INTERNATIONAL REFERENCE PRICING

Lessons Learned from Abroad

AIMEDALLIANCE

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INTRODUCTION

For decades, the rising cost of health care, health insurance, and prescription drugs has been a major concern for American consumers, caregivers, health care providers, and employers.[1] Despite landmark reforms, such as the Patient Protection and Affordable Care Act (ACA) expanding health care for millions, and the Inflation Reduction Act (IRA) setting prescription drug caps for Medicare beneficiaries, health care costs continue to climb.[2] Notably, out-of-pocket spending increased by 7.2% in 2021, and hospital expenditures grew by 10.4% in 2023, substantially faster than the 3.2% inflation rate recorded in 2022.[3]

While health care costs continue to rise across the entire health care ecosystem, policy reforms have primarily focused on prescription drug costs. Importantly, prescription drug costs increased by 11.4% between 2022 and 2023.[4] In addition, the average list price for brand-name drugs increased by over 30% from 2016 to 2022, far outpacing the inflation rate of 8.5 percent over that same period.[5] While list prices do not fully measure consumer affordability, research shows that out-of-pocket costs remain unaffordable. For example, a 2022 survey found that nearly one in five U.S. adults reported skipping doses, taking less medication, or leaving prescriptions unfilled due to cost.[6]

In response, federal and state lawmakers have pursued a range of strategies to curb prescription drug costs. At the federal level, the IRA marked a significant policy shift by granting Medicare the authority to negotiate drug prices for select high-cost prescription drugs.[7] Several states have also created Prescription Drug Affordability Boards (PDABs), which are relatively new and experimental bodies tasked with reviewing drug prices and, in some cases, setting reimbursement caps known as upper payment limits (UPLs). However, progress has been limited. Despite years of activity, only one PDAB has established a UPL.[8] These initiatives are a large undertaking for states with smaller budgets, limited staff, and less capacity than the federal government.[9] Notably, in 2025, one state PDAB reversed course and closed its board entirely.[10]

Policymakers have also explored importing prescription drugs from outside the United States at discounted prices to reduce high costs. Specifically, under the FDA's Section 804 Importation Program, states and other non-federal entities may apply for permission to import prescription drugs from Canada.[11] While several proposals have been submitted to the FDA, only one program has received FDA approval, and no Section 804 programs have been implemented as of December 2025.[12]

In 2025, the federal government began pursuing a different strategy to address prescription drug costs, described by the Trump Administration as a "Most-Favored-Nation" (MFN) pricing.[13] Although MFN traditionally refers to a trade principle that prohibits countries from discriminating in trade arrangements, such as offering lower tariff rates for a particular item or service to one trading partner over another, the Administration uses the term to refer to aligning U.S. prescription drug prices with those paid by other countries within the Organization for Economic Co-operation and Development (OECD).[14] This type of pricing mechanism is more commonly referred to as international benchmark pricing or international reference pricing (IRP). Underpinning these directives is the Administration's argument that Americans pay substantially more for prescription drugs

than consumers in other countries, resulting in unfairly high costs.[15] Although prescription drug costs in the U.S. are significantly higher than those in OECD countries, important structural differences between health care systems, such as cost drivers, access pathways, and availability of treatments, impact how prices are set and complicate efforts to align U.S. prices with foreign benchmarks.

As of January 2026, the Trump Administration has proposed three potential pathways for implementing international benchmark pricing: GENEROUS (GENErating Cost Reductions fOr U.S. Medicaid) Model;[16] GLOBE (Global Benchmark for Efficient Drug Pricing) Model[17]; and GUARD (Guarding U.S. Medicare Against Rising Drug Costs) Model.[18] Collectively, these proposed rules would subject Medicaid, Medicare Part B and Part D drugs to some form of international reference pricing (IRP).[i]

This paper examines the potential application and implications of IRP models in the United States. By analyzing how international health systems set drug prices and how their health care ecosystems differ from the U.S., this paper aims to inform future policy decisions and assess the feasibility of integrating IRP principles into U.S. drug pricing policy.

METHODOLOGY

To develop consensus on the potential impact of IRP pricing models in the United States, explore patient-centered alternatives, and identify best practices in international value assessments, Aimed Alliance convened a consensus meeting with international patient group stakeholders and advocates representing patients, providers, and caregivers from Europe, Oceania, and North America. Participants provided valuable feedback and informed the key concerns of international patients, best practices, and recommendations.

To begin assessing the implications for patients if IRP models were implemented in the United States, Aimed Alliance conducted an extensive review of 23 international drug pricing systems across OECD countries that could serve as potential reference points for a U.S. IRP approach. This analysis included systems in Austria, Australia, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Republic of Korea, Spain, Sweden, Switzerland, and the United Kingdom. A detailed comparison of these systems is provided in Appendix A.

Following this research and additional individual interviews with participants, Aimed Alliance hosted a roundtable discussion with participants to discuss findings across countries. Based on these discussions, Aimed Alliance finalized and published this report, which provides an overview of patient concerns regarding IRP implementation in the U.S., patient-centered recommendations to improve prescription drug pricing domestically, and best-practices and lessons learned from international drug pricing assessments.

i. President Trump's Executive Order "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" frames its drug pricing objective as an MFN approach. In May 2025, HHS defined the MFN target price as "the lowest price in an OECD country with a GDP per capita of at least 60 percent of the U.S. GDP per capita." Later, in December 2025, HHS's GENEROUS model adopted a different definition, identifying the MFN price as "the second lowest country specific manufacturer reported net price, adjusted by gross domestic product per capita using a purchasing power parity method." By contrast, HHS's GLOBE and GUARD models do not use the MFN terminology at all. Given these varying definitions and applications of MFN across the Administration's initiatives, this paper uses the term "international referencing pricing" IRP) when referring the Administration's overall pricing approach, and reserves "MFN" for instances where the Administration specifically uses the term.

BACKGROUND

President Trump's MFN Announcements

On May 12, 2025, President Trump issued an Executive Order titled "Delivering Most-Favored Nation Prescription Drug Pricing to American Patients.[19] The Order alleges that Americans are paying higher prescription drug costs than other developed nations, effectively subsidizing lower prices abroad.[20] To address this disparity, the Order directs the Department of Health and Human Services (HHS) to facilitate programs that allow pharmaceutical manufacturers to sell their products directly to American patients at a MFN and communicate MFN price targets to manufacturers in an effort to align U.S. prices with those in comparable OECD countries. If manufacturers do not make "significant progress" toward meeting these targets, the Secretary of HHS must develop a rulemaking plan to impose MFN pricing through regulation, to the extent allowed by law.[21] The Order also directs the United States Trade Representative to take "necessary and appropriate" actions to eliminate "unreasonable or discriminatory" practices that result in Americans paying more for prescription drugs than other developed countries.

Following the Executive Order, President Trump sent letters to 17 pharmaceutical manufacturers requesting they take steps to address prescription drug affordability by:[22]

- Providing MFN prices to all Medicaid patients;
- Committing not to offer other developed nations better prices for new drugs than those offered in the United States;
- Creating pathways for manufacturers to bypass middlemen and sell medicines directly to consumers at prices no higher than those in OECD nations; and
- Leveraging trade policy to support manufacturers in raising international prices, provided that increased revenues abroad are reinvested towards lower costs for American patients and taxpayers.

Companies were given until September 30, 3025, to respond to President Trump's demands.

In response, some companies proposed raising prices abroad to align European list prices with U.S. prices,[23] but did not explain how these increases would reduce costs for American consumers. Others reached one-off agreements with the White House to lower prices for specific drugs.[24] For example, in exchange for broader coverage in Medicare and Medicaid, Eli Lily and Company and Novo Nordisk agreed to lower prescription drug prices for GLP-1 obesity treatments for Medicare and Medicaid beneficiaries.[25] As of December 2025, 14

manufacturers have reached various agreements to lower the price of certain drugs.[26] While these agreements represent progress and demonstrate opportunities for reform, individual agreements with the White House pose challenges to achieving long-term prescription drug affordability, as these agreements fail to address systemic drivers of high costs, such as pharmacy benefit managers (PBMs) and insurer practices.

On November 14, 2025, CMS released a Request for Applications for its GENEROUS model, which will allow state Medicaid programs to *voluntarily* seek supplemental rebates from participating pharmaceutical manufacturers to align prices with those paid in the U.K., France, Germany, Italy, Canada, Japan, Denmark and Switzerland.[27] Under the model, the IRP is defined as "the second lowest-country specific manufacturer-reported net price" adjusted for differences in GDP per capita using a purchasing power parity method. Participating manufacturers would be required to include their entire portfolio of single-source and innovator multiple-source Medicaid-rebate-eligible drugs and must report their net prices in each of the referenced countries. In turn, CMS will negotiate standardized coverage criteria with manufacturers for each model drug and subsequently communicate the agreed-upon standardized terms to all states, which may choose whether to participate.

On December 19, 2025, CMS also proposed the GUARD and GLOBE Models, which would *mandate* pharmaceutical manufacturers to provide Medicare Part B and D drugs with comparable rebates to OECD countries. Both models would be deployed across randomly selected geographic regions encompassing approximately 25% of Medicare beneficiaries, and they would require manufacturers to issue rebates that better align Medicare prices with those in 19 economically comparable countries.

The GLOBE model proposes establishing a manufacturer rebate calculation benchmark tied to international pricing information for certain Part B single-source and sole source biological products within specific therapeutic areas, including antigout agents, antineoplastics, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, and ophthalmic agents. The model applies to drugs with more than $100 million in annual Part B spending, excluding those subject to an established maximum fair price (MFP) under the IRA or newly approved drugs until CMS establishes a baseline price under the Drug Inflation Rebate Program. The required rebate would equal the difference between the current Part B payment (Average Sales Price plus 6%) and the GLOBE benchmark price. The benchmark would be the greater of (1) derived from international pricing information available to CMS for other economically comparable countries, or (2) derived from manufacturer reported international pricing information. The Model excludes 340B claims from its rebate calculations, but acknowledges it may indirectly affect a drug's AMP and Best Price. The GLOBE model would have a seven-year test period that includes 5 performance years beginning October 1, 2026.[28]

The GUARD model proposes establishing a manufacturer rebate calculation benchmark based on international pricing information for some Part D sole-source drugs and sole-source biological products in 17 therapeutic categories[ii] when a drug generates more than $69 million in annual gross Part D spending. The model would exclude generics, biosimilars, or drugs and biologics with an established MFP. The required rebate would equal the difference between the current Part D payment amount and the GUARD Model applicable international benchmark. The benchmark would be the greater of (1) the default international benchmark, derived from international pricing information available to CMS for other economically comparable countries, or (2) the updated international benchmark, derived from manufacturer reported international pricing information. The model would span a seven year testing period, which includes five performance years beginning on January 1, 2027.[29]

ii Analgesics, anticonvulsants, antidepressants, antimigraine agents, antineoplastics, antipsychotics, antivirals, bipolar agents, blood glucose regulators, cardiovascular agents, central nervous system agents, gastrointestinal agents, genetic or enzyme or protein disorder: replacement or modifiers or treatment, immunological agents, metabolic bone disease agents, ophthalmic agents, and respiratory tract/pulmonary agents.

COMPARATIVE ANALYSIS OF U.S. AND FOREIGN HEALTH CARE SYSTEMS

Private v. Public Health Care Systems

Unlike other countries, the United States health care system is predominantly private, with the exception of Medicaid and Medicare programs, which support low-income, disabled, and elderly beneficiaries. In contrast, all OECD countries operate public health insurance systems where national governments provide certain essential health benefits, such as doctor visits, tests, and hospital care.[30] To fund these benefits, consumers in OECD countries typically pay up to 20% more in national taxes.[31]

While patients in OECD countries face low or no cost-sharing at the point of care, public health systems present challenges related to wait times and access. For example, the average wait time to see a specialist in the U.S. is 31 days,[32] whereas patients in the United Kingdom may wait up to 18 weeks.[33] Countries such as Denmark, Portugal, the Netherlands, Finland, New Zealand, and Norway have spent the last two decades working to address similar delays.[34] Participants noted that despite efforts to address these challenges, consumers still experience delays and difficulties accessing specialists. Participants highlighted that in some cases, consumers go out of the country to see a specialist, creating financial inequities in care. Participants also noted that health care providers in OECD countries experience frustration with the current system related to reimbursement rates and high-patient caseloads. These extended wait times reflect a systemic tradeoff in public insurance models, where universal coverage comes at the cost of slower access to care – an issue U.S. consumers can largely avoid due to its more flexible, market-driven delivery system. However, while U.S. consumers may have swifter access to care these gains come at a financial cost, as an estimated 40% of Americans carry some form of health care debt.[35]

Beyond provider access, OECD countries experience slower adoption of novel treatments compared to the U.S. For example, one RAND study found that of 287 new drugs introduced in 2022, U.S. consumers had access to 74%, while Germany, the next highest, had access to 52% of new drugs.[36] Moreover, more than half of new drugs were first launched in the U.S., with major OECD countries like Australia, Canada, France, Germany, Italy, Japan, and the United Kingdom typically seeing launches nearly 12 months later.[37] Importantly, the study recognizes that the lack of reference pricing in the U.S. may contribute to its role as the primary launch market.[38]

Conversely, roundtable participants noted that OECD countries place greater emphasis on preventative care, screening programs, and public health under public insurance systems. However, access to these preventative services was viewed as complementary to innovative treatment. **One participant noted that innovation, prevention, and social care are perceived as complementary, rather than as competing priorities**. While preventative care is critical to overall health management, it does not necessarily equate to an overall better health care system. For example, in 2022, Europe accounted for 20% of global cancer cases despite representing 10% of the global population.[39] Similarly, a 2018 study reported 280 cancer deaths per 100,000 in Europe, compared to 189 per 100,000 in the U.S.[40] However, participants also noted that the U.S. health care system is incredibly complicated and consumers often struggle to navigate insurance policies, appeals, provider requirements, and specialty care.

Ultimately, neither system is perfect for patients, and each government must pursue reforms that reflect its own unique challenges; because every health system presents different barriers for consumers – whether affordability, access to specialists, or timely treatment – countries are best served by solutions tailored to the specific needs of their patients, caregivers, and providers.

Drug Pricing Systems

The United States drug pricing system is unique. Individual payers, including private employers, state Medicaid programs, and Medicare, negotiate with PBMs and pharmaceutical companies to determine prescription drug prices and rebates. This substantially differs from practices in OECD countries, where government bodies negotiate directly with pharmaceutical companies to set the prices of prescription drugs. Most OECD countries use either a quality-adjusted-life-years analysis, international reference pricing, or a combination of both.

Quality-Adjusted-Life-Years

Participant discussions focused on variations in value assessment frameworks and the entities conducting these assessments. Most OECD countries reviewed in this paper rely on health technology assessments (HTAs), typically incorporating quality-adjusted life-years (QALYs) into their frameworks. HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system. A health technology is an intervention developed to prevent, diagnose, or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system.[41] Assessments often include clinical effectiveness; safety; costs and economic implications; ethical, social, cultural and legal issues; organizational and environmental aspects; as well as wider implications for the patient, relatives, caregivers, and the population. The overall value may vary depending on the perspective taken, the stakeholders involved, and the decision context.[42]

A common HTA method is quality-adjusted life-years (QALY), a value assessment framework that attempts to measure whether a treatment is cost-effective relative to its health benefit. However, the use of QALY is controversial because it discriminatorily assigns a value of 1 to a "healthy person," while individuals who cannot attain "perfect" health, such as those with disabilities, are valued lower (e.g., 0.8 or 0.5).[43] For example, if a treatment extends life by 10 years, a person starting at .5, would receive a QALY score of 5, whereas a person without a pre-existing disability, who started 1, would receive 10.[44] This creates inherent inequities, as treatments for people with disabilities are perpetually deemed less valuable. Participants also noted that QALY assessments can perpetuate disease stigma. For instance, value assessments may improperly consider obesity a lifestyle or behavioral choice rather than a chronic and relapsing disease, thereby perpetuating stigmas that contribute to low reimbursement rates of obesity treatments. Moreover, without patient-centered and patient-led reviews, assessment can misplace where patients find value in treatments, ultimately impacting the outcome of the assessment.[45]

Despite these concerns, many countries, including Australia, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, Japan, The Netherlands, Norway, New Zealand, the Republic of Korea, Spain, Sweden, and the United Kingdom,[iii] still use QALYs in their pricing assessments.[46] Consequently, any IRP model relying on these reference countries would import their discriminatory valuations, resulting in less coverage or lower pricing for treatments for individuals with disabilities or chronic conditions.

Adopting international reference pricing in the U.S. from any of the above-mentioned countries, or a combination of these countries, poses significant legal challenges. Federal law, under the Patient Protection and Affordable Care Act (ACA), prohibits the use of comparative clinical effectiveness research in Medicare.[47] Specifically, 42 U.S.C. 1320(e)-1 bars the Secretary of Health and Human Services (HHS) from using "evidence or findings from comparative clinical effectiveness research [. . .] in determining coverage, reimbursement, or incentives [. . .] that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill."[48] Importantly, this prohibition applies to the direct and indirect use of these metrics.[49]

iii Within the United Kingdom, England, Scotland, and Wales each use distinct HTA authorities.

Therefore, if the U.S. were to adopt an international reference price from any of the above-referenced countries, it would indirectly incorporate QALY-based valuations into reimbursement decisions, which is expressly prohibited under federal law. As a result, participants noted any attempt to apply OECD-based reference pricing in Medicare would likely face legal challenges and potentially be struck down in court for violating federal law. In practice, this would leave U.S. patients facing continued delays in accessing care and persistent affordability challenges while federal resources are diverted to pursuing these policies.

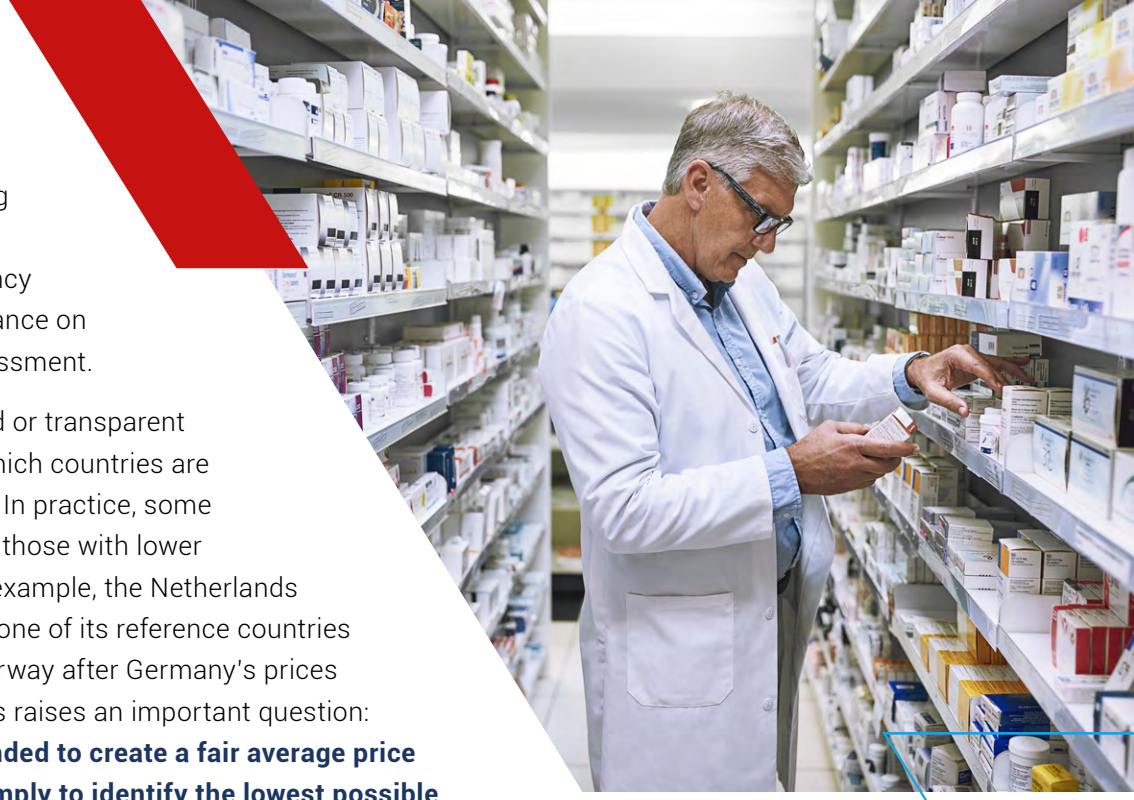
International Reference Pricing

While some OECD countries rely exclusively on QALYs, others incorporate both QALYs and international reference prices, such as Canada, the Czech Republic, Ireland, Italy, Japan, Norway, the Netherlands, and the Republic of Korea. In contrast, only Austria, Iceland, Israel, Luxembourg, and Switzerland use only international reference pricing.[50] There is no uniform set of countries applied for reference pricing, rather, each nation draws from a diverse mix of countries for comparison:

Reference Country:[iv]	Used in Reference Pricing By:
Czech Republic	18 – Belgium, Croatia, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden
France	7 – Canada, Israel, Japan, Luxembourg, The Netherlands, the Republic of Korea, Switzerland
Germany	7 – Canada, Israel, Japan, Luxembourg, Norway, the Republic of Korea, Switzerland
Belgium	6 –Canada, Israel, Luxembourg, The Netherlands, Norway, and Switzerland
United Kingdom	5 – Japan, Canada, Israel[vi], The Netherlands, and Norway
The Netherlands	4 – Canada, Israel, Norway, and Switzerland
Sweden	4 – Canada, Iceland, Norway, and Switzerland
Denmark	3 – Iceland, Norway, and Switzerland
Finland	3 – Iceland, Norway, and Switzerland
Norway	3 – Canada, Iceland, and The Netherlands
Austria	2 – Norway and Switzerland
Spain	2 – Canada and Israel
Switzerland	2 – Canada and the Republic of Korea
United States	2 – Japan and the Republic of Korea
Australia	1 – Canada
Hungary	1 – Israel
Italy	1 – Canada
Ireland	1 – Norway
Japan	1 – Canada

iv Austria, Ireland, and Italy all use reference pricing, but do not state which countries are included in their comparisons.

vi Israel only looks at England not the entire United Kingdom.



Under current systems, international reference pricing poses significant challenges, including a lack of transparency on country selection and reliance on another country's value assessment.

First, there is no standardized or transparent methodology for selecting which countries are included in reference pricing. In practice, some countries appear to prioritize those with lower prescription drug costs. For example, the Netherlands previously used Germany as one of its reference countries but later substituted it for Norway after Germany's prices were deemed too high.[51] This raises an important question: **are these comparisons intended to create a fair average price for prescription drugs, or simply to identify the lowest possible price?** This is an important distinction. A fair price reflects the value a drug provides to patients, caregivers, and providers, what the market can reasonably pay, and the investment required to develop it. In contrast, the lowest possible price focuses on what a system can pay, often placing less consideration on the infrastructure, research, and innovation necessary to bring the drug to market. Participants noted that for U.S. policymakers, this issue is critical as the need for an IRP model is based on the principle that Americans bear an unfair share of these global costs. Thus, ***when evaluating IRP adoption, policymakers should consider which policies and approaches will ensure fair global pricing***, which countries seek to balance affordability with sustainability, and which focus solely on securing the lowest costs regardless of global and patient consequences.

Second, when a country adopts a price comparison mechanism, it also essentially inherits the underlying analysis behind that price, including its determination of patient value. This adoption brings both strengths and weaknesses. For example, the original analysis may lack a mandated or codified patient engagement process or may be based on population-specific data that does not represent the diversity of another country. For U.S. policymakers, this is a critical concern. In 2020, the U.S. Census Bureau reported that racial and ethnic diversity has continued to grow since 2010, making the U.S. far more heterogeneous than many OECD countries.[52] The homogeneity of other nations means their treatment evaluations may overlook the needs of racially and ethnically diverse populations that are more prevalent in the U.S. This issue is particularly pronounced for novel therapeutics introduced abroad, as 75% of clinical trial participants are white.[53] The initial value assessments at drug approval often rely heavily on clinical trial data. If that data is homogeneous and fails to capture outcomes across diverse communities, treatments may be undervalued due to a non-wholistic assessment. Importantly, participants noted that the obligation to ensure an appropriate understanding of treatment benefits for diverse populations should be placed with government officials, as well as pharmaceutical companies, when developing clinical trials. Thus, adopting data and value assessments that are not reflective of the U.S. patient population could result in a perpetuating of devaluations of treatments for certain communities, resulting in less access to appropriate care and worse health outcomes.

Value of Patient Perspectives

As noted earlier, U.S. patients generally have faster and broader access to novel treatments compared to patients in other countries. Within the U.S., stakeholders often attribute this to the belief that American patients place a higher value on innovation and are therefore willing to pay more and navigate complex insurance processes to receive treatments they believe are in their best interest. This perception is sometimes linked to the concept of "American exceptionalism,"[54] or merely the expectation that health care in the U.S. is inherently expensive.

However, according to participants, this assumption is inaccurate. Across geographical regions, participants consistently value innovation and seek access to novel treatments and treatment options. While some participants acknowledge that cost and the collective responsibility to ensure broad health care access can limit the availability of novel treatments, the desire for these therapies is nonetheless present. Thus, the lack of value recognition in novel treatments does not come from patients.

Instead, research and participant discussions indicated that the gap lies with government bodies or entities responsible for setting prescription drug prices. Although many countries have established authorities and processes for drug pricing, these frameworks often lack a clear, mandated, or codified mechanism for incorporating patient insights, engagement, considerations, and decision-making. Alarmingly, only 9 of the 23[vii] countries reviewed have a formal patient engagement process.[viii] While a majority of these are codified in law, some states like, Spain, included consumer representatives in pricing decisions without a mandate, others like the Czech Republic only mandate patient engagement for orphan drugs.[55] Participants noted that other countries are also actively developing patient engagement frameworks, even if not mandated by law or regulation.

Only 9 out of 23 countries have a codified or mandated patient engagement process.

As a result, fewer than half of the value assessments conducted by these countries ensure that patient feedback is meaningfully represented in the final determination. Understandably, a recurring criticism across nearly all reviewed value assessments is the lack of transparency regarding how input from patients, providers, and caregivers influences decisions and outcomes on specific prescription drugs.[ix] Participants noted that this challenge may be attributable to the growing international understanding of a "patient expert." As the recognition of a patient expert stems from the understanding that lived-experience with health care systems can be equally, or even more valuable than the traditional academic qualifications. Comparatively, the U.S. Food and Drug Administration has recognized the need for patient-expert participation since 2012 under the Food and Drug Administration Safety and Innovation Act (FDASIA).

vii The Czech Republic does include a patient engagement process for orphan drugs, but not more broadly. Therefore, it was not included in this calculation.
viii Australia, Belgium, Canada, Denmark, France, Germany, New Zealand, and United Kingdom.
ix Appendix A demonstrates that no country pricing assessment reconciles patient feedback with decisions.

While some recommendations and reports acknowledge that patient and caregiver perspectives were collected, they rarely explain how this feedback was incorporated in rendering the ultimate decision. For example, one report from Ireland simply stated, "A patient organization submission was received from [named advocacy organization]," without detailing how feedback was provided, how it was evaluated, or how it impacted the ultimate decision.[56] In contrast, countries such as Australia and New Zealand offer more comprehensive summaries of patient and caregiver responses. Although Australia has made progress over the last couple of years, participants noted that there is still room for improvement, with a 2024 report identifying 50 recommendations to improve Australia's HTA assessment, including recommendations for improving consumer engagement.

While many countries are making strides in the right direction, none of the reviewed countries currently reconcile this feedback with the reimbursement body's decision and rationale. Participants consistently reported this lack of reconciliation presents a significant challenge when engaging with drug pricing authorities. Therefore, as international reference prices continue to be adopted by other countries, they risk perpetuating price frameworks that fail to capture patient priorities.

This gap is particularly concerning because it suggests that what *patients value in treatments* may not be adequately reflected in drug pricing decisions.

Importantly, the challenge of reconciling feedback is not unique to non-U.S. systems. During the initial federal negotiations under the IRA, CMS held patient listening sessions, which were later criticized for their brevity and for failing to reconcile how patient feedback influenced pricing decisions. While these issues exist in the U.S., they are far more limited in scope, demonstrating it is reasonable and feasible for CMS to improve its policies and practices to reflect the values of U.S. consumers, caregivers, and providers. However, if the U.S. were to adopt a broad IRP framework that relies on foreign value assessments lacking strong patient involvement, reintegrating U.S. patient perspectives into those models would be exceedingly difficult, if not impossible, leaving patients without a meaningful voice in decisions that directly shape their treatments, care, and lives.

Ultimately, adopting IRP models would effectively import these patient-excluded systems into the U.S., putting U.S. consumers at risk for slower access and pricing decisions that do not reflect their lived realities.

Rare Disease Patients

Globally, more than 10,000 rare disorders affect over 400 million people.[58] However, the definition of a rare disorder varies across countries. In the U.S., the Orphan Drug Act defines a rare disease or condition as one affecting fewer than 200,000 people.[59] In comparison, New Zealand and England use a threshold of 1 in 2,000 people.[60] Australia and Germany define it as 5 in 10,000;[61] Japan as fewer than 50,000 people;[62] and the Republic of South Korea as fewer than 20,000.[63]

Although science has substantially improved the identification of these complex conditions, treatment, research, and development remain slow, with fewer than 5% of rare disorders having approved and available therapies.[64] This gap stem from multiple factors, including the scientific complexity and investment risk for pharmaceutical companies. For example, one promising approach involves genetically-targeted technologies (GTTs), such as antisense or mRNA treatments.[65] These complex treatments are unique because they effectively tell the body to "switch on" or "switch off" the underlying genetic anomaly, to address the disease at its foundation.[66] Despite their potential, GTTs are costly and challenging to develop, with only 21 GTTs approved by the FDA as of 2024.[67] As such, these technologies are difficult and more costly to develop. Moreover, given the small patient populations these therapies serve, companies must weigh whether they can invest in research that is riskier, more time-intensive, and offers fewer opportunities to recoup research and development costs.

Importantly, even when treatments are approved, they are not always available due to a lack of reimbursement by public insurance programs. For example, Spain covers fewer than 67% of orphan drugs approved for use in Europe.[68] This creates a harsh reality for patients living with rare disorders, with one participant noting the right to life cannot have a monetary price; we all deserve hope for a better quality of life. Patients often resort to fundraising campaigns, pursuing legal action, or seeking treatment abroad, resulting in an inequitable care system based on economic means rather than place of residence. Participants noted the challenges in receiving positive reimbursement outcomes are also attributable to the often-perceived uncertainty of the effectiveness of the treatments as a result of small clinical trial numbers, given smaller patient population sizes.

> **"the right to life cannot have a monetary price; we all deserve hope for a better quality of life."**

Recognizing these challenges, some countries have adopted specific evaluation policies for rare disorders. For example, Germany reimburses 98% of orphan drugs approved by the European Medicines Agency and allows for reimbursement without a positive benefit analysis, which can be difficult to demonstrate for certain rare disorders due to their small population sizes, limited endpoints, and scarce natural history data to understand disease progression or regression.[69] In Australia, the TGA and the PBS also waive submission fees for orphan drugs to encourage submission, even for small populations. Similarly, other OECD countries, such as Norway,[70] Japan,[71] and the Republic of Korea,[72] have expanded or waived QALY thresholds for orphan drugs.

Access to rare disease treatments in the U.S. are in stark contrast to OECD countries, as private insurers cover these treatments in 99% of cases.[73] Importantly, this paper reviews prescription drug reimbursement practices generally and does not fully explore global approaches to orphan drug value assessments. However, the aforementioned approaches underscore the wide variations in pricing and reimbursement for this narrower set of treatments. As such, the adoption of an IRP policy across these diverse pricing structures would be difficult and likely detrimental to U.S. rare disease patient's access. As such policymakers, policymakers must consider a tailored approach and reimbursement framework to ensure continued access to these complex treatments.

WHAT COULD BRINGING AN IRP POLICY TO THE U.S. MEAN?

Patient Impact

Participants recognized the challenges U.S. patients face in accessing affordable prescription drugs, while also acknowledging that adopting an IRP policy could have global consequences for patients, caregivers, and providers.

Expert participants expressed concerns that IRP implementation could slow research and development, reducing the number of new drugs entering the market. They also warned that pharmaceutical companies might withdraw certain products from comparative markets and delay new product launches to avoid comparison pricing. For rare diseases and disorders, this could exacerbate existing challenges with delayed approvals and strict reimbursement requirements.

Participants further noted that IRP adoption in the U.S. could drive up prices in the EU and comparative countries. As a result, governments with stringent reimbursement policies may be unwilling to negotiate and pay higher prescription drug prices, resulting in certain treatments never reaching patients in those markets. Participants also voiced particular concern about the risk of approved and priced drugs being removed from markets. One participant emphasized that patient advocacy organizations are particularly concerned about educating their communities on the potential global impact of an IRP policy on international markets, as they fear that the withdrawal of a life-saving or life-changing treatment could lead to severe consequences, including self-harm or suicide.

Finally, participants questioned whether IRP adoption in the U.S. would improve prescription drug affordability in the United States. They noted that current proposals do not require savings from IRP models to be passed down to consumers through lower premiums or out-of-pocket costs. Without broader PBM and insurer reform, these entities may profit from any prescription drug savings while consumers and private payers continue to face high health care and prescription drug costs.

Industry Impact

As a global leader in innovation and drug development, U.S. policy decisions often have far-reaching implications for how new therapies are launched and which therapeutic areas pharmaceutical companies invest in. The U.S. currently pays higher prices for prescription drugs, accounting for 60% of OECD prescription drug revenue despite representing only 24% of total sales.[74] If U.S. prescription drug prices were substantially reduced to align with lower-paying OECD countries, research and development would be significantly affected. For example, a University of Chicago report estimates that **implementing an IRP pricing model in the U.S. could result in the loss of 21 new drugs annually, impacting more than 6.5 million lives over a decade.**[75]

Globally, countries are beginning to recognize the global ripple effects of an IRP in the U.S. Advocates warn that such a policy may lead pharmaceutical companies to delay or withhold new medicine launches to avoid price comparison, raise prices globally, and disrupt current global pricing systems and health technology assessments.[76] Participants also noted concerns that new drugs would be launched solely in the U.S. and novel treatments would be inaccessible or substantially delayed globally. While delayed launches abroad may not limit U.S. access, they will impact affordability, because without international price comparators, any IRP model would be inapplicable. Essentially, U.S. consumers would stay stuck in the same affordability challenges while key drivers of health care costs, PBMs and insurers, continue to operate unchecked.

MOVING FORWARD: PUTTING PATIENTS FIRST

This paper demonstrates that while globally, patients value innovation and access to new treatments, these priorities are not always reflected in cost-effectiveness measures used by OECD countries. Given the unique structure of the U.S. health care system, reforms should focus on measures that meaningfully benefit U.S. consumers, payers, and providers. Prescription drug affordability is fundamentally a U.S. health care challenge that requires a targeted U.S.-specific approach addressing the root causes of high costs. Participants support more impactful reforms which could include:

Address Consumer Out-of-Pocket Costs

The IRA was monumental in the United States for a multitude of factors, however, one of its most meaningful impacts for consumers is the annual out-of-pocket cap for Medicare beneficiaries and the Medicare Prescription Payment Plan. Under the IRA, Medicare Part D prescription drug costs are capped at $2,000 annually.[97] In addition, the IRA also allows Medicare beneficiaries to spread their $2,000 costs over 12-months.[98] Both these measures ensure consumer affordability is prioritized and directly impacted. Policymakers should consider expanding these protections to Medicare Part B drugs, as well as the commercial market.

In addition, when commercial insurance patients cannot afford their medications, they may rely on financial assistance from pharmaceutical manufacturers and other third parties to meet cost-sharing responsibilities and fill prescriptions. Traditionally, the value of this financial assistance counts toward the health plan's deductible or maximum out-of-pocket limit. However, under copay accumulator programs, this assistance is excluded from calculations. As a result, once the financial assistance is exhausted, patients may be forced to switch or stop taking their treatment because they cannot afford their out-of-pocket costs. These programs may disproportionately impact patients with conditions treated by specialty-tier drugs, which typically require higher cost-sharing. Ultimately, copay accumulators, increase consumers' out-of-pocket burdens to meet cost-sharing requirements. For example, in 2025, an individual enrolled in an ACA plan with a maximum out-of-pocket of $9,200 would face very different outcomes depending on whether a copay accumulator applies:

Example 1: Plan Without a Copay Accumulator Program[99]

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	Insurer Collects
Copay Assistance	$1,680	$1,680	$1,240	$840	$840	$840	$80	$0	$0	$0	$0	$0	$0	
Remaining Deductible	$2,920	$1,240	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$8,550
Patient Pays	$0	$0	$0	$0	$0	$0	$760	$590	$0	$0	$0	$0	$1,350	

Example 2: Plan With a Copay Accumulator Program[100]

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	Insurer Collects
Copay Assistance	$1,680	$1680	$1,680	$1,680	$480	$0	$0	$0	$0	$0	$0	$0	$7,200	
Remaining Deductible	$4,600	$4,600	$4,600	$4,600	$3,400	$1,720	$40	$0	$0	$0	$0	$0	$0	$15,160
Patient Pays	$0	$0	$0	$0	$1,200	$1,680	$1,680	$40	$840	$840	$840	$840	$7,960	

Credit: The Aids Institute, Discriminatory Copay Policies Undermine Coverage for People with Chronic Illness, Copay Accumulator Adjustment Policies in 2023.

Addressing the use of copay accumulators can directly improve consumer prescription drug affordability. The federal government could eliminate this practice through two approaches: (1) passing the HELP Copays Act (S.864), or (2) clarifying that the definition of cost-sharing under 42 U.S.C. 156.122 includes all payments by or on behalf of the consumer.

Prioritize Broad Reform over Individual Agreements with Pharmaceutical Manufacturers

While individual efforts from pharmaceutical companies to enter into agreements with the White House to lower prescription drug costs are important, these agreements do not guarantee long-term improvements for prescription drug costs or consumers. As such, the Administration should focus on institutional changes that directly address the U.S. health care system, such as PBM and insurer practice reforms.

USTR Investigation into the Use of International PBM Rebate Aggregators

Rebate aggregators are companies that negotiate rebates on behalf of PBMs in exchange for having a drug listed on the PBMs' formularies.[77] Pharmaceutical manufacturers pay rebates to the aggregator, which retains an undisclosed portion as a fee before passing the remainder to the PBM.[78] The PBM may then share a percentage of this amount with the plan sponsor, but not necessarily the full rebate. Even when regulations require PBMs to pass 100% of the rebate they receive to the plan sponsor, this only applies to the amount received from the aggregator, not the true full rebate amount.

For example, if a pharmaceutical manufacturer offers $1,000 rebate, the aggregator might keep 50%, passing $500 to the PBM. The PBM could then retain another 50% of the rebate, leaving only $250 for the plan sponsor.

In some cases, rebate aggregators are subsidiaries of PBMs, meaning that while it appears the PBM only kept $250 of the $500 rebare, the combined entities actually retain nearly 75% of the rebate. Alarmingly, an increasing number of rebate aggregators are based internationally, a practice that, according to the Chairman of the House Committee on Oversight and Government Reform, may be intended to "evade transparency and oversight in the United States."[79]

This underscores an urgent need to investigate how PBMs and rebate aggregators use international structures to avoid accountability, perpetuating high health care and prescription drug costs for U.S. consumers and payers.

Medicaid Carve-Outs for Prescription Drugs

While states have a limited ability to influence commercial prescription drug prices, they hold significantly more leverage within their Medicaid programs. Since 2017, several states' Medicaid programs have recognized the benefits of carving out prescription drug benefits from MCOs, including California,[x] Kentucky,[xi] Missouri, North Dakota, Ohio,[xii] New York, Tennessee, Wisconsin, and West Virginia.[80] These carve-outs have generated substantial savings. For instance, North Dakota saved $17 million in one-year, and Missouri saved $4.4 million in 2024.[81] Some states generated even greater savings. For example, California initially projected $150 million in annual savings, but reported approximately $405 million in 2024.[82] Similarly, New York estimates annual savings of over $400 million, and more than $2 billion within two years.[83]

Given these results, the federal government should evaluate and support states considering Medicaid prescription carve-outs. This approach may provide a more direct and meaningful opportunity to reduce state and federal budgets, and prescription drug spending.

State	Savings
California	$405 million (2024)
Kentucky	$282.7 million (2021-2022)[84]
Missouri	$4.4 million (2024)[85]
North Dakota	$17.26 million (2019)[86]
Ohio	$140 million (2022-2024)[87]
New York	$400 million (2023)[88]
Tennessee	Data unavailable
Wisconsin	Data unavailable
West Virginia	$54.4 million (2018)[89]

x California: In 2019, the California Governor signed an executive order mandating the California Department of Health Care Services switch from offering its prescription drugs via managed care plans to a fee-for-service model. The carve-out was implemented as of January 1, 2022. Abigail Coursolle, California's Delivery of Prescription Drugs to Medi-Cal Recipients Undergoes Major Change on January 1st (Dec. 20, 2021), https://healthlaw.org/californias-delivery-of-prescription-drugs-to-medi-cal-recipients-undergoes-major-change-on-january-1st/; Prior to the prescription drug carve-out, California prescription drug spending was increasing at steady pace each year with rebates increasing as well. However, with their Medi-Cal prescription drug carveout prescription drug spending continued to increase, but rebates grew much larger than average. See CA Department of Managed Health Care, Prescription Drug Cost Transparency Report (SB17) Measurement Year 2017, https://www.dmhc.ca.gov/Portals/0/Docs/DO/sb17.pdf (In 2017, prescription drug spending exceeded $8.7 billion, with $915 million in rebates); CA Department of Managed Health Care, Prescription Drug Cost Transparency Report Measurement Year 2018, https://www.dmhc.ca.gov/Portals/0/Docs/DO/2018SB17PrescriptionDrugTransparencyReport.pdf (In 2018, prescription drug spending exceeded $9.1 billion, with $1.058 billion in rebates): CA Department of Managed Health Care, Prescription Drug Cost Transparency Report Measurement Year 2019, https://www.dmhc.ca.gov/Portals/0/Docs/DO/2019SB17PrescriptionDrugTransparencyReport.pdf (In 2019, prescription drug spending exceeded $9.6 billion, with $1.205 billion in rebates; CA Department of Managed Health Care, Prescription Drug Cost Transparency Report Measurement Year 2020, https://www.dmhc.ca.gov/portals/0/Docs/DO/SB17-2020ReportAccessible.pdf (In 2020, prescription drug spending exceeded $10.1 billion, with $1.437 billion in rebates); CA Department of Managed Health Care, Prescription Drug Cost Transparency Report Measurement Year 2021, https://www.dmhc.ca.gov/Portals/0/Docs/DO/SB172021Report.pdf (In 2021, prescription drug spending exceeded $10.7 billion, with $1.674 billion in rebates); CA Department of Managed Health Care, Prescription Drug Cost Transparency Report Measurement Year 2022, https://www.dmhc.ca.gov/Portals/0/Docs/DO/SB172022Report.pdf (In 2022, prescription drug spending exceeded $12.1 billion, with $2.1 billion in rebates); CA Department of Managed Health Care, Prescription Drug Cost Transparency Report Measurement Year 2023, https://www.dmhc.ca.gov/Portals/0/Docs/DO/SB172023Report.pdf (In 2023, prescription drug spending exceeded $13.1 billion. With $2.6 billion in rebates). Some groups allege Medicaid carve outs increase costs for the state see i.e. Report Summary "Assessment of Medi-Cal Pharmacy Benefits Policy Options", https://hcpsocal.org/wp-content/uploads/2019/09/Summary-of-Menges-Group-Report-May-15-2019.pdf. However, based on real-world data this analysis is inaccurate.

xi By creating a single PBM Kentucky saved $282.7 million in 2021-2022. National Community Pharmacists Association, Medicaid Reform, https://ncpa.org/medicaid.

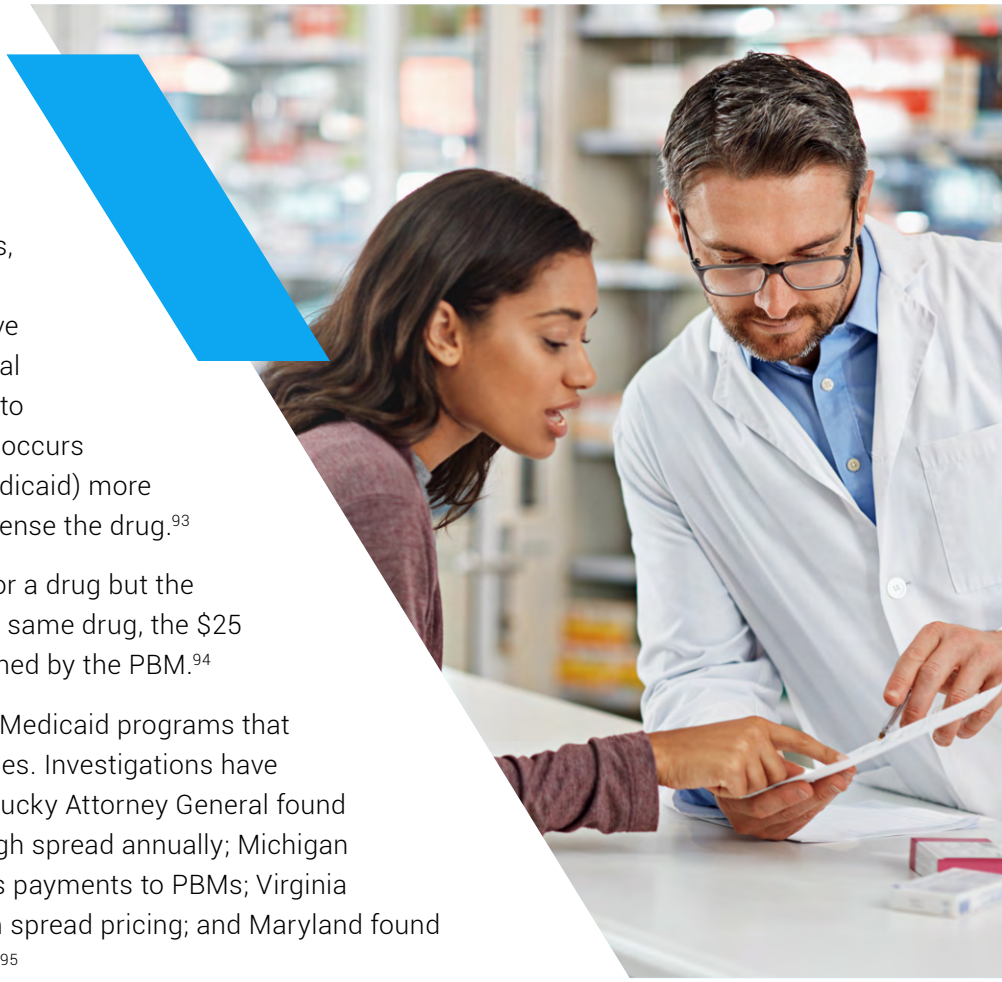
xii Between 2022-2024, Ohio saved $140 million. Id.

PBM Reform – Transparency

Addressing prescription drug affordability in the United States is challenging for many reasons, but one of the most significant barriers is the lack of transparency within the health care system. For example, PBMs are not required to disclose the rebates received or the percentage passed on to payors. Similarly, there are no reporting or disclosure requirements for when PBMs require beneficiaries to use PBM-owned or affiliated pharmacies.[90] Additional transparency measures could include requiring PBM to disclose prescription drug costs, prices, reimbursements, fees, markups, discounts, aggregate payments received for their services, and fiduciary duty obligations.[91] Greater transparency and accountability into these incentive structures could provide regulators and policymakers a clearer understanding of the drivers behind high drug costs and ensure policy reforms directly and sustainably address root causes.

PBM Reform – Ban Spread Pricing

In 2021, Medicaid programs nationwide spent over $80 billion on outpatient prescription drugs and received more than $40 billion in rebates, resulting in net spending of nearly $40 billion.[92] However, Medicaid could achieve substantially greater savings if the federal government implemented PBM reforms to eliminate spread pricing. Spread pricing occurs when a PBM charges the payer (e.g., Medicaid) more than it reimburses the pharmacy to dispense the drug.[93]



For example, if Medicaid is billed $100 for a drug but the pharmacy is paid $75 for dispensing the same drug, the $25 difference, known as the spread, is retained by the PBM.[94]

This practice diverts critical funds from Medicaid programs that could be used to better serve beneficiaries. Investigations have revealed the scale of this issue: the Kentucky Attorney General found that PBMs retained $123.5 million through spread annually; Michigan Medicaid identified $64 million in excess payments to PBMs; Virginia reported $29 million in PBM profits from spread pricing; and Maryland found $72 million in PBM spread pricing gains.[95]

PBM Reform – Delink Rebates from List Prices

Under the current system, PBMs rebates are calculated as a percentage of the drug's list price.[96] This creates a perverse incentive for PBMs to favor high-priced drugs, as higher list prices yield larger rebates. As such, mandating delinking between rebates and drug costs would help ensure PBMs develop formularies based on clinical value and affordability, rather than the size of rebate. While the Consolidated Appropriations Act of 2026, "delinks" Part D prescription drugs from rebates, broader reform is need for these protections to equally apply across the commercial and self-insured markets.

ESSENTIAL PATIENT PROTECTIONS

While the alternatives outlined above could more directly address prescription drug spending and affordability in the United States, participants acknowledged that the Administration may choose to proceed with international reference pricing policies despite patient concerns. If the Administration moves forward with such policies, the following recommendations should be implemented to ensure patients, caregivers, and providers have a meaningful opportunity to engage in the process.

IRP as a Benchmark, Not a Baseline

As discussed above, international reference pricing has many challenges. As such, any use of an international reference price should be in addition to an independent U.S. pricing assessment that more accurately reflects requirements of federal law, U.S. patient values, and diverse populations.

Prohibit the Discriminatory Use of QALYs

Federal law prohibits the direct and indirect use of QALY data in Medicare. Policymakers should ensure this prohibition is upheld in any international reference pricing program. Given the discriminatory assessments used in QALYs, policymakers should ensure this prohibition applies to all federal programs, including Medicaid.

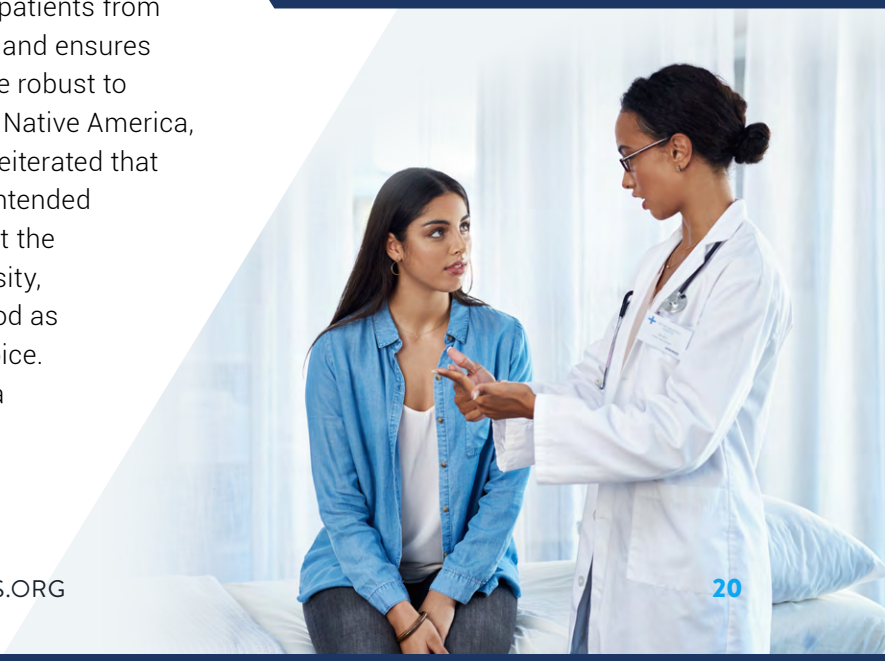
Participants also noted that policymakers should consider alternative quality of life and value assessments that reduce the risk of discrimination. Participants noted that part of creating an improved assessment framework includes developing more robust data during clinical trials to justify and develop an evidence base that supports a case for pricing and reimbursement.[101]

Ensure Patient Engagement from the Development Stage

Developing a pricing system that accurately reflects consumer costs and values is challenging; however, involving patients, providers and caregivers from the beginning can substantially improve this process and ensure more equitable and accurate outcomes.

> **"patients should be placed at the center of the healthcare system and their participation should be structural, early and binding, not just consultative."**

Developing a program and then seeking feedback results in having to re-invent the wheel. However, including patients from the start creates a system that works for patients and ensures their engagement. Patient inclusion should also be robust to include racial and ethnic communities, as well as, Native America, Alaskan, and Hawaiian populations. Participants reiterated that including patients from the outset can ensure unintended stigma and disease misconceptions do not impact the analysis. For example, for patients living with obesity, their participation can ensure obesity is understood as a chronic disease, not a lifestyle or behavioral choice. Patient engagement can also help address stigma across other complex chronic conditions.



Opportunities to Provide and Reconcile Feedback

A key challenge reiterated across communities globally is the lack of understanding on how decision-makers use patient, caregiver, and provider feedback. As such, patients who are impacted by an IRP should be provided an opportunity to comment on the value of the drug and learn from decision-makers how their feedback and insights were used in rendering pricing decisions.

Protect Rare Disorders

Treatments for rare disorders and orphan drugs should be excluded from IRP pricing. Pricing for rare disorders is challenging due to small population sizes, resulting in these treatments rarely satisfying QALY criteria. Participants noted that, given the distinct challenges and needs of the rare disease community, additional research is recommended to understand best practices in rare disease value assessments.

Protect Innovation

The United States is a global leader in biotechnology and pharmaceutical innovation, often introducing novel treatments before they are available in other countries.[102] This leadership is critical for U.S. patients who rely on timely access to cutting-edge treatments. Pharmaceutical manufacturers have long argued prescription drug pricing mandates could negatively impact innovation and access for patients. In response to these concerns, lawmakers have incorporated measures to protect innovation in the U.S.

For example, under the IRA, which authorizes Medicare to negotiate prices for select prescription drugs, Congress included two key provisions: a small biotech exception and a delayed negotiation eligibility.[103] The small biotech exemption allows pharmaceutical manufacturers to request an exemption from IRA negotiations if their drug accounts for less than 1% of Part D expenditures and represents at least 80% of the manufacturer's Part D spending under a Coverage Gap Discount Program agreement.[104] This provision ensures that smaller biotech companies, often with limited portfolios and less capacity to recoup lost profits, could continue investing in research and development.[105]

Similarly, the IRA also states that small molecule drugs are not eligible for negotiation until 7 years have passed since FDA approval, and large molecule drugs are only eligible after 11 years.[106] Again, through this provision, Congress wanted to ensure pharmaceutical companies had sufficient time to recoup their research and development costs before being subject to government negotiations. However, health policy advocates have expressed concerns that variations between small-molecule and large-molecule drugs will create a disadvantage for investment in small-molecule drugs. As such, federal legislatures are considering legislation that creates a singular timeline for negotiations. Thus, if policymakers adopt an IRP delay, they should consider the benefits of a uniform timeline across all therapeutics.

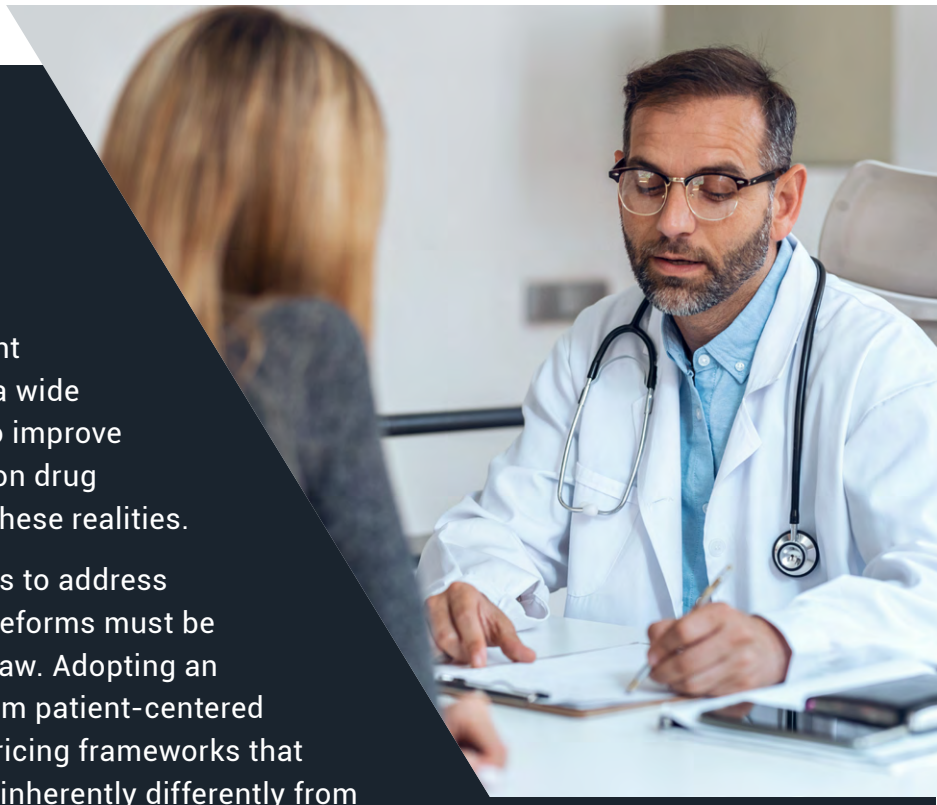
To maintain global access to novel treatments, any IRP structure should incorporate similar protections. Without such safeguards, manufacturers may choose to launch certain products exclusively in the U.S. and delay introductions to avoid triggering reference pricing benchmarks. For instance, given the size of the U.S. market, a pharmaceutical company might prioritize a U.S. launch while delaying availability elsewhere to avoid being subject to an international reference price in the U.S. Ultimately, resulting in continued higher costs for U.S. consumers and less access for patients abroad. As such, implementing a delay in reference pricing applicability could help ensure novel therapeutics continue to reach patients worldwide, while allowing the U.S. to benefit from comparative pricing at a later stage.

Supply Chain Control Exception

An international reference price system operates under the mentality that one pharmaceutical company is responsible for the cost of their drugs globally. However, many smaller pharmaceutical companies may sell the rights of their product to other international companies to market and sell abroad.

For example, Company A may make Treatment A, a multiple sclerosis treatment. However, because Company A is small, it sells the rights to Treatment A marketing and sales to Company B. As such, Company B negotiates with foreign companies for the price of Treatment A, not Company A.

Under such an arrangement, it would be difficult for a company to be influenced by an international reference price without control over the international market. Under the proposed GLOBE Model, CMS has explicitly recognized these challenges and the need for potential exceptions or exclusions. As such, policymakers should consider adopting such exceptions or exclusions for both GUARD and GLOBE models.



CONCLUSION

The U.S. health care system is uniquely complex, diverse, and centered on patient choice, rapid access to innovation, and a wide range of treatment options. Any effort to improve health care affordability—and prescription drug affordability in particular—must reflect these realities.

Although the U.S. urgently needs reforms to address our high prescription drug costs, these reforms must be consistent with U.S. values and federal law. Adopting an IRP model would move the U.S. away from patient-centered decision-making by importing foreign pricing frameworks that are used in health systems that operate inherently differently from the U.S. and currently struggle to meaningfully incorporate patient insights in reimbursement decisions, resulting in diminished access and coverage for patients.

Patients, providers, and caregivers need practical and meaningful reform that addresses the barriers within our unique system that are driving costs—such as PBM practices, insurer benefit design, and lack of transparency. In conclusion, U.S. policymakers should pursue solutions that improve affordability without sacrificing the principles that matter most to its patients: choice, timely access, and meaningful involvement in decisions that fundamentally shape their lives.

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