

September 12, 2016

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

RE: ICER National Call for Proposed Improvements to its Value Assessment Framework

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 in response to the national call for suggestions on how to improve its value assessment framework released on July 14, 2016. AMCP appreciates the work of ICER in developing its value assessment framework and believes that it is important and critical to help move health care in the United States towards a value-based model, and further applauds ICER for seeking public feedback on how it can be improved. ICER's value assessment framework is one of the many tools utilized by managed care pharmacists and other health care providers in their comprehensive and holistic approach to evaluating the totality of evidence in determining whether medications and other health services are appropriate for the patient populations they serve. AMCP offers comments on the following elements of the ICER value assessment framework that it believes should be re-examined to further enhance the utility and relevance of the value assessment framework:

- Transparency, adaptability, and usability of the economic model
- Incorporation of real-world evidence and patient-reported outcomes
- Stakeholder representation on voting panels

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.

The Economic Models Used in the ICER Value Assessment Framework 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, accurate, and valid. 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.¹ 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 ICER Value Assessment Framework Should Incorporate Real-World Evidence and Patient Reported Outcomes

AMCP commends ICER for reviewing and incorporating a diverse catalog of studies in its value assessment framework. However, AMCP urges ICER to develop a process for incorporating real-world evidence (RWE) and patient reported outcomes (PROs) into the catalog of evidence that informs the economic models for its value assessment framework. Furthermore, AMCP urges ICER to include managed care pharmacists as a key stakeholder during this process because many are pharmacoeconomic experts and have been collecting, analyzing, and using RWE in their practice settings for many years. In addition, pharmacists are easily accessible to patients and collect PRO data through the provision of pharmacy services such as academic and non-academic outcomes research, payer clinical programs and disease management, medication therapy management, and patient counseling.

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

Voting Panels for ICER Value Frameworks Should Include Broad Stakeholder Representation with Pharmacoeconomic and Clinical Expertise

AMCP urges ICER to ensure voting panels include managed care pharmacy representation, clinical experts in the specific disease state being evaluated, other health care providers, and the patient perspective. Finally, AMCP urges ICER to develop a transparent process and minimal qualifications to ensure that voting panel members have an appropriate knowledge of what pharmacoeconomic information is, understand the concept of overall value versus cost, and can evaluate the economic models for credibility.

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