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The Fate of the Advancing American Kidney Health Initiative in a Biden Administration

Seth Shepherd

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The Fate of the *Advancing American Kidney Health Initiative* in a Biden Administration

Seth Shepherd

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I. INTRODUCTION

The Secretary of the Department of Health and Human Services (HHS) has a spacious, stylish suite inside the Herbert H. Humphrey Building just off the National Mall in Washington, D.C. To enter the suite, staffers must show an identification badge and must pass through large, gold-rimmed automatic doors. Inside the doors is a wide, carpeted hallway with spacious offices. These offices contain sizeable windows that overlook the National Mall. On sunny days, the offices, which face north, glow with sunlight. Before the Biden Administration, Secretary Alex Azar and his team occupied these offices as they implemented President Trump’s federal healthcare agenda. After the Biden Administration took over on January 20, 2021, however, new leadership at HHS, led by Xavier Becerra, moved and began working to alter course on federal healthcare.

President Biden announced his cabinet pick for HHS on December 8, 2020 during an event where he revealed a number of his administration’s healthcare leaders, including Dr. Anthony Fauci as the Director of the National Institute for Allergy and Infectious Disease (NIAID).¹ Although President Biden mispronounced Becerra’s name, and claimed he was nominating him to the “Department of Health and Education Services,” he correctly noted that Becerra had defended the Affordable Care Act during his twenty-four years in Congress and as California’s Attorney General.²

¹ *Biden Health-Related Nominees and Appointees*, C-SPAN (Dec. 8, 2020), <https://www.c-span.org/video/?507086-1/president-elect-biden-announces-health-team-covid-19-priorities-100-days>.

² *Id.*

Becerra, who is sixty-two years old, has vast political experience, but no healthcare experience.³ Before being elected as California's Attorney General, Becerra served in the United States House of Representatives for twelve terms (twenty-four years) representing part of Los Angeles.⁴ During his time as Attorney General, Becerra was one of the most aggressive state attorney generals fighting against the Trump Administration. He challenged the administration in court on immigration, healthcare, and environmental issues.⁵

It is difficult to know exactly how Becerra will influence Biden's healthcare policy as HHS Secretary because Becerra has almost no healthcare experience, a fact Republicans have been quick to point-out.⁶ Although presidents prioritize strong leadership experience when choosing an HHS Secretary nominee, and some past Presidents have nominated individuals without healthcare experience, Biden's selection of Becerra is noteworthy given Becerra will be taking the position during a global pandemic.⁷ Despite Becerra's lack of experience, the American Hospital Association issued a press release praising his nomination:

America's hospitals and health systems applaud the nomination of California Attorney General Xavier Becerra to be the next Secretary of the Department of Health and Human Services. As California Attorney General, he has led the effort

³ Bret Samuels, *Biden to Name California AG Becerra as HHS Secretary*, THE HILL (Dec. 6, 2020), <https://thehill.com/policy/healthcare/528982-biden-to-name-california-ag-becerra-as-hhs-secretary>.

⁴ *Id.*

⁵ *Id.*

⁶ Michael Hiltzik, *Column: The Attacks on Becerra as Biden's HHS Nominee Are Amazingly Dishonest. Here's Why*, L.A. TIMES (Dec.15, 2020), <https://www.latimes.com/business/story/2020-12-15/becerra-attacks-hhs>.

⁷ *Id.*

to protect the Affordable Care Act and its important protections and coverage for patients.⁸

Although Becerra has vigorously defended the Affordable Care Act (ACA), an attractive trait to Biden, he is personally in favor of a single-payer healthcare system.⁹ In 2019, Becerra said, “For me, health care is a right. I’ve been a single-payer advocate all my life.”¹⁰ However, Becerra will have to sideline his personal views during his time in the Biden Administration because Biden has repeatedly said he is not in favor of a government takeover of health insurance.¹¹

Although members of the President’s cabinet “are seen as advocates for their policy domain, champions for the workers in their departments, and aggressive seekers of budget resources,” presidents have, for years, sidelined cabinet members’ roles in policy decision-making in favor of White House staff.¹² As frustrating as it is for the cabinet Secretaries to see younger White House staff controlling policy-making, presidents since John F. Kennedy have

⁸ Rick Pollack, *AHA Statement on the Nomination of Xavier Becerra as HHS Secretary*, AMERICAN HOSP. ASS’N (Dec. 7, 2020), <https://www.aha.org/press-releases/2020-12-07-aha-statement-nomination-xavier-becerra-hhs-secretary>.

⁹ *Xavier Becerra in His Own Words: “Health Care Is a Right,”* CAL. HEALTHLINE (Dec. 7, 2020), <https://californiahealthline.org/news/article/xavier-becerra-in-his-own-words-health-care-is-a-right/>. In the current United States’ healthcare system, a multitude of different healthcare payers, including private insurance companies, government agencies, and individual citizens, pay medical costs. In a “single-payer” system, a single public or quasi-public agency would cover all costs. Individual citizens would still have the option to choose where to obtain medical services, but the federal government would be the only entity paying in the system. Andrea S. Christopher, *Single Payer Healthcare: Pluses, Minuses, and What it Means for You*, HARV. HEALTH PUB., <https://www.health.harvard.edu/blog/single-payer-healthcare-pluses-minuses-means-201606279835> (last updated June 23, 2020).

¹⁰ CAL. HEALTHLINE, *supra* note 9.

¹¹ Tucker Higgins, *Biden Says Coronavirus’ Impact on Health System Hasn’t Changed His Mind on Single-Payer*, CNBC (Mar. 30, 2020), <https://www.cnbc.com/2020/03/30/biden-says-coronavirus-hasnt-changed-his-mind-on-single-payer.html>.

¹² James Pfiffner, *Cabinet Secretaries Versus the White House Staff*, BROOKINGS (Mar. 24, 2015), <https://www.brookings.edu/blog/fixgov/2015/03/24/cabinet-secretaries-versus-the-white-house-staff/>.

recognized a need for “coordination of administration policy from the president’s perspective” and have chosen to coordinate policy in the White House, often without the relevant cabinet Secretary present.¹³ However, cabinet members still maintain control over implementation of administrative policy and likely always will.¹⁴

Understanding Becerra’s healthcare perspective and how it interacts with the Biden Administration’s priorities is necessary to predict what will become of key Trump Administration health initiatives. Among those initiatives is the HHS *Advancing American Kidney Health Initiative (Initiative)*, which was created through Executive Order by President Trump on July 10, 2019.¹⁵ The *Initiative*’s purpose was to combat kidney disease, which, in 2018, was the ninth leading cause of death in the United States.¹⁶

This article analyzes the Biden Administration’s healthcare priorities, contrasts them with those of the Trump Administration, discusses how Presidential administrations determine whether to continue policies, and examines the proper procedures for continuing previous administration policies. This article will then examine whether the *Initiative* will have a place in the Biden Administration’s healthcare policy. Part II considers Biden’s overall approach to healthcare. Part III discusses what the Trump Administration’s healthcare policy accomplished. Part IV dissects the *Initiative* and begins a discussion regarding its effectiveness. Part V explores an administration’s decision-making process regarding retention or rejection of a previous administration’s policies and details the procedural steps an administration must take to continue

¹³ *Id.*

¹⁴ *Id.*

¹⁵ Executive Order No. 13879, 84 Fed. Reg. 33,817 (July 15, 2019).

¹⁶ National Center for Health Statistics, *Leading Causes of Death*, CTR. FOR DISEASE CONTROL AND PREVENTION (Oct. 30, 2020), <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>.

a policy. Part VI concludes with an argument that the Biden Administration should continue the *Initiative* because kidney disease is a major health concern and the *Initiative* has been successful in combatting it.

II. THE BIDEN APPROACH TO HEALTHCARE

Biden's healthcare plan prioritizes increased government involvement in the healthcare system.¹⁷ The Biden Administration will prioritize expanding the Affordable Care Act and passing a stimulus bill to support struggling doctors, hospitals, and nursing homes.¹⁸ Although Biden is not in favor of "Medicare-for-all," as many Democratic 2020 candidates were, he does want to see the federal government become more involved in healthcare.¹⁹

Biden's eagerness to increase federal involvement in healthcare can be seen in his response to the COVID-19 pandemic. As his campaign website reads,

Biden believes we must spend whatever it takes, without delay, to meet public health needs and deal with the mounting economic consequences. The federal government must act swiftly and aggressively to help protect and support our families, small businesses, first responders and caregivers essential to help us face this challenge, those who are most vulnerable to health and economic impacts, and our broader communities – not to blame others or bail out corporations.²⁰

¹⁷ See generally Dennis Thompson, *If Elected, Joe Biden Has Big Plans for Health Care*, U.S. NEWS & WORLD REP. (Nov. 6, 2020), <https://www.usnews.com/news/health-news/articles/2020-11-06/if-elected-joe-biden-has-big-plans-for-health-care> (detailing Biden's plan to expand the ACA and create a public option); *The Biden Plan to Combat Coronavirus (COVID-19) And Prepare For Future Global Health Threats*, BIDEN HARRIS, <https://joebiden.com/covid-plan/> (last visited January 20, 2021) (explaining Biden's desire to create a strong federal response to the COVID-19 pandemic).

¹⁸ Thompson, *supra* note 17.

¹⁹ *Id.*

²⁰ BIDEN HARRIS, *supra* note 17.

On his first day in office, President Biden signed Executive Orders addressing the COVID-19 pandemic,²¹ the most aggressive of which declared a “nationwide face mask and social distance mandate in federal buildings, on federal lands[,] and by federal employees and contractors.”²² He also reinstated a position called the “Directorate for Global Health Security and Biodefense,” which President Obama originally created during the 2014 Ebola epidemic, but President Trump later eliminated by dispersing its roles to other administrative positions.²³ Biden and his team believe the Directorate is vital to ensuring America is prepared to handle the COVID-19 pandemic.²⁴ In addition to the Directorate, Biden appointed a “response coordinator” who reports to him regarding the vaccine, testing, and personal protective equipment production, supply, and distribution across the United States.²⁵ Additionally, on his first day, Biden signed orders for the United States to rejoin the World Health Organization (WHO), which President Trump left after it criticized his decision to close travel to the U.S. from China.²⁶ The day after Biden’s inauguration, Dr. Anthony Fauci, Director of NIAID, joined a meeting with other world health officials in the WHO.²⁷

²¹ Bo Erickson, *Biden Signs Executive Actions on COVID, Climate Change, Immigration And More*, CBS NEWS (Jan. 21, 2021), <https://www.cbsnews.com/news/biden-signs-executive-orders-day-one/>.

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ Chuck DeVore, *Left Hates Travel Bans Except When They Keep Americans From Work and School*, TEX. PUB. POL’Y FOUND. (Mar. 24, 2020), <https://www.texaspolicy.com/left-hates-travel-bans-except-when-they-keep-americans-from-work-and-school/>.

²⁷ Yaron Steinbuch, *Fauci Lays Out US Support for WHO Under Biden Administration* (Jan. 21, 2020, 7:05 AM), <https://nypost.com/2021/01/21/fauci-lays-out-us-support-for-who-under-biden-administration/>.

Just as increased federal involvement is critical to President Biden’s COVID-19 pandemic response, increased federal involvement is his policy toward the U.S. healthcare system as well.²⁸ Specifically, President Biden would like to expand the Affordable Care Act and create a public health insurance option.²⁹

a. WHAT IS THE ACA?

The Obama Administration designed the ACA, also known as “Obamacare,” to expand healthcare to the uninsured by increasing private and public healthcare options.³⁰ It sought to accomplish this through three goals: (1) making affordable health insurance more available by providing “premium tax credits” to people making 100% to 400% of the poverty level, (2) expanding Medicaid to include people making lower than 138% of the poverty level, and (3) supporting innovative medical care delivery methods to reduce costs.³¹

The ACA’s primary purpose was to increase participation in the healthcare industry by covering the thirty-two million uninsured Americans.³² To this end, the ACA required employers to cover their workers or pay penalties (although the ACA did exempt smaller employers from the penalties), and it required individuals to have insurance or pay an additional tax.³³ The National Federation of Independent Business challenged the constitutionality of this last

²⁸ See generally Thompson, *supra* note 17.

²⁹ See *infra* Part II (a), (b).

³⁰ *The Affordable Care Act: A Brief Summary*, NAT’L CONF. OF ST. LEGISLATURES (Mar. 2011), <https://www.ncsl.org/research/health/the-affordable-care-act-brief-summary.aspx>.

³¹ *Affordable Care Act*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/affordable-care-act/> (last visited Jan. 20, 2020).

³² *The Affordable Care Act: A Brief Summary*, *supra* note 30.

³³ *Id.*

requirement, known as the “individual mandate,” in the Supreme Court case, *National Federation of Independent Business v. Sebelius*.³⁴

The individual mandate required that, by 2014, individuals who had failed to obtain health insurance pay a tax penalty.³⁵ The question the Supreme Court addressed in *Sebelius* regarded whether such a tax penalty, which penalized individuals for failure to take affirmative action to acquire health insurance, was constitutional under Congress’s taxing power.³⁶ In a five to four decision on that issue, the Supreme Court ruled that the individual mandate was constitutional under Congress’s Article I taxing power.³⁷ Although the individual mandate survived the constitutional challenge at the Supreme Court, years later Republicans struck it from the law through the Tax Cuts and Jobs Act of 2017 when they controlled Congress.³⁸

President Biden stated that he will seek to re-institute the ACA’s individual mandate.³⁹ President Biden sees the individual mandate as necessary to increase healthcare coverage and make healthcare costs manageable. As the argument goes, “[w]ithout a financial prod . . . many healthy people would forego insurance, driving up costs for others in the markets for individual

³⁴ *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012).

³⁵ *Id.* at 539.

³⁶ *Id.* at 540.

³⁷ *Id.* at 563.

³⁸ Judson Berger, *Trump Predicts Mandate Repeal Will Kill ObamaCare, Spur Replacement Plan*, FOX NEWS (Dec. 26, 2017), <https://www.foxnews.com/politics/trump-predicts-mandate-repeal-will-kill-obamacare-spur-replacement-plan>.

³⁹ Jessica Bursztynsky, *Biden Vows to Bring Back Obamacare’s Individual Mandate Penalty for Not Having Insurance*, CNBC (July 5, 2019), <https://www.cnbc.com/2019/07/05/joe-biden-vows-to-bring-back-obamacare-individual-mandate-penalty.html>.

policies.”⁴⁰ During Biden’s campaign, one of his campaign officials stated that Biden would continue his “longstanding history of getting stuff done in Congress to get legislation to build on the Affordable Care Act” and would use executive orders to undo the changes to the ACA.⁴¹

b. PRESIDENT BIDEN’S WORK TO EXPAND THE ACA

When President Biden was running for office, he made clear his intentions to expand the ACA despite the damage Republicans inflicted on it. President Biden stated that he wanted to eliminate the 400% poverty level cap required to receive tax credit for health insurance costs.⁴² Biden’s campaign website states the following:

As President, Biden will help middle class families by eliminating the 400% income cap on tax credit eligibility and lowering the limit on the cost of coverage from 9.86% of income to 8.5%. This means that no family buying insurance on the individual marketplace, regardless of income, will have to spend more than 8.5% of their income on health insurance.⁴³

⁴⁰ Zachary Tracer, *The Individual Mandate*, BLOOMBERG (Dec. 22, 2017), <https://www.bloomberg.com/quicktake/individual-mandate>.

⁴¹ Chelsea Stahl, *Meet the Press Blog: Latest News, Analysis and Data Driving the Political Discussion*, NBC NEWS, <https://www.nbcnews.com/politics/meet-the-press/blog/meet-press-blog-latest-news-analysis-data-driving-political-discussion-n988541/ncrd1030086#blogHeader> (last updated Oct. 6, 2021, 9:22 AM).

⁴² *Health Care*, BIDEN HARRIS, <https://joebiden.com/healthcare/> (last accessed Jan. 20, 2020).

⁴³ *Id.*

Within the first two years of his term, President Biden accomplished this goal.⁴⁴ The American Rescue Plan Act, signed on March 11, 2021,⁴⁵ expanded subsidies to individuals with incomes over 400% of the poverty level who purchased health insurance for themselves.⁴⁶

Republican efforts to eliminate the individual mandate reduced the government's involvement in healthcare by eliminating the tax penalty on individuals who chose not to purchase health insurance. True to his wholistic attitude towards healthcare, Biden's efforts to expand the ACA are meant to increase the federal government's involvement in healthcare in the hopes that it will even the playing field, increase healthcare coverage, and limit the burden of healthcare costs on everyday Americans.⁴⁷

c. PRESIDENT BIDEN'S PUBLIC OPTION

Although President Biden made clear that he is not interested in pursuing a single-payer healthcare system in the United States, he openly expressed his interest in creating a public option as a viable, competitive healthcare alternative for Americans.⁴⁸ This focus comes from Biden's frustration with fourteen states who have refused to expand the ACA's Medicaid eligibility, which, as Biden argues, denies access to Medicaid for nearly five million adults.⁴⁹ As

⁴⁴ Matthew Rae, Cynthia Cox, Gary Claxton, Daniel McDermott, & Anthony Damico, *How the American Rescue Plan Act Affects Subsidies for Marketplace Shoppers and People Who Are Uninsured*, KAISER FAMILY FOUND. (Mar. 25, 2021), <https://www.kff.org/health-reform/issue-brief/how-the-american-rescue-plan-act-affects-subsidies-for-marketplace-shoppers-and-people-who-are-uninsured/>.

⁴⁵ *Remarks by President Biden at Signing of the American Rescue Plan*, WHITE HOUSE (Mar. 11, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/11/remarks-by-president-biden-at-signing-of-the-american-rescue-plan/>.

⁴⁶ Rae, *supra* note 44.

⁴⁷ Tracer, *supra* note 40.

⁴⁸ *Health Care*, *supra* note 42.

⁴⁹ *Id.*

Biden sees it, after creating a public option, his administration could automatically enroll individuals who qualify for the option when they interact with certain public institutions (e.g. public schools and the Supplemental Nutrition Assistance Program).⁵⁰ Additionally, Biden hopes his public option will help combat healthcare costs because the government can use its pricing power to decrease costs, which would lower premiums that participants pay.⁵¹

With the global pandemic and his focus on expanding the ACA and creating a public healthcare option, Biden and his team at HHS had many healthcare policy decisions to distract them from the *Initiative*. An administration has limited time and political capital, especially after barely prevailing in a contentious election.⁵² For these reasons, the Trump Administration's *Initiative* will almost certainly not be a priority for Biden's team; and, in fact, within the first year and a half of his administration, President Biden did not address kidney health. However, it is possible the *Initiative*'s wise goals and past effectiveness will convince Secretary Becerra and the Biden Administration to address it in some capacity.

III. THE TRUMP APPROACH TO HEALTHCARE

President Trump's healthcare agenda focused on decreasing federal government involvement in healthcare, and the *Initiative* fit into that that plan.⁵³ Simply:

⁵⁰ *Id.*

⁵¹ Jeffrey Young & Jonathan Cohn, *Trump vs. Biden On Health Care: A Stark Choice For Voters*, HUFFPOST (Oct. 20, 2020), https://www.huffpost.com/entry/trump-biden-health-care_n_5f8741c8c5b6c4bb54723669.

⁵² Benjamin Swasey & Connie Hanzhang Jin, *Narrow Wins In These Key States Powered Biden to the Presidency*, NPR (Dec. 2, 2020), <https://www.npr.org/2020/12/02/940689086/narrow-wins-in-these-key-states-powered-biden-to-the-presidency>; cf. Thomas E. Mann, *Reflections on the 2000 U.S. Presidential Election*, BROOKINGS (Jan. 1, 2001), <https://www.brookings.edu/articles/reflections-on-the-2000-u-s-presidential-election/>.

⁵³ Selena Simmons-Duffin, *What Biden's Election Means For U.S. Health Care and Public Health*, NPR (Nov. 9, 2020), <https://www.npr.org/sections/health-shots/2020/11/09/932071991/what-bidens-election-means-for-u-s-health-care-and-public-health>.

Trump’s nearly four years as president have been marked by a scaled-back federal investment and involvement in health care in a range of ways – giving states more authority to run their own health insurance markets, for example, and leaving them to come up with their own strategies for COVID-19 testing, contact tracing and more.⁵⁴

Because the Trump Administration did not push for a large-scale, federal expansion of healthcare, it possessed the manpower and political strength to address American kidney health with the *Initiative*. In contrast with the Obama-era, marked by a calculated push to pass and implement the ACA, the Trump Administration never worked on a comparably sizable healthcare policy package. The Trump administration did not seek to convince Congress to pass legislation that overhauled healthcare, so it possessed the time and political capital to address kidney health, a rising health issue in the nation.⁵⁵

However, the Trump Administration’s lack of a largescale health plan was not because healthcare was not a priority for them, but because the administration believed that leaving healthcare to the private sector and states to determine what was best for themselves would result in a stronger, more competitive healthcare industry nationwide.⁵⁶

Although President Trump campaigned on repealing and replacing the ACA, he was unable to accomplish this because of congressional resistance.⁵⁷ However, President Trump still

⁵⁴ *Id.*

⁵⁵ *37 Million American Adults Now Estimated to Have Chronic Kidney Disease*, NAT’L KIDNEY FOUND. (July 17, 2019), <https://www.kidney.org/news/37-million-american-adults-now-estimated-to-have-chronic-kidney-disease>.

⁵⁶ *Healthcare*, WHITE HOUSE, <https://trumpwhitehouse.archives.gov/issues/healthcare/> (last accessed Jan. 21, 2020).

⁵⁷ Marie Fishpaw & Doug Badger, *A Look Back at Trump’s Health Care Reforms*, HERITAGE FOUND. (Oct. 12, 2020), <https://www.heritage.org/health-care-reform/commentary/look-back-trumps-health-care-reforms>.

addressed the portions of the ACA putting pressure on small businesses.⁵⁸ He eliminated rules stripping small businesses of short-term healthcare options.⁵⁹ Additionally, he created a rule that allowed small businesses to band together to provide healthcare to employees and to create accounts where their employees could purchase private health insurance.⁶⁰ President Trump saw the ACA as attempting to artificially increase the total number of people with healthcare coverage by overly regulating small businesses and stifling their healthcare options.⁶¹

An Executive Order President Trump signed during the fall of 2019 highlighted his affinity for private sector competition. In the Executive Order, he directed HHS and White House officials to work on expanding options in Medicare Advantage (MA), a private health insurance alternative to Medicare's government-controlled fee-for-service option.⁶² President Trump enacted the Executive Order to direct his administration to work to decrease regulations in various ways to make it easier on private health insurance to create competitive Medicare Advantage plans⁶³

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ Dan Mangan, *Donald Trump Blasts Obamacare – With A Lot of Help from Running Mate Mike Pence*, CNBC (Nov. 1, 2016), <https://www.cnbc.com/2016/11/01/donald-trump-blasts-obamacare--with-a-lot-of-help-from-running-mate-mike-pence.html>.

⁶² James C. Capretta, *Trump's Lightweight Alternative to Medicare for All*, AM. ENTER. INST. (Oct. 11, 2019), <https://www.aei.org/op-eds/trumps-lightweight-alternative-to-medicare-for-all/>.

⁶³ *Id.*

Because President Trump's focus was on decreasing government involvement in healthcare and increasing private competition, his administration could prioritize addressing specific healthcare concerns in the nation, such as the opioid crisis and kidney health.⁶⁴

When President Trump took office, the United States was suffering from an opioid crisis, which impacted many Americans.⁶⁵ President Trump created a bipartisan opioid commission that issued fifty-six recommendations to help manage the crisis.⁶⁶ He also directed HHS to declare the opioid crisis a public health emergency and designated grant money toward combating abuse.⁶⁷ To battle the smuggling of illegal opioids into the U.S., President Trump also signed the International Narcotics Trafficking Emergency Response by Detecting Incoming Contraband with Technology (INTERDICT) Act, giving customs agents nine million dollars for screening tools at the border.⁶⁸ True to his persistent anti-China rhetoric, President Trump also successfully convinced China to close a loophole that allowed Chinese fentanyl merchants to legally ship the compound worldwide, much of which found its way to the United States.⁶⁹

⁶⁴ See *Healthcare*, WHITE HOUSE ARCHIVE, <https://trumpwhitehouse.archives.gov/issues/healthcare/> (last accessed Apr. 16, 2022).

⁶⁵ *Opioid Overdose: Understanding the Epidemic*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 19, 2020), <https://www.cdc.gov/drugoverdose/epidemic/index.html>.

⁶⁶ EXEC. OFFICE OF THE PRESIDENT, PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS FINAL REPORT (2017).

⁶⁷ Katherine Faulders & Alexander Mallin, *Trump Declares Opioid Crisis a National Public Health Emergency*, ABC NEWS (Oct. 26, 2017, 12:31 PM), <https://abcnews.go.com/Politics/trump-declares-opioid-crisis-national-public-health-emergency/story?id=50718774>.

⁶⁸ Gregory Korte & David Jackson, *To Combat Drug Smuggling, Trump Signs Bill to Provide \$9 Million for Opioid Sensors*, USA TODAY (Jan. 10, 2018, 5:53 PM), <https://www.usatoday.com/story/news/politics/2018/01/10/combat-drug-smuggling-trump-signs-bill-provide-9-million-opioid-sensors/1022548001/>.

⁶⁹ *Healthcare*, *supra* note 64; DRUG ENFORCEMENT AGENCY, DEA INTELLIGENCE REPORT: FENTANYL FLOW TO THE UNITED STATES, 2 (2020).

The Trump administration could put a wholehearted effort into fighting the opioid crisis because it was not attempting to pass wide-sweeping healthcare policy changes in Congress or implement any massive overhauls in the government's approach to the healthcare industry.

IV. HHS KIDNEY INITIATIVE

The Trump administration made many ambitious claims about its accomplishments during the four years it held the White House.⁷⁰ Including President Trump's own statements, the Trump administration claimed that President Trump was the greatest President America has ever had and that the economy (before the national pandemic forced a shut-down) was the most productive in U.S. history.⁷¹ But did the results of the Trump administration's efforts match their claims, specifically when it came to the area of healthcare, an area about which voters are especially concerned?⁷²

One healthcare area the Trump administration attempted to address was American kidney health. On July 10, 2019, President Trump announced, through Executive Order 13879, the *Advancing American Kidney Health Initiative*.⁷³ The *Initiative* highlighted the concerning number of deaths caused by kidney disease, noted the high costs associated with the disease, and

⁷⁰ Jamie Ross, *Trump Says He's Unimpeachable Because He's the 'Greatest' 'Most Successful' President*, DAILY BEAST (January 4, 2019), <https://www.thedailybeast.com/trump-says-hes-unimpeachable-because-hes-the-greatest-most-successful-president>; Joseph Zeballos-Roig & Andy Kiersz, *Trump Boasts the US Economy Is the Best It's Ever Been Under His Watch. Here Are 9 Charts Showing How It Compares to the Obama and Bush Presidencies*, MARKETS INSIDER (Jan. 21, 2020), <https://markets.businessinsider.com/news/stocks/9-charts-comparing-trump-economy-to-obama-bush-administrations-2019-9-1028833119>.

⁷¹ See sources cited *supra* note 70.

⁷² *Important Issues in the 2020 Election*, PEW RES. CTR. (Aug. 13, 2020), <https://www.pewresearch.org/politics/2020/08/13/important-issues-in-the-2020-election/>.

⁷³ *HHS Launches President Trump's 'Advancing American Kidney Health' Initiative*, DEP'T OF HEALTH & HUMAN SERVS. (July 10, 2019), <https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html>.

tasked the Department of Health and Human Services with taking steps to fight kidney disease and improve kidney care across the country.⁷⁴

a. THE STATE OF KIDNEY HEALTH IN AMERICA

i. CHRONIC KIDNEY DISEASE

Chronic Kidney Disease (CKD) occurs when a patient's kidneys begin to lose their ability to function.⁷⁵ This often occurs when a patient has diabetes or hypertension and the strain on the patient's kidneys damage them to the extent the kidneys are no longer able to clean the patient's blood.⁷⁶

In each kidney, there are a million tiny filters called nephrons.⁷⁷ A nephron consists of a filter, called the glomerulus, and a tubule.⁷⁸ As blood pours into the nephron, the glomerulus filters the blood, removing waste, water, and tiny molecules which the tubule collects.⁷⁹ After the glomerulus filters blood, the filtered blood runs through a blood vessel alongside the tubule.⁸⁰ As the blood travels through this vessel, it reabsorbs much of the water, minerals, and nutrients the

⁷⁴ Executive Order No. 13879, *supra* note 15 at 33,817.

⁷⁵ *Kidney Disease: The Basics*, NAT'L KIDNEY FOUND., <https://www.kidney.org/news/newsroom/factsheets/KidneyDiseaseBasics> (last accessed Feb. 15, 2021).

⁷⁶ *Id.*

⁷⁷ *Chronic Kidney Disease: Topic Overview*, KAISER PERMANENTE (Dec. 17, 2020), <https://healthy.kaiserpermanente.org/health-wellness/health-encyclopedia/he.chronic-kidney-disease.aa65427>.

⁷⁸ *Your Kidneys & How They Work*, NAT'L INST. OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (June 2018), <https://www.niddk.nih.gov/health-information/kidney-disease/kidneys-how-they-work>.

⁷⁹ *Id.*

⁸⁰ *Id.*

body needs.⁸¹ The tubule removes the waste from the kidney.⁸² If nephrons are damaged, they stop working and force healthy nephrons to take on more blood to account for the missing nephrons.⁸³

Diabetes and high blood pressure are the leading causes of CKD in adults.⁸⁴ Other factors that can contribute to kidney damage are heart disease, old age, obesity, a family history of CKD, and past damage to kidneys.⁸⁵ Each of these conditions increases stress on the kidneys and destroys nephrons, leading to CKD.⁸⁶

One of the most difficult challenges to addressing kidney disease is that most patients with kidney disease are not aware they are suffering from the condition.⁸⁷ According to data from 2019, nine out of ten patients with CKD did not realize they had it.⁸⁸ Adults with CKD face a higher risk of death than adults of comparative age without the disease.⁸⁹ Additionally, CKD puts patients at risk for heart disease or strokes.⁹⁰

⁸¹ *Id.*

⁸² *Id.*

⁸³ *Chronic Kidney Disease: Topic Overview*, *supra* note 74.

⁸⁴ *Chronic Kidney Disease Initiative*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 11, 2019), <https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html>.

⁸⁵ *Id.*

⁸⁶ *What Is Chronic Kidney Disease (CKD)?*, HEALTHLINE, <https://www.healthline.com/health/chronic-kidney-disease> (last reviewed Apr. 20, 2017).

⁸⁷ *Chronic Kidney Disease Initiative*, *supra* note 84.

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.*

ii. END-STAGE RENAL DISEASE

The result of untreated CKD is End-Stage Renal Disease (ESRD), a condition where a patient's kidneys cease to function at a level where they can keep the patient alive.⁹¹ When this occurs, the patient requires long-term dialysis and ultimately a kidney transplant to survive.⁹² Dialysis is a medical procedure that performs the function of the kidneys.⁹³ Dialysis removes waste, salt, and excess water from the bloodstream and keeps safe chemicals in the blood.⁹⁴ Dialysis can also help reduce high blood pressure.⁹⁵ Although dialysis can be effective in the short term, it cannot cure kidney failure on a long term basis.⁹⁶ As of 2019, there were approximately 95,000 patients on the waitlist for a kidney transplant.⁹⁷ In 2021, there were approximately 91,000 patients on the waitlist.⁹⁸

⁹¹ *End-Stage Renal Disease (ESRD)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (June 30, 2020), <https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Coordination-of-Benefits-and-Recovery-Overview/End-Stage-Renal-Disease-ESRD/ESRD>.

⁹² *Id.*

⁹³ *Dialysis*, NAT'L KIDNEY FOUND. (Oct. 30, 2020), <https://www.kidney.org/atoz/content/dialysisinfo>.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Kidney Transplant in Adults: The Kidney Transplant Waiting List in the United States*, UPTODATE, <https://www.uptodate.com/contents/kidney-transplantation-in-adults-the-kidney-transplant-waiting-list-in-the-united-states> (last accessed Mar. 28, 2021); *see also HHS Launches President Trump's 'Advancing American Kidney Health' Initiative*, DEP'T OF HEALTH & HUMAN SERVS. (July 10, 2019), <https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html>.

⁹⁸ *Organ Procurement and Transplant Network*, DEP'T OF HEALTH & HUMAN SERVS, <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#> (last accessed Mar. 28, 2021).

b. HHS KIDNEY HEALTH INITIATIVE

The Trump Administration drafted the *Initiative* to accomplish three clear goals: (1) to prevent CKD and ESRD so fewer patients would develop kidney failure, (2) to reduce the number of patients receiving dialysis in dialysis centers, and (3) to increase the number of kidneys available for transplant.⁹⁹

i. THREE INITIATIVES

1. FEWER PATIENTS DEVELOPING KIDNEY FAILURE

One of the best ways to battle CKD and ESRD is to prevent them from occurring in the first place. To this end, the Trump administration sought to increase efforts to detect CKD at an early stage.¹⁰⁰ In a paper published by HHS's Assistant Secretary for Planning and Evaluation detailing the administration's efforts, HHS explained that it would increase diagnoses of CKD by advancing public health awareness and identifying population areas where CKD is prevalent.¹⁰¹

One way to effectively detect CKD in the early stages is to conduct research to determine which patients might be at risk.¹⁰² The health community already understands that patients who suffer from diabetes or high blood pressure are at risk for CKD,¹⁰³ but HHS sought to determine additional indicators to increase detection of CKD.

⁹⁹ Executive Order No. 13879, *supra* note 15 at 33,817-19.

¹⁰⁰ *Advancing American Kidney Health*, DEP'T OF HEALTH & HUMAN SERVS., <https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf> (last accessed Feb. 15, 2021).

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ CTRES. FOR DISEASE CONTROL & PREVENTION, *supra* note 80.

To this end, the CDC “manages the national CKD Surveillance System, the only interactive and most comprehensive collection of CKD-related data in the United States, helpful for monitoring progress toward achieving national Healthy People objectives.”¹⁰⁴ Through this system, the CDC continues strengthening its understanding about factors contributing to kidney disease, its prevalence, and the risks associated with it.¹⁰⁵

2. FEWER PATIENTS RECEIVING DIALYSIS IN DIALYSIS CENTERS

Patients find it difficult to stay up-to-date with their dialysis treatment because they either struggle to find transportation to their dialysis centers, fail to attend follow-up meetings, or feel too sick to attend the treatment in the first place.¹⁰⁶ To help patients complete their dialysis treatment, the *Initiative* tasked HHS with coordinating with healthcare providers to ensure that dialysis is a one-stop, comprehensive treatment where patients can go directly home after treatment.¹⁰⁷ Further, the *Initiative* HHS tasked with pursuing an at-home dialysis option for patients.¹⁰⁸

¹⁰⁴ *Advancing American Kidney Health*, *supra* note 100.

¹⁰⁵ *Id.*

¹⁰⁶ *Postdialysis Fatigue*, KIDNEY NEWS ONLINE (Aug. 2018), <https://www.kidneynews.org/kidney-news/practice-pointers/postdialysis-fatigue>.

¹⁰⁷ *Advancing American Kidney Health*, DEP’T OF HEALTH AND HUMAN SERVICES, <https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf> (last accessed February 15, 2021).

¹⁰⁸ Executive Order No. 13879, *supra* note 15 at 33,818.

3. MORE KIDNEYS AVAILABLE FOR TRANSPLANT

a. UPDATING OUTMODED AND COUNTERPRODUCTIVE REGULATIONS

The Executive Order further tasked HHS with revising the Organ Procurement Organization (OPO) “rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance.”¹⁰⁹ To ensure greater organ availability for the thousands of patients who needed them, the Trump Administration sought to clean-up the organ procurement process, obtaining more organs and better preserving them during transportation.¹¹⁰

The United Network for Organ Sharing (UNOS) manages the list of available organs across the United States and the patients waiting for transplant.¹¹¹ When it comes to kidney transplants, UNOS does not distribute kidneys on a first-come, first-serve basis because kidney transplant requires blood-type and antibody matching.¹¹² UNOS also includes analysis of needs when determining who receives kidneys for transplant.¹¹³ UNOS prioritizes children and live-kidney donors.¹¹⁴ In response to the *Initiative*, UNOS began research to determine whether increasing the availability of “hard-to-place” kidneys would increase their use.¹¹⁵ UNOS did this

¹⁰⁹ *Id.*

¹¹⁰ *Advancing American Kidney Health*, *supra* note 100.

¹¹¹ *The Kidney Transplant Waitlist – What You Need to Know*, NAT’L KIDNEY FOUND. (Feb. 10, 2017), <https://www.kidney.org/atoz/content/transplant-waitlist>.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Kidney Accelerated Placement Project Launched in 2019*, UNOS (Dec. 19, 2019), <https://unos.org/news/kidney-accelerated-placement-project-for-national-offers-begins-july-18/>. “Hard-to-place” kidneys are kidneys that receive a Kidney Donor Profile Index (KDPI) of 80% or higher. *Id.* The

through the Kidney Accelerated Placement Project (KAPP).¹¹⁶ KAPP’s purpose was to “improve placement of national kidney offers and was based on feedback from the community.”¹¹⁷ Hard-to-place kidneys are not useless, and if health professionals can find the right patient quickly, even hard-to-pace kidneys can be just as effective as more easily-placed kidneys.

b. ARTIFICIAL KIDNEYS

Although the development of artificial kidneys has room for improvement,¹¹⁸ President Trump’s Executive Order instructed HHS to seek premarket approval of wearable or implantable artificial kidneys to incentivize developers to continue innovating breakthrough technology.¹¹⁹ Because FDA regulations for medical devices are often extensive and costly, the FDA must put strong incentives in place to encourage developers to continue to pursue more effective medical treatments.¹²⁰

KDPI “combines a variety of donor factors into a single number that summarizes the likelihood of graft failure after deceased donor kidney transplant.” *Kidney Donor Profile Index (KDPI) Guide for Clinicians*, DEP’T OF HEALTH AND HUMAN SERVS., <https://optn.transplant.hrsa.gov/resources/guidance/kidney-donor-profile-index-kdpi-guide-for-clinicians/> (last accessed Mar. 28, 2021). The KDPI number signifies how likely a deceased donor kidney is to fail in relation to all other donor kidneys recovered in the United States for that year. *Id.* The higher the number, the shorter the lifespan of the kidney. *Id.*

¹¹⁶ *Kidney Accelerated Placement Project Launched in 2019*, *supra* note 115.

¹¹⁷ *Id.*

¹¹⁸ *Artificial Kidney Development Advances, Thanks to Collaboration by NIBIB Quantum Grantees*, NAT’L INST. OF BIOMEDICAL IMAGING AND BIOENGINEERING (Feb. 8, 2018), <https://www.nibib.nih.gov/news-events/newsroom/artificial-kidney-development-advances-thanks-collaboration-nibib-quantum>.

¹¹⁹ Executive Order No. 13879, *supra* note 15 at 33,818.

¹²⁰ *See id.* (requiring that the Secretary of HHS shall “announce that the Department will consider requests for premarket approval of wearable or implantable artificial kidneys in order to encourage their development and to enhance cooperation between developers and the Food and Drug Administration.”).

i. KIDNEYX

The Kidney Innovation Accelerator (KidneyX) is a public-private partnership between the U.S. Department of Health and Human Services (HHS) and the American Society of Nephrology (ASN) meant to accelerate innovation in the prevention, diagnosis, and treatment of kidney diseases.¹²¹ KidneyX seeks to identify and leverage rapidly emerging technologies that can successfully detect and treat kidney disease.¹²² New technologies include “advanced nanofiltration for toxin removal, miniaturized wearable dialyzers, real-time infection and clotting sensors, cell-based implantable dialyzers, and regenerative kidneys.”¹²³

ii. CMS AND THE CENTER FOR MEDICARE AND MEDICAID INNOVATION (CMMI) PAYMENT PLANS

The Executive Order instructed the Centers for Medicare and Medicaid Services (CMS) to introduce new payment plans incentivizing patients to receive dialysis at home.¹²⁴ In addition to this, under the new payment plans, the Trump administration harnessed the power of Medicare and Medicaid to aid in early detection of CKD.¹²⁵

If the Trump Administration had accomplished their goals, at-home dialysis would be the future of kidney treatment.¹²⁶ One of those goals was to ensure that by 2025 eighty percent of

¹²¹ *KidneyX: Innovation Accelerator*, DEP’T OF HEALTH AND HUMAN SERVS. (Nov. 6, 2020), <https://www.hhs.gov/cto/initiatives/kidneyx/index.html>.

¹²² *Advancing American Kidney Health*, *supra* note 100 at 16.

¹²³ *Id.*

¹²⁴ *HHS to Transform Care Delivery for Patients with Chronic Kidney Disease*, CTRS. FOR MEDICARE AND MEDICAID SERVS. (July 10, 2019), <https://www.cms.gov/newsroom/press-releases/hhs-transform-care-delivery-patients-chronic-kidney-disease>.

¹²⁵ *Id.*

¹²⁶ Judith Graham, *What the Trump Home Dialysis Plan Would Really Look Like*, KAISER HEALTH NETWORK (Aug. 16, 2019), <https://khn.org/news/what-the-trump-diy-home-dialysis-plan-would-really-look-like/>.

patients newly diagnosed with ESRD would receive in-home dialysis.¹²⁷ At-home dialysis is more convenient and allows patients to receive therapy more often and in a less taxing manner.¹²⁸

Further, under the proposed new CMS and CMMI payment plans, patients have the option to select the ESRD treatment plan that works best for their family.¹²⁹

iii. PUBLIC AWARENESS CAMPAIGN

1. ARE YOU THE 33%?

Because so many CKD patients are unaware that they have the disease,¹³⁰ and because the disease was the ninth leading cause of death in the United States,¹³¹ President Trump's Executive Order instructed HHS to initiate a public awareness campaign in an attempt to reach at-risk patients with information about the condition.¹³² HHS joined forces with the National

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *HHS to Transform Care Delivery for Patients with Chronic Kidney Disease*, *supra* note 124.

¹³⁰ *Increase the Proportion of Adults with Chronic Kidney Disease Who Know They Have It – CDK-02*, OFF. OF DISEASE PREVENTION & HEALTH PROMOTION, <https://health.gov/healthypeople/objectives-and-data/browse-objectives/chronic-kidney-disease/increase-proportion-adults-chronic-kidney-disease-who-know-they-have-it-ckd-02> (last visited Feb. 15, 2021).

¹³¹ *National Center for Health Statistics: Leading Cause of Death*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 1, 2021), <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>.

¹³² Executive Order No. 13879, *supra* note 15 at 33,817.

Kidney Foundation and the American Society of Nephrology in the “Are You the 33%?” campaign to raise awareness about CKD.¹³³

The campaign focuses on providing information about early signs of CKD to adults who might be at risk.¹³⁴ Actress Wilmer Valderrama, the star formerly in *That ‘70s Show* and currently in CBS’s series *NCIS*, leads the campaign.¹³⁵ “The campaign will include many pathways to reach the [thirty-three] percent of Americans at risk, including a social media campaign, compelling visuals, and a [public service announcement] featuring Valderrama.”¹³⁶ The campaign pushes a quiz through the website “minuteforyourkidneys.org” that helps individuals recognize when they are at risk.¹³⁷ The CEO of the National Kidney Foundation announced the campaign’s ambitious goal to reach eighty million American adults who may be at risk for kidney disease.¹³⁸ The campaign’s bold target is motivated by the fact that so many who are suffering from kidney disease will not realize they are sick until they have ESRD and need dialysis or a kidney transplant in order to survive.¹³⁹

¹³³ *Secretary Azar Statement on Launch of Kidney Risk Awareness Campaign*, U.S. DEP’T OF HEALTH & HUMAN SERVS. (Mar. 2, 2020), <https://www.hhs.gov/about/news/2020/03/02/secretary-azar-statement-on-launch-of-kidney-risk-awareness-campaign.html>.

¹³⁴ Killian Gause, *NKF Launches “Are You the 33%?” Campaign to Raise Public Awareness for Adults at Risk of Developing Kidney Disease*, KIDNEY NEWS ONLINE (Mar. 2, 2020), <https://archive.kidneynews.org/policy-advocacy/leading-edge/nkf-launches-%E2%80%9CCare-you-the-33%E2%80%9D-campaign-to-raise-public-awareness-for-adults-risk-of-developing>.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

Although not connected to the *Initiative* or the “Are You the 33%?” campaign, the television show *B Positive*, directed by Chuck Lorre, starring Thomas Middleditch and Annaleigh Ashford, centers around kidney failure and kidney transplant.¹⁴⁰ The show timely addresses kidney issues and likely raises awareness regarding kidney health among its viewers.

iv. REFORM ORGAN TRANSPLANT SYSTEM TO MAKE MORE ORGANS AVAILABLE

As of January 11, 2016, over 100,000 people of the 121,678 on the organ transplant waitlist were waiting for a kidney transplant.¹⁴¹ Although this was over three years before President Trump’s Executive Order, it paints a dire picture of what kidney health in America is like.¹⁴² This data also indicates why HHS chose to prioritize a kidney health initiative in 2019. According to the same data, 3,000 new patients join the kidney waitlist each month.¹⁴³ Tragically, thirteen people die every day waiting for a lifesaving kidney transplant.¹⁴⁴ In 2014, a total of 4,761 died while on the waitlist for a kidney transplant.¹⁴⁵ That same year, 3,668 people became too sick for a kidney transplant while they were on the kidney transplant waitlist.¹⁴⁶

¹⁴⁰ Peter White, ‘*B Positive*’: CBS Hands Chuck Lorre Comedy Five-Episode Back Order, DEADLINE (Dec. 21, 2020), <https://deadline.com/2020/12/b-positive-cbs-chuck-lorre-comedy-five-episode-back-order-1234660192/>.

¹⁴¹ *Organ Donation and Transplantation Statistics*, NAT’L KIDNEY FOUND., <https://www.kidney.org/news/newsroom/factsheets/Organ-Donation-and-Transplantation-Stats> (last visited Feb. 15, 2021).

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

President Trump’s Executive Order sought to increase the number of organs available by incentivizing donors through a broader range of reimbursement options.¹⁴⁷ As directed by the executive order, the Department of Health and Human Services promulgated a final rule expanding reimbursement options for live organ donors.¹⁴⁸ Specifically, the rule expanded reimbursement to include payment for child-care services, elder-care services, and lost wages during the donation process.¹⁴⁹

c. HHS KIDNEY HEALTH INITIATIVE EFFECTIVENESS

A little over a year after announcing the *Initiative*, HHS issued a press release detailing the progress they have made on policy areas they were tasked with under the President’s Executive Order.¹⁵⁰ Along with beginning a public awareness campaign¹⁵¹ and promulgating new CMS and CMMI payment plans to benefit patients receiving ESRD treatment, the agency also issued a number of notices of proposed rulemaking for new rules in-line with the executive order.¹⁵²

¹⁴⁷ Executive Order No. 13879, *supra* note 15 at 33, 818.

¹⁴⁸ 42 C.F.R. § 121 (2020).

¹⁴⁹ *Id.*

¹⁵⁰ *HHS Reports Progress on President Trump’s ‘Advancing American Kidney Health’ Initiative*, DEP’T OF HEALTH & HUMAN SERVS. (Aug. 17, 2020), <https://www.hhs.gov/about/news/2020/08/17/hhs-reports-progress-on-president-trumps-advancing-american-kidney-health-initiative.html>.

¹⁵¹ Gause, *supra* note 134.

¹⁵² *HHS Reports Progress on President Trump’s ‘Advancing American Kidney Health’ Initiative*, *supra* note 150.

In addition to the press release, the Assistant Secretary for Planning and Evaluation released a separate Progress Report detailing HHS’s activities in response to the President’s executive order.¹⁵³

i. COVID-19 COMPLICATIONS

The COVID-19 pandemic tragically emphasized the need for quality kidney care within the United States. Patients with kidney disease or those who have had a kidney transplant are at a higher risk of developing complications from COVID-19.¹⁵⁴ Not only are CKD patients at a higher risk if they contract COVID-19, but ESRD patients are more likely to contract COVID-19 in the first place.¹⁵⁵ In response to this troubling data, HHS has—since the beginning of the pandemic—coordinated with the kidney health community to develop strategies for keeping at-risk kidney patients healthy.¹⁵⁶

d. THE HHS KIDNEY INITIATIVE’S PLACE IN A BIDEN HEALTHCARE WORLD

President Biden and his team have one solution for almost all healthcare issues: get the federal government involved.¹⁵⁷ As has already been noted, the Biden administration’s focus on healthcare is almost entirely on increasing government involvement by enlarging the federal government’s response to COVID-19, expanding the ACA, and creating a public healthcare

¹⁵³ *Advancing American Kidney Health*, *supra* note 100.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *See Health Care*, BIDEN HARRIS, *supra* note 42.

option.¹⁵⁸ Each of these agendas will take much of the administration's time and energy. This, coupled with the stigma of continuing an *Initiative* started by the previous administration, an administration Biden continually attacked throughout his presidential campaign, will discourage the Biden administration from continuing the *Initiative* no matter how effective it has been.¹⁵⁹ Indeed, within the first year and a half in office, the Biden Administration had taken no action toward American kidney health, to say nothing about continuing Trump's *Initiative*.

V. WILL BIDEN KEEP THE KIDNEY INITIATIVE?

The American people elected President Biden to the office of the Presidency because they wanted a change in leadership and direction. President Trump's approval rating was high during his final days in office,¹⁶⁰ but the American people voted for Biden to change course. Almost all of Biden's first acts as President were to undo actions that President Trump had taken.¹⁶¹ Beyond simply disagreeing with policy decisions, President Biden and his administration believe President Trump weakened the country's institutions.¹⁶² Because of this

¹⁵⁸ See *id*; *The Biden Plan To Combat Coronavirus (COVID-19) And Prepare For Future Global Health Threats*, BIDEN HARRIS, <https://joebiden.com/covid-plan/> (last visited Jan. 20, 2021) (explaining Biden's desire to create a strong federal response to the COVID-19 pandemic).

¹⁵⁹ Jarrett Renshaw, *Biden Attacks Trump Health Policy as 'Cruel' in Election Battleground State*, REUTERS (June 24, 2020), <https://www.reuters.com/article/us-usa-election-biden/biden-attacks-trump-health-policy-as-cruel-in-election-battleground-state-idUSKBN23W0GC>.

¹⁶⁰ Jeffery Martin, *Trump Job Approval Rating Rises As He Leaves Office, Faces Impeachment Trial: Rasmussen Poll*, NEWSWEEK (Jan. 19, 2021), <https://www.newsweek.com/trump-job-approval-rating-rises-he-leaves-office-faces-impeachment-trial-rasmussen-poll-1562794>.

¹⁶¹ Alice Ollstein, Arjun Kakkar, & Beatrice Jin, *The 17 Things Joe Biden Did on Day One*, POLITICO (January 21, 2021), https://www.politico.com/interactives/2021/interactive_biden-first-day-executive-orders/.

¹⁶² *Biden Administration's First White House Press Briefing With Jen Psaki on Inauguration Day*, REV (January 20, 2021), <https://www.rev.com/blog/transcripts/biden-administrations-first-white-house-press-briefing-with-jen-psaki-on-inauguration-day> (attacking the previous administration in her first press briefing, Secretary Jen Psaki stated "When the President asked me to serve in this role, we talked about the important of bringing truth and transparency back to the briefing room . . ."). *Id.*

attitude, and how vocal the Biden administration has been denouncing President Trump, it will likely be a difficult decision for them to continue any of the Trump Administration's agency policies, even uncontroversial ones like the HHS *Initiative*.

a. HOW PRESIDENTIAL ADMINISTRATIONS MAKE THESE DECISIONS

The decision to maintain, ignore, or reject the *Initiative* was a policy decision the Biden Administration faced when it entered office; and the Biden Administration appears to have rejected the *Initiative*, as it has taken no action to improve American kidney health within the first year and half controlling the executive branch. Although it is not uncommon for administrations to choose to continue a policy initiative of a previous administration when they are taking over after an administration of the same party, presidents of differing parties want to alter course from what their predecessor wished to accomplish.¹⁶³ When it comes to heavily politicized issues, it would be political suicide for an administration to continue a policy the opposing party had set in place.¹⁶⁴ However, for largely non-political issues that are out of the national spotlight, an administration might choose to continue the initiative if it fits into their overall healthcare agenda.¹⁶⁵

President Biden and Secretary Becerra have made it a priority to expand the ACA and to address the pandemic. Thus, they face a difficult decision on whether to devote the necessary resources to the Initiative, especially during a national pandemic. A wise counselor to the

¹⁶³ Bridget C. E. Dooling, *An Overview of Biden's First Regulatory Year*, BROOKINGS (Jan. 20, 2022), <https://www.brookings.edu/blog/up-front/2022/01/20/an-overview-of-bidens-first-regulatory-year/>.

¹⁶⁴ See John Cassidy, *Obama and the Bush Legacy: A Scorecard*, THE NEW YORKER (May 31, 2012), <https://www.newyorker.com/news/john-cassidy/obama-and-the-bush-legacy-a-scorecard>.

¹⁶⁵ See *id.*

President could see this as an opportunity for the Biden team; the Trump administration, after all, already put much research and effort into this *Initiative* and has found some success. Kidney health is an issue for millions across the United States,¹⁶⁶ and the Biden Administration could easily co-opt the *Initiative* into their own healthcare agenda, use the Trump administration’s research and innovation to pursue the *Initiative*’s goals, and claim any success from their efforts as their own. In other words, while the Biden administration will likely flinch at the idea of actively continuing a Trump Administration policy, using the manpower and research the Trump Administration put into the *Initiative* could help an already spread-thin HHS.¹⁶⁷

b. EXAMPLE OF POLICY CHANGES BETWEEN ADMINISTRATIONS

The oft changing “Waters of the United States” rule provides a helpful case-study in understanding Presidential transitions and policy changes at agencies.¹⁶⁸ Understanding how administrations have altered the Waters of the United States rule is instructive in understanding the fate of the *Initiative*. Although changes to the Waters of the United States rule deal with a final rule and must go through the extensive rulemaking process,¹⁶⁹ how administrations choose

¹⁶⁶ *37 Million American Adults Now Estimated to Have Chronic Kidney Disease*, NAT’L KIDNEY FOUND., *supra* note 55.

¹⁶⁷ Jon Sanders, *Biden’s HHS: We Don’t Have Time to Review Regulations, We’re Too Busy Enforcing Them*, AM. INST. FOR ECON. RES. (Nov. 23, 2021), <https://www.aier.org/article/bidens-hhs-we-dont-have-time-to-review-regulations-were-too-busy-enforcing-them/> (stating that “HHS is so chock-full of regulations to enforce that it would be a terrible strain on staffing resources just to see which regulations are not worth enforcing.”).

¹⁶⁸ *See About Waters of the United States*, ENVTL. PROTECTION AGENCY, <https://www.epa.gov/wotus/about-waters-united-states> (last updated Dec. 20, 2021).

¹⁶⁹ *See generally A Guide to the Rulemaking Process*, OFF. OF THE FED. REG., https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf (last accessed Feb. 15, 2021) (discussing how an agency, to create a final rule, must follow established procedure and publish a copy of the proposed rule in the Federal Register before publishing the final version. This is formally called “Advanced Notice of Proposed Rulemaking” but is commonly referred to as “notice and comment” rulemaking. During notice and comment, any interested party, including individuals and organizations, can provide the agency with their opinion of the rule and how the rule might impact them. Notice and

to make changes and the processes Presidents take to alter the rule are similar to how the Biden Administration dealt with the *Initiative*.

i. “NAVIGABLE WATERS” UNDER THE CLEAN WATER ACT

Per the Environmental Protection Agency (EPA), “[t]he Clean Water Act (CWA) establishes the basic structure for regulating discharges of pollutants into the waters of the United States and regulating quality standards for surface waters.”¹⁷⁰ However, in the early 2000s, disputes arose regarding which “waters” the EPA could control.¹⁷¹ In 2001 and 2009, the Supreme Court refused to apply the Clean Water Act’s restrictions in landfill and wetland scenarios.¹⁷² In response to this confusion, the Obama administration promulgated a rule called the “Clean Water Rule” (WOTUS) in 2015 that “define[d] which wetlands and streams [were] subject to protection under the Clean Water Act.”¹⁷³ The new rule took effect on August 28, 2015.¹⁷⁴ Immediately, it faced court challenges from twenty-seven states.¹⁷⁵ The states argued

comment generally last somewhere between thirty to sixty days. Although an agency must incorporate a response to comments, an agency is not permitted to base its conclusion and the final rule on the number of comments in support of the rule over those against it. After considering all the comments gathered during the notice and comment period, and detailing any data behind the rule, an agency may publish a final rule in the Federal Register. The final rule will include a date on which it becomes effective, usually no less than thirty days after the date of publication of the final rule in the Federal Register.).

¹⁷⁰ *Summary of the Clean Water Act*, ENV’T PROTECTION AGENCY (Sept. 9, 2020), <https://www.epa.gov/laws-regulations/summary-clean-water-act>.

¹⁷¹ *Defining Waters of the United States / Clean Water Rule*, HARV. ENV’T & ENERGY L. PROGRAM (Sept. 22, 2017), <https://eelp.law.harvard.edu/2017/09/defining-waters-of-the-united-states-clean-water-rule/>.

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

that the new rule violated the Clean Water Act and previous Supreme Court rulings.¹⁷⁶ The U.S. District Court for the District of North Dakota issued a preliminary injunction, which prevented implementation of the 2015 Clean Water Rule in 13 states challenging the rule in court.¹⁷⁷

Where states implemented the Clean Water Rule, it created “regulatory uncertainty since much of the jurisdiction [was] left to case-by-case determination and [was] burdensome given the large fines imposed by the Clean Water Act.”¹⁷⁸ Thus, protection under the Clean Water Rule made it difficult to interpret if the clean water act applied.¹⁷⁹ Fines for mistakes were expensive, sometimes totaling over \$25,000 for violators.¹⁸⁰ In addition to this costly confusion, critics noted that the rule failed to adequately address significant sources of water pollution like “nonpoint emissions.”¹⁸¹ Point source emissions “means any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged.”¹⁸² In contrast, nonpoint source emission “is defined to mean any source of water pollution that does not meet the legal definition

¹⁷⁶ Timothy Cama, *27 States Challenge Obama Water Rule in Court*, THE HILL (June 30, 2015), <https://thehill.com/policy/energy-environment/246539-27-states-challenge-obama-water-rule-in-court>.

¹⁷⁷ *Defining Waters of the United States / Clean Water Rule*, *supra* note 158.

¹⁷⁸ Nathan P. Hendricks, *Waters of the US Rule and Clean Water Act fail to Provide Cost-Effective Improvements in Water Quality*, AM. ENTER. INST. (Nov. 30, 2017), <https://www.aei.org/research-products/report/waters-of-the-us-rule-and-clean-water-act-fail-to-provide-cost-effective-improvements-in-water-quality/>.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Polluted Runoff: Nonpoint Source (NPS) Pollution*, ENV'T'L PROTECTION AGENCY (October 8, 2020), <https://www.epa.gov/nps/basic-information-about-nonpoint-source-nps-pollution>.

of ‘point source.’”¹⁸³ The Obama administration’s rule left nonpoint emissions largely exempt.¹⁸⁴

The American Enterprise Institute argued in 2017 that “the WOTUS rule fail[ed] to address pollution from nonpoint sources and ongoing farming activity. It [did] not estimate the cost and benefit trade-offs well. In the past 25 years, water quality has seldom improved.”¹⁸⁵

While the situation marinated in the courts, the United States elected Donald Trump President.¹⁸⁶ Within two months of his inauguration, Trump issued an Executive Order directly addressing the WOTUS rule:

In connection with the proposed rule described in section 2(a) of this order, the Administrator [of the EPA] and the Assistant Secretary [of the Army for Civil Works] shall consider interpreting the term “navigable waters,” as defined in 33 U.S.C. 1362(7), in a manner consistent with the opinion of Justice Antonin Scalia in *Rapanos v. United States*, 547 U.S. 715 (2006).¹⁸⁷

Justice Scalia’s definition did “not refer to water in general; rather, [the] term include[d] only relatively permanent, standing or flowing bodies of water.”¹⁸⁸ The Trump administration repealed the Obama-era Clean Water Rule and replaced it with their own rule that “drastically narrow[ed] the definition” of the applicable term.”¹⁸⁹ Although the Trump administration touted

¹⁸³ *Id.*

¹⁸⁴ Hendricks, *supra* note 178.

¹⁸⁵ *Id.*

¹⁸⁶ *Trump Wins Presidency, Defeats Clinton in Historic Election Upset*, FOX NEWS (Nov. 8, 2016), <https://www.foxnews.com/politics/trump-wins-presidency-defeats-clinton-in-historic-election-upset>.

¹⁸⁷ *Restoring the Rule of Law, Federalism, and Economic Growth by Reviewing the “Waters of the United States” Rule*, WHITE HOUSE (Feb. 28, 2017), <https://www.federalregister.gov/documents/2017/03/03/2017-04353/restoring-the-rule-of-law-federalism-and-economic-growth-by-reviewing-the-waters-of-the-united>.

¹⁸⁸ *Rapanos v. United States*, 547 U.S. 715, 732 (2006).

¹⁸⁹ Lisa Friedman & Coral Davenport, *Trump Administration Rolls Back Clean Water Protections*, N.Y. TIMES (Sept. 12, 2020), <https://www.nytimes.com/2019/09/12/climate/trump-administration-rolls-back-clean-water-protections.html>.

the rule change as fulfillment of a campaign promise and the “end [of] an egregious power-grab,” environmentalists feared the new rule would allow water pollution.¹⁹⁰ Patrick Parenteau, an environmental law professor at Vermont Law School, said the new rule would be “an opportunity to really drive a stake through the heart of federal water protection.”¹⁹¹ Laura Rubin from Healing Our Waters-Great Lakes Coalition said, in response to the Trump administration rule, “[w]ith many of our cities and towns living with unsafe drinking water, now is not the time to cut back on clean water enforcement.”¹⁹²

However, although many environmentalist groups had harsh words for the new, narrow rule, a myriad of voices supported it, including members of Trump’s cabinet, Senators, governors, United States Representatives, state officials, and water industry stakeholders.¹⁹³

Notably, Indiana Attorney General Curtis Hill praised the new rule, saying:

“The final Navigable Waters Protection Rule appropriately replaces the Obama-era rule that expanded the definition of ‘waters of the United States’ to include land areas that only get wet when it rains. This broad designation allowed federal authorities to claim jurisdiction over private property in Indiana. Hours after I had the privilege of meeting President Trump at the White House in February of 2017, he announced an executive order directing federal authorities to review the WOTUS rule, demonstrating his resolve to properly balance the needs to protect our environment, promote economic growth and respect the constitutional roles of the U.S. Congress and the individual states.”¹⁹⁴

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² *Id.*

¹⁹³ *News Release: More Widespread Support for EPA and Army’s Navigable Waters Protection Rule – A New Definition of WOTUS*, ENVTL. PROTECTION AGENCY (Jan. 24, 2020), <https://www.epa.gov/newsreleases/more-widespread-support-epa-and-armys-navigable-waters-protection-rule-new-definition>.

¹⁹⁴ *Id.*

In addition to praise from Indiana state officials, Daren Bakts, Heritage Foundation Senior Research Fellow, commended the federal rule, writing that

For decades, the EPA and [Army] Corps [of Engineers] have ignored the Clean Water Act and the U.S. Constitution to regulate almost every water imaginable, culminating in the Obama Administration's WOTUS rule that took the disrespect for the rule of law to a new level. To its credit, the Trump Administration is trying something different with its new final rule on navigable waters: it is trying to actually follow the law.

While the law may be an inconvenient nuisance for those who believe in concentrated federal power, the EPA and Corps may not simply ignore what Congress has directed or the limits placed on the agencies by the U.S. Constitution. Beyond simply following the law, this new rule rightfully rejects the idea that Washington bureaucrats must regulate every drop of water in the country in order to effectively protect our nation's waters.

The final rule is also designed to protect the environment while respecting the property rights of all Americans. The Navigable Waters Protection Rule will help end the excessive overreach of the past that caused regulatory nightmares for so many Americans, including farmers who simply wanted to farm their land and families looking to build their homes. Further, by having greater clarity, the EPA and Corps will be better able to implement and enforce the law, which should help lead to a cleaner environment.¹⁹⁵

The Trump Administration reversed the direction the Obama-era EPA had taken regarding the Clean Water Act, and the Biden Administration has indicated it will reverse the Trump Administration's approach and attempt to return to the Obama-era.¹⁹⁶ In an Executive Order issued on Inauguration Day, President Biden revoked Trump's Executive Order instructing the EPA and Army Corps of Engineers to alter the Clean Water Rule.¹⁹⁷ In response, the

¹⁹⁵ *Id.*

¹⁹⁶ *Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis*, WHITE HOUSE (Jan. 20, 2021), <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-protecting-public-health-and-environment-and-restoring-science-to-tackle-climate-crisis/>.

¹⁹⁷ *Id.*

Department of the Army, Corps of Engineers, Department of Defense, and the Environmental Protection Agency issued a proposed rule aimed at revising the Waters of the United States definition.¹⁹⁸ Those agencies have continued working on that proposed rule since they published the notice on December 7, 2021.¹⁹⁹

c. COMPARING WOTUS TO THE *INITIATIVE*

When deciding whether to keep a policy or not, presidential administrations weigh the policy's goals against the goals of the administration.²⁰⁰ In early 2017, when the Trump Administration arrived on the scene, they saw the Obama-era Clean Water Rule as government overreach.²⁰¹ Donald Trump had made a campaign promise of curtailing government regulations in an attempt to boost the economy.²⁰² Thus, when the Trump Administration took over, they weighed the Clean Water Rule's goals against their own goals. The Obama Administration created the Clean Water Rule to empower the EPA to carefully monitor pollution of bodies of water and waterways in the United States.²⁰³ Although the Trump Administration also wanted to

¹⁹⁸ Revised Definition of "Waters of the United States," 86 Fed. Reg. 69372 (proposed Dec. 7, 2021) (to be codified at 40 C.F.R. pt. 120 and 33 C.F.R. pt. 328).

¹⁹⁹ Ryan J. Strasser, Tanner Brantley, Morgan Gerard, & Timothy McHugh, *Biden Administration Presses Forward With Revised WOTUS Rule*, ENVTL. L. AND POL'Y MONITOR (Feb. 1, 2022), <https://www.environmentallawandpolicy.com/2022/02/biden-administration-presses-forward-with-revised-wotus-rule/>.

²⁰⁰ See NCC Staff, *Executive Orders 101: What Are They and How Do Presidents Use Them?*, NAT'L CONST. CTR. (Jan. 23, 2017), <https://constitutioncenter.org/blog/executive-orders-101-what-are-they-and-how-do-presidents-use-them/>; *Executive Orders*, THE HERITAGE FOUND., <https://www.heritage.org/political-process/heritage-explains/executive-orders> (last visited Apr. 16, 2022).

²⁰¹ Friedman, *supra* note 189.

²⁰² Clyde Wayne Crews Jr., *Donald Trump Promises to Eliminate Two Regulations for Every One Enacted*, FORBES (Nov. 22, 2016), <https://www.forbes.com/sites/waynecrews/2016/11/22/donald-trump-promises-to-eliminate-two-regulations-for-every-one-enacted/>.

²⁰³ *Summary of the Clean Water Act*, ENVTL. PROTECTION AGENCY, <https://www.epa.gov/laws-regulations/summary-clean-water-act> (last accessed Mar. 29, 2021).

maintain clean water, they felt the Obama Clean Water Rule was overly burdensome and ineffective in accomplishing its intended purpose.²⁰⁴ As such, President Trump signed an Executive Order requesting the EPA to change the order.²⁰⁵

Similarly, when the Biden Administration took over in early 2021, they were far less concerned with President Trump's deregulation efforts. President Biden prioritized environmental issues while campaigning and even discussed clean water.²⁰⁶ His emphasis on the environment, along with his desire to return the United States to an Obama-style era, makes clear why his administration has strong incentive to reinstate the Obama-era Clean Water Rule.

In addition to these policy preferences, Presidential administrations consult industry players and policy think tanks when implementing new policy.²⁰⁷ When analyzing the Clean Water Rule, the Trump administration listened to state attorney generals, mining and agricultural organization CEOs, and Heritage Foundation Senior Fellows.²⁰⁸ The Biden administration will likely consider environmentalist group's input when creating the new WOTUS rule.

These policy and industry preferences will influence the Biden Administration's decision to keep or reject the *Initiative*.²⁰⁹ Since the Biden Administration has emphasized a desire for a

²⁰⁴ See Friedman, *supra* note 189.

²⁰⁵ *Id.*

²⁰⁶ Jacob Pramuk, *Read Joe Biden's Full 2020 Democratic National Convention Speech*, CNBC (August 21, 2020), <https://www.cnbc.com/2020/08/21/joe-biden-dnc-speech-transcript.html>; Joseph Biden, 2020 Democratic National Convention Nominee Acceptance Speech, (Aug. 20, 2020) (transcript available at <https://www.cnbc.com/2020/08/21/joe-biden-dnc-speech-transcript.html>).

²⁰⁷ See *supra* Part V(b)(i).

²⁰⁸ *News Release: More Widespread Support for EPA an Army's Navigable Waters Protection Rule – A New Definition of WOTUS*, *supra* note 193.

²⁰⁹ See *supra* Part V(b)(i).

strong federal healthcare response, they will likely weigh that preference against the *Initiative's* goals.²¹⁰ In addition, the Biden administration's, focus on expanding the ACA and creating a new public option (when the administration is not dealing with the coronavirus pandemic) will lessen their ability to address lingering Trump administration initiatives.²¹¹

Just as the Biden administration will weigh the *Initiative's* policy goals and effectiveness, it will likely also consider industry input.²¹² Notably, the kidney world wants to see President Biden continue focusing resources on kidney health.²¹³ Over twenty healthcare organizations wrote a letter to the Biden administration to request that his administration prioritize kidney health.

On behalf of the nation's 37 million Americans living with kidney diseases and the tens of thousands of kidney health professionals who care for them, we, the undersigned organizations, stand ready to collaborate with you and your administration to advance policies that will benefit people with kidney diseases and their families.

Our organizations are dedicated to improving the lives of people affected by this costly and under-recognized public health epidemic—an epidemic marked by its disproportionate effect on communities of color and worsened by the COVID-19 pandemic. For example, Black Americans make up just 13 percent of the U.S. population, but approximately 33 percent of those on dialysis. People on dialysis who suffer from COVID-19 are hospitalized more frequently than any other group of Medicare beneficiaries, and in many previously healthy patients, the novel SARS-COV2 virus causes acute and sometimes lasting kidney impairment. The COVID-19 pandemic has made many of our organizations' goals on behalf of people with kidney diseases all the more urgent to achieve and sustain.

²¹⁰ *See supra* Part II.

²¹¹ *Id.*

²¹² *See supra* Part V(b)(i).

²¹³ Letter from Kidney Health Professionals to President Biden & Vice President Harris, (Feb. 1, 2021) https://cdn.ymaws.com/www.renalmd.org/resource/resmgr/legregscomp/federal_agencies/21.2.1bidenco mmsignonletter0.pdf.

As the country begins to build back better under your leadership, our organizations urge you to seize the moment on behalf of people with kidney diseases and those at risk for kidney diseases.²¹⁴

The National Kidney Foundation went so far as to encourage the Biden administration to continue President Trump's *Initiative*:

In July 2019, the Trump Administration launched the Advancing American Kidney Health initiative (AAKH), a public health initiative focused on improving the lives of Americans suffering from kidney disease, expanding options for patients, and reducing healthcare costs.

NKF encourages the Biden-Harris Administration to maintain the ESRD Treatment Choices Model (ETC) and the Kidney Care Choices Models, which are designed to slow the progression of kidney disease, expand patient access to home dialysis, and increase kidney transplantation.

NKF also encourages the new Administration to build on the main pillars of AAKH[] and expand the initiative's focus on public health infrastructure for kidney disease, kidney care disparities, access to kidney transplant, care partner support for home dialysis patients[,] and innovative approaches to treatment kidney failure.²¹⁵

If the Biden administration hears industry voices supporting a kidney approach, and enough industry voices specifically request that he continue implementing the *Initiative*, the Biden team might determine to keep the *Initiative*.²¹⁶ However, since the Biden administration favors direct federal involvement and the *Initiative* does not focus on federal regulation to solve kidney health issues, a Becerra-directed HHS might ignore the *Initiative* and create their own kidney health initiative in its place.²¹⁷

²¹⁴ *Id.*

²¹⁵ *National Kidney Foundation Calls on Biden-Harris Administration to Prioritize Kidney Disease in the First 100 Days*, NAT'L KIDNEY FOUND. (Dec. 3, 2020), <https://www.prnewswire.com/news-releases/national-kidney-foundation-calls-on-biden-harris-administration-to-prioritize-kidney-disease-in-the-first-100-days-301185679.html>.

²¹⁶ *See* Josh Lederman & Zoe Richards, *Biden Administration to Resume Leasing for Oil and Gas Drilling on Federal Lands*, NBC NEWS (Apr. 15, 2022, 6:09 PM), <https://www.cnbc.com/2022/04/15/biden-administration-to-resume-leasing-for-oil-and-gas-drilling-on-federal-lands.html>.

²¹⁷ *See supra* Part II.

a. PROCEDURAL PROCESS FOR MAINTAINING THE *INITIATIVE*

The Clean Water Rule demonstrates how Presidential administrations keep and revoke agency policies, when possible, using Executive Order.²¹⁸ Because President Trump empowered HHS to advance the *Initiative* through an Executive Order issued on July 10, 2019, President Biden may revoke the Executive Order to render it powerless.²¹⁹ However, Article II of the Constitution empowers the President to execute federal laws, so President Biden’s HHS team could also refuse to implement the *Initiative*.²²⁰ If Becerra and the Biden HHS team refuse to focus efforts on the *Initiative*, they will have constructively rescinded it.²²¹ However, similarly, the Biden administration can enforce the *Initiative* simply by prioritizing its implementation at HHS.²²² In other words, President Biden would not have to issue another Executive Order for HHS to focus on the *Initiative*.²²³

i. MIDNIGHT RULEMAKING

“During the final months of recent presidential Administrations, federal agencies have issued an increased number of regulations. The phenomenon is often referred to as ‘midnight rulemaking.’”²²⁴ The out-going administration’s motivation for this midnight rulemaking is to

²¹⁸ See *supra* Part V(b)(i).

²¹⁹ See *White House Revokes Prior Administration’s Regulatory Reform Executive Orders*, JONES DAY (Jan. 2021), <https://www.jonesday.com/en/insights/2021/01/white-house-revokes-prior-administrations-regulatory-reform-executive-orders>.

²²⁰ U.S. CONST. art. II, § 1, cl. 1.

²²¹ *Presidential Transitions: Issues Involving Outgoing and Incoming Administrations*, CRS REPORT (May 17, 2017), <https://www.everycrsreport.com/reports/RL34722.html>.

²²² See generally *id.*

²²³ See *id.*

²²⁴ *Id.*

solidify its positions through regulations that are difficult to reverse.²²⁵ However, one concern with midnight rulemaking is the lack of political accountability.²²⁶ The administration is leaving office because they have either lost an election or their term is up, and they no longer need to maintain a high approval rating for re-election.²²⁷ Another issue is that the quality of midnight rules might suffer because they are hastily written without due input from affected parties.²²⁸ Despite these issues, a 2012 study from the Administrative Conference of the United States found that midnight regulations are “relatively routine matters not implicating new policy initiatives by incumbent administrations,” and the “majority of the rules appear to be the result of finishing tasks that were initiated before the Presidential transition period or the result of deadlines outside the agency’s control (such as year-end statutory or court-ordered deadlines).”²²⁹

ii. PUTTING A STOP TO MIDNIGHT RULEMAKING

When a new President takes office, one of the first things he does is issue an order to the federal agencies to stop all active rulemaking.²³⁰ “Such moratoria have sometimes been accompanied by a requirement that the departments and agencies postpone the effective dates of certain rules that were issued at the end of the previous President’s term.”²³¹ For example, in

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ *Id.*

²²⁸ *Id.*

²²⁹ Jack M. Beermann, *Midnight Rules: A Reform Agenda*, BOS. U. SCH. OF L. (Mar. 3, 2012), https://scholarship.law.bu.edu/faculty_scholarship/61/.

²³⁰ CRS REPORT, *supra* note 221.

²³¹ *Id.*

2009, President Obama’s Chief of Staff, Rahm Emanuel, sent a memorandum to the executive agencies ordering that they:

(1) not send proposed or final rules to the Office of the Federal Register, (2) withdraw from the Office rules that had not yet been published in the *Federal Register*, and (3) consider postponing for 60 days the effective dates of rules that had been published in the *Federal Register* but had not yet taken effect.²³²

To thwart these efforts, however, previous administrations sometimes direct the executive agencies to complete any rulemaking before the end of the term.²³³

From this, it is clear an administration seeking to end a previous administration’s policy created through executive order (like the HHS *Initiative*) must issue its own order.²³⁴ Career employees at an agency will continue to work on the previous administration’s policies until they are directly told otherwise by the new President or his team.²³⁵

This means HHS will continue to implement the *Initiative* unless the Biden Administration dictates otherwise through an executive order.²³⁶ The Biden Administration may divert HHS from the *Initiative* by pushing their own healthcare agenda.²³⁷ Indeed, in the first year and a half of his Presidency, President Biden’s ambitious healthcare goals resulted in his administration taking no action toward American kidney health.

²³² *Id.*

²³³ *Id.*

²³⁴ See Meredith Conroy, *Why Revoking Trump’s Executive Orders Isn’t Enough to Undo Their Effects*, FIVETHIRTYEIGHT (Feb. 11, 2021, 6:00 AM), <https://fivethirtyeight.com/features/why-revoking-trumps-executive-orders-isnt-enough-to-undo-their-effects/>.

²³⁵ See *id.* (stating that “[o]nce an agency moves in [a] direction — updating standard operating procedures and perhaps even agency culture — it can be difficult to reverse course.”).

²³⁶ See generally *id.*

²³⁷ See *supra* Part II.

VI. CONCLUSION

For the reasons discussed above, the Biden administration should continue implementing the *Initiative*. The COVID-19 crisis has emphasized the need for a strong focus on increased kidney care in the United States.²³⁸ Kidney health is a major issue, especially during a national pandemic, and President Trump's HHS team correctly focused kidney health efforts on notifying millions of Americans who have kidney disease and are not aware they are sick.²³⁹ In addition, President Trump's HHS team worked on in-home dialysis for kidney patients.²⁴⁰ In-home dialysis is effective because it allows patients to conduct dialysis more frequently and in a more comfortable environment.²⁴¹

President Trump's HHS team also focused on incentivizing and encouraging development of artificial kidneys to reduce the number of patients on the waitlist for kidneys.²⁴² However, while engineers develop effective artificial kidneys, President Trump's HHS team worked to change payment plans to make it more convenient for willing parties to participate in kidney donor programs.²⁴³

Since his inauguration in early 2021, President Biden and his HHS team have focused on the COVID-19 pandemic and expanding the ACA, but they would be wise to also continue President Trump's *Initiative*.²⁴⁴ The *Initiative* has proven successful in the short-term and would

²³⁸ *Advancing American Kidney Health*, *supra* note 100.

²³⁹ *Secretary Azar Statement on Launch of Kidney Risk Awareness Campaign*, *supra* note 133.

²⁴⁰ Graham, *supra* note 126.

²⁴¹ *Id.*

²⁴² Executive Order No. 13879, *supra* note 15 at 33,818.

²⁴³ *Id.*

²⁴⁴ Alyssa Llamas & Dawn Joyce, *Biden Lays Out His Health Policy Agenda*, CAL. HEALTH CARE FOUND. (Mar. 25, 2022), <https://www.chcf.org/blog/biden-lays-out-his-health-policy-agenda/>.

likely lead to healthier kidneys nationwide during President Biden’s first term.²⁴⁵ The Biden administration could claim any kidney-health success under the *Initiative* as their own. An HHS team sincerely dedicated to bettering American public health should continue the *Initiative* because the *Advancing American Kidney Health Initiative* will do just that for millions of sick kidney patients across the country.

²⁴⁵ *Advancing American Kidney Health*, *supra* note 100.