HEALTH POLICY OUTLOOK FOR 2024

McDermott+ Consulting

Health Policy Outlook for 2024

As we flip the calendar, we welcome the second session of the 118th Congress, the start of a presidential and congressional election year and look ahead to the major health policy topics on the agenda for 2024.

The new congressional session starts where the first session failed to finish: funding the federal government for fiscal year 2024. That unfinished business is first on Congress's plate, with the deadline of January 19, 2024, for four appropriations bills and health extender policies, and a February 2, 2024, deadline for the remaining government funding bills, including for the US Department of Health and Human Services (HHS). Potentially tied up with this work is action to address US border policies and funding for Ukraine and Israel. And all of that is before Congress turns to work that would regularly fill the legislative calendar for the current year.

Looking ahead to the possibilities for healthcare legislating in 2024, here are a few broad points to keep in mind:

- **CONGRESS IS CLOSELY DIVIDED:** In the US Senate, Democrats maintain a 51–49 hold on the majority. In the US House of Representatives, Republicans have a very slim 220–213 majority, which will shrink to 219–213 on January 21, 2024, when Rep. Bill Johnson (R-OH) resigns. The margin for Republicans in the House remains incredibly fragile.

- **THE HOUSE HAS A NEW SPEAKER:** Speaker Mike Johnson (R-LA) is still new to the role of speaker of the House. He's not well-known to the other leaders with whom he will be negotiating, and he faces the same extreme difficulties as former speaker McCarthy in getting a majority of House Republicans to support compromise policy. That poses challenges in a divided Congress where Speaker Johnson must negotiate with a Democratic Senate and president and still maintain the support of the majority of the House Republican Conference. The pressure created by that conundrum caused Speaker McCarthy to lose his gavel and is likely to drive a smaller legislative package than the typical massive omnibus.

- **TRENDS FROM THE FIRST SESSION OF THE 118th CONGRESS MAY CONTINUE:** Only 27 bills passed both the House and Senate and were signed into law in 2023. Even in a divided Congress, that is far below historical standards. Many Members of Congress no longer prioritize legislative achievements as was once the case. There is little expectation for the new year to suddenly bring a bevy of legislating. Expect less and you are less likely to be disappointed.

- **ELECTION YEARS, ESPECIALLY PRESIDENTIAL ELECTION YEARS, LIMIT LEGISLATING:** Those of us in Washington, DC, often joke about "even-numbered years" and how little time they offer to get policymaking done because so much focus turns to the campaign trail. Congress's task of completing last year's undone business will only further shrink the potentially productive time period.

- **AFTER THE ELECTION COMES LAME DUCK:** Congress will inevitably have to return to session post-election to complete business left undone. Many issues may be held to be addressed at that time. Work done during the pre-election period also will be very relevant for what is possible in lame duck.

With those broad themes in mind, this report provides a look into how those in the healthcare sector should view the policymaking potential of 2024.

HEALTH POLICIES THAT COULD SEE ACTION IN 2024

Medicare and Medicaid Payment and Coverage

Physician Payment Reforms – Payments under the Medicare Physician Fee Schedule (PFS) drop by 3.4% in 2024 unless Congress intervenes to reduce or eliminate the cut. Multiple legislative proposals are under consideration by Congress, with stakeholders urging that a fix be included as part of the upcoming government funding bills to avoid having to reprocess or hold claims.

The recent forced reductions to the PFS conversion factor (CF) began in 2021, when the Centers for Medicare and Medicaid Services (CMS) finalized changes to evaluation and management services and created a new add-on code for complexity (whose effective date Congress delayed to CY 2024). These policies resulted in an across-the-board reduction to the CF of more than 10% to preserve budget neutrality. Congress has been chipping away at that major reduction ever since.

	Cut Finalized in PFS Final Rule	Congressional Fix	**Final Cut**
CY 2021	-10.2%	+6.9%	**-3.3%**
CY 2022	-3.8%	+3.0%	**-0.8%**
CY 2023	-4.5%	+2.5%	**-2.0%**
CY 2024	-3.4%	?	**?**

If Congress provides relief early in January 2024, payments could be adjusted in accordance with that fix and may not be paid at a rate that includes the full CF reduction (provided the legislation includes a retrospective change to January 1, 2024). Past the two-week mark, if Congress has not acted, it is less clear how CMS will process claims with dates of service from the beginning of 2024. When faced with a similar situation in the past, CMS instructed Medicare Administrative Contractors (MACs) to hold certain claims for payment and start to release other claims for payment on a "rolling basis."

In 2024, there also may be a push for legislation that would permanently reform how physician payments are updated every year so that some of these patches can be avoided in the future. Multiple bills have been introduced in the House that would address some of the perceived issues with the PFS, including the budget neutrality requirement and the lack of an inflationary update. With key legislators who have focused on physician issues retiring at the end of the year (*e.g.*, Representatives Michael Burgess (R-TX), Brad Wenstrup (R-OH) and Larry Bucshon (R-IN)), there may be more impetus to enact meaningful PFS reforms this year.

Site-Neutral Policies – Congress remains keenly interested in policies to equalize Medicare payments across certain care settings, especially because the Congressional Budget Office (CBO) scores these policies as big cost savers. The House-passed **Lower Costs, More Transparency Act** includes a provision that would cap Medicare payment for drug administration services furnished at off-campus departments of a hospital at a PFS-equivalent rate. If that provision is left out of the health package expected as part of the January and February appropriations process, it could re-emerge later in the year. And Congress could decide to go even further. House Energy and Commerce Committee Chairwoman Cathy McMorris Rodgers (R-WA) signaled her intent to do so at a May 2023 committee markup when she offered—but ultimately withdrew—an amendment that would have applied a site-neutral payment rate across a broader set of services furnished at hospital outpatient departments and ambulatory surgical centers. The Medicare Payment Advisory Commission has also continued to explore site-neutral payments for other care settings.

Congress likely will continue to look at site neutrality policies in 2024 as it seeks pay-fors for other health policy priorities.

Coverage of Emerging Technologies – Since the Obama Administration, CMS has been working on developing a new coverage pathway for innovative new technologies. In January 2020, CMS issued a final regulation to implement the Medicare Coverage for Innovative Technologies (MCIT) program. MCIT granted devices with breakthrough designation temporary national coverage for at least four years, to be followed by either a national coverage determination (NCD) by CMS or a local coverage determination at MAC discretion. The Biden Administration delayed implementation of MCIT and repealed it entirely in November 2021 for several reasons, including the fact that MCIT did not require any evidence generation as a condition of temporary coverage.

In MCIT's place, CMS proposed the Transitional Coverage for Emerging Technologies (TCET) program in June 2023. The proposed TCET framework would provide temporary coverage and would require evidence generation as a condition of coverage. In addition to the proposed TCET framework, CMS issued the first in a series of guidance documents "to provide a framework for more predictable and transparent evidence development." The first document is proposed guidance for how CMS reviews evidence during the NCD process. CMS also issued proposed guidance on clinical endpoints for knee osteoarthritis, identifying "health outcomes of interest to CMS" during an NCD. CMS expects innovators to use this document to shape clinical trial design for future new technologies. CMS received substantial public comments on these documents.

In 2024, CMS is expected to finalize the TCET program and finalize guidances for evidence review and knee osteoarthritis. CMS also has indicated that it plans to issue additional clinical endpoint guidance for other therapeutic areas so that innovators incorporate relevant endpoints into future clinical studies in these spaces. CMS's ability to execute TCET will depend on the availability of resources, including staff and funds for external consultants that are needed to pursue these initiatives.

Medicaid Unwinding – Legislation enacted early in the COVID-19 pandemic provided states with an enhanced Federal Medical Assistance Percentage (FMAP) to maintain continuous coverage for Medicaid beneficiaries who had coverage during the COVID-19 public health emergency. In the Consolidated Appropriations Act of 2023, Congress allowed states to begin Medicaid eligibility redeterminations and renewals as of April 1, 2023, regardless of whether the COVID-19 PHE had ended. At the same time, it also phased down the enhanced FMAP to states. Since then, states have begun conducting redeterminations and disenrolling individuals from the Medicaid program.

Since December 2023, more than 13 million people have been disenrolled from Medicaid in every state and Washington, DC, through the eligibility redetermination process. Many individuals disenrolled for procedural reasons may still be eligible. CMS has also noted that 29 states plus Washington, DC, have self-identified as erroneously making administrative renewal decisions on a household level rather than on an individual level as federal regulations require, resulting in inappropriate disenrollment of many children in particular.

Congress did establish guardrails for the Medicaid unwinding process, and CMS has released guidelines to states to create processes and enforcement actions relating to unwinding. States are required to submit monthly reports about eligibility determinations through June 30, 2024. CMS has already taken enforcement action, including requiring many states to pause procedural terminations, reinstate coverage, implement mitigation strategies, and fix their systems and processes. CMS will likely continue to release subregulatory guidance to states on ways to unwind without terminating coverage improperly, and states will conduct redeterminations according to their own priorities and understanding of the law. In the year ahead, CMS will assess how to engage states and whether to impose punitive measures. Should punitive measures be imposed, the expectation is that it would quickly become a legal battle.

Healthcare Access

Rural Healthcare – The Medicare Dependent Hospital (MDH) program supports small rural hospitals at which Medicare patients constitute at least 60% of inpatient days or discharges. Both the MDH program and the Low-Volume Hospital Payment Adjustment, which helps hospitals that have a low volume of total discharges, are set to expire on September 30, 2024. Bipartisan legislation was introduced in 2023 to extend these programs permanently (S. 1110) or for a five-year period (H.R. 6430), and extensions are generally supported by leaders of the committees of jurisdiction (the Senate Finance Committee and the House Ways and Means Committee). The duration and timing of the next extension are major factors to watch. While rural health champions would prefer the longest extension possible to provide more financial certainty, budgetary constraints often dictate shorter extensions. Other rural health provisions, such as updating Medicare reimbursement base years for Sole Community Hospitals and MDHs paid on the basis of their hospital-specific rate, are also in the mix, although they too face budgetary constraints.

Health Equity – Addressing health equity was a top priority for the Biden Administration in 2023. For example, the 2024 PFS created separate coding and payment for several new services to help underserved populations, including addressing unmet health-related social needs that can potentially interfere with the diagnosis and treatment of medical problems. The Administration also released several guidelines and recommendations targeted specifically at improving health equity, such as the CMS Strategic Plan for Health Equity Fact Sheet, the Call to Action to Address Health Related Social Needs, and the States Advancing All-Payer Health Equity Approaches and Development Model.

HHS and CMS will continue to encourage health equity improvement efforts among specific populations, such those receiving maternal healthcare. For maternal health, CMS will continue to implement its Maternity Care Action Plan and the White House Blueprint for Addressing the Maternal Health Crisis, and this year we should expect more targeted efforts to address this persistent concern. The Centers for Medicare and Medicaid Innovation is also scheduled release the Transforming Maternal Health Model funding opportunity in 2024.

Healthcare Workforce – Leaders on both sides of the aisle and in both the House and Senate have expressed strong interest in advancing legislation to address healthcare workforce challenges. Key topics include alleviating growing physician shortages in rural and underserved areas, improving training and education opportunities for healthcare staff, and addressing burnout and rising violence against healthcare workers. A final HHS nursing home staffing rule also is expected this year. Some stakeholders contend that the minimum staffing ratios included in the proposed rule would exacerbate already significant workforce shortage issues, so the policies included in the final rule could drive legislative action in this arena. While these issues offer an opportunity for bipartisan cooperation, the political realities of 2024 may limit Congress's ability to advance significant healthcare workforce legislation this year. At the committee level, however, we expect oversight and legislative work to continue, building upon recent requests for information and related efforts.

CMS Medicaid Regulations – CMS released two major Medicaid proposed rules in 2023 and received thousands of written comments that highlighted concerns about implementation of the rules as proposed. Stakeholders are concerned about increased burden from the proposed creation of additional reporting and evaluation requirements, significantly increased costs for states and providers, and the so-called 80/20 rule in home- and community-based services (HCBS), described below. CMS is expected to release final versions of these rules in 2024. If the final rules include controversial requirements, Congress could intervene with legislation.

- *Medicaid Access Proposed Rule* – On May 3, 2023, CMS published a proposed rule that seeks to increase transparency in payment rates, standardize data and monitoring, and create new opportunities for states to promote active beneficiary engagement in Medicaid programs, with the

goal of improving access to care. The rule also has a particular focus on the delivery of HCBS, including direct care worker compensation requirements, grievance process development, critical incident reporting definitions and HCBS quality reporting.

A leading concern among certain stakeholders arises from the proposal that at least 80% of Medicaid payments for personal care, homemaker and home health aide services be spent solely on compensation for direct care workers. Many stakeholders expressed support for the intent to bolster the direct care workforce but noted a need for greater clarity in definitions of relevant terms. They also suggested that the 80% threshold should be reconsidered and aligned with evidence-based standards that account for factors such as differences in provider size, rural/urban status and risk of closure.

- *Medicaid Managed Care Proposed Rule* – On May 3, 2023, CMS published a proposed rule that would make transparency-related updates to state directed payments and require states to submit an annual payment analysis that compares managed care plans' payment rates for routine primary care services, obstetrical and gynecological services, and outpatient mental health and substance use disorder services as a proportion of Medicare's payment rates. The proposal would establish a framework for states to implement a Medicaid or Children's Health Insurance Program (CHIP) quality rating system to create a "one-stop-shop" for enrollees to compare Medicaid or CHIP managed care plans based on quality of care, access to providers, covered benefits and drugs, cost and other plan performance indicators. The rule would also require states to submit an annual payment analysis that compares managed care plans' payment rates for homemaker services, home health aide services and personal care services as a proportion of the state's Medicaid state plan payment rate.

Mental Health – Efforts to improve behavioral health coverage and access remains a priority for the Biden Administration and both parties in Congress. The SUPPORT Act reauthorization bill, which passed the House in late 2023 and was also reported from the Senate HELP Committee, focuses on prevention, treatment and recovery services for behavioral health services. This legislation is necessary to continue to fund many behavioral health programs that need reauthorization. The bill is bipartisan, and it likely will be enacted early this year. The Senate Finance Committee also has worked to develop bipartisan legislation focusing on improving mental health access through the Better Mental Health Care, Lower-Cost Drugs, and Extenders Act, which advanced out of the committee in November 2023. We expect the Biden Administration and Congress to continue to examine ways to improve access to behavioral health services in 2024.

Innovation

AI – Potential progress toward regulating artificial intelligence (AI) tools is anticipated with the implementation of the president's executive order. Deadlines for some agencies are fast approaching and will give stakeholders insight into how the Administration plans to tackle complex issues around AI use in healthcare. Congress will likely continue hearings to help identify areas for legislation, including broad regulation of AI and/or bills specific to AI in healthcare, such as its use in prior authorization activities.

Telehealth, Virtual Care and Hospital at Home – Many virtual care flexibilities created during the pandemic and extended to varying degrees since the end of the public health emergency will end on or before December 31, 2024, including almost all Medicare telehealth flexibilities, certain private market access waivers, and the extension of the acute hospital care at home waivers and flexibilities. Congressional action therefore is necessary for broad access to virtual care to continue beyond 2024. To add another layer of complexity, congressional action on these extensions will run up against proposed rules for 2025 that are expected from CMS. Proposals in the PFS rule, which provide payment and coverage for virtual care, are usually released in July and finalized in November. Given the December 31 deadline, it is unlikely that Congress will act before CMS proposes its 2025 polices, meaning that CMS will likely make decisions based

on an assumption that these flexibilities will expire. Stakeholders should be prepared for a high level of uncertainty heading into the last quarter of 2024.

Lawmakers are also waiting for the US Drug Enforcement Administration (DEA) to release revised requirements this year regarding the use of telehealth to prescribe controlled substances. This rulemaking would have significant implications for access to appropriate healthcare professionals and medications for patients struggling with substance use disorder and other mental health issues. The DEA initially proposed more restrictive rules for prescribing controlled substances via telehealth compared to the policies in place during the COVID-19 PHE. After receiving public input, including concerns from Members of Congress, the DEA decided to extend the COVID-19-era telehealth policies twice, with the latest extension ending on December 31, 2024. The DEA will have to finalize permanent telehealth policies for prescribing controlled substances by November 2024, 60 days before the current extension ends. Lawmakers will be scrutinizing this rule closely and may choose to take legislative action.

Consumer Protections and Market Regulation

No Surprises Act – There are still many moving parts with respect to the implementation of the 2020 No Surprises Act. In the first few months of 2024, providers will once again have the opportunity to initiate batched disputes in the federal independent dispute resolution (IDR) process, and providers will have until March 14, 2024, to initiate disputes that became eligible for the IDR process since the IDR portal initially closed on August 3, 2023. Although providers have until March to initiate batched disputes, there is an artificial deadline of January 22, 2024, when higher IDR fees come into effect.

In addition, comments on the IDR operations proposed rule are due in early 2024 (the comment period initially closed on January 2, but CMS announced that it will be reopened). The IDR operations rule is likely to be finalized in 2024, as the proposed effective dates for many policies fall during the year. Besides this final rule, the federal departments implementing the law may begin to implement other provisions of the No Surprises Act, such as those related to advanced explanation of benefits, continuity of care requirements, provider directory requirements and information to be included on patients' insurance identification cards. There also are still ongoing lawsuits related to No Surprises Act implementation. The departments have appealed or plan to appeal two out of the four major Texas Medical Association (TMA) lawsuits: *TMA II* and *TMA III*. There may be more changes to IDR policies and operations throughout this year and next as the legal process for these two cases plays out.

Healthcare Transparency – Transparency was the health policy buzzword of the first session of the 118th Congress, and interest in all things transparency likely will continue in 2024. Last year, three House committees—Energy and Commerce, Ways and Means, and Education and the Workforce—advanced legislation that would codify (and in some respects, modify) current requirements around hospital and health plan price transparency, with provisions ultimately being included in the House-passed Lower Costs, More Transparency Act. Any transparency provisions left out of early 2024 legislation to fund the government and extend various healthcare policies could re-emerge later in the year.

Healthcare Consolidation and Private Equity – In 2023, several House and Senate committees held hearings raising concerns about consolidation in the healthcare marketplace and the effects it has on access and cost. The House-approved Lower Costs, More Transparency Act includes a provision that would require the Secretary of HHS to submit an annual report on the impact of certain Medicare regulations on provider and payer consolidation. The bill also would require the CMS Innovation Center to consider the extent to which models impact consolidation. The role that private-equity-backed organizations play in consolidation and in the cost of healthcare generally is another issue that has captured policymakers' attention. While provisions to address that topic were left out of the Lower Costs, More Transparency Act in the House, they

have been explored recently by several committees. Provisions like these could be included in House-Senate compromise legislation, if such legislation advances.

FDA Legislation and Regulation

- *LDT Proposed Rule* – In the first half of 2024, we could see the US Food and Drug Administration (FDA) finalize its regulation related to laboratory developed test (LDTs). In September 2023, the FDA issued a proposed regulation that would end its existing enforcement discretion and engage in more direct oversight of LDTs. The proposed regulation seeks to amend the FDA's regulations to make explicit that *in vitro* diagnostic products (IVDs) are considered devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the IVD is a laboratory. If the regulation is finalized as proposed, the FDA would phase out its existing general enforcement discretion approach for most LDTs in five stages over four years. Tests currently offered as LDTs could remain on the market until the FDA completed its review of the lab's application, although the FDA noted its authority to pursue enforcement action against "violative IVDs" at any time.

- *VALID Act* – Some stakeholders have questioned the FDA's authority to regulate in this space. For several years, Congress has considered (but not passed) the Verifying Accurate, Leading-edge IVCT Development (VALID) Act to clarify the FDA's authority and provide a framework for regulating LDTs. While a legislative compromise was close at the end of 2022, no final agreement was reached, and no progress was made by the end of 2023. Congress may wish to revisit the VALID Act before the FDA finalizes the LDT regulation in 2024, or it could choose to make changes to FDA policy after the final regulation is issued.

- *Cures 2.0 Act* – Champions of the original 21st Century Cures legislation began assembling a 2.0 version in 2022 but made little progress in 2023. Some of the provisions included in the original draft have since been addressed via other legislation or have been included in other legislative efforts that may advance. Congressional leaders of the Cures Act continue to evaluate policies that could be part of a new draft bill. While significant action might not happen in 2024, the bill's leaders will at least use this year to explore policies and potentially release requests for information, open letters, white papers and discussion drafts.

Prior Authorization Reforms – Legislative and regulatory efforts addressing prior authorization practices could advance in 2024. In December 2022, CMS released a proposed regulation that would require health insurers to implement an electronic prior authorization process, shorten the timeframes to respond to prior authorization requests, include a specific reason when they deny a prior authorization request and respond to prior authorization requests within certain timelines. The final rule is currently pending at the Office of Management and Budget and therefore likely will be released this year. Congress is also looking at legislation to reform the prior authorization process in the Medicare Advantage program. The House Ways and Means Committee advanced legislation in July 2023 that would require Medicare Advantage plans to implement electronic prior authorization. This legislation is similar to the Improving Seniors' Timely Access to Care Act, which passed the House in 2022. Its $16 billion CBO score stalled further congressional consideration. If CMS finalizes its rule and addresses some of the legislation's provisions through regulation, CBO's cost estimate will likely decrease, which may help the legislation advance.

Prescription Drugs

IRA Implementation – 2024 is a crucial year in the timeline for implementing the Medicare drug price negotiation provisions of the Inflation Reduction Act. Last year, CMS published the first 10 drugs selected for negotiation, and this year those negotiations begin in earnest. In February, CMS will send drug companies initial offers, and in August, the negotiation period to arrive at a "maximum fair price" concludes. In

September, CMS is expected to publish final prices for negotiated drugs, and those prices will become effective in 2026. Ongoing litigation also could impact implementation.

PBM Reform – Congress has been keenly interested in pharmacy benefit manager (PBM) reform, with both the House and Senate Finance Committee advancing significant legislation in 2023. Lawmakers are advocating for many of these policies to be included in the legislation to fund the government, and it is expected that several will be included, especially policies related to transparency, pharmacy performance measures and delinking administrative fees from drug prices. Given the strong bipartisan support for reforming PBMs, it is expected that many of the policies not included in the government funding package will remain in play and could resurface in future healthcare legislation. Policies related to out-of-pocket costs and rebate pass-throughs often generate a significant score from CBO that would have to be paid for in order to move forward in legislation.

Market Competition Reforms – The Senate Judiciary Committee passed several bipartisan bills in 2023 that seek to address anticompetitive behavior in the prescription drug market. In general, these measures would allow more generic drugs and biosimilars to enter the market, thus improving competition among pharmaceuticals. These bills also produce savings: CBO found that they would save between $2 billion and $3 billion over 10 years. Those savings estimates make it possible that these bills will advance in 2024.

340B Program – On November 2, 2023, CMS finalized a rule to addresses how the agency will restore payments to hospitals affected by a 2018 decision to cut reimbursement amounts under the hospital Outpatient Prospective Payment System for drugs purchased under the 340B program. This rule is responsive to a Supreme Court of the United States opinion finding that the 2018 payment cuts were not consistent with CMS authority to set Medicare payments to hospitals for outpatient drugs. CMS estimates that the total payments to hospitals will be $9 billion. It is expected that these payments will be made in early 2024. Hospitals eligible to participate in the 340B program also continue to face challenges with a growing number of pharmaceutical manufacturers placing restrictions on 340B pricing for contract and community pharmacies. As of September 2023, 25 manufacturers restricted 340B pricing. This activity may continue in 2024, and Congress or the Administration could take steps to intervene.

FINAL THOUGHTS: CONGRESS, THE ADMINISTRATION AND THE 2024 PRESIDENTIAL CYCLE

There are several competing dynamics as we head into 2024, but the healthcare landscape offers no shortage of policies for the taking if Congress and the Administration are interested. We could see a very active year, with movement across the health policy landscape, or political and election year influences could stymie action. Stakeholders should prepare to leverage any windows of opportunity that may emerge and get comfortable with a high level of uncertainty.

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