

June 2, 2017

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

***Re: Abuse Deterrent Formulations of Opioids: 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 evidence report titled “*Abuse Deterrent Formulations (ADFs) of Opioids: Effectiveness and Value*” released on May 5, 2017. 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 managed care organizations and other health care decision makers critically evaluate ADFs to effectively manage the use of opioids in a clinically appropriate manner. AMCP previously provided detailed comments<sup>1</sup> in September 2016 to ICER on the draft scoping document for this work, and offers additional commentary regarding the transparency, adaptability, and usability of the economic model and considerations for future updates to the evidence report.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

**The Economic Models Used Should be Made Available to Managed Care Pharmacists and Other Health Care Providers**

While AMCP appreciates that the general components considered in the ICER value assessment framework are transparent, the economic models used to evaluate treatments are currently not made publicly available. AMCP supports economic models that when appropriately used, should be transparent, disclosed, reproducible,

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<sup>1</sup> AMCP Comments Re ICER Draft Scoping Document for Abuse Deterrent Formulations of Opioids: Effectiveness and Value. September 27, 2016. Available at: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=21478>. Accessed June 2, 2017.

accurate, and valid.<sup>2</sup> Furthermore, AMCP believes economic models should be made available to managed care pharmacists and other health care providers to download, audit, and test the model by modifying the assumptions of the model based on their perspectives and their covered populations. Specifically, the availability of the economic models would, at minimum, allow for the following:

- Realistic adoption rates that accurately reflect the anticipated uptake of a medication based upon utilization management programs and/or the relevance to the population served;
- 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 acquisition cost;
- Flexibility to extrapolate the data for a short-term (one year) versus long-term (five years) forecast to better understand the immediate budget impact versus overall value of the medication;
- Adaptability for rare diseases or precision medications; and
- Validation that the economic model is applicable to the relevant patient population.

In addition, AMCP urges ICER to consider a process by which stakeholders could be given an opportunity to test and validate the economic models when in draft format and provide feedback on how they can be improved prior to finalization. With this approach, the economic models are more likely to reflect current real-world conditions.

In supporting the need for transparent economic models, AMCP also recognizes that it is important to ensure that individuals who have access to the models have the appropriate training and qualifications to properly evaluate and modify the model. Therefore, AMCP recommends that ICER consider a free licensing process that would allow ICER to evaluate the qualifications of the requestor prior to releasing the economic model, similar to the approach used by the National Institute for Health and Care Excellence (NICE). Many managed care pharmacists have considerable expertise in pharmacoeconomics and therefore, AMCP recommends that ICER work with AMCP and other stakeholders to develop the list of criteria to use in selecting eligible recipients of the economic models and the creation of a process to minimize barriers to access.

### **The Evidence Report Should be Updated to Incorporate New Evidence as it Becomes Available**

AMCP commends ICER for reviewing and incorporating a diverse catalog of studies in its evaluation of ADFs and for being transparent with the current limitations to the methodology used. However, AMCP urges ICER to develop a process for incorporating real-world evidence (RWE), patient reported outcomes (PROs), and other forms of new evidence as they become available into the catalog of evidence that informs the economic models and then updating the evidence report accordingly. Furthermore, AMCP urges ICER to consider methodology that would allow for a parallel analysis of ADFs to other preventative measures for opioid misuse as new evidence becomes available.

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<sup>2</sup> 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.

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](mailto:scantrell@amcp.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell", with a long horizontal flourish extending to the right.

Susan A. Cantrell, RPh, CAE  
Chief Executive Officer