

May 26, 2017

Nancy S. Berg, BsC.
Chief Executive Officer
International Society for Pharmacoeconomic and Outcomes Research
505 Lawrence Square Boulevard, South
Lawrenceville, NJ 08648

Re: AMCP Comments on Draft Special Task Force Report “A Health Economics Approach to US Value Assessment Frameworks”

Dear Ms. Berg:

The Academy of Managed Care Pharmacy (AMCP) thanks the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) for the opportunity to comment on the *Draft Special Task Force Report “A Health Economics Approach to US Value Assessment Frameworks”* issued on May 4, 2017 as part of its Initiative on US Value Assessment Frameworks. AMCP appreciates the opportunity to participate as a member of the Stakeholder Panel review group for this initiative. AMCP supports the use of value frameworks as a resource for determining the value of pharmaceuticals and other health technologies when the frameworks are based on sound methods using good scientific evidence and economic models. AMCP supports the need to evaluate the elements of value frameworks that impact population health and clinical decision making separately. AMCP also supports the recommendation by the Special Task Force that cost-effective analysis for value constructs be based on incremental total health care costs and QALY elements. AMCP provides general comments on the issues considered by the draft document and also provides specific comments on some sections.

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.

AMCP appreciates ISPOR’s recognition that value frameworks complement other approaches, including the AMCP Format for Formulary Submissions v4 (AMCP Format).¹ Since 2000, the Format has been used as a framework by manufacturers to provide health care economic information (HCEI) to consider new health technologies for formulary coverage. As health technology and ways to communicate and evaluate HCEI evolve, AMCP has focused on examining value frameworks in the context of population level decision-making. AMCP’s Format Executive Committee will evaluate and consider whether revisions to the Format are

¹ The Format for Formulary Submissions Version 4.0. Academy of Managed Care Pharmacy; April 2016. <http://www.amcp.org/FormatV4/>. Accessed May 26, 2017.

necessary in the current context of value-based decision-making. AMCP has also adopted a policy that includes the following principles for value frameworks:

- Developers should consider key stakeholder perspectives from across the healthcare continuum, including patients, providers, payers and other health care decision makers, and pharmaceutical manufacturers;
- Analytic methodology, and economic models used in the development of a value framework should be validated and made publicly available;
- Value frameworks should incorporate scientifically valid evidence from a variety of sources, including real-world evidence and patient-reported outcomes, as part of the evaluation of a medication or other health technology, a process fully described in the AMCP Format, v. 4.0;
- Value frameworks should provide interpretable outputs that allow health care decision makers and health care providers to conduct assessments of medications and health technologies in order to make value-based policy and treatment decisions for patients;
- Value frameworks intended for patient audiences should provide sufficient information in formats that can be understood by patients;
- The identities, credentials, qualifications and/or conflicts of interest of those involved in the development or approval of value frameworks should be publicly available; and
- Value frameworks should be updated with the most current product evaluation techniques and should continue to provide accessible information to stakeholders.²

As noted above, use of value assessment frameworks 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 looks forward to working with ISPOR and other stakeholders in harmonizing value assessments for populations and for patients and clinicians.

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.³ 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;

²AMCP Where We Stand on Value Frameworks. Available at: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=22039>. Accessed May 17, 2017.

³ 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 (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 to general comments above, AMCP offers the following specific comments in response to the draft report.

Section 1: Introduction

ISPOR’s initial reference to the Format and in footnotes should be cited as its official name: AMCP Format for Formulary Submissions v4. AMCP also suggests that the final document consider including information on the need to educate government officials on value assessments. Often laws and regulations are approved with little regard to these concepts resulting in impediments to achieving the goals of value-based decision making.

Section 4: Aggregating elements of value to individual and population levels

This section considers two “aggregation” issues with value assessments:

- Current methods for CEA, CUA, and CBA are focused on utility maximization for an individual and therefore these methods can’t readily address societal value at a population level. This issue is important because many resource allocation decisions should be based on societal value.
- Current methods cannot accommodate additional elements of value beyond the single metric output for CEA, CUA, and CBA. For example, the output of CUA is cost per QALY.

Various novel methods are discussed to address these challenges but the summary concludes that “No existing method completely or perfectly ...” solves the two aggregation issues. The authors do not recommend any of the methods discussed for immediate adoption by decision makers and recommend additional research. AMCP agrees with this assessment and recommends that ISPOR consider processes used by pharmacy and therapeutics committees or health technology assessment agencies.

This section also mainly focuses on new technologies, and especially pharmaceutical products. It would be useful for readers and users of this document if ISPOR described the current state of the art approaches to value assessment for various types of technologies and for other healthcare practices such as delivery reform where value assessments apply. Then, the document should make clear which specific types of products, services, and systems are in scope for certain value frameworks, which are not in scope, and the rationale for this approach. If the overall goal is to create a more efficient healthcare system, we believe that focusing on one specific area for value assessments does not make sense if there are existing low value areas in other parts of the healthcare system.

AMCP also supports consideration and potential advantages of a “deliberative process” used by health technology assessment bodies and entities such as the United States Preventive Services Task Force as described in Section 4.5.

Section 5: Reaching a Decision: Objectives, Budgets, Thresholds, and Opportunity Costs

AMCP provides the following recommendations for improving this section.

- ISPOR should consider explaining the difference between affordability and budget as part of Section 5.2. Also, consider elaborating on what role results from budget impact analyses should play in value frameworks
- The conclusion of this section states that “several clear recommendations” have been made as part of this section including the need to adopt a decision rule about defining good value and consistent use of a cost-per-QALY threshold. However, decision-makers will likely still have difficulty defining appropriate (non-arbitrary) thresholds for their organization based on the information in this document. Decision-makers require actionable, clear guidance for establishing an appropriate decision rule about what is good value for money, so ISPOR should consider including examples in this section.

AMCP seeks clarity on the following statement that appears in lines 147-150:

“Recommendations for disinvesting and switching resources into new uses seems to assume that cost-effectiveness estimates for all technologies are known.” Is this a correct assumption? If so, the authors may want to consider the practicality of establishing the cost-effectiveness estimates of all technologies.

Section 6: Recent US Value Frameworks: Suggestions and Implications

AMCP is particularly pleased that in Section 6.4, Recommendations for Value Framework Conceptualization and Design, the Special Task recognizes that cost-effective analyses are different for population-level decisions and individual clinician-patient decisions. AMCP agrees with this assessment and will work with ISPOR and others to ensure that analyses correctly define the basis for the underlying value construct.

AMCP once again thanks ISPOR for the opportunity to comment on the draft report and to be a part of the Initiative on US Value Frameworks. If you have any questions regarding AMCP’s comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,



Susan A. Cantrell, RPh, CAE
Chief Executive Officer