



The Health Care Priorities of the Biden-Harris Administration and Post-Election Outlook for the 117th Congress

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FOLEY HOAG LLP

SUMMARY

In a historic presidential election that began during the COVID-19 pandemic and ended with record voter turnout and mail in ballots, former Vice President Joseph Biden of Delaware was declared the 46th president of the United States, and Senator Kamala Harris of California was elected the first woman, African-American, and Asian-American to hold the office of Vice President. As President-elect Biden prepares for the transition to the presidency, President Trump's campaign and the Republican National Committee have filed numerous legal challenges in several battleground states. Additionally, two run-off elections in Georgia on January 5, 2021 will determine the majority of the Senate.

Health care issues loomed large throughout the campaign. The federal government's response to the COVID-19 pandemic was a central issue, particularly in the closing weeks as President Trump and other senior administration officials tested positive for the coronavirus. The confirmation battle over Justice Amy Coney Barrett to the Supreme Court of the United States, and oral arguments in *California v. Texas* scheduled exactly one week after the presidential election, focused debate on the future of the Affordable Care Act (ACA). Additionally, President Trump campaigned that he "has already done more than any other President to lower drug costs," while the Biden campaign championed drug pricing policies based on government negotiation and importation of drugs.

While it is not certain how the next several weeks will play out with the legal challenges and Senate run-off elections, it is clear that President-elect Biden plans to move aggressively on a national plan to combat the COVID-19 pandemic, prioritize strengthening the ACA, and address health disparities and persons with disabilities. Much of the early efforts of the Biden-Harris Administration will be through executive branch actions to reverse Trump Administration policies, and develop new administrative actions and rulemakings. Below is a high-level overview of the transition process and key health care priorities of the Biden-Harris Administration.

THE TRANSITION PERIOD

In the days following the election, President Trump's campaign launched legal challenges in Michigan, Pennsylvania, Arizona, Georgia, and Nevada. While judges have rejected many of these suits, these legal challenges could frustrate the transition process. In addition, the Trump campaign will pursue recounts in several states, including Wisconsin and Georgia, which could take weeks to resolve. With the Senate majority still unresolved, the lame duck session of Congress will be overshadowed by two Senate runoffs in Georgia that will determine the Senate majority in the next Congress.

While the Trump Administration may seek to finalize various health care regulations in the remaining weeks, an incoming Biden Administration can block implementation of any

regulations released by the Trump Administration after the election, while disrupting the implementation of older ones. For rules that are proposed but not yet published as final in the Federal Register, a Biden Administration could halt those rules and impose a moratorium on rulemaking across federal agencies. For published rules that have not yet taken effect, because of the APA's mandatory 30-day waiting period, a Biden Administration could postpone the effective dates of those rules, likely by 60 days (given the practices of previous Presidents). The Biden Administration may attempt to use Interim Final Rules to repeal postponed Trump rules without notice and comment.

Examples of recently proposed rules include the "Securing Updated and Necessary Statutory Evaluations Timely," issued by HHS on November 4th, which provides that all regulations issued by HHS shall expire at the end of two calendar years after the year that the proposed rule first becomes effective, ten calendar years after the year of the regulation's promulgation, or ten calendar years after the last year in which the Department assessed the regulation. Additionally, prior to the election, Trump Administration officials had indicated they would finalize several drug pricing policies including the Medicaid Drug Rebate Program (MDRP) proposed rule. While there was support for some aspects of the proposed rule such as value-based arrangements for pharmaceutical products, there was significant opposition to line extension policy. It is unclear whether the Administration will attempt to finalize these policies, and whether the incoming Administration would block them.

During the final weeks of the campaign, President Trump suggested he might take action against key Administration officials following the election, such as against Dr. Anthony Fauci, under the October 21 executive order removing civil service protections from career federal officials. Any such actions would also be opposed and reversed by the incoming Biden Administration.

Biden/Harris Transition Team

President-elect Biden and Vice-president elect Harris will move full speed with the transition process while the legal challenges play out. The Biden-Harris transition team has already announced a task force led by former Surgeon General Vivek Murthy, former FDA Commissioner David Kessler, and Yale associate dean Marcella Nunez-Smith to promote widespread COVID-19 testing and social distancing measures prior to the distribution of a vaccine, and to assure equitable distribution of FDA-approved SARS-CoV-2 vaccines. The 12-member Biden transition task force on COVID-19 will also include: **Luciana Borio**, former assistant FDA commissioner; **Rick Bright**, former BARDA director; **Ezekiel Emanuel**, former Obama administration health policy adviser; **Atul Gawande**, Brigham and Women's hospital professor of surgery; **Celine Gounder**, NYU Grossman School of Medicine assistant professor; **Dr. Julie Morita**, former Chicago public health commissioner; **Michael Osterholm**, director of the Center for Infectious Disease Research and Policy at the University of Minnesota; **Loyce**

Pace, executive director of the Global Health Council; **Dr. Robert Rodriguez**, UCSF emergency medicine professor; and **Eric Goosby**, former Ryan White Care Act director.

During the campaign, Biden had announced that his former chief of staff and former Senator Ted Kaufman (D-DE), along with co-chairs New Mexico Governor Michelle Lujan Grisham and Representative Cedric Richmond (D-LA), would head his transition team. The Biden transition team has been vetting potential candidates for months and will present the president-elect with potential choices in the coming days. President-elect Biden is expected to start to announce his cabinet in the coming weeks with the first announcements involving public health and the economy, including the secretaries of the Treasury and Health and Human Services. Speculation on potential HHS nominees includes New Mexico Gov. Michelle Lujan Grisham and Congressional Black Caucus leader Rep. Karen Bass (D-Calif.)—as well as former Surgeon General Vivek Murthy and North Carolina Health Secretary Mandy Cohen.

COVID-19 PANDEMIC RESPONSE

Consistent with his campaign promises, President-elect Biden has announced that the first priority of his transition and the early part of his Administration will be combatting the COVID-19 pandemic in a more comprehensive and science-based fashion than has the Trump Administration. Biden has stressed the importance of following the science in making his decisions, and is expected to give prominence to government experts such as Dr. Anthony Fauci. It is likely the new Administration will designate a “COVID-19 czar” to coordinate the Federal response, as the Obama Administration did for Ebola.

While issuance of Emergency Use Authorizations (EUAs) of COVID-19 vaccine candidates is likely to occur during the lame duck period, the Biden-Harris Administration will be focused intensely on rapid production and nationwide distribution of the vaccine. The campaign has supported an additional \$25 billion for distribution of the vaccine to promote access without cost. Similarly, the Biden-Harris Administration will enhance and accelerate additional testing capacity and technologies for both diagnostic and screening testing, scrutinizing and augmenting investments to date by NIH and BARDA to accelerate the development of rapid diagnostic and screening tests (as well as vaccines). The new Administration also plans to establish a Pandemic Testing Board to oversee the production and distribution of tens of millions of tests, establish at least ten mobile testing sites and drive-through facilities per state, and expand CDC sentinel surveillance programs.

The Biden Administration plans to take a national approach to combatting the pandemic in close coordination with state and local elected officials. The Administration through the CDC will establish a common set of standards and best practices for states and local communities to implement based on the level of risk and degree of viral spread in a community. Biden is likely to encourage mandates by state and local governments on residents to wear masks when around

people outside the home. The Administration may also invoke the Defense Production Act in additional ways to increase mask, face shield, and other PPE production so that supply exceeds demand and stockpiles are replenished. With respect to schools, a Biden Department of Education is likely to focus on developing best practices for schools to open safely with appropriate PPE, testing and social distance protocols. A major increase in screening and diagnostic testing capacity and turnaround time is likely to be a critical priority with respect to reopening schools. Another important priority will be the need to better support frontline workers with respect to access to PPE and COVID-19, as well as childcare assistance and other emergency COVID-19 support. Biden also supports premium pay for frontline workers, though this would likely require legislation.

A Biden Administration is expected to be particularly focused on high-risk groups like the elderly and front line workers, along with health disparities disadvantaging minority populations. One step the campaign touted was creating a National Pandemic Dashboard to allow Americans to check local transmission by ZIP code so older Americans and others at risk can take appropriate precautions. Vice President-elect Harris and Dr. Nunez-Smith have also spoken extensively about the need to address the disparate impact of COVID-19 on minority communities. Biden has promised to create a COVID-19 Racial and Ethnic Disparities Task Force to offer recommendations and oversight relative to public health and pandemic response disparities. After the pandemic, the campaign has indicated that this task force would become a permanent Infectious Disease Racial Disparities Task Force.

Finally, with respect to preparedness for future pandemics, the Biden Administration would likely focus primarily on reinstating and expanding the anti-pandemic tools put in place by the Obama Administration. This will probably include restoring White House National Security Council Directorate for Global Health Security and Biodefense and USAID's pathogen tracking project (PREDICT). A Biden Administration will rejoin the World Health Organization (WHO), and expand the global deployment of CDC "disease detectives." Biden is also likely to maintain a focus on the manufacturing sector, having made the renewal of US manufacturing of PPE in preparation for future crises a centerpiece of his recovery plan.

FOOD AND DRUG ADMINISTRATION

In addition to a principal focus on COVID-19 countermeasures, the Food and Drug Administration (FDA) under the Biden-Harris Administration will take steps to reinforce its reputation for science-based decision-making on product approvals in order to reverse the Trump Administration's actions and rhetoric that cast doubts among some stakeholders on the integrity and independence of FDA decisions, such as on hydroxychloroquine, remdesivir, and COVID-19 vaccine candidates. This will likely include rapid replacement of current Commissioner Stephen Hahn, an oncologist and long-time GOP donor, who supported President Trump's unverified statements as to the effectiveness of convalescent plasma against COVID-19.

As stated above, the FDA will be in the center of crucial initial EUAs of COVID-19 vaccines, as well as their eventual full licensure, and—crucially for public confidence—the essential post-market surveillance of these vaccines’ safety following mass immunizations nationwide. FDA will also continue to place priority upon coordination with NIH, BARDA, the Defense Department, and sponsors, on the clinical development of additional therapeutics, diagnostics and other COVID-19 countermeasures, as well as on their rapid but rigorous premarket reviews.

Beyond the immediate pandemic response, FDA will continue to negotiate and prepare for the reauthorization of user fee programs that fund a sizeable proportion of FDA reviews and operations for branded and generic prescription drugs, medical devices, and other regulated products. The Prescription Drug User Fee Act (PDUFA) of 1992, for example, must be reauthorized before September 30, 2022. The five-year user fee reauthorization cycle typically serves as a vehicle for other FDA-related regulatory reforms, and the Biden-Harris Administration will likely give substantial deference to career FDA views on such proposals, with a strong focus on consumer safety, enhancing global inspection capabilities, and augmenting the FDA’s science base, including its capabilities for rapid response to future emerging infectious disease threats.

ACA EXPANSION AND HEALTH CARE REFORM

President-elect Biden campaigned on an ambitious health insurance reform agenda to build on and strengthen the Affordable Care Act (ACA) with proposals to increase the size of premium tax credits, create a public health insurance option available to anyone who wishes to purchase it on the ACA marketplace exchanges, and lower the age of Medicare eligibility to 60. With control of the Senate yet to be determined, initial focus on health insurance policies will be through administrative actions, rulemaking, guidance, and Executive Orders. Specifically, the Biden Administration will prioritize rescinding and replacing Trump Administration actions aimed at undermining the ACA, as well as any recently finalized regulations.

The pending U.S. Supreme Court review in *California v. Texas* of whether the individual mandate is constitutional now that the penalty is set at \$0—and, if unconstitutional, whether it is severable from the ACA—will also impact the Biden Administrations’ policies and options over the next several months. While a decision is not expected until June 2021, the Biden Administration may seek a technical legislative amendment to restore some de minimis penalty in order to remove the basis for the lawsuit. With a divided Congress, such a legislative fix would be far from assured.

Altogether, the top health care insurance priorities for the Biden Administration will likely be (1) to strengthen and protect the ACA, primarily through regulation and guidance; and (2) to reverse

many Trump Administration policies related to the Medicaid program, including new authorities for states to impose cost-sharing and benefit limitations.

Strengthen and Protect the ACA

We expect the Biden Administration to utilize rulemaking and sub-regulatory guidance to reverse many Trump Administration policies intended to undermine or weaken the requirements of the ACA. The Biden administration is likely to reinstate Obama-era restrictions on the marketing of short-term health plans and association health plans, and restore limits previously imposed on these products. A 2018 guidance document on 1332 state innovation waivers, which authorized loosened guardrails in the waiver program, will likely be retracted (and recent waivers approved under this authority, including in Georgia, could be reconsidered). The Biden Administration is also likely to utilize the annual Notice of Benefit and Payment Parameters (NBPP) rulemaking process to strengthen the health insurance exchanges by, for example, strengthening the risk adjustment program for issuers. Furthermore, the Biden Administration may also choose to reinstate cost-sharing reduction (CSR) payments to health insurers participating in the individual marketplace exchanges. Regarding the individual marketplace, the Biden Administration may announce a special enrollment period for the newly uninsured to enroll in the ACA marketplace exchanges, extend the open enrollment period for states using the federal marketplace platform, and restore marketplace outreach, education, and enrollment assistance funding. Additionally, the Biden Administration is expected to revive an Obama-era interpretation of discrimination “on the basis of sex” for purposes of Section 1557 of the ACA that encompassed sexual orientation and gender identity. The Administration is also expected to roll back two Trump-era regulations that allowed employers with claimed religious or moral objections to decline to cover contraceptives for employees and students and allowed health care professionals to refuse to provide care for religious or moral reasons.

We simultaneously expect the Biden Administration to pursue a legislative strategy with Congress to achieve its policy goals. While the creation of a new public health insurance option is unlikely to move in a divided Congress, the Administration may seek to pursue more narrowly tailored policies: increasing the value of the advance premium tax credits for individuals earning less than 400% of the federal poverty level, creating a new pathway for low-income individuals in non-expansion states to access health insurance through the exchanges, and by addressing more systemic issues in our current healthcare system (including “surprise billing”).

Changes to Medicaid Policy

With respect to Medicaid policy, the Biden Administration will revisit and roll back several Medicaid guidance documents (primarily in the form of State Medicaid Director letters) and

regulations that have departed from Obama-era policies. We expect the incoming Administration will take a serious look at the recently finalized Medicaid Managed Care final rule (designed to afford states and MCOs greater flexibility than the 2016 Obama-era rule) and roll back some of these new flexibilities. So too, a Biden Administration will retract current-CMS policies allowing states to impose work requirements, reduce benefits, and increase cost-sharing in their Medicaid programs through section 1115 waivers. It is yet to be seen whether the Biden administration will take the unusual step of actually terminating currently approved waivers that do not align with the new Administration's defined objectives for the Medicaid program.

In the near-term, the Biden Administration will likely revisit a recent interim final rule that would allow states receiving a temporary 6.2 percentage point increase in their federal share of Medicaid funding (FMAP) to terminate individuals *not validly enrolled*, as the statutory authority for this enhanced FMAP was originally interpreted to require these states to maintain enrolment and coverage for all Medicaid beneficiaries through the end of the COVID-19 PHE. The Biden Administration may also seek support from Congress to provide further support for state Medicaid programs during the COVID-19 PHE, including through greater enhanced FMAP and greater flexibility for retainer payments.

DRUG PRICING

While the major health care issues of the 2020 campaign were the Administration's response to the COVID-19 pandemic and review of the ACA by the Supreme Court, drug pricing continues to poll as a very important issue among voters, particularly seniors. One common point of contention on the campaign trail was who would lower drug pricing more as between Biden and Trump. The Biden-Harris campaign drug-pricing platform incorporated a broad and familiar set of drug pricing proposals, including government negotiation for drug prices, Part D benefit redesign for out of pocket costs, Medicare Part B inflationary rebates, generic drug competition, and drug importation.

The Trump Administration asserted broad Executive Branch authority to address drug pricing through Executive Orders on importation, government negotiation, and transparency, in addition to CMS, FDA, and HHS rulemakings. To start, the Biden Administration will also look for administrative options to take immediate steps to address drug pricing, particularly given the lack of a clear majority in the Senate. While Biden campaigned on empowering Medicare to negotiate prices directly and reducing drug payments by Medicare, the Medicare statute prohibits government negotiation in Part D through the non-interference clause and sets drug reimbursement methodology in detail under Part B. As a result, similar to the Trump Administration and the Obama Administration, the Biden Administration will look to the authority of CMMI to administratively pursue drug-pricing policies. However, there are significant limits to CMMI's waiver authority. Moreover, developing and implementing a CMMI demonstration likely would take time.

More realistically, the Biden Administration is likely to rely on incremental reforms through Executive Orders and rulemaking, some of which may build off policies that HHS and CMS considered in the Trump Administration. Prior proposals that were never finalized include allowing Part D plans to exclude drugs with certain year-over-year price increases from Part D formularies, including among protected classes. The Trump Administration also introduced novel policies that could be expanded or curtailed by a Biden Administration, such as, prior authorization for certain outpatient items and services, authorization of accumulator programs for certain commercial plans, and CMS' proposed interpretation of "reasonable and necessary" under the Medicare program.

The Biden Administration may attempt to promulgate 340B rulemaking that the Obama Administration proposed but was unable to finalize. This includes promulgating an Alternative Dispute Resolution (ADR) rule for the 340B program, potentially issuing a 340B program "mega-guidance" to provide clarity on key aspects of the 340B program. The Trump Administration withdrew an Obama proposed rule and never reissued its own version.

DISABILITY AND LONG TERM CARE

President-elect Biden has long championed disability issues and promoted inclusiveness across his entire policy agenda. As President, Biden has said he would look to strengthen civil rights for all Americans, expand access to home- and community-based services, and promote access to services across federal programs. These programs extend across the life span from education, to health care, to employment, and to civil rights – all of which feel the impact of the COVID epidemic. People with disabilities and chronic illnesses significantly depend on publically funded programs to live full lives with their families and in their communities.

During this period of transition through the "lame duck" session, the most important issue for people with disabilities will be the passage of another relief bill, including an increased FMAP for Medicaid. Because President Trump lost the election, the expectation is no bill will move; however, regulations will continue to roll out from the Administration.

For the disability community, the repeal of rulemaking concerning Section 1557 of the Affordable Care Act, which prohibits discrimination in health care based on disability and other factors, will be a priority. Other important Executive Orders that could be repealed include (1) a ban on diversity and inclusion training in government grant employment sites, (2) use of lowest drug prices abroad (the favored nation plan), to lower drug prices for Medicare prescriptions, and (3) the use of QALY metrics to define appropriate care and treatment.

On health care, disability groups have advocated for access to comprehensive services and supports for disabled persons through options afforded under both the public programs of

Medicaid, Medicare, and CHIP, as well as commercial health care coverage. The ACA leveled the health coverage playing field by covering pre-existing conditions and establishing “essential health benefits” that need to be covered. Stakeholders in the disability community will be focused on ensuring that the Biden Administration protects these health care advancements going forward.

On education issues, education and early childhood programs under IDEA are the fundamental building blocks to the developmental achievements and success of children with disabilities. As we move to the new Congress, top priorities will include supporting the use of universal design in educational approaches, using the lessons learned from the experience of distance learning throughout the pandemic. The reauthorization of IDEA, Head Start, Early Head Start, and the Higher Education Act will be important bills to follow for their emphasis on access and opportunities for this population. It is worth noting that First Lady Dr. Jill Biden may have a prominent role on education issues.

Employment of people with disabilities has also been a major priority in the disability community over the past decade. As more students leave special education with stronger skills and self-confidence, their desire to be independent and self-directed drives their decisions related to their future. Work opportunities were previously based on a model of low expectations within a “take care of mentality.” That has all changed as the “ADA kids” have come through the educational system. With the integration of people with disabilities into the statewide workforce systems, there has been more opportunity for successful competitive integrated employment experiences for individuals with disabilities. Issues surrounding 14(c) and the reauthorization of WIOA and the Assistive Technology Act will raise important employment policy questions.

OUTLOOK FOR 117TH CONGRESS

The outlook for the 117th Congress will turn on the outcome of two Senate runoff elections in Georgia. With Republicans holding a 50-48 margin in the Senate, Democrats will need to win both runoff elections in order to control the Senate with Vice President Harris serving as the tie-breaking vote. The prospects for an ambitious legislative agenda to pursue the health care policies that the Biden-Harris Administration campaigned on throughout the 2020 election will be significantly diminished if the Republicans maintain a majority in the Senate.

Addressing COVID-19 with support from Congress will be President Biden’s first challenge working with a potentially divided Congress. Biden’s approach will be conveying that bipartisanship on the federal response to COVID-19 is in the best interest of the country. Since May, Congress has been unable to agree on major COVID-19 relief legislation. Recent negotiations between Speaker Pelosi and Treasury Secretary Steven Mnuchin failed to bridge the gap between the \$2.4 trillion package passed by the House and the \$1.8 trillion package supported by the Trump Administration. Democrats have been primarily focused on

unemployment assistance and aid to state and local governments, while Republicans have pushed for additional Paycheck Protection Program funding and expressed some concern with additional unemployment assistance and “bailouts” to states.

Although President-elect Biden will control the executive branch and Democrats held the House (albeit with a reduced majority), the potential for a Republican Senate makes an extensive package based on the campaign priorities such as the HEROES Act unlikely. Thus, the Pelosi-Mnuchin negotiations may represent a starting point for new relief efforts during the lame duck session with much of the COVID-related relief negotiations waiting for the new Congress.

Other potential priorities of the Biden-Harris Administration may require separate legislation, or could be included in a stimulus package. The Biden campaign proposed to create a U.S. Public Health Jobs Corps to mobilize at least 100,000 Americans to perform contact tracing, assist with COVID vaccine distribution, and protect at-risk populations. In addition, Biden has strongly supported a renewable fund to assist states and local governments with budget shortfalls, emergency funding to ensure that schools have resources needed to adapt to COVID-19, and a “restart package” to assist small businesses to cover costs of necessities for reopening, like PPE and Plexiglas. Though these initiatives may have bipartisan support, they could run into opposition in a Republican Senate due to spending concerns.

On drug pricing, a number of bills were considered with bipartisan support during the 116th Congress and President Trump had openly pushed for drug pricing legislation but no agreement could be reached in the Senate. The Biden-Harris Administration and House Democrats will continue their quest for ambitious drug pricing agenda, however, policies like enabling Medicare to negotiate drug prices will face opposition in the Senate, particularly if Republicans maintain the majority. That said, the Biden Administration could pursue a set of policies based on the Grassley-Wyden Senate bill, S. 2453, the Prescription Drug Pricing Reduction Act of 2020 (PDPRA). Aspects of PDPRA such as the Part D benefit redesign, including OOP caps for Part D beneficiaries, could provide the basis for further bipartisan negotiation in the new Congress.

Where drug-pricing proposals arise in the next Congress may be in the context of a pay-for to offset spending on larger legislative packages such as the COVID-19 pandemic response, or funding public health programs. Some of the largest potential offsets—Part B and D price controls or government negotiation—have historically garnered limited Republican support. If Democrats are able to secure the majority in the Senate, a key question is whether the Biden Administration could pursue drug-pricing policies through reconciliation.

On the ACA, the Biden-Harris Administration will pursue a combined approach of administrative action to undo a number of Trump Administration policies that sought to undercut the ACA along with an ambitious legislative agenda to expand and strengthen the ACA. As an early first step, the Biden Administration will unveil a set of priorities for Congress to consider for “Bidencare”, which will be considered in the House of Representatives, and could be influenced in the Senate by any outcome in *California v. Texas*. However, it is difficult to

envision the Senate working in a bipartisan away to significantly expand the ACA beyond technical adjustments.

Historically, disability policy issues have been considered bipartisan in recent years. Therefore, disability issues are a likely area of compromise during the Biden Administration, particularly around expanding home and community-based services (HCBS). Given the concern and attention on congregate living during the COVID-19 pandemic, expanding HCBS has become a priority. A number of workforce issues are raised by the expansion of HCBS across the country. Direct Support Professionals (DSPs) are integral to ensuring the health and well-being of patients. A key policy question moving forward will be whether DSPs will be designated as essential health workers so they can reasonably access PPE and the forthcoming vaccine.

The issues outlined above represent the key issues to look to in the next Congress, and they will certainly be influenced by the outcome of the lame duck session.

For more information on our post-election outlook, please contact your Foley Hoag attorney or the following contacts by topic:

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