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April 22, 2025

Oregon State Legislature House Committee on Rules 900 Court St. NE, Salem Oregon 97301

Via electronic mail

RE: HB 3409 as amended

Dear Honorable Chairman Bowman, Vice-Chairs Drazan and Pham, Members of the Oregon House Committee on the Rules, and your respected staff,

The Community Access National Network (CANN) writes in **OPPOSITION** to **HB 3409 as amended**, which would confound oversight of the 340B program by suggesting an unvetted, potentially highly conflicted model of claims reporting, and will likely run abreast of other provisions and regulatory designs in federal law.

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. The 340B Drug Pricing Program is of profound importance to our community.

The 340B program is a vital resource in sustaining public health programs, such as the AIDS Drug Assistance Program (ADAP, in Oregon CAREAssist). CANN advocates on behalf of patients benefiting from a strong, well-regulated program, which lacking sufficient oversight, can be prone to abuse, particularly by actors within the system that are more "margin-motivated" than "mission-motivated".

HB 3409 as amended suggests use of a nationally *discussed* but <u>never</u> <u>implemented</u> oversight design by way of a "claims clearing house". To be clear, federal regulatory design around the 340B program places all responsibility for sufficiency and accuracy of claims and ensuring the prohibition on duplicate

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discounts on covered entities (CEs) and those payors and contract pharmacies in which CEs do business. "Claims modifiers" are a tool to ensure each claim is not duplicative and is not subject to multiple federal program discounts (such as Medicaid).

Some testimony suggested a "clearing house", specifically RxParadigm as announced in a March 28, 2025 <u>press</u> release had been "used in other states" or was otherwise sanctioned under federal regulatory designs. In actuality, no "state" has adopted use of any clearing house, rather RxParadigm has contracted with specific providers to offer clearing house services. Those contracts are *not* vetted, being only established as early as November of 2024. It is important to note that private contracting with providers as a party to a specified contract is *not* what has been suggested in the national 340B discussion. Indeed, quite the opposite.

Instead what *has* been suggested is a "prime vendor" design, wherein the clearing house would be a contract established with HRSA (in the case of a state design, such a design would be with the state - not a CE). There are necessary parts of this that speak directly to the insufficient language within the amendment - specifically the lack of definition in "conflict of interest". A design in which a company contracts with a CE would *necessarily* create a conflict of interest *because* the contract exists between a specifically interested party - the CE. Any consideration of this bill as amended *must* include clear definitions of conflict of interest.

Furthermore, even in situations of a "prime vendor", depending on the compensation design, we've already witnessed exceptional abuse of the program. On January 15, 2025, the *New York Times* an extraordinarily egregious example of profiteering within the program by Apexus. Marsha Simon, a staff member to the late Senator Kennedy, and one of the architects of the 340B program described Apexus' operation as having "a license to hunt". In essence, the company's compensation design as a "small percentage of sales", which has incentivized Apexus to exploitatively recruit new users and steer for more 340B claims. Part of the motivation may be that Apexus is owned by a company called Vizient - which is owned by hospitals that stand to profit from the 340B program. A "clearing house" without extremely stringent definitions of "conflict of interest" and being contracted with the *state*, rather than an interested party like CEs, would face similar abuse.

We would also like to address a couple of other things said during the hearing. 1) A clearing house does not absolve CEs of their responsibility within the program, rather it can confound them by shifting blame for any errors or data failures, making compliance more onerous. 2) Contrary to claims, *no* CE is "audited" or even receives a site visit (a pre-audit review) based upon a "single mistake", rather, HRSA was directed by provisions of the Affordable Care Act to establish an "administrative dispute resolution" process ("ADR", this is yet another area of hot debate). Absent the ADR process, what's left is manufacturers suing CEs for compliance because the HRSA audit process is exceptionally cumbersome and HRSA is, in essence, either incapable or unwilling to enforce the program's intent. Indeed, because this exact thing was happening at an incredible frequency, which is why HRSA was directed to establish the ADR to begin with. 3) It was mentioned the 8th Circuit agreed with state legislation prohibiting certain manufacturer limitations on contract pharmacies. This bill is not that. Furthermore, the DC Circuit Court of Appeals has reaffirmed the ability for manufacturers to implement such restrictions. A Circuit split is prime for additional action from the Supreme Court of the United States. States looking at this or any other

In my verbal testimony, I shared that other federal statute and regulatory design must also be considered. Here the implementation of the Inflation Reduction Act's drug price negotiation program requires manufacturers to ensure a lack of duplicate discounts interacting with the 340B program. This responsibility *requires* manufacturers to take certain actions to ensure compliance, a claims modifier is but one, other restrictions may also be appropriate, placing the state of Oregon on a potential collision course with federal regulatory design and the rights and responsibilities placed on manufacturers as such.

Another mechanism available to manufacturers is already in place as the model is exemplified in ADAPS - a rebate model. Rebate model implementation is the subject of current federal litigation but nonetheless, legislators in Oregon should be aware of the consequences for smaller CEs in such a design. A rebate model would require CEs to purchase qualified medications and then seek "back end" savings at a later date after verifying the quality of . For their part manufacturers have promised such later dates would not be long. However, this design disadvantages smaller CEs in particular, who may not have the cash on hand to float even "a few days" of operational costs.

If the state of Oregon approves a claims modifier prohibition and insists on electing a highly-conflicted, never vetted "clearing house" design, then the state must also take responsibility for inviting harsher oversight mechanisms.

Lastly, the notion that 340B "was not designed to benefit patients directly" is patently offensive. In fact, the gold-standard of the 340B program, ADAPs, does exactly that with limited to no abuse allegations against them. Indeed, 340B is an essential tool in combating HIV, enacting our promises to honor "not one more death" by delivering no-cost to patient anti-retroviral therapies. ADAPs present one of the most highly effective public health programs in the United States specifically *because* the program provides no-cost medications with the financial support found in 340B.

CANN represents the patient interest. We recognize the efficacy a well run 340B program. We also recognize that the converse is equally true: every abuse of this program is a cut against patients, against health equity, and a denial of life-saving medication and care for people who are already being left behind by the rest of society. We deserve a well-regulated program serving our needs. Indeed, that's why the statutory intent of 340B begins with "...to reach more eligible patients." Oregon legislators would do well to remember that as well.

Thank you for your time and consideration. If you wish to discuss these details or any other aspect of the 340B program or public health programs, we stand ready to offer our perspective and expertise.

Ever yours in service,

James

Jen Laws President & CEO Community Access National Network