WHITE PAPER / STRATEGY & TRANSFORMATION

THE STATE OF HEALTHCARE IF TRUMP IS RE-ELECTED

In our latest non-partisan white paper, Douglas Hervey, JD/MBA, provides a high-level overview of ten relevant healthcare categories that a second-term Trump Administration would impact.

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THE STATE OF HEALTHCARE IF TRUMP IS RE-ELECTED

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This article will provide a high-level overview of ten relevant healthcare categories that a second-term Trump Administration would impact. It explores how policies might unfold across these categories in a hypothetical second term. This article will also discuss various regulatory and legislative mechanisms for change as well as healthcare-related bipartisan dynamics.

TEN HEALTHCARE AREAS TO TRACK

If former President Trump were re-elected and implemented changes to healthcare, the following ten areas would be most important to track: 1) drug price reforms; 2) pharmacy benefit managers (PBMs) and drug rebates; 3) price transparency; 4) interoperability and information sharing; 5) Medicare Advantage; 6) telehealth; 7) value-based care; 8) Section 1332 state innovation waivers, including association and short-term plans; 9) individual marketplace enrollment and subsidies; and 10) 340B drug discounts.

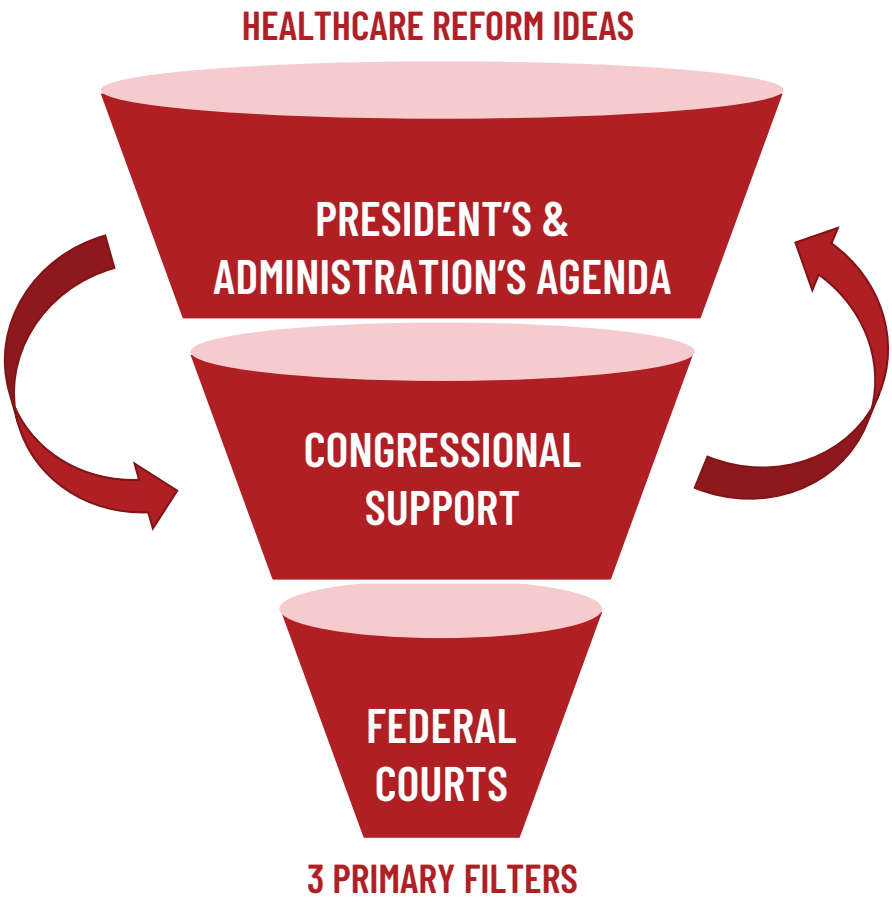
Exhibit 1: Ten Important Healthcare Topics to Track

TEN FOCUS AREAS

1	DRUG PRICE REFORMS	6	TELEHEALTH
2	PBMS & DRUG REBATES	7	VALUE-BASED CARE
3	PRICE TRANSPARENCY	8	SECTION 1332 WAIVERS
4	INTEROPERABILITY & INFORMATION SHARING	9	INDIVIDUAL MARKET ENROLLMENT & SUBSIDIES
5	MEDICARE ADVANTAGE	10	340B DRUG DISCOUNTS

Movement on any one of these will depend on a combination of presidential, administrative, congressional, and federal court support.

Exhibit 2: Filtering Mechanism on Healthcare Reform Ideas



Reform impetus can come from Congress or the executive branch. Filtering occurs either way. Courts are proving to be an active arbitrator in most healthcare issues covered below.

Although each of these ten topics could merit an entire policy brief, this article will provide a panorama of the topics rather than exhaustive coverage of any specific category. Cicero does not endorse platforms or policies, nor does it endorse any positions covered in previous whitepapers. Rather, Cicero highlights perspectives across the political spectrum to further educate and engage readers in key areas that could impact their families, businesses, and communities.

1. DRUG PRICE REFORMS

The Inflation Reduction Act, passed with the Biden Administration's support, required the U.S. Department of Health and Human Services (HHS) to identify Medicare's 100 most expensive drugs and then select ten for price negotiations starting in 2023. Those prices would be live in 2026, and another ten drugs would be added two years later. Building on the Inflation Reduction Act, as it relates to Medicare, the Biden Administration has tried to strengthen Medicare's hand by extending its negotiating power for more drugs and enabling negotiations to occur sooner after a drug's launch.[i] He reemphasized this goal in his most recent State of the Union address calling for Medicare to negotiate up to 500 drugs over the next decade to create $200 billion in cost savings.[ii]

President Biden also wants to limit Medicare Part D cost-sharing to no more than $2 for high-value generic drugs prescribed to treat specific chronic conditions, such as hypertension and high cholesterol.[iii] The Biden Administration also aims to penalize drugmakers for increasing prices beyond inflation by mandating that they refund private customers when they do so.[iv] Lastly, it has proposed to cap insulin prices at $35 per month.[v]

Similarly, the Trump Administration was also tough on Pharma and engaged on several fronts in drug price and rebate reforms. His Administration pushed for reform in areas including drug importation,

international reference-based pricing, and rebates. [vi] [vii]

Drug importation regulations have allowed states to import drugs from Canada and/or allow drug makers to import products and sell them under different drug codes. Former President Trump announced an executive order while in office to allow for personal drug importation from other countries that have comparable regulatory entities to the FDA.[viii]

As for international reference-based pricing, former President Trump's executive orders while in office called for limiting Medicare Part B payments to the lowest price charged in "any economically comparable" developed country. [ix] The Trump Administration had previously supported tying payments to an average international price. [x]

The Administration never considered further regulating drugs dispensed at pharmacy counters. They only sought to regulate physician-administered drugs. [xi] A proposed policy offered during his tenure would have modified physician payments toward a fixed price for administering a drug rather than paying a percentage of the drug's average sales price.[xii] [xiii]

The Trump Administration also required drug makers to disclose list prices in television ads, but courts blocked those efforts in the name of free speech. [xiv] [xv] Of note, President Trump previously supported an executive order requiring domestic production of some "essential" medicines—seeking to reduce the U.S.'s dependence on foreign nations for medicines during pandemics. [xvi]

Addressing rising drug prices post-2024 is almost certain, regardless of who wins the Presidential race. But no matter who is president, the pharmaceutical industry is prepared to fight rules suggesting taxing drug companies who refuse to participate in new negotiation processes. Drugmakers, including Merck and Bristol-Myers Squibb, as well as the Pharmaceutical Research and Manufacturers of America (PhRMA), are expected to lead the challenge.[xvii]

Exhibit 3: Overview of Key Drug Reform Provisions from the Inflation Reduction Act[xviii]

OVERVIEW OF KEY DRUG REFORM PROVISIONS FROM THE INFLATION REDUCTION ACT

Description of Change	Actions	Intended Impact
Lower Prices Through Drug Price Negotiation	• Secretary of HHS required to negotiate prices with drug companies for several single-sourced brand-name drugs for Medicare Part D (starting in 2026) and Part B (starting in 2028)	• Put downward pressures on Part D premiums • Reduce out-of-pocket drug costs for Medicare users
Prescription Drug Inflation Rebates	• Drug manufacturers required to pay a rebate to federal government if prices for single-source drugs and biological drugs under Part B and all drugs under Part D increase faster than the rate of inflation	• Reduce out-of-pocket drug costs for Medicare users
Cap Out-of-Pocket Spending for Medicare Part D Enrollees	• For 2024: Eliminates 5% beneficiary coinsurance requirement above catastrophic threshold, effectively capping out-of-pocket costs at $3,250 for year • For 2025 and Beyond: Adds hard cap on out-of-pocket spending of $2,000 (with annual adjustments thereafter)	• Decrease spending for Part D beneficiaries with large out-of-pocket costs
Reduce Liability for Government on Spending Above the Out-of-Pocket Cap	• Develops program for drug manufacturers to provide discounts to beneficiaries who have incurred costs above annual deductible beginning in 2025	
Limit Medicare Premium Growth	• Adds hard cap for beneficiaries to limit monthly premiums to no more than 6% annual increase from 2024-2030	
Limit Cost Sharing of Insulin for People with Medicare	• Limits monthly cost sharing for insulin products to no more than $35 for Medicare beneficiaries • Removes any deductible being applied	• Reduce out-of-pocket drug costs for Medicare insulin users
Eliminate Cost Sharing for Adult Vaccines Covered Under Part D and Improve Access to Adult Vaccines in Medicaid and CHIP	• Adult vaccines covered under Medicare Part D recommended by ACIP be covered at no cost, making vaccine cost coverage consistent with Medicare Part B vaccines • State Medicaid and CHIP programs must cover all approved adult vaccines recommended by ACIP without cost sharing	• Increase vaccine uptake among older adults • Lower out-of-pocket costs for those who need Part D-covered vaccines
Expand Eligibility for Part D Low-Income Subsidies	• Individuals with incomes up to 150% of Federal Poverty Line to receive full premium subsidies and a $0 deductible	• Reduces out-of-pocket costs for poorest beneficiaries

2. PHARMACY BENEFIT MANAGERS (PBMS) AND DRUG REBATES

Legislation targeting PBMs stands prominently on the federal agenda—whether it occurs pre- or post-election. The House, in one of its final significant actions of 2023, approved the Lower Costs More Transparency Act of 2023. This legislation mandates hospitals, laboratories, PBMs, and other entities to disclose pricing information and imposes regulations on how PBMs negotiate prescription drug prices for employers and health insurance firms. Although a similar bill has not progressed to the floor in the Senate, both the Finance Committee and the Health, Education, Labor, and Pensions Committee have endorsed bipartisan legislation encompassing many of the same provisions. Notably, this legislation extends its scrutiny to PBMs, aiming to prohibit 'spread pricing' practices and the tying of PBM compensation to inflated drug list prices. Expressing optimism, Finance Committee ranking member Mike Crapo (R-Idaho) anticipates the potential merging of House and Senate legislation, either within a broader healthcare bill or as part of the fiscal 2024 spending package.[xix]

The Trump Administration had also expressed a willingness to confront PBMs—particularly their ability to keep a percentage of rebates and discounts. A rule that the Trump Administration once supported would have eliminated PBM protections and placed rebates under anti-kickback review if the HHS secretary confirmed that it would not raise premiums, taxpayer spending, or out-of-pocket costs. [xx] The Biden Administration delayed the rule's implementation.[xxi]

Reform proponents suggest that rebates incentivize PBMs to select drugs with high prices and rebates. Drug makers also support reforms as patients' copays would decrease. But Trump's previous stance faced harsh resistance among some Republicans, insurance plans, PBMs, and consumer advocacy groups who feared the rebates could raise Medicare premiums and end up costing over $200 billion over a decade. [xxii]

These positions collectively demonstrate President Trump's willingness—at least in rhetoric—to go against the policy positions of more conservative Senate Republicans. This is particularly true on capping drug prices.

Exhibit 4: A Chart of Select Federal Congressional Committees' Legislation on PBMs in 2023[xxiii] [xxiv]

A CHART OF SELECT FEDERAL CONGRESSIONAL COMMITTEES' LEGISLATION ON PBMS IN 2023

	Title	Committee(s)	Passed	Key Features Impacting PBMs*
HOUSE	**H.R. 5378- the Lower Costs, More Transparency Act**	Energy and Commerce, Ways and Means, and Education and Workforce	12/11/2023	**Transparency Around PBM Business Practices** • Require PBMs to semi-annually provide employer-sponsored health plans with detailed data on prescription drug spending, including acquisition costs and total out-of-pocket spending • Requires Medicare Advantage (MA) organizations to report to HHS information relating to healthcare providers, PBMs and pharmacies with which they share common ownership **Spread Pricing** • Bans spread pricing in Medicaid
SENATE	**Modernizing and Ensuring PBM Accountability Act**	Finance	7/26/2023	**Transparency Around PBM Business Practices** • Require PBMs to disclose ownership or affiliation with pharmacies used to dispense prescriptions and the share of total prescriptions filled at those pharmacies. Would also need to disclose costs of prescriptions compared to nonaffiliated pharmacies • Require PBMs to provide prescription drug plan sponsors (PDPs) with information about rebates, discounts, and net prices paid for covered drugs **Spread Pricing** • Bans spread pricing in Medicaid • Prohibits any form of spread pricing that exceeds the amount paid to a pharmacy or provider that is meant to claim federal Medicaid matching payments
	Pharmacy Benefit Manager Reform Act	HELP	5/11/2023	**Transparency Around PBM Business Practices** • Require PBMs to report to plan sponsors any ownership of in-network pharmacies and any design benefits or parameter that encourage/require usage of those pharmacies • Require PBMs to report percentage of total prescriptions and list of all drugs dispensed from pharmacies where they have an ownership stake **Spread Pricing** • Prohibits group health plans and PBMs from charging prices for drugs in excess of prices paid to pharmacy **Rebate Pass-Through** • Require PBMs to pass on 100% of rebates they get from manufacturers to group health plans
	Pharmacy Benefit Manager Transparency Act of 2023	Commerce, Science, and Transportation	3/23/2023	**Transparency Around PBM Business Practices** • Require PBMs to report to FTC on differences between reimbursement practices and direct and indirect remuneration fees on pharmacies owned, controlled, or affiliated with PBM vs other pharmacies • Require PBMs to report to FTC amounts of generic effective fee rates, DIR fees charged to pharmacies, and payments clawed back from pharmacies • Require PBMs to report to FTC explanation of changes to formulary **Spread Pricing** • Prohibit PBMs from charging a health plan or payer prices for drugs in excess of prices paid to pharmacy • Prohibit PBMS from reducing, rescinding, or clawing back reimbursement payments to pharmacies • Prohibit PBMs from increasing fees or lowering reimbursement to a pharmacy to offset payment changes

3. PRICE TRANSPARENCY

The Biden Administration has not prioritized price transparency, but it has continued to support it. The Centers for Medicare and Medicaid Services (CMS) announced this past year its intention to bolster enforcement of the hospital transparency rule by implementing stricter timelines and expediting fine imposition. CMS adopted a more rigorous approach and eliminated previously granted flexibilities designed to facilitate compliance. For instance, the Agency automatically imposes civil monetary penalties on hospitals failing to furnish corrective action plans or remaining non-compliant for over 90 days subsequent to plan submission. CMS has ceased issuing warning notices to non-compliant facilities that demonstrate no intent to comply, instead promptly demanding corrective action plans. CMS also raised the penalty for a full calendar year of noncompliance to a minimum of $109,500 and a maximum of $2 million per hospital.[xxv]

President Trump placed price transparency front and center. He advocated for transparency to control rising prices and address market inefficiencies such as demand inelasticity. Consequently, his Administration released a hospital price transparency rule that became effective in January 2021, requiring hospitals to disclose their charges online in a machine-readable manner.[xxvi] At a minimum, hospitals needed to publish prices for 300 "shoppable" services, including 70 services the CMS selects.

Hospitals also needed to disclose their third-party payer negotiated rates. Health plans not only had to publicly disclose negotiated rates but were also required to share how much they were willing to pay out-

of-network providers.[xxvii] Opponents, including America's Health Insurance Plans (AHIP) and the American Hospital Association, have argued that published prices will lead to unlawful collusion and higher prices rather than have the desired effect.[xxviii]

While price transparency reforms have faced legal hurdles—voters can expect a Trump Administration to double down on their efforts in a hypothetical post-2024 presidency. His Administration released a proposal on May 11, 2020, requiring privately negotiated prices between hospitals and private payers to inform how Medicare pays for healthcare services.[xxix] A rule issued during his Administration also required hospitals to report the median of payer-specific negotiated rates by diagnosis-related group (DRG) on their Medicare cost report.[xxx]

Hospital adherence to the mandate requiring public disclosure of prices has varied, with some facilities opting to pay civil monetary penalties rather than furnish publicly accessible data regarding their chargemaster prices, negotiated rates with health insurance companies, and cash prices.[xxxi]

4. INTEROPERABILITY AND INFORMATION SHARING

The Biden Administration is acting on interoperability and information sharing blocking. Healthcare organizations that engage in practices referred to as information blocking, which hinder appropriate access to patient data within electronic health records (EHRs), could face significant penalties under a proposed rule the HHS and CMS proposed in October 2023. The Office of the National Coordinator for Health Information (ONC) aims to deter and address obstructive information blocking behaviors in the healthcare sector. It outlines various sanctions, including potential reductions in Medicare reimbursements, for hospitals, physicians, and Accountable Care Organizations (ACOs) found to have knowingly impeded other providers, insurers, and stakeholders from accessing EHR data.[xxxii]

On March 9th, 2020, ONC and the CMS released two final interoperability rules that emphasized the need to reduce information blocking, enhance interoperability, and ultimately prioritize patients at the center of the U.S. healthcare system. While the rules were delayed due to Covid[xxxiii], they facilitate providers,' insurers,' and patients' abilities to exchange health data, largely due to provider and insurer requirements to adopt standard application programming interfaces (API)—technology that connects third-party apps to information technology systems such as EHRs.[xxxiv]

The CMS now publicly reports eligible clinicians and hospitals that may be involved in information-blocking. Hospitals accepting Medicare and Medicaid must also electronically let healthcare facilities or community providers know when a shared patient is admitted, discharged, or transferred.[xxxv]

The Trump Administration clearly discouraged unnecessary barriers to health data exchange and broader access of patients to their health records. President Trump invested his personal political capital in this issue when he proposed addressing interoperability at the Healthcare Information and Management Systems Society (HIMSS) conference.[xxxvi] And his Administration approved a final rule to enhance patient information sharing and care coordination for substance use disorders.[xxxvii]

5. MEDICARE ADVANTAGE

The Biden Administration has actively been regulating Medicare Advantage plans from a rate cut, risk adjustment, marketing, star ratings, prior authorization, and health equity perspective, among other categories. Earlier this year, CMS proposed another reduction in the Medicare Advantage base payment rate, posing additional challenges for health insurers grappling with escalating costs.[xxxviii] The proposed rule suggests that the Medicare Advantage benchmark for calendar year 2025 would be reduced by -0.16% compared to current policy, excluding risk adjustment.[xxxix] This adjustment would represent the second consecutive year of a lower benchmark rate, with CMS aiming to finalize the rule by April 1. And this past year, CMS announced that Medicare Advantage carriers will be on the hook for risk adjustment errors made in diagnostic coding dating back to 2018.

Regarding other Medicare Advantage topics, CMS now prohibits advertisements that do not explicitly reference specific plan names, and it mandates that marketing materials refrain from including potentially

misleading elements, such as the Medicare logo. And CMS plans to replace the reward component for Star Ratings with a health equity index and reduce the significance of patient experience and complaints in quality scores. Insurers have attributed declines in ratings to CMS's decision to double the weight of patient surveys last year.

Additionally, CMS also aims to incentivize health insurance companies to prioritize quality care for underserved communities. CMS is also alleviating the burden of prior authorizations on providers and patients by requiring insurers to expedite response times, extend approvals throughout treatment courses, and eliminate preapproval requirements for emergency behavioral healthcare. CMS does not mandate that insurers inform beneficiaries when behavioral health or primary care providers leave their networks.[xl]

The Trump Administration strongly supported offering seniors more attractive alternatives to traditional Medicare fee-for-service, including innovative Medicare Advantage offerings with telehealth and supplemental benefits. President Trump signed an executive order in early October 2019 that offered seniors more affordable Medicare Advantage options, which Biden built on.[xli] [xlii]

Under President Trump's order known as "Protecting and Improving Medicare for our Nation's Seniors," seniors could share more in cost savings the plans generated, and the order ensured that traditional Medicare would not be promoted or able to receive particular advantages over Medicare Advantage. The order also stated that Medicare Advantage plans could offer increased coverage for social determinants of health-affecting conditions where people live, work, play, and learn. Examples may include a host of non-medical benefits such as offering rides to the grocery store or church, new air conditioners, in-home pest control, and fall prevention programs.[xliii]

While the Trump Administration lacked specifics and left much text to interpretation, it is clear the Trump Administration strongly supports the privatized Medicare Advantage program. In previous years, Republicans have opposed efforts to constrain Medicare Advantage, whereas Democrats have aimed to decrease federal assistance for the privatized Medicare program. But there does seem to be some Republican willingness to challenge unfettered Medicare Advantage support.[xliv]

6. TELEHEALTH

While federal agencies can determine the fate of remote prescribing, telehealth reimbursement requires congressional action. In December 2022, President Biden signed into law waivers extending telehealth reimbursement flexibilities until December 31, 2024.[xlv] Without intervention from Congress, these provisions will expire. Noteworthy provisions include the absence of a requirement for providers to be licensed in the same state as the patient receiving care, expanded eligibility for telehealth practitioners, authorization of audio-only telehealth services, and postponement of the in-person requirement for mental health patients seeking telehealth treatment.

Additionally, the December 2022 omnibus bill prolonged telehealth services through 2024 for federally qualified health clinics and rural health clinics. This extension also mandated the HHS secretary to conduct a study assessing the impact of telehealth on Medicare beneficiaries' overall health outcomes and identifying potential geographic disparities in telehealth usage. This study, coupled with an examination of medical claims data related to telehealth, is due by October 1, 2024.[xlvi]

Despite the challenges associated with passing legislation during a presidential election year, there is reason to remain cautiously optimistic. There exists bipartisan enthusiasm for expanding the delivery of care through technology, particularly amidst workforce shortages.[xlvii] Enhanced telehealth flexibilities garnered support across two presidential administrations, not only from Biden but also from President Trump.

President Trump issued an executive order in late July 2020 for HHS to review and continue Medicare's coverage of telehealth services. CMS subsequently proposed to permanently enable Medicare providers to use telehealth for evaluation and management services in-home visits and for certain patients with

cognitive impairments. CMS also temporarily extended telehealth services for emergency department visits and other services. [xlviii]

Even before COVID-19, President Trump issued a Medicare Advantage executive order that included support for telehealth adoption among Medicare Advantage enrollees. [xlix] This order called on the Health and Human Services (HHS) Secretary to propose a regulation for beneficiaries to have improved access to health outcomes through telehealth services. Further, the order asked CMS to "encourage innovation for patients" by expediting the approval of telehealth so that innovative telehealth products "are appropriately reimbursed, are widely available, and are consistent with principles of patient safety, market-based policies, and value for patients." [l] The policies encouraged more cost-saving telemedicine technology and enabled enrollees to have greater access to care irrespective of where they live and their physical access to providers in their local markets. [li]

Outside Medicare, the Trump Administration has supported enhanced telehealth access for Veterans and for beneficiaries within the private sector. [lii] Given telehealth developments among Veterans and Medicare Advantage, one can expect the private insurance market to follow the federal government's lead.

Post-2024 telehealth coverage and reimbursement will not revert to pre-COVID-19 levels. Telehealth costs are likely to become permanently allowable administrative costs as long as the technology is "skilled services being furnished, is outlined on the plan of care, and is tied to a specific goal indicating how such use would facilitate treatment outcomes." [liii] The greatest possible headwind is whether CMS would continue paying the same for virtual visits as for in-person care. Equalizing payment during the pandemic was one of the driving forces behind expansion. Telehealth reimbursement is probably not going to be a one-to-one equilibrium. [liv]

7. VALUE-BASED CARE

This year, nearly half of fee-for-service Medicare beneficiaries, totaling 13.7 million individuals, are enrolled in Accountable Care Organizations (ACOs), representing a 3% increase. The Medicare Shared Savings Program (MSSP) currently encompasses 480 ACOs, including 71 renewal participants, 50 additional preexisting ACOs, and 19 newly formed ACOs. These organizations collectively comprise nearly 635,000 providers, serving over 10.8 million beneficiaries. Notably, this provider network encompasses over 9,000 community health centers, rural health clinics, and critical access hospitals, reflecting a 27% increase compared to the previous year, per CMS data. [lv]

Additionally, the ACO Reach model has attracted over 173,000 participants, including more than 1,000 community health centers, rural health clinics, and critical access hospitals, across 122 ACOs, which collectively oversee the care of approximately 2.6 million beneficiaries. Furthermore, Kidney Care Choices (KCC) extends coverage to more than 282,000 individuals through 123 ACOs, which include over 9,200 providers. [lvi]

Value-based care reform efforts have largely avoided the partisan rhetoric so often on display in other healthcare topics. [lvii] The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) formalized many innovative value-based payment reforms and received over 90% support from Congress. While there is less bipartisan consensus on whether models should be mandatory in nature, there is widespread agreement that the current fee-for-service system fosters the wrong kinds of incentives. [lviii]

Given it is an election year, it is expected that President Trump will use most healthcare bandwidth to focus on consumer issues such as telemedicine and transparency. That said, during the last election race, CMS announced payment boosts for maternity care bundles, end-stage renal disease capitated payments, and other bundled payments. [lix] Trump also ordered HHS and CMS to form and evaluate a new value-based payment model for rural providers. [lx]

Expect the value-based care movement to pick up even more steam after the election. In particular, the movement's acceleration will likely occur through models such as MSSP, ACO Reach, and KCC, as discussed above, as well as more bundled programs. A Trump Administration would likely promote "value-based

competition" like cost and quality—particularly within Medicare Advantage.[lxi]

If Trump gets re-elected, his Administration will have to tread a difficult path of advancing value-based care without creating even greater incentives for providers to restrict care, cherry-pick low-risk patients, dump patients, and/or manipulate or falsify outcomes data. [lxii]

8. SECTION 1332 STATE INNOVATION WAIVERS, INCLUDING ASSOCIATION AND SHORT-TERM HEALTH PLANS

Section 1332 allows states to waive certain Affordable Care Act (ACA) requirements, subject to approval from HHS and the Treasury. These innovation waivers enable states to consider different coverage methods within the individual and small-group markets that conform to ACA goals. As a funding mechanism, the federal government can share the money it would have spent on premium tax credits, cost sharing reductions, and small employer credits. [lxiii] The Trump Administration relaxed Section 1332 guardrails by enhancing access to association and short-term plans (more below). Trump's support for 1332 waivers will not likely change in a post-2024 re-election scenario.[lxiv]

Association Health Plans (AHPs) enable small businesses, such as dairy farmers, car dealers, and accountants, to pool resources to buy health insurance on the premise that more enrollees would offer a more attractive and less costly healthcare benefit for employees. AHPs have been around for decades, but the ACA heightened oversight of AHPs, subjecting them with little exception to individual and small-group market rules requiring essential health plans.

Through the Department of Labor (DOL), the Trump Administration significantly expanded AHP's scope and reach. In 2018, the DOL increased the number of circumstances where aggregated small groups could be labeled as large groups. While federal court decisions have found that the health plans violate federal law, AHPs are likely to receive continued support under the Trump Administration. [lxv]

The Trump Administration also loosened restrictions on short-term health plans, and a final rule released in July of 2018 reversed an Obama Administration mandate that short-term plans be limited to 90 days. As a result, short-term plans became legal for up to 12 months and can also be renewed for up to three years. The Biden Administration later proposed to ensure short-term products may last a maximum of three months, plus a one-month renewal.[lxvi] A re-elected Trump could seek to expand short-term plan availability in the coming years. [lxvii]

9. INDIVIDUAL MARKET ENROLLMENT AND SUBSIDIES

Transitioning to the ACA Marketplace, it has emerged as the most dynamic segment within health insurance. As of December 23, 2023, enrollment in the ACA marketplace stands at over 20 million individuals, with projections indicating it may reach 23 to 24 million individuals by 2024. This marks a significant surge in overall enrollees.[lxviii]

The ACA Marketplace stands out as the swiftest-growing sector in health insurance, mostly due to the Biden Administration's support.[lxix] The primary drivers propelling growth in the ACA Marketplace from 2023 into 2024 include:

1. Expanded subsidies stemming from the American Rescue Plan, further extended by the Inflation Reduction Act through 2025, with over 75% of ACA enrollees benefiting from government support.
2. Medicaid redeterminations fostering increased 'off-season' and ongoing enrollments as processes unfold.
3. Non-Expansion states witnessing remarkable enrollment growth, notably in Texas and Florida.

Should current trends persist, overall marketplace enrollment in 2024 is anticipated to witness a substantial 20-25%+ growth from 2023. This growth carries significant implications for stakeholders investing in the exchange, such as Centene, Oscar, and others, as well as related downstream trends like Individual Coverage Health Reimbursement Arrangement (ICHRA).[lxx]

When examining trends within the ACA, Centene, with its substantial existing market share, and Oscar, experiencing a remarkable resurgence akin to a Cinderella story fueled by marketplace growth, emerge as particularly noteworthy players. Additionally, CVS has demonstrated indications of Marketplace presence in 2024 and beyond, and even health systems are exploring opportunities within this domain.[lxxi]

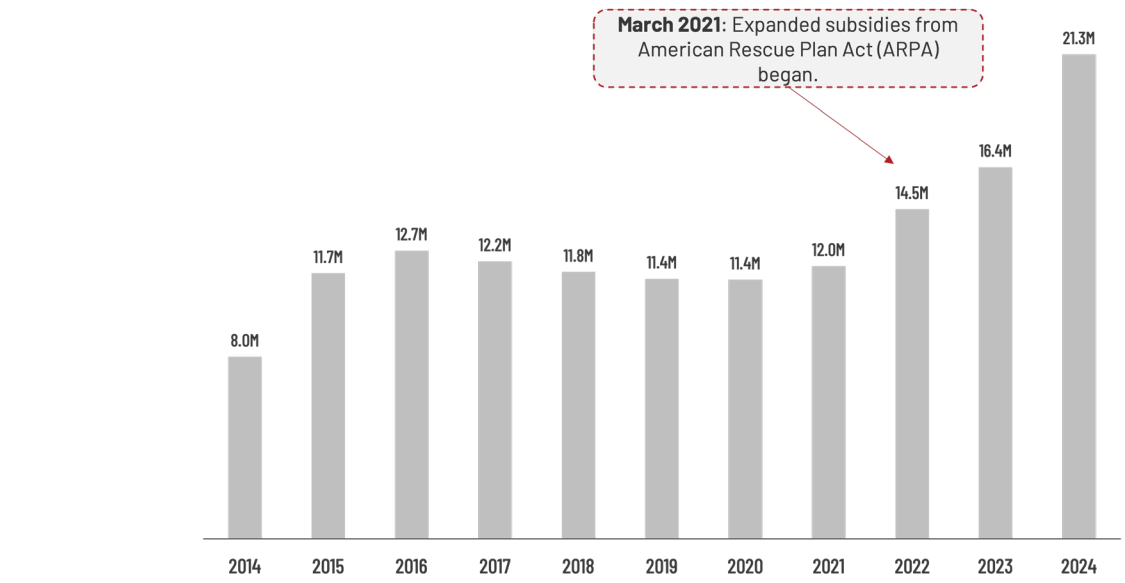
In essence, the ACA Marketplace remains buoyed by substantial federal support, with over 20 million individuals enrolled in 2024. Its enduring significance is undeniable. Multiple payors have identified the exchange as a pivotal growth driver for their overall portfolio, and the Biden Administration would like to make enhanced premium tax credits permanent.[lxxii]

That said, the Trump Administration withheld support for the ACA individual marketplace. The Trump Administration refused requests to create a nationwide enrollment opportunity.[lxxiii] The Trump Administration also pulled several levers that directly impacted the individual market, including eliminating cost-sharing subsidies, reducing advertising dollars, and removing the individual mandate.

In 2017, the Trump Administration eliminated cost-sharing reduction subsidies that had served as motivators for insurers to continue providing ACA marketplace coverage and keep premiums down.[lxxiv] This change forced insurers to offer subsidies to low-income individuals without any federal government reimbursement. Many individual market payers decided to increase silver plan pricing on the exchanges, which ironically increased the expenses that the federal government paid to subsidize consumers' premiums.[lxxv]

The Trump Administration also significantly cut advertising dollars and navigator program funding meant to help people sign up for ACA marketplace coverage. And it lowered the tax burden to $0 for those without insurance, which opened the entire ACA to risk in the courts.[lxxvi] Absent a heavy hand from the federal government, it appears ACA enrollment would remain fairly stable as more insurers have become accustomed to the challenges they face in that market.

Exhibit 4: Affordable Care Act Enrollment-National[lxxvii]



10. 340B DRUG DISCOUNTS

The 340B program, established by Congress in 1992, grants hospitals treating low-income and uninsured patients substantial discounts on drugs, with discounts potentially reaching 50%. The program's enrollment has experienced significant growth in the past twenty years, prompting both drug

manufacturers and policymakers to examine whether hospitals are utilizing the program appropriately.[lxxviii]

The primary objective behind the inception of the 340B drug discount program was to provide substantial drug discounts to hospitals serving large populations of low-income and uninsured patients. The expectation was that these hospitals would utilize the resultant savings to bolster charity care initiatives. Several types of hospitals, including cancer centers, children's hospitals, and rural providers, frequently collaborate with external pharmacies to fulfill prescriptions under the 340B program. Presently, approximately 2,600 hospitals are active participants in the program. Pharmacy Benefit Managers (PBMs) capitalize on the 340B program by directing patients to pharmacies affiliated with their parent companies and levying referrals and dispensing for filling their patients' prescriptions.[lxxix]

In November 2023, HHS and CMS announced that providers enrolled in the 340B drug discount program would receive approximately $9 billion as compensation for previous years' reductions. CMS distributed these funds in lump sums to eligible providers to reverse reimbursement cuts dating from 2018 to 2022, which were invalidated by a 2022 Supreme Court ruling.[lxxx]

That said, a policy announced by the Health Resources and Services Administration (HRSA) in late 2023 is likely to result in the loss of eligibility for certain hospital outpatient clinics in the 340B drug discount program. Hospitals participating in the program are now required to register offsite clinics with HRSA and include them in Medicare cost reports to qualify for 340B benefits. This policy reversal from HRSA, which contrasts with their 2020 initiative to streamline 340B certifications during the COVID-19 pandemic, introduces stricter registration requirements.[lxxxi]

These requirements represent one of several legal and regulatory challenges that could impede providers' access to the discounts provided by the 340B program. These discounts, estimated to save hospitals, physician groups, and outpatient facilities treating low-income and uninsured patients between 25% to 50% on outpatient drugs (as discussed above), have become a focal point in ongoing disputes between providers and drug manufacturers. Data from the University of Southern California Schaeffer Center indicate a significant increase in the number of 340B-eligible entities from 2000 to 2020, prompting efforts from drug manufacturers to restrict eligibility.[lxxxii]

A recent ruling by the Third Circuit Court of Appeals, which largely favored three drug companies seeking to limit discounts distributed through contract pharmacies, has led over 20 drugmakers to announce their intention to provide 340B discounts solely to hospitals and their registered affiliates.[lxxxiii]

The Trump Administration was also mired in litigation involving controversial 340B hospital payments for drugs. CMS had planned to cut reimbursements by nearly 30%. National hospital groups challenged the Administration on the grounds that they overstepped their legal authority in the 2018 outpatient prospective payment system (OPPS) rule. Because courts initially supported the hospitals, the Administration pushed forward with smaller but continued 340B cuts in its 2020 OPPS rule. [lxxxiv] On July 30th, 2020, a federal appeals court ruled that the original HHS policy was legal—reversing a lower court decision. [lxxxv]

B. MECHANISMS FOR CHANGE

This article outlined several hypothetical changes above for a re-election scenario, but how could these changes occur? If Trump is re-elected, he may pursue healthcare reforms via legislative and/or regulatory mechanisms. While changing some policy and legislative domains would require federal legislation, Trump could implement other reforms through administrative rulemaking or executive orders. In some circumstances, the Administration could pursue joint legislative and regulatory paths.

Several political conditions would need to be met for President Trump's proposed healthcare policies to be enacted. To pass legislation to enact partisan policies, the Republicans would have to hold the House and retake the Senate in 2024, and, of course, President Trump would need to be re-elected. Even then, Senate support and filibuster avoidance could affect whether a bill could proceed via reconciliation and a 50-vote majority.

Some domains face more bi-partisan political support than others. Consequently, laws and/or rules that have general collective political support have a better chance of moving forward despite any focused interest group's opposition.

Further, court rulings could decide if administrative rules and/or legislation allegedly run afoul of existing legislative, regulatory, and/or constitutional provisions.

CONCLUSION

In conclusion, the ten-item list outlined above clearly does not cover all of the Trump Administration's healthcare focus areas. For example, the Trump Administration also supported efforts to help nurse practitioners and physician assistants practice at the top of their licenses and be reimbursed based on the services offered as opposed to their medical titles. The Administration also sought to curb fraud, waste, and abuse.

On top of the political battles and industries' interactions with the administrative rule-making process, Federal district and appellate courts will continue to weigh in on several of these matters.

While one cannot predict future specifics, this article has analyzed past trends to identify likely focus areas moving forward. Some areas are significant to voters and consequently may influence public platforms. But even if an issue is not top-of-mind for consumers, it may still matter immensely to focused and directly impacted interest groups who also carry much leverage. It is important to map the impact of possible scenarios to defensibly stress test projections, minimize risk, and maximize the potential to create a sustainable business model that serves the healthcare community well into the future.

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