

## Year-Ahead Outlook

Congress ended 2022 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 Act (PAHPA);
- The expiration of several provisions included in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities 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 of 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, which 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. Though the upcoming reauthorization of PAHPA offers an opportunity to bolster the U.S. public health system, it will likely be challenging for lawmakers to find viable policy options with bipartisan support in the current legislative environment.

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.



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 The ETS remains in effect until superseded by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





| care or care for dually eligible beneficiaries. A bipartisan group of<br>Senators issued a request for information late last year seeking input<br>on ways to improve care for dual-eligibles, which may spur<br>legislative action.  | Emergency, CMS plans to issue a <u>final rule</u> modifying state<br>requirements for the temporary 6.2 percentage point FMAP increase.<br>Additionally, CMS plans to issue a <u>final rule</u> in November 2023 intended<br>to streamline the Medicaid and CHIP application and enrollment<br>processes. In April 2023, CMS plans to release proposed rules to<br>improve access to Medicaid and CHIP broadly as well as Medicaid<br>managed care (e.g., <u>here</u> and <u>here</u> ). CMS is also expected to issue<br>guidance on how state Medicaid programs can improve health outcomes<br>of justice-involved individuals and support their reentry into the<br>community by using Section 1115 demonstrations to cover certain health<br>services pre-release from incarceration. Several states have already<br>submitted related demonstration requests to CMS that are pending<br>approval.<br>In addition to the <u>annual notice of benefit and payment parameters</u> for<br>2024, CMS plans to pursue rulemaking to strengthen protections under<br>the ACA. In April, the Administration plans to <u>propose changes</u> to the<br>regulation of short-term, limited-duration insurance to ensure this type of<br>coverage does not undermine the ACA. CMS is also expected to issue a<br>proposed rule regarding religious and moral exemptions as they relate to<br>coverage of certain preventive services (e.g., reproductive health care).<br>Lastly, the Administration will issue a slate of rules implementing the No<br>Surprises Act related to <u>independent dispute resolution</u> , provider<br><u>nondiscrimination requirements</u> , <u>advanced explanation of benefits</u> , <u>air<br/>ambulance services</u> .<br>Rules involving ERISA-regulated health plans will be issued jointly by<br>HHS and Labor. |
|---|---|
| Reproductive Health   |   |
| Sweeping activity to strengthen access to reproductive health<br>services is unlikely in the new Congress. House Republicans have<br>already engaged in efforts to cement their position on abortion by<br>passing a <u>resolution</u> and a <u>bill</u> that condemns violence against anti-<br>abortion organizations and affirms the rights of infants that are born<br>following an unsuccessful abortion, respectively. However, it is<br>unlikely any such measures would be successful in the Senate. By | In response to the President's <u>executive order</u> last year on reproductive rights, the Administration will continue to do what it can to ensure individuals can access abortions and build on recent agency actions. For example, the Food and Drug Administration (FDA) recently <u>issued</u> <u>changes</u> that allow certain pharmacies to be certified to dispense mifepristone (i.e., an abortion pill). The Department of Justice also   |

and the second



| 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.  | recently issued a <u>legal opinion</u> allowing the U.S. Postal Service to mail<br>abortion drugs to states that have strict limits.<br>Notably, HHS recently <u>proposed</u> a rule to partially rescind a never-<br>implemented Trump Administration regulation that allowed providers to<br>deny care – including abortions – based on religious or conscience<br>reasons. HHS is also in the process of finalizing regulations to<br>strengthen section 1557 protections, which would prohibit providers from<br>discriminating on the basis of pregnancy or related conditions (including<br>abortion).   |  |
|--|--|--|
|  |  |  |
| Equitable Care   |  |  |
| In a divided Congress, we do not expect substantive legislative<br>activity to advance health equity. However, efforts to reform mental<br>health care, improve care for duals, and other potential legislative<br>efforts could have an impact on health equity.  | 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.   |  |
| Drug Pricing   |  |  |
| While House Republicans will likely engage in various oversight<br>activities over the Administration's implementation of the Inflation<br>Reduction Act's drug pricing provisions, it is unlikely Congress will<br>pass any additional drug-focused legislation this year. However, we<br>do expect Congress to engage in efforts to reform the pharmacy<br>benefit manager (PBM) industry. Potential changes could include<br>additional transparency requirements around copay assistance,<br>rebates, out-of-pocket spending, prohibiting spread pricing or<br>clawbacks, or requiring rebates to be passed on at the point of sale. | The Administration has released <u>details</u> on its implementation plan for<br>the Medicare Drug Price Negotiation Program. Notably, HHS said it will<br>release guidance for the program's initial price applicability year 2026<br>and will issue revised guidance in response to stakeholder feedback<br>later this summer. By September 1, HHS says it will publish its list of 10<br>Part D selected drugs for the initial price applicability year.<br>Pursuant to an <u>Executive Order</u> from last year, HHS is also expected to<br>announce a new drug pricing-focused measure under the Center for<br>Medicare and Medicaid Innovation (CMMI), which may potentially<br>feature changes to Part B pricing to incentivize greater use of generics<br>and biosimilars. |  |
| Health IT & Inno   | ovative Technologies   |  |





| The 117 <sup>th</sup> Congress featured some notable bipartisan legislation to | The Administration has previewed several new regulations to improve  |
|--|--|
| improve health care technology, which may inform action in the                 | health care technologies. A sizeable chunk of these pertain to improving                                     |
| current Congress. The Improving Seniors' Timely Access to Care                 | interoperability and prior authorization (e.g., <u>here</u> , <u>here</u> , <u>here</u> , and <u>here</u> ). |
| Act attained substantial support from both parties though was not              | The Administration is also planning to issue <u>regulations</u> to establish a                               |
| ultimately included in the omnibus. The legislation would impose               | new coverage pathway for emerging technologies, which is expected to   |
| new electronic prior authorization requirements upon Medicare                  | be informed by a series of listening sessions CMS hosted on the topic  |
| Advantage plans. The recent rulemaking from the Centers for                    | last year.   |
| 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.                         |  |

