June 7, 2019

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

Dear Dr. Pearson,

As organizations representing veterans and individuals in the military living with diverse conditions and diseases, as well as their families, caregivers and providers, we are pleased to provide feedback on the Institute for Clinical Economic Review (ICER) 2020 Value Assessment Framework.

On June 27, 2017, ICER announced an agreement to work with the Department of Veterans Affairs (VA) Pharmacy Benefits Management Services office (PBM) to support its use of ICER drug assessment reports. As we understand, under this agreement, ICER is working with VA staff to integrate ICER's academic reports into the VA formulary management process of evaluating the comparative effectiveness and value of drugs. Therefore, for us, updating ICER's value framework holds particular significance due to its influence over the care that veterans and members of the military are able to access.

ICER Should Abandon the Discriminatory Quality-Adjusted Life Year and Similar Metrics

ICER utilizes a quality-adjusted life year (QALY) metric as the basis for its value assessments that is very controversial for its discriminatory impact on people with disabilities and serious chronic conditions. The QALY inherently discriminates against patients and people with disabilities by placing a lower value on their lives. In fact, in 1992, the U.S. Department of Health and Human Services denied a state waiver application after determining the use of QALYs in Medicaid would be discriminatory and potentially violate the Americans with Disabilities Act (ADA). Also, Medicare has a statutory ban against use of QALYs and similar metrics for coverage decisions. We have significant concerns that similar protections against the use of a cost-per-QALY value assessment do not exist for our members. It is profoundly unfair and offensive to those who have served this country to allow for this kind of discrimination in the veterans health system. Therefore, we urge ICER to abandon the use of the QALY in its value assessments and instead work toward more patient-centered strategies for assessing value that are not based on averages so that our Veterans' health system is not susceptible to this kind of discrimination.

1 See https://icer-review.org/announcements/va-release/
ICER's Value Framework Should Better Reflect the Value of Treatments for Individuals

Under the existing methodology, ICER's value determinations are based on population-level averages that do not reflect individual differences among veterans. Additionally, ICER tends to conduct their value assessments at a stage when inadequate data is available to reflect subpopulations, especially veterans in particular. No veteran is average and treating them as such only undermines the clinical knowledge of providers in the veterans' health system that may not yet be reflected in the research. We are concerned that the use of ICER's assessments will further limit access to care tailored to individual veterans, thereby exacerbating the existing access challenges that they and their caregivers often face. In an era when policy-makers and stakeholders want to improve care to veterans, the VA's health system should embrace patient-centeredness, as opposed to becoming entrenched in a one-size-fits-all perspective of health care value. Different people respond differently to the same drugs and no two veterans are the same or have the same health care needs. Each veteran deserves care from a health system that recognizes his or her unique needs and characteristics.

Any ICER Value Assessment Used by the VA Must Incorporate Feedback from Veterans

ICER's research is often criticized by patients for failing to incorporate their input or focus on the outcomes that matter to them. We are unaware of ICER surveying veterans for information about the outcomes that matter most to them or the goals for their treatment. Certainly, we have not been directly engaged in the development of any value assessments conducted by ICER for the VA's use in developing their formularies. Veterans have unique health challenges that cannot be averaged out alongside civilian populations. The point of a health system managed by and for veterans is to ensure that there exists an infrastructure for treating veterans with disabilities and serious chronic conditions that is responsive to their unique needs and characteristics. Without specific engagement of veterans, ICER cannot develop a value assessment that would be constructive for use by the VA to achieve outcomes that matter to veterans in the real world.

Care that Fails Veterans Leads to Higher Costs

Standardized care decisions create barriers to certain treatments for veterans that don't meet "average" thresholds, leading to increased costs when treatments fail the patient. When patients cannot access treatments that work for them, the VA system bears the cost of reduced treatment adherence, increased hospitalization and other acute care episodes, as well as the societal costs of increased disability over time. In this age of personalized medicine, we want the VA to rely on expertise that will drive the agency to reduce costs and improve care quality by better targeting treatments shown to work on patients with similar characteristics, needs and preferences, thereby avoiding the waste of valuable resources on care that veterans do not value.

In conclusion, prescription drug coverage determinations based on ICER's currently flawed analyses are not the answer and can only serve to further limit access to care for veterans with disabilities and serious chronic conditions, thereby exacerbating the challenges that they and their caregivers often face. We want ICER's value framework to be updated in a manner that would constructively assist VA to be a model for putting patients first by engaging patients. Otherwise, it is not appropriate for the VA to be referencing ICER's studies at all.

Thank you for this opportunity to comment. In light of your direct relationship with the VA, we hope that you will act on our recommendations.

In Comradeship,

Larry Leonardo, Sr.
State Commander, Dept of California
The American Legion

"TO CONSECRATE AND SANCTIFY OUR COMRADESHP BY OUR DEVOTION TO MUTUAL HELPFULNESS"