

MEMORANDUM

To: Powers Clients

From: Powers Legislative Practice Group

Date: December 8, 2022

Re: 2022 Election Summary as of December 8, 2022 and Analysis from a Health

Care Perspective

This memorandum provides a detailed analysis of the 2022 election results to date, the elections' implications for the Executive Branch, and composition of the 118th Congress, including the following:

- I. Detailed Analysis of Election Dynamics
- II. Key Changes to Congressional Committees Overseeing Health Policy
- III. Select Ballot Initiatives and Referenda
- IV. Health Care Impact and Analysis
 - a. Lame Duck Preview
 - b. Preview of Agenda for 118th Congress
 - c. Preview of Biden Administration Health Care Priorities

With all but one House race left uncalled, it is clear that Democrats will retain a slim majority in the Senate and Republicans will gain control of the House of Representatives, with 221 Republicans elected to Democrats' 213. Democrats flipped three governors' seats (in Maryland, Massachusetts, and Arizona) while Republicans flipped one seat in Nevada.

I. Detailed Analysis of Election Dynamics (as of Dec. 8)

Confirmed Seats in the 2020 Congressional & Governors Races

| | Senate | House | Governors |
|------------------|---------------------|-------|-----------|
| Democrats | 51 | | |
| | (including 2 | | |
| | independents who | 213 | 24 |
| | conference with the | | |
| | Democratic party) | | |
| Republicans | 49 | 221 | 26 |
| To Be Determined | 0 | 1 | 0 |

¹ We are monitoring election results from multiple reputable sources including the Associated Press, Bloomberg Government, and Politico.



U.S. Senate

Democrats retained the majority in the Senate with key incumbent victories in Nevada, Georgia, and Arizona in conjunction with a flipped political party seat in Pennsylvania. Democrats held all their current seats, and the party will retain a slim majority in the 118th Congress, holding 51 seats to Republicans' 49. Pennsylvania is the only state to flip a Senate seat with Lt. Gov. John Fetterman (D) beating opponent Mehmet Oz (R), filling the seat left open by the retirement of Sen. Patrick J. Toomey (R). In Nevada, incumbent Sen. Catherine Cortez Masto (D) defeated opponent Adam Laxalt (R) and in Arizona, incumbent Sen. Mark Kelly (D) defeated Blake Masters (R).

On December 6th, Georgia held a runoff election between incumbent Sen. Raphael Warnock (D) and challenger Herschel Walker (R). Under Georgia's election laws, a runoff is held when no candidate receives at least 50% of the vote in the general election. The race was called for Sen. Warnock late that evening, allowing Democrats to slightly expand their majority over the 117th Congress (when a 50-50 Senate split required Vice President Kamala Harris' vote to break a tie).

With a true majority next Congress, Democrats will hold the majority of seats on each Senate committee, rather than having to negotiate a power-sharing agreement with Republicans as in the 117th Congress. Further, the power of any individual Democratic Senator will be lessened somewhat, as moderates like Sen. Joe Manchin (D-WV) and Kyrsten Sinema (D) will no longer be able to hold "veto" power over a given vote.

Sen. Chuck Schumer (D-NY) will almost certainly retain his position as Senate Majority Leader after the Democratic leadership elections in early December, while Sen. Mitch McConnell (R-KY) easily defeated a challenge from Sen. Rick Scott (R-FL) to remain Senate Minority Leader, Sen. McConnell's first challenge in his 15 years as the top Senate Republican.

Of the 35 Senate races, the following 13 were, at most times during 2022, the most competitive.

Battleground (Most Competitive) Senate Races

| State | Elected | Defeated |
|----------------|-------------------------|---------------------|
| Arizona | Mark Kelly (D)* | Blake Masters (R) |
| Colorado | Michael Bennet (D)* | Joe O'Dea (R) |
| Florida | Marco Rubio (R)* | Val Demings (D) |
| Georgia | Raphael Warnock (D)* | Herschel Walker (R) |
| Iowa | Chuck Grassley (R)* | Mike Franken (D) |
| New Hampshire | Maggie Hassan (D)* | Don Bolduc (R) |
| Nevada | Catherine Cortez Masto* | Adam Laxalt (R) |
| North Carolina | Ted Budd (R) | Cheri Beasley (D) |
| Ohio | J.D. Vance (R) | Tim Ryan (D) |
| Pennsylvania | John Fetterman (D) | Mehmet Oz (R) |
| Utah | Mike Lee (R)* | Evan McMullin (I) |
| Washington | Patty Murray (D)* | Tiffany Smiley (R) |
| Wisconsin | Ron Johnson (R)* | Mandela Barnes (D) |

^{*} Indicates Incumbent | **Bold indicates a flipped seat**



U.S. House of Representatives

Republicans have secured 221 seats (to Democrats' 213), enough to take over the House, although one outstanding race (CO-03) has yet to be formally called pending a mandatory recount. Despite predictions of a "red wave" with a broad Republican sweep in the House, there will be only a slim majority for Republicans. Rep. Kevin McCarthy (R-CA) formally won the Republican nomination for Speaker of the House but fell short of the 218 needed to win the position outright, with 31 GOP Members voting against him. McCarthy is expected to eventually win the gavel, but he will need to shore up more Republican votes ahead of the deciding vote in January 2023.

Current House Speaker Nancy Pelosi (D-CA) announced that she will be resigning her position as House Speaker/Minority Leader, though she will maintain her seat in Congress for her 19th term. House Majority Leader Steny Hoyer (D-MD) and Majority Whip James Clyburn (D-SC) also announced they will be stepping back from their current leadership roles, opening the door for new members to lead the Democratic Minority in the 118th Congress. In late November, House Democrats elected Rep. Hakeem Jeffries (D-NY) to serve as the next Democratic leader, with Reps. Katherine Clark (D-MA) and Pete Aguilar (D-CA) elected as Democratic Whip and Caucus Chair, respectively.

Rep. Clyburn was elected to serve as Assistant Democratic Leader, House Democrats' fourth leadership slot, and will be the sole holdover from the previous generation of leadership. Rep. Hoyer will be returning to the House Appropriations Committee and may seek to deploy his seniority to take over one of the subcommittees, though he has not yet announced his plans. Rep. Pelosi has announced she does not plan to serve on committees while she serves in an informal "Speaker Emeritus" role.

Of the 435 House races, the following seats were, at most times during 2022, the most competitive. This list also includes districts that "flipped" from Democrat to Republican or viceversa; some of these did not result in close races given redistricting.

Battleground (Most Competitive) House Races

| State and District | Elected | Defeated |
|--------------------|-----------------------|-------------------------|
| $AK-AL^2$ | Mary Peltola (D)* | Sarah Palin (R) |
| AZ-01 | David Schweikert (R)* | Jevin Hodge (D) |
| AZ-02 | Eli Crane (R) | Tom O'Halleran (D)* |
| AZ-06 | Juan Ciscomani (R) | Kirsten Engel (D) |
| CA-03 | Kevin Kiley (R) | Kermit Jones (D) |
| CA-05 | Tom McClintock (R)* | Mike Barkley (D) |
| CA-13 | John Duarte (R)* | Adam Gray (D) |
| CA-21 | Jim Costa (D)* | Michael Maher (R) |
| CA-22 | David Valadao (R)* | Rudy Salas (D) |
| CA-27 | Mike Garcia (R)* | Christy Smith (D) |

² Rep. Mary Peltola won a special election in August 2022 to fill the seat of the late Rep. Don Young, defeating Reps. Sarah Palin (R) and Nick Begich (R) in Alaska's first ranked-choice voting election. Peltola prevailed against the same two challengers in the November general election.



| CA-47 | Katie Porter (D)* | Scott Baugh (R) |
|--------------------|-------------------------|------------------------------|
| CA-49 | Mike Levin (D)* | Brian Maryott (R) |
| CO-03 ³ | TBD | TBD |
| CO-08 | Yadira Caraveo (D) | Barbara Kirkmeyer (R) |
| CT-05 | Jahana Hayes (D)* | George Logan (R) |
| FL-04 | Aaron Bean (R) | LaShonda Holloway (D) |
| FL-07 | Cory Mills (R) | Karen Green (D) |
| FL-13 | Anna Paulina Luna (R) | Eric Lynn (D) |
| GA-06 | Rich McCormick (R) | Bob Christian (D) |
| IA-03 | Zach Nunn (R) | Cindy Axne (D)* |
| IL-13 | Nikki Budzinski (D) | Regan Deering (R) |
| IL-17 | Eric Sorenson (D) | Esther Joy King (R) |
| IN-01 | Frank Mrvan (D)* | Jennifer-Ruth Green (R) |
| ME-02 | Jared Golden (D)* | Bruce Poliquin (R) |
| MI-03 | Hillary Scholten (D) | John Gibbs (R) |
| MI-07 | Elissa Slotkin (D)* | Tom Barrett (R) |
| MI-10 | John James (R) | Carl Malinga (D) |
| MN-02 | Angie Craig (D)* | Tyler Kistner (R) |
| NC-13 | Wiley Nickel (D) | Bo Hines (R) |
| NE-02 | Don Bacon (R)* | Tony Vargas (D) |
| NJ-07 | Tom Kean (R) | Tom Malinowski (D)* |
| NV-01 | Dina Titus (D)* | Mark Robertson (R) |
| NV-03 | Susie Lee (D)* | April Becker (R) |
| NH-01 | Chris Pappas (D)* | Karoline Leavitt (R) |
| NM-02 | Gabe Vasquez (D) | Yvette Herrell (R)* |
| NY-03 | George Santos (R) | Robert Zimmerman (D) |
| NY-04 | Anthony D'Esposito (R) | Laura Gillen (D) |
| NY-17 | Mike Lawler (R) | Sean Patrick Maloney (D)* |
| NY-19 | Marc Molinaro (R) | Josh Riley (D) |
| NY-22 | Brandon Williams (R) | Francis Conole (D) |
| NC-13 | Wiley Nickel (D) | Bo Hines (R) |
| OH-01 | Greg Landsman (D) | Steve Chabot (R)* |
| OH-13 | Emilia Sykes (D) | Madison Gesiotto Gilbert (R) |
| OR-05 | Lori Chavez-DeRemer (R) | Jamie McLeod-Skinner (D) |
| OR-06 | Andrea Salinas (D) | Mike Erickson (R) |
| PA-07 | Susan Wild (D)* | Lisa Scheller (R) |
| PA-08 | Matt Cartwright (D)* | Jim Bognet (R) |
| PA-17 | Chris Deluzio (D) | Jeremy Shaffer (R) |
| RI-02 | Seth Magaziner (D) | Allan Fung (R) |
| TX-15 | Monica De La Cruz (R) | Michelle Vallejo (D) |
| TX-28 | Henry Cuellar (D)* | Cassy Garcia (R) |

_

³ The Colorado 3rd District race has not been formally called, and the narrow margin will likely trigger an automatic recount under the state's election procedures. However, Democratic challenger Adam Frisch conceded the race to incumbent Lauren Boebert (R) on Nov. 18.



| TX-34 | Vicente Gonzalez (D)* | Mayra Flores (R)* |
|-------|-----------------------------|-------------------|
| VA-02 | Jen Kiggans (R) | Elaine Luria (D)* |
| VA-07 | Abigail Spanberger (D)* | Yesli Vega (R) |
| WA-03 | Marie Gluesenkamp Perez (D) | Joe Kent (R) |
| WA-08 | Kim Schrier (D)* | Matt Larkin (R) |
| WI-03 | Derrick Van Orden (R) | Brad Pfaff (D) |

^{*} Indicates incumbent | Bold indicates flipped seat

Gubernatorial Races

Of the 36 gubernatorial races that took place, Republicans picked up one seat with Joe Lombardo (R) defeating Steve Sisolak (D) in the race to replace outgoing Democratic Governor Charlie Baker in Nevada. The Democrats flipped 3 seats. Maura Healey (D) won the Massachusetts election against Geoff Diehl (R), succeeding the outgoing Republican Governor Charlie Baker; Wes Moore (D) won his race in Maryland, defeating his opponent Dan Cox (R), and is set to replace the outgoing Governor Larry Hogan (R); and Democrat Katie Hobbs of Arizona narrowly defeated Republican Kari Lake to replace the outgoing Republican Governor Doug Ducey. Democrats will hold 24 Governor seats while Republicans will hold 26.

In addition to flipped seats and other highly contested gubernatorial races, many states saw historic results. Arkansas, Massachusetts, and New York each elected its first female governor while Oregon and Massachusetts elected the first-ever openly lesbian governors.

Notable Gubernatorial Races

| State | Elected | Defeated |
|---------------|-----------------------------|----------------------|
| Arizona | Katie Hobbs (D) | Kari Lake (R) |
| Georgia | Brian Kemp (R)* | Stacey Abrams (D) |
| Kansas | Laura Kelly (D)* | Derek Schmidt (R) |
| Maryland | Wes Moore (D) | Dan Cox (R) |
| Maine | Janet Mills (D)* | Paul LePage (R) |
| Massachusetts | Maura Healey (D) | Geoff Diehl (R) |
| Michigan | Gretchen Whitmer (D)* | Tudor Dixon (R) |
| Nevada | Joe Lombardo (R) | Steve Sisolak (D)* |
| New Mexico | Michelle Lujan Grisham (D)* | Mark Ronchetti (R) |
| New York | Kathy Hochul (D)* | Lee Zeldin (R) |
| Oregon | Tina Kotek (D) | Christine Drazan (R) |
| Pennsylvania | Josh Shapiro (D) | Doug Mastriano (R) |
| Texas | Greg Abbott (R)* | Beto O'Rourke (D) |
| Wisconsin | Tony Evers (D)* | Tim Michels (R) |

^{*} Indicates incumbent | Italics indicates uncalled race | Bold indicates flipped seat



II. Key Changes to Congressional Committees Overseeing Health Policy

The four committees of jurisdiction over health care in Congress will experience changes in membership due to elections and retirements. Projected changes to the Senate Finance Committee; the Senate Health, Education, Labor, and Pensions (HELP) Committee; the House Ways and Means Committee; and the House Energy and Commerce Committee are detailed below. (Note: Formal committee leadership elections and assignments will not take place until early in the new Congress, but most incumbent members are expected to remain on their committees unless otherwise noted or announced).

Senate

The Senate Finance Committee saw a few changes with the retirements of Richard Burr (R-NC), Rob Portman (R-OH), and Patrick J. Toomey (R-PA). Chairman Ron Wyden (D-OR) and Ranking Member Mike Crapo (R-ID) retained their seats.

Senate Finance Committee Changes

| 2011W00 1 111W1100 0 0 111W11800 | | |
|----------------------------------|--------------------|---------------------------------------|
| State | Senator | Status on Committee |
| Idaho | Mike Crapo (R) | Ranking Member |
| Nebraska | Ben Sasse (R) | Resigning seat in Congress in January |
| North Carolina | Richard Burr (R) | Retiring |
| Ohio | Rob Portman (R) | Retiring |
| Oregon | Ron Wyden (D) | Chairman |
| Pennsylvania | Patrick Toomey (R) | Retiring |

Bold indicates not returning

The Senate Health, Education, Labor, and Pensions (HELP) Committee will see a change in leadership, though most Committee members will remain. Chairwoman Patty Murray (D-WA) will seek leadership of the Senate Appropriations Committee, and if approved by the Senate Democratic Caucus (which is expected), she will give up her seat atop the HELP Committee. Sen. Bernie Sanders (I-VT) is running to replace her as HELP Committee Chair. On the Republican side, Ranking Member Richard Burr (R-NC) is retiring, and Sen. Bill Cassidy (R-LA) is seeking to become the next Ranking Member. All other members serving on these committees who were up for reelection retained their seats.

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

| State | Senator | Status on Committee |
|----------------|--------------------|--|
| Louisiana | Bill Cassidy (R) | Running for Ranking Member |
| North Carolina | Richard Burr (R) | Ranking Member, retiring |
| Vermont | Bernie Sanders (I) | Running for HELP Chair |
| Washington | Patty Murray (D) | Former Chair, running for Appropriations Chair |

Bold indicates not returning



House of Representatives

In the House, there will be some shuffling of seats on key committees with jurisdiction over health care, and as Republicans take over the chamber, seat allotments will shift to reflect the new majority. New committee assignments (including incumbents who are rotating off and new members) will be issued early in the new Congress.

The House Ways and Means Committee saw three retirements, including Ranking Member Kevin Brady (R-TX) and Reps. Ron Kind (D-WI) and Thomas Suozzi (D-NY). While Rep. Richard Neal is expected to remain the Democratic leader on the Committee, there is a tight race to determine who will take over from Rep. Brady as the Chair of the Committee in the 118th. Reps. Vern Buchanan (R-FL), Jason Smith (R-MO), and Adrian Smith (R-NE) are all seeking the gavel, with no clear front-runner as of this writing.

House Ways and Means Committee Changes

| State/District | Representative | Status on Committee |
|----------------|----------------------|---|
| FL-07 | Stephanie Murphy (D) | Retiring |
| FL-16 | Vern Buchanan (R) | Reelected, Potential Chair |
| MA-01 | Richard Neal (D) | Chairman, will become Ranking Member |
| MO-08 | Jason Smith (R) | Reelected, Potential Chair |
| NE-03 | Adrian Smith (R) | Reelected, Potential Chair |
| NY-03 | Thomas Suozzi (D) | Resigning seat, sought NY Governor nomination |
| SC-07 | Tom Rice (R) | Lost primary |
| TX-08 | Kevin Brady (R) | Ranking Member, retiring |
| WI-03 | Ron Kind (D) | Retiring |

Bold indicates not returning

Members of the Energy & Commerce Committee not returning include Bobby Rush (D-IL), G.K. Butterfield (D-NC), Kathleen Rice (D-NY), Fred Upton (R-MI), Mike Doyle (D-PA), Jerry McNerney (D-CA) and Adam Kinzinger (R-IL), who are all retiring. Further, Tom O'Halleran (D-AZ), was defeated by opponent Eli Crane (R). Kurt Schrader (D-OR) and David B. McKinley (R-WV) each lost their primaries, while Billy Long (R) lost a primary bid to be Missouri's Republican Senate nominee. Rep. Donald McEachin passed away on November 28 shortly after winning reelection for his fifth term in Congress. Leadership on the Committee will remain stable, with current Ranking Member Cathy McMorris Rodgers (R-WA) taking over as Chair and Rep. Frank Pallone (D-NJ) becoming the Ranking Member.

House Energy and Commerce Committee Changes

| State | Representative | Status on Committee |
|-------|-----------------------|--------------------------------------|
| NJ-06 | Frank Pallone (D) | Chairman, will become Ranking Member |
| IL-01 | Bobby Rush (D) | Retiring |
| PA-18 | Michael Doyle (D) | Retiring |
| NC-01 | G. K. Butterfield (D) | Retiring |
| CA-09 | Jerry McNerney (D) | Retiring |
| VT-AL | Peter Welch (D) | Elected to US Senate |
| OR-05 | Kurt Schrader (D) | Lost primary |



| AZ-02 | Tom O'Halleran (D) | Defeated |
|-------|----------------------------|-----------------------------------|
| NY-04 | Kathleen Rice (D) | Retiring |
| WA-05 | Cathy McMorris Rodgers (R) | Ranking Member, will become Chair |
| MI-06 | Fred Upton (R) | Retiring |
| WV-02 | David B. McKinley (R) | Lost primary |
| IL-16 | Adam Kinzinger (R) | Retiring |
| MO-07 | Billy Long (R) | Lost Senate primary |
| OK-02 | Markwayne Mullin (R) | Elected to US Senate |
| VA-04 | Donald McEachin (D) | Passed Away Nov. 28 |

Bold indicates not returning

III. Select Ballot Issues and Referenda

In addition to the federal races, several states voted on high-profile ballot issues and other state policies impacting health care. The following is a brief summary of some of the more notable results:

- Arizona: Voters approved Proposition 209, reforming the treatment of medical debt in Arizona. The ballot measure will set a maximum of 3% for annual interest rates on medical debt. Proposition 209 also raises the amount of money in bank accounts subject to protection from debt collection up to \$5,000 rather than \$300. Additionally, debt collectors can now only collect wages at 10% rather than 25%.
- <u>California</u>: Voters rejected Proposition 29, which would have placed increased regulations on kidney dialysis clinics. California passed Proposition 31 which prohibits the sale of flavored tobacco products.
- <u>Colorado:</u> Voters said "yes" to Proposition 122, which decriminalizes psychedelic mushrooms for adults.
- Oregon: Voters passed Measure 111, making Oregon the first state in the country to declare affordable health care a fundamental right.
- <u>South Dakota:</u> Voters approved a measure to expand Medicaid eligibility to approximately 40,000 low-income adults. South Dakota is the 41st state, including the District of Columbia, to expand Medicaid.
- <u>Massachusetts:</u> Massachusetts became the first state in the country to require dental insurers to spend, at minimum, 83% of premiums related to patient care services. The law is effective in 2024. The measure is comparable to the Affordable Care Act's 80/20 rule and is aimed at improving quality of care.
- <u>Maryland and Missouri:</u> Both states approved the use of recreational marijuana, bringing the total number of states that have legalized marijuana for recreational purposes to 21. Similar ballot measures in Arkansas, North Dakota, and South Dakota did not pass.
- <u>California, Kentucky, Michigan, Montana, and Vermont:</u> Each of these states addressed abortion:
 - California—passed Proposition 1 which makes abortion a state constitutional right.
 - o *Kentucky*—rejected an amendment which would have added clear language to the state's constitution specifying that abortion is *not* a right.
 - o *Michigan*—passed Proposal 3 which makes abortion a state constitutional right.



- o *Montana*—rejected Legislative Referendum 131 which would have required health care service providers to render life-saving care to all infants born alive.
- Vermont—passed Proposal 5 which makes the right to reproductive freedom a constitutional right in the state.

IV. Health Care Impact and Analysis

End of Session Preview ("Lame Duck")

Following the election, Congress is preparing for transition to a new session (the 118th Congress) and a divided government for the first time during the Biden Administration. While Congress typically does not act on major legislation during these "lame duck" sessions, there are several major priorities that could or even must be addressed before the 118th Congress is sworn in.

Must Be Addressed – FY 2023 Appropriations

Funding for federal government agencies and programs is set to expire on December 16. Before that deadline, Congress must agree to either a final Fiscal Year (FY) 2023 appropriations package or a continuing resolution (CR) to fund the government at current levels for a defined period of time or risk a government shutdown. In recent years, Congress has increasingly opted to pass an "omnibus" spending bill, which compiles individual appropriations bills into one large package, along with any additional policy riders and/or supplemental funding provisions. As of this writing, committee leaders have yet to come to an agreement on "topline" numbers, which has prevented any meaningful negotiations on the details of a potential appropriations bill. House Minority Leader Kevin McCarthy (R-CA) has publicly called on Senate Minority Leader Mitch McConnell (R-KY) to stall further negotiations until January, when Republicans will take over the House and expand their bargaining power with Democrats. As the Dec. 16 deadline approaches and the two parties remain billions of dollars apart, a CR is all but certain, and it remains to be seen whether Congress can agree on a bipartisan deal to fund the government and include any compromise policy riders (such as those detailed below) before the end of the year. With the Senate's top two appropriators (Sens. Richard Shelby and Patrick Leahy) retiring, there will certainly be a push to find a resolution before the end of the year.

Could Be Addressed – Omnibus Package Riders

If Congress does pass an omnibus spending bill, policymakers will seek to include policy riders to what will likely be the last moving vehicle before the end of the session.

• Medicare Payment: Medicare providers are facing a series of payment cuts that will go into effect on January 1, 2023, compounding the impact of the 2% Medicare sequester currently in effect as well as the longer-term impact of inflation and the continued consequences of the COVID pandemic. The 2023 Physician Fee Schedule (PFS) final rule released by the Centers for Medicare and Medicaid Services (CMS) in early November incorporates a nearly 4.5% reduction to the conversion factor, which is used to calculate all payments to providers paid under the PFS. CMS lacks authority to change these cuts given the legislative requirement that the PFS be "budget neutral" year-to-year. Additionally, Medicare programs are expected to be cut by another 4% due to the



statutory Pay-As-You-Go Act (PAYGO) requirement, which can only be waived through Congressional action.

Most observers expect that Congress will address some, but not all, of the looming payment cuts. A waiver or additional delay of the 4% PAYGO cut is expected, as Congress has never actually allowed PAYGO cuts to go into effect. Additionally, the House is considering legislation (H.R. 8800, the <u>Supporting Medicare Providers Act of 2022</u>) which would mitigate the majority of the PFS cuts by instituting a one-year 4.42% "boost" to the Fee Schedule. Given the high cost of addressing these cascading cuts, Congress seems unlikely to address the sequester cuts already in effect and may only partially mitigate the PFS conversion factor decrease.

- FDA Policy Riders: In late September, Congress passed a "clean" reauthorization of the Food and Drug Administration's (FDA) User Fee Programs, including those for prescription drugs (PDUFA), medical devices (MDUFA), generic drugs (GDUFA), and biosimilars (BsUFA). Negotiations on the inclusion of additional FDA-related policies stalled prior to the election, but leadership on the House Energy & Commerce and Senate HELP Committees will seek to advance some—or all—of these policies in a year-end package. Policies to enhance diversity in clinical trials and reform the FDA's accelerated approval process appear poised to advance (and were included in House-passed legislation this past summer), while H.R. 4128/S. 2209, the <u>VALID ACT</u> (standardizing FDA's oversight of lab-developed and in vitro diagnostic tests)⁴ and reforms to the agency's oversight of dietary supplements and cosmetics may face a more difficult path.
- Telehealth Extensions: The vast majority of the temporary flexibilities expanding the use of telehealth in the Medicare program are tied to the COVID-19 public health emergency (PHE) declaration. Congress previously enacted legislation extending these flexibilities for 151 days after the end of the PHE, which could be lifted as soon as mid-April 2023. There is bipartisan support for further, even permanent extension of these telehealth authorities, but questions remain as to any guardrails that should be put in place to protect against fraud and abuse, proper reimbursement rates, and more. There will be a bipartisan effort to include another telehealth extension in a year-end package, most likely time-limited for another year or two past the current end date.

The House passed H.R. 4040, the <u>Advancing Telehealth Beyond COVID-19 Act</u> (which would extend the Medicare flexibilities through the end of 2024) in July 2022, but the Senate has not yet considered the bill. Congress seems less likely to extend one provision allowing high-deductible health plans to cover telehealth visits before beneficiaries reach their deductibles; this is currently set to expire on December 31 and has already been allowed to lapse once from January to March 2022.

• **Mental Health**: Mental health policy reform has been a key focus of the 117th Congress, with some provisions passing in the *Bipartisan Safer Communities Act* enacted in June 2022. House Democrats are hoping to include the House-passed H.R. 7666, the *Restoring*

⁴ FDA Commissioner Robert Califf has publicly stated that if Congress does not pass the *VALID Act*, the agency may seek to implement similar changes through regulation.



Hope for Mental Health and Well-Being Act of 2022, in a year-end package, bipartisan legislation that would reauthorize and update a series of mental health programs as well as support federal coordination, prevention, and treatment efforts for mental health, behavioral health, and substance use disorders. The Senate Finance Committee also released several legislative drafts focused on mental health, including telehealth, youth mental health, health care workforce, and care coordination. We expect a push to include some or all of these policies in an omnibus package, but it is unclear how many can get enough bipartisan support and agreement on funding offsets to pass by the end of the year.

• **Prior Authorization Reform**: A bipartisan majority in the House (and a near-majority in the Senate) signed on to support the *Improving Seniors' Timely Access to Care Act*, legislation that would begin to reform the use of prior authorization in the Medicare Advantage program. The House passed the legislation in September, and supporters are seeking to include it in a year-end package, though a score from the Congressional Budget Office (\$16 billion over ten years) will make it difficult to include without offsetting provisions. A recently released proposed rule from CMS may seek to implement some of the bill's provisions through regulation, which could significantly reduce the CBO's projections and make the legislation easier to pass.

Other Possible Action

• **Debt Ceiling**: The Treasury Department will likely meet its cap on borrowing (the federal debt ceiling) by mid-2023, currently projected for June. Democratic Congressional leaders and the White House floated the idea of trying to preemptively lift the debt ceiling during the lame duck session, seeking to ward off a partisan showdown in a divided Congress next year. However, no Republican senators indicated their support for such an approach. Additionally, it will be nearly impossible to rush through another budget reconciliation bill before the end of the session, even if all 50 Democratic senators were on board.

Preview of Congressional Agenda for the 118th Congress

Divided Government

While there are still some outstanding races to be called, it has been established that the 118th Congress will be split between a Republican House and a Democratic Senate – both chambers with especially slim majorities. Neither party will likely be able to pass policies that are considered radical or strongly partisan, and Congressional action will be limited to bipartisan legislation and oversight by the majority parties in each chamber. Given the narrow margins in the House and Senate, moderates on both sides of the aisle will likely continue to have significant power.

The legislative filibuster remains in place, requiring 60 votes in the Senate to pass most legislation. While Democrats were able to use the budget reconciliation process to pass sweeping changes (through the *American Rescue Plan Act* and the *Inflation Reduction Act*) with only 51



votes in the 117^{th} Congress, Republican control in the House will close off this pathway when the new Congress is sworn in.

House Republicans are expected to use their new majority to wield oversight powers over the Biden Administration, particularly regarding its health care policies. We expect to see frequent hearings in the House calling on Administration officials to testify on the Administration's COVID response policies, including the justification for the continued PHE declaration, the role of Dr. Anthony Fauci, and the distribution of federal relief funds. Other topics may include the origins of the COVID pandemic, oversight of general research being conducted at the National Institutes of Health (NIH), and changes related to implementation of drug price negotiation and the Affordable Care Act (ACA).

In the Senate, a Democratic majority will allow continued advancement of Biden Administration appointees, including federal judges and key positions impacting health policy, especially the yet-to-be-named Director for NIH who will replace longtime agency leader Dr. Francis Collins after his retirement in December 2021.

Health Care Priorities

In 2023 and beyond, there will be several health care priorities on the Congressional agenda, including some areas where there may be room for bipartisan agreement.

- **Telehealth:** Even if Congress reaches an agreement on extending telehealth during the lame duck session, both parties are expected to revisit the issue in the 118th Congress. While most lawmakers recognize the value of telehealth and support keeping virtual care in the mainstream, many questions remain, including:
 - o how telehealth should be reimbursed compared with in-person care,
 - o what (if any) limitations should be on who can provide telehealth services and to which beneficiaries.
 - o whether certain services currently authorized for telehealth should be continued or return to in-person only, and
 - how to protect against waste, fraud, and abuse in an already strained Medicare budget.

Broad telehealth legislation such as S. 1512, the <u>CONNECT for Health Act</u>, is likely to be reintroduced and may be able to advance even in a partisan environment.

• Mental Health: Congress is expected to maintain its focus on mental health policy in the next session, and any previously released policies (including the House-passed bill and Finance Committee drafts noted above) that do not pass in the year-end package will likely be reintroduced in the 118th Congress. So far, mental health has been an area of relative bipartisan agreement, though funding questions will likely be the main roadblock to additional legislation. Several programs operated by the Health Resources and Services Administration (HRSA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) require reauthorization, and any programs not reauthorized in 2022 will likely be the central pieces of any mental health package addressed in 2023.



- Pandemic Preparedness: Though Congress has not approved additional COVID supplemental funding, there is bipartisan interest in reforming the government's pandemic response capabilities to prepare for the next pandemic. Senate HELP Committee Chairwoman Patty Murray and retiring Ranking Member Richard Burr developed S. 3799, the *PREVENT Pandemics Act*, which would create a legislative task force to investigate the COVID response, provide funding for public health preparedness centers, enhance the collection and dissemination of public health data, support public health workforce programs, and enhance the Strategic National Stockpile and domestic manufacturing of medical countermeasures, among other priorities. The next Congress is likely to consider pandemic preparedness legislation, though it is unclear who will take up the issue with both champions leaving their leadership posts on the HELP Committee (Sen. Murray taking the gavel on Appropriations and Sen. Burr leaving Congress).
- Medicare Payment Reform: Even if Congress acts to mitigate the Medicare cuts set to begin in 2023, there is bipartisan interest in long-term reforms to the Medicare payment system to avoid the year-to-year debates that have complicated the Congressional agenda for the past decade. Reps. Ami Bera (D-CA) and Larry Bucshon (R-IN) introduced legislation to avert PFS cuts in previous years and did the same in 2022 with H.R. 8800. Reps. Bera and Bucshon also sought stakeholder feedback on a comprehensive solution to reform Medicare physician payment, through both the PFS and the Merit-Based Incentive Payment System (MIPS) instituted in 2015. Though no legislative proposals have been introduced, we expect Medicare payment reform to be a hot topic in the 118th Congress, if Republicans and Democrats are able to come to an agreement on potential solutions.
- Cures 2.0: Rep. Diana DeGette (D-CO) and Rep. Fred Upton (R-MI) spent much of the 117th Congress seeking to advance a successor to the landmark 21st Century Cures Act, introduced as H.R. 6000, the Cures 2.0 Act, which garnered 100 cosponsors in the House. The bill seeks to advance bipartisan reforms to the biomedical research and development system in the U.S. by reforming expedited approvals of breakthrough devices by the FDA, creating a companion breakthrough coverage pathway at CMS, expanding access to Medicare and Medicaid claims data for clinical registries, and expanding the authorization for the Advanced Research Projects Agency for Health (ARPA-H). Rep. DeGette is likely to reintroduce the bill and push for advancement, though she will need to seek a new Republican champion to replace Rep. Upton who is retiring from Congress.

Preview of Biden Administration Agenda

With a divided Congress for the first time in his Administration, President Biden will face significant hurdles in getting his priorities enacted in legislation, and the White House will likely focus more on policymaking through executive action and agency regulations. Some key areas of the Administration's health care agenda are likely to include:

• **PHE Unwinding**: Though the exact date is not yet certain, the Biden Administration is expected to lift the public health emergency declaration for COVID-19 in 2023. This action will have a significant impact on the various authorities granted during the PHE,



including telehealth flexibilities, expanded Medicaid enrollment, and waivers of certain requirements impacting health care providers. Managing the so-called "PHE unwinding," particularly for millions who will no longer be eligible for Medicaid coverage (and potentially transferring them to the ACA Marketplace), will be a major focus of the Administration's regulatory and sub-regulatory efforts in the coming year.

- **Drug Price Negotiation:** After the enactment of the landmark *Inflation Reduction Act* allowing Medicare to negotiate prescription drug prices for the first time, CMS will need to develop regulations to implement its new authority and operationalize the negotiation process. The Administration will have significant leeway to determine how the drug pricing program works, and the White House will have to balance its own goals and priorities while facing strong opposition from Republican policymakers, through Congressional oversight and expected litigation.
- Medicare Coverage for New Technology: The Biden Administration is seeking to propose a new expedited Medicare coverage pathway, known as Transitional Coverage for Emerging Technologies (TCET), by April 2023. The long-awaited rule will replace the Medicare Coverage for Innovative Technology (MCIT) pathway previously finalized during the Trump Administration and then rescinded early in the Biden Administration. CMS recently released a framework with key principles for the forthcoming proposed rule, but the device industry—along with patient and provider groups—will seek significant input in the development and implementation of this new process.
- Nondiscrimination in Health Programs: The Biden Administration is expected to continue implementing new protections against discrimination on the basis of disability in health programs and activities, as well as other protected classes. The Administration is expected to release a final rule implementing changes to the ACA's antidiscrimination provisions (Section 1557) in late 2022 or early 2023, as well as a proposed rule revamping Section 504 of the Rehabilitation Act, which prohibits federal programs from discriminating against people with disabilities. The Section 504 rule is expected to cover a wide range of health care policies, including crisis standards of care, organ transplantation, accessible medical equipment and technology, health care value assessment methodologies, and more.
- Affordable Care Act Regulation: Bolstering the ACA through enhanced Navigator funding, extending open enrollment, and rolling back Trump-era changes was a key priority of the Biden Administration in its first two years. While many of these initial goals have already been finalized, we expect the White House to continue focusing on strengthening the program. Such Administration actions could include limiting the availability of short-term, limited-duration health plans, offering new proposals through the annual Notice of Benefit and Payment Parameters, and protecting the recently finalized "family glitch" fix, which some House Republicans have sought to challenge as an overreach of agency authority.

For more information, please contact the attorney or government relations professional at Powers with whom you typically work.