

2023 Year-Ahead Outlook

Congress ended last year having accomplished a sizable amount of policymaking on health. In addition to the several bipartisan provisions included in the fiscal year (FY) 2023 omnibus, lawmakers also passed bipartisan legislation on mental health and gun reform, and congressional Democrats were successful in advancing substantial drug pricing reforms and coverage expansions via the Inflation Reduction Act.

Following a highly productive 2022, the federal outlook for health policy in 2023 appears slated to feature a familiar set of priority areas. We expect that conversations will focus on issues such as health equity, affordability, public health, mental health, health care coverage, and health technology, among others. However, we expect that a greater share of the work on health policy will be advanced through the Administration and that less will be accomplished by Congress. This is largely because the political appetite for additional health policy legislation may wane following the activity of the year prior. A divided Congress will also complicate the ability for lawmakers to coalesce around bipartisan solutions for health reform.

Despite this dynamic for 2023, a number of upcoming deadlines may necessitate a must-pass vehicle focused on health policy, which could feature additional bipartisan riders. Notably, a number of major expirations for federal programs and other policy changes will occur at the end of the fiscal year (i.e., September 30, 2023), including:

- The expiration of the Pandemic and All-Hazards Preparedness (PAHPA);
- The expiration of several provisions included in the SUPPORT Act;
- The Farm Bill; and
- The scheduled Medicaid Disproportionate Share Hospital cuts, which are set to go in effect at the beginning of fiscal year 2024.

Beyond this, Medicare physician payments are scheduled to decrease at the beginning of calendar year 2024, which may prompt legislative activity to prevent such decreases from taking effect by the end of the calendar year. Congress will also have to address the debt ceiling in the summer and resolve how to fund the government for FY 2024.

Still, the ability for Congress to pass substantial health-focused legislation appears slim. The focus on mental health last year may remain this Congress – especially the Senate Finance Committee’s mental health provisions were not included in the omnibus – though there may be a greater emphasis on substance use disorder as attention shifts to address the SUPPORT Act reauthorizations. Congress also must pass the Farm Bill, which will reauthorize crucial programs including the Supplemental Nutrition Assistance Program (SNAP) and The Emergency Food Assistance Program (TEFAP), and may include notable nutrition-related policies. Aside from these efforts, however, it remains uncertain whether Congress will accomplish much else on the health policy front. And efforts to further bolster the U.S. public health system – despite an opportunity to do so with the upcoming PAHPA reauthorization – do not appear viable following the successful inclusion of several public health provisions in the fiscal year 2023 omnibus.

Instead, the Biden-Harris Administration is planning to engage in multiple rulemaking efforts to advance its health-related priorities. For example, we expect to see more from the Administration this year on its plans for implementing the drug pricing provisions included in the Inflation Reduction Act. We also anticipate additional work on advancing the Administration’s behavioral health integration strategy, which it unveiled last year. Last, the Administration is expected to end the COVID-19 public health emergency (PHE) this year and will begin supporting health care providers, states, and other stakeholders in the unwinding of the various pandemic-related flexibilities and requirements that have been in place since 2020. The Administration will also likely move forward on a variety of efforts to support access to reproductive health, support public health systems, and improve access to equitable care.

An overview of potential activity on both the legislative and regulatory fronts is provided in the table below.



Overview of Potential Legislative and Regulatory Activity on Federal Health Policy Areas

Legislative	Regulatory
<i>Public Health</i>	
<p>The fiscal year 2023 omnibus included most provisions in the bipartisan PREVENT Pandemics Act. The upcoming reauthorization of the Pandemic and All-Hazards Preparedness (PAHPA) provisions, which are set to expire at the end of the current fiscal year (September 30, 2023), presents an opportunity to build upon the new reforms and address gaps.</p>	<p>The Occupational Safety and Health Administration is expected to soon issue the highly anticipated permanent COVID-19 standard for health care. The final rule arrived at OMB for review on December 7, 2022. Back in June 2021, OSHA implemented an emergency temporary standard (ETS) establishing requirements for employers to protect workers from COVID-19 in health care settings. The ETS remains in effect until superseded by a permanent standard.</p> <p>In September 2023, OSHA plans to propose a standard intended to protect workers from infectious diseases. This broader standard would apply to more settings beyond health care, such as correctional facilities, homeless shelters, drug treatment programs, and occupational settings.</p>
<i>Mental Health</i>	
<p>The fiscal year 2023 omnibus included a range of mental health provisions, which mostly focused on reauthorizing existing federal programs (though some notable changes were included as well). However, a number of bipartisan provisions contemplated by the Senate Finance Committee were not included in the legislation. Senate Finance may therefore attempt to advance a more robust mental health package this year, though the appetite for additional mental health reform could decrease this year following the activity on mental health last year. Instead, there may be a shift to focusing on substance use disorder, especially considering the upcoming expiration of various provisions from the SUPPORT Act.</p>	<p>The Administration will continue to advance its behavioral health integration strategy, which it formally announced last September. This will largely consist of federally-sponsored training programs for mental health professionals, increased compliance with mental health parity requirements, increased health IT interoperability to facilitate communication between mental and physical health providers, and improved quality measures. On the rulemaking front, the Administration has previewed it plans to issue a proposed rule to implement the mental health parity provisions included in the Consolidated Appropriations Act of 2021. The regulation could come as early as quarter one of this year. The Administration is also aiming to pursue rulemaking intended to improve care for those with substance use disorder (e.g., here and here), also potentially in the early part of this year.</p>
<i>Coverage & Access</i>	
<p>Sweeping legislation to expand health insurance coverage, such as closing the Medicaid coverage gap, is unlikely under the divided Congress. However, lawmakers may pursue more narrow coverage reforms to increase access to care, such as mental health care and improving care for dually eligible beneficiaries. On this latter point, a</p>	<p>In support of President Biden's executive orders (January 2021, April 2022), the Administration will continue to use regulatory levers to strengthen Medicaid and the ACA. In response to the decoupling of the Medicaid unwinding period from the COVID-19 Public Health Emergency, CMS plans to issue a final rule in January to modify state</p>

<p>bipartisan group of Senators issued a request for information late last year seeking input on ways to improve care for dual-eligibles, which may spur legislative action.</p>	<p>requirements for the temporary 6.2 percentage point FMAP increase. Additionally, CMS plans to issue a final rule in November 2023 intended to streamline the Medicaid and CHIP application and enrollment processes. In April 2023, CMS plans to release proposed rules to improve access to Medicaid and CHIP broadly as well as Medicaid managed care (e.g., here and here).</p> <p>In addition to the annual notice of benefit and payment parameters for 2024, CMS plans to pursue rulemaking to strengthen protections under the ACA. In April, the Administration plans to propose changes to the regulation of short-term, limited-duration insurance to ensure this type of coverage does not undermine the ACA. CMS is also expected to issue a proposed rule regarding religious and moral exemptions as they relate to coverage of certain preventive services (e.g., reproductive health care).</p> <p>Lastly, the Administration will issue a slate of rules implementing the No Surprises Act related to independent dispute resolution, provider nondiscrimination requirements, advanced explanation of benefits, air ambulance services. As currently projected, the Administration would promulgate this series of regulations in the spring and summer of 2023.</p> <p>Rules involving ERISA-regulated health plans will be issued jointly by HHS and Labor.</p>
<p><i>Reproductive Health</i></p>	
<p>Sweeping activity to strengthen access to reproductive health services is unlikely in the new Congress. House Republicans have already engaged in efforts to cement their position on abortion by passing a resolution and a bill that condemns violence against anti-abortion organizations and affirms the rights of infants that are born following an unsuccessful abortion, respectively. However, it is unlikely any such measures would be successful in the Senate. By the same token, however, it is also unlikely Democrats will be able to codify the right to abortions with a Republican majority in the House.</p>	<p>In response to the President's executive order last year on reproductive rights, the Administration will continue to do what it can to ensure individuals can access abortions. Notably, HHS recently proposed a rule to partially rescind a never-implemented Trump Administration regulation that allowed providers to deny care – including abortions – based on religious or conscience reasons. HHS is also in the process of finalizing regulations to strengthen section 1557 protections, which would prohibit providers from discriminating on the basis of pregnancy or related conditions (including abortion).</p> <p>On the Food and Drug Administration (FDA) side, the agency recently issued changes that allow certain pharmacies to be certified to dispense mifepristone (i.e., the abortion pill). The Department of Justice also recently issued a legal opinion allowing the U.S. Postal Service to mail abortion drugs to states that have strict limits.</p>

<i>Equitable Care</i>	
<p>In a divided Congress, we do not expect substantive legislative activity to advance health equity. However, efforts to reform mental health care, improve care for duals, and other potential legislative efforts could have an impact on health equity.</p>	<p>The Administration will primarily drive work at the federal level on health equity, which remains a priority on the regulatory front. Notably, the Administration plans to engage in rulemaking to increase access to culturally competent care (here), as well as propose regulations to prevent against discrimination on the basis of disability in health care (details). The Department of Health and Human Services (HHS) also plans to better assure access to Medicaid services (here), which should also drive towards more equitable care. These actions are expected in March and April of this year.</p>
<i>Medicare Payment & Value-Based Care</i>	
<p>In 2022, a bipartisan group of representatives issued a request for information seeking input on ways to improve the Medicare Access and CHIP Reauthorization Act (MACRA). Stakeholder feedback may be used to craft legislation that would reform Medicare physician payments to better encourage the transition to value-based care arrangements. The upcoming expiration of the existing incentive payment for clinicians participating in advanced alternative payment models (AAPMs) may act as a cliff for prompting such legislative action. The recently appointed Chair for the Senate Committee on Health, Education, Labor, and Pensions (HELP), Bernie Sanders (I-VT), also recently stated that increasing access to primary care will be a focus for him this Congress, which may align with MACRA reform efforts. Notably, the Medicare Payment Advisory Commission has begun exploring ways to alter Medicare payments to primary care providers in such a way that improves access to care and supports the primary care workforce (details).</p>	<p>In September, the Administration is planning to propose a new mandatory Medicare payment model, though does not specify what this model would entail.</p> <p>Recently, the CMS Innovation Center stated it will be announcing additional models this year to specifically advance its accountable care strategy. The models are expected to support safety net providers' participation in value-based care models, integrate specialty care, and advance health equity. The Innovation Center is also considering a model that will enable participating states to manage the total cost of care in the state.</p> <p>On the Medicare payment front, CMS will be engaging in its annual Medicare payment update cycle. Details follow.</p> <ul style="list-style-type: none"> • CMS will kick off first with the fiscal year (FY) 2024 Medicare proposed payment updates in April and will then finalize the updates around August. The FY-cycle updates include the Inpatient Prospective Payment System, the Hospice Wage Index, the Inpatient Psychiatric payment system, the Inpatient Rehabilitative Facility payment system, and the Skilled Nursing Facility payment system. • CMS will also propose updates to the calendar year (CY) 2024 Medicare payment updates in June, which it will finalize around November. The CY-cycle updates include the Outpatient Prospective Payment System, the Medicare Physician Fee Schedule, the End Stage Renal Disease payment system, the Home

	Health payment system, and the Durable Medical Equipment, Prosthetics, Orthotics and Supplies fee schedule.
<i>Drug Pricing</i>	
<p>While House Republicans will likely engage in various oversight activities over the Administration’s implementation of the Inflation Reduction Act’s drug pricing provisions, it is unlikely Congress will pass any additional drug-focused legislation this year. However, we do expect Congress to engage in efforts to reform the pharmacy benefit manager (PBM) industry. Potential changes could include additional transparency requirements around copay assistance, rebates, out-of-pocket spending, prohibiting spread pricing or clawbacks, or requiring rebates to be passed on at the point of sale.</p>	<p>The Administration has released details on its implementation plan for the Medicare Drug Price Negotiation Program. Notably, HHS said it will release guidance for the program’s initial price applicability year 2026 and will issue revised guidance in response to stakeholder feedback later this summer. By September 1, HHS says it will publish its list of 10 Part D selected drugs for the initial price applicability year.</p> <p>Pursuant to an Executive Order from last year, HHS is also expected to announce a new drug pricing-focused measure under the Center for Medicare and Medicaid Innovation, which may potentially feature changes to Part B pricing to incentivize greater use of generics and biosimilars.</p>
<i>Health IT & Innovative Technologies</i>	
<p>The 117th Congress featured some notable bipartisan legislation to improve health care technology, which may inform action in the current Congress. The Improving Seniors’ Timely Access to Care Act attained substantial support from both parties though was not ultimately included in the omnibus. The legislation would impose new electronic prior authorization requirements upon Medicare Advantage plans. The recent rulemaking from the Centers for Medicare & Medicaid Services (CMS) may limit interest among lawmakers to advance this legislation in the new Congress. The Access to Prescription Digital Therapeutics Act of 2022 – which also gained bipartisan support in the last Congress – would increase coverage of and access to digital health technologies.</p>	<p>The Administration has previewed several new regulations to improve health care technologies. A sizeable chunk of these pertain to improving interoperability and prior authorization. Two are expected early this year (here and here) while others are slated for later this fall (here and here).</p> <p>In April, the Administration is also planning to issue regulations to establish a new coverage pathway for emerging technologies, which is expected to be informed by a series of listening sessions CMS hosted on the topic last year.</p>

Food and Drug Administration

Several of the Food and Drug Administration (FDA) user fee reauthorization policy riders were included in the omnibus, including reforms to the Accelerated Approval Program and requirements to increase clinical trial diversity. However, a notable exclusion was the [Verifying Accurate Leading-edge IVCT Development \(VALID\) Act](#), which would allow the FDA to regulate laboratory-developed tests. The bill was opposed by academic medical centers for the potential to discourage test innovation, but similar legislation could be reintroduced this year with an academic medical center exemption. We also expect that the [Pioneering Antimicrobial Subscriptions to End Surging Resistance \(PASTEUR\) Act](#) will also be reintroduced.

In May, the FDA plans to issue the final rule that would amend regulations related to direct-to-consumer (DTC) advertisements of prescription drugs to require disclosure of side effects in the major statement in a clear, conspicuous, and neutral manner

The FDA intends on finalizing its regulation aimed at banning tobacco product flavors this August. The first would ban menthol in cigarettes and the second would prohibit characterizing flavors in cigars.

In October, the agency plans on finalizing its nonprescription final rule, which will increase access to over-the-counter medicines that ensure appropriate self-selection by the consumer.

Nutrition

The upcoming Farm Bill reauthorization will create an opportunity for the potential inclusion of several nutrition-focused policies that could serve to address equity concerns. These could include, for example, increasing online purchasing options for the Supplemental Nutrition Assistance Program (SNAP) and allowing SNAP beneficiaries to purchase hot and prepared foods.

Additional details are available [here](#).

The Administration will continue to refine its nutrition assistance programs. In April, the Administration for Children and Families plans to [propose new regulations](#) that would strengthen the Temporary Assistance for Needy Families program, pursuant to President Biden’s Executive Order on advancing racial equity and support for underserved communities. Later in May, the Food and Nutrition Service also plans to improve access to baby formula through [finalized changes](#) to the Special Supplemental Nutrition Program for Women, Infants, and Children. Other upcoming changes include [proposed](#) school nutrition standards based on new dietary guidelines and [final changes](#) to improve child nutrition program integrity. In addition to these efforts, the Administration will continue to implement its national strategy on hunger, nutrition, and health ([details](#)) through various sub-regulatory activities.