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(HEAL) Group
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National ADAP Working Group (NAWG)

November 15, 2024

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

RE: Comment on Proposed UPL Legislative Report Draft

Honorable Members of the Oregon Prescription Drug Affordability Board,

The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions.

Today, we write with exceptional concerns and suggestions regarding the proposed draft of the UPL Legislative Report.

Cost/Necessary Additional Appropriations Due to UPL Impacts Requires Consideration of UPL as a Failed Approach

Data weakness should not be diminished or washed over (page 32)

In the *Current Analysis of Potential Costs and Savings* section the Board lists a range of potential Upper Payment Limit (UPL) scenarios. It was acknowledged that the interpretations were largely theoretical due to the variations in quality and completeness of data. Additionally, the potential "savings" are described as being nearly equal to potential "costs". Insisting on additional UPL action without greater clarity diminishes the potential magnitude of the negative implications of a UPL. It is important to remember that CMS projected any 'savings' would likely be due to cost-shifting -- any governmental savings, no matter how minimal, would result in increased out-of-pocket costs for patients. The [Centers for Medicare and Medicaid Services' National Health Expenditure Projections \(2023-2032\)](#) also explains how the Inflation Reduction Act is expected to result in increases in Medicare spending due to institution of drug price negotiations,

otherwise referred to as the “Maximum Fair Price” (MFP). National Health Expenditure growth is expected to outpace average GDP growth largely due to hospital and provider payments and Medicaid enrollment is expected to decline. These are all health expenditure issues, directly affecting patients financially in which a UPL does not address. Similarly, imposition of the MFP is not necessarily expected to cause overall “savings”, rather cost shift, as discussed further below.

Clarification Needed to Effectively Describe WAC Manipulation by PBMs

Transaction Relationships in the Supply Chain: Manufacturers (page 13)

This section asserts that drug manufacturers are solely responsible for, control, and set the Wholesale Acquisition Cost (WAC). There is nuance in that this is not unequivocally true. The recent [complaint filed by the Federal Trade Commission](#) against Pharmacy Benefit Managers (PBMs) explains that while manufacturers offer multiple WACs per medication, PBMs often select higher WAC medications since that allows PBMs to obtain a larger rebate retention which increases the overall WAC. The following citations from the FTC complaint illustrate this:

139. Rather than cutting list prices on their existing insulin products and risking losing formulary access, Lilly, Novo, and Sanofi each launched new, unbranded low WAC products. These low WAC insulin versions were identical to the high WAC versions in all clinical respects. The only differences were that they did not include branding and were significantly lower list price.

143. The insulin manufacturers continued to offer the high WAC, highly rebated versions while pricing their low WAC insulin at roughly "net price parity" with the branded versions. Essentially, although the low WAC version had a different list price, the smaller rebate it offered resulted in a net price roughly equivalent to that of its high WAC counterpart. Manufacturers adopted this pricing strategy "so that the payer would be neutral" or "indifferent" between the two versions.

144. The PBM Respondents, however, were not indifferent between the high WAC and low WAC insulin versions. Instead, they methodically disfavored the low WAC insulin products on their flagship commercial formularies, preferring only the high WAC versions, with high rebates and fees.

PBMs Gatekeep Formularies and Plan Design, Patient Experiences in “Affordability” and Access

Transaction Relationships in the Supply Chain: Pharmacy Benefit Managers (PBMs) (page 14)

In this section, it is important to emphasize PBM gatekeep formularies. According to the FTC, the three largest pharmacies administer approximately 80% of all prescriptions in the United States. Additionally, they base the coverage, tier, prior authorization and other formulary decision metrics on what is profitable to PBMs, not what is ‘affordable’ for patients or government payers.

Roles Should be Better Defined

Transaction Relationships in the Supply Chain: Pharmacy Benefit Managers (Payers) (page 14)

The report conflates the roles of "payers," PBMs, and Managed Care Organizations (MCOs) in the case of Medicaid. These roles should not be commingled. Employers and governmental bodies should be ascribed the role of payer separate from PBMs. Much of what is currently attributed to payers is managed by PBMs and MCOs.

Plight of Independent Pharmacies Needs Greater Emphasis as Access and System Sustainability Issue

Transaction Relationships in the Supply Chain: Pharmacies (page 15)

This section does not explicitly address concerns raised by non-chain, independent pharmacies. A UPL's impact must be explicitly described within this particular context of the ecosystem. These independent pharmacies are faltering because of PBM under-reimbursement. According to the National Community Pharmacists Association, 32% of independent pharmacies are exploring closing in 2024.

Perverse Incentives Drive PBM Practices

Perverse incentives caused by PBM practices (page 16)

The report effectively notes how PBMs may use rebates to identify preferred formulary placement. However, the report doesn't mention the perverse incentives this causes. The FTC complaint explains that PBM profitability is the product of a focus on rebate chasing as a priority. This results in selecting higher WAC because higher list price = better formulary placement. This adversely affects affordability for patients and the system because the better formulary placement is not based on clinical benefit or medical necessity for patients. The board would be served well to encourage investigations similarly situated to those of OH (Attorney General Dave Yost) and [Indiana's overspending to the tune of \\$1B because of PBM greed](#). Investigating these situations as they do or do not apply to Oregon would have a more direct benefit to both the state and patients in Oregon, without the risks a UPL poses on access.

CMS Data Needs to be Included

UPL Potential Methodologies (page 19)

This discussion Fails to mention CMS' [National Health Expenditure Projections \(2023-2032\)](#) analysis conclusions. CMS expects both patient and system costs to rise most significantly related to hospital care and physician and clinical services, whereas CMS projects prescription drug spending to slow. It is important to note CMS *also* projects that implementation of the MFP will largely cost shift rather than "save", reducing government spending while increasing patient out-of-pocket costs. A UPL, either as established by MFP or independently, similarly risks such a shift, further reducing patient "affordability" and access.

Reference Pricing is Problematic, Disregards Statutory Prohibition on use of QALYs, and Runs Counter to Federal Non-Discrimination Rules

Other countries' prices should not be used as references (page 20)

The "Reference Pricing to Existing Benchmarks" section includes referencing pricing to other countries. Other countries use discriminatory quality metrics, such as Quality Adjusted Life Years (QALYs), which are prohibited by Oregon's convening statute and by federal non-discrimination rules, *inviting unnecessary litigation*. Referencing other countries' pricing considerations directly undermines statutory requirements. The board considering international reference of any kind should be prohibited as it is a "back door" vehicle of QALY use.

The U.S. Department of Health and Human Services and Centers for Medicare and Medicaid Services finalized federal rules recognizing “quality adjusted life years” and similarly situated metrics as necessarily discriminatory toward persons with chronic health conditions and older patients. Those same rules, integrating protections under the Americans with Disability Act and Section 504 are directly addressed in terms of “cost containment” efforts as detailed below from 89 FR 4006, Nondiscrimination on the Basis of Disability In Programs or Activities Receiving Federal Assistance (Section: Value Assessments [84.57]);

Comment:

The Department requested comment on how value assessment tools and methods may provide unequal opportunities to individuals with disabilities. Numerous commenters indicated that value assessment methods could limit people with disabilities' access to health care goods and services, including pharmaceutical interventions, and expressed concern that the use of the QALY unfairly limited access to emerging pharmaceutical interventions that could extend the lives of people with disabilities.

Response:

While the nondiscriminatory use of value assessment is an important tool for health care cost containment, the Department agrees that discriminatory usages of value assessment harm people with disabilities and provide unequal opportunities.

Comment:

One commenter argued that the use of the QALYs and other methods of value assessment that frequently entail discounting the value of life extension on the basis of disability are not discriminatory because they are "only one step" in a process of decision-making, noting that policymakers also take into account other factors in their ultimate decision-making.

Response:

Although recipients may make use of multiple factors to influence their decision-making, the use of a measure of value that assigns lower value to extending the lives of people with disabilities to determine eligibility, referral, or provision or withdrawal of an aid, benefit, or service can be nonetheless discriminatory.

Additional Data Limitations

There are additional limitations of the Oregon APAC data (page 27)

APAC data does not capture denials or other actions by payers which may negatively impact patient experience and affordability. Furthermore, APAC data is not often audited for actuarial assessment. Any use of APAC data must recognize the limitations and that all data points provided are done solely through the lens of PBM stakeholders.

We Applaud the 340B Impact Analysis

We applaud the 340B revenue impact analysis (page 28)

We thank you for your discussion of the UPL’s possible impacts on 340B providers and pharmacists. Additionally, we’d like to add that you must also include potential for funding allocation to Medicaid and other state payers, like the State AIDS Drug Assistance Programs (ADAP), which might face similar concerns.

Request for Additional Authority is Inappropriate, given Report Content

All told, the Board's Own Report Evidences No Need for Additional Authority (page 30)

The board has self-identified the condition of not presently having sufficient data or a developed, amplified, “fleshed-out” plan. As such it would appear presently inappropriate to seek additional statutory authorities when they may not fit within the plans that the board finally develops. Additionally, ineffectively requesting the additional authorities now could adversely affect the granting of requests for additional powers that result after more deliberation and information gathering.

Clarification of Factors Driving Patient Costs

Correction needed under “Current Analysis of Potential Costs and Savings” (page 32)

Patient copayments and other aspects of plan design are NOT based on the total cost of a medication but based on profitability to the PBM ([see FTC complaint](#)). The Board's conclusions in this respect are troubling considering these facts and further support this not being the appropriate juncture at which to seek additional authority.

Pertinent Data cannot be Omitted

Senate Bill 192 requires a thorough analysis of the costs of implementing a plan: Future Analysis of Potential Costs and Savings (page 34)

This section states that a detailed analysis is premature currently. The Board does not have the option to disregard the cost of implementation from various stakeholders in the supply chain. Disregarding the requisite analysis also necessarily means the Board has not considered all costs associated with implementing a UPL - further undermining the likelihood of any "savings" and only increasing the potential costs as unpleasant surprises for the legislature to grapple with later down the line.

340B Risks are Facts not Merely Personal Interpretation

340B effects are not just survey perspectives but actual fact (page 39)

The observation section on page 39 catalogs the adverse effects of a UPL on 340B covered entities, especially FQHCs, as concerns listed by survey respondents. This information should be listed as factual assessment and not just community interpretation. The 340B risks to the health equity efforts of covered entities, such as FQHCs, should be listed as facts under the **340B Covered Entities** segment of the *Future Analysis of Potential Costs and Savings* section of the report beginning at the end of page 36 going into page 37. Categorizing these effects under community survey response diminishes the issue as ‘subjective opinion’ or ‘emotional response’ instead of data-driven fact.

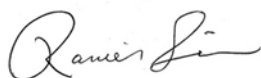
Recommendations Continue to Fail to Establish Monitoring Metrics

One of the most significant failures of this report is the lack of monitoring metrics designed to evaluate continued patient access to lifesaving and life-sustaining medications. Similarly, the lack of the metrics also fails to continue assessments of patient “affordability” because of either legislative or Board actions.

In totality, the Board's effort regarding this report is extensive and should be applauded. However, by and large the conclusions of the report can be summarized as "we don't know, things could be bad but let us find out anyways". This approach recklessly disregards not only patient access to care, but the legislature's fiduciary duty to taxpayers, and significantly consequential impacts on providers and the state's public health programs.

We encourage you to consider our commentary in the development of the legislative draft letter. We also appreciate all your continued mindful efforts in effectively deliberating what is best for Oregon patients as well the healthcare system.

Respectfully submitted,



Ranier Simons
Director of State Policy
Community Access National Network

On behalf of

Jen Laws
President & CEO
Community Access National Network