of/competence in safe and effective opioid pain management and prevention/management of opioid use disorder (OUD). Also, less than 51 percent of participants identified specific practice changes they would implement regarding opioid pain management and preventing/managing OUD. Our conclusions demonstrated the need for reinforcement or further education.

ASA supports conducting a pilot study to evaluate the effectiveness of REMS-compliant CE.

ASA believes it would be challenging to specifically evaluate the effect of a REMS CE activity on prescriber behavior and patient outcomes. While it is difficult to evaluate any one program's efficacy, access to free continuing education is important, and we know CME can improve physician performance and patient outcomes. ASA supports conducting a study to specifically evaluate the effects of REMS-compliant CE. One possibility would be a pilot study to partner with a health system or institution to assess prescribing practices and patient outcomes between a group targeted with REMS CE education versus a group that did not receive education. A 1-year post-intervention period would be a reasonable amount of time to assess changes. Prescribing practices could be assessed by well-defined metrics (e.g., MME/day, co-prescription of naloxone, rates of co-prescription of benzodiazepines and opioids, etc.), and patient outcomes could be measured by rates of overdose, OUD, and long-term opioid prescriptions. Pain-related outcomes might be more challenging to assess and may not even be directly impacted by a REMS program (function, etc.).

ASA also encourages the FDA to revisit some of the studies discussed in its issues paper, *Methods for Evaluating the Opioid Analgesic Risk Evaluation and Mitigation Strategy*, which was released in conjunction with the December 11, 2020 meeting, as the climate around prescribing has changed and some of these studies could be more feasible now. The past 5-10 years saw a dramatic shift in opioid prescribing behavior that could be attributed to a multitude of educational opportunities as well as federal Centers for Disease Control and Prevention guidelines and individual state recommendations. This rapidly changing environment made assessment of the efficacy of a specific REMS intervention difficult to calculate. Most of these educational programs and the adoption of guidelines has occurred across the country and there is now a "steady state" of opioid prescribing. Revisiting these studies as they pertain to a single REMS program may in fact yield more accurate information than in times past.

ASA recommends fulfilling state requirements for REMS education.

ASA also recommends efforts to fulfill state requirements with REMS. There would likely be further uptake in the training if it meets state or licensing board requirements. One challenge ASA experienced when attempting to engage our own members in REMS education was that they already had other existing requirements to fulfil within their own states or were being urged to take a specific offering by their own health systems instead of our training. Greater alignment in education that fulfils state requirements would increase uptake.

ASA agrees with many of the sentiments expressed in the FDA issues paper and understands the challenges in evaluating an effective REMS education program. However, we still believe there is value in an educational program even when you cannot conclude that any one improvement in physician practice

or behavior is the result of that education. The benefits of widely accessible and free education outweigh any barriers to measuring how effective the program is specifically. In addition, we know that constant reinforcement increases learning so ensuring the availability of education through REMS training is preferable.

ASA is pleased to comment on this matter and appreciates FDA's efforts to evaluate and improve the REMS education program. We welcome the opportunity to work with the FDA to explore solutions. If you have any questions, please contact Ashley Walton, JD, at a.walton@asahq.org or 202-289-2222.

Sincerely,

Beverly K. Philip, MD, FACA, FASA
President
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