

April 25, 2019

Mr. Gabriel Petek
Legislative Analyst
Legislative Analyst's Office
925 L Street, Suite 1000
Sacramento, CA 95814

Dear Mr. Petek:

On April 5, 2019, the California Legislative Analyst's Office (LAO) published its report titled, "The 2019-20 Budget: Analysis of the Carve Out of Medi-Cal Pharmacy Services From Managed Care." The Partnership to Improve Patient Care (PIPC) shares concerns emphasized in the report about the affordability of healthcare for patients and people with disabilities and supports patient-centered solutions to address affordability challenges. Unfortunately, we often find that policies increasingly put patients and people with disabilities in the middle of the fight to reduce health care costs by restricting access to care. Therefore, we oppose the use of cost-effectiveness analysis for preference of drugs and as reference for spending caps — a strategy that ultimately uses discrimination and restricted access to lower costs. In the end, policies that prevent patients and people with disabilities from getting the right care at the right time based on their unique characteristics and priorities adversely impact health and increase costly adverse events such as hospitalizations. Therefore, we reject any approach that fails to consider the implications for discrimination and adverse health outcomes in its analysis of the formal use of cost-effectiveness analysis for preference of drugs in Medi-Cal and use of a drug spending cap, similar to the State of New York.

States Should Reject Use of Discriminatory Quality-Adjusted-Life-Year (QALY)-based Cost-Effectiveness Standards and Honor the Safeguards Against Their Misuse

As you may know, quality-adjusted-life-years (QALYs) assign a financial value to health improvements and outcomes. When applied to health care decision-making, the results can mean some patients, people with disabilities, veterans, and seniors are deemed "too expensive" to receive care. We are very concerned that, in adopting this construct, California would undermine core protections against discrimination for patients, people with disabilities, veterans, seniors, and others. Section 504 of the Rehabilitation Act ensured that individuals with disabilities would not "be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination," under any program offered by any Executive Agency, including Medicare.¹ Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments.² In 1992, the federal government, under President George H.W. Bush, established that it was a violation of the ADA for states to employ cost-effectiveness standards in Medicaid out of concern that it would discriminate against people with disabilities.³

¹ 29 USC Sec 794, 2017. Accessed December 5, 2018. [Web](#).

² 42 USC Sec 12131, 2017. Accessed December 5, 2018. [Web](#).

³ See <https://www.nytimes.com/1992/09/01/opinion/l-oregon-health-plan-is-unfair-to-the-disabled-659492.html>

Additionally, the Affordable Care Act very clearly states that the Secretary of Health and Human Services has no authority to deny Medicare coverage of items or services “solely on the basis of comparative effectiveness research,” nor to use such research “in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.”⁴

The Affordable Care Act specifically prohibits the development or use of a “dollars-per-quality-adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended.” Additionally, “The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII” (Medicare).⁵

These provisions of statute reflect long-standing opposition by policymakers, and the American public, of this blunt, subjective standard in public policy to determine the value of caring for patients and people with disabilities. The U.S. has repeatedly rejected QALYs and similar cost-effectiveness assessments as the basis for making coverage and reimbursement decisions, instead opting for a more patient-centered legislative and regulatory framework that protects vulnerable populations from this kind of discrimination.

Moral and Ethical Implications of Relying on QALYs and Similar Metrics

Opposition to QALY-based cost-effectiveness thresholds in health care policy reflect its basic ethical and methodological flaws. The QALY methodology assumes that a year spent in certain states (such as perfect health, represented by 1.0) is more desirable than a year spent in other states (such as paraplegia, ranked by some QALY systems at approximately 0.5, implying that the lives of people with paraplegia are worth approximately half the lives of individuals without).⁶

When applied to assessing a treatment’s value, medicines specifically for younger, and otherwise healthy people have the ability to achieve “better value” than medicine that treats older or disabled populations. This inherent characteristic of the QALY calculation results in discrimination towards chronically ill patients, seniors, and people with disabilities. Consequently, the QALY methodology also tends to undervalue treatments that delay disease progression, helping patients maintain their current QALY level, compared to treatments that can improve a patient’s QALY level.

This method of determining the value of a treatment completely disregards the fact that an individual living with a chronic condition or disability may be just as satisfied with their life as an individual with perfect health and should not be afforded less access to treatment.⁷ From an ethical perspective, valuing

⁴ 42 USC Sec 1320e, 2017. Accessed December 4, 2018. [Web](#).

⁵ 42 USC Sec 1320e, 2017. Accessed December 4, 2018. [Web](#).

⁶ Partnership to Improve Patient Care, “Measuring Value in Medicine: Uses and Misuses of the QALY,” White Paper. Accessed December 5, 2018. [Web](#).; Haagsma JA, Polinder S, Cassini A, Colzani E, Havelaar AH. Review of disability weight studies: comparison of methodological choices and values. *Popul Health Metr*. 2014;12:20. Published 2014 Aug 23. doi:10.1186/s12963-014-0020-2

⁷ Pettitt, D., Raza, S., Naughton, B., Roscoe, A., Ramakrishnan, A., Davies, B., . . . Brindley, D. (2016). The Limitations of QALY: A Literature Review. *The Journal of Stem Cell Research & Therapy*, 6(4).

“perfect health” over “less than perfect” health is fraught with issues. Indeed, our nation’s constitutional foundation of equality and our public policies such as Emergency Medical Treatment and Labor Act (EMTALA) — a federal law that requires anyone coming to an emergency department to be stabilized and treated regardless of their ability to pay⁸ — indicates our national ethic to provide the gold standard in care to patients and people with disabilities.^{9, 10}

For example, at a roundtable of patient organizations in 2016, “It was strongly suggested that policymakers engage with patients and people with disabilities so they are achieving ‘value’ from the patient perspective and based on reliable information that accurately reflects the conditions under consideration, recognizing that efforts to achieve cost effectiveness should not be at the expense of our moral and ethical obligation to patients and people with disabilities.” This statement remains our position today.¹¹

Use of Cost-Effectiveness Analysis in Other Countries Demonstrates Implications for Discrimination

As currently drafted, the LAO encourages the California Legislature to take steps to explore greater use of cost-effectiveness analysis in deciding which prescription drugs are placed on Medi-Cal’s preferred drug list, as compared to approaches in other countries. By contrast, in December 2018, a letter signed by 17 national advocacy organizations expressed serious concerns about the discrimination experienced in other countries that use cost-effectiveness to make reimbursement and coverage decisions, and called on policymakers to “work with us to develop sound, patient-centered solutions that recognize that each of us has value and shared human dignity.”¹²

Concerns with flawed cost-effectiveness standards are not merely theoretical. In other countries, we already see the painful realities of these standards when put into practice.¹³ For example, while U.S. patients have access to 95 percent of new cancer medicines released in the past eight years, patients in the U.K. have access to 74 percent, Japanese patients just 49 percent, and Greek patients only 8 percent.¹⁴ Our perspectives on the danger of importing QALY-based thresholds are informed by the experiences of patients and people with disabilities in countries where cost-effectiveness measures determine coverage and reimbursement rates. This kind of one-size-fits-all policymaking dismisses the life-changing impact of treatments on real people.

⁸ Centers for Medicare & Medicaid Services. (2012, March 26). *Emergency Medical Treatment & Labor Act (EMTALA)*. Retrieved 2018, from <https://www.cms.gov/regulations-and-guidance/legislation/emtala/>

⁹ Rosenbaum, S. (2007). The Americans with Disabilities Act in a Health Care Context. In *The Future of Disability in America*. National Academy of Sciences. Retrieved from <https://www.ncbi.nlm.nih.gov/books/NBK11429/>

¹⁰ Ervin, D. A., Hennen, B., Merrick, J., & Morad, M. (2014, July). Healthcare for Persons with Intellectual and Developmental Disability in the Community. *Frontiers in Public Health*, 2, 1-8. Retrieved from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4098023/pdf/fpubh-02-00083.pdf>

¹¹ http://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_roundtable_summary_-_value_to_the_patient.pdf

¹² http://www.pipcpatients.org/uploads/1/2/9/0/12902828/ipi_comment_letter_updated.pdf

¹³ The Editorial Board, “Why Are Drugs Cheaper in Europe?” Opinion, *The Wall Street Journal*, October 28, 2018. Accessed December 5, 2018. [Web](#).

¹⁴ Ibid.

For example, cancer patients in other developed countries have access to new cancer medicines on average two years later than patients in the U.S.¹⁵ Even when other health authorities eventually approve new medicines, additional access restrictions, such as limiting treatment durations, continue to create barriers for patients.¹⁶ Nearly 80 percent of cancer medicines approved for coverage in the U.K. between 2007 and 2014 had some kind of access restriction.¹⁷ And patients pay the price for delayed and restricted access to life-saving medicines: five-year survival rates for breast, colon, lung, and prostate cancers are higher in the U.S. than in Canada, France, Germany, Italy, Japan, and the U.K.¹⁸ Policymakers and analysts in the U.S. should not replicate these unfavorable outcomes, but should instead consider how the use of cost effectiveness analysis in other countries impacts access to care among their beneficiaries with disabilities and serious chronic conditions.

Arbitrary Thresholds for Coverage Would Define Populations That Are Worth (and Not Worth) Treating

On February 22, 2019, a letter with signatures from 45 advocates and organizations was sent to New York legislators opposing their use of third-party value assessments. The LAO references New York's cap on drug spending as being similar to Governor Newsom's executive order but indicates that California should go as far as New York to exclude drugs from its preferred list. We would emphasize the LAO's concern that by barring all of a manufacturer's drugs from the preferred drug list in cases where the manufacturer does not offer sufficient rebates, the state is further limiting beneficiary access to certain drugs than under the California administration's approach. Further consideration should be given to the implications of such a policy so as to avoid undermining protections that protect access to care for patients and people with disabilities.

Thresholds of cost effectiveness fail to consider important differences among patients by relying on averages to define value — but in practice, no patient is “average.” A recent study published by Tufts University found that less than one quarter of cost-effectiveness analyses accounted for even the most basic differences among patients.¹⁹ When coverage policies are based on cost-effectiveness calculations, accountants and actuaries make medical decisions for patients and people with disabilities, overriding individual patient-centered decisions that are based on personal needs, preferences, and their physicians' judgments.

While we agree that lowering health care costs and increasing affordability represent important policy challenges, we do not think that any state should facilitate restrictions on access to medically necessary treatments that can improve or even save the lives of patients. State policy should not establish a mechanism that deems some patients and people with disabilities as “too expensive” to receive care. Instead, and consistent with the ADA, states should avoid use of discriminatory methods that rely on a cost-per-QALY or similar metrics to determine reimbursement and coverage decisions.

¹⁵ IQVIA. Global Oncology Trends 2018, May 2018.

¹⁶ “Mum with lung cancer taken off life-saving drug,” November 7, 2018. Accessed December 5, 2018. [Web](#).

¹⁷ Zhang Y et al. [Comparing the Approval and Coverage Decisions of New Oncology Drugs in the United States and Other Selected Countries](#). *J Manag Care Spec Pharm*. 2017;23(2):247-54. [Web](#).

¹⁸ World Health Organization (WHO). WHO mortality database. PhRMA analysis of WHO mortality database, using age-specific death rates. Accessed May 2018. [Web](#).

¹⁹ T Lavalley, D Kent, et al. “Patient variability seldom assessed in cost-effectiveness studies.” *Medical Decision Making*. 2018.

Conclusion

The State of California has significant opportunities to improve the quality of healthcare and lower costs by promoting patient access to care that is tailored to their individual needs, circumstances, and priorities. We are excited to see innovation and progress in the development of patient decision aids, patient-centered outcomes research, shared decision-making, and other strategies to connect patients to the right care. Restricted access to the most appropriate care for the patient is not cost effective, nor is it morally and ethically appropriate. We hope the State of California will institute policies that instead improve access and help patients and providers improve health care decisions as part of a state-wide strategy for improving quality and reducing costs.

Sincerely,



Tony Coelho
Chairman, Partnership to Improve Patient Care