

What is included in this newsletter:

- Congressional State of Play
- Appropriations Update
- Issue Overview: Medicare Pay Reform
- House E&C Chair Announces Retirement
- In the News

Congressional State of Play

While recent legislative activity has involved significant bipartisan compromises on tax and supplemental appropriations packages, conflicts between the chambers now threaten to hinder the passage of either proposal. Despite the recent burst of activity on these measures, lawmakers will soon be compelled to redirect their attention back to appropriations – as the looming two-tiered government shutdown deadlines of March 1 and March 8 persist. Although lawmakers were able to reach an agreement on overall spending just before the end of January, the breakdown of recent bipartisan compromises coupled with ongoing debates over the inclusion of contentious policy provisions jeopardizes any potential to pass all twelve appropriations measures before the respective deadlines. Both the House and Senate are scheduled to break for recess this month, meaning lawmakers will once again return to DC with a short timeline to reach an appropriations compromise before government funding runs out at the start of March.

In the Senate, four months of negotiations culminated on February 4 with a bipartisan unveiling of a \$118 billion proposal for a national security supplementary appropriations bill that would include funding for Taiwan, Ukraine, Israel, and immigration enforcement. The bill would have represented some of the most significant immigration reforms seriously considered by the Senate in years. However, the proposal quickly lost momentum after nearly half of Republican Senators, Speaker of the House Mike Johnson (R-LA), and former President Donald Trump all announced their opposition based on rumors of the package's contents. Speaker Johnson's opposition, outlined in a letter he shared with House Republicans, compelled Senate Minority Leader Mitch McConnell (R-KY) to acknowledge that the package did not have a realistic path forward despite widespread support in the Senate. While Majority Leader Chuck Schumer (D-NY) still brought the package up for a procedural vote on February 7, after that vote failed, he pivoted quickly to drop the measure's immigration provisions before reconsideration. Additionally, Republican Senators are delaying consideration of the House's bipartisan tax package over frustrations that they were excluded from the negotiating process. The GOP Senators are demanding an opportunity to review the bill in committee and submit amendments – threatening to block the measure entirely if their demands aren't met.

In the House, Speaker Johnson suffered two significant defeats in back-to-back votes at the hands of his members on the evening of February 6, further complicating a Republican conference that has only grown more frustrated with Johnson's leadership abilities. The first measure to fall short was Speaker Johnson's response to the bipartisan national security supplemental appropriations package that is moving through the Senate, an Israel aid-only version of the measure out of protest for the Senate's refusal to negotiate with the House on the package's immigration provisions. While Johnson's standalone Israel-aid bill had been expected to fail, later the same evening the House's Republican Majority also narrowly failed to impeach Homeland Security Secretary Alejandro Mayorkas for his handling of illegal immigration. The high-profile impeachment defeat, coming after months of Republican-led investigations and plenty of consternation from the Speaker over whether to proceed with the heavily politicized effort, was deeply embarrassing for Republican leadership who appear to have underestimated Democratic attendance for the vote. Even just hours ahead of the final vote, Johnson had expressed confidence that the measure would pass, despite the exceedingly tight margin. While several Republicans have committed to revisiting both proposals once Majority Whip Steve Scalise (R-LA) returns from treatment the week of February 12, there is no doubt that the tandem of highly visible defeats for the Republican leadership has only further driven speculation about Johnson's ability to govern the caucus and deliver votes on pressing matters like appropriations."

Appropriations Update

On January 26, Senate Appropriations Chair Patty Murray (D-WA) and House Appropriations Chair Kay Granger (R-TX) announced they had reached a deal on the topline spending totals for each of the twelve appropriations measures. The individual funding topline, known as '302b' numbers, are the split of the roughly \$1.7 trillion federal budget that will be allocated to each appropriations subcommittee to draft their respective appropriations measures. With the 302b numbers in hand, it allows subcommittee leaders to begin crafting the finer points of policy and funding priorities for the spending bills that fall under their jurisdiction. Although the 302b numbers are customarily safeguarded until the subcommittees unveil their initial drafts, Rep. Sanford Bishop (D-GA), the leading Democrat on the agriculture appropriations subcommittee, has hinted in interviews that his subcommittee's allocations surpass those designated for FY2023. While this information alone cannot project the totals for other spending bills, there's a possibility of additional funding details emerging through media reports as the deadlines for federal appropriations draw near.

Equipped with the topline numbers, Chairs and Ranking Members of the Appropriations subcommittees in both the House and Senate engaged in meetings during the week of February 5 to discuss the programmatic details of the individual bills under their purview. However, discussions about potential policy riders attached to the final House and Senate versions of each measure are notably absent from these deliberations. This year, the House opted to incorporate several highly contested policy riders, particularly those restricting abortion access, deemed as "poison pill" provisions by many Congressional Democrats. While temporarily setting aside the possibility of these provisions making it into the final appropriations bills may be the only way to achieve consensus on other aspects of the legislation, lawmakers will need to address these details before the government funding deadlines on March 1 and 8 to avert a shutdown. Despite this looming threat, Committee leaders Rosa DeLauro (D-CT) and Tom Cole (R-OK) have expressed confidence in their ability to resolve any outstanding disagreements ahead of the March 1 deadline.

In addition to the provisions within each spending bill, there are still lingering questions about how pass the final measures – a growing concern given the limited timeframe. Discussions persist among lawmakers in both chambers about consolidating the dozen FY2024 funding bills into one omnibus package, a mechanism that has been staunchly opposed by Congressional Republicans throughout the past year. Sen. John Kennedy (R-LA), the ranking Republican on the Energy-Water subcommittee, predicts that the government will either be funded through an omnibus or a continuing resolution until September, depending on the popularity of the omnibus among his Republican colleagues. On the opposite side of the Capitol, counterparts of Kennedy, like Rep. Mario Diaz-Balart (R-FL), chair of the State-Foreign Operations funding panel, assert that a large omnibus is not on the table, emphasizing the Speaker's clear stance against it.

While the fate of FY2024 appropriations remains uncertain, the White House has disclosed that President Joe Biden will present his FY2025 budget request to Congress on March 11, just three days after the second government funding deadline lapses. This document will outline the Biden administration's funding priorities and establish a framework for congressional action. The release of the budget will also exert new pressure on Congress to initiate work on fiscal 2025 bills at the conclusion of a tumultuous and protracted fiscal 2024 appropriations process that has already necessitated three short-term funding extensions.

Issue Overview: Medicare Pay Reform

SNO has undertaken the initiative to assess reforms to the Medicare physician reimbursement system, aiming to establish a more equitable structure that accurately reflects the comprehensive services provided and the intricate care demanded by patients with brain tumors. While existing billing codes encompass a variety of services beyond direct brain cancer treatment, there is a notable absence of codes specifically quantifying the unique time and effort invested in addressing cases related to brain cancer and other complex pathologies. The varied origins, manifestations, and complications associated with brain tumor development pose a distinctive challenge, influencing treatment options and strategies. Crafting a precise and individualized treatment plan demands the involvement of neuro-oncologists and other specialized professionals in activities that go beyond the routine services provided during a patient visit. These activities include in-depth case research, collaborative information sharing with colleagues in both office settings and conferences, and tumor modeling—activities not adequately addressed by current billing codes. Existing codes, such as 99367 for medical team conferences involving an interdisciplinary team of healthcare professionals or 99358 for prolonged evaluation and management services before and/or after direct patient care, come with cumbersome stipulations. For instance, they may require multiple participants to be engaged in the face-to-face treatment of the same individual or demand that services must fall within a narrow window preceding face-to-face time. These conditions create limitations that hinder the codes from effectively capturing the nuanced and comprehensive care provided in cases of brain tumors.

A potential avenue for advancing the Medicare pay emerged on February 9 when Senators Catherine Cortez Masto (D-NV), Marsha Blackburn (R-TN), John Thune (R-SD), John Barrasso (R-WY), Debbie Stabenow (D-MI), and Mark Warner (D-VA) jointly announced the formation of a bipartisan Medicare payment reform working group. According to the group's press releases, their primary goal is to conduct a thorough examination and propose enduring reforms to the physician fee schedule (PFS) while also making essential updates to the Medicare Access and CHIP

Reauthorization Act (MACRA). Recognizing the dynamic nature of the healthcare system, the Senators contend that the current physician payment system is inadequate in keeping pace with the actual cost of care and advancements in new services and technologies. Underlining the crucial role of Medicare Part B in delivering essential services to millions of Americans, the Senators believe this initiative will underscore the necessity for Congress to address reimbursement challenges and transition towards a payment system aligned with patient outcomes. The working group aims to ensure financial stability for healthcare providers, improve patient outcomes, promote access to quality care, and encourage the adoption of emerging healthcare technologies. They plan to seek bipartisan solutions through stakeholder feedback and policy development in the coming weeks.

House E&C Chair Announces Retirement

On February 9, Representative Cathy McMorris Rodgers (R-WA), the leading Republican on the House Energy and Commerce Committee, announced her decision not to seek reelection, joining the ranks of a number of senior Republicans on the committee that have opted for retirement in recent weeks rather than stand for re-election this November. To provide context, the Energy and Commerce Committee holds broad jurisdiction encompassing a spectrum of policy areas, with a particular focus on health-related matters and shaping the structure of the nation's healthcare system. Chair McMorris Rodgers, in particular, has earned recognition for her endeavors in reforming US health policy, playing a crucial role in negotiating the five-year reauthorization of the FDA's user fee program, among other initiatives. The announcement of her departure creates a notable opening at the helm of one of the House's most influential committees, triggering a race to succeed her. Although McMorris Rodgers has declared her intent to complete her current term, several colleagues have not hesitated to express their ambitions to replace her. The following Members of Congress have either announced or are expected to announce their intention to succeed Chair McMorris Rodgers:

- Rep. Brett Guthrie (R-KY), chair of the E&C Health Subcommittee, will run to replace her, his office confirmed.
- Rep. Bob Latta (R-OH), who will be the most senior Republican on the E&C Committee next Congress, is running for the chair, per two people with knowledge of the matter.
- Rep. Richard Hudson (R-NC), chair of the National Republican Congressional Committee, is also being encouraged to run for the top committee role, according to two high-level Republicans familiar with the matter. If he ultimately launches a bid, that would mean Hudson would forgo seeking another term in leadership.

In The News

[Sen. Cortez-Masto PR](#) (2/9/2024): **CORTEZ MASTO, BLACKBURN, THUNE, BARRASSO, STABENOW, WARNER ANNOUNCE FORMATION OF MEDICARE PAYMENT REFORM WORKING GROUP** - U.S. Senators Catherine Cortez Masto (D-Nev.), Marsha Blackburn (R-Tenn.), John Thune (R-S.D.), John Barrasso (R-Wyo.), Debbie Stabenow (D-Mich.), and Mark Warner (D-Va.) today announced the formation of a Medicare payment reform working group. The primary goal of this group is to investigate and propose long-term reforms to the physician fee schedule (PFS) and make necessary updates to the Medicare Access and CHIP Reauthorization Act (MACRA).

To Interested Parties: As the health care system has evolved since the inception of the Medicare program, the physician payment system has failed to keep pace with the actual cost of care and the improvements in new services and technologies. Medicare Part B is a lifeline for tens of millions of Americans, covering a wide array of services, including primary and outpatient care, preventive services, durable medical equipment, and more. Despite efforts like the 2015 Medicare Access and CHIP Reauthorization Act (MACRA), which made significant strides towards a value-based payment system, further action is needed to address reimbursement challenges and shift toward a system that aligns payment incentives with patient outcomes. We believe Congress must make changes to the current Medicare physician payment system to ensure financial stability for providers, improve patient outcomes, promote access to quality care, and incentivize the utilization of emerging health care technology. Today, we are beginning work as a bipartisan working group to help achieve these goals and put Medicare on a sustainable path for the future. This working group is committed to exploring and proposing policy solutions for stable physician payments and necessary updates to MACRA, ensuring sustained access to quality care for patients. We will be reaching out to stakeholders in the coming weeks to seek feedback and to begin developing policies that will address Medicare physician payment for the long-term.

Politico Pro (2/8/2024): E&C Chair McMorris Rodgers announces retirement - House Energy and Commerce Committee Chair [Cathy McMorris Rodgers](#) will not run for reelection. The Washington state Republican — who leads a powerful committee with oversight of health care and energy policy — is the latest member to announce plans to retire. "We will spend this year honoring the Committee's rich history — plowing the hard ground necessary to legislate on solutions to make people's lives better and ensure America wins the future," McMorris Rodgers said in a statement. McMorris Rodgers, who has been in Congress since 2005, was instrumental in negotiating a five-year reauthorization of the FDA's user fee program. She also worked with ranking member [Frank Pallone](#) (D-N.J.) to co-author a major consumer privacy bill last Congress. Rep. [Brett Guthrie](#) (R-Ky.), the current chair of the health subcommittee, is vying to replace her. "He's running," Guthrie spokesperson DJ Griffin said. Rep. [Bob Latta](#) of Ohio, who will be the most senior Republican on E&C next Congress, is running for chair of Energy and Commerce, per two people with knowledge of the matter. Rep. [Richard Hudson](#) of North Carolina, chair of the National Republican Congressional Committee, is also being encouraged to run for the top committee role, according to two high-level Republicans familiar with the matter. If he ultimately did launch a bid, that would mean Hudson would forgo seeking another term in leadership.

Politico Pro (2/8/2024): Sanders, Dems slam pharma CEOs for drug prices, profits at hearing - The CEOs of three major pharmaceuticals appeared before Congress Thursday to receive a tongue lashing from Sen. [Bernie Sanders](#) (I-Vt.) over their high-priced drugs, but they weren't ready to commit to new drug price cuts. The HELP Committee hearing was more theater than a forum to discuss pending legislation with the participants sticking to familiar scripts. Democrats pushed drugmakers to care more about patients than profits and Republicans touted the benefits of a market-driven system that produces blockbuster lifesaving drugs. When the leaders of Johnson & Johnson, Merck and Bristol Myers Squibb were asked to commit to cutting prices, they demurred. "The outrageous cost of prescription drugs in this country means that 1 out of 4 Americans cannot afford the medicine their doctors prescribe," Sanders, who chairs the committee, said. "How many die and how many suffer unnecessarily, nobody knows but my guess is that it's in the millions."

Why are U.S. prices so high? The CEOs acknowledged affordability challenges, asked that discounts won by the middlemen of pharmacy benefit managers be passed on to patients and urged Congress to protect the U.S. biopharmaceutical industry from an economic environment that hinders the discovery of new medicines. “We have a role to play in addressing affordability and stand ready to partner with Congress and others to address this issue for patients in a holistic manner, but in developing those solutions, we should not abandon our system for one that denies U.S. patients the broad and rapid access to vital medicines that they appreciate today,” Bristol Myers Squibb CEO Chris Boerner said. Sanders told POLITICO that he plans to introduce new drug-pricing legislation soon, but declined to give any details. He said the drugmakers’ comments reining in drug prices were “certainly not enough.”

Politico Pro (2/6/2024): Ways and Means takes its turn on drug shortages - A key question behind chronic drug shortages is what policy levers Congress could use to mitigate Americans not being able to get the drugs they need. The problem is acute for lower-priced generics with manufacturers blaming supply-chain issues and innumerable regulations. In a hearing Tuesday, House Ways and Means Chair [Jason Smith](#) (R-Mo.) floated changes to Medicare reimbursement policy to address pervasive drug shortages. “Government policies and consolidation in the supply chain force manufacturers to close drug production because they can’t make the math work,” Smith said. “Medicare’s reimbursement system ensures affordability and access for seniors, but should be reexamined to avoid making the situation worse.” Smith didn’t offer details about what changes are needed. He also raised concerns about relying too much on foreign countries like China for the drug supply chain. Smith pointed to private-sector solutions like long-term contracts and state investments. He said “health care, tax and trade policy” should be used to boost domestic manufacturing. Ranking member [Richard Neal](#) (D-Mass.) also pointed the finger at supply-chain dynamics, citing exclusive contracts with just one manufacturer in particular. He touted Biden administration actions to boost domestic production, such as leaning on the Defense Production Act, and said cost remains an access issue, hammering Republicans for not supporting the Inflation Reduction Act that launched the first Medicare drug price negotiations. Executives from McKesson Pharmaceutical Solutions & Services, nonprofit generic drug firm Civica Rx and the American Society of Clinical Oncology testified Tuesday, among others.

Politico Pro (2/6/2024): House GOP lawmakers slam FDA no-show at hearing - A House subcommittee hearing Tuesday on foreign inspections of drugmakers was overshadowed by a lawmaker-agency dustup over why the FDA wasn’t there to testify. Virginia Republican [Morgan Griffith](#), chair of the Energy and Commerce Oversight and Investigations Subcommittee, told POLITICO the FDA had been invited to appear about two weeks ago, but an FDA spokesperson said it did not receive an invitation that was “timely or formal.” “We understand the importance of our foreign inspection program to the health and safety of the American public and the agency has been responsive to the Committee’s inquiries on this issue,” FDA spokesperson Jeremy Kahn wrote in an email. “We will continue to engage with any specific questions they have on this or related topics.” “Completely unacceptable,” Energy and Commerce Chair [Cathy McMorris Rodgers](#) (R-Wash.) said at the hearing. CJ Young, a spokesperson for the Democrats on the Energy & Commerce committee, said in an email that Republicans’ complaint about the FDA’s no-show represents an effort to score political points. “The [GOP] majority chose to informally notify FDA about this hearing without sufficient notice to attend,” Young said, noting that three weeks notice

is standard practice on most congressional committee invites to federal agencies. “A week is not unreasonable to send a representative,” Griffith said. “If we expect to get the head guy, we probably need to give them a little bit more time. But to get somebody here to discuss it, two weeks is plenty.” Griffith said the committee plans to hold additional hearings on FDA’s foreign inspection program — and urged the agency to testify. Regardless, lawmakers on both sides of the aisle said the FDA must do a better job boosting the number of in-person inspections in countries like China and India, which supply about 45 percent of the active pharmaceutical ingredients used in the nation’s drugs, [according to a letter](#) from the committee sent to the FDA in July.

[Bloomberg](#) (2/2/2024): Biden Will Send Congress His 2025 Budget Proposal on March 11 - President Joe Biden will send lawmakers his fiscal 2025 budget proposal March 11, days after his State of the Union address and a deadline to avoid a shutdown, White House Office of Management and Budget staff exclusively told Bloomberg Government. Biden’s March 11 budget plan follows fiscal 2024 funding deadlines on March 1 and March 8 and the president’s annual address to Congress, scheduled for March 7. It will cap a frantic few days with lawmakers likely racing to finish this year’s government-funding bills — more than five months late — before quickly turning to fiscal 2025 negotiations. Lawmakers already acknowledged the late start, combined with election-year politicking, will make it difficult to make much progress on appropriations bills ahead of the Sept. 30 funding deadline. The budget proposal is technically due the first Monday in February, though presidents rarely met that deadline in recent years.

[Politico Pro](#) (2/1/2024): Health AI rule hits a snag - An HHS rule finalized in December that would require more transparency in artificial intelligence now faces potential delays. The rule, published on Jan. 9, is in limbo because HHS’ Office of the National Coordinator for Health IT did not allow sufficient time after transmitting it to Congress before finalizing it. A 1996 law requires agencies to wait 60 days, but ONC finalized the rule about a month after it went to Congress, [according to the Government Accountability Office](#). The rule is to go into effect at the end of 2024. It’s unclear whether the snafu will delay implementation. An ONC spokesperson said the agency is “aware of the 60-day requirement and ... working to address the discrepancy.” The spokesperson didn’t answer questions about a potential delay. The sweeping ONC regulations will apply to clinicians using HHS-certified decision support software that’s used in the vast majority of hospitals and doctor’s offices. It would fill a substantial void in regulation and intends to help providers choose safer artificial intelligence. The regulations will require software developers to provide more data to customers to allow providers to determine whether AI is “fair, appropriate, valid, effective and safe.”

[Politico Pro](#) (1/31/2024): She built the modern FDA, despite controversies - Retiring Janet Woodcock helped transform drug approval in the United States, speeding medicines to market and revolutionizing the structure of one of America’s most powerful federal agencies. Known as a straight shooter with an unusual grasp of scientific knowledge and how Washington works, Woodcock, the FDA’s No. 2, delayed stepping down to help shepherd the agency through the Covid-19 pandemic and a nationwide infant formula crisis that rattled confidence in the FDA. Woodcock was key to building the agency’s modern drug-review and safety-monitoring processes, and helped Congress establish how copycat complex medicines are approved and overhaul how FDA regulates over-the-counter drugs. She also drew criticism for her role in the opioid crisis, the implementation of companies paying the regulator for drug reviews and the approval of at least

one controversial drug against the advice of staff. Woodcock, who is stepping down today as principal deputy commissioner, spoke to POLITICO about her nearly four-decade record overseeing the U.S. pharmaceutical industry, saying her sometimes controversial decisions were based on her scientific conclusions. POLITICO spoke with 24 current and former officials, lawmakers, congressional staff and advocates, who agreed that Woodcock's departure leaves a gaping hole at the agency that ensures food and drug safety for the nation. The picture that emerges is one of an accomplished regulator who will be remembered for advancing the FDA's mission despite controversy. Early in the Biden administration, she failed to overcome opposition from lawmakers like Sen. Joe Manchin (D-W.Va.), who questioned her role in greenlighting controversial treatments, including Aduhelm for Alzheimer's disease, and managing the fallout of an opioid epidemic that has claimed the lives of hundreds of thousands of Americans. A spokesperson for Manchin referred to his previous statements about Woodcock when asked about her retirement.

Politico Pro (1/29/2024): House GOP doctors to ask Schumer to boost Medicare physician pay - Republican doctors in the House plan to appeal directly to Senate Majority Leader [Chuck Schumer](#) (D-N.Y.) to reverse a Medicare pay cut their fellow physicians took on Jan. 1. Unless Congress reverses the 3.4 percent cut to Medicare reimbursements, more doctors will leave their independent practices or medicine altogether, GOP Doctors Caucus leaders [Michael Burgess](#) of Texas, [Greg Murphy](#) of North Carolina and [Brad Wenstrup](#) of Ohio say. Democrats have sought to pair more money for doctors with increased funding for community health centers, Medicaid and mental health care, but Republicans have resisted. The Centers for Medicare and Medicaid Services ordered the 3.4 percent cut last year in accord with a mandated payment formula, as directed by Congress in the law that created Medicare. The doctors want a fix in a pending fiscal 2024 appropriations bill that Congress must pass by March 1 to avoid a partial government shutdown. Doctors are "facing unprecedented burnout due to low reimbursement rates, health care consolidation, administrative burdens, and record high inflationary pressures," the GOP doctors write in a letter they've drafted to Schumer and Senate Finance Chair Ron Wyden (D-Ore.).

Politico Pro (1/27/2024): Dozen funding totals struck as Congress races to avert another shutdown cliff - Top appropriators have reached a deal on the totals for a dozen spending bills, clearing a critical hurdle toward securing a broader government funding agreement before federal cash expires for a swath of agencies in less than five weeks. Senate Appropriations Chair [Patty Murray](#) (D-Wash.) and House Appropriations Chair [Kay Granger](#) (R-Texas) reached the deal late Friday night, according to two sources familiar with talks. Both sides aren't releasing the numbers for the 12 funding bills, which will provide federal agencies with updated budgets for the current fiscal year. The deal, which came together after weeks of tough negotiations, follows [the announcement of a government funding framework](#) hashed out by staff for Senate Majority Leader [Chuck Schumer](#) and Speaker [Mike Johnson](#). It will allow lawmakers to hash out the finer policy and funding points of each individual bill. Appropriators have been anxious to get their hands on the figures, acknowledging that time is short to finalize a government funding accord that will top \$1.7 trillion. Government funding for veterans, transportation, agriculture and energy programs runs out March 1. Funding for the rest of the government, including the military and the biggest domestic programs, expires March 8.

[Stat](#) (1/26/2024): ‘The response defies belief’: Year of inaction leaves children at risk from bad cancer drugs – A year after an investigation revealed widespread use of a substandard cancer drug, the World Health Organization and national drug regulators around the world have come under fire for failing to protect children from the dangerous chemotherapy. The WHO plays a major role in protecting people worldwide from bad medicines. One of the fastest ways it is able to warn governments about a dangerous or ineffective drug is by issuing a medical product alert. This prompts governments to take action such as recalling the drugs or investigating the manufacturers. But the WHO has issued no alert about the problematic cancer drug. [Last January](#), the Bureau of Investigative Journalism (TBIJ), in [partnership with STAT](#), revealed that at least a dozen brands of asparaginase, a key childhood chemotherapy drug, had failed quality tests. In some cases they fell well below the standard needed to treat cancer and many contained contaminants such as bacteria. It put an estimated 70,000 children — mostly in low- and middle-income countries — at risk. One year on, neither national governments nor the WHO has taken meaningful action, with both sides claiming communication breakdowns and a lack of evidence. And doctors are frustrated that these brands are still for sale.

[Politico](#) (1/26/2024): New Digital Health Caucus— The Consumer Technology Association will host a briefing with Reps. Troy Balderson (R-Ohio) and Robin Kelly (D-Ill.) next week to [launch the Congressional Digital Health Caucus](#). The caucus will aim to ensure that “all Americans benefit from the transformative power of digital health tools.” The Feb. 1 event will have a panel on artificial intelligence in health care with speakers from Google, Microsoft, Amazon Web Services and Hippocratic AI. The caucus’ launch comes amid a surge in interest in health technology like AI, telehealth, wearable technology and remote patient monitoring to address issues in health care.

[Bloomberg](#) (1/26/2024): Bipartisan legislative plans to address generic drug shortages – Plans are in the works at the Senate Finance Committee, Chair Ron Wyden (D-Ore.) and ranking Republican Mike Crapo (R-Idaho) said. The pair released a [white paper](#) yesterday outlining concerns from a [hearing](#) last month that tackled the topic as well as ideas to address drug shortages. The Finance Committee is looking into Medicare and Medicaid proposals for legislative development this year including potential payment reforms under Medicare Part A and B to stabilize the supply of generic sterile injectable medicines and Medicare Part D pilot initiatives to encourage pharmacies to purchase generic drugs from companies that invest in mitigating shortages.

[Politico Pro](#) (1/26/2024): Merck, J&J CEOs to testify on US drug prices, avoiding possible subpoena - Merck CEO Robert Davis will testify before the Senate HELP Committee next month during a hearing on the cost of prescription drugs in the U.S., the company confirmed to POLITICO Friday, relenting to a subpoena threat from Committee Chair [Bernie Sanders](#) (I-Vt.). And Johnson & Johnson's CEO Joaquin Duato has also agreed to testify, according to a Senate HELP statement Friday afternoon. "We trust that this will be a productive hearing aimed at enhancing the committee's understanding of the pharmaceutical industry and finding common sense solutions to the challenges facing patients," Merck spokesperson Bob Josephson said. The company earlier had offered its U.S. president as a witness, arguing that official was better equipped to field questions about U.S. drug pricing. But [Sanders said Thursday](#) he believed he had the votes to subpoena Davis and Duato to compel their testimony. He had set a committee meeting for Jan. 31

to vote on the subpoenas. Bristol Myers Squibb CEO Chris Boerner had already committed to testifying if at least one other pharma executive showed up.

Politico Pro (1/24/2024): Doctors are in the waiting room — and they hate it - It's an annual rite of fall at the Capitol: Physicians and their allies descend to protest Medicare payment cuts, warning it will imperil their practices and their patients. Congress typically obliges, reducing or eliminating the cuts before they take effect. But nearly a month into 2024 lawmakers are late — and doctors are fuming. "Medical practices are feeling like it is death by a thousand cuts," said Anders Gilberg, the senior vice president of government affairs for the Medical Group Management Association. Congress' failure to mitigate the 3.4 percent Medicare rate cut that took effect this month could prompt doctors to reconsider whom they serve, according to Rep. Greg Murphy (R-N.C.), a surgeon and one of the leaders of the GOP Doctors Caucus. "You're really destroying access for a growing number of Medicare patients," he said. The Biden administration finalized the reduced rates last fall relying on a mandated payment formula last revised in 2015. The announcement triggered a fervent but unsuccessful lobbying effort from doctor groups who were counting on lawmakers to stave off the cuts as they had often done before. But 2023 wasn't like earlier years. There was no big funding package in December and the prolonged spending fight means any fix for physicians likely won't come until March, the next deadline to keep the government open. "That's when, process-wise, I think that could happen," said Sen. Bill Cassidy (R-La.), also a physician and the top Republican on the Senate Health, Education, Labor and Pensions Committee. The panel is working with the Finance Committee on a health care bill that could be a vehicle.

Politico Pro (1/18/2024): House sends yet another shutdown-averting bill to Biden's desk - The House cleared a stopgap spending bill on Thursday afternoon that officially keeps federal agencies funded through early March, sending the measure to President Joe Biden's desk. The chamber approved the shutdown-averting legislation hours after the Senate's relatively speedy passage, with lawmakers hoping to avoid travel complications caused by an impending snowstorm set to bear down on Washington, D.C. The measure, known as a continuing resolution, passed with mostly Democratic support in a 314-108 vote, a point sure to irritate conservatives who are already fuming over spending. With parts of the government now funded through March 1 and March 8, leading appropriators have a tremendous amount of work to do in just a matter of weeks. They're looking to finalize a dozen annual spending bills that Congress has so far failed to pass as House conservatives seek deeper cuts. If lawmakers fail to clear those bills over the next six weeks, appropriators warn that Congress might have to fall back on yet another a stopgap spending bill, this time through the rest of the fiscal year. That would saddle federal agencies with flat budgets or, worse, steep funding cuts.

Politico Pro (1/18/2024): Health panel set to subpoena pharma CEOs over drug prices – The Senate HELP Committee will vote on Jan. 31 to issue subpoenas for the CEOs of two major drug companies to testify about their drug pricing strategies for the U.S. compared to other countries, Chair [Bernie Sanders](#) said Thursday. If authorized, as expected, the subpoenas for Johnson & Johnson CEO Joaquin Duato and Merck CEO Robert Davis would be the first issued by the panel since 1981, according to the committee. Bristol Myers Squibb CEO Chris Boerner has agreed to testify before the committee "alongside at least one of the other pharmaceutical CEOs," the committee said in a statement. Sanders and every committee Democrat wrote to the three

pharma leaders in November, [inviting them to testify](#) about why the U.S. pays more for prescription drugs than other industrialized economies and how drug prices are set. All three companies make drugs that CMS has selected for the first price negotiations under Medicare and have sued the government over the program in courts across the country. The government's initial price offers are due to drugmakers Feb. 1.

[Politico Pro \(1/19/2024\): FDA leaders tout proposed agency overhaul](#) – FDA officials are working to inform employees about how the agency's proposed reorganization aims to make it more nimble and effective, senior leaders said Friday. "We're trying to move to a more enterprise system" with a "holistic look," Principal Deputy Commissioner Janet Woodcock said during a webinar led by the Alliance for a Stronger FDA, which advocates for more appropriations for the agency. The reorganization wouldn't require additional funding from Congress, Woodcock said. "We knew we couldn't go and ask for money," she said. Moving compliance programs into the medical product and food centers, Woodcock said, will streamline agency operations and should save the FDA money. The reorganization isn't final. The Department of Health and Human Services and the White House's Office of Management and Budget must sign off on the plan, said FDA Chief Scientist Namandjé Bumpus, who will succeed Woodcock next month when she retires. The FDA also must give Congress 30 days notice of the reorganization and publish a Federal Register notice, she said. The agency also must negotiate with unions that represent impacted staff, she added. The Office of Regulatory Affairs — which is proposed to be rebranded as the Office of Inspections and Investigations — will shrink to nearly 3,600 full-time equivalent employees from about 5,100, said Michael Rogers, associate commissioner for regulatory affairs. "This is the largest reorganization in FDA's history," he said. "It's a huge culture change."

[Stat \(1/17/2024\): Congress' negotiations over doc pay, health centers fell apart ahead of spending extension](#) - Negotiations to add extra health care policies to Congress' stopgap funding bill fell apart late last week, five sources told STAT. The provisions at issue included a bump to physicians' Medicare pay rates and efforts to increase funding for community health centers and enact some behavioral health policies.

When lawmakers were negotiating a deal to extend government funding until March, congressional leaders were also considering attaching new health care spending items to the package that hadn't been included in prior short-term funding bills. Those are the talks that ultimately broke down, said a congressional aide, two lobbyists, and a health care industry source. Lawmakers decided instead to simply extend policies that had already been included in prior bills. The breakdown isn't final — talks are expected to continue, now that lawmakers are likely to extend government funding deadlines to March. But the tenor of the discussions offers hints about Democrats' and Republicans' health priorities heading into those bigger negotiations. The government funding package is likely the only vehicle for new health care policy ahead of the 2024 election.

[Politico Pro \(1/14/2024\): What's in the funding patch for health care](#) - Congressional leaders on Sunday night unveiled a [proposed stopgap measure](#) that would extend government funding, including a number of major health programs, through early March. The continuing resolution would again set two deadlines for funding the government — March 1 for FDA and VA programs, and March 8 for HHS funds. If lawmakers reach a deal, the stopgap measure would be the third

used to avoid a government shutdown since September. Lawmakers have until Friday to avert a partial government shutdown — including the FDA and VA — and Feb. 2 for the rest of the government, including HHS. House Speaker [Mike Johnson](#) has backed the plan to give more time for lawmakers to come to an agreement on spending bills. The proposal will likely require significant support from Democrats to pass the House because Republican hardliners are pressing to abandon a topline spending deal reached recently with Senate Majority Leader [Chuck Schumer](#). **The details:** Sunday night’s proposal is similar to previous spending patches. Through March 8, it would:

- Continue funding for community health centers, teaching health centers and the National Health Service Corps
- Extend special diabetes programs
- Avert steep cuts to hospitals that have a high volume of Medicaid and uninsured patients
- Continue the Sexual Risk Avoidance Education program, which aims to prevent teen pregnancy and domestic violence

The legislation doesn’t address [the myriad expired health programs](#) that Congress still has to fund, including global HIV/AIDS program PEPFAR; the SUPPORT Act, which tackles the opioid epidemic; and the Pandemic and All-Hazards Preparedness Act.

Lawmakers are expected to attempt to address them in a potential March funding deal. There [are also efforts](#) to attach sweeping legislation adding price transparency requirements for pharmacy benefit managers, insurers and hospitals, and other measures onto a deal.

[Politico Pro \(1/12/2024\): Q&A: Rep. Cathy McMorris Rodgers](#) - Transparency is one of the hottest health policy topics in Washington, and Energy and Commerce Chair [Cathy McMorris Rodgers](#) (R-Wash.) is one top lawmaker pushing it. Her bill, the [Lower Costs, More Transparency Act](#), sailed through the House last month in a 320-71 vote, after negotiations with the House Committee on Education and the Workforce and the House Ways and Means Committee. That legislation would increase reporting requirements for insurers, hospitals and pharmacy benefit managers. It would also change Medicare payment policy so drugs administered in a hospital outpatient department are reimbursed at the same rate as a doctor’s office, a policy known as site-neutral payments. Hospitals and PBMs have railed against the bill. Rodgers hopes to reach a deal with Senate leaders — who have their own PBM and site-neutral proposals — to get the legislation across the finish line. In an interview with POLITICO Thursday, Rodgers said negotiations between the House and Senate are focused on “technical differences.” Negotiations are occurring at the staff level and between lawmakers themselves, Rodgers said. Senate HELP Chair [Bernie Sanders](#) [has introduced legislation](#) alongside Sen. [Mike Braun](#) (R-Ind.) with similar provisions, and Senate Finance Chair [Ron Wyden](#) (D-Ore.) has pushed his own legislation aiming to rein in PBMs. Wyden concurred with Rodgers and told POLITICO that negotiators have made “a lot of progress.” Rodgers spoke with POLITICO about the path forward for the closely-watched bill.

[Politico Pro \(1/11/2024\): The FDA approved Florida’s drug import plan. Colorado wants to be next](#) - Colorado Gov. Jared Polis wants his state to be the next to import prescription drugs from Canada. The Democratic governor, during his State of the State address on Thursday, urged the FDA to allow the state to move forward with plans to purchase prescription drugs from Canada, a move state health officials estimate would save Coloradans between \$53 million and \$88 million annually. Polis’s request comes [nearly a week after](#) federal health officials greenlit a similar plan

in Florida. “The simple truth is that Coloradans, and people across the United States, are tired of being ripped off for the prices of necessary medications that cost a fraction of the amount in other wealthy nations,” Polis said. “That’s why we continue urging the FDA to approve our application to allow for more lower-cost prescription drugs by importing prescription drugs from Canada.” Colorado lawmakers approved a plan to import drugs from Canada in 2019. After the state submitted its initial application in 2022, the FDA asked for additional information last spring. The state is updating its proposal to include a new cost-savings analysis and plans to submit it early this year. Colorado wants to import 112 drugs, including medications to treat cancer, diabetes and HIV.

Politico (1/10/2024): On Health Care, a Congressional Laundry List - With all the shuffle on the Hill and programs expiring, we’d forgive you for forgetting some things lawmakers want to get done. Here’s a rundown from Ben of key issues they hope to address:

- Government Funding
- Transparency and Site-Neutral
- PEPFAR
- PAHPA
- Doctor Pay
- Other Funding
- Telehealth
- HSA Reform
- Opioid Epidemic

Politico Pro (1/9/2024): GOP physicians to meet with House speaker on doctor pay fix - The GOP Doctors Caucus is scheduled to meet with House Speaker [Mike Johnson](#) Thursday to ask for the Louisiana Republican’s help blocking a cut in Medicare reimbursements for physicians. Two people with knowledge of the meeting told POLITICO the group, which is made up of GOP lawmakers who are doctors, plans on discussing priorities for a funding package with Johnson — including language to avert a 3.4 percent cut to how much Medicare pays doctors this year. The Centers for Medicare and Medicaid Services [finalized that cut](#) in November. Congress has often passed legislation in the past to stop or reduce cuts to doctor pay. Leaders in the Doctors Caucus have supported legislation that would halt the cut, as well as [larger reforms](#) to how Medicare pays physicians. But lobbyists for physicians have said privately that stopping the cut [doesn’t seem likely](#) this year — so they’re instead looking to reduce its size. Congress has to pass new spending legislation covering CMS by Feb. 2, and the doctors hope to get language into the new law.

Politico Pro (1/5/2024): NASA's next moonshot: Ending cancer - Two hundred and fifty miles above Earth, astronauts on the International Space Station have embarked on an audacious mission: curing cancer. Because cells age faster in the absence of gravity, they’re using the atmosphere on board to conduct experiments that could speed development of treatments. The efforts could aid President Joe Biden’s so-called cancer moonshot — a plan to cut the cancer death rate in half over 25 years, a goal that would be easier to hit with rapid development of new drugs. But supporters, including NASA, will need to persuade a cost-conscious Congress to back research by funding public-private partnerships and to help a transition to commercial space stations. Pharmaceutical companies are increasingly interested in space to develop and improve drugs, and

to extend their patents. Still Congress isn't sold on increasing NASA's budget. Biden [proposed ramping up](#) opportunities for public-private collaboration aboard the space station in his fiscal 2024 budget, but both the Republican-controlled House and Democratic-controlled Senate [want to cut](#) NASA funding. The agency is operating at fiscal 2023 funding levels while Congress decides what to do ahead of a Feb. 2 deadline.