

September 27, 2016

Steven D. Pearson, MD, MSc, FRCP
President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

***RE: ICER Abuse-Deterrent Formulation of Opioids in Pain Management:
Effectiveness and Value***

Dear Dr. Pearson:

The Academy of Managed Care Pharmacy (AMCP) thanks the Institute of Clinical and Economic Review (ICER) for the opportunity to provide comments on the draft scoping document that will examine the clinical effectiveness and value of abuse-deterrent formulation (ADF) of opioids in pain management released on September 8, 2016. AMCP appreciates the broad input from payers as well as patients, pain management specialists, and pharmaceutical manufacturers. ADFs present a management challenge for health care decision makers, including managed care organizations (MCOs), health plans, and other payers because of the lack of evidence regarding their effectiveness. AMCP applauds ICER in undertaking this challenging but valuable assessment of ADFs and believes that it is an important component in helping pharmacists, physicians, and nurses in MCOs and other health care decision makers critically evaluate ADFs to effectively manage the use of opioids in a clinically appropriate manner.

AMCP is a professional association of pharmacists and other practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 8,000 members develop and provide a diversified range of clinical, educational, medication and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

Opioid analgesics have proven to be very effective in controlling short and long-term pain due to a large number of causes. These drugs are also the most commonly abused medications in the United States, reaching epidemic levels. AMCP is concerned both about the proper management of patients suffering from uncontrolled pain, as well as limiting abuse and diversion of opioids because the improper use of opioids carries enormous costs to our society that go beyond traditional health care costs. Pharmacists,

physicians, and nurses who work in managed care organizations have a responsibility to implement medication management programs and services to ensure appropriate use of opioids in the populations they serve and to work with other health care providers, patients, and caregivers to reduce the potential for misuse, abuse, or overdose of opioids.

Managed care organizations must carefully balance the unique and varied needs of patients who are taking these medications against the probability of abuse and diversion. Therefore, AMCP supports the ability of health plans, pharmacy benefit managers (PBMs), accountable care organizations, and integrated delivery systems to use managed care tools to effectively manage the use of opioids in a clinically appropriate manner. The use of frameworks is one potential resource to help make these determinations.

AMCP appreciates the thoughtful approach described under the analytic framework and believes the population of focus, interventions, and comparators outlined are appropriate. AMCP supports the breakdown of the populations that distinguishes therapeutic and non-therapeutic use of opioids; recreational users; and, opioid addicts because often this type of specificity is not always readily available in reviewing data. Generally reviews are based upon use of opioids in cancer and non-cancer patients.

AMCP supports the use of real world evidence on outcomes associated with specific opioids. This review should include analysis of payer data supplementary to conducting a systematic literature review and collecting other data. The payer information and the systematic literature review could help payers and other decision makers to make informed coverage determinations for ADFs and help to inform whether legislative and regulatory coverage mandates are consistent with existing evidence.

AMCP suggests that the economic evaluation and modeling used to determine the cost-effectiveness of ADFs should be made available to managed care pharmacists and other health care providers to facilitate to downloading, auditing, and testing the models by modifying the assumptions of the model based on their perspectives and their covered populations.¹ This could also allow for health care providers and decision makers to modify the assumptions of the model based on their perspectives and their covered populations. Health economic analyses would also be fully disclosed, meaning that bibliography, supporting documents, limitations, and potential biases would be fully detailed. Specifically, the availability of the economic models would, at minimum, allow for the following:

- Realistic adoption rates that accurately reflect the anticipated uptake of ADFs based on state legislation;
- Consideration of an appropriate quality-adjusted life year (QALY) threshold after consultation with available literature or an organization's bioethics committee;
- Adjustment of the cost of a medication to more accurately represent the actual net cost;

¹[AMCP Partnership Forum: FDAMA Section 114—Improving the Exchange of Health Care Economic Data](#). Journal of Managed Care & Specialty Pharmacy 2016 22:7, 826-831

- Flexibility to extrapolate the data for a short-term versus long-term forecast to better understand the immediate budget impact versus overall value of ADFs;
- Adaptability for factors such as emergency department, hospital utilization, or medication addiction treatments; and
- Validation that the economic model is applicable to the relevant patient population.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with ICER. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-683-8416 or scantrell@amcp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell". The signature is fluid and cursive, with a long horizontal stroke extending from the end.

Susan A. Cantrell, RPh, CAE
Chief Executive Officer