

The Post-Election Future of Employee Benefits Policy

Health Policy Edition

November 6, 2020

While the tallying of votes continues and recounts and legal challenges ensue, it appears that former Vice President Joe Biden will be deemed the winner of the presidency. Likewise, it appears the Senate will remain in Republican hands while the Democrats will definitely hold the majority in the House of Representatives. As this document is written, certainly one (and possibly two) Senate races in Georgia may be headed for a runoff election on January 5. This could leave Senate control in limbo until early 2021.

The following is a detailed summary of the probable impact of the election on health policy on the assumption that there will be a Biden presidency, the House retains a Democratic majority and the Senate retains a Republican majority. A discussion of the impact on policy relating to paid leave is also included. (For the corresponding summary relating to retirement policy, click here.)

Table of Contents

Executive Summary	3
Overview	4
Health Care Coverage	
Build on the ACA	6
Remove the Marketplace Subsidy "Firewall" For Employees	7
Public Option	8
Lowering the Medicare Eligibility Age	9
Health Care Costs	10
Negotiated Rates with Providers	10

	Marketplace Subsidy Expansion	10
	Antitrust Authority	11
	Surprise Billing	11
	Transparency	11
	Value-Based Design, High Deductible Health Plans and Health Savings Accounts	12
P	Prescription Drug Costs	13
	Price Caps	13
	Inflation Rebates	13
	Drug Importation and Increasing Competition	14
	PBM-Related Proposals	14
(COVID-19	15
	"Lame Duck" Action	15
	COVID-19 Testing and Tracing	15
	COVID-19 Treatment	15
	Accelerating the Development of COVID-19 Vaccines and Treatments	15
	Health Insurance Coverage during the COVID-19 Crisis	16
	Telehealth and Other COVID-Related Relief	16
	Social Determinants of Health/Health Disparities	17
	Paid Leave	17
F	Regulatory Action	18
	Health Care Nondiscrimination Rules	19
	Association Health Plans	19
	Short-term Insurance	19
	Price Transparency	20
	Individual Coverage HRAs	20
	Wellness Plans	21
	Direct Primary Care Arrangements	21
	Mental Health Parity	21
	Form 5500 Reporting	22
	Sub-Regulatory Guidance Procedures	22
	Post-Regulatory Litigation	22

EXECUTIVE SUMMARY

The impact of Biden's election on employer-sponsored health coverage will not be as profound as if a Democratic sweep of the White House and Congress had materialized. Without the support of a fully Democratic Congress, President-elect Biden's broad health plan will be largely stalled. However, there may be some opportunities for more targeted bipartisan health care legislation and the Biden administration will turn to executive action to pursue policy changes without Congress. If Democrats win both Senate seats in Georgia and the Democratic sweep does materialize, more dramatic changes for employer-sponsored coverage may lie ahead. The Council has analyzed the divergent approaches of the outgoing and incoming administrations to provide members with an outlook of what may come.

- **Health Care Coverage:** The topline message of Biden's health care plan is that his administration will "protect and build on" the Affordable Care Act (ACA) as the law faces an uncertain fate in the Supreme Court. The ultimate resolution of that pending litigation will play an outsize role in determining the direction of any legislative or regulatory action on health policy. However, a Republican-controlled Senate is likely to block Biden's proposals for expanding the number of individuals eligible for Marketplace subsidies (*including those with employer coverage*), increasing the generosity of those subsidies, creating a public health insurance option like Medicare that would be available to all individuals through the ACA Marketplace, and lowering the Medicare eligibility age from 65 to 60. Therefore, without a Democratic sweep, we expect the Biden administration to take more limited regulatory action to try to achieve its goals of ACA support and expansion and we may see state activity aimed at these goals as well.
- Health Care Costs: President-elect Biden's plan to lower health care costs centers on
 aggressively using antitrust authority to address health care market consolidation,
 as well as the government negotiating rates with providers within a public option –
 a non-starter in the Senate. Whether bipartisan agreement can be reached on other
 measures to reduce health care costs remains to be seen.
- **Prescription Drugs:** With a divided Congress, the pricing provisions in the prescription drug legislation that passed the House of Representatives a year ago (H.R. 3) is unlikely to be enacted. However, policy changes may come through the regulatory process and more narrow bipartisan legislation.
- COVID-19: Depending upon what happens during the post-election "lame-duck" session of Congress, COVID-19 relief and stimulus legislation could be among the first orders of business in the next Congress. Whether provisions ensuring health

care coverage during the pandemic are included remains to be seen, and disputes over COBRA subsidies in a divided Congress likely remain. It also not yet clear whether COVID-related legislative and regulatory relief that has been provided to employers, plans and employees, including those related to expanded telehealth access, will be extended under the Biden administration. The new administration is also expected to focus on the health disparities among racial and socio-economic groups that so clearly have been brought into focus by the pandemic.

- Paid Leave: Paid sick and paid family and medical leave legislation is expected to be
 a priority for the Biden administration and Democrats in the new Congress.
 However, consensus among Democrats and Republicans on federal legislation has
 yet to emerge. The Council's Statement of Principles provides a framework for our
 ongoing advocacy for federal legislation that would preempt state and local laws
 and enable uniform nationwide standards that leverage private sector solutions.
- **Regulatory Action:** With a divided Congress, the new administration will likely turn more aggressively to regulatory action to try to advance their policy objectives. The Biden administration is likely to revise or undo a number of rules promulgated by the current administration, such as those on health care nondiscrimination, association health plans and short-term insurance. Others, such as the recently released transparency rules, may well stay in place.

OVERVIEW

President-elect Joe Biden presented voters with a dramatically different vision of health care from that of the current administration. However, with Republican control of the Senate, much of Biden's legislative agenda will be stalled in Congress. While the sweeping changes in health care benefits policy envisioned by Biden are not on the horizon, despite pressure from the Democratic House of Representatives, more narrow bipartisan legislation may emerge. Furthermore, there are still important changes that could come without Congress. The incoming administration is expected to turn its sights to executive action to achieve the same or similar objectives, albeit on a more limited basis. The logjam in Congress may also spur state legislation to fill the federal legislative vacuum, presenting potential challenges for nationwide employers. This paper examines the impact of Biden's election and an expected divided Congress on health policy and what this means for businesses and the future of employer-sponsored health coverage.

The COVID-19 pandemic and ensuing economic crisis have brought the employersponsored system under intense scrutiny, with questions about the linkage of health coverage to employment in the face of almost unprecedented job losses. Unlike many of his challengers for the Democratic nomination advocating for Medicare-for-All, Biden's health policy platform envisions a continued role for private insurance. However, the incoming president's endorsement of a new government-run "public option" that would be available on the ACA Marketplaces, along with expansion of the ACA premium subsidies, may nonetheless, as described in greater detail below, contribute to the ongoing debate about employer-sponsored health coverage. It could potentially find some degree of fruition through the regulatory process and spur state legislative efforts to expand coverage – even though federal legislative changes to establish a public option are not politically feasible.

Beyond polices to expand access to health care coverage, the incoming administration and congressional Democrats intend to take an aggressive approach to reducing prescription drug and other health care costs - an approach at odds with a number of Senate Republicans, limiting the scope of any potential legislation. To the extent these goals can be accomplished through executive action, questions about the application and impact of these policies on the commercial market remain and will be of critical importance for employer plan sponsors.

Differing approaches to responding to the COVID-19 pandemic were top of mind for many voters and seen to fuel Biden's victory in part. With the pandemic likely to be still raging on inauguration day, a broad COVID-19 relief and economic stimulus bill could be the first order of business of the new Congress, depending upon what, if any, package is passed in the lame-duck session of the current Congress. The prospects for Congress acting on a COVID-19 package before the end of this year likely increased in the wake of the election. Ongoing efforts to combat the virus and its economic fallout will likely continue to dominate the agenda well into next year. Whether health policy changes come through legislation and/or regulation will depend on the extent to which legislation can advance in the Senate.

Even as the Biden administration looks to regulatory action to pursue its agenda the Republican-controlled Senate will still have a critical role in shaping the makeup of the administration by virtue the confirmation process. President-elect Biden may need to opt for more centrist nominees to secure their confirmation in the Senate. We can expect Biden nominees to face intense scrutiny in the Senate, tempering the selection of more progressive potential candidates for the Cabinet positions and the polices the departments may pursue under their direction.

Republicans will continue to hold the gavel on committees, setting their hearing, legislative and oversight agendas. However, changes in the chairmanship of the key Senate committees of jurisdiction may have important implications for health policy and employer-sponsored coverage in the next Congress. The retirement of Senator Lamar Alexander (R-TN) leaves a vacancy at the top of the Senate Health, Education, Labor and Pensions (HELP) Committee and in Senate health policy leadership and understanding and support for employer-sponsored coverage. Next in line in seniority

is Senator Richard Burr (R-NC). Burr gave up his Intelligence Committee chairmanship amid a legal investigation, which is reportedly not expected to affect his ability to take the chairmanship at the HELP Committee. Should Burr not fill the top slot, next in line is Senator Rand Paul (R-KY). Paul, a staunch advocate for association health plans, would likely have a very different view of employee benefits and health policy than that of Chairman Alexander.

The gavel will also change hands on the Senate Finance Committee in the next Congress. Current Finance Committee Chair Chuck Grassley (R-IA) is set to return to the Senate Judiciary Committee in the next Congress. Grassley has been a driving force on health and tax policy, willing to buck Senate Leadership at times to pursue his legislative priorities. Health policy has not been a focus of Senator Mike Crapo (R-ID), who is in line to replace Grassley. These changes in committee leadership in the next Congress inject increased uncertainty into the outlook for benefits health policy and advocacy for employer-sponsored coverage.

Meanwhile, the Supreme Court will soon consider a challenge to the ACA supported by the current administration. If the court does strike down all, or significant provisions, of the ACA, President Biden and House Democrats will seek to respond quickly to prevent those with ACA coverage from becoming uninsured and perhaps go even further, putting pressure on Senate Republicans to act.

Below, we discuss key health policy issues that could arise in the new Biden administration and the 117th Congress.

HEALTH CARE COVERAGE

Build on the ACA

The topline message of Biden's <u>health care plan</u> is that his administration will "protect and build on" the ACA, "instead of starting from scratch and getting rid of private insurance." As such, the expected focus will be actions intended to increase access to affordable coverage by expanding the ACA. While there are ways to achieve these high-level goals, at least in part, both legislatively and regulatorily, the major policies set out in Biden's health plan will require legislation. The likelihood of such legislation is substantially reduced by the expected Republican-controlled Senate.

In general, the Biden plan emphasizes increasing the number of individuals eligible for the ACA Marketplace subsidies and increasing the generosity of those subsidies. Policy elements include removing the current prohibition on subsidies for those with household incomes over 400% of the federal poverty level. Instead subsidies would be provided so that, for all individuals, Marketplace coverage would cost no more than

8.5% of household income, and in many cases much less. Also, the amount of the subsidies would be based on a "gold" plan (with an 80% actuarial value), rather than the current less-generous "silver" benchmark plan (with a 70% actuarial value). Although the chances of these expansions becoming law would have been much higher in the event of a Democratic Congress, it is possible that some modified elements could be included in future bipartisan legislation, especially if the Supreme Court strikes down significant ACA provisions and if the Biden administration and Democratic House are willing to also pass some priorities for the Republican-controlled Senate, including health savings account (HSA) reforms.

However, due to the legislative barrier of a Republican-controlled Senate, we expect the Biden administration to take regulatory action, including early on, to achieve its goals of ACA support and expansion. These changes would be much less significant than possible legislative changes but noteworthy nonetheless. While the Biden administration's regulatory plans have not been outlined, we expect those plans to include some Marketplace operational changes, including expanding the open enrollment period, which the current administration significantly shortened, and increasing funding for Marketplace outreach and the "Navigator" program, which the current administration significantly reduced. There are a panoply of other possible policies, many in response to changes in the opposite direction by the current administration, including reducing the indexing factors used to determine the amount individuals must contribute to receive a Marketplace subsidy, narrowing the types of waivers states can receive from the ACA under the "state innovation waiver" program, and increasing the actuarial values associated with the different "metal" levels in the Marketplace, to provide more robust coverage. It may also be the case that we see additional efforts at the state level to expand Marketplace subsidies and coverage, as is currently done in California.

Remove the Marketplace Subsidy "Firewall" For Employees

Of direct significance to employers, the Biden plan also calls for removing the current prohibition (i.e. "firewall") on Marketplace subsidies for employees with offers of employer-sponsored coverage (including affordable, high-quality coverage). The potential removal of this prohibition, which would allow employees to choose to go to the Marketplace with a subsidy, if otherwise eligible, would also have a direct effect on the employer mandate unless the basis upon which the penalty is imposed is changed. Currently, the employer mandate penalty is based on the number of full-time employees who receive Marketplace subsidies.

Although Biden's health care plan does not explain if and how the employer mandate would change, it seems likely it would, or else employers would face the prospect of paying a penalty even if they offered coverage that meets the ACA standards. There are a range of possibilities, including increasing the employers'

requirement toward affordability or changing the trigger for the penalty so that it is simply based on what is offered without regard to whether employees choose coverage in the Marketplace. Even if there had been a completely Democratic Congress, eliminating the penalty altogether seemed unlikely given the significant impact on the federal budget. It also stands to reason that if there are changes to the employer mandate, changes to the related ACA reporting will follow.

Although this goal of the Biden administration is important to understand, due to the Republican-controlled Senate, and how expensive it would be from a federal budgeting perspective to eliminate the employer mandate firewall (likely hundreds of billions of dollars) it is very unlikely to transpire. It is possible, including as part of legislation in response to the ACA Supreme Court case, that Congress could instead decide to lower the amount employees are required to contribute for employer coverage to be deemed "affordable." Currently, workers can be required to contribute as much as 9.78% of their income. This number could be lowered, for example, to 8.5% of income and this limit could become applicable to family plans (rather than employee-only plans). This could be a 'less expensive' way to make coverage more affordable for lower-wage workers and to potentially expand the employee population eligible for Marketplace subsidies. Although this is also highly unlikely due to the expected Republican Senate, it is a possibility and something to monitor.

Not all elements of the Biden plan to expand access to coverage are revisions to the ACA. Some would be new and significant, but also highly unlikely to be achieved through legislation given Senate opposition.

Public Option

The Biden plan includes a new federal public plan option that would be offered to any and all individuals through the ACA Marketplace, including employees (and their families) who have access to employer-sponsored coverage. The public option would negotiate prices with providers (these prices would not extend to employers under the Biden plan) and would be provided to some, without cost, in states that did not expand Medicaid as allowed under the ACA. Although unrealistic with a Republican Senate, this policy is noteworthy as it was one of the incoming administration's points of focus during the campaign, and we may see remnants in other administration policy initiatives or as part of future congressional negotiations. We may also see efforts at the state level to create public options, which has already been done in Washington state, or to otherwise expand coverage.

Lowering the Medicare Eligibility Age

In addition, Biden has called for lowering the Medicare eligibility age from 65 to 60 but allowing those who prefer to remain on their employer plans to do so and prohibiting employers from excluding older workers from coverage. A statutory change would be needed for Biden to achieve this goal and the odds of the Senate adopting such a change, in part due to its cost, seem extremely unlikely. However, we expect Biden's focus on improving health care for older Americans to continue, which he could attempt to achieve in other ways, including regulatorily.

Although this array of potential health coverage policy changes is unlikely to become law, we expect to see efforts by the administration to advance these goals, and it may be that some pieces of this plan are included in health care legislation, should the Supreme Court overturn significant portions of the ACA. As such, we note that these policies raise significant issues for employers, which are complicated, uncertain and depend on which subset of policies are adopted and the ultimate parameters of those policies. Potential concerns include:

- Increased taxes on employers to pay for expanded coverage.
- Cost-shifting from public to private plans (assuming the rates negotiated for the public option would not be extended to the private market).
- Weakening of the employer plan risk pool (if lower risk employees choose the Marketplace but higher risk employees retain employer-sponsored coverage, including due to narrower networks and higher out-of-pocket costs in many Marketplace plans).
- Degradation of the employer-sponsored system.
- Reduced quality/value of care for employees and their families.

Potential advantages include:

- Increased health care access and choices for some employees.
- Improvements to the employer risk pool (if higher risk employees are covered by Medicare or choose the Marketplace because it covers all essential health benefits).
- Reduced costs in employer-sponsored coverage.
- Reduced "job lock."

Even assuming buy-in from Senate Republicans for some of these policies, which is quite unlikely, the cost of any or all of these changes to the federal government would also be a major issue. Congressional Budget Office (CBO) cost estimates would shape both the parameters of the provisions that would ultimately be adopted and lead to some items being jettisoned. According to reports of statements by the Biden campaign, they estimate the health care plan to have a net cost of \$750 billion over 10 years, taking into account savings expected from certain aspects of the plan, including prescription drug cost reform (which we would expect to face problems in the Senate), described later in this paper. According to Biden's campaign materials, the health care plan would be paid for by raising income taxes on high-income individuals and raising the capital gains tax. The cost would have been a major issue even if Democrats controlled Congress and will be much more so with a Republican-controlled Senate, for which tax increases along these lines would likely be a non-starter.

HEALTH CARE COSTS

While not as prominent as the policy priorities regarding expanding access to coverage and building on the ACA, Biden's health care plan also includes several items intended to lower health care costs.

Negotiated Rates with Providers

Some elements of Biden's plan to reduce health care costs reiterate aspects of the plan to increase coverage, including the public option, which is intended to provide lower prices as negotiated by the federal government. Although a public option does not seem viable, we note that a major potential concern with negotiated prices in a public option is cost-shifting to the employer market if the rates available in the public option are not available in the private market. This is a familiar concern we monitor in other possible policy changes that limit prices in government-sponsored programs and not in the private market.

Marketplace Subsidy Expansion

The Biden plan includes, as part of efforts to address affordability, expanded eligibility for and generosity of the Marketplace subsidies, which would allow individuals and families to purchase higher value plans with lower out-of-pocket costs. As noted earlier, the prospects for legislation along these lines are not strong and the ability to meaningfully achieve the same end-result through regulations is doubtful. In addition, although increasing access to, and generosity of, Marketplace plans can be

helpful to specific individuals seeking coverage, it does not address the separate, significant issue of reducing underlying system-wide health care costs.

Antitrust Authority

The Biden plan for lower health care costs does not just reiterate the Marketplace expansion and public option ideas but also includes some distinct ideas, including "aggressively" using existing antitrust authority to address concentration of market power, among hospital and physician practices. Although certain aspects of Biden's plan to address health care costs (e.g., the public option) will be substantially constrained in the Senate, the administration's ability to increase antitrust enforcement under existing authority remains.

Surprise Billing

The Biden plan also calls for barring health care providers from "surprise" billing patients at out-of-network rates in in-network settings, which, although subject to different approaches over the years, has been a bipartisan issue. However, on surprise billing, the Biden plan does not address surprise bills in the emergency room setting, nor does it address a benchmark rate for group health plans and health insurers to pay for out-of-network services. Those details will be crucial in terms of how a policy change would affect employers and employees. And although there is very limited time, it is important to consider that there could be legislative activity on surprise billing in the post-election "lame duck" session of Congress, including possibly as part of further COVID-19 response legislation.

Additionally, the White House recently issued an executive order directing executive branch agencies to address surprise bills regulatorily if Congress does not adopt a solution by the end of 2020. This could include efforts to prohibit surprise bills for patients as a condition of Medicare participation for health care providers, among other possibilities. While it would be difficult for the current administration to address this issue regulatorily in the first half of January alone, the work that is being done now, including by ongoing career staff in the federal agencies, may well continue into the Biden administration, if Congress does not address the issue.

Transparency

There have been recent efforts in Congress and in the executive branch to lower health care costs by increasing transparency, including legislation to prohibit anticompetitive contract terms that limit the ability of plan sponsors to pursue value-based insurance designs. During the lame-duck session of Congress, we could see legislation along these lines.

In terms of the next administration, based on materials provided so far, transparency does not seem to be an emphasis in the Biden health care plan. However, as discussed below, we expect the recently finalized regulations regarding price transparency for group health plans, at least largely, to stand.

Value-Based Design, High Deductible Health Plans and Health Savings Accounts

It is notable that the Biden plan does not address how his administration would address and incentivize quality and value in health care, which is another essential element of reducing health care costs. Although the Biden plan does not include discussion of value-based design, we expect that as the administration's health policy team is built and their plans develop, this may be an area for some action and agreement on a bipartisan basis.

More specifically, although historically, health savings accounts (HSAs) and high deductible health plans (HDHPs) have not been a policy focus for Democrats, it may be that through legislation or regulations, we see efforts to enhance the types of predeductible coverage that individuals can have while covered by an HSA-eligible HDHP, including primary care, treatment and management of chronic conditions, and more robust onsite clinics. Ensuring access to these types of care is widely understood to be essential to improving health care quality and reducing health care costs, and value-based care has broad support as well. In addition, in the Marketplace, many of the plans qualify as HDHPs. Consequently, relaxing the HDHP rules would allow more flexibility and improvements to some of the less expensive Marketplace plans, which could be appealing to the Biden administration. We may see other administration efforts to support value-based design as well, including in Marketplace plans.

Other HSA and HDHP changes, such as increasing the HSA contribution limits or allowing HSA contributions for those with non-traditional coverage, seem much less likely. However, we may see expansion efforts from the Senate, including as part of compromise legislation that includes some of the Biden health policy priorities. It may also be the case the HSAs receive more focus and support in relation to recent increased efforts to provide consumers with greater price transparency, which may allow them to more effectively consider which coverage to seek pre-deductible and how best to use their HSAs.

PRESCRIPTION DRUG COSTS

Price Caps

Lowering the cost of prescription drugs was a focus of efforts by the current Congress and administration prior to the pandemic. Significant regulatory action to reduce drug pricing failed to come to fruition and Congress did not reach consensus on the <u>different legislative approaches</u>, including the House of Representatives-passed Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3), the Prescription Drug Pricing Reduction Act (S. 2543), approved by the Senate Finance Committee, the Lower Health Care Cost Act (S.1895), approved by the Senate HELP Committee, and the Lower Costs, More Cures Act (H.R. 19). Although there were common, bipartisan elements to these drug-pricing proposals, the White House and many congressional Republicans remained opposed to the central feature of H.R. 3 – empowering Medicare to base prescription drug reimbursements on the amounts paid by six other countries.

With the Senate in Republican hands next Congress, sweeping prescription drug legislation including this pricing provision is unlikely to be enacted. However, if Democrats do gain control of the Senate, the pricing provision and other elements of H.R. 3 seem likely to be enacted, at least in some form. Specifically, Biden's health care plan and the Biden-Sanders Unity Platform would direct the Medicare program "to target excessively priced prescription drugs that face little or no competition" and create an independent review board to evaluate value, attribute the federal contribution through publicly sponsored research and development and recommend price parameters for prescription drugs. The Secretary of Health and Human Services (HHS) would be empowered to negotiate prices that are capped to a level associated with the average price in other countries. Under H.R. 3 (and, presumably, the Biden plan), the negotiated rate would apply to Medicare and would also be available to private plans in the group and individual markets. Without the legislative authority for HHS to negotiate prices, it remains unclear what regulatory action the Biden administration can pursue to try to achieve similar objectives. The impact of administrative action taken with respect to Medicare drug pricing on commercial markets will bear close scrutiny.

Inflation Rebates

The Biden plan calls for imposing inflation limits for certain drugs under Medicare and the public option. Both H.R. 3 and the bill approved by the Senate Finance Committee included similar provisions requiring manufacturers to pay a "rebate" to Medicare if the price of a drug rises faster than inflation. However, this proposed inflation rebate only applies to Medicare. Although details remain sparse, it appears the Biden proposed inflation rebate would be limited to Medicare and the public option. Consequently, the effects of the inflation rebate could negatively affect employer plans

if costs rise on non-governmental plans. With Grassley no longer at the helm of the Senate Finance Committee in the next Congress and the opposition of other Senate Republicans to the inflation rebate, the legislative prospects for this provision are more remote.

Drug Importation and Increasing Competition

Biden supports allowing consumers to buy prescription drugs from other countries if HHS has certified that those drugs are safe. The current administration and outgoing Senate Finance Committee Chairman Grassley (R-IA) also back drug importation, but it is unclear if this will become a reality under the new administration and next Congress. Also under the banner of enhancing competition are proposals to improve the supply of quality generics and prohibit practices that delay the entrance of a generic into the market. A number of these proposals have bipartisan support and may well advance, even if more sweeping drug pricing legislation stalls in the Senate.

PBM-Related Proposals

Notably absent from Biden's plan is a proposal of the current administration to require that drug manufacturers' rebates to pharmacy benefit managers (PBMs) be passed along to consumers in privately administered Medicare Part D prescription drug plans. Congressional Democrats had raised objections to this proposal and concerns about its impact on Medicare premiums, so it seems this idea is unlikely to be pursued by the Biden administration. It is unclear if the new administration and next Congress will take other action directed at PBMs, such as requiring greater transparency or curbing spread pricing - the difference between the payment the PBM receives and the reimbursement amount it pays to the pharmacy dispensing to the beneficiary.

The Council's February 4, 2020, letter to Congress stated, "as the largest purchaser of prescription drugs in the United States, employers are deeply concerned about prescription drug costs" and "bold action is needed to lower prescription drug costs and increase transparency to ensure that public and private payers and patients spend resources more wisely." Sweeping legislative action on prescription drug pricing is less likely with the next Congress remaining divided. However, bipartisan legislation on less sweeping changes seems viable, along with aggressive regulatory action. The Council will continue to advocate for policies that bring lower cost and higher value to commercial and public markets alike.

COVID-19

"Lame Duck" Action

The COVID-19 pandemic and the federal government's response to the twin public health and economic crisis was the defining issue in the election for many voters. Biden presented a starkly different view of the pandemic and the federal response to it than Donald Trump. It surely will be the consuming issue for Biden upon his inauguration when the country is likely to still be in the throes of the pandemic.

While policymakers failed to reach agreement on COVID-19 relief before the election, they could advance a bill during the lame-duck session, especially if the health and economic consequences significantly worsen in the coming weeks.

COVID-19 Testing and Tracing

Biden's <u>COVID plan</u> calls for a more robust and coordinated federal response, vowing to make tests widely available and free. He will also seek a national system for tracing the exposure path for those diagnosed with the virus as part of a larger public health corps. The Biden administration is expected to use the levers of executive action to accomplish this goal, with or without congressional action.

COVID-19 Treatment

Group health plans and insurers are already required to cover COVID-19 testing and vaccines without cost-sharing under the Families First Coronavirus Response Act and the Coronavirus Aid, Relief and Economic Security (CARES) Act. Biden's COVID plan, consistent with the Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act, passed by the House of Representatives in May 2020, would require group health plans to cover COVID-19 treatment without cost-sharing. As noted previously, Biden's plan prohibits surprise balance billing, but without details on how this will work and any applicable reimbursement rate to providers. Although supported by the Biden administration and House Democrats, it is unclear whether this provision will indeed be included in any COVID relief and stimulus legislation.

Accelerating the Development of COVID-19 Vaccines and Treatments

The new administration would likely build upon and re-brand the efforts of the current administration's Operation Warp Speed. Biden's plan provides explicit authority for the HHS Secretary to approve the commercial price of vaccines that are developed in conjunction with federally funded research. According to the plan: "This

ensures that the private, as well as the public sector, will not be subjected to vaccine prices that fail a 'fair and reasonable' cost standard and, even if the vaccine is available free of charge, will protect the taxpayer from being gouged." On October 28, the current administration issued an interim final rule on the CARES Act requirement for group health plans and health insurers to promptly cover the cost of the COVID-19 vaccine without cost-sharing. However, numerous questions remain about the scope of group health plans' and employers' actions with respect to the distribution and cost of the vaccine for their workforce.

Health Insurance Coverage during the COVID-19 Crisis

According to a Biden campaign fact sheet, for workers who lost their employerbased coverage because they lost their job, the federal government would step in and cover 100% of the cost of keeping them on their employer-based plan with COBRA subsidies. The Council and Alliance to Fight for Health Care have been advocating for Congress to pass COBRA subsidies and similar continuation coverage of at least 90% to help workers who have lost their job or been furloughed to stay on their employer plans. This provision was in the original HEROES Act but removed in the revised HEROES Act and replaced with access to ACA premium subsidies during the pandemic for individuals receiving unemployment compensation, regardless of income. For individuals with higher incomes, premium subsidies will be determined as if their income was 133% of the poverty level. With the Senate remaining under Republican control, disputes over the application of "Hyde Amendment" abortion funding restrictions to COBRA subsidies will likely persist. However, it is not entirely clear what route the new administration and next Congress will take with respect to health coverage for workers who have lost their job or to assist employers maintaining jobs and health benefits for their employees. However, measures to enhance the ability to obtain coverage in the individual insurance market appear likely to be considered.

Telehealth and Other COVID-Related Relief

Throughout the pandemic various forms of legislative and regulatory relief and guidance have been provided to employers, plans and employees, much of it time-limited to either the public health emergency or some similar period. This includes relief related to telehealth, including a CARES Act provision allowing HSA-eligible HDHPs to cover telehealth pre-deductible and guidance allowing employers to offer stand-alone telehealth to non-benefits eligible employees. The COVID-19 crisis has dramatically increased the use and availability of telehealth and, due to this fundamental shift, some of the relief and guidance that has been provided temporarily may well become permanent. More generally, there is an array of other crisis-related guidance, including allowing HDHPs to cover COVID-19 treatment pre-deductible and employee assistance programs (EAPs) to provide COVID-19 testing. It remains to be

seen how long this type of guidance and relief will extend under a Biden administration.

Social Determinants of Health/Health Disparities

The COVID-19 pandemic and its disproportionate impact on people of color has shined a light on health disparities and social determinants of health. Addressing these disparities is expected to be a priority for the Biden administration. The Biden-Sanders Unity Platform recommends "in the strongest possible terms that Democrats commit to ending health inequities by race, ethnicity, gender, and geography through a sustained, federal effort, led by President Biden, that engages the whole of the government to solve health inequities that have long plagued us, including those that emerge from social determinants of health like inadequate housing, hunger, mass incarceration, and gun violence." The Council's ongoing work to address the social determinants of health and benefit plan inequities will seek to inform and help shape this important activity.

Paid Leave

The COVID-19 pandemic has renewed calls for federal paid leave legislation, and such legislation will no doubt be a priority for the Biden administration and congressional Democrats. Long-advocated Democratic proposals to require paid sick leave and paid family and medical leave for workers include the Healthy Families Act, spearheaded by Representative Rosa DeLauro (D-CT) and Senator Patty Murray (D-WA), which will ensure workers receive seven days of paid sick leave for routine personal and family health needs, as well as time for survivors of domestic violence and sexual assault to seek services. The Family And Medical Insurance Leave (FAMILY) Act, sponsored by DeLauro and Sen. Kristen Gillibrand (D-NY) would provide workers access to 12 weeks of paid family and medical leave through the creation of a government-run program funded through employer and employee payroll deductions. The HEROES Act would extend the Families First Coronavirus Response Act emergency paid leave provisions to employers with 500 or more employees. Notably, none of these bills would preempt the growing number of state and local paid leave laws. The Council's Statement of Principles on Paid Leave provides the framework for the Council's continued advocacy that seeks federal legislation enabling uniform nationwide standards that preempt state and local laws and leverage private sector solutions.

The Biden plan calls for passage of the Healthy Families Act with the addition of an emergency plan that will require 14 days of paid leave for those who are sick, exposed, or subject to quarantines. The paid leave plan will create a federal fund to cover 100% of weekly salaries or average weekly earnings capped at \$1,400 a week — the weekly amount that corresponds with about \$72,800 in annual earnings. Biden's emergency

plan will provide reimbursement to employers or, when necessary, direct payment to workers for up to 14 days of paid sick leave or for the duration of mandatory quarantine or isolation, which will be in addition to existing paid leave provided by a business's existing policies. The Biden plan also calls for permanently providing the type of comprehensive 12 weeks of paid family and medical leave envisioned in the FAMILY Act. Biden has also proposed \$775 billion over 10 years for childcare and elder care.

These proposals face an uncertain fate in the Senate. Bipartisan consensus on broad paid leave legislation has yet to emerge. Senator Bill Cassidy (R-LA) and Senator Kyrsten Sinema (D-AZ) have introduced a targeted bipartisan proposal that allows parents to advance \$5,000 from their Child Tax Credit upon the birth or adoption of a child to finance time off from work. However, the proposal is limited to parental leave and would not address the challenge that the patchwork of state and local paid leave laws presents to nationwide employers. Even with a divided Congress, momentum for federal paid leave legislation may build. In the absence of federal legislation, state and local efforts to enact paid leave legislative will likely further accelerate.

REGULATORY ACTION

Over the last several years, as legislation has stalled, there has been increased pressure and activity on the regulatory front. Although most of the major policy priorities in the Biden health care plan require law changes, it is likely that with a Republican Senate, the Biden administration will also seek to accomplish some of its policy goals through regulations if possible, as discussed earlier in this paper. In addition, if health care legislation is adopted, including in response to the ACA Supreme Court case, or if health care related legislation is passed during the lame-duck session of Congress, we would expect substantial regulatory activity implementing and explaining the new law(s).

As a high-level note, the cabinet secretaries of the relevant federal agencies will have a substantial role to play in shaping health policy and related regulatory activity. During the confirmation process for these executive branch political appointees, Republican senators will try to get the nominees to publicly commit not to pursue certain policy initiatives.

Moreover, in addition to considering the extent to which the Biden administration can accomplish its major health policy goals through regulations, it is also worth monitoring which Trump administration regulatory actions that the Biden administration will potentially undo, including the following.

Health Care Nondiscrimination Rules

The current administration substantially revised and narrowed regulations the Obama administration had issued to implement Section 1557 of the ACA, which prohibits discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs or activities, which can include employer-sponsored plans to the extent they receive federal financial assistance (e.g., Medicare part D drug subsidies). Among other things, the present administration's regulations eliminated the protections for gender identity, repealed certain notice requirements, and significantly reduced the scope of applicability. After these rules were finalized, the Supreme Court issued a ruling, related to a different law, which indirectly calls into question the elimination of the protection against discrimination based on gender identity. Litigation challenging the regulations then followed, resulting in a preliminary injunction that remains in effect. Biden's health care plan indicates a Biden administration will take action to undo these efforts. This could be pursued early in the new administration, as a result of (or in response to) the ongoing litigation, depending on the status of those cases when Biden takes office.

Association Health Plans

It is also possible that the Biden administration will revise or withdraw regulations, issued by the current administration, that expanded the ability of small employers to join together to offer health insurance as an "association health plan" and which were intended to provide more affordable coverage options to small employers by applying the less stringent large group market insurance rules. These regulations are the subject of ongoing litigation; the regulations were struck down by a trial court, but the appeals court has not yet ruled. It is possible that the Biden administration could effectively undermine these rules, which were perceived by some as by an end-run around the ACA, by declining to continue to defend the rules in court, although an opinion from the appeals court is expected shortly. Alternatively, the new administration could undo the current rules through the regulatory process. This is not likely to be a top-tier issue but there may be activity in the near term depending on the outcome and status of the ongoing litigation. In addition, with an expected Republican-controlled Senate, including some major proponents of association health plans, we may see legislative efforts to expand these types of plans as well, including in response to more restrictive regulatory actions.

Short-term Insurance

The current administration expanded the maximum duration of "short-term" insurance policies, which are not subject to the ACA or general insurance market rules,

to three years, up from the three-month maximum under Obama administration regulations. These rules survived a court challenge. However, due to concerns about these policies' impacts on consumers and on the individual market risk pool, short-term policies are a likely target for yet another round of regulations, re-narrowing the duration and scope, likely in the near term.

At the same time, there are a number of health care regulations that we would *not* expect the Biden administration to overturn, although it is always possible that it will revise or refine any number of regulations. The most significant regulations in this category relevant to employers include:

Price Transparency

The current administration recently finalized regulations requiring group health plans and health insurers to meet certain price transparency disclosure requirements, including providing an on-line cost-sharing estimate tool and making public in-network negotiated rates, out-of-network allowed amounts, and certain drug costs. These regulations implement an ACA provision, which the Obama administration never implemented outside of the Marketplace and are intended to increase transparency for consumers and lower health care costs. Although the Biden health care plan does not emphasize increased transparency, it would be unexpected for the Biden administration to undo these rules, due to their basis in the ACA, their consumer focus, and their potential to address health care costs. In addition, due the regulation's effective date which spans, in part, to 2024, the Biden administration may well need to issue sub-regulatory guidance regarding these regulations, to the extent interpretive and implementation questions and issues arise.

Individual Coverage HRAs

Consumer-directed health care has been a focus of the present administration, including in regulations allowing employers to provide employees with tax-free funds in health reimbursement arrangements to purchase individual insurance policies (individual coverage HRAs). The Obama administration had prohibited this practice by regulation, largely due to concerns about impact on the individual market risk pool if employers were to send only their highest risk employees to the individual market. Although the current administration undid this prohibition, it did so after years of developing guardrails intended to protect the individual market. These regulations were understood to be possibly beneficial to the individual market and were not subject to litigation. Because of the substance of the individual coverage HRA rules and the expected Biden administration emphasis on strengthening the individual market, it is unlikely that action to undermine these rules would be a priority.

There are also a number of other regulatory items where prospects for future activity are uncertain.

Wellness Plans

In June 2020, the Equal Employment Opportunity Commission (EEOC) held an open meeting explaining new draft proposed wellness regulations regarding permissible incentive limits under the Americans with Disabilities Act (ADA), following litigation and withdrawal of regulations on this topic by the Obama administration. The rules described in the June meeting have not yet been released and timing and prospects for those rules are unclear, in part because two new EEOC Commissioners have recently been confirmed and the Biden administration may weigh in with new and different views.

Direct Primary Care Arrangements

Also outstanding are possible final regulations by the Treasury Department and the IRS on direct primary care arrangements, under which a health care provider agrees to provide primary care services to individuals for a fixed dollar periodic (often monthly) fee. Some employers offer these arrangements in addition to traditional health plans, to ensure primary care access in geographic areas where it is otherwise limited and to address affordability issues for lower income employees. The current administration made efforts to expand access to these arrangements but the regulations they proposed were narrow and did not allow individuals with direct primary care arrangements to contribute to HSAs, which is a significant outstanding issue.

A hearing was recently held on the proposed regulations and many comments have been submitted. It remains to be seen whether these rules will be finalized before the end of this administration and, if not, whether they will ever be finalized. However, with a likely Republican Senate, it is also possible that there will be efforts through legislation to allow individuals with direct primary care arrangements to contribute to HSAs, as Republicans have previously introduced and championed legislation along these lines.

Mental Health Parity

As a general matter, the focus on mental health, and access to mental health care, have only increased during the pandemic. Biden's health care plan indicates his administration will focus on these issues, including by emphasizing mental health parity enforcement. However, enforcement of the mental health parity law has continued at a steady pace over the last several years, and even increased, so it remains

to be seen how much will change.

Form 5500 Reporting

The Obama administration made efforts to increase Form 5500 reporting, including for group health plans. Although those rules received resistance from the regulated community and were not finalized, and the current administration did not take action, it is worth monitoring whether the new administration might revive that project, although it is unlikely to be a priority.

Subregulatory Guidance Procedures

Although not specific to health care, also significant to future regulatory activity are the current administration's actions intended to limit inappropriate sub-regulatory guidance by federal agencies and increased efforts by the White House Office of Management and Budget to control, and be involved in, the guidance process. The White House required all agencies to implement more robust guidance procedures, which many agencies have done, and which while adding more chances for notice and comment could also slow down the guidance process. It will be interesting to see if the new administration rolls back any of those new procedures, in particular, if there are new major laws to implement which, historically, have required avenues for rapid, responsive guidance outside the confines of the formal notice and comment rulemaking process.

Post-Regulatory Litigation

Another process point to monitor is the extent to which new health care regulations that are issued by the Biden administration are litigated. Over the past four years, many health care regulations were litigated following finalization, such that the regulatory process seemed to include an extended "tail" period during which almost all regulations had to make their way through the courts. It may be the case that this is a new reality going forward and this practice will continue, but it may also dissipate, providing more finality to final regulations.