Mid-Terms: Healthcare, Oversight, Deficit Reduction

Winners: MedTech, Biopharma, Value Based Care, Plans, Clinical Labs
Losers: Hospitals, PBMs

ICYMI: Please contact team@capitol-street.com for our Post-Election Healthcare Deck

The mid-term election typically favors the party opposite the Administration, but Democrats performed better than expected by holding onto the Senate. We have a new House majority which means that less legislating will take place, along with more oversight, while the agencies continue to fire on all cylinders.

- **House flips Republican with the Senate Democratic and even (again).** Republicans have focused on homeland security, education and economic issues this season.
    - **HOUSE.** Kevin McCarthy (CA) is expected to be House Speaker, but he will be challenged given lackluster GOP results and a fractured House Republican caucus. Cathy McMorris-Rodgers (WA) is set to run Energy & Commerce (Medicaid, Public Health), with multiple potential members to run the all-important Ways & Means Committee [Vern Buchanan (FL), Jason Smith (MO), Adrian Smith (NE)].
    - **SENATE**. Democrats managed to maintain a slim majority with incumbents in AZ and NV keeping their seats. Chuck Schumer (NY) remains the Majority Leader. In Senate Finance, we expect continued collaborative work between Ron Wyden (OR) and Mike Crapo (ID). In Senate HELP committee, Senate Democrats will avoid any probes as they will be setting the agenda for Senate committees. Bernie Sanders (VT) is expected to be HELP chair: he favors Medicare for All & Drug reimportation.
- **Healthcare is not high on the Republican agenda, unless it is oversight related, with the IRA Drug Negotiation as the new "Repeal & Replace**." Instead, inflation/economy, domestic security and education are priorities. Oversight of Biden officials over (1) COVID origin (2) vaccines and therapeutic FDA approvals (3) government spending on COVID medicines (4) enhanced reimbursement and provider relief will be persistent headlines in 2023. Expect the new Repeal & Replace to be around Inflation Reduction Act, Drug Negotiation provision. We do not see the IRA as being repeal-able with modest tweaks do-able in the next 1-2 years.
- **Mental health reforms & telehealth are bipartisan areas of agreement, as is the focus on Biomanufacturing (anti-China) and oncology care.** The House and Senate are concurrently working on behavioral health bills, which we could see passing in chunks over the next 1-2 years. Telehealth has shown promise during COVID and most lawmakers want it to continue. Life sciences (Biopharma, Medtech) are winners from the increased focus on Cancer Moonshot, Biomanufacturing, ARPA-H and public-private partnerships with industry.
- **The end of the PHE may be kicked out to April, which means that Medicaid rolls will fall (2024), and Exchange plans will capture some lives.** The unwinding of the PHE should be a dimmer switch versus on/off light. Recall that states have 14 months to re-verify individuals on Medicaid, which may be the largest unwinding event in history.
- **Medicare Advantage (MA) plans face potential headwinds via RADV audits, marketing rules and 2024 rate notice.** We do not believe that CMS will want to lower the boom on plans that serve

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50% of the Medicare population. We view reductions as more of a haircut versus a draconian cut. The fall technical rule (Nov/December) will likely contain additional MA marketing and Stars guidance.

- **Deficit reduction (2023-24) impacts all of healthcare – and is typically done about once a decade, with a Democratic president and divided congress.** The military is rarely impacted when the government tries to get its fiscal house in order. Recall that the Debt limit must be raised in mid-2023.

- **Lame duck includes budget action with the following healthcare riders that aid (1) clinical labs (2) telehealth (3) value based care (4) specialist physicians.** There may be some helpful provisions for providers facing cuts as of Jan 1. We see dialysis providers as less likely to get relief if their provision scores as a cost, which is looking to be the case. See Background for full list of likely policies in lame duck.

- **INSIDE:** See inside for macro healthcare themes, sector winners & losers, as well as GOP Healthcare Committee leadership in the House, as well as bipartisan leadership in the Senate.

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Lame Duck (Nov-Jan) Health Policy Outlook

One year extension of telehealth. We think that one year post PHE is likely given telehealth's importance and utility gleaned during COVID.

One year value-based care MACRA bonus. Congress passed MACRA in 2015 as a solution to the yearly physician SGR payment adjustments, which consists of a 5% advanced alternative payment model path for providers or the MIPS quality reporting program. Funding for the AAPM 5% bonus expires at the end of 2022 and costs about $600 M per year to extend the program. Hospital, physician and specialty groups are advocating for a 1-to-2-year extension

Some clinical lab relief is likely to pass by year-end, but it is less likely to be the SALSA Act and more likely to be a one year delay. The SALSA Act has wide bipartisan support, in both the Senate and House by Sens. Brown (D-OH) and Burr (R-NC), along with Reps. Bill Pascrell (D-NJ), Scott Peters (D-CA), Richard Hudson (R-NC), Gus Bilirakis (R-FL) and Kurt Schrader (D-OR). The SALSA Act score is about $6 B, which is an untenable score for year-end policies. With a mixed Congress post mid-terms, we do not see major policy passing during the lame duck session of Congress. A more likely scenario is PAMA delay. A one year delay saves ~ $780 M. Given the savings score, we see higher odds of passage, along with a commitment to work on SALSA/permanency more generally in the next Congress.

Specialist physician pay restoration (partial) from the physician fee schedule. As finalized by the Physician Fee Schedule (2023) rule included a 4.42% payment adjustment for many clinicians. There is a push by hospitals and some physician groups to delay of the cut, estimated to cost $6 B for one year.

The dialysis (DVA, FMS) industry was dealt a blow by the Supreme Court in June 2022 and will likely see relief if the score is a saver, which it may not be. In a 7-2 ruling the Court held that the Marietta Plan coverage terms do not violate the statute because those terms apply uniformly to all covered individuals (same coverage for those with end stage renal disease and those without). A recently introduced bill would obligate health plans to cover dialysis the same way they do treatments for other chronic illnesses and would increase reimbursement. It would also impact a multibillion-dollar line item in the Medicare budget, but could cost up to $8B.

Possibilities in Lame Duck

Both VALID Act and PREVENT Pandemics Act stalled in 2022 despite passage in the Senate HELP committee earlier this year. We noted previously that either bill could pass in the end of the year package as a tribute to the retiring Richard Burr (R- NC), ranking member in Senate HELP. Recall that VALID Act would regulate laboratory-developed tests and in vitro diagnostics and would adopt a risk-based framework that would require premarket FDA review for high-risk tests. PREVENT Pandemics Act aims to counter future pandemics by providing funding for supply chain reform and government stockpiles, modernizing FDA's infrastructure, establishing a new federal office for pandemic preparedness, and improving collection of public health data.

FDA riders (AA reform, clinical trial diversity, generic flexibilities, rare disease provisions) are expected to come back. Several FDA riders are expected to be revisited in the end of the year package. These include provisions for accelerated approval reform which allows the FDA to require post-approval studies, provisions to improve clinical trial diversity including improving access to decentralized trials, provisions to change the proposed labeling requirements for generics, and

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provisions to clarify orphan designations which became restricted following the SC's decision on *Catalyst Pharms., Inc. v. Becerra.*

Healthcare Priorities 2023+

DEFICIT REDUCTION

It happens once in a decade and typically with a Democratic President and Republican Congress. Healthcare gets cut in this scenario – all payers & providers – Plans, Physicians, Hospitals, Post-Acute, Dialysis. There are no sacred cows.

Healthcare spending is expected to continue to be a key topic as Congress looks to an end of the year package and new year priorities. The past 2 years has seen a significant increase in healthcare spending from passage of several COVID-19 relief bills, including the Families First Coronavirus Response Act, CARES Act, Continuing Appropriations Act of 2021, and from the recently passed IRA. GOP members have long been critical of excess spend, and we may see a deficit reduction coming in cuts to healthcare spending in 2023. Historically, there has been deficit reductions under a Democrat president and Republican Congress, and macro-pressure points, including rising inflation, recession outlook, and the upcoming debt ceiling, makes a deficit reduction more likely in the new legislative session. Cuts comes at a time of rising healthcare costs for both public and private payers. In the employer-sponsored market, employer's medical plan costs per employee are expected to rise +5.6% on average in 2023, according to a survey by Mercer. Private payers will also seek to cost shifting as a result and these changes may negative impact providers in the future.

COVID OVERSIGHT, PANDEMIC LESSONS LEARNED

The GOP has been particularly vocal in its critique of federal agencies and of disorganized federal COVID-19 spending with lack of oversight and the stories of widespread fraud fueling GOP discontent. With the change in House leadership, we can expect increased attention on key agencies (CMS, FDA, CDC, NIH) and accountability on pandemic spending. With House control, we predict the GOP will be more resistant to additional pandemic funding despite a potential COVID wave this winter and will likely aim to reallocate already passed funding. House Reps. will be looking to organize more hearings on pandemic and government oversight and call upon top officials from agencies including FDA commissioner Robert Califf, MD, and soon-to-be-retired NIH head Anthony Fauci, MD, to testify.

GOP MEDICARE REFORM UNLIKELY

While we don't see these policies as coming to fruition, GOP legislators are seeking to reform Medicare to reduce federal costs and improve care access, particularly for rural and disadvantaged beneficiaries that they represent, as they are increasingly concerned about Medicare solvency. The Republican Study Committee, the largest conservative caucus in the House, has suggested raising the age for Medicare to 67 in their 2023 proposed budget. Other reforms like the expansion of site-neutral payments have come from the GOP Healthy Future Taskforce. In 2023, upcoming changes to Medicare include coverage of certain dental services under Part B, extended coverage of certain temporary telehealth services, and provider expansion for mental health services. Recall 2023 Medicare open enrollment started October 15, 2022.

MENTAL HEALTH

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The House and the Senate are on a multi-year effort to address mental health. In the Senate, see draft bills per Finance Committee working groups below.

Enhancing the Mental Health Workforce: (1) expanding psychiatrist workforce through Medicare graduate medical education is expensive but calls for 400 new residency slots / year, (2) reducing burnout: access to mental health programs for physicians, (3) access to Medicare clinical social workers, (4) improving distribution of the workforce to shortage areas through Medicare bonus, (5) Medicaid workforce capacity demonstration project, (6) updating Medicare for coverage of clinical social worker services, (7) Medicaid guidance on increasing mental health and substance use disorder care (8) flexibility in Medicare's supervision rules for psychologist trainees, (8) leveraging occupational therapists to support mental health and substance use disorder care.

Telehealth's Role in Care: Draft bill includes provisions that would remove Medicare's in-person visit requirement for telemental health services, establish benefit transparency for mental health care delivered via telehealth, and direct Medicare and Medicaid to support provider use of telehealth. Released by Senate Finance Committee members Sens. Ron Wyden (D-OR), Mike Crapo (R-ID), Ben Cardin (D-MD) and John Thune (R-SD).

Youth Mental Health: Draft includes policies that would allow all providers to receive Medicaid reimbursement for behavioral and physical health services delivered on the same day, support mental health care in schools, and direct Medicaid to guide states on how to cover treatment for foster youth with mental health care needs. Released by Sens. Ron Wyden (D-OR), Mike Crapo (R-ID), Tom Carper (D-DE) and Bill Cassidy (R-LA).

Combining Behavioral & Primary Care: CMMI must consider support for behavioral health integration adoption when developing new demonstration models or revising existing models. From 2025 through 2027, Medicare payment rates for behavioral health integration services would be increased. Aims to help offset startup costs that providers incur when transitioning to this model. The bill also supports the development of Medicare quality measures that assess the degree of clinician practice integration of behavioral health and primary care. Mobile crisis response teams and peer support would be provided.

Changes Afoot on IPF

From an agency perspective, CMS is likely to consider changes to the IPF (Inpatient Psychiatric Facility) system.

In January 2022, the Committee on Ways and Means asked MedPAC to conduct an analysis on the availability and utilization of mental health services for Medicare beneficiaries. During the October MedPAC meeting, inpatient psychiatric facility (IPF) care was discussed. Generally, individual and group therapy, psychosocial rehabilitation, prescription drugs, and electroconvulsive therapy are covered by Part A, with services from physicians being covered by Part B.

MedPAC believes that caring for patients with psychiatric illnesses is important. They signal to CMS and highlight the following: (1) better data collection is necessary (more information on the type of care, who is served, geographic areas (maybe separate commercial and Medicare sectors; separate by nonprofit, for profit, and government), (2) CMS has not taken the need for reasonable diligence for outcomes very seriously, but are backing up, going in the direction of less robust, granular data, (3) shortage of the types of measures related to outcomes, (4) 35,000 beneficiaries have exceeded the 190-day lifetime limit, which is outdated and needs to be rethought, (5) organizations are disjointed, and (6) consider more clear definitions for better understanding of the space as a whole.

MedPAC recognizes that IPFs are only a small part of the continuum (ER admissions), and the problem cannot be addressed without understanding all of this. MedPAC is currently conducting interviews with IPFs 2022 but plans to run analyses of Medicare beneficiaries' use of outpatient behavioral health services and submit a chapter on the subject in the June 2023 report to Congress.

LIFE SCIENCES BOON: BIOMANUFACTURING & CANCER MOONSHOT

PDUFA, MDUFA, BSUFA, and GDUFA passage are a clear positive for the FDA as the bill provides certainty in funding for the next 5 years. With passage of the user fees, FDA will be able to implement several pilot programs meant to improve review time for products that meet an unmet medical need. Due to a clean "passage" of the user fees in September, we expect Congress to revisit additional FDA policies in end-of-the-year discussions including accelerated approval reform, clinical trial diversity reform, and improving generic flexibilities.

We note that this administration has heavily invested in life sciences and biomanufacturing as well.

A fall executive Order on Biomanufacturing (here) provides dollars to the sector.

Biotechnology harnesses the power of biology to create new services and products, which provide opportunities to grow the United States economy and workforce and improve the quality of our lives and the environment. The economic activity derived from biotechnology and biomanufacturing is referred to as "the bioeconomy."

The COVID-19 pandemic has demonstrated the vital role of biotechnology and biomanufacturing in developing and producing life-saving diagnostics, therapeutics, and vaccines that protect Americans and the world. Although the power of these technologies is most vivid at the moment in the context of human health, biotechnology and biomanufacturing can also be used to achieve our climate and energy goals, improve food security and sustainability, secure our supply chains, and grow the economy across all of America.

Cancer Moonshot is a presidential priority, and it is in its second iteration as v 1.0 was a Joe Biden priority when he was VP. Moonshot has updated goals, new timelines, and experienced leadership with a focus on public-private partnerships. The administration has also launched an executive order aimed at improving onshore biomanufacturing and improving supply chains. These executive initiatives along with the newly enacted ARPA-H shows a recognition of the innovation in private markets, and companies may have more opportunities to engage with the administration as agencies seek feedback and ideas to invest in.

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Industry Outlook: Positives & Negatives

BIOPHARMA

Positives

Biomanufacturing and Cancer Moonshot provide government projects that help biopharma.

Cures 2.0. Cures 2.0 failed to pass this fall and is unlikely to pass this December. The torch is being handed off as Rep. Fred Upton (R-MI), the key GOP House advocate retires. However, Rep. Cathy McMorris Rodgers, a key House Republican and next House Energy and Commerce chair, continues to support the bill and it is likely to pass in a GOP-controlled House. Introduced with no companion Senate bill, Cures 2.0 funds a pandemic preparedness, rare disease support program, establishes a subscription model to pay for critically needed antimicrobial drugs (PASTEUR Act), directs HHS to establish two additional FDA Centers of Excellence, codifies the Medicare Coverage of Innovative Technology pathway (now called TCET), among other research focused provisions. We could see passage in Oct 2023, with the simultaneous passage of Animal Drugs User Fee Act (ADUFA) and Pandemic All Hands Preparedness Act (PAHPA).

PDUFA, GDUFA passage provide funding stability for 5 years. Some other FDA policies are below.

Rare Disease Endpoint Advancement Pilot Program supports the development of efficacy endpoints for rare diseases. This program provides a way for sponsors to collaborate with FDA throughout the endpoint development process. However, the pilot is relatively limited in scope. Manufacturers can begin submitting RDEA program proposal requests starting in July 2023, but FDA will accept only one RDEA proposal. For fiscal years 2024 through 2027, FDA will accept up to one RDEA proposal per quarter with a maximum of three RDEA proposals per year.

Split Real Time Application Review or STAR pilot program is designed to shorten the review time of existing drugs and biologics where there is an unmet medical need. The program accepts supplemental NDAs, and supplemental BLAs with new potential uses for already approved therapies. However, the program does not accept real-world data to justify substantial improvement of efficacy supplements. The pilot program splits applications into two parts where submissions are sent approximately 2 months apart; and the PDUFA clock starts once FDA receives the second part of the application.

Supply chain, onshore manufacturing reform. Improving onshore manufacturing of PPE and active ingredients became a key issue during the pandemic. We know that PREVENT Pandemics Act contains several provisions to improve domestic manufacturing capacity, including the advanced manufacturing technologies designation pilot program which directs the FDA to implement a pilot program to designate an advanced manufacturing technology that sunsets in 2029.

Negatives

Implementation of the Drug Negotiations, Inflationary Rebates. In 2023, several IRA provisions go into effect. For inflationary rebates, Part B provisions will go into effect in January 2023. Part D provisions have been in effect since October 2022, and rebate payments will be required in a year. For Medicare drug negotiations, we expect the selected drug list to be published in September 2023. The insulin copay cap for Medicare also goes into effect in 2023. From January 2023 to March 2023, Part D sponsors and MA plans must reimburse enrollees for any cost-sharing paid that exceeds the $35-dollar monthly cap. Other benefit changes in 2023 include coverage of certain adult vaccines under Part D with no cost sharing. We do not anticipate the IRA to be repealed, but we do anticipate some tweaks

based on industry asks and GOP support. One expected tweak is the exclusivity period for selected drugs. The drug negotiation provisions favor biologics by given them a 2-year additional period of exclusivity compared to small molecules. Pharma is expected to ask for a change to 13 years for small molecules to match biologics in terms of when negotiations go into effect.

340B reform. We expect Congress to take action to reform the 340B program by asking for transparency and accountability. We note that drug manufacturers have been alarmed about the program's fast expansion, from 8,100 provider sites (including both hospitals and pharmacies) in 2000 to 50,000 by 2020. HRSA data suggests that discounted purchases under the 340B program reached $44 B in 2021. In response, manufacturers began placing restrictions on 340B pricing to entities that dispense medication through contract pharmacies. Contract pharmacies have reported continued difficulty in their 340B program (see Walgreens Q3 earnings). There is continued Congressional interest in 340 B. In May 2022, Sen. Chuck Grassley (R–IA) put pressure on the Inspector General's office by requesting an update on their investigation into manufacturers in the program, and asking if enforcement action will be taken against drug manufacturers' noncompliance with the 340B program. We note that the program has historically lacked transparency and oversight, and with increased rhetoric on transparency, the program may see new requirements for participants, particularly for manufacturers, and for HRSA.

CMMI demonstrations (Part B). In October 2022, an EO directed CMS Center for Innovation (CMMI) to work on Rx reform models. CMMI currently has its hands full with implementing ACO REACH and the new oncology model and upcoming Specialist model, but we do expect a report by January 2023. We do not anticipate CMMI implementing a new drug reform model, but the report will indicate where they see "excess" and could cut reimbursement, including PBMs. We could see a pilot program floated that addresses Part B biologics.

Penny Pricing (Medicaid). Starting in 2024, manufacturers may have to pay states more than what the state Medicaid programs reimburse for their drugs if their drugs outpace the rate of inflation. This is a result of the American Rescue Plan Act of 2021 ie, removing the Medicaid rebate cap. The policy change will have the largest impact on brand drugs whose prices have been or will be consistently raised and have reached the 100% rebate cap. The provision pertains to insulin and other products.

PHARMACY BENEFIT MANAGERS (PBMs)

While PBMs play a key role in the healthcare system, their non-transparent business model role in pharmaceutical supply chain is often questioned by lawmakers.

Negatives

Ongoing FTC 6B study. A FTC 6B study into PBM practices and revenue generation is ongoing. We noted previously that FTC is looking into what PBMs are getting as rebate aggregators. While PBMs have legal recourse in going to the courts to limit the scope of the investigation, PBMs have been largely compliant. A report is still expected in 2023 given the Congressional pressure on the agency and FTC Chair Lina Khan's laser focus on pharmaceuticals and PBMs. We noted that Lina Khan has been pushing the idea of using FTC rulemaking. FTC can also monetarily fine PBMs, but it will take another 6 months to a year after the completion of the report.

INSULIN Act. The Improving Needed Safeguards for Users of Lifesaving Insulin Now (INSULIN) Act may pass under a GOP Congress. We note that this is going to be Senate Diabetes Caucus Co-Chairs Jeanne Shaheen (D-N.H.), and Susan Collins's (R-ME) main ask. Introduced earlier this year, the bill caps insulin co-pays at $35 or 25% of the list price per month in commercial group/individual, and

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ERISA. The bill also prohibits plans from imposing prior authorization on insulin products. If passed, the bill is expected to negatively impact PBM margins, and may be tweaked.

IRA implementation**.** Following implementation of IRA insulin co-pay cap, lower rebates from higher-priced drugs are expected in Medicare. Drug pricing negotiations which goes into effect in 2026 is also expected to lower rebates for PBMs.

Banning spread pricing. Earlier this year, the Pharmacy Benefit Manager Transparency Act of 2022 advanced in the Senate Commerce Committee with bipartisan support, indicating it has a chance at passage in the upcoming legislative session. The bill bans the dissemination of "false" information related to PBM services and bans spread pricing. We note that spread is still allowed in Medicaid and Commercial, but it is nearly impossible in Medicare Advantage. The the bill may be revisited if Congress seeks to "cut the fat" in healthcare costs or enact PBM reform. Currently, much of PBM oversight is occurring at the state level with several states (VA, NY, DE) having enacted spread pricing bans.

PBM Transparency Reform. Earlier this year, the House passed the Restoring Hope for Mental Health and Well-Being Act which reauthorized several federal mental health and substance use disorder programs and aims to improve mental health service access through additional provisions. To offset costs, the House also included PBM transparency provisions that require PBMs to provide group health plans and reports at least every six months on copayments, rebates, discounts, net payments, costs, and drugs covered. We note that the package did not pass the Senate, but it was a bipartisan effort that could be taken up in 2023 as the Senate Finance Committee complete its mental health bills. This saves approx. $2.2 B.

Rebate reform. The rebate reform rule issued under the Trump administration is legislatively delayed until 2032. Note that this is the 2020 final rule that would have eliminated rebates negotiations between drug manufacturers and PBMs or plan sponsors in Medicare Part D by removing the safe harbor provisions under the federal anti-kickback statute. We do not expect rebate reform to ever materialize.

PBM 340B reform. States (CO, MD, OH, VA) are enhancing guardrails for PBMs. This trend may filter up to the federal level, depending on the appetite for healthcare legislation in 2023. Several states have introduced bills to prohibit PBMs and health plans from discriminating against 340B-covered entities and their contract pharmacies. This may be a part of the 340B reform sought by Congress in 2023. Buddy Carter (R-GA) wants to enhance transparency and accountability around 340B, as a former pharmacist.

MEDICAL TECHNOLOGIES & DIAGNOSTICS

Positives

Potential return of Transitional Coverage of Emerging Technologies (TCET). The initial MCIT rule offered coverage of breakthrough devices under national Medicare coverage for 4 years but was repealed in 2021. The new proposed program for Medicare coverage of breakthrough devices is called the Transitional Coverage of Emerging Technologies (TCET). Two managers at CMS recently penned an op-ed in JAMA and stated that a proposed rule could be coming in Spring 2023. We believe coverage will be incremental versus automatic and extensive. Cures 2.0 language may improved upon TCET if the rules underwhelm industry.

MDUFA passage. MDUFA V passage was a win for FDA and manufacturers. We note that MDUFA has increased the FDA's base funding level to help meet the increased device review submissions. FDA will also enact a TPLC Advisory Program (TAP), a pilot review program launched under MDUFA, aimed to

streamline medical device development, and reduce the time from concept to commercialization. By providing more timely interactions and strategic input from stakeholders and CDRH, it hopes to de-risk the medical device "valley of death." The first phase is the TAP Pilot Soft Launch, during FY 2023, where CDRH intends to enroll up to 15 devices. Afterwards, the FDA intends to expand the TAP Pilot to enroll up to 45 additional devices in FY 2024, and up to 65 additional devices in FY 2025.

Post-COVID environment. Another positive for medical devices is the return to utilization norms for medical services. Healthcare service companies have recently noted that utilization is back up with outpatient surgeries appearing to be back to normal. Individuals are also seeking preventive care again, with COVID have less of an impact on utilization versus previous periods. However, there we note that the triple threat of a COVID surge, historic levels of flu and RSV may impact or slow this recovery this winter.

Executive focus on biomanufacturing**. I**n our macro trend section above, we noted that there an increased federal focus on biotech innovations. These include federal actions like the release of the biomanufacturing EO, creation of ARPA-H, and revival of Cancer Moonshot. We note that ARPA-H, which centers on public-private partnerships shows a recognition by the government that industry is moving ahead rapidly. Biological innovations like liquid biopsies (EXAS, Grail) and synthetic bio (DNA) are improving patient standard of care and improving the market outlook as the field grows.

Negatives

Deflationary environment**.** Medical devices typically fare well in a recessionary environment which is a positive for the industry. However, we also see an increasingly deflationary pricing environment for medical devices with increasing inflationary pressures on supply chains and cost of goods. This will particularly impact commoditized products like traditional orthopedic products that face strong competitive pressures and struggle to pass on costs through their products.

Hospital purchasing. To the extent that hospitals are pressured big ticket item spending may slow. This applies to some, not all, medical technologies.

HEALTH INSURERS

Positives

Medicare Advantage. We will likely see MA industry growth overall (currently ~50% of Medicare beneficiaries are in MA), while Congressional Progressives are advocating for increased oversight. Despite RADV and the potential for lower 2024 rates, the outlook for MA is positive.

RADV
Risk adjustment data validation (RADV) audits may return, which could be bad news for plans. Audits would also add administrative burden for plans, marking increased federal oversight. We expect MA-RADV rules by Feb 1, 2023. We will be watching for the following three main levers:

(1) *FFS Adjuster*. CMS has said that the application of the FFSA is not necessary, which plans argue against. So, does CMS finalize what they proposed, with no FFSA? CMS performed a study on the topic & subsequently announced it believes there is no need for FFSA. CMS commissioned a study and looked for differences between its unaudited and audited model.

(2) *Retroactive (vs. Prospective) audits.* There is regulatory text that allows CMS to extrapolate the results from the audits, going as far back as 2011. Some argue the agency has always had the

authority to look back. The plan community would have a strong argument, in our view, to solely make RADV prospective, and/or go back only a handful of years.

(3) *Extrapolation*. There is n=200 (sample size) for audits. Basically 200 persons are selected, and the auditors will ask plans to provide up to 5 medical records to validate whether the Hierarchical Condition Category (HCC) is supported by any of the medical records. Medical records must be from medical providers i.e., from i/p, o/p and physician. A radiology claim, for instance, would not be allowed. The medical record has to be signed. CMS uses a medical record contractor to conduct reviews (not recovery audit contractors, or RACs).

Plan Marketing Oversight

The federal government continues to grapple with complaints from seniors of aggressive marketing tactics used by MA plans. Senate and House members join CMS in consideration of potential solutions for this problem that continues to plague seniors, recall 2023 Medicare open enrollment started October 15, 2022. Agents & brokers are supposed to be adhering to new CMS guidelines as of Oct 1, including the requirement to record all calls with beneficiaries.

CMS addresses Medicare Advantage (MA) marketing complaints, not state DOIs. CMS reports that beneficiary complaints regarding MA and Part D marketing plan materials have more than doubled from 2020 to 2021. CMS has received approximately 40,000 complaints so far. MA plan sponsors are subject to rule changes and policies going forward. Given the scrutiny over aggressive and predatory practices, we could see CMS enact tougher marketing guidelines possibly borrowing from the Senate report. We will keep an eye on this headwind for plans as we enter the lame duck session.

2024 MA Rates (1Q23)

The final CY 2023 MA rate enjoys a 4.88% effective growth rate. There is concern that the generous approximate 5% increases we have witnessed over the years will not be the norm going forward, for 2024 rates. CMS adjusts plan payments to reflect diagnosis coding differences between MA plans and FFS providers. For 2023, CMS finalized a coding pattern adjustment of 5.9%, which is the minimum adjustment for coding pattern differences required by statute. There remains a push to apply an adjustment that is higher than the minimum requirement. However, at the same time, some MA plans have been accused of unethical risk codes that artificially inflate reimbursements from Medicare. We are watching this, as CMS may bump up the 5.9% adjustment.

Fall Technical Rules (4Q22)

We could see Fall 2022 Medicare Advantage (MA) Technical Rules hit on MA plans & marketing practices harder. Each fall CMS releases technical rules that act as a “clean up” collection of policies for MA plans and general rules of the road e.g., network adequacy, provider directory rules.

MEDICAID MCOs

Positives

Recession

Medicaid enrollment will likely pick back up during the recession, which most expect to be in full force in 2023.

South Dakota

Voters in South Dakota decided to expand Medicaid to more than 40,000 people under the *Affordable Care* Act via ballot initiative. South Dakota will be the seventh GOP-controlled state to expand Medicaid at the ballot box in the last five years.

Negatives

Redeterminations
The PHE was most recently pushed to mid-January and we will likely see a renewal until April due to expected spikes in winter COVID cases. CMS has given states 14 months from the end of the PHE to complete all redeterminations. 89 M enrollees must be redetermined, and approximately 15 M would lose Medicaid coverage. States also lose the 6.2% FMAP they have been enjoying once the PHE ends, so there is an incentive for them to speed through the process. There is opportunity for plans such as Medicaid MCOs and plans on the Marketplace to benefit from the rollover of lives. CMS is encouraging states to work closely with plans in order to promote a seamless transition.

EXCHANGE (ACA) PLANS

With Medicaid redeterminations around the corner, Exchange plans will likely see a boost in enrollment.

Positives

Family Glitch in Effect as of 2023 The "family glitch" refers to 2013 ACA rule that eligibility for premium subsidies was based on available employer-sponsored insurance is affordable for the employee, rather than the family (for whom it may not be affordable). Biden's EO from January 2021 touched on fixing the family glitch, which was followed by a proposed rule reviewed by OMB in March 2022. The IRS finalized the rule change in October 2022, right before the open enrollment period for 2023 beginning on November 1. The fix means that the employee's dependents are eligible for premium subsidies on ACA plans if the family premium exceeds 9.5% of the family's income in 2022. Around 5 M people fall into the family glitch. Families of small business employees, service workers, low-paid workers, and youth under 18 will benefit the most from this fix.

VALUE BASED CARE // PRIMARY CARE

Positives

CMMI Vision. CMS's Innovation Center is doubling down on its vision and strategic direction per a Nov 7 update. Goals include (1) drive accountable care, (2) advance health equity, (3) support innovation, (4) address affordability, and 5) partner to achieve system transformation. CMMI is focused on models increasing the number of patients in accountable care relationships with providers (through advanced primary care and ACOs). Following will be used to measure health equity progress. (1) All new models require participants to collect and report demographic and SDOH data on beneficiaries, (2) all new models will include patients from underserved populations and safety net providers, such as community health centers and disproportionate share hospitals, and CMMI will identify areas for reducing inequities at the population level, such as avoidable admissions, and set targets for reducing those inequities.

VBC Bonus. The 5% VBC contracting bonus, created under the *Medicare Access and CHIP Reauthorization Act* (MACRA), is set to expire in 2023. The newly formed Alliance for Value-Based Patient Care is hoping to convince Congress to keep the bonus to doctors that participate in the Advanced Alternative Payment Model (AAPM). Groups in the alliance include the National Association of Accountable Care Organizations, American Medical Association, Premier, the Health Care Transformation Task Force, America's Physician Groups and the American Medical Group Association. Advocates of the model say that the bonus helps attract physicians to the model and cover startup costs. About 300,000 physicians rely on the incentive, and CMS projects that a third may drop out of models without the bonus. Initial costs of investment in switching to VBC are high. Compounded with

the Physician Fee Schedule rule's 4.5% cut to Medicare payments, the outlook may be grim for providers. Advocates have their sights set on a December 16 spending package to accommodate requests. CMS supports the bonus payments, but ultimately the decision lies with Congress.

Direct Contracting. Allows providers to receive full or partial capitated rates for defined Medicare services. Considered the next logical step for accountable care. The program terminates on December 31, 2022. Replaced by ACO REACH.

ACO REACH. CMS's emphasis on value-based care will continue via ACO REACH, a transformative approach to expanding patient-centered, affordable, and high-quality care. Through this initiative, CMS supports PCPs and specialists transitioning from traditional FFS models to VBC care. Participants aren't big fans of retrospective trend adjustments however and we may start to see the move to MSSP (See below) or MA Plans.

Physician Fee Schedule Pay Cut to Specialists On November 1, CMS finalized a 4.5% pay cut for physicians. Advocacy efforts to stall this cut will follow in the coming weeks. AMA warns that these rate cuts fail to consider inflation and COVID-related financial challenges. The cut has a far-reaching impact, as MSSP is the country's largest ACO program, including 500,000+ providers and more than 11 M patients. There is a slight bump for primary care, with internists enjoying a 3% bump. Critical care (+1%), infectious disease (+4%), nephrology (+1%), nurse practitioners (+1%), physical medicine (+2%), psychiatry (+2%), geriatrics (+2%), and pulmonary disease (+1%) are the few providers that received a pay bump. Specialists ranging from neurologists and dermatologists to general surgeons and oncology received cuts ranging from 1-2%. Specialty cuts may be reversed or mitigated in the lame duck session of Congress or 2023.

Medicare Shared Savings Program (MSSP). To promote the agency's VBC vision, CMS will offer advance shared savings payments to new and low-revenue ACOs (one-time payment of $250,000 and quarterly payments of the first two years in a five-year period). If the ACO generates savings, CMS will recoup the money. If not, the dollars will not be recouped, but the ACO must remain in the program for 5 years. CMS is generally trying to incentivize more providers to switch into VBC models.

PAYGO Sequester Relief. Advocates are pressing congress to delay the 4% cut under the PAYGO law, which was triggered by the passage of the American Rescue Plan Act. When totaled with the Physician Fee Schedule 4.5% cut, physician payments may be cut by 8.5% in 2023. Industry is hoping for end-of-year relief, which we think may happen.

HOSPITALS

Negatives

PHE Medicaid Redeterminations. Hospitals generally benefit from 20% add-on DRGs and other COVID era assistance. Redeterminations post PHE may negatively impact hospitals from a volume perspective, but this would mainly depend on state and payer success in rolling over lives to the Exchange and preventing complete loss of coverage.

COVID and Flu / RSV. Beds are full, straining hospital capacity, staffing, and finances.

Labor issues and supply costs. Inflation and labor issues are negatively impact acute care hospitals around the country.

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Nonprofit scrutiny. Lawmakers are looking into the non-profit status of myriad hospitals. This could be a GOP priority of Rep. Banks (IN).

Site-neutral reforms. We note that site-neutral reform is one of the solutions proposed by the GOP Healthy Future taskforce. They hope to expand the site-neutral payment policy for newly acquired provider-based, off-campus hospital outpatient departments throughout the Medicare program. Legislation has been previously introduced for this purpose, the Hospital Competition Act back in 2020 by Rep. Jim Banks (R-ID).

CLINICAL LABS

Positives

Clinical Laboratory Fee Schedule (CLFS) tests and services will see Medicare cuts of up to 15% on January 1, 2023. Potential relief at the end of the year. In the form of a delay, would help clinical labs. The SALSA Act could pass in 2023.

Saving Access to Laboratory Services *Act* (SALSA Act). A bipartisan and bicameral bill introduced by Sens. Brown (D-OH) and Burr (R-NC) on June 22, 2022 reduces Medicare cuts to laboratory services. SALSA offers provisions to promote laboratory services accessibility for the elderly. Some clinical lab relief is likely to pass by year-end, but it is unlikely to be the SALSA Act. The SALSA Act score is about $6 B, which is an untenable cost for year-end policies. If history is any guide, we see a short-term clinical lab fix with a one-year PAMA delay passing December 2022, given savings score, along with Medicare extenders. Congress will need to address the budget when the CR ends Dec 16. We view SALSA passage as more likely in 2023+.

HOME HEALTH

Positive

Although the home health final rule was released with pay cut relief on November 1, the industry is looking for more of a reprieve. CMS believes that HHs were overpaid by ~$2.1 B in 2020 and 2021 due to provider behavior changes in coding. CMS finalized a 7.85% permanent payment adjustment, -a 3.9% adjustment, and a 0.7% increase (or +$125 M) to provider payments in 2023. CMS originally proposed a -7.69% permanent adjustment to the 30-day payment rate and a 4.2% decrease (or -$810 M) to provider payments in 2023. This help action is very small.

Negatives

Permanent cuts and the clawback for more than $2 B of overpayments in 2020-21 are finalized. Overpayments and cuts remain up in the air. The Preserving Access to Home Health Act, bicameral and bipartisan legislation introduced this past summer, could be an under-the-radar means of saving the industry from cuts, as the bill prevents CMS from making cuts until 2026 (placing a three-year hold). The bill is pending in both chambers but could make it into a year-end package. However, it is unclear if Congress wants to pass this, as it may be expensive. There would need to be a change in the methods used by CMS to consider budget neutrality. CMS's positioning in this final rule calls for Congressional action if the home health industry is to get relief.

The final route to avoid cuts would be through legal action, although this would be a last resort. Legal precedent from American Hospital Association (AHA) v. Becerra (rate cuts for hospitals) indicates that the courts could side with industry.

The home health industry is facing increased labor costs, a high inflation rate, and additional increased costs related to COVID-19. The industry warns that HHAs across the country will not be able to withstand the cuts.

DIALYSIS

Positives

Payment Update The overall '23 ESRD payment update is +3.1%, an increase of $300 M, positive for Large Dialysis Organizations (LDOs) such as DVA and FMS in 2023. CMS is finalizing its requirement that an ESRD facility's wage index for 2023 will not be less than 95% of its final wage index for 2022. The final PPS base rate is $265.57, up from 257.90 in 2022, reflecting the application of the wage index budget neutrality adjustment factor and a productivity-adjusted market basket increase of +3%. Total Medicare spending for ESRD facilities in the coming year is projected to be about $7.9 B, considering a projected 3.5% *decrease* in FFS Medicare beneficiary enrollment in 2023. CMS dialysis final pay is in-line with expectations and good news (for 2023). New pay starts Jan 2023.

CA Proposition 29 – Kidney Dialysis. For the third time in four years, CA voters were asked to vote on kidney centers in the state (with 2018 and 2020 attempts failing to go through). The proposition is supported by Service Employees International Union-United Healthcare Workers West, a Bay area union. It was not approved, but Proposition 29 would have required dialysis centers to have a nurse practitioner, physician assistant, or physician on the premises during practice hours. Clinics would also be required to disclose physician ownership interests and report patient infection data. Approximately 600 dialysis clinics in California serve around 80,000 patients a month. DaVita and Fresenius Medical Care, two private for-profit companies, own most clinics. Both opposed the proposition.

Negatives

MSP Changes. We think the odds of ESRD-friendly legislation passing to aid LDOs are lower in Dec 2022 due to a potentially high CBO score. Legislation that modifies Medicare as a Secondary Payer (MSP) and ESRD pay save costs several billion dollars. While health plan trade associations such as AHIP oppose the bill, we think government savings will be too attractive to pass up.

Due to the negative SCOTUS June 2022 ruling, DaVita & Fresenius have been pushing for a legislative fix. The Supreme Court ruled against DaVita and held that the Ohio Marietta Plan is not liable for the disparate impact that DaVita was claiming because of the limited coverage on outpatient dialysis and the Marietta Plans coverage terms do not violate the statutes because those terms apply uniformly to all covered individuals (same coverage for those with ESRD and those without). DaVita sued the Marietta plan (OH) because it believed the plan's limited coverage of outpatient dialysis violated the Medicare Secondary Payer statute. This statute says that a plan cannot differentiate the coverage of individuals for services (including dialysis).

House Flips: Changes in Committee Leadership

Speaker of the House: Kevin McCarthy *(R-CA)*

Rep. Kevin McCarthy (R-CA) is set to be the next Speaker of the House following GOP party elections. McCarthy's healthcare focus has largely been on addressing opioid use disorders, biomedical research, and most recently COVID-19 oversight. In 2018, he supported the passage of the *SUPPORT for Patients and Communities Act* which was a package of bills that provide federal funding for additional Medicaid and Medicare flexibilities for hospitals and providers in treating opioid use and mental health disorders. He helped create the 17-member Healthy Future Task Force to develop policy solutions for rising healthcare costs and improve care.

Pet issues include insurance affordability, HSAs/HDHPs, telehealth and promoting American made medicines and therapies. He also likely supports direct contracting / ACO REACH.

We note that he has been working on legislation to treat and cure Valley Fever, a fungal disease, for decades. Back in 2015, he was supportive of *21st Century Cures Act*. Most recently, he advanced the *Finding Orphan-disease Remedies With Antifungal Research and Development (FORWARD) Act* with the House-passed FDA user fees. The bill would require the FDA to hold a public workshop and issue guidance on the development of new Valley Fever drugs and vaccines and expand qualified infectious disease product (QIDP) incentives to antifungal biologics. Top donors include Amgen, American Hospital Association, Eli Lilly, and Blue Cross Blue Shield.

Majority Leader of the House: Steve Scalise *(R-LA)*

While Steve Scalise had previously stated the possibility of running for speaker, he is now running for Majority Leader and supporting Kevin McCarthy in his bid for speakership. If not this legislative session, he is likely to run for a future speakership. Similar to McCarthy, he is focused on COVID oversight as he is Ranking Member of the Select Subcommittee on the Coronavirus Crisis. He has a personal history with complex injury rehabilitation as he was a victim of the shooting at a Congressional Baseball practice in 2017 and is supportive of improving the healthcare workforce.

We note that he was one of the most vocal critics of the ACA, but repeal has not been a priority for some time. He is supportive of private insurance choice for individuals, Health Savings Accounts, and funding biomedical research. He was a cosponsor for and helped pass the *Accelerating Access to Critical Therapies for ALS Act* which establishes grant programs to address neurodegenerative diseases like ALS. Top donors include Centene, Emergent Biosolutions, UnitedHealth Group, and Abbott Laboratories.

House Ways and Means (Medicare, Tax)

There will be a fight for leadership here.

Possible Chair: Rep. Vern Buchanan (R-FL)

Rep. Buchanan is a former businessman by trade and has chaired 5 of the 6 Ways and Means subcommittees including the Health Subcommittee. He is supportive of Medicare Advantage, expanding telehealth, and increasing employer plan and HSA flexibilities. In July 2022, he and Rep. Terri Sewell (AL-07) helped introduce *Preserving Access to Home Health Act* which block CMS from making cuts to home health services through 2026.

He was critical of CMS coverage restriction on Aduhelm and helped introduce *Mandating Exclusive Review of Individual Treatments (MERIT) Act* which requires the CMS to evaluate treatments and cures individually rather than on a drug class.

He is co-chair of Healthy Future taskforce. Policy solutions from Healthy Future include site neutral reform, removing barriers for employers to participate in advanced payment initiatives, and changing the mandated benefits under the ACA. Top donors include Advocate Radiation Oncology, Select Medical Holdings, Blue Cross Blue Shield, American Dental Association, and Millennium Physician Group.

Possible Chair: Rep. Jason Smith (R-MO)

Rep. Smith is the former ranking member on the House Budget Committee. He is supportive of expanding telehealth after the PHE, and a champion for Medicare Advantage. He has advocated for price transparency in private markets and expanding rural access to mental and behavioral health. In May 2021, he and Rep. Josh Gottheimer (D-NJ) introduced the *Permanency for Audio-Only Telehealth Act*, which remove geographic and originating site restrictions and extends Medicare coverage of audio-only visits. Top donors include Community Health Systems and Blue Cross Blue Shield.

Possible Chair: Rep. Adrian Smith (R-NE)

Rep. Adrian Smith is focused on protecting intellectual rights of pharmaceuticals, expanding telehealth flexibilities, and improving rural health access, including access to alternative payment models. He is critical of the TRIPS waiver and, in April 2022, he and Rep. Vern Buchanan (R-FL) introduced the *Protecting American Innovation Act* which makes any TRIPS waiver subject to congressional approval.

In 2021, he and Rep. Judy Chu (D-CA) introduced the *PEERS in Medicare Act* which expands access to peer support mental health specialists in Medicare. In May 2022, he, and Reps. Tom O'Halleran (D-AZ) and Kelly Armstrong (R-ND), introduced the *Connecting Rural Telehealth to the Future Act* which extends PHE telehealth flexibilities for two years. Top donors include the American Association of Oral & Maxillofacial Surgery, the American Dental Association, and the American Health Care Association.

House Energy and Commerce (Medicaid, FDA, and Public Health Issues)

Chair: Rep. Cathy McMorris-Rodgers (R-WA)

Rep. Cathy McMorris-Rodgers (R-WA) is the current Ranking Member of the E&C committee and will take on the role of chair. She is a strong proponent of veteran health care, mental health reform and has a strong interest in rural health due to her constituency (she is a co-chair of the House Rural Health Care Coalition). As chair, she will play a critical role in Republican efforts to alter portions of the recently passed Inflation Reduction Act. She has also been vocal in her criticism of federal agencies' pandemic response, and we can expect to see FDA or CDC oversight in the form of additional HELP hearings or in legislation introduced.

McMorris-Rodgers has introduced legislation on expanding funding for mental health programs (particularly for youth), modernizing the VA healthcare system, and improving Medicare coverage of speech-generating devices. As ranking member, she helped introduce *the Lower Costs, More Cures Act* in April 2021. This bill was the GOP solution to rising drug costs and had several Medicare reforms, including required reporting of drug discounts, setting up a new variable ASP system, and a $3,100 out-of-pocket cap for Part D enrollees. House GOP could look to move this bill in 2023 as they attempt to unwind portions of the IRA.

She has been a vocal opponent of government excess spending. We note that she voted against the bipartisan *Consolidated Appropriations Act* back in March 2022, a $1.5 T government spending bill. Top donors include New York Cancer & Blood Specialists, and Blue Cross Blue Shield.

House Appropriations (Medicare, Medicare, FDA, NIH)

Chair: Rep. Kay Granger (R-TX)

Rep. Kay Granger (R-TX) is the current Ranking Member of the House Appropriations Committee and will take on the role of chair. Her agenda has largely not been healthcare focused, but her voting record

speaks to her priorities. She is supportive of telehealth expansion, tax credits to help individuals purchase insurance, and maintaining Medicare solvency. She a cosponsor for the Lower Costs, More Cures Act. Rep. Granger is also supportive of cancer research and in 2013 she cosponsored the Recalcitrant Cancer Research Act, which advances research on recalcitrant cancers (cancer with a 5-year relative survival rate below 50%). She is also a strong supporter of permanently fixing the Medicare physician reimbursement rate cuts and helped the House pass the SGR Repeal and Medicare Provider Payment Modernization Act in 2014 which would have enacted a permanent fix. Top healthcare donors include Creative Solutions In Healthcare (a long-term care co. in TX).

Senate: Democrats Maintain Majority

Senate HELP (FDA, Public Health, Commercial Health Insurance)

Chair: Bernie Sanders (I-VT)

Sen. Bernie Sanders is the next expected chair for the HELP committee as Senator Murray departs to lead the Senate Appropriations Committee.

Sen. Sanders is the highest-profile progressive in the Senate. Bernie is known for his support of Medicare-for-all, his stance on eliminating medical debt, and controlling drug costs (he was a key supporter of Medicare negotiations). We note that he was deeply disappointed in the modesty of the *Inflation Reduction Act* and attempted to introduce additional amendments like requiring Medicare to pay no more for prescription drugs than the VA and Medicare coverage of dental, vision, and hearing benefits. We can expect him to take up previous healthcare issues as Chair with a focus on protecting the provisions of the IRA and incorporating additional healthcare asks. He also supports drug reimportation. He is known for his strong support of a single payer healthcare system and reintroduced his signature *Medicare for All* legislation this past summer which establishes a federally administered national health insurance program. Top donors include Kaiser Permanente.

Ranking Member: Senator Rand Paul (R-KY)

Rand Paul, MD, is next in line to succeed Burr as HELP ranking member, but Senator Rob Portman's (R-OH) retirement also leaves an opening on the Homeland Security and Governmental Affairs Committee where he is the current ranking member of the subcommittee on Federal Spending Oversight and Emergency Management (FSO).

Senator Paul is critical of government overreach and waste. A former ophthalmologist, Paul had championed overturning the ACA, and has been advocating for reform and oversight of the FDA and CDC. Paul continues to champion the *VITAL Act* which would codify that LDTs are subject only to CLIA oversight even during an emergency and kickstart a process to modernize the CLIA regulations. This bill reflects his sensitivity to government regulations, being much less restrictive than the proposed *VALID Act*.

He is in favor of modernizing the FDA and improving drug approval process. He and Senator Cory Booker's (D-NJ) introduced and helped the Senate pass the *FDA Modernization Act 2.0* to end animal testing mandates for clinical trials. He also helped introduce the *Increasing Transparency in Generic Drug Applications Act*, which requires the FDA to identify the differences more clearly between the generic and brand name drug during the approval process. Top donors include Amgen and Humana.

Possible Ranking Member: Bill Cassidy, MD (R-LA)

The next in line in seniority is Susan Collins (R-ME), but she will take up the top GOP position in the Senate Appropriations Committee. This leaves Bill Cassidy as the likely ranking member if Rand Paul does depart for the Governmental Affairs Committee.

A former physician, Sen. Cassidy is supportive of addressing maternal mortality, controlling prescription drug costs, and mental health reform. He is supportive of addressing public health disparities especially in maternal health as Louisiana has one of the highest maternal mortality rates in the country. Earlier

this year, he cosponsored bipartisan legislation, *John Lewis NIMHD Research Endowment Revitalization Act,* which funds research into minority health disparities. To lower prescription costs, he has focused on increasing access to generics and biosimilars. In 2021, the *Ensuring Innovation Act,* a bill introduced with Senators Tina Smith (D-MN) and Roger Marshall (R-KS), passed. The legislation codifies awarding exclusivity based on a drug's "active moiety" rather than its "active ingredient," limiting when drug sponsors can obtain new exclusivity periods.

In 2020, Cassidy helped author and pass the No Surprises Act which limits a patient's out-of-network costs and prohibits surprise billing. This year, he has reintroduced legislation to re-authorize his Mental Health Reform Act of 2016 which funds several federal mental health and substance use disorder programs. Top donors include Oceans Healthcare (behavioral healthcare provider), Urology Centers, and Amneal Pharmaceuticals.

Senate Finance (Medicare, Medicaid, and Tax)

Chair: Senator Ron Wyden (D-OR)

Sen. Wyden is vocal on health care issues. He has vilified PBMs, wants to lower the cost of drugs for Medicare, and is focused on mental health reform of late.

Under his leadership, the Senate Finance committee released a report this year highlighting shortfalls in the mental healthcare system and the committee has held several hearings to discuss mental health reform. This will continue to be a key issue for Wyden as his state has consistently ranked worst in prevalence of mental illness and in lower access to care. He has guided the Finance committee to release legislative drafts on youth mental healthcare, improving the mental health workforce, and increasing telemental health in Medicare.

While he has been supportive of Medicare Advantage due to high utilization in his home state, he has also become increasingly critical of third party marketers. In August 2022, he launched an investigation into potentially deceptive marketing tactics by MA plans. Top donors include Blue Cross Blue Shield, Centene, and Gene Tools.

Ranking Member: Sen. Mike Crapo (R-ID)

Hailing from a rural state, Mike Crapo favors rural health issues (hospitals, mental health access), supports Medicare Advantage (MA), and is a strong advocate for improving cancer care (being a cancer survivor himself). He has historically worked well with Chair Wyden (OR) as they have similar priorities, and we can expect the collaborative relationship to continue.

In 2021, he helped reintroduce the *Medicare Multi-Cancer Early Detection Screening Coverage Act*, which would provide Medicare coverage of multi-cancer liquid biopsy tests. In 2019, Crapo joined his colleagues – Mike Enzi (R-WY), Richard Burr (R-NC), Thom Tillis (R-NC), John Barrasso (R-WY) and Jim Risch (R-ID) – to introduce the *Lower Costs, More Cures Act* in the Senate. Top donors include UnitedHealth Group.

Crapo is not known as particularly healthcare laser-focused, as he prefers to weigh in on tax and trade issues.

Senate Appropriations (Medicare, Medicare, FDA, NIH)

Chair: Senator Patty Murray (D-WA)

Sen. Murray will depart from her role as Senate HELP chair to lead the Senate Appropriations Committee, following the retirement of Senator Patrick Leahy (D-VT). Sen. Murray is a strong proponent of mental health reform, women's health, and investment in research and technology, as well as the medical workforce. Murray has authored legislation ensuring safety precautions for drugs and medical devices; drafted the original authorization for poison control centers across the country; and introduced a bill that would protect women's access to reproductive-health services.

She is likely going to make codifying Roe v. Wade (*Women's Health Protection Act*) and improving reproductive health access a priority as these were key election promises. And she is expected to oppose any GOP efforts to alter the Inflation Reduction Act. She was also instrumental in crafting the *PREVENT Pandemics Act* alongside Ranking Member Sen. Burr and will likely push for passage, given Burr's upcoming retirement and continued concerns about the federal agency's current capabilities to handle future pandemics.

She is in favor of reducing healthcare costs through increased federal oversight as she was instrumental in introducing and passing the *No Surprises Act* which prohibits surprise billing as of January 2022 and establishes a payment dispute resolution process. Top donors include Pfizer.

Ranking Member: Senator Susan Collins (R-ME)

Senator Collins is a strong proponent of controlling drug costs and advancing federal research. In 1997, she founded the Senate Diabetes Caucus and helped spearhead the effort to more than tripling federal funding for diabetes research. She is also the founder and co-chair of the Congressional Task Force on Alzheimer's Disease and has worked to increase funding for Alzheimer research.

Her legislative history in drug pricing includes the Senate's first bipartisan investigation into price spikes for off-patent drugs in 2015, a bill to improve generic competition that was signed into law as part of the FDA Reauthorization Act in 2017, and a 2018 legislation to prohibit the use of pharmacy "gag clauses" which was signed into law.

She most recently introduced the *INSULIN Act* which limits insulin co-pay cap to $35 or 25% of the list price. She also co-introduced the recently passed *MOBILE Healthcare Act*, which provides community health centers with the flexibility to use federal funds to establish mobile health clinics. Unlike other GOP members, she is supportive of reproductive health legislations and co-signed onto the *Reproductive Freedom for All Act* which codifies Roe v. Wade. Top donors include Argentum, a trade organization representing senior living communities.