

NASTAD Drug Pricing and Access Principles

Treatment and biomedical prevention advances – and the innovative research and development behind them – have revolutionized our ability to end the HIV and hepatitis epidemics and have provided lifesaving interventions to millions of people worldwide. HIV treatment and biomedical prevention drugs, hepatitis C direct acting antivirals, and opioid reversal drugs are critical public health tools, and our ability to access them must be considered a public health imperative. Yet access has been inefficient, expensive, and profoundly inequitable. Federal, regional, and local efforts to end these epidemics serve as an important catalyst to approach drug pricing and access with the goal of achieving sustainable systems of treatment and prevention.

The entire drug pricing and delivery system – including pharmaceutical manufacturers, public and private payers, pharmacy benefit managers (PBMs), and government entities – has a role to play in reducing drug prices and improving access. The following principles are based on NASTAD’s mission and commitment to ending the HIV, hepatitis, and overdose epidemics and to addressing the health disparities that have fueled disproportionate access to healthcare in the United States.

- I. **Drug list prices – including launch prices and price increases on existing products – must be reined in to increase and sustain access across public and private payers.** Legislative and regulatory action is needed where existing policy and market competition failures have occurred, particularly for brand-name and generic drugs essential to public health. Legislation and regulations that include caps on list prices are necessary. Barring a significant and immediate overhaul to the way drugs and biologics are priced across various coverage and payer systems, existing prescription drug cost controls – including rebate and discount programs – should be strengthened to protect patients and payers from egregious pricing schemes.
- II. **Competition is essential to sustainable access to medications.** Efforts to accelerate development of generic, quasi-generic, and lower-cost brand-name medications are critical. Federal regulation is needed to end anti-competitive practices that delay generic alternatives, including manufacturer pay-for-delay legal settlements; Risk Evaluation and Mitigation Strategies (REMS) abuses, whereby brand-name manufacturers deny samples of drugs to generic manufacturers seeking to conduct bioequivalence studies; and evergreening or product hopping, whereby manufacturers make minor formulation modifications to existing drugs to extend their patent life.
- III. **Public and private insurance formularies must ensure access to medications based on evidence-based clinical standards of care.** Formulary inclusion and management decisions must be closely regulated and monitored at the state and federal levels to ensure plan designs do not discriminate against people living with or at increased risk for HIV and hepatitis by limiting access to high-cost medications for those with clinical indications for use. Potentially discriminatory utilization management practices include adverse tiering, arbitrary and excessive prior authorization not in line with clinical standards

of care, and non-clinically based step therapy. We will not end the HIV and hepatitis epidemics without private insurance, Medicaid, and Medicare formularies that are grounded in science. Regulatory protections, monitoring, and enforcement are also necessary to ensure plan designs do not discriminate against people whose lives and health depend on high-cost medications.

IV. Cost sharing, including commercial market copayment and coinsurance structures, must be reformed.

The use of cost-sharing tiers to manage drug or biologics utilization is a pervasive tactic employed by insurers to discourage the utilization of high-cost drugs in favor of lower-cost options (including generics). This can undermine access to an essential medication considered to be the safest, most effective, or only prevention or treatment option for the patient. Alternatives to current cost cost-sharing structures, which hinge on drug pricing reform in general, need to be explored in close collaboration with scientific, public health, and community stakeholders. Dollar limit caps on patient cost sharing across public and private markets must be a part of any comprehensive drug pricing reform.

V. Access to medications across public and private payers and public health programs must balance clinical, ethical, and sustainability considerations.

As the HIV, hepatitis, and overdose medication markets become more competitive, particularly as generics become more prevalent and novel drug administration routes emerge, payers, providers, and systems will need to make difficult choices about how to ensure and sustain equitable access to clinically appropriate treatment and prevention medications to everyone who needs them. As the number of regimens with comparable safety and efficacy increase, cost must be a factor in determining access, provided there are safeguards that ensure access to an appropriate medication based on clinical indication and evidence-based best practices. While open formularies may be highly desirable, their feasibility, sustainability, and clinical justification are increasingly being questioned in a climate where cost containment is essential. There must be transparent dialogue – grounded in ethical access and sustainability principles – across public health, clinical, payer, and consumer stakeholders to determine the value and appropriate and sustainable price of new and existing medications.

VI. Drug rebates secured by pharmacy benefits managers (PBMs) in the commercial market should be subject to increased scrutiny and transparency to ensure that rebates benefit consumers.

State and federal regulation is necessary to ensure that PBMs are acting in the interest of both plans and consumers. Legislation and regulations are necessary to ensure additional transparency with regard to rebates generated and how they are used, direct registration and licensing of PBMs by state departments of insurance, and to guarantee that savings associated with rebating practices result in cost savings that accrue to insurance plan members.

VII. Manufacturer, government, and philanthropic investments in research and development must be reflected in drug and biologic product pricing.

Public-private partnerships in research and development are essential to biomedical innovation and the development of state-of-the-art disease prevention, treatment, and curative modalities, particularly for diseases of public health significance. List prices for new or expanded-indication prescription drugs should reflect government and philanthropic investments in discovery and translational research, to ensure affordable and equitable access to emerging public health tools. Similarly, public-private partnerships should maintain sufficient investments in research and development to demonstrate the value of new drug and biologic products over existing standard-of-care options, particularly in the setting of stringent payer formulary design to contain prescription drug spending.

VIII. The 340B Drug Pricing Program is essential to secure access to HIV, hepatitis, and overdose medications

for low-income, vulnerable populations, particularly in non-Medicaid expansion states. The 340B Program has allowed AIDS Drug Assistance Programs; Ryan White HIV/AIDS Program providers; STD clinics and programs funded under Section 318 of the Public Health Service Act; and other safety net programs to ensure access to discounted medications for un- and under-insured individuals. Another core component of the 340B program is reinvestment of savings to expand access to services, including services that are not readily funded through public grantmaking and payer reimbursement. In non-Medicaid expansion states in particular, 340B savings have been critical to providing basic public health infrastructure and services to low-income people. This structure means that any dramatic overhaul of the 340B program will destabilize our public health infrastructure. Indeed, the very legislative and regulatory reforms that are necessary to lower drug and biologic prices have the potential to negatively impact the ability of 340B covered entities to continue to provide critical public health services. Drug pricing and 340B reforms should recognize the different functions, geographic variability, patient populations, and otherwise limited financial resources for 340B program entities. Great care must therefore be taken to ensure that programs dependent on 340B program savings be made whole to ensure the continuity of critical medical and support services.

IX. We must evaluate and address our significant reliance on manufacturer charitable contributions as the

foundation of our public health medication access system. Manufacturer contributions – in the form of patient assistance programs for low-income uninsured individuals, co-pay assistance programs for underinsured individuals, drug donation programs, and grant-making to support direct service delivery and advocacy – have helped to increase access to lifesaving medications and cover gaps in the healthcare system, particularly in our most heavily impacted jurisdictions and in jurisdictions that have failed to expand access to Medicaid. However, the overreliance on charitable medication programs masks deep-seated structural inadequacies in our healthcare system to optimally serve vulnerable people impacted by the HIV, hepatitis, and overdose epidemics. Continuing dependence on these programs poses a threat to the integrity and sustainability of services by creating a dependence on such charity. It exacerbates an inefficient patchwork delivery system at odds with goals of wholistic and integrated services. Manufacturer support will continue to be important to fill gaps in our current broken system – particularly in states with more limited healthcare access – but our efforts must simultaneously include rapid identification and scale up of sustainable public health systems built on a range of funding mechanisms.