Holland & Knight

HEALTH DOSE: POST-ELECTION EDITION
Holland & Knight Healthcare & Life Sciences Policy Team
November 11, 2024

Holland & Knight's Healthcare & Life Sciences Policy Team regularly provides updates through our weekly Health Dose. This special Health Dose: Post-Election Edition is intended to outline the short- and long-term potential impacts of the 2024 election. There is much that is still not known, including which party will control the U.S. House of Representatives. We will continue to provide analysis as events unfold and warrant.

For questions or to follow up, please contact the following partners and professionals and we will steer you to the right healthcare and life sciences leader on our team. For additional information please contact any of the authors of this memorandum on the Healthcare & Life Sciences Policy Team: Lisa Hawke, Robert Bradner, Miranda Franco, Michael Werner, John Vaughn, Sara Klock, Parker Reynolds, Sarah Crossan and Abigail Hemenway.

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I. KEY TAKEAWAYS

The election of Donald J. Trump as the 47th president and the change in the U.S. Senate control from the Democrats to the Republicans will substantially impact the healthcare enterprise, presenting both opportunities and challenges for healthcare stakeholders. Though the outcome of control of the U.S. House of Representatives is unknown at the time of this writing, Republican leaders are expressing confidence that they will retain a small majority. Democratic leaders continue to state that they still see a path to control.

On the immediate horizon, U.S. Congress may seek a short-term continuing resolution to fund the federal budget, perhaps through March 2025. There are a number of bipartisan initiatives in the health arena in this Congress that could be addressed in a 2024 year-end health package before Christmas. Several critical health "extenders," such as funding for community health centers, ambulances and safety-net hospitals, must be addressed, perhaps through a one-year extension. However, if Congress elects to delay the final appropriations legislation until March 2025, it is certainly possible that these health "extender" provisions could also be temporarily continued through the same March 2025 timeframe.

Going into 2025, we are likely to see the Trump Administration use its rulemaking and executive action authorities to examine and potentially reverse a number of the Biden Administration's actions and advance the new president's priorities. We could also see the use of the Congressional Review Act to repeal recent U.S. Department of Health and Human Services (HHS) rules if Republicans gain control of the House.

On Capitol Hill, reducing the size of the deficit and debt remain critical priorities for many Republicans. If the Republicans retain control of the House of Representatives, we anticipate that they will move a "budget resolution" to advance key priorities, particularly around extending the expiring provisions of the Tax Cuts and Jobs Act, and addressing additional promises made during the campaign such as eliminating the tax on tips and Social Security. As part of that "budget reconciliation" legislation, the Republicans may seek to include a number of tax-related healthcare provisions, such as expanding the limitations on health savings accounts and equalizing the tax treatment of individual and employer-sponsored health plans. Further, we expect budget legislation to include "site-neutral" Medicare payments for outpatient services, which would have an adverse financial impact on hospitals, but would bring substantial program savings.

We do not anticipate at this time that a Republican-controlled Congress, if that occurs, would seek a full repeal and replace of the Affordable Care Act (ACA). However, there are a number of other Republican priorities in healthcare, some of which can be included in the budget reconciliation legislation under Senate rules and some of which cannot, but could be advanced through the regular legislative process or perhaps part of a larger healthcare package. Some key themes that we expect from the Republicans in the White House and Senate, at least, include increasing price transparency, reducing consolidation in the healthcare industry (including in the hospital sector), empowering patients to make healthcare choices and enhancing competition among providers, including eliminating the ban on physician-owned hospitals.

II. ELECTION RESULTS (as of Nov. 11, 2024)

President of the United States – Donald J. Trump

- Former President Trump has secured the presidency, garnering almost 75 million votes and flipping Pennsylvania, Michigan, Georgia, Wisconsin, Nevada and Arizona for 312 electoral votes.
- Vice President Kamala Harris has received approximately 71 million votes and 226 electoral votes.
- While there are still some votes uncounted, the total votes for Vice President Harris are about 13 million fewer than were cast for President Joe Biden in 2020.

U.S. Senate – GOP Majority (At Least 53 Seats; Final TBD)

- The map this cycle favored Republicans, who only needed to flip one other seat in addition to West Virginia (GOP won) to gain a majority.
- Republicans have won a total of 53 races so far, with one race still undecided (Arizona).
- With wins in Montana, West Virginia and Ohio, Republicans have secured an operational majority of at least 53 seats.
- Notably, although *The Associated Press* (AP) has called the Pennsylvania Senate race in favor of David McCormick, Sen. Casey has not yet conceded.

U.S. House of Representatives – TBD

- Democrats needed a net gain of four seats to secure the majority, but Republican wins in Pennsylvania, Michigan and North Carolina offset losses in New York.
- As of Nov. 11, 2024, *AP* had called 416 of 435 seats, with Republicans holding 214 seats and Democrats holding 203 seats.
- 18 seats remain to be called. This includes nine close races in California, where absentee ballots can be counted up to a week after Election Day, as long as they are postmarked by that day.

III. LEADERSHIP CONTESTS

House of Representatives

In the House, the GOP is proceeding with leadership elections on the assumption that it will retain the majority. Speaker Mike Johnson (R-La.), Majority Leader Steve Scalise (R-La.) and Majority Whip Tom Emmer (R-Minn.) are all expected to win their respective reelections, and in Speaker Johnson's case, renomination. Speaker Johnson is likely to secure renomination for Speaker during the GOP Conference elections scheduled for Nov. 13, 2024, where he will need only a 50 percent majority. However, he would like to get as close to 218 votes as possible. Some members of the GOP may vote against Johnson in the conference as a signal of discontent over certain decisions he made this year, particularly regarding the March 2024 spending package. The actual election of a new Speaker for the 119th Congress will occur on Jan. 3, 2025, and Speaker Johnson will likely be working intensively between now and then to shore up support.

The House Democratic leadership is also expected to remain static; Minority Leader Hakeem Jeffries (D-N.Y.) and Minority Whip Katherine Clark (D-Mass.) both plan to remain in their leadership positions. Earlier in the year, Assistant Leader James Clyburn (D-S.C.) stepped down from his leadership role and was replaced by Democratic Policy and Communications Committee Chair Joe Neguse (D-Colo). House Democrats indicated they'll hold leadership elections Nov. 19, 2024. Should the Democrats take control of the House, this same group of three leaders would be expected to accede to the Speaker, Majority Leader and Whip positions, respectively.

Senate

Sen. Mitch McConnell (R-Ky.) is stepping down as Senate Republican leader, creating the first opening for the installation of a new Republican leader in decades. Sens. John Thune (S.D.) and John Cornyn (R-Texas) have long been seen as the frontrunners in the Senate Republican leadership race. Both have been actively campaigning for months. Sen. Rick Scott (R-Fla.) is also running and is touting his close personal relationship with President-Elect Trump. Notably, Steve Daines (R-Mont.), who for weeks was considered a potential contender in the event of a Trump victory, recently expressed support for Thune's candidacy. The race for Majority Leader takes place behind closed doors and only requires a majority vote to declare a winner. The election is scheduled for Nov. 13, 2024.

Sen. John Barrasso (R-Wyo.) is running unopposed for Republican Whip. Sen. Tim Scott (D-S.C.) seems poised to take over the National Republican Senatorial Committee (NRSC). Sens. Joni Ernst (R-Iowa) and Tom Cotton (R-Ark.). are both seeking the Senate Republican Conference chair, the third-ranking Senate Republican leadership position.

As in the House, there is much less uncertainty expected on the Democratic side despite the fact that they lost control of the Senate. Sen. Chuck Schumer (D-N.Y.) is expected to remain in his leadership role as Minority Leader with Sen. Dick Durbin (D-Ill.) in the number two position. Sen. Debbie Stabenow (D-Mich.) did not run for reelection and is currently the number three Democrat in the Senate leadership. Sens. Cory Booker (D-N.J.) and Amy Klobuchar (D-Minn.) are expected to run to replace her. Sen. Kirsten Gillibrand (D-N.Y.) is reported running to lead the Democratic Senatorial Campaign Committee (DSCC).

Makeup of Key Healthcare Committees

HOUSE COMMITTEES

In the House, Speaker Johnson and Minority Leader Jeffries will need to agree on committee ratios (i.e., the number of Republicans and Democrats) for each House committee before new members can be assigned. Minority Leader Jeffries may withhold agreement until Speaker Johnson secures the Speaker vote on the floor, potentially delaying committee assignments. Democrat and Republican committee leaders who did not retire or move on to other offices are generally expected to remain in place.

House Committee on Energy and Commerce

The 119th Congress will yield a shakeup in the House Committee on Energy and Commerce. Current Energy and Commerce Chair Cathy McMorris Rodgers (R-Wash.) is retiring, and Reps. Brett Guthrie (R-Ky.) and Bob Latta (R-Ohio) are both running to become the lead Republican for the committee. Rep. Guthrie currently serves as the chair of the Health Subcommittee, so if he is promoted to chair/ranking member, there will be a new subcommittee chair. Reps. Buddy Carter (R-Ga.), Morgan Griffith (R-Va.) and Gus Bilirakis (R-Fla.) are possible contenders for that role should it open up. Rep. Richard Hudson (R-N.C.), who currently chairs the National Republican Congressional Committee (NRCC), could also throw his hat in the ring for Chair/Ranking Member of the Committee or the Health Subcommittee.

On the Democratic side, Ranking Member Frank Pallone (D-N.J.) will likely continue as the committee's top Democrat. Rep. Anna Eshoo (D-Conn.), the Health Subcommittee ranking member, is retiring this Congress, and Rep. Diana DeGette (D-Colo.) is the most likely member to take on this role.

Steering Committees for each party will determine top committee leaders, subject to ratification by the conference, and the committees then generally determine subcommittee chair and ranking member positions. Steering Committee leadership assignments are typically completed before the process of assigning members to open positions on committees.

The current ratio on the Committee is 29 Republicans to 23 Democrats. If the Republicans retain the House that ratio would not be likely to change appreciably, and if the Democrats were to take control it would of course be reversed but, again, not much different.

House Committee on Ways and Means

Unlike Energy and Commerce, the House Committee on Ways and Means will look substantially similar to how it looks now. The 118th Congress Ways and Means Chair Jason Smith (R-Mo.) and Ranking Member Richard Neal (D-Mass.) will likely remain as the committee's leaders. There likely will not be changes to Ways and Means Health Subcommittee leadership – Reps. Vern Buchanan (R-Fla.) and Lloyd Doggett (D-Texas).

The current ratio on the Ways and Means Committee is 25 Republicans to 18 Democrats. Like the discussion above, the ratio should be similar in the 119th Congress.

House Appropriations Committee

While changes are possible among the 12 chairs and ranking members on the spending subcommittees, the most likely scenario is that Reps. Robert Aderholt (R-Ala.) and Rosa DeLauro (D-Conn.) would remain at the top of the Labor, Health and Human Services, Education and Related Agencies subcommittee.

SENATE COMMITTEES

Given the one-vote Senate Democratic margin in the 118th Congress, Senate Committee ratios provided for one additional Democrat. With a majority of 53 or more Republican Senators, this ratio will likely expand to provide a margin of two GOP Senators on each Committee. The Senate has a longstanding tradition of respect for seniority in determining committee leaders.

Senate Committee on Health, Education, Labor and Pensions (HELP)

Current HELP Chair Bernie Sanders (I-Vt.) has indicated he is "interested" in pursuing a seat on the Senate Committee on Finance. He would not necessarily need to give up his leadership role on HELP to do so. Should he step down, Sen. Tammy Baldwin (D-Wis.) or Sen. Chris Murphy (D-Conn.) would likely take his place.

Current Ranking Member Bill Cassidy (R-La.) is expected to become chairman of the committee. Although Sen. Rand Paul (R-Ky.) could invoke his seniority to take the HELP Chair, it is expected that he will decline to do so and instead chair the Senate Committee on Homeland Security and Governmental Affairs (HSGAC). It is also possible that Sen. Susan Collins (R-Maine) could claim the HELP chairmanship should Sen. McConnell claim the Appropriations Committee chairmanship, but he is not expected to do so.

Several slots are likely to open up "down dais" on the Republican side of the HELP Committee as Sens. Mike Braun (R-Ind.) and Mitt Romney (R-Utah) are not returning in the 119th Congress. The two freshman Republican senators currently serving on HELP – Sens. Markwayne Mullin (R-Okla.) and Sen. Ted Budd (R-N.C.) – may opt to give up their HELP seats in favor of other committee assignments.

Senate Finance Committee

Current Ranking Member Sen. Mike Crapo (R-Idaho) will likely become chairman of the Senate Committee on Finance. All of the Republicans currently serving on the committee are returning in the 119th Congress, so significant shuffling is not expected.

Sen. Ron Wyden (D-Ore.) will almost certainly retain his leadership position as the ranking member. Additionally, a notable number of down-dais seats on the Democratic side will become vacant. Sens. Debbie Stabenow (D-Mich.), Tom Carper (D-Del.), Ben Cardin (D-Md.) and George Helmy (D-N.J.) are all leaving office. And Sens. Sherrod Brown (D-Ohio) and Bob Casey (D-Pa.) were not reelected.

Senate Committee on Appropriations

Sen. McConnell could reclaim his seniority on the Appropriations Committee when he relinquishes his leadership role. However, the expectation is that he will not do so and will instead take the chairmanship of the Defense Appropriations Subcommittee. This would leave Susan Collins (R-Maine)

as the committee chair. The Labor, HHS, Education and Related Agencies Subcommittee will likely remain with Sen. Shelley Moore Capito (R-W.Va.) as chair and Sen. Tammy Baldwin (D-Wis.) as ranking member.

IV. KEY HEALTHCARE PLAYERS TO WATCH

The Biden Administration's political appointees will likely tender their resignations on or before the inauguration of President-Elect Trump. The process of vetting, nominating and installing Trump Administration leaders can be expected to take some time, especially where Senate confirmation is required. In addition, career civil servants in leadership positions may be reassigned and replaced by the new administration or may choose to leave public service.

The Trump transition team is currently vetting and recommending political appointees. Generally speaking, President-elect Trump is likely to bring back allies who served in his previous administration, key members of his current and former campaigns, and leaders of conservative policy organizations. Governors and retiring members of Congress could also be considered for important positions. Notably, the Trump/Vance transition team has to date eschewed the traditional General Services Administration (GSA)-provided transition assistance. It is unclear whether this could slow the process.

The following individuals are among possible leaders who could shape healthcare policy under the second Trump Administration:

1. ***Brian Blase, Paragon Health Institute***
   Currently the president of Paragon Health Institute, Blase previously served as special assistant to President Trump for economic policy, where he focused on healthcare deregulation and insurance reforms. With his extensive background in policy analysis from both the Senate Republican Policy Committee and the House Oversight and Government Reform Committee, Blase is well positioned for a senior healthcare policy role in a second Trump administration.

2. ***Michael Caputo, Former HHS Assistant Secretary for Public Affairs***
   Caputo, a close ally of President Trump with deep political connections, notably to Roger Stone, served as assistant secretary for public affairs at HHS during the first Trump administration. His media acumen and loyalist reputation suggest he could return to a key public-facing healthcare role, potentially advising on communications strategy in a second term.

3. ***Joe Grogan, Former Director of the Domestic Policy Council (DPC)***
   Grogan led the DPC under President Trump and was a key player in drug pricing reform and the administration's COVID-19 response measures. With his experience at both the DPC and the Office of Management and Budget (OMB), Grogan is a likely candidate to return to a senior healthcare policy position, particularly in regulatory reforms or health crisis management.

4. ***Bobby Jindal, Former Governor of Louisiana***
   Jindal, who served as governor of Louisiana from 2008 to 2016, was previously considered for HHS secretary during Trump's first term. Now chairing the America First Policy Institute's (AFPI) Center

for a Healthy America, Jindal's deep experience in healthcare reform and executive leadership could place him back in the running for a top health policy role, potentially even Secretary of HHS.

5. ***Valerie Huber, Former Special Representative for Global Women's Health***
   Huber served as special representative for global women's health at HHS, where she was involved in reproductive health policies during the first Trump Administration. She could be brought back into the fold for another leadership role, particularly in women's health policy.

6. ***Charlie Katebi, Deputy Director of AFPI's Center for a Healthy America***
   Katebi led the HHS Office of Civil Rights during President Trump's first term and has since become deputy director at the AFPI's Center for a Healthy America. His experience in conservative healthcare advocacy, including civil rights in healthcare and opposition to government overreach, positions him as a potential candidate for a key healthcare or civil rights role in a second Trump Administration.

7. ***Ed Martin, Political Strategist and Author***
   Martin has been instrumental in shaping President Trump's 2024 campaign platform on reproductive health, working closely with other conservative leaders such as Russ Vought and Paul Evans. A longtime Republican strategist and co-author of *The Conservative Case for Trump*, Martin could take on a senior advisory role within HHS or be involved in shaping health policy strategy from a political standpoint.

8. ***Theo Merkel, Former Special Assistant to the President for Economic Policy***
   Merkel was a driving force behind the June 2019 executive order on healthcare price transparency, and his expertise in economic and healthcare policy makes him a strong contender for another advisory role in a Trump Administration. Previously a legislative director for former Sen. Pat Toomey, Merkel's focus on transparency and market-driven healthcare solutions would align with Trump's deregulatory agenda.

9. ***Roger Severino, Vice President for Domestic Policy at the Heritage Foundation***
   Severino led the HHS Office of Civil Rights during President Trump's first term and has since been a leading voice at the Heritage Foundation, where he authored the healthcare section of Project 2025. His strong advocacy for religious freedom and opposition to the expansion of government-run healthcare would likely make him a key figure in shaping conservative healthcare policy, possibly with a return to HHS.

10. ***Abe Sutton, Former Health Policy Advisor During the First Trump Administration***
    Sutton served as a health policy advisor under the first Trump Administration, holding positions at the National Economic Council (NEC), the Domestic Policy Council (DPC) and Center for Medicare and Medicaid Innovation (CMMI). He was the "architect" of Trump's 2019 Advancing American Kidney Health Executive Order, which established CMMI's mandatory End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model. Sutton also was closely involved with the DPC's drug pricing and individual insurance market reforms and worked to implement President Trump's 2017 executive order on healthcare choice and competition.

11. ***Eric Hargan, Former Acting HHS Secretary During the First Trump Administration***
    Hargan is a Chicago-based healthcare lawyer who was appointed by then-President Trump in 2017 to serve as HHS deputy secretary following the resignation of HHS Secretary Tom Price. He was an "architect" of Trump's hospital price transparency rule and was closely involved with the pandemic-era Operation Warp Speed COVID-19 vaccine development initiative. Hargan is a strong proponent for telehealth and other health technology, including data sharing. He previously served at HHS under the Bush Administration.

12. ***Robert F. Kennedy Jr.***
    Kennedy's decision to abandon his presidential bid, endorse Trump and become involved in his campaign is expected to result in him playing an as-yet undefined role in the new administration. Trump transition co-chair Howard Lutnick has indicated that Kennedy would likely have a role under the Trump Administration – at least nominally – focused on "health and vaccine data." Other sources suggest he could have broader responsibility. It is believed that he would not take a position requiring Senate confirmation but might take a White House position related to overseeing food safety issues and efforts to reform the U.S. Food & Drug Administration (FDA), Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH).

13. ***Paul Mango***
    Former Deputy Chief of Staff at HHS under the first Trump Administration. Mango was instrumental in launching Operation Warp Speed at the onset of the pandemic. Currently, he is an advisor at the Paragon Health Institute. Mango's work at HHS also encompassed initiatives in transparency and interoperability, and he previously held roles as chief principal deputy administrator and chief of staff at the Centers for Medicare & Medicaid Services (CMS) under President Trump. He has also run for governor in Pennsylvania.

V. CONTEXT FOR HEALTHCARE POLICY

Healthcare was not as significant an issue in the 2024 election as it was in the 2016 election. There were certainly proposals from Vice President Harris that would have expanded access to care, such as Medicare for elder care. Reproductive care was a major issue on both sides. However, in winning the election, Republicans did not campaign universally on any particular approach to healthcare, other than the need to reduce healthcare costs. This is a markedly different situation than in 2016 when the Republicans had run on "repealing and replacing" the ACA.

In considering what the incoming Trump Administration or a Republican majority in Congress may pursue in healthcare, it's also important to note what they are not likely to pursue at the outset. For example, President-Elect Trump campaigned to protect Social Security and Medicare for seniors. Whether that means that they will not seek to change reimbursement for providers caring for those seniors may be a different matter. President-Elect Trump did not focus much attention on Medicaid during the campaign, but it has grown exponentially since the enactment of the ACA in 2010, and changes to it may be considered by the Trump Administration within its statutory authority or by Congress.

As mentioned, when Republicans won the House, Senate and White House in 2016, they had run on "Repeal and Replace" the ACA. As their healthcare legislation began moving through the Congress, aspects of it were perceived as threatening consumer protections in the ACA, such as protecting individuals with health conditions. Democrats and many provider groups heavily criticized the legislation for restructuring safety-net programs, particularly Medicaid. Republicans were unsuccessful in part because they had not unified around a replacement for the ACA and faced internal division, culminating in the "thumbs down" from Senator John McCain, which halted the legislation. After that healthcare reform effort failed, they turned to the Tax Cuts and Jobs Act, and utilized a tax mechanism to eliminate the "individual mandate" that required individuals to have health insurance. ***This experience may have a profound impact on the Republican healthcare strategy in the 119th Congress.***

During the past four years, a number of influential conservatives began to develop more cohesive and comprehensive plans around healthcare reform, both in Congress and in think tanks around Washington, D.C. To understand the policies that the Republicans intend to pursue, both in Congress and in the Trump Administration, it is worth examining these proposals, and focus on key themes and positions that cross many of them. Among several papers that are instructive on the Republican perspective and approaches they may take are the following:

- The Republican Study Committee (RSC) released ***A Framework for Personalized, Affordable Care***, in 2020, when now Speaker Johnson headed the RSC. According to the authors, the plan: "PROTECTS the vulnerable – especially those with pre-existing conditions; EMPOWERS individuals with greater control over their health care choices and dollars; and PERSONALIZES health care to meet individual needs and reduce premiums, deductibles, and the overall cost of health care." The RSC in 2022 put forth its *RSC Debt Limit Playbook*, and a series of positions for addressing the federal debt and deficit that would have potentially impact a variety of health programs, including entitlement programs and discretionary grant programs. This remains instructive in how Republicans in Congress may approach spending.

- In May 2024, the Paragon Institute released a report called *Follow the Money: How Tax Policy Shapes Health Care.* Its authors, Theo Merkel and Brian Blase, are influential in conservative healthcare circles and may rejoin the Trump Administration. The report provides a history behind many of the tax provisions affecting healthcare and recommendations for changes to the code, which, from their perspective "would improve the efficiency of the U.S. health care system and the value Americans receive from it."

VI. CONGRESSIONAL OUTLOOK

Post-Election Congressional Docket

When Congress left for the campaign trail in September 2024, much unfinished business was left behind. None of the 12 spending bills that fund the government has been enacted, and numerous

expiring provisions of law have not been extended. Congress will reconvene Nov. 12, 2024, for a "lame-duck" post-election session with temporary government funding expiring Dec. 20, 2024. Plans for the year-end session will likely come into greater focus this week as the members return and when the incoming Trump Administration makes its preferences known. However, given the election results, there is potential for funding to be temporarily extended into 2025, perhaps March 2025, in lieu of resolving all the bills before year end. Congress may also want to finalize the National Defense Authorization Act (NDAA) for fiscal year (FY) 2025, and there is a pressing need to replenish disaster relief funding for the Federal Emergency Management Agency (FEMA), the Small Business Administration (SBA) and the western land management agencies following recent hurricanes and wildfires. Additionally, the military will likely need supplemental funding for expanded operations in the Middle East.

Left in limbo are also numerous healthcare-related items that have worked their way through House and Senate Committees over the past two years. In one category is a package of measures to extend expiring provisions of law. This includes Medicaid Disproportionate Share Hospital (DSH) funding, Federally Qualified Health Center (FQHC) and Teaching Health Center funding, Medicare Low-Volume Payment Adjustment, expanded Medicare telehealth authorities, the Acute Hospital Care at Home (AHCAH) Initiative, FDA priority review vouchers for rare diseases, National Health Service Corps (NHSC) funding and certain diabetes programs. Closely related to these "extenders" is legislation to mitigate some or all of the proposed 2.83 percent cut in physician and other clinician reimbursement under Medicare and address the Advanced Alternative Payment Model (APM) bonus payment. Additionally, an extension of a temporary US Drug Enforcement Administration (DEA) policy around the prescription of certain controlled substances through telemedicine needs to be addressed. The current extension ends December 31, 2024, without further action from DEA (a pending rule is at Office of Management and Budget).

There is a strong desire on the part of a number of retiring members of Congress to finalize a number of issues in a year-end package. There may be an effort to clear a package addressing these items, perhaps for one year, but it is unclear if it will succeed, and a temporary extension, possibly aligned with a continuing resolution such as through March 2025, is also possible. The Congress may also finalize the reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPA).

Another key factor influencing how productive the lame duck session will be is whether Congress can reach agreement on funding for specific provisions. The Medicare Improvement Fund, with a reserve of $3.2 billion, is available to support health-related measures during the lame duck period, such as extending Medicare telehealth flexibilities. Policymakers are likely considering additional Medicare funding options, which could include proposals like Medicare site-neutral payment reforms and reforms for pharmacy benefit managers (PBMs). For instance, site-neutral payment changes under the Lower Costs, More Transparency Act are projected to save about $3.7 billion over ten years, while the PBM reforms are estimated to save $1 billion over the same period. However, due to the controversial nature of these proposals it is likely policymakers may choose to not utilize them. Another possible funding approach is the repeal of the Minimum Staffing Standards for Long-Term Care Facilities and the Medicaid Institutional Payment Transparency Reporting Final Rule.

Unless an agreement is reached on the funding discussion mentioned above, a broader set of initiatives – covering areas like transparency, pharmacy benefit management reform, the SUPPORT Act, Medicare prior authorization protections, reform of the 340B drug discount program, "site-neutral" Medicare payment adjustments, and other key issues – are more likely to be set aside in 2024 and revisited in 2025. Some issues, such as BIOSECURE, may be attached to the National Defense Authorization Act (NDAA), although the legislation appears to be having its desired impact even without becoming law.

The productivity of the lame duck session will factor into how the 119th Congress gets underway in 2025, as Republicans are expected to quickly introduce a major tax package, and begin discussing how to address the debt limit, while also needing to confirm Trump's Cabinet nominees.

Outlook for 119th Congress

Looking ahead to 2025, a Republican-controlled Senate could streamline confirmation of President Trump's preferred nominees in the administration's initial days. Additionally, key policies, such as the expanded ACA premium subsidies and tax cuts are set to expire at the end of 2025 without new Congressional action. Depending on which party controls the House, extending these policies may lead to negotiations between Congressional Democrats and Republicans, potentially opening a pathway for advancing other health-related legislation. This could include policies currently under consideration, such as pharmacy benefit manager (PBM) and 340B drug pricing reforms, or incremental adjustments to the IRA drug pricing provisions.

That said, if Republicans retain control of the House, they are ready to draft a "budget reconciliation" bill that could navigate congressional budget process rules to achieve their priorities. A major purpose of this legislation would be to extend the expiring provisions of the Tax Cuts and Jobs Act of 2017 (TCJA), and address other tax-related proposals made by President-Elect Trump during the campaign, such as lowering the corporate rate and eliminating taxes on tips, Social Security and overtime. Repealing various tax incentives included in the Inflation Reduction Act (IRA) is also of great interest. It is conceivable that in this context Republications will pursue changes to the tax code to effectuate longstanding health policy preferences as part of that larger tax legislation, such as dramatically expanding health savings accounts and equalizing the tax treatment of employer and individual health plan costs.

Budget reconciliation is a process that allows for the "expedited" consideration of revenue and spending legislation. Through reconciliation, the Senate may bypass the 60-vote filibuster threshold and approve legislation by a simple majority provided that no "extraneous" provisions (items that don't affect revenues or spending) are included. Budget reconciliation is the process that Democrats used to enact the ACA in 2010 and Republicans used in a thwarted attempt to repeal the ACA in 2017. Additionally, the Inflation Reduction Act, the American Rescue Plan Act, and the Tax Cuts and Jobs Act were all passed via reconciliation. If Democrats were to hold the House, the process for addressing changes to the tax code would look very different. Specifically, many Democrats will want to keep most of the expiring individual tax reductions and would oppose repealing IRA incentives. In this scenario, a protracted negotiated solution is likely.

Assuming they retain control of the House, Republicans are starting with a broad range of policies for reconciliation, though these will almost certainly be narrowed by rulings from the Senate Parliamentarian, scoring considerations from the CBO and members' concerns about potentially "controversial" provisions. GOP leadership will want to move quickly on reconciliation in 2025 that will probably be largely focused on expiration of most of the individual tax reductions enacted in the TCJA. It is possible to divide reconciliation into more than one bill. Under this approach, a tax code-only bill could be expedited, and a second bill could address spending and the debt limit.

Republicans may use reconciliation legislation to address the debt limit, reforms to the IRA and site-neutrality of Medicare payments in outpatient settings which would have a significant impact on hospitals. One provision that may receive attention as well is the Orphan Drug Tax Credit (ODTC), which provides a 25 percent credit to product developers for clinical expenses.

It is very important to underscore that, under Senate rules, budget reconciliation legislation must effectuate changes to federal expenditures; policy changes that do not affect federal expenditures cannot be included. This means that a number of health policy changes that Republicans would like to address, including changes to the ACA insurance market requirements, may not be able to move on a reconciliation bill and would need to be considered in separate legislation.

That said, Republicans are likely to push for measures to amend certain aspects of the ACA. Additionally, reforming PBMs, a bipartisan effort ongoing for nearly two years, will likely remain a focus. Reform on the 340B Drug Pricing Program and site-neutrality are also expected to be key priorities. Site-neutral payment is a bipartisan policy with momentum. Recently, Sens. Cassidy and Maggie Hassan (D-N.H.) introduced a framework establishing site-neutral payments in off-campus hospital outpatient departments and for common outpatient services. Modernization of 340B has gained bipartisan momentum, and one of its key leaders is Sen. Thune, who is running for Senate Majority Leader.

Also on the docket for next year, the FDA's user fee program for Over-the-Counter Monograph Drug User Fee Program (OMUFA), which is set to expire. Congress will begin to consider policy priorities and potential riders for inclusion of the OMUFA reauthorization package beginning early in the first quarter of 2025. We also expect debate surrounding the legal status of cannabis. During his campaign, President-Elect Trump has expressed support for ballot initiatives to legalize recreational use of marijuana in states. However, the prospects for national policy are less clear and in his first administration did not support re-scheduling. The Drug Enforcement Administration (DEA) is holding a preliminary hearing in December 2024 regarding its rescheduling proposal. It is too soon to tell what the FDA's enforcement policies regarding CBD and cannabis will be.

VII. EXECUTIVE OUTLOOK

Governmental Reforms

The Trump campaign emphasized the need to scale back the size and scope of the federal government. While it remains unclear yet how that will occur and who will be driving it, such as Elon Musk or Robert F. Kennedy Jr. in the health arena, it is worth examining the GAO High-Risk List, most recently published in 2023, which identifies a number of areas within the federal government that it believes warrants particular focus because it "identifies government operations with vulnerabilities to fraud, waste, abuse, and mismanagement, or in need of transformation." In the 2023 update, the GAO included the following areas on the high-risk list, which may be some of the areas upon which the Trump Administration will focus its attention:

- strengthening Medicaid integrity
- improving federal oversight of food safety
- protecting public health through enhanced oversight of medical products.
- HHS leadership and coordination of public health emergencies (new in 2022)
- Medicare program and improper payments

Reducing and scaling back regulations will again be a priority for the Trump Administration. In this regard, the *Loper Bright* decision may help the administration identify and scale back regulatory action previously taken that they believe exceeds the statutory authority provided by the Congress.

Affordable Care Act

The Trump Administration will likely pursue reforms to the ACA in the regulatory sphere including allowing insurers to divide enrollees into different risk pools and offer different plans based on those health risks. The new administration may also reinstate favorable rules regarding so-called "association health plans" which enable small businesses to band together to purchase insurance with greater market leverage. The administration may also enhance "short-term limited duration health insurance" which is not subject to the ACA's "essential health benefits" insurance requirements and allows for more flexible benefits plans.

Additionally, the Trump Administration could reduce the budget for "navigators," which are outreach professionals who help people find and enroll in health plans. Most significant are the enhanced premium tax credits for the purchase of ACA policies that will expire at the end of 2025. Maintaining these enhanced credits was a high priority for President Biden but is unlikely to be supported by Congressional Republicans and the Trump Administration.

Medicare

Physician Payment Reform. President Trump has repeatedly stated that he will not cut Medicare or Social Security, but it is unclear the extent to which this philosophy extends to payments to providers. His prior administration drove a realignment of physician payment from specialty to primary care; and it is unclear whether he would support reform of the Medicare Physician Fee Schedule (MPFS) to address chronic problems with underpayment of doctors and other clinicians.

Value Based Care. The CMMI has faced substantial criticism from Republicans – highlighted in a June Energy and Commerce hearing – for issues like program complexity and limited cost savings. Despite these critiques, CMMI's model flexibility is significant compared to other CMS demonstration authorities – with broader latitude in scale, ability to be mostly nationwide, exempt from budget-neutrality requirements and no time limits. Given this scope, CMMI is likely to remain central to policy efforts in the next administration, In Trump's first term, the Trump Administration emphasized value-based payment reforms with payer – as opposed to provider – centric approaches.

Medicare Advantage. It can be expected that an embracing approach to Medicare Advantage (MA) will generally prevail, and that transparency and competition will be organizing principles. Changes to the quality bonuses that MA plans receive were made during the Biden Administration to make them less generous. This could be revisited as well as the process by which MA benchmark payments are risk adjusted to account for the composition of the insured population. There is bipartisan concern over payment rates and risk adjustment presenting an opportunity for plans to re-shape the payment environment.

Medicaid

Securing major statutory changes to Medicaid, such as "block grants" or "per capita caps" have been attempted before and may prove difficult on Capitol Hill with Democrats pushing back as hard as they did in 2017. However, the second Trump Administration may seek to effectuate change within its statutory authority through regulatory actions and executive orders. For example, they may impose work requirements as a condition of Medicaid eligibility.

One potential area of concern for providers, particularly hospitals, is the Medicaid Managed Care regulations which allow for state directed payment programs (SDP). Since 2016, CMS has allowed states to direct certain payments through managed care organizations to providers that are based on value or innovation. These SDP programs now total over $100 billion, which is a considerable percentage of Medicaid's overall expenditures of approximately $860 billion in 2023. Because these payments were created under a regulatory rubric, it is possible that they could be altered or scaled back under a new regulatory approach as well.

Other CMS Policies

Under a second Trump Administration, CMS would likely continue some policies while reverting to previous positions on others. Key Trump-era policies included:

- **Site-Neutral Payments**. The calendar year (CY) 2019 Outpatient Prospective Payment System (OPPS) rule applied PFS-equivalent rates for clinic services at off-campus provider-based departments.

- **Moving Procedures to Less Acute Settings**. CMS expanded outpatient services, removing total knee and hip arthroplasty, spinal surgeries and other procedures from the inpatient-only list. The CY 2021 OPPS rule finalized eliminating the list over three years.

- **Ambulatory Surgical Centers (ASC)**. The CY 2019-2021 rules added cardiovascular, knee and hip procedures to the ASC list, expanding outpatient coverage for these services.

- **New Payment Pathways**. CMS created additional payment routes for new FDA-approved technologies, including breakthrough devices and qualified antimicrobial products.

- **Increased Rural Hospital Payments.** The FY 2020 IPPS rule raised the wage index for hospitals below the 25th percentile to address disparities between high and low-wage hospitals.

Artificial Intelligence (AI)

President Biden signed a sweeping executive order in October 2023 and invoked the Defense Production Act to establish the first set of standards for using AI in healthcare and other industries, calling for greater public oversight and regulation of AI. HHS, in compliance with this executive order, established an AI Safety Program to track harmful incidents involving AI in healthcare settings, established an AI Task Force and finalized a rule requiring transparency requirements for AI under certain certified health information technology. President-elect Trump's platform seeks to repeal this executive order. President Trump has indicated that he will allow the technology industry more latitude to self-regulate and permit greater innovation for uses of AI in healthcare. Furthermore, health data interoperability and data sharing regulations enabled by the Trusted Exchange Framework and Common Agreement (TEFCA) pursuant to the 21st Century Cures Act are likely to continue to be implemented. That said, concerns about cybersecurity and patient privacy will likely lead to some rulemaking under the new administration.

Drug Shortages

President-Elect Trump's approach to resolving drug shortages could involve using tariffs and reviving a "Buy American" executive order. Though President Trump issued such an order in 2020, President Biden and Vice President Harris later broadened the focus to include supply chain resilience. President Trump has been critical of U.S. reliance on drugs sourced from China and previously supported companies that manufactured pharmaceuticals domestically. In a second term, he could pursue partnerships with these companies to address drug shortages and incentivize domestic production of medical supplies. Notably, tax incentives to boost U.S.-based manufacturing in the medical sector could become a focal point during next year's tax bill discussions.

Related to this topic is whether the FDA will change its policy relative to its drug shortage list. In

particular, how to address increasing access to compounded drugs is on the docket for the next administration.

IRA's Drug Price Negotiation Program

Under the IRA, CMS must announce the next 15 drugs selected for Medicare price negotiation by Feb. 1, 2025. CMS has indicated it will collaborate with the incoming administration's transition team to facilitate the upcoming negotiation round, allowing the Trump Administration to assume control of the process immediately following inauguration on Jan. 20, 2025.

It remains uncertain how a second Trump Administration would handle the IRA's drug price negotiation program. President Trump has previously been vocal about high drug costs, proposing several policies aimed at reducing these costs during his first term, including the Most Favored Nation (MFN) rule. While the MFN rule was invalidated by the courts on procedural grounds, it's possible that a Trump Administration might seek to incorporate similar measures into the IRA framework.

Although it would be challenging for the new administration to significantly alter the program for 2025, this area may present an opportunity for President-Elect Trump to work with a GOP-led Congress to amend the program in the future. Additionally, expect a heightened focus on cost-sharing disparities and PBM practices, as consumer dissatisfaction with drug costs continues to rise.

Public Health Agency Reforms

Reform of several public health agencies is highly likely to be a serious and immediate discussion. This subject was driven in part by criticism of the response to the COVID pandemic, in part by a genuine interest in greater efficiency, and in part by the influence of Robert F. Kennedy Jr. and others on the Trump campaign's views on conflicts of interest. Reform is likely to be most immediately reflected in the hiring of agency heads and the retention – or lack thereof – of nonpolitical agency staff.

- **CDC Reform.** The CDC does not have an explicit, formal authorizing statute and often relies on general public health authorities under the Provincial Health Services Authority (PHSA). During President Trump's first term, CDC's interpretation of its PHSA mandate led to significant controversy and a number of high-profile legal challenges. Of note are proposals to split the CDC into smaller entities focused respectively on data gathering, infectious disease and chronic illness. Chronic disease, and childhood chronic disease specifically, have been a central focus of President-Elect's Trump's public remarks related to health policy in recent weeks. There are also proposals to move certain CDC functions into the private sector. And some policymakers are concerned about possible conflicts of interest related to donations to the agency's foundation.

- **NIH Consolidation.** Other proposals would consolidate the NIH's institutes and centers into a more streamlined agency. President Trump's previous administration called for reduced topline funding for NIH and a "major reorganization" that would eliminate some NIH Centers and consolidate a number of external agencies within NIH, among other consolidations and

structural changes. These reforms would require congressional action. On the House side, current Energy and Commerce Chair Rep. Cathy McMorris Rodgers (R-Wash.) released a plan to consolidate the NIH's 27 disease centers down to 15. The House plan would also impose a five-year term limit for NIH directors, among other reforms. Additionally, top HELP Committee Republican Sen. Cassidy (R. La.) has released a white paper examining policy options for NIH reform. Both chambers' proposals may see renewed attention in the 119th Congress.

- **Federal Workforce and "Conflicts of Interest."** As noted above, President Trump has expressed an interest in reducing the federal government workforce, with a particular focus on public health agencies. He may revive his Schedule F Executive Order. Additionally, perceived conflicts of interest in public related external business relations or external funding sources (e.g., FDA user fees and NIH royalties) may see increased scrutiny.

- **FDA User Fees.** As noted above, FDA's OTC drug user fee program is slated for reauthorization next year. The user fee programs for prescription drugs, medical devices, generics and biosimilars will all require reauthorization in September 2027. A budget proposal laid out by the Trump Administration in his first term would have increased industry-collected user fees significantly. The second Trump Administration may have a different position; Robert F. Kennedy Jr. has repeatedly called for the complete elimination of user fee programs to coincide with his criticism of the agency's regulation of different food and medicinal products.

Reproductive Health

President-elect Trump has said that he would leave it to the states to establish their own abortion policies, but there are a number of reproductive health-related issues that fall squarely upon the federal government. Other than expressing "strong support" for in vitro fertilization (IVF), President-elect Trump has largely avoided such issues in his public statements thus far.

- **Emergency Medical Treatment and Active Labor Act (EMTALA) Interpretation**. Whether to continue the Biden Administration's interpretation of EMTALA as requiring the provision of emergency abortion services

- **Health Insurance Portability and Accountability Act (HIPAA) and Reproductive Protected Health Information (PHI).** Interpreting HIPAA to protect the disclosure of certain abortion-related information to local and state law enforcement agencies.

- **Mifepristone/Mifepristol (Abortion Pill/Chemical Abortion) Access**. President Trump indicated last summer his openness to FDA rules allowing for the dispensing and use of Mifepristone/Mifeprostol without a physician consultation. Notably, enforcement of the Comstock Act prohibition on the shipment of such drugs in interstate commerce will also likely be a focus.

- **Title X Family Planning/ "Global Gag" Rule/"Mexico City Policy."** The new Trump Administration will likely reinstate the "gag rule" barring recipients of Title X family planning

funds from counseling and referring patients regarding the option to terminate a pregnancy. Funding for family planning and related activities under this title has been inconsistent since it was established in 1970, with a back-and-forth between Republican and Democratic administrations.

Maternal Health

The 2022, the Biden Administration issued an executive order on Addressing the Maternal Health Crisis, which established federal health and safety requirements for maternal emergency and obstetric services in hospitals and extended postpartum Medicaid coverage. Just this month, CMS announced new baseline health and safety requirements for hospitals and Critical Access Hospitals (CAHs) providing obstetrical (OB) services to make pregnancy, childbirth and postpartum care safer. President-elect Trump previously signed a maternal health bill into law in 2019 but may still rollback the Biden maternal executive order due to the elements of the order addressing diversity. As mentioned prior, Medicaid caps may be implemented.

Gender Health

The incoming Trump Administration will likely pull back the Biden Administration's rule interpreting Section 1557 of the Affordable Care Act as prohibiting the withholding of gender affirming care. They may also withdraw federal Medicaid matching funding to cover such care on the basis that it is unproven (experimental). Other changes regarding the provision of this care by the U.S. Department of Defense (DOD) and through programs such as the Ryan White Act are also possible.

Notably, Republican-led legislation to withhold Title IX funding from institutions that provide gender-affirming care gained some traction last Congress. Considering the expected balance of power in the 119th, similar legislation may be reintroduced and again become a hot-button topic.