



PATIENT ACCESS & AFFORDABILITY PROJECT

Empowering Patient Perspective.

Patient Access & Affordability Project (PAAP) Policy Recommendations for the Biden Administration and the 117th Congress

May 12, 2021

The healthcare system in the United States has become complex, expensive, and impersonal.

To many Americans, it may seem that any healthcare policy debate has become nothing but a food fight between politicians, providers, insurance companies, and the biopharma industry. ***This has left the patient without a voice.***

The American healthcare system remains the world-leading market-based system that rewards scientific advancement and medical innovation. But currently, there are too many barriers and entrenched interests working against meaningful change in how healthcare is provided.

Together, we can bring down those barriers: we must empower patients; continue to pursue advances in medicine; and disrupt the payment landscape to accommodate innovative medicine that will save lives.

This platform outlines the three areas of reform that will be PAAP's focus for the 117th Congress: 1) Empowering Patients, 2) Advancing Medical Innovation, and 3) Reforming Healthcare Finance.

1. Empowering Patients

In virtually every instance, insurance is designed to protect against high-cost events – except in healthcare. Our system has distorted health “insurance” into a high-premium, pre-payment over value insurance model. That means the current structure is designed to focus on cost savings for providers and insurers – both private and public – and Pharmacy Benefit Managers (PBMs), and not on value and results for patients. Patients are frequently left with limited choices, coverage gaps, and excessive out-of-pocket costs on top of high-priced premiums. This must change on the most basic level. Our healthcare system must be centered around the patient and opened up for providers and innovators to create better value and results.

Policy Agenda:

- **Patients should have low out-of-pocket costs.**
 - Insurance companies, Medicare, and Medicaid should honor co-pay assistance.
 - Ban co-pay card accumulators and maximizers, which financially penalize patients and provide a windfall for insurance companies.
 - Authorize and expand financial tools to help patients stretch their healthcare dollar further.

- **All Americans should have equitable access to healthcare.**
 - Outlaw the use of discriminatory health economics measures, like the Quality-Adjusted Life Year (QALY), that are used to influence prescribing and reimbursement decisions.
 - Prohibit Medicaid from using formularies based on those developed by Institute for Clinical and Economic Review (ICER) that limit patient access.
 - Audit federal initiatives to promote health equity and strengthen policies and programs.
 - Empower communities and health systems with flexible financial and payment models to tailor health services toward the needs of the communities they serve.
 - Strengthen reimbursement and funding models to improve maternal care in communities of color and across rural America.
 - Increase telehealth to rural and underserved communities across America through expanded broadband coverage and further streamlining licensure requirements.

- **Health insurance must improve patient access, not create more barriers.**
 - Preserve the doctor-patient relationship as the central and best decision maker in healthcare.
 - Insurance markets should be competitive and offer patients a variety of health plans.
 - Eliminate disruptive insurance practices that limit patient access, like step therapy and excessive prior authorizations.
 - End coding games on preventative diagnostics, medicines, and procedures that lead to unexpected medical bills, as well as lengthy and unnecessary appeals by the patient.

2. Advancing Medical Innovation

The continued pursuit of cures and better treatments is vital to the health and wellbeing of patients worldwide. No other country supports and values medical innovation like the United States. It is imperative that we continue to lead the world by advancing novel medicines and therapies while ensuring the patients for whom they are designed have affordable access to these innovations. A healthy and vibrant life sciences sector working in tandem with an independent and efficient FDA is an integral part of that process.

Policy Agenda:

- **Encourage a more patient-centric culture at the FDA.**
 - Conduct a regulatory audit of all barriers to speedy approval of innovative medicines.
 - Empower and encourage FDA to apply best practices from the COVID-19 response to more flexibly allocate resources, rapidly use advances in regulatory science, and increase simultaneous reviews to speed up approvals of important medicines.
 - Require FDA to more readily adopt digital health technologies, digital endpoints, and innovative clinical trial designs.
- **Work with industry to improve disease-specific diversity in clinical trials.**
 - Commission a study to better understand the challenges and barriers in clinical trial recruitment of a diverse population that is reflective of disease

- demographics, taking into account diversity in race, ethnicity, age, gender, and socioeconomic status.
- Determine and prioritize diseases and therapeutic areas where clinical trial diversity is especially critical to understanding a new therapy's profile.
 - FDA should reward and incentivize successfully diverse clinical programs by offering sponsors a pathway to speedier reviews and approvals.
- **Encourage a patient-centric culture at CMS.**
 - Grant the patient a real voice in reimbursement decision-making.
 - Conduct a regulatory audit of all barriers to reimbursement and access to medicines.
 - CMS should encourage innovative patient support models that allow patients, not insurance companies, to benefit from savings.
 - CMS must support the use of value-based coverage recommendations driven by the clinical value of the treatments, patient input, and real-world evidence.
 - Increase transparency of costs, rebates, and outcomes throughout the health system.
 - Maintain a ban on the use of the discriminatory QALY in Medicare budgeting and coverage decision-making.
 - Eliminate the Most Favored Nations rule, which threatens access to lifesaving medications for Medicare Part B patients.

3. Reforming Healthcare Finance

Healthcare budgeting and reimbursement in the U.S. has not changed much since the 1960s. Policymakers have merely continued to build on top of an outdated system that is neither patient-focused, efficient, nor cost-effective. Considering how much science and medicine have changed, it is completely inappropriate to continue using a 60-year-old healthcare finance system.

America spends twice as much as other industrialized countries on healthcare as a share of our economy. This is due – at least in part – to the perverse incentives created by a dated hodgepodge of federal policy that eliminates efficiency and creates excessive spending throughout the system.

Medical innovation is unfolding rapidly and our current healthcare finance system is not designed to accommodate it. We must change our healthcare finance system to become more efficient, nimble, and responsive to that innovation.

Policy Agenda:

- **Establish a healthcare finance and payment model that rewards improvements in the long-term care of patients.**
 - Incentivize innovative insurance and finance models that are designed to reward and encourage major breakthroughs in therapies and cures, while keeping the cost to patients low.
 - Stop the use of flawed coverage recommendations based on inappropriate measurements – including QALY – from organizations like ICER.

- **Reject European-style health systems that have led to limited patient choice, caused major delays in access to cutting edge medicine, and prioritized low cost over patient care.**
 - Eliminate the adoption of reference pricing, such as the Most Favored Nations rule.
 - Oppose a new centralized and bureaucratic system to purchase or set formulary policy for drugs, which adds further complexity to the health system and further removes the patient from decision-making.
 - Prohibit academics and health economists from using a flawed algorithm and discriminatory ICER-style model for evaluating and pricing drugs as part of a national drug pricing system.
 - Seek price parity on drugs by demanding European and other wealthy countries pay their fair share for advances in innovative medicine.
 - Ensure that doctors, nurses, and other healthcare providers are able to make decisions independently to provide optimal patient care.

- **Embolden the market-based healthcare model that encourages patient choice and maintains American leadership in life sciences and medical innovation.**
 - Audit policies and practices that can create perverse incentives and lead to unnecessary treatments like surgeries or other expensive procedures.
 - Reestablish transparency across the health system to understand the actual drivers of healthcare inflation.

- Encourage entrepreneurial disruption that leads to the health system competing for patients, which would help lower costs and improve the use of health resources.
- Patients, not companies like pharmacy chains, should benefit financially from the data collected on individuals.