



To: Senator Rhonda Fields, Chair Senate Health and Human Services Committee  
Members, Senate Health and Human Services Committee

From: Bill Keeton, Chief Advocacy Officer, Vivent Health

Re: Support for HB22-1122 Relating to Pharmacy Benefit Manager Prohibited Practices

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**Summary:**

Vivent Health strongly supports the Pharmacy Benefit Managers (PBMs) reforms included in HB22-1122. The prohibition of discriminatory reimbursement by PBMs, also known as PBM pickpocketing, included in this bill will ensure that the intent and desired impact of the federal 340B Drug Pricing Program are carried out and that necessary funding reaches community-based clinics and other health care and social service safety net providers. These critical health care providers need these financial resources to meet the growing needs of the patients and communities they serve.

***Vivent Health encourages you to support HB22-1122. These proposals are similar to bills in other states, including more than 15 bipartisan bills that have passed to ban the practice of discriminatory reimbursement.***

**About Vivent Health:**

More than 2,100 Colorado residents affected by HIV rely on Vivent Health services every year for their healthcare.

Vivent Health (previously Rocky Mountain Cares) is a 501(c)3 non-profit organization offering our services in Denver and Pueblo. Today, Vivent Health is one of Colorado's leading providers of HIV prevention, care, and treatment services, offering a unique integrated, comprehensive model of care that brings together medical, dental, and mental health care; clinical and traditional pharmacy services; food pantry and nutrition services; housing assistance; legal aid; and care management and coordination services for people living with HIV. Vivent Health also provides prevention programs, including Pre-Exposure Prophylaxis (PrEP), testing and harm reduction services to help reduce the transmission of HIV. ***All the services Vivent Health provides are available regardless of the ability of the people we serve to pay for them, or their insurance status.***

### **HIV in Colorado:**

Today, there are more than 15,000 people living with HIV in Colorado, with approximately 400 new cases of HIV diagnosed annually. HIV disproportionately impacts people of color, men who have sex with men, and people who inject drugs. While the highest prevalence rates of people living with HIV are in and around Denver, sixty-one of Colorado's sixty-four counties have people with HIV living there, demonstrating that HIV is a statewide issue.

HIV also has a disproportionate impact on individuals who already face significant socioeconomic barriers to health, known as social determinants of health. These barriers can include poverty, lack of access to health care services, lack of insurance, transportation challenges, food insecurity, housing instability, racism, discrimination, violence, language barriers and unemployment. These challenges and barriers are often exacerbated in Colorado's rural areas as well as in cities.

### **HIV Prevention, Care and Treatment:**

Recent and significant advancements in HIV prevention and treatment mean that people living with HIV can live long, healthy lives, and also that it is realistic to talk about ending HIV as a pandemic by reducing the number and rates of new HIV infections.

The two critical pathways for ending HIV as a pandemic are:

- 1.) Ensure every person with HIV has access to and the support needed to stay adherent to appropriate antiretroviral therapy and treatment regimens to achieve HIV virologic suppression; and
- 2.) Ensure every person at-risk for HIV has access to appropriate and effective prevention services including harm reduction programs (condoms, syringe services, counseling, and education) and biomedical interventions (pre-exposure prophylaxis, or PrEP).

Virologic suppression, also known as an 'undetectable viral load' or 'being undetectable,' is the most important clinical indicator related to HIV disease management for people living with the virus. Virologic suppression means that the

individual with HIV is managing their HIV disease as well as possible, leading to both normal immune system function and an inability to transmit HIV to someone else – a scientifically validated and CDC endorsed phenomenon known as Undetectable = Untransmittable.

Achieving virologic suppression is not only a critical personal health outcome for people living with HIV, but also a key HIV prevention strategy. ***Unfortunately, in Colorado only about 70% of people living with HIV are achieving virologic suppression. To end HIV as a pandemic in Colorado, it is necessary that greater than 90% of people living with HIV achieve virologic suppression.*** Achieving this goal will require fully leveraging all resources and funding streams to eliminate the barriers to care caused by social determinants of health. These resources are integral to engaging and reengaging individuals who have been lost to care or who have not yet been diagnosed with HIV.

In addition to ensuring people with HIV can achieve virologic suppression, increasing the number of people at-risk for HIV who are able to access HIV prevention programs, especially PrEP, is also critical to ending HIV as a pandemic. PrEP is the use of medications used to treat HIV disease to prevent the acquisition of the virus by people who are exposed to it. PrEP is more than 95% effective at preventing HIV transmission from sex, and at least 74% effective at preventing HIV transmission among people whose main risk factor for HIV is injection drug use. ***While the United States and Colorado have seen gradual increases in the rates of people at-risk for HIV who are using PrEP, only about 25% of people who could benefit from PrEP are using it.***

The costs associated with the management of HIV disease over a lifetime are between \$490,285 for someone diagnosed early and successfully adherent to treatment regimens and \$1,079,999 for individuals who may be diagnosed later in disease progression or who have experienced challenges in staying adherent to care.<sup>1</sup>

**The Federal 340B Drug Pricing Program (340B Program):**

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<sup>1</sup>Bingham, Adrienna et al. "Estimated Lifetime HIV-Related Medical Costs in the United States." *Sexually transmitted diseases* vol. 48,4 (2021): 299-304.  
doi:10.1097/OLQ.0000000000001366

***The 340B Drug Pricing Program was created by Congress in 1992 to help certain safety net health care providers such as disproportionate share hospitals, children’s hospitals, federally qualified health centers (FQHCs) and Ryan White HIV/AIDS clinics like Vivent Health and State AIDS Drug Assistance Programs (ADAPs), known collectively as covered entities, “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>2</sup>***

Under the 340B program, pharmaceutical manufacturers participating in Medicaid agree to sell outpatient medications to safety net providers at significantly reduced prices. In turn for these reduced prices, safety net providers reinvest the savings from the lower prices into programs and services for their patients. These services can include access to medications, health care services including medical, dental, mental health and clinical pharmacy services, and services designed to overcome barriers to care and address social determinants of health.<sup>3</sup>

To participate in the program, eligible organizations must register with the Health Resources and Services Administration’s (HRSA) Office of Pharmacy Affairs (OPA) and comply with significant program requirements designed to ensure the program operates as intended.<sup>4</sup>

**Vivent Health Uses the 340B Program to Benefit Patients:**

***Eighty-six percent (86%) of Vivent Health patients in Colorado are living at or below 250% of the Federal Poverty Level (FPL), with 34.3% of our patients enrolled in Medicaid, 14.6% in Medicare, and 6.3% uninsured.*** These statistics demonstrate that Vivent Health is serving medically and socio-economically vulnerable individuals who would otherwise face significant challenges in having their health care and social services needs met. All the services Vivent Health provides are available regardless of the ability of the people we serve to pay for them, or their insurance status.

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<sup>2</sup> Health Resources & Services Administration, Office of Pharmacy Affairs; <https://www.hrsa.gov/opa/index.html>; accessed Feb. 27, 2022

<sup>3</sup> Ibid.

<sup>4</sup> Ibid.

While Vivent Health prides ourselves in serving a large and growing number of patients, it is the quality of our care and breadth and integration of our services that are driving the health outcomes we help our patients achieve. ***Because of the integrated and comprehensive model of care that we provide – something made possible through the 340B Program – 95% of Vivent Health patients in Colorado are achieving virologic suppression, far outpacing state and national benchmarks.***

Unfortunately, direct investment by the federal government in discretionary HIV prevention, care and treatment programs has not kept up with need and has remained flat in recent years.<sup>5</sup> ***This means Vivent Health must leverage all resources available, including the 340B Program to meet the growing needs of the patients and communities we serve and to help offset the more than \$10 million in uncompensated care we provided last year. Without the savings made available to Vivent Health under the 340B program, Vivent Health would not be able to continue to provide the high quality, effective care that people affected by HIV need.***

#### **Pharmacy Benefit Managers (PBMs), Discriminatory Reimbursement and Vivent Health:**

The 340B Program is an integral component of how the United States funds the health care safety net for low income, vulnerable individuals. Unfortunately, ***pharmacy benefit managers (PBMs) and other third party health care payors are attacking this program and the health care services it makes possible by offering lower reimbursement rates to 340B covered entities when compared to non-340B entities. This practice is known to covered entities as ‘discriminatory reimbursement’ or ‘PBM pickpocketing.’***

Discriminatory reimbursement negatively impacts covered entity patients by forcing health care providers like Vivent Health to pass 340B savings on to the PBMs instead of reinvesting these savings in care and treatment programs. This is directly contrary to the federally defined intent of the program, specifically, ***“to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”***

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<sup>5</sup> Kaiser Family Foundation; HIV/AIDS; <https://www.kff.org/hiv/aids/fact-sheet/u-s-federal-funding-for-hiv-aids-trends-over-time/>

The Federal government, through HRSA, has stated its concerns with discriminatory reimbursement as a threat to the 340B program, covered entities and the patients who benefit from the program. HRSA explains that “if covered entities were not able to access resources freed up by the drug discounts when they...bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities.”<sup>6</sup> Further, HRSA has stated that ***the 340B program is in place to provide additional financial resources to safety net providers without increasing the federal budget. The costs savings generated by the 340B program and its lower acquisition cost combined with normal reimbursement rates from third party payors are exactly the benefit Congress intended to create. If Congress had intended these savings to go to PBMs, their clients, and their shareholders, it would have explicitly stated so in the legislation.***

Ultimately, ***discriminatory reimbursement harms low-income and medically vulnerable individuals who rely on safety net providers participating in the 340B Program for their health care.*** The Government Accountability Office has found that providers use 340B to: offset losses incurred from treating some patients, continue providing existing pharmaceutical and clinical services, lower drug costs for low-income patients and serve more patients, and provide additional services, such as case management to facilitate access to appropriate care.<sup>7</sup>

#### **HB22-1122 Relating to Pharmacy Benefit Manager Prohibited Practices will end Discriminatory Reimbursement**

Ending HIV as a pandemic is an achievable goal. We have the medical and pharmaceutical tools necessary to help people with HIV avoid transmitting the virus to others, and help people at-risk for HIV avoid acquiring it, should they become exposed.

The true challenge we have is in ensuring the financial resources needed to get these tools into the hands of everyone who are available. ***The practice of discriminatory reimbursement, or pickpocketing, by PBMs not only runs counter to the intent of the***

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<sup>6</sup> HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act (July 2005).

<sup>7</sup> GAO, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, at p. 17 (Sept. 2011).

***Federal 340B Program, it also makes achieving the goal of ending the HIV epidemic all the more difficult as resources needed to reach a growing number of people living with and at-risk for HIV are siphoned off by third party payors.***

The prohibitions on PBMS and third party payors outlined in HB22-1122 are critical if we are to achieve health equity for all and ensure access to health care and treatment for Colorado's most vulnerable.

Vivent Health strongly encourages you to support HB22-1122.

April 28, 2022

Senate Health & Human Services Committee  
Colorado General Assembly  
200 E. Colfax  
Denver, CO 80203

Dear Committee Members,

On behalf of the over 720 life sciences companies and organizations in Colorado that drive health innovations to save and change lives around the world, we appreciate the opportunity to provide feedback on HB22-1122 Pharmacy Benefit Manager Prohibited Practices. Of particular concern to the Association and our members is that the bill includes a prohibition on pharmacy benefit managers from requiring pharmacies to identify claims when a drug discounted under the federal 340B Drug Discount Program has been dispensed to a patient.

The claims modifier prohibition outlined in the bill would needlessly make it more difficult for entities across the supply chain including payers and manufacturers to identify illegal duplicate discounts and diversions of 340B drugs. This issue has become a greater concern in recent years as we have seen the 340B program experience exponential growth in Colorado and across the country. With this growth, it is essential that there are measures in place to ensure the proper tracking of these claims to prevent waste, and abuse of this critical program for uninsured and underinsured patients.

Congress created the 340B program in 1992 to provide recipients of Health Resources and Services Administration (HRSA) grants and safety-net hospitals access to the voluntary discounts pharmaceutical manufacturers had provided before the enactment of the Medicaid rebate statute. Under the program, manufacturers are required to provide covered outpatient drugs at a substantial discount which typically ranges between 23.1% to 50%, going as high as 100% depending on the specific Medicaid rebate. The discounts substantially reduce the burden on covered entities that provide uncompensated or under-compensated care. And covered entities may benefit financially from the difference between the discounted drug cost and the amount reimbursed by the patient's insurer in most cases.

Covered entities under the 340B program include hospitals that meet the following criteria: children's hospitals, critical access hospitals, rural referral centers, free-standing community hospitals, and disproportionate share. Non-hospital covered entities are eligible for the program by receiving one of ten federal grants outlined in the law including Federally Qualified Health Centers, and Ryan White Programs.

In 2010, HRSA issued additional guidance allowing all 340B covered entities, even those with their own outpatient pharmacies, to contract with an unlimited number of third-party pharmacies. This change along with 340B providers expanding sales through new increased hospital outpatient facility "child sites" registrations has opened the doors for all covered entities to generate additional profits on 340B purchased drugs.

HRSA's rule change regarding third-party pharmacies dramatically increased the role of for-profit pharmacies and other third parties benefiting from the program, since 2010 program participation grew by 4,228%<sup>1</sup>. And between 2013 and 2020, over 30,900 locations registered with HRSA's covered entities database, with 73% of that growth due to child-site registrations.

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<sup>1</sup> "It's Time to Fix the 340B Program" Colorectal Cancer Alliance, November 20, 2021: <https://www.ccalliance.org/blog/get-involved/fix-the-340b-program>

The Berkley Research Group released a new analysis earlier this year, showing that 50.5% of every dollar spent on brand medicines went to payers, middlemen, providers, and other stakeholders in 2020<sup>2</sup>. The amount hospitals, pharmacies, and other health care providers receive from the sale of brand medicines is also growing. The amount these entities now receive reached \$81 billion last year, up from \$24.7 billion in 2013. This trend was primarily driven by the growth of the 340B program, the amount hospitals and other 340B entities received from the sale of brand medicines purchased through the 340B program grew by 1,100% between 2013 and 2020.

The evolution of contract pharmacies' role in the program has fundamentally altered the 340B program and resulted in for-profit entities earning substantial profits through complex profit-sharing agreements with the 340B covered entities. More than half of all profits realized by 340B contract pharmacies are concentrated in just four companies that utilize vertical integration. The companies consist of a health insurance plan, pharmacy, PBM, and a third party 340B services firm.

The growing prevalence of these arrangements is taking the 340B program farther away from its original intended goal of helping safety-net entities provide care to vulnerable patients. With entities across the supply chain now profiting off this safety-net program, we believe it is essential that there are measures in place to ensure the proper tracking of these claims to prevent waste, and abuse which will ultimately harm patients. For these reasons, we are opposed to the claims modifier prohibition in HB22-1122.

Sincerely,



Michael Crews  
Vice President  
Colorado BioScience Association

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<sup>2</sup> Vandervelde, Aaron, et al., For-Profit Pharmacy Participation in the 340B Program, BRG Group, October 2020.