

Trump Healthcare Platform Overview

Over the last three and half years, the Trump Administration has made significant changes to the US healthcare system and our nation's healthcare policies. As we prepare for the 2020 election, healthcare remains a top policy priority for the President as he seeks reelection. The table below reflects some of the healthcare efforts implemented by the Trump Administration and areas where the Administration has expressed interest in taking further action during a second term, if re-elected. This document does not summarize all Trump Administration healthcare actions, but rather focuses on areas that might be revisited if President Trump is re-elected.

The extent of what a second-term Trump Administration may accomplish will be constrained by <u>party control of Congress</u>. Healthcare stakeholders nevertheless should be familiar with the Trump Administration's past and potential future actions in order to anticipate possible policy changes in 2021 and beyond.



Issue	Trump Healthcare Plan
	Coverage
Coverage	The Trump Administration does not support a public option or Medicare for All, policy proposals championed by Democrats. The Administration has continued to make repealing and replacing the <u>Affordable Care Act (ACA)</u> a priority. President Trump supported congressional efforts to repeal and replace the ACA in 2017. The Administration also supports the ongoing lawsuit to overturn the ACA, which will be a key issue in 2021. The Administration has also implemented policies counter to the ACA, such as short-term limited duration insurance (STLDI) plans.
	In September 2020, President Trump signed the <u>Executive Order</u> (<u>EO</u>) on An America-First Healthcare Plan. The EO includes a commitment to protect individuals with pre-existing conditions. However, the Trump Administration has expanded policies, such as STLDI plans, that are not required to cover pre-existing conditions for beneficiaries.
	Marketplace
Individual mandate	President Trump signed into law the <u>Tax Cuts and Jobs Act</u> , which eliminated the individual mandate penalty effective January 1, 2019. This is now the basis for the constitutional challenge to the ACA and may be at the forefront of the policy agenda for 2021.
STLDI plans	In 2018, the Trump Administration finalized a rule on <u>short-term</u> , <u>limited-duration Insurance</u> that expanded STLDI plans, allowing them to be sold for up to 12 months and renewed or extended (at the insurer's option) for up to 36 months. Litigation challenging the legality of this rule is ongoing.
	Drug Pricing
International benchmarking for prescription drugs	On September 13, 2020, President Trump signed the <u>EO on</u> <u>Lowering Drug Prices by Putting America First</u> . This EO instructs a rulemaking process to support policies in which the Medicare program should not pay more for costly Part B prescription drugs or biological products than the most-favored-nation price. The EO would also develop a similar plan for Part D drugs. The most-favored-nation price is defined as the lowest price for a drug or biological product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per-capita GDP. It directs the Secretary of the US Department of Health and Human Services (HHS) to establish a payment model that would examine whether paying no more than the most-favored-nation price affects the clinical outcomes and expenditures associated with other drug costs. A proposed rule or specific guidance on this issue has not yet been released.



	In October 2018, the Centers for Medicare and Medicaid Services (CMS) issued an <u>advance notice of proposed rulemaking</u> seeking feedback on the potential parameters of the International Pricing Index (IPI) Model. The IPI Model would aim to preserve or enhance quality of care for beneficiaries while reducing expenditures for Medicare Part B drugs to more closely reflect international comparator countries. The IPI Model would test whether increasing competition for private-sector vendors to negotiate drug prices, and aligning Medicare payments for drugs with prices that are paid in foreign countries, improves beneficiary access and quality of care while reducing expenditures. The model is currently under review by the Office of Management and Budget.
Drug importation	On September 24, 2020, the Trump Administration published a final rule on <u>importation of prescription drugs</u> . This rule allows the importation of certain prescription drugs from Canada. Under this final rule, states and Indian Tribes (and in certain future circumstances, pharmacists and wholesalers) may submit importation program proposals to the US Food and Drug Administration (FDA) for review and authorization. Under the rule, private individuals are not be allowed to import drugs on their own. The Trump Administration also issued a <u>request for proposals</u> on how to implement waivers for individuals to import drugs directly.
Pharmacy benefit managers rebates	On July 24, 2020, the president signed the <u>EO on Lowering Prices</u> for Patients by Eliminating Kickbacks to Middlemen. This EO eliminates rebates for health plan sponsors and pharmacy benefit managers (PBMs) that operate the Medicare Part D program. The order directs the Secretary of HHS to complete rulemaking to exclude retroactive price reductions that are not applied at the point-of-sale (including rebates to PBMs, pharmacies and health plan sponsors) from safe harbor protections under the federal anti-kickback statute. It also directs the Secretary to establish a new safe harbor that would allow PBMs, pharmacies and plan sponsors to pass such discounts along to patients at the point-of- sale, and allow the use of certain bona fide PBM service fees.
	Importantly, before completing this rulemaking, the Secretary must confirm that doing so will not increase federal spending, Medicare premiums or patients' out-of-pocket costs. A proposed rule or specific guidance on this issue has not yet been released.
Insulin costs	In September 2020, the Trump Administration published the final rule <u>Implementation of Executive Order 13937</u> , <u>Executive Order</u> <u>on Access to Affordable Lifesaving Medications</u> . This rule requires health centers funded under section 330(e) of the Public Health Service Act to provide access to insulin and injectable epinephrine to low-income patients at the price at which the health center





	purchased these two drugs through the 340B Drug Pricing	
	Program.	
	Also in September 2020, CMS released information that seniors	
	who use insulin will be able to choose a plan in their area that	
	offers insulin savings through the Part D Senior Savings Model,	
	and noted that coverage will be provided for a broad set of	
	insulins, each for no more than \$35 per month.	
	Medicaid	
	The Trump Administration issued <u>guidance</u> encouraging states to implement Medicaid work requirements and approved eleven	
Medicaid work requirements	1115 waivers to implement work requirements as a condition of	
	eligibility for Medicaid. Several federal courts have struck down	
	the Administration's approval of work requirement waivers.	
	In 2017, the Trump Administration issued a letter to State	
	Medicaid Directors to encourage states to utilize 1115 Medicaid	
	waivers to provide services to patients in institutions for mental	
Medicaid IMD exclusion	diseases (IMDs). Currently, 28 states have an approved IMD	
	payment exclusion waiver for substance use disorder treatment,	
	and four states have an approved IMD payment exclusion waiver	
	for mental health treatment.	
	In November 2019, the Trump Administration released the	
	proposed Medicaid Fiscal Accountability Regulation, which would	
Medicaid supplemental	have made significant changes to the structure, definition and	
payments	utilization of Medicaid supplemental payments. CMS withdrew this	
	rule in September 2020. If President Trump is re-elected, this rule	
	could be revisited.	
	In 2020, the Trump Administration released a <u>State Medicaid</u>	
	Director letter and fact sheet encouraging states to pursue block	
	grant or per capita cap funding mechanisms through their	
Medicaid financing structure	Medicaid programs. The initiative, called the Healthy Adult Opportunity initiative, would allow states to submit a Section 1115	
	waiver to implement a block grant or per capita cap for certain	
	Medicaid populations, while being granted increased flexibility in	
	administering the program.	
Medicare		
	In 2018, CMS lowered the payment rate for clinic-visit services	
	furnished at grandfathered off-campus provider-based	
	departments to match the rate for similar services at physician	
Site-neutral payments	offices, addressing what it saw as a discrepancy between	
	outpatient rates and physician office rates. In 2019, when this	
	"site-neutral" policy was set to go into effect, the payment change	
	was anticipated to cut \$380 million in reimbursement for hospitals	
	operating off-campus departments. This policy is currently being	
	challenged in courts.	





Coverage for breakthrough technologies	On October 3, 2019, President Trump issued the <u>EO on</u> <u>Protecting and Improving Medicare for Our Nation's Seniors</u> , aimed at speeding Medicare coverage of innovative technologies. Based on the EO, CMS proposed a new Medicare coverage pathway, the Medicare Coverage of Innovative Technology, to spur access to FDA-designated breakthrough medical devices.
Medicare Advantage	In general, the Trump Administration has taken a flexible pro- growth approach toward Medicare Advantage. Issues to watch in the coming year include CMS' approach to risk adjustment and quality ratings.
	COVID-19
Addressing the COVID-19 pandemic	In addressing the Coronavirus (COVID-19) pandemic, the Trump Administration has largely deferred to states to handle the pandemic at the local level. The Administration took action to support onshore production of medical products, increase flexibilities for telehealth, create special enrollment periods for Medicare beneficiaries and support providers through various funding initiatives.
	The Trump Administration created <u>Operation Warp Speed</u> , a plan to produce and deliver 300 million doses of safe and effective COVID-19 vaccines, with the initial doses available by January 2021. We expect that if President Trump is re-elected, the Administration will implement its plan for vaccine distribution.
	Other
Regulatory Sprint to Coordinated Care	The Regulatory Sprint to Coordinated Care aimed to quickly remove specific regulatory barriers related to the physician-self referral law, anti-kickback statute, 42 CFR 2 and HIPAA. Final rules on revisions to Stark Law, the anti-kickback statute and interoperability have not yet been finalized. We would expect the Administration to continue to implement and finalize these rules if President Trump is re-elected.
Transparency	On November 15, 2019, the Trump Administration finalized the Hospital Outpatient Prospective Payment System (OPPS) Policy Changes: Hospital Price Transparency Requirements, mandating that hospitals provide patients with accessible information about the "standard charges" they should expect to face. Once these requirements go into effect in January 2021, hospitals will be required to make public payer-specific negotiated charges, the amount the hospital is willing to accept in cash from a patient for an item or service, and the minimum and maximum negotiated charges for 300 common services that a consumer can schedule in advance (<i>e.g.</i> , x-rays, laboratory testing or bundled services), or pay a penalty. While set to begin January 1, 2021, this new policy is being challenged in federal court.



Couple with the hospital transparency regulation, on November 15, 2019, HHS, the US Department of Labor, and the US Department of the Treasury released the proposed rule <u>Transparency in Coverage</u> . The proposed rule outlines new reporting requirements for group health plans and issuers in the individual and group markets regarding beneficiary cost sharing, in-network provider negotiated rates and historical out-of-network allowed amounts. The rule also proposes changes to medical loss ratio (MLR) rules. Comments on this rule were due January 2020 and could be finalized if President Trump is re-elected.
The Trump Administration also released a direct-to-consumer (DTC) advertising final rule, the <u>Regulation to Require Drug</u> <u>Pricing Transparency</u> , which would have required drug manufacturers to include list prices in DTC advertisements. However, this regulation was ultimately overruled in federal court.



Payment models	The Trump Administration has embraced payment models that move to capitation and cost containment. Examples of voluntary models include Direct Contracting and Primary Care First. CMS also has advanced mandatory models, such as the <u>Radiation Oncology Model</u> and the <u>End-Stage</u> <u>Renal Disease Treatment Choices Model</u> , which will begin on January 1, 2021. If President Trump is re-elected, the Administration is expected to continue to implement these payment changes through voluntary and mandatory models.
Surprise billing	In September 2020, President Trump signed the <u>EO on An</u> <u>America-First Healthcare Plan</u> . The EO states that the Secretary of HHS shall work with Congress to find a legislative solution to surprise billing by December 30, 2020. If a solution cannot be reached, the Secretary should take administrative action to end surprise billing. The Trump Administration has not issued a statement on whether it favors a benchmark rate setting or arbitration to settle surprise billing disputes.
	Additionally, the Department of Health and Human Services has included surprise billing prohibitions in the Terms and Conditions all recipients of Provider Relief Fund monies must sign.
Mental health and opioids	In October 2018, President Trump signed into law the <u>SUPPORT for Patients and Communities Act</u> , which aims to address the US opioid overdose epidemic.
	On October 26, 2017, President Trump officially declared the opioid crisis a "public health emergency." This public health emergency has continued to be renewed.
	President Trump also signed into law the <u>EO on Saving</u> <u>Lives Through Increased Support For Mental- and</u> <u>Behavioral-Health Needs</u> on October 5, 2020. This EO is aimed to prevent suicides, drug-related deaths and poor behavioral-health outcomes as a result of the COVID-19 pandemic. If the president is re-elected, we would expect the Administration to implement provisions of the EO.

McDermott+Consulting LLC is an affiliate of the law firm of McDermott Will & Emery LLP. McDermott+Consulting LLC does not provide legal advice or services and communications between McDermott+Consulting LLC and our clients are not protected by the attorney-client relationship, including attorney-client privilege. The MCDERMOTT trademark and other trademarks containing the MCDERMOTT name are the property of McDermott Will & Emery LLP and are used under license.