Impact of the Inflation Reduction Act on Patient Access and Out-of-Pocket Costs

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The Inflation Reduction Act (IRA) represents a recent policy enactment that will influence prescription drug pricing. This paper examines the IRA's elements and their impact on patients' access to medications, specifically around programs funded by the Centers for Medicare and Medicaid. This review analyzed grey literature on patient medication access concerning the IRA, along with the legislation itself. It finds that the IRA contains six key provisions with the potential to impact patients' access to medications and stakeholder business practices: insulin and vaccine cost share, OOP cost limits, premium stabilizations, drug negotiations, and low-income subsidy programs. Although the IRA presents cost-saving provisions, it may exert downstream effects on new drug innovation, increased medication utilization management by payers and pharmacy benefit managers (PBMs), and how healthcare providers, manufacturers, and payers/(PBMs) work together to balance patient well being with fair economic returns for all stakeholders.

Keywords: Medicare, health care policy, health equity, drug prices, health economics, out-of-pocket-costs

INTRODUCTION

The Inflation Reduction Act (IRA) was signed into law in August 2022, proposing a policy that will significantly change the structure of Medicare Parts B and D (CMS, 2022a). Public health organizations have advocated for health policy improvements for years, and the IRA can be a potential breakthrough in enacting drug pricing reforms. Based on major healthcare reform timelines, the IRA is the newest major healthcare reform since the Affordable Care Act of 2010 (Manchikanti et al., 2017; Kaiser Family Foundation, 2011), which focused on expanding healthcare coverage rather than managing costs. Prior to the passing of the IRA, approximately five million Medicare patients struggled to afford their prescription drugs (ASPE, 2011). The substantial cost of prescription medications presents one of the largest access

barriers for these patients. The IRA introduces significant new policies to prescription drug pricing, including allowing CMS to directly negotiate prices for certain Medicare Part D drugs, limiting price increases by pharmaceutical manufacturers, and reducing out-of-pocket costs for Part D beneficiaries (CMS, 2022b). The question of how the agency will implement these provisions and the downstream effects on patients is still pending exploration.

This review aims to address the following research question to analyze the implications of the government, payers and providers pulling the IRS into practice and its impact on patient's access to medications: What provisions of the IRA may impact patient access, specifically around programs funded by the Centers for Medicare and Medicaid (CMS)? The answer to this research question will be important to understand as it will help healthcare providers, manufacturers, and payers navigate this new policy and its downstream implications, which will be critical for ensuring the highest standard of care for patients.

This gray literature review provides multiple contributions and insights in addressing which elements of the IRA may impact Medicare beneficiaries' access to medications. It explores the implications of each provision of the IRA as it relates to pharmaceutical industry professionals and healthcare providers, and it proposes research questions for future empirical research investigations. By examining the specific elements of the IRA impacting patient medication access, this work aims to provide a comprehensive understanding of the policy, healthcare stakeholders, and the resulting downstream effects on patient care. This research also aims to guide healthcare providers, manufacturers, and payers on navigating this new policy and its downstream implications in order to achieve optimal patient outcomes. Additionally, by proposing research questions for future empirical research investigations, this paper aims to contribute to the ongoing discussion about the effectiveness of the IRA and to provide a foundation for future research on this topic.

This paper charts the following path. It starts with a comparison of past implementation of healthcare legislation followed by study methods. Next is an analysis of the different provisions of the IRA, followed by a discussion of relevant insights, limitations, and additional research to explore.

Previous Legislation

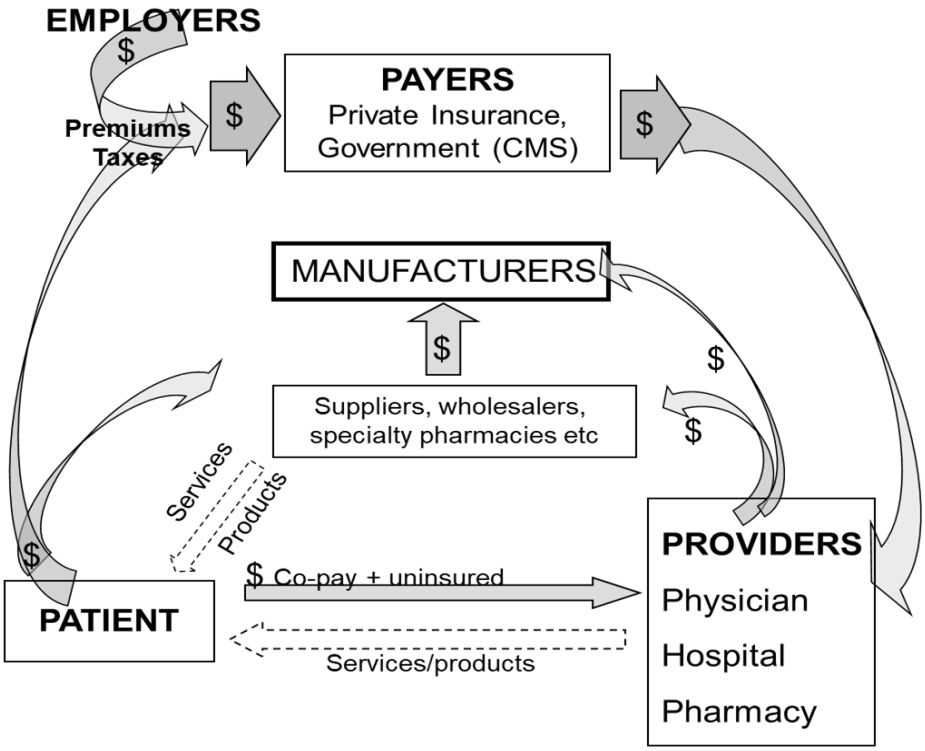
With the IRA being a detailed and complex law that is still in the process of being implemented, it is not possible to assess its true impact until much further down the line. Historically, new government policies like the Affordable Care Act (2010) (ACA) and Consolidated Appropriations Act (2021) (CAA) have not provided implementation guidance (US Department of Labor, 2021; Keisling J, 2019), thus resulting in considerable ambiguity for all relevant stakeholders. For example, the CAA required health plans and issuers to send participants, beneficiaries, or enrollees an Advanced Explanation of Benefits notification in clear and understandable language starting January 1, 2022 (US Department of Labor, 2021). Stakeholders expressed their frustrations around the challenges with developing the technical infrastructure necessary to transmit information to health plans and issuers (US Department of Labor, 2021). The Department of Health and Human Services (HHS) received these concerns and agreed to delay the applicability date of this provision until the department established standards for the data transfer between providers, facilities, plans, and issuers. This delay allowed stakeholders to build the infrastructure necessary to support the effort (US Department of Labor, 2021). As a result, HHS incorporated this feedback and stated that it would create appropriate data transfer standards and rulemaking in the future to implement this provision and increase implementation compliance (US Department of Labor, 2021). Although Congress enacted the ACA in 2010, the government drastically delayed its implementation (Keisling J, 2019). For example, the ACA faced many implementation challenges, including substantial state resistance to Medicaid expansion, legal pushback, and an inefficient 2013 rollout of HealthCare.gov (Oberlander, 2016). The upcoming months will lead to monitoring the development of new CMS/HHS guidance on the Inflation Reduction Act and evaluation of how various stakeholders respond.

US Healthcare System

The US Healthcare System is a complex web of stakeholders, each with a unique role in the distribution and reimbursement system for pharmaceutical products (Mehta, 2008). One of the most significant players

in this system is the pharmaceutical manufacturer. These manufacturers are involved in various steps in the process, from drug development and production to the commercialization and distribution of products. They often form contracts with wholesalers, who play a crucial role in the distribution process. These wholesalers purchase products in bulk to secure discounts off the wholesale acquisition cost (WAC) and then distribute the products to a wide range of customers, including dispensing pharmacies, public and private hospitals, long-term care facilities, and other medical practices. Ultimately, patients receive these drug products from a downstream entity, such as a community or specialty pharmacy or other healthcare practice (i.e., hospital, private clinic).

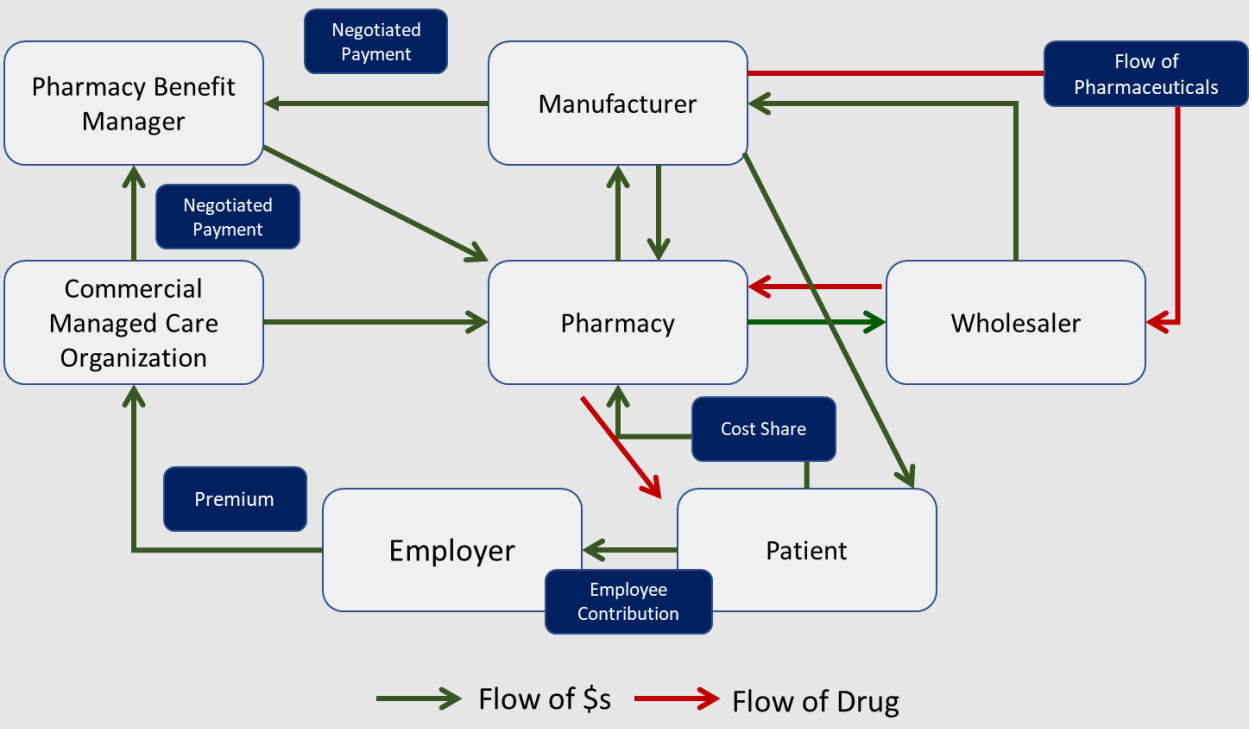
FIGURE 1
US HEALTHCARE SYSTEM AND THE FLOW OF MONEY



Note. Adapted from Mehta, 2008

Patients receiving pharmaceutical treatments can pay the full out-of-pocket amount or seek financial support from their health insurance provider. Typically, patients with insurance coverage will be responsible for cost-sharing in the form of a deductible, copay, or coinsurance. Insured patients can receive drugs from a pharmacy if covered under their pharmacy benefit, managed by a Pharmacy Benefit Manager (PBM) (Rubinstein et al., 2013). Alternatively, uninsured or cash-paying patients will not have cost-sharing assistance. Fortunately, services such as GoodRx or SingleCare provide patients with medication coupon cards, allowing patients to obtain discounts on their prescription prices, resulting in lowered out-of-pocket payments.

FIGURE 2
UNDERSTANDING PHARMACY BENEFITS ALONG WITH THE FLOW OF DOLLARS AND PRODUCTS



Note. Adapted from Rubinstein E. et al., 2013

PBMs manage a formulary of "covered drugs" primarily through negotiations with pharmaceutical manufacturers. The tier at which a payer or PBM places a drug on the formulary is correlated to the type of utilization management (UM) required for the product and defines a patient's copayment or coinsurance. Not all PBM structures are alike, but generally, patients pay higher out-of-pocket costs for medications on higher tiers (Fein, 2023). UM are cost-saving strategies that PBMs utilize when maintaining formularies. Some examples of UM include prior authorizations (PAs), drug quantity limits, "refill too soon" limits, or step-therapy, where a patient must use a cheaper guideline-directed alternative before using the originally prescribed medication. In addition, manufacturers provide PBMs rebates or discounts to gain favorable formulary placement and avoid restricted management. Patients receiving drugs must participate in cost sharing in the form of certain out-of-pocket costs like deductibles, copays, and coinsurance. All these factors determine the access or restrictions that patients have to their necessary treatments.

TABLE 1
COMMON PHARMACY BENEFIT PLAN DESIGNS

Tier	Two-Tier Design	Three-Tier Design	Four-Tier Design	Five-Tier Design	Six-Tier Design
1	Generic	Generic	Generic	Generic	Generic
2	Brand	Preferred Brand	Preferred Brand	Preferred Brand	Preferred Brand
3		Non-preferred Brand	Non-preferred Brand	Non-preferred Brand	Non-preferred Brand
4			Specialty	Preferred Specialty	Preferred Specialty
5				Non-Preferred Specialty	Non-Preferred Specialty
6					Lifestyle

Note. (Adapted from Fein, 2023)

METHODS

This narrative review engaged peer review and gray literature to explore the emerging conversation relevant to the IRA. An initial search of the peer-reviewed literature led to limited results on the IRA at the time of the analysis (Fall, 2022). This finding led to the performance of a non-systematic, narrative examination of the publicly available gray literature. This effort used electronic databases and keyword-searching methods to locate online sources on the topic. This research utilized multiple portals to locate publications for this review, including Lexis-Nexus, ABI/Inform, EBSCO, Web-of-Science, JMCP, JAMA, Google Scholar, and World Wide Web search engines. The Web-of-Science database was useful in locating full-text academic, legal, and non-biased government documents. Web-of-Science is a multi-subject database that allows researchers to perform tailored searches. In this case, this effort utilized political science and education databases to retrieve sources related to the IRA and patient medication access. This effort also included the use of the Journal of the American Medical Association (JAMA) to locate sources. It aided in locating gray literature that described the provisions of the new prescription drug pricing reforms. The third impactful source of locating information was the World Wide Web search engines. This effort located full-text IRA legislation as well as other documents using search engines.

Gathering the most relevant information involved utilizing the following keywords: *Medicare, healthcare policy, health equity, drug prices, health economics, and out-of-pocket-costs.* To focus our efforts on identifying IRA elements that impact patient access, researchers performed a Boolean analysis across each database. The search terms used for this effort encompassed ("Inflation Reduction Act" OR "Medicare" OR "health insurance ") AND ("health care" OR "prescription" OR "medication" OR "drug")). Search criteria comprised government, legal, and academic sources dated August 01, 2022 – November 30, 2023. This research recognized that anyone could publish false or misleading information online. Therefore, in this exploratory data analysis, this effort reviewed each piece of literature's credibility and appraised each author's background. Evaluation of the authors involved using a series of questions: 1) Did the author have any organizational affiliations? 2) What were the qualifications of the author? 3) What is the publishing entity? Moreover, 4) finally, was the author cited in other texts? Furthermore, this work utilized pre-set screening criteria highlighted in Table 2.

TABLE 2
SELECTION CRITERIA FOR EXPLORATORY DATA ANALYSIS

Inclusion	Exclusion
• Language: English • Dates: 08/01/22 – 11/30/23 • Document Types: Unbiased Government, Legal and Academic sources, Opinion, Press Release • Sources: Google Scholar, Lexis-Nexus, JAMA, ABI/Inform, EBSCO, Web-of-Science, World Wide Web and JMCP • Search Strings: "Inflation Reduction Act" OR "Medicare" OR "Health Insurance AND Healthcare" OR "Prescription" OR "Medication" OR "Drug."	• Document types: Opinion, Editorials, Trade, and News Pieces • Search Strings: "Commercial Insurance" AND "Regional Plan" OR "Rebate" OR "Medicaid."

An initial screen of the citations' titles and abstracts from 37 document screenings led to a final group of 29 sources for full document examination (Figure 3). Selected sources included in the review are unbiased government, law, and academic texts. This grey literature review applied what was learned from Adams J. (2017), using a tiered approach when assessing the grey literature (Figure 4). The categorization of literature using grey shades rather than discrete bands allows us to recognize that experts generate a range of material that may be of scholarly interest (Adams et al., 2017). This review process made explicit judgments about which relevant grey literature was included on a project-by-project basis as sources and knowledge evolve (Adams et al., 2017). The review excluded sources that did not meet the search and credibility criteria, including nonaccredited opinion pieces, trade publications, and news articles. It is important to note that some opinion and news pieces that met the author criteria were included in this review because multiple authors referenced them and/or viewed them as educational pieces in advancing IRA research.

FIGURE 3
LITERATURE REVIEW SCREENING FLOW LEADING TO FINAL ARTICLES INCLUDED FOR ANALYSIS

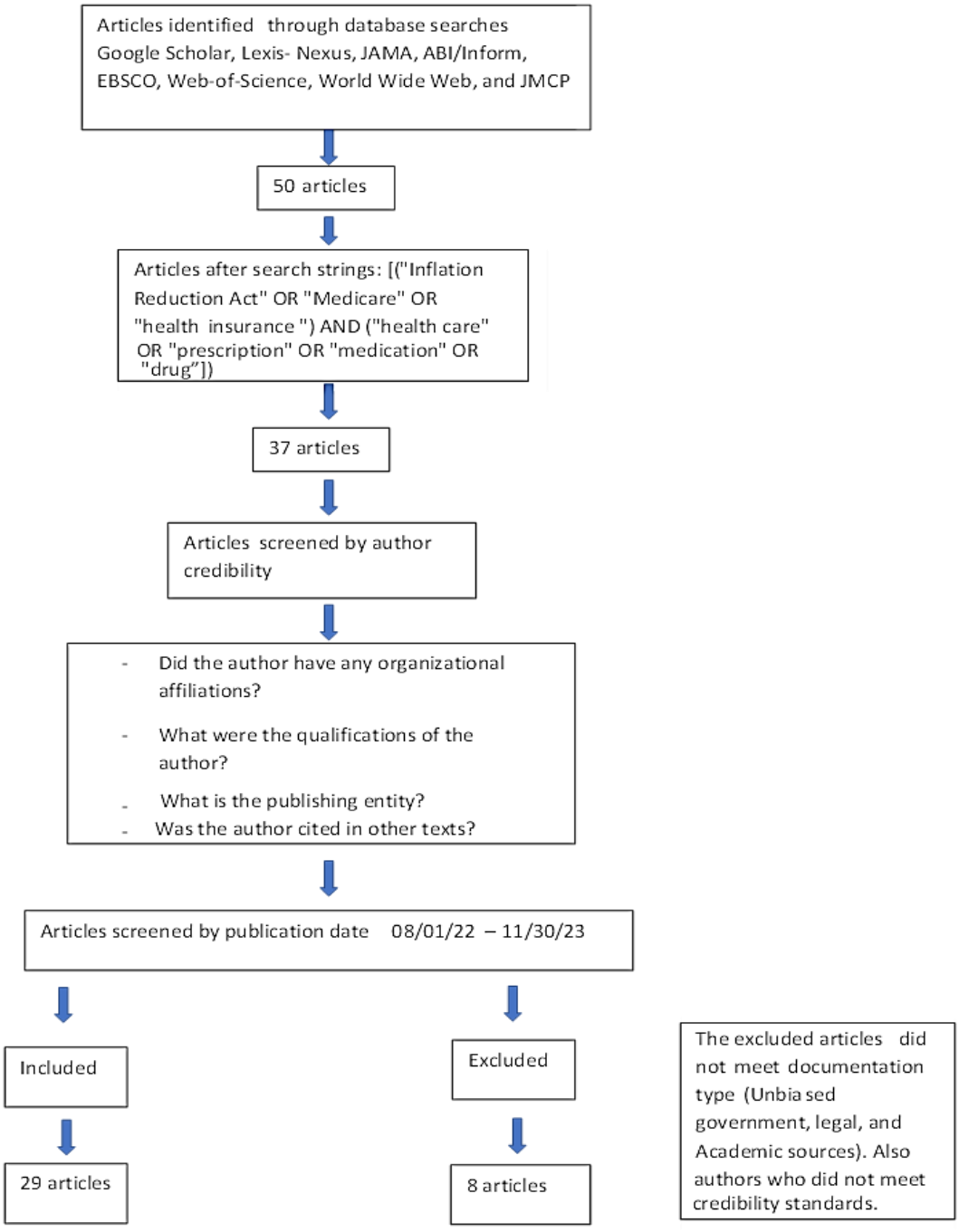
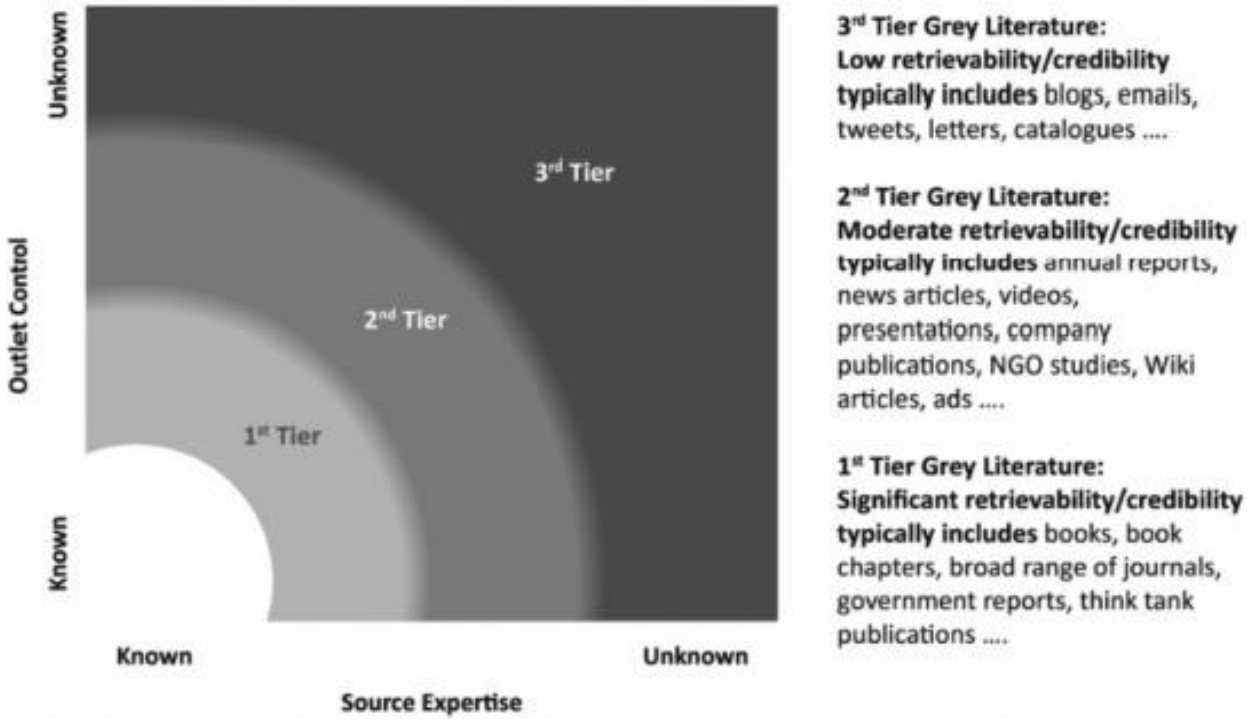


FIGURE 4
SHADES OF GREY LITERATURE



Note. Adapted from Adams et al., 2017

RESULTS

Analysis of the 29 pieces of literature identified six key provisions impacting patient medication access, with five relevant to access. Table 3 presents a descriptive summary of publications related to the IRA's implications and a historical review of US healthcare reform.

TABLE 3
DESCRIPTIVE SUMMARY OF THE LITERATURE

Authors	Type	Journal Type	Tier of Gray Literature	Year
Center for Medicare and Medicaid Services	Timeline	CMS.gov	1	2022
US Government Publishing Office	Public Law	Congress.gov	1	2022
Amin et al.	Policy Brief	Kaiser Family Foundation	2	2022
Center for Medicare and Medicaid Services	Fact Sheet	CMS.gov	1	2022

Authors	Type	Journal Type	Tier of Gray Literature	Year
Levitt L.	Opinion	Found on Web-of-Science, but published by JAMA Health Forum	2	2022
Center for Medicare and Medicaid Services	Fact Sheet	CMS.gov	1	2022
Cutler D.M.	Review	JAMA Health Forum	2	2022
Cubasnki et al.	Policy Brief	Kaiser Family Foundation	2	2023
Gottlieb S.	Opinion	JAMA Health Forum	2	2023
Center for Medicare and Medicaid Services	Policy Brief	CMS.gov	1	2023
Center for Medicare and Medicaid Services	Policy Brief	CMS.gov	1	2023
Eli Lilly	Press Release	Lilly Investor News	2	2023
Novo Nordisk	Press Release	Novo Nordisk News	2	2023
Sanofi	Press Release	Sanofi News	2	2023
Grant J.	Community Post	Cystic Fibrosis Foundation	3	2022
Department of Health and Human Services	Guidance Document	HHS.gov	1	2021
Keisling J.	Research Article	American Action Forum (Center for Health and Economy)	2	2019
Oberlander J.	Research Article	Journal of Health Politics, Policy, and Law (Duke University Press)	1	2016
Manchikanti L. et al.	Review Article	Pain Physician Journal	2	2017

Authors	Type	Journal Type	Tier of Gray Literature	Year
Kaiser Family Foundation	Timeline	Kaiser Family Foundation	2	2011
Adams R.J. et al.	Research Article	International Journal of Management Reviews	1	2017
Fein A.	Market Research Report	Drug Channels	2	2023
Mehta S.	Book	Cambridge University Press	1	2008
Rubinstein E. et al.	Book	Academy of Managed Care Pharmacy	1	2013
Council for Affordable Health Coverage	Post	CAHC Newsroom	3	2023
Partnership for Health Analytic Research	Issue Brief	PHAR	2	2023
O'Neill Institute for National and Global Health Law	Issue Brief	Georgetown University Law Center	2	2023
Manalac T.	Post	Biospace.com	3	2023
Center for Medicare and Medicaid Services	Fact Sheet	CMS.gov	1	2023

A thematic analysis of the included documents' texts revealed two overarching themes influencing patient access to healthcare due to the IRA. These included "increased access" and "reduced patient expenditures." Key components noted in the literature review include the implementation of a $2,000 out-of-pocket (OOP) cap on Part D medications, limiting the increase of Part D premiums to no more than 6% per year through 2029, an insulin copayment cap of $35 per month, elimination of Part D vaccine cost-sharing, low-income subsidies and Medicare drug negotiations. The OOP cap, insulin copayment cap, and vaccine cost-sharing take effect in 2025, followed by drug negotiations starting in 2026 and the limitation of the Part D premium increase taking effect through 2029. Such elements have significant implications for patient care, as outlined in Table 4.

TABLE 4
KEY POLICIES THAT IMPACT PATIENT CARE

Insulin Cost Sharing	Vaccine Cost Sharing
• Effective 2023, monthly insulin costs will be capped at $35/Month for Medicare patients who receive prescription drug coverage for insulin or inject insulin via a pump (Amin et al., 2022) • No deductible is required for prescription-covered insulin products (Amin et al., 2022) • This provision should impact at least 1.4 million Medicare patients (Amin et al., 2022) • The provision does not indicate what constitutes a 30-day supply for patients who require additional units within the same month (Amin et al., 2022)	• Effective 2023, Medicare patients will have no OOP costs for the Advisory Committee on Immunization Practices recommended vaccines, including those for shingles and Tetanus-Diphtheria-Whooping Cough (CMS, 2022a) • Providers already bill most vaccines through Part B with a $0 copay, but this change will increase the availability of immunizations billed through Part D, such as the Shingrix® vaccine.
Part D Out-of-Pocket (OOP) Limit	**Part D Premium Stabilization**
• Effective in 2024, a $3,100 annual cap for OOP Medicare drugs will go into effect; in 2025, that annual OOP cap will become $2,000 (CMS, 2022b) • Medicare Part D patients can now spread their prescription payments throughout the year rather than simultaneously paying the $2,000 (CMS, 2022)	• Effective in 2024, the average premium increase for most D plans will be limited to 6% (CMS, 2022b)

Note. Derived from CMS, 2022a; CMS, 2022b; Amin, et.al., 2022

Insulin Cost Share

The provision from the IRA entitled "Appropriate Cost-Sharing for Covered Insulin Products Under Medicare Part D" targets the growing cost of insulin within the United States through fee modifications for insulin medications included in the Medicare Part D prescription drug benefit (US Congress, 2022). This provision lowers Medicare Part D deductibles and cost-sharing for insulin products. For plan years 2023 and beyond, the deductible for Medicare Part D will apply to any FDA-approved insulin product (US Congress, 2022). The provision also establishes a tiered system for payments for covered insulin products under Medicare Part D (US Congress, 2022). The plan covers any insulin product between 2023 and 2024, with a copayment required for a monthly supply (US Congress, 2022). This coverage applies regardless of whether the individual has reached the initial coverage limit or out-of-pocket threshold (US Congress, 2022). For plan years beginning in 2025 and next years, the insurance provides benefits for any covered insulin medication before an individual reaches the out-of-pocket threshold for a month's supply that does not exceed the set copayment amount of $35 (US Congress, 2022). This provision defines the copayment as the lower of either $35 or 25% of the maximum fair price for the insulin product determined under the Drug Price Negotiation Program (CMS, 2022b; US Congress, 2022). The applied copayment amount will adjust based on changes in the consumer price index for all urban consumers effective 2026 (CPI-U) (US Congress, 2022). Lawmakers also created a unique rule in place for the first three months of 2023 requiring a Medicare Part D drug plan or a Medicare Advantage Prescription drug plan (MA-PD) sponsor to reimburse enrollees for any cost-sharing payments that exceed the cost-sharing applied by the plan for a monthly supply of a covered insulin product at the point of sale (US Congress, 2022).

Vaccine Cost Share

The provision from the IRA entitled "Improving Access to Adult Vaccines Under Medicaid and Children's Health Insurance Program (CHIP)" targets enhancing access to adult vaccines under CMS and CHIP by requiring states to include adult vaccines under both programs and eliminate cost-sharing for specific vaccines (US Congress, 2022). Under this provision, states enrolled in Medicare, Medicaid, and CHIP must provide their members access to adult vaccines as part of their mandatory benefit package (US Congress, 2022). Specifically, states must cover vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) for adults aged 19 or older (CMS, 2022b; US Congress, 2022). The provision also calls for states to eliminate patient payments for these vaccines (US Congress, 2022). To incentivize states to conform to these necessities, the IRA increases the federal medical assistance percentage (FMAP) for adult vaccines and their management under Medicare, Medicaid, and CHIP (US Congress, 2022). Increasing this percentage means that the federal government will absorb most of the costs (US Congress, 2022). The increased FMAP is only available to states that comply with the requirements to cover adult vaccines and eliminate cost-sharing for these vaccines (US Congress, 2022).

Medicare Out-of-Pocket Limit

The provision from the IRA entitled "Medicare Part D Benefit Redesign" seeks to improve access to affordable prescription drugs for Medicare Part D beneficiaries by introducing a maximum monthly and annual cap on cost-sharing payments under Medicare Part D and Medicare Advantage programs (MA-PD) (US Congress, 2022). The maximum monthly limit is adjusted to account for any remaining out-of-pocket costs and additional out-of-pocket costs incurred in subsequent months (US Congress, 2022). The maximum monthly cap cannot exceed the annual out-of-pocket threshold; the IRA proposes a $2,000 annual cap for beneficiaries' Part D spending (US Congress, 2022). This provision aims to provide Medicare Part D beneficiaries with more predictable and affordable prescription drug costs by capping their monthly out-of-pocket expenses and allowing them to pay their OOP costs spread over the year in a process called smoothing (US Congress, 2022). By limiting cost-sharing payments, this provision may also reduce financial barriers to accessing necessary prescription drugs, particularly for those with high drug costs or chronic conditions (CMS, 2022a; US Congress, 2022).

Premium Stabilizations

The "Medicare Part D Premium Stabilization" provision of the IRA seeks to maintain consistent and predictable costs for beneficiaries' Medicare Part D premiums. By capping premium increases at 6% annually, this provision aims to prevent prescription drug coverage from becoming unaffordable for beneficiaries (US Congress, 2022). Hopefully, this provision will help deter insurers from dramatically increasing premiums to offset the extra liability they now have from the Medicare Part D benefit redesign. Furthermore, the premium stabilization provisions only apply to the base beneficiary premium, which is the premium paid by most beneficiaries, and other factors can still affect the total OOP spending (US Congress, 2022).

Drug Negotiations

The provision entitled "Lowering Prices Through Drug Price Negotiations" establishes several key timelines and definitions related to the negotiation process (CMS, 2022b, p. 3). Historically, pharmaceutical manufacturers could negotiate drug prices independently with commercial and government payers (e.g., pharmacy benefit managers, health plans, integrated delivery networks (IDNs), and group purchasing organizations [GPOs]) without any oversight by a government entity. These negotiations benefit stakeholders, manufacturers, and payers in that the manufacturer can maintain or improve access to their medications, and payers can sustain an additional stream of revenue in the form of discounts or rebates off the list price of products. The resulting net price of a drug is ultimately what the PBM or plan sponsor is responsible for handling. Meanwhile, patients are responsible for copays or coinsurance based on the higher list price. This new legislation aims to provide lower prices for certain high-priced single-sourced drugs (CMS, 2022b). "Single-source drugs" are medications marketed by a single manufacturer and have no equal

therapeutic alternative (CMS, 2022b, p. 4). Under this legislation, the Secretary of Health and Human Services (HHS) is responsible for selecting drugs, negotiating a maximum fair price with their manufacturers, and entering into agreements with each manufacturer (CMS, 2022b). HHS will focus on the most costly brand-name drugs between Medicare Part B and D (CMS, 2022b). The law allows 10 drugs to be negotiated by 2026, 15 in years 2027 and 2028, then rises to 20 by 2029 (Levitt, 2022). In addition, the provision also establishes penalties for manufacturers who fail to comply with the terms of their agreements (CMS, 2022b). Although negotiations are not beginning now, the HHS secretary must develop a strict plan to ensure that CMS, payers, and providers implement these changes effectively (Levitt, 2022). Overall, the program may lower drug prices and improve patient access to crucial medications despite its potential complexities (CMS, 2022b; Levitt, 2022).

Low-Income Subsidy

The Medicare Low Income Subsidy (LIS) is a program meant to supplement insurance coverage to help people with Medicare Part D pay for their prescription drugs. Medicare Part D members become eligible for this program if their monthly income is below 135 percent of the federal poverty line (FPL) and their assets are less than or equal to $10,590 (less than $16,630 if married) (CMS, 2022c). The "extra" benefits offered through the LIS program can be full or partial, depending on where an individual falls with their monthly income and assets. Individuals enrolled in LIS qualify for lower costs for prescription drugs as well as support for payment of their Part D premium (up to a state-specific benchmark amount). Continuation in the Medicare LIS program requires an individual to continue to meet the eligibility requirements outlined by their state. Under the IRA provision, beginning January 01, 2024, the eligibility for LIS coverage will expand to cover those at or below 150 percent of the FPL (CMS, 2022c).

DISCUSSION

The implications of the IRA's downstream effect on the implementation of this policy are multifaceted. While the specific ramifications of the IRA remain uncertain, lessons from analogous initiatives, such as the Affordable Care Act, offer valuable insights. These insights suggest that the enactment of healthcare legislation should first involve payers and manufacturers, followed by Pharmacy Benefit Managers (PBMs) and, ultimately, patients. Through an exploratory data analysis, this study effectively addresses the research question, uncovering six key provisions that significantly influence patient access. These provisions include factors such as vaccine and insulin cost sharing, limitations on out-of-pocket (OOP) costs, premium stabilization, low-income subsidy reform, and Medicare drug negotiations. Evidently, these elements present cost-saving opportunities for Medicare beneficiaries. The findings suggest that industry specialists should rethink current business practices and prioritize new patient-focused regulations and implementations to ensure improved access to medications for patients.

Key Learnings

Without full implementation guidance from CMS, it is difficult to predict the lasting impacts these provisions will have. However, one can consider several predictions. Initial findings lead us to hypothesize that while patients will see lowered drug costs (e.g., insulin), there may be increased payer utilization management through mechanisms such as new step therapy or prior authorization requirements. Due to the lack of data, it is unclear how PBMs will include the IRA provisions in their business, ultimately affecting patients' drug access.

Whatever the mechanism by which payers and PBMs execute these provisions, it is important to note that implementing a maximum monthly cap on cost-sharing payments may also create unintended consequences. For example, it may result in higher premiums for all Medicare Part D beneficiaries to offset the payer's cost-sharing loss.

After highlighting the impacts of the IRA on Insulin, this research suggests that the law could potentially lead to an increase in demand for insulin products. Beneficiaries may be more likely to purchase insulin with the reduction of cost-sharing requirements. It is unclear how this policy impacts clinical

practice, and further research must occur targeting outpatient dispensing pharmacies, ambulatory care clinics, and PBMs. Although the provision from the IRA caps out-of-pocket expenses for Medicare Part D beneficiaries and allows individuals to enroll in a Medicare payment prescription plan (smoothing), it still poses significant implications for both payers and pharmaceutical manufacturers. For payers, this provision may increase their cost-sharing responsibility, thus reducing their overall revenue. This dynamic makes utilization management more viable for plans than in the past, and we will likely see plans try to step through more products, even those classified under Medicare Part B. Also, the provision may pressure PBMs to negotiate lower prices and higher rebates for prescription drugs with manufacturers to keep patient costs low. For manufacturers, introducing a maximum monthly and annual cap on cost-sharing payments under Medicare Part D and Medicare Advantage programs may limit revenue generated from these plans.

Interestingly, the three largest manufacturers of insulin products, Eli Lilly, Novo Nordisk, and Sanofi, have all recently announced a lowering of prices for insulin for all patients (commercial, Medicare, and Medicaid patients). Eli Lilly announced a reduction of insulin prices by 70% and a cap on patient insulin out-of-pocket costs at $35 per month (Eli Lilly & Company, 2023). Novo Nordisk announced a plan to lower prices of pre-filled insulin pens and insulin vials by as much as 75% starting January of 2024. Novo will also be capping out-of-pocket costs for patients at $25-35 per month (Novo Nordisk, 2023). Sanofi announced a 78% price reduction in the most widely prescribed insulin in the US, Lantus (insulin glargine), starting January 2024 (Sanofi, 2023). All three companies made these announcements months after the signing of the IRA, which mandates lower insulin out-of-pocket costs for Medicare Part D patients. These cost reductions likely mean easier access to insulin for patients but not necessarily lower costs for payers. Patients may end up paying higher costs in other areas in the form of premiums or deductibles.

The IRA also requires drugmakers to pay supplemental rebates to CMS if the cost of medications increases faster than the rate of inflation (Gottlieb, 2023). However, it is interesting that the IRA does not limit drug launch pricing as it does with these price inflation penalties. Manufacturers may respond to the reduction of patient cost-sharing liability by increasing launch prices (Cutler, 2022; Cubanski et al., 2023). The Part D restructuring and cap on out-of-pocket expenses may discourage manufacturers from spending large amounts on patient assistance programs, as beneficiaries will be better insured and only liable for $2,000 in out-of-pocket costs (Cutler, 2022). Furthermore, considering the downward pressure on Part D premiums and out-of-pocket costs, payers may offset savings by reducing the utilization of other medications by step therapy, prior authorizations, or other reduced access strategies. Restricted access may discourage manufacturers from developing new indications for patients with high drug costs or chronic conditions due to limitations with cost-sharing payments for these drugs. This cost share restructure provision may also increase the competition among manufacturers to offer the most cost-effective drugs and may lead to more transparency in the pricing and development of drugs.

Our findings led us to believe that the IRA will potentially bring lower out-of-pocket patient costs due to the new benefit design and CMS's drug pricing negotiation. Any patient cost reductions due to drug price decreases will be determined by which drugs end up being subject to negotiation, the number of patients who are utilizing those drugs, and the magnitude of the price reductions. The drug negotiation poses downstream implications affecting manufacturer profits, new drug development, and discovery. The government can now leverage the combined lives covered under the Medicare Part D benefit to negotiate discounts with pharmaceutical manufacturers. Negotiations done on Medicare Part D drugs will almost inevitably have downstream effects on the commercial side of the business. The authors have seen this adoption in the past with the introduction of specialty tiers on commercial formularies in response to Part D stipulations, which require drugs over $830 per month for placement in a separate tier, requiring patients to share a percentage of the cost of the drug. One of the potential negative effects of Part D negotiations will be the stifling of innovation as manufacturers seek to prioritize the development of products that have a lower likelihood of facing CMS negotiations.

The litigation surrounding the Inflation Reduction Act (IRA) involves several lawsuits, reflecting a broad challenge to the Act's provisions, particularly those related to drug pricing (O'Neill Institute for National and Global Health Law, 2023). These legal actions primarily focus on the IRA's impact on healthcare and pharmaceutical industries: The US Chamber of Commerce has filed a lawsuit arguing that

the IRA grants "unfettered and unchecked power" to the Department of Health and Human Services (HHS). The Chamber of Commerce contends that government-imposed price controls, as proposed in the IRA, could harm patients by limiting access to medicine and stifling American innovation. They assert that such controls violate the fundamental protections for free enterprise. The pharmaceutical industry has launched a concerted effort against the IRA, with multiple companies and industry groups filing lawsuits. These legal actions target different aspects of the IRA, particularly its drug price negotiation provisions. For instance, Merck & Co. and Bristol Myers Squibb have specifically challenged the Act using constitutional grounds. In August 2023, AstraZeneca filed a lawsuit against HHS challenging a guidance document from the Centers for Medicare and Medicaid Services (CMS) (Manalac, 2023). This document outlines the criteria for selecting medicines subject to the first round of drug price negotiations under the IRA. AstraZeneca's legal action questions the methodology and implications of this guidance. Following the Biden administration's release of a list of the first ten drug products affected by the IRA's drug negotiations, Novartis and other pharmaceutical companies have joined the litigation. These ten drugs collectively cost the US government around $50 billion in Medicare Part D spending from June 2022 to May 2023, highlighting the significant financial stakes involved (CMS, 2023b). These lawsuits collectively represent a major legal challenge to the IRA, particularly its provisions on drug pricing. They reflect the tension between government efforts to control healthcare costs and the pharmaceutical industry's concerns about innovation, access to medicines, and free enterprise principles. The outcomes of these cases could have significant implications for healthcare policy, drug pricing, and the balance between government regulation and market forces in the healthcare sector.

As a result of the drug negotiation policy, manufacturers will not be able to enjoy profit protection like they once had. Under the IRA, a small molecule drug may be subject to negotiation 7 years after initial FDA approval and open to price limits. In contrast, large molecule products (biologics) may be eligible for negotiation 11 years post-approval. Therefore, manufacturers may limit research and development spending on future small molecule products or additional indications for rare diseases derived from these formulations. This direction may be partly due to the value of patent protection not ensuring manufacturers that a long runway is needed to recoup their investment vs. large molecules. Thus, there is a preference to move treatments towards protein-based biotech products such as monoclonal antibodies and other biologics that are significantly more costly because of development, production, and administration cost elements. This innovative shift by manufacturers may reduce investing in new ad hoc research for post-FDA-approved products, specifically focusing on small molecules (CAHC, 2023). Even though researching these types of products could lead to accelerated access at possibly cheaper prices for patients than if a manufacturer was beginning clinical development. For example, a publication by the Partnership for Health Analytic Research (PHAR) demonstrated that 61% of small molecule oncology products received at least one post-approval indication, and 41% of post-approval indications in oncology occurred seven or more years after a medicine's initial FDA approval (PHAR, 2023). Given that post-approval clinical development takes place several years after initial FDA approval, the IRA's pill tax means there could be a possibility that many orphan products will never reach the market, making patients lose access to new treatments and cures.

Another strategy a manufacturer may use is to shift utilization from a high Part D spend product onto another product or formulation to avoid losing additional dollars to discounts or rebates.

A second possible consequence of drug pricing negotiations may be the reduction in manufacturer investment in various patient assistance programs (PAPs). Manufacturers have traditionally held up PAPs to increase access to medications for patients who are underinsured or lack insurance altogether. Manufacturers have made it known that they are willing to change or modify the extent to which they offer copay assistance and free drugs through these programs. Notably, Vertex Pharmaceuticals recently updated the assistance offered through its Vertex GPS™ program in order to fight against PBM implementation of various copay accumulators and maximizer programs. Vertex is now offering an annual copay assistance maximum of $20,000 while only offering $3,500 per month for those with a copay accumulator or maximizer on their plan and $8,950 per month for those without one (Grant, 2022). The flexibility that

pharmaceutical manufacturers have in changing or modifying these types of offerings to recoup revenue lost in other segments of their business is clear.

Congress intends for the IRA to address prescription savings and patient access. However, the timetable for when and how the administrative burden, communication strategy, and education plan for healthcare providers will take effect raises questions about the actual impact the law could have. Additionally, the response from industry leaders will pose new implications for healthcare management and patient access. The IRA will likely change how each healthcare entity communicates, posing a new way of working in the future with new access hurdles and pathways. Collectively, the IRA's provisions may reduce costs for beneficiaries, but it may result in more restricted drug utilization from payers and decreased innovation in some therapeutic areas by manufacturers. Highlighting the need for all stakeholders to work together to find a commonality between ensuring access to affordable drugs and maintaining fair profitability for the industry.

Limitations and Future Research

Researchers acknowledge that this paper has limitations. Firstly, finding reliable and valid sources of information on the IRA was a challenge for the researchers, primarily because peer-reviewed literature on the IRA is sparse, making the widely available information largely gray literature. Current contributions around the IRA's provisions on patient access are emerging, and the literature is naïve and developing due to the recency of the legislation. This timeliness presents gaps in current literature relevant to patient medication access and the adoption of this new policy amongst manufacturers, payers, pharmacies, and PBMs. Online research finds that most of the literature available includes newsletters, fact sheets, and government reports. The available literature provides utility in the general understanding of the IRA, but scholars, practitioners, and policymakers need to conduct further research in this area. Since the law is relatively new, articles that discuss the ensuing effects of the IRA are limited, and peer-reviewed evidence on this topic is lacking. This scarcity of information makes it difficult for healthcare providers, manufacturers, and payers to navigate this new policy and its downstream implications. Although the government has legally put the IRA into effect, stakeholders in the healthcare system need to adopt and pull through the new provisions to ensure improved patient medication access. Nevertheless, the IRA poses a call to action for all health industry stakeholders to implement the new provisions in a manner that keeps the patient at the center of new policy and business practice. Secondly, the analysis did not evaluate Medicare and Medicaid plans managed by commercial entities, regional health plans, and commercial plans; therefore, scholars, practitioners, and policymakers need to explore additional research in these areas. Accordingly, a relevant practice research question emerges from this exploratory review: To what extent will patient medication access be affected due to upcoming payer and manufacturer policy changes resulting from the IRA? This question could be assessed through a qualitative survey of industry leaders from PBMs, payors, manufacturers, and dispensing pharmacies to evaluate perspective on patient access after implementing IRA provisions. Secondly, a slightly different analysis of the specific challenges faced by healthcare providers, payers/PBMs, and pharmaceutical companies in adapting to the regulatory changes caused by the IRA would offer valuable insights into the practical implications of the legislation. Lastly, we would also evaluate the new ways of working between these players. This qualitative work would allow researchers to outline the framework of the best communication strategy amongst the key healthcare stakeholders needed to execute the IRA's true intentions effectively and contribute to the development of more effective patient-centered healthcare policies and interventions.

CONCLUSION

The IRA provides the healthcare industry with a change in legislative policy that leads to agency regulations, influencing access at the PBM and patient levels. This work offers multiple learnings of the IRA with a specific scope towards healthcare industry professionals and patient access. The findings of this paper, specifically around the drug pricing negotiation provision, show the critical implications for patient access to medications. Suppose the litigation pursued by the pharmaceutical industry succeeds. In that case,

it may result in the continuation of current pricing models, which may continue to limit patient access to these high-cost medications. If the courts uphold the IRA's provisions, the unintended consequence of government-negotiated prices could cause stifling of innovation due to pivoting by pharmaceutical manufacturers towards the development of specialized large molecule biologics to avoid negotiations. The outcome of these negotiations and litigation presents a need to balance the criticality of making medications affordable and accessible to patients and ensuring the industry incentives to innovate and develop new drugs.

Scholars, practitioners, and policymakers need to consider the future implications of the IRA for additional research. It is important to carefully evaluate and monitor this provision's potential impacts and unintended consequences to ensure it effectively achieves its objectives without causing negative effects. While the provisions do not eliminate out-of-pocket costs, they may help mitigate rising expenditures' impact on beneficiaries' budgets. Over the next five years, as the government and the health care system implement various provisions of the bill, it will be imperative that the government and other stakeholders in the health care system implement these policies fairly, transparently, and rationally.

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