On behalf of the Massachusetts disability rights community, the undersigned organizations write to express our profound concern with elements of the proposed regulation 958 CMR 12.00: DRUG PRICING REVIEW. While we support measures designed to address high drug prices, we refuse to sit idly by as people with disabilities are caught in the middle of a fight between payers and manufacturers. Many of our members are reliant on pharmaceuticals to survive and thrive. When prices are high, we bear the brunt, as public insurers refuse to cover higher-priced and name brand medication or require onerous prior authorization requests. Private insurers will use proposed Health Policy Commission values as justifications for non-coverage, time-intensive prior authorization procedures, and higher co-pays for targeted medications. For instance, we have already seen CVS Caremark propose to allow the insurers it works with to deny coverage for any and all drugs that cost more than $100,000/Quality Adjusted Life Year gained, a decision which poses substantial risk to persons with disabilities and chronic illnesses

We have been proud to support numerous approaches to making the drug companies stop gouging our state, including H. 1133/S. 706, which would set an upper payment limit, proposals to import drugs from Canada, federal efforts to license more generic drugs, and expanded transparency and disclosure provisions. We wholeheartedly support the provisions of these regulations that empower EOHHS and the HPC to demand information, hold hearings, and force drug companies to justify their pricing to the public.

On the other hand, some proposed solutions to high drug prices seek to achieve their ends by undercutting our civil rights and literally devaluing our lives. Measures like Quality Adjusted Life Years are based on the idea that the lives of people with disabilities are less worthwhile than those of people without disabilities, and that the more disabled someone is judged to be, the less MassHealth and private insurers should be willing to pay to keep them alive or increase their quality of life. Last month the National Council on Disability, our government's highest disability body, condemned QALYs as discriminatory and called for a categorical ban on their use throughout Medicare and Medicaid. QALYs have previously been banned from use in the Affordable Care Act, by the Patient Centered Outcomes Research Institute, and their use in an Oregon cost-saving plan was struck down as violating the ADA. Our community is unanimous in opposing this approach, and we cannot support any regulation, however noble, that risks enshrining in state code the principle that we are less than human.

Specifically, section 12.05: Identification of a Proposed Value calls for evaluating a drug's price versus its "therapeutic benefits," but provides no details on how those therapeutic benefits will be calculated other than considering the seriousness and prevalence of the condition that is treated. "Seriousness" is in part determined by the affected population of patients. For example, a person with a chronic condition whose discomfort could be alleviated by a high cost drug would consider constant pain or irritation serious, while evaluators might only consider conditions that are life-threatening or that progressively damage organs as serious. Further, it is unclear how the prevalence of the condition will affect the determination of target value, an obvious concern for both those who have common conditions and those who have rare conditions. Finally, the notion of "seriousness" poses a particular concern when conditions are evaluated using deeply flawed survey instruments that are common in cost-effectiveness analysis but badly misunderstand disability. For instance, the EQ-5D, the most common instrument used to establish condition severity for QALY analysis, presumes that all people who cannot walk are

"confined to bed" –severely misrepresenting the quality of life of anyone with a mobility impairment/

Furthermore, we believe that any cost-effectiveness analysis should be required to include specific information on the assumptions and limitations of the analysis specific to the metrics used to define and measure disease, disability and quality. Public disclosures should include outcomes for subpopulations likely to lose access to treatment or face additional administrative burdens from utilization management.[1] The public should be able to challenge the designation of information as proprietary,[2] with release of information if the danger of competitive damage is not shown to be greater than the public interest.

We also are concerned about additional criteria used to establish value. Within section 12.05, Subsection 2(a) calls for the consideration of clinical efficacy. Efficacy and effectiveness should be considered. Efficacy is how the medication works in a controlled setting; effectiveness is how the medication works in real life settings. Some older drugs with side effects significant to patients may be efficacious but not effective because patients abandon their use due to those side effects. This is true for many psychiatric medications.[3] The reverse may be true for newer, high-priced medications. Subsection 2 (f) refers to whether a drug has "pharmaceutical equivalents," but no standard for establishing equivalence is provided. In states like New York, as well as under private insurance, people with disabilities have been subjected to "fail first" provisions that force us to take the cheapest drug first and work our way up to the one our doctors actually prescribed—a policy that proved fatal this year for beloved disability activist Carrie Ann Lucas, who died after a $2,000 inhaled antibiotic was deemed not "cost-effective" compared to an "equivalent" drug. Pharmaceutical equivalents must have the same active ingredient(s), have the same dosage form and route of administration, and have identical strength or concentration. However, because the "fillers" may be different, not all patients will be able to tolerate the so-called equivalent medication. Further, while bioequivalence may be tested on populations with few co-morbidities, persons with disabilities who constitute a significant portion of MassHealth enrollees, may not tolerate switching between brand name and generic drugs. Without consideration of these factors, the disability community is highly concerned that this regulatory approach could lead to discriminatory and dangerous outcomes. We would ask that EOHHS and the HPC consult with the disability community to develop protective standards that ensure the wellbeing of our community is safeguarded. Moreover, given that any decisions made under this regulation will likely have their greatest impact on people with disabilities and chronic illnesses we believe it is vital that organizations representing people with disabilities are given a voice on

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[1] Impact on subpopulations should be included in EOHHS analyses, not just those done by third parties.
[2] Challenges to designations of "proprietary" would apply to information other than that designated clearly by statute to be protected from disclosure.
[3] *See,* D. SAĞLAM AYKUT, *et al, Adverse Effect of Medication and Quality of Life in Patients Receiving Second Generation Antipsychotics: A Comparison of Long Acting and Oral Therapies*, 28 Turk. J. Psych. 1 (2017) (The side-effects of antipsychotic medications (such as akathisia, impairment of sexual function and weight loss), frequently lead to non-compliance with and rejection of medication in patients with schizophrenia). *See also,* LaRosa JH and LaRosa JC, *Enhancing drug compliance in lipid-lowering treatment*, 9 Arch Fam Med 1169 (2000)(non-compliance with medication primarily due to cost and side effects).

the commission, and would ask that an organization representing individuals with disabilities be given a seat on the HPC.

The process for determining prices for negotiation and target value is marred by lack of transparency and mandated input from affected populations. There is no requirement that import elements of these analyses be disclosed to the public unless they are conducted by a third party. We welcome the transparency provisions for third party analyses under Section 12.08(b), but the proposed regulation does not go nearly far enough. It is not at all clear to us why its requirements should only apply when a cost-effectiveness analysis is conducted by a third party. Cost-effectiveness analyses should be subject to a full disclosure of the methodology involved in reaching it, assumptions within that methodology and anticipated impact on subgroups regardless of whether a cost-effectiveness analysis is conducted by a third-party or EOHSS. Disclosure should include full transparency of the models and data used in the cost-effectiveness analyses.

EOHHS and the Health Policy Commission should be required to hold a public hearing on each value assessment process they undertake. Patients with the condition relevant to the medication under consideration, the disability community, and their advocates should be named as "interested persons" consulted under 12.08(d). Far too often, employers, insurers, and providers are the only parties called to the table at critical times in the decision-making process. All notices, including the required notice provided for under Section 12.08(a), should be provided to the public as well as the manufacturer.

Most importantly, we think it is vital that the regulations specifically bar the use of methods that discriminate against people with disabilities and devalue our lives Specifically, we call for an absolute prohibition on the use of the Quality Adjusted Life Year and any other measure that considers disabled life as worth less than non-disabled life. Such a prohibition would be consistent with existing federal law regarding the Medicare program and the Affordable Care Act's Patient-Centered Outcomes Research Institute (PCORI). The use of QALYs by EOHHS or the HPC, on the other hand, would be tantamount to an endorsement by our government of the notion that the lives of its disabled citizens are worth less than the lives of its non-disabled citizens. It would represent an assault on the basic principle of full equality for people with disabilities, and would violate both the Americans with Disabilities Act and Article CXIV of the Massachusetts Constitution, which bars discrimination against people with disabilities "under any program or activity within the commonwealth." Disclosure of discriminatory metrics is insufficient. We must instead actively refuse to discriminate, and uphold the fundamental principle that the life of every Massachusetts resident is equally valuable.

Sincerely,
Disability Policy Consortium
Mental Health Legal Advisors Committee
NAMI Massachusetts
Disability Law Center
Boston Center for Independent Living
Metrowest Center for Independent Living
Independence Associates
AdLib
Disability Resource Center