PIPC Partnership to Improve Patient Care

February 11, 2019

Patrick M. Shanahan
Acting Secretary of Defense
U.S. Department of Defense
770 Arlington Boulevard
Falls Church, VA 22042

Re: DOD-2018-HA-0062: TRICARE Pharmacy Benefit Program Reforms

Dear Acting Secretary Shanahan:

The Partnership to Improve Patient Care (PIPC) appreciates the opportunity to submit comments to the Department of Defense (DOD) on the interim final rule (IFR) concerning the TRICARE Pharmacy Benefits Program.[1] Since its founding, PIPC has been at the forefront of applying principles of patient-centeredness to the nation's health care system – from the generation of comparative clinical effectiveness research at the Patient-Centered Outcomes Research Institute (PCORI), to the translation of evidence into patient care in a manner that achieves value to the patient. Having driven the concepts of patient-centeredness and patient engagement in the conduct of research, PIPC looks forward to bringing the voices of patients and people with disabilities to the discussion of how to advance patient-centered principles throughout an evolving health care system.

Patients and people with disabilities, particularly in military families and veterans, followed closely the debate on Capitol Hill related to provisions of the NDAA seeking to pay for value. Section 702 of the final statute seeks to "to encourage the use by covered beneficiaries of pharmaceutical agents that provide the best clinical effectiveness to covered beneficiaries" by allowing the Pharmacy and Therapeutics Committee to "exclude from the pharmacy benefits program any pharmaceutical agent that the Secretary determines provides very little or no clinical effectiveness to covered beneficiaries and the Department under the program." This provision also allows the Secretary to "adopt special reimbursement methods, amounts, and procedures to encourage the use of high-value products and discourage the use of low-value products."

Our comments will provide insights on how clinical effectiveness is defined and measured, as well as how value *to the patient* can be best achieved. Our hope is that this provision is implemented in a nondiscriminatory manner that advances patient-centered decision-making.

[1] Department of Defense, TRICARE Pharmacy Benefits Program Reforms, 83 Fed. Reg. 63574 (Dec. 11, 2018).

Clinical Effectiveness Varies by Patient and Should Not Entrench One-Size-Fits-All Value Judgements

We encourage the DOD not to drive physicians to treat patients based on one-size-fits-all academic value determinations, and instead empower treatment decisions based on the needs of the individual patient. In determining clinical effectiveness, the DOD has an opportunity to take advantage of comparative clinical effectiveness research generated by the Patient-Centered Outcomes Research Institute (PCORI) and others to align Tricare with efforts to deliver personalized and precision medicine to patients and people with disabilities. The statute creating PCORI provides the following definition:

> *The terms 'comparative clinical effectiveness research' and 'research' mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items.*

In implementing comparative clinical effectiveness research:

> *The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be pre- vented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items…*[2]

We encourage the DOD to reference the PCORI model and to consider clinical effectiveness and value from the perspective of individual patients and avoid looking for one-size-fits-all definitions that create arbitrary thresholds for coverage. No patient is average, which is especially true among those being served by Tricare. Yet, we see an opportunity in this provision for Tricare to advance shared decision-making and patient decision aids that help individuals identify what treatments are of value to their specific needs and characteristics, instead of arbitrarily excluding or forcing higher copays for drugs that are not deemed to be "cost effective." We hope this program leads to an informed healthcare system whereby Tricare beneficiaries see fewer, not more, hurdles to access medications that they value.

[2] See https://www.pcori.org/sites/default/files/PCORI_Authorizing_Legislation.pdf

DOD Has an Opportunity to Advance a Program that Mitigates Discrimination Against People with Disabilities and Serious Chronic Conditions

The use of cost effectiveness research to determine the "value" of treatments has been widely criticized by patients and people with disabilities. Today, by law, PCORI and Medicare are precluded from using quality-adjusted-life-year (QALY) thresholds for cost effectiveness in research and to determine coverage, reimbursement, or incentive programs.[3] In fact, by the definition of clinical effectiveness embraced by law in PCORI's statute, cost is not a consideration in determining clinical effectiveness. Additionally, in 1992, the U.S. Department of Health and Human Services (DHHS) rejected a state Medicaid waiver due to its use of the cost-per-QALY for being "discriminatory and inconsistent with the Americans with Disabilities Act."[4] We encourage DOD not to allow this new program to open a door to discrimination against those with disabilities and serious chronic conditions.

Patients Deserve a Voice in Defining Health Care Value

Everyone wants health care that is "high value." The challenge is that high value to one person may be low value to another. Depending on an individual's goals for their treatment and other health characteristics, value can vary significantly from beneficiary to beneficiary. We are in the midst of a movement toward personalized medicine, but "one-size-fits-all" definitions of treatment value based on cost-per-QALY are, in effect, at odds with tailoring care to the individual patient. No single patient, or beneficiary, is average.

Therefore, we recommend the creation of an infrastructure for patient and beneficiary engagement in uniform formulary development under Tricare, to give members of the military and their families a voice in the determination of the value of treatments under the program, and throughout Tricare. We also recommend the incorporation of incentives for health care providers to use shared decision-making tools and decision aids that will enhance the ability for patients and their physicians to assess the highest value treatment for that individual patient. In this way, Tricare can deliver on the intent of this program to deliver high value care by arming beneficiaries with information to improve health decisions instead of putting hurdles in front of the care they need.

We look forward to working with the DOD in its implementation of this important program.

[3] See http://www.pipcpatients.org/resources/white-paper-uses-and-misuses-of-the-qaly-ethical-issues-and-alternative-measures-of-value

[4] See https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html

Sincerely,

Tony Coelho
Chairman, Partnership to Improve Patient Care