

August 24, 2017

Richard J. Willke, PhD
Chief Science Officer
International Society for Pharmacoeconomic and Outcomes Research
505 Lawrence Square Boulevard, South
Lawrenceville, NJ 08648

Re: Initiative on US Value Assessment Frameworks: Draft Special Task Force Report

Dear Dr. Willke:

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”* as updated on July 7, 2017. AMCP appreciates the opportunity to participate as a member of the Stakeholder Panel review group for this initiative. AMCP [commented](#) on the original draft report issued on May 4, 2017. AMCP’s additional comments focus on Section 7 - Summary: Key Points and Recommendations that is a new section included in the revised draft report. AMCP appreciates that the revised draft incorporates feedback submitted in response to the initial draft. In general, AMCP supports the concepts summarized and advanced by ISPOR in Section 7.6 of the document that emphasize no single value assessment framework easily accommodates both population and patient decision-making and that developers must clearly articulate the value construct and purpose of the framework according to the targeted audience.

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 concepts advanced in the draft that suggest the need to evaluate the elements of value frameworks that impact population health, clinical decision making, and the patient perspective separately and that frameworks must clearly define the targeted audience.

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

¹ The Format for Formulary Submissions Version 4.0. Academy of Managed Care Pharmacy; April 2016. <http://www.amcp.org/FormatV4/>. Accessed August 22, 2017.

- 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 continuing work with ISPOR and other stakeholders in harmonizing value assessments for populations and for patients and clinicians.

AMCP supports economic models in framework assessments that are 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;
- 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.

²AMCP Where We Stand on Value Frameworks. Available at: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=22039>. Accessed August 22, 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

Convening a Special Task Force to Collaborate on a White Paper on the Definition and Use of High Value Frameworks

AMCP supports ISPOR's objective to convene a Special Task Force (STF) and engage stakeholders to identify perspectives, approaches, and methodology for use of high quality value frameworks. AMCP recommends that the STF not just focus on a white paper, but also continue to engage as additional ways to assess -value frameworks that emerge. The STF and other stakeholders should also continue to advocate for the adoption of improvements in identifying assessments and methodologies used in framework assessments. Furthermore, the STF should develop a dissemination strategy for the white paper and other tools.

Recommendation 1.1: Begin with and Build upon Cost-Effectiveness Analysis (CEA)

AMCP appreciates that the recommendation considers that value assessment frameworks should consider health gains as measured by QALY to inform payer and policy maker deliberations. In comments to the initial draft, AMCP recommended use of QALY assessments based on literature analyses for populations. The recommendation to consider QALY and then consider health resource allocation when relevant to a setting, population, or intervention is a positive step to help payers and population health decision-makers in decision making.

Recommendation 2.1: Clarify Importance of Perspective and Decision Context

This section outlines one of the current challenges when seeking to use value frameworks as a sole source of information to review evidence: that value frameworks are written from the perspective of the entity providing the analysis. Therefore, AMCP supports the recommendation to clarify and specifically outline the perspective of the value framework developer to ensure that users better understand the goals and of the framework developers when analyzing the evidence. This recommendation also highlights the fact no single value framework will replace a comprehensive evidence review by pharmacists and other health care providers who manage populations or use evidence to make treatment decisions.

Recommendation 3.1: Apply CEA to Inform Public and Private Coverage and Reimbursement Decision Making

As outlined above, AMCP agrees that the cost-per-QALY metric should serve as the core component of value assessments that inform public and private coverage reimbursement decisions in the United States.

Recommendation 3.2: Support Additional Research that Enhances the Applicability, Scope, and Relevance of Cost-Effectiveness Analysis for Decision Making

In comments on the draft assessment, AMCP provided feedback on various proposed cost effectiveness analyses (CEA) suggested by ISPOR and others for value frameworks and found that there are shortcomings in all models, including QALY, the preferred approach. AMCP supports testing of novel approaches that may lead to better resource allocation within the health care system. These approaches must balance scientific and clinical information for populations and find ways to incorporate the patient perspective of value to provide a sound basis for decision making. AMCP recommends that payers, health care providers, patients and other stakeholders be given the opportunity to test the validity of these options or a combination of options as they are advanced. The STF should also continue to engage in activities to evaluate the new emerging options.

Recommendation 4.1: Utilize Value Thresholds—Expressed as in the Cost-per-QALY Metric Potentially Considering Other Elements—to Help Guide Coverage and Reimbursement Decisions

AMCP appreciates the flexibility that this approach takes in comparison to other approaches that provide specific monetary or budget thresholds and do not limit independent analyses by decision makers.

Recommendation 4.2: Manage Budget Constraints and Affordability

AMCP appreciates that ISPOR recommends an analysis of the affordability of health care technology that considers the full impact of new technologies, including adjustment costs on spending and the impact of immediate or delayed implementation of new technology. This analysis is a critical factor in encouraging the use of high value treatments and technology that balances appropriate utilization with good financial stewardship.

Recommendation 5.1: Use and Test Structured Deliberative Processes

AMCP supports the development of more research on multi-criteria decision analysis (MCDA) modeling and use as a means to provide a deliberative process for explicit frameworks. AMCP also supports the recommendations that MCDA models should include comparing resource allocation implications with those of conventional or augmented CEA-based decision making and other alternative approaches.

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,

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

Susan A. Cantrell, RPh, CAE
Chief Executive Officer