

Hart Health Strategies Inc.



Policy Briefi

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President's Fiscal Year (FY) 2023 Budget

The White House released President Joe Biden's \$5.8 trillion fiscal year (FY) 2023 budget request last week. The President's budget request is a non-binding document used by congressional appropriators to consider the administration's priorities as they craft government funding legislation for the coming year. The President's budget calls for \$1.598 trillion in discretionary spending, a 5.7% increase over the FY 2022 omnibus spending bill signed into law earlier this year – with \$813 billion for defense-related programs and \$769 billion for domestic spending. The budget increases funding for nearly every federal agency, while also emphasizing deficit reduction - reducing deficit spending by \$1 trillion over the next decade. It includes a minimum 20% tax on households worth more than \$100 million that would target both standard taxable income as well as unrealized capital gains. It also includes a corporate tax rate hike from 21% to 28%. The budget proposes \$81.7 billion in mandatory funding over the next five years for health agencies to prepare for future pandemics.

The <u>U.S. Department of Health and Human Services</u> (HHS) would receive \$127.3 billion in discretionary funding, a nearly 27% increase over FY 2021.

The President requests \$5 billion in discretionary funds for the creation of the Advanced Research Projects Agency for Health (ARPA-H). During a hearing before the House Appropriations Committee on the President's budget request last week, HHS Secretary Xavier Becerra confirmed that ARPA-H would be established within the National Institutes of Health (NIH), though the ARPA-H Director would report directly to the HHS Secretary. This decision has drawn concerns from several lawmakers, including Appropriations Chair Rosa DeLauro (D-Conn.) and **Energy and Commerce** Health Subcommittee Chair

Inside

House Passes Insulin Pricing, Marijuana Legalization Bills2
Lawmakers Near Agreement on \$10 Billion in New COVID Aid2
Finance Committee Releases Bipartisan Report on U.S. Mental Health Care3
April 1 Marks Return of Medicare Sequester
OSHA Proposed Rule on Workplace Reporting3
Upcoming Congressional Hearings and Markups4 Recently Introduced Health Legislation4

Anna Eshoo (D-Calif.), who have argued that tethering ARPA-H to the NIH bureaucracy will not allow the new agency to nimbly achieve the breakthrough research and development it was established to accomplish. The President proposes to grow the budget of the NIH by \$20 billion for a total of \$62 billion in FY2023. However, \$12 billion of those funds are designated for the larger pandemic preparedness effort and \$5 billion for ARPA-H. The Food and Drug Administration (FDA) would receive a total budget of \$8.4 billion, a 34% increase over FY 2022. This includes \$1.6 billion to strengthen the agency's IT and laboratory system as a part of the broader pandemic preparedness portion of the President's budget. The FDA also seeks new authority over the design of post-approval studies conducted by pharmaceutical manufacturers for products approved via the accelerated approval pathway as a part of the budget request, and to revise the FDA's procedures for withdrawing an accelerated approval. The budget would give federal regulators the authority to fine insurers that violate mental health parity law, with \$275 million provided to the Department of Labor to audit health plans for compliance, and states would be provided with \$125 million for mental health parity enforcement. The budget would also allow HHS to apply parity law to all plans and insurers, including Medicare plans. The budget does not detail any of the measures contained in the President's now stalled Build Back Better agenda, but instead includes a deficit-neutral reserve fund as a placeholder for a future agreement between congressional Democrats and the administration on the reconciliation package.

House Passes Insulin Pricing, Marijuana Legalization Bills

The House of Representatives passed the *Affordable Insulin Now Act* (H.R. 6833) last week to cap out-of-pocket costs for insulin by a vote of 232-193. Twelve Republicans joined every House Democrat in support of the measure. The legislation would limit out-of-pocket costs for selected insulin products under private insurance and Medicare to the lesser of \$35 a month or 25% of a plan's negotiated price. The bill's chances remain unclear in the Senate, where Sen. Raphael Warnock (D-Ga.) is working on a slightly broader drug pricing measure containing the insulin cost cap with Sens. Jeanne Shaheen (D-N.H.) and Susan Collins (R-Maine). Shaheen recently stated that an agreement has been reached in principle on the bipartisan proposal, but that details of the bill are not yet finalized.

The House also passed the *Marijuana Opportunity Reinvestment and Expungement (MORE) Act* (H.R. 3617) last week, which would end the federal prohibition of marijuana and eliminate criminal penalties for its distribution or possession. The bill passed largely along party lines in a 220-204 vote, with three Republicans joining all but two Democrats in support of the measure. It remains unclear whether the bill could garner the 60 votes necessary to pass the Senate. Majority Leader Chuck Schumer (D-N.Y.) plans to introduce a separate marijuana legalization proposal later this month.

Lawmakers Near Agreement on \$10 Billion in New COVID Aid

Lawmakers have reached an agreement in principle on an additional \$10 billion in COVID-19 emergency aid that will be fully offset. The Senate could vote on the measure as early as this week, though Democrats are reportedly still working to ensure the proposal includes funds to support global vaccine response. According to Sen. Mitt Romney (R-Utah), who has been negotiating the package on behalf of the GOP, Republicans are still awaiting an analysis of the package from the Congressional Budget Office (CBO). Romney has stated that the bill will be offset in part by the rescission of unspent funds previously appropriated in response to the pandemic. The \$10 billion figure is significantly smaller than the \$22.5 billion initially requested by the White House to continue the administration of vaccines, care for the uninsured, provide global coronavirus aid, and maintain supplies of COVID-19 tests and treatments – increasing the likelihood that Congress will need to return to the issue of COVID funding shortly. Senate Majority Leader Chuck Schumer has already teed up a House-passed bill (H.R. 4373) to serve as a vehicle for the next COVID-19 funding measure. Lawmakers had hoped to send a bill to the President for his signature before departing for a two-week recess at the end of this week.

Finance Committee Releases Bipartisan Report on U.S. Mental Health Care

The Senate Finance Committee released a bipartisan report last week detailing potential solutions to address mental health care access problems in the U.S. The report describes the mental health workforce's issues, including a shortage of providers, an uneven geographic distribution of mental health professionals across the nation, and provider burnout following the drastic increase in requests for care since the start of the coronavirus pandemic. The report states that Americans wait for an average of 11 years between the onset of mental health symptoms and first receiving treatment. Finance Committee leadership is currently working to negotiate a package of mental health related legislation they hope to advance later this year.

In related news, the Centers for Disease Control and Prevention (CDC) has released a <u>survey</u> regarding the toll of the COVID-19 pandemic on the mental health of teenagers. The survey found that more than one in three U.S. high school students characterized their mental health as poor during the pandemic. More than half experienced emotional abuse by a parent or other adult in the home.

April 1 Marks Return of Medicare Sequester

Congress did not act to prevent the return of the Medicare sequester – beginning with a 1% cut to reimbursements – effective April 1. While lawmakers have been under pressure from health care stakeholders to avert the return of the sequester, which had thus far been postponed throughout the COVID-19 pandemic, there was little support on either side of the aisle for further delaying the cuts. The 1% sequester will be effective until June 30, and the full 2% sequester will resume on July 1.

HRSA to Delay PRF Recoupment, Allow More Time for Reporting

The Health Resources and Services Administration (HRSA) recently announced on its website that it will delay its recoupment of money from certain Provider Relief Fund (PRF) recipients who failed to meet the required reporting deadlines and provide a new opportunity to submit financial information and other details to retain the funds. Providers who received \$10,000 or more in COVID-19 relief in a roughly six-month period are required to submit certain financial information and details on how they used the relief funds. The first reporting deadline was November 30, 2021, applied to relief received before June 30, 2020. The second reporting deadline was March 31, 2022, applied to relief funds received between July 1, 2020, and December 31, 2020. Providers have 30 days after the reporting deadline to return unused funds; those who missed the deadline have 30 days after the final notice to return all the relief. HRSA's latest announcement will provide an opportunity for non-compliant providers to complete a report as a result of specific extenuating circumstances. While the specifics of this new process are not currently available, HRSA notes that providers should monitor this webpage for additional information.

OSHA Proposed Rule on Workplace Reporting

The Occupational Safety and Health Administration (OSHA) released a proposed rule last week to update its occupational injury and illness recordkeeping regulation. The current regulation requires certain employers to electronically submit injury and illness information, that they are required to keep, to OSHA. The proposed rule would require certain establishments in high-hazards industries to electronically submit additional information from their Log of Work-Related Injuries and Illnesses and their Injury and Illness Incident Report.

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Upcoming Congressional Hearings and Markups

Senate Health, Education, Labor, and Pensions (HELP) Committee hearing "FDA User Fee Agreements: Advancing Medical Product Regulation and Innovation for the Benefit of Patients;" 10:00 a.m.; April 5

Senate Finance Committee hearing "The President's Fiscal Year 2023 Health and Human Services Budget;" the witness will be The Honorable Xavier Becerra, U.S. Department of Health and Human Services (HHS) Secretary; 10:00 a.m.; April 5

House Natural Resources Subcommittee on Oversight and Investigations hearing "The Opioid Crisis in Tribal Communities;" 10:00 a.m.; April 5

House Energy and Commerce Subcommittee on Health hearing "Communities in Need: Legislation to Support Mental Health and Well-being;" 10:15 a.m.; April 5

House Ways and Means Committee hearing "Proposed Fiscal Year 2023 Budget with Health & Human Services Secretary Becerra;" 2:00 p.m.; April 5

House Education and Labor Committee hearing "Examining the Policies and Priorities of the U.S. Department of Health and Human Services;" 9:00 a.m.; April 6

Senate Armed Services Committee hearing to examine suicide prevention and related behavioral health interventions in the Department of Defense; 10:00 a.m.; April 6

Recently Introduced Health Legislation

S.3937 — A bill to establish a home-based telemental health care demonstration program for purposes of increasing mental health services in rural medically underserved populations and for individuals in farming, fishing, and forestry occupations; Sponsor: Sen. Rounds, Mike [R-SD]; Committees: Senate - Health, Education, Labor, and Pensions

S.3940 — A bill to amend the Public Health Service Act to authorize the Assistant Secretary for Mental Health and Substance Use to award grants, contracts, and cooperative agreements for planning, establishing, or administering programs to prevent and address the misuse of opioids, related drugs, and other drugs commonly used in pain management or injury recovery, as well as the co-use of one or more such drugs with other substances, by students and student athletes, and for other purposes; Sponsor: Sen. Shaheen, Jeanne [D-NH]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.7232 — To provide for improvements in the implementation of the National Suicide Prevention Lifeline, and for other purposes; Sponsor: Rep. Cárdenas, Tony [D-CA-29]; Committees: House - Energy and Commerce

H.R.7233 — To amend title XIX of the Social Security Act to provide for requirements under Medicaid State plans for health screenings and referrals for certain eligible juveniles in public institutions; and to require the Secretary of Health and Human Services to issue clear and specific guidance under the Medicaid and Children's Health Insurance programs to improve the delivery of health care services, including mental health services, in elementary and secondary schools and school-based health centers; Sponsor: Rep. Hudson, Richard [R-NC-8]; Committees: House - Energy and Commerce

H.R.7234 — To amend the Public Health Service Act to reauthorize certain programs with respect to mental health conditions and substance use disorders, and for other purposes; Sponsor: Rep. Spanberger, Abigail Davis [D-VA-7]; Committees: House - Energy and Commerce

- H.R.7235 To amend title XIX of the Public Health Service Act to make certain improvements with respect to block grants for substance use prevention, treatment, and recovery services, and for other purposes; Sponsor: Rep. Tonko, Paul [D-NY-20]; Committees: House Energy and Commerce
- H.R.7236 To amend title XIX of the Social Security Act to expand the availability of mental, emotional, and behavioral health services under the Medicaid program, and for other purposes; Sponsor: Rep. Eshoo, Anna G. [D-CA-18]; Committees: House Energy and Commerce
- H.R.7237 To amend the Public Health Service Act to reauthorize certain mental health, suicide prevention, and crisis care programs, and for other purposes; Sponsor: Rep. Griffith, H. Morgan [R-VA-9]; Committees: House Energy and Commerce
- H.R.7238 To direct the Secretary of Health and Human Services shall revise opioid treatment program admission criteria to eliminate the requirement that patients have been addicted for at least 1 year prior to being admitted for treatment; Sponsor: Rep. Bucshon, Larry [R-IN-8]; Committees: House Energy and Commerce; Judiciary
- H.R.7241 To amend title XIX of the Public Health Service Act to reauthorize the community mental health services block grant program, and for other purposes; Sponsor: Rep. Crenshaw, Dan [R-TX-2]; Committees: House Energy and Commerce
- H.R.7246 To amend the Public Health Service Act to authorize the Assistant Secretary for Mental Health and Substance Use to award grants, contracts, and cooperative agreements for planning, establishing, or administering programs to prevent and address the misuse of opioids, related drugs, and other drugs commonly used in pain management or injury recovery, as well as the co-use of one or more such drugs with other substances, by students and student athletes, and for other purposes; Sponsor: Rep. Gottheimer, Josh [D-NJ-5]; Committees: House Energy and Commerce
- H.R.7248 To amend title V of the Public Health Service Act to reauthorize certain mental health programs for children, and for other purposes; Sponsor: Rep. Joyce, John [R-PA-13]; Committees: House Energy and Commerce
- H.R.7249 To amend the Public Health Service Act to provide education and training on eating disorders for health care providers and communities, and for other purposes; Sponsor: Rep. Matsui, Doris O. [D-CA-6]; Committees: House Energy and Commerce
- H.R.7253 To amend the Federal Food, Drug, and Cosmetic Act to provide for clarification of requirements for the remanufacturing of medical devices, and for other purposes; Sponsor: Rep. Peters, Scott H. [D-CA-52]; Committees: House Energy and Commerce
- H.R.7254 To authorize the Secretary of Health and Human Services to award grants to States and political subdivisions of States to hire, employ, train, and dispatch mental health professionals to respond in lieu of law enforcement officers in emergencies involving one or more persons with a mental illness or an intellectual or developmental disability, and for other purposes; Sponsor: Rep. Porter, Katie [D-CA-45]; Committees: House Energy and Commerce; Judiciary
- H.R.7255 To amend title V of the Public Health Service Act to reauthorize the Garrett Lee Smith Memorial Act, and for other purposes; Sponsor: Rep. McMorris Rodgers, Cathy [R-WA-5]; Committees: House Energy and Commerce
- H.R.7258 To eliminate the individual and employer health coverage mandates under the Patient Protection and Affordable Care Act, to expand beyond that Act the choices in obtaining and financing affordable health insurance coverage, and for other purposes; Sponsor: Rep. Sessions, Pete [R-TX-17]; Committees: House Energy and Commerce; Ways and Means; Education and Labor

H.R.7259 — To amend the Controlled Substances Act to direct the Attorney General to register practitioners to transport controlled substances to States in which the practitioner is not registered under the Act for the purpose of administering the substances (under applicable State law) at locations other than principal places of business or professional practice; Sponsor: Rep. Sessions, Pete [R-TX-17]; Committees: House - Energy and Commerce; Judiciary

S.Res.560 — A resolution recognizing the significance of endometriosis as an unmet chronic disease for women and designating March 2022 as "Endometriosis Awareness Month"; Sponsor: Sen. Duckworth, Tammy [D-IL]; Committee on the Judiciary

S.Res.566 — A resolution recognizing the 100th anniversary of the American College of Surgeons Commission on Cancer and the importance of Commission on Cancer-accredited programs in ensuring comprehensive, high-quality, patient-centered cancer care; Sponsor: Sen. Van Hollen, Chris [D-MD]; Committee on the Judiciary

H.R.7265 — To amend the Public Health Service Act to authorize the Secretary of Health and Human Services to carry out a program of research related to cerebral palsy, and for other purposes; Sponsor: Rep. Cohen, Steve [D-TN-9]; Committee on Energy and Commerce

H.R.7275 — To increase interagency cooperation and coordination and to require policies and procedures to detect and prevent duplicate payments for the same medical services by the Department of Veterans Affairs, Department of Health and Human Services, and Department of Defense, and for other purposes; Sponsor: Rep. Luria, Elaine G. [D-VA-2]; Committee on Veterans' Affairs, and in addition to the Committees on Armed Services, Ways and Means, and Energy and Commerce

H.R.7277 — To improve the methods by which the Secretary of Veterans Affairs identifies health care providers that are not eligible to participate in the Veterans Community Care Program; Sponsor: Rep. Pappas, Chris [D-NH-1]; Committee on Veterans' Affairs

H.R.7279 — To amend the Internal Revenue Code of 1986 to provide for a credit against tax for expenses for translational research regarding neurodegenerative diseases and psychiatric conditions; Sponsor: Rep. Thompson, Mike [D-CA-5]; Committee on Ways and Means

S.Res.569 — A resolution supporting the goals of World Tuberculosis Day to raise awareness about tuberculosis; Sponsor: Sen. Brown, Sherrod [D-OH]; Committees: Senate - Foreign Relations

S.Res.571 — A resolution supporting the goals and ideals of Deep Vein Thrombosis and Pulmonary Embolism Awareness Month; Sponsor: Sen. Grassley, Chuck [R-IA]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.3959 — A bill to amend the Public Health Service Act to provide the Secretary of Health and Human Services with the authority to suspend the right to introduce certain persons or property into the United States in the interest of the public health; Sponsor: Sen. Hagerty, Bill [R-TN]; Committees: Senate - Health, Education, Labor, and Pensions

S.3963 — A bill to protect survivors from brain injury by authorizing the Secretary of Health and Human Services to collect data on the prevalence of brain injuries resulting from domestic and sexual violence; Sponsor: Sen. Cortez Masto, Catherine [D-NV]; Committees: Senate - Health, Education, Labor, and Pensions

S.3964 — A bill to amend title 38, United States Code, to modify the family caregiver program of the Department of Veterans Affairs to include services related to mental health and neurological disorders, and for other purposes; Sponsor: Sen. Moran, Jerry [R-KS]; Committees: Senate - Veterans' Affairs

- S.3968 A bill to improve State, local, and Tribal public health security; Sponsor: Sen. Warren, Elizabeth [D-MA]; Committees: Senate Health, Education, Labor, and Pensions
- H.R.7281 To amend the Occupational Safety and Health Act of 1970 to repeal the Secretary's authority to issue emergency temporary standards, and for other purposes; Sponsor: Rep. Clyde, Andrew S. [R-GA-9]; Committees: House Education and Labor
- H.R.7286 To establish a commission to assess the total cost spent on relief during the COVID-19 pandemic, and for other purposes; Sponsor: Rep. Cawthorn, Madison [R-NC-11]; Committees: House Oversight and Reform
- H.R.7289 To provide for the National Academies to study and report on a Federal research agenda to advance the understanding of PFAS, and for other purposes; Sponsor: Rep. Fletcher, Lizzie [D-TX-7]; Committees: House Science, Space, and Technology
- H.R.7296 To establish the Artificial Intelligence Hygiene Working Group, and for other purposes; Sponsor: Rep. Lawrence, Brenda L. [D-MI-14]; Committees: House Oversight and Reform
- H.R.7299 To require the Secretary of Veterans Affairs to obtain an independent cybersecurity assessment of information systems of the Department of Veterans Affairs, and for other purposes; Sponsor: Rep. Mrvan, Frank J. [D-IN-1]; Committees: House Veterans' Affairs
- H.R.7300 To prohibit the delivery of opioids by means of the dark web, and for other purposes; Sponsor: Rep. Pappas, Chris [D-NH-1]; Committees: House Judiciary; Energy and Commerce; Financial Services
- H.R.7301 To protect survivors from brain injury by authorizing the Secretary of Health and Human Services to collect data on the prevalence of brain injuries resulting from domestic and sexual violence; Sponsor: Rep. Pascrell, Bill, Jr. [D-NJ-9]; Committees: House Energy and Commerce
- S.3972 A bill to improve research and data collection on stillbirths, and for other purposes; Sponsor: Sen. Booker, Cory A. [D-NJ]; Committees: Senate Health, Education, Labor, and Pensions
- S.3974 A bill to prohibit the consideration of patients' race, color, religion, sex, national origin, age, disability, vaccination status, veteran status, or political ideology or speech in determining eligibility for monoclonal antibody doses distributed by the Federal Government; Sponsor: Sen. Cruz, Ted [R-TX]; Committees: Senate Health, Education, Labor, and Pensions
- S.3983 A bill to amend the Federal Food, Drug, and Cosmetic Act to require, for purposes of ensuring cybersecurity, the inclusion in any premarket submission for a cyber device of information to demonstrate a reasonable assurance of safety and effectiveness throughout the lifecycle of the cyber device, and for other purposes; Sponsor: Sen. Cassidy, Bill [R-LA]; Committees: Senate Health, Education, Labor, and Pensions
- S.3984 A bill to amend the Controlled Substances Act to provide a process to lock and suspend domain names used to facilitate the online sale of controlled substances illegally, and for other purposes; Sponsor: Sen. Klobuchar, Amy [D-MN]; Committees: Senate Judiciary
- S.3985 A bill to prohibit the consideration of COVID-19 vaccination status in determining eligibility for organ donation or transplantation, and in providing services to Medicare or Medicaid beneficiaries; Sponsor: Sen. Cruz, Ted [R-TX]; Committees: Senate Health, Education, Labor, and Pensions

H.R.7308 — To direct the Inspector General of the Department of Health and Human Services to investigate and report on the Vaccine Adverse Event Reporting System, and for other purposes; Sponsor: Rep. Greene, Marjorie Taylor [R-GA-14]; Committees: House - Energy and Commerce; Ways and Means

H.R.7315 — To require the Secretary of Veterans Affairs to formally recognize caregivers of veterans, notify veterans and caregivers of clinical determinations relating to eligibility for caregiver programs, and temporarily extend benefits for veterans who are determined ineligible for the family caregiver program, and for other purposes; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Veterans' Affairs

H.R.7316 — To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to furnish hyperbaric oxygen therapy to veterans with traumatic brain injury or post-traumatic stress disorder; Sponsor: Rep. Biggs, Andy [R-AZ-5]; Committees: House - Veterans' Affairs

H.R.7322 — To require coverage for scalp cooling items under group health plans and group and individual health insurance coverage, specified Federal health care programs, and the Federal Employees Health Benefits Program; Sponsor: Rep. DeLauro, Rosa L. [D-CT-3]; Committees: House - Energy and Commerce; Ways and Means; Armed Services; Veterans' Affairs; Oversight and Reform

H.R.7335 — To improve coordination between the Veterans Health Administration and the Veterans Benefits Administration with respect to claims for compensation arising from military sexual trauma, and for other purposes; Sponsor: Rep. Luria, Elaine G. [D-VA-2]; Committees: House - Veterans' Affairs

H.R.7346 — To amend title XVIII of the Social Security Act to provide for coverage and payment of Alpha-1 Antitrypsin Deficiency Disorder treatment under part B of such title, and for other purposes; Sponsor: Rep. Salazar, Maria Elvira [R-FL-27]; Committees: House - Energy and Commerce; Ways and Means

H.R.7353 — To amend title XXVII of the Public Health Service Act, the Employee Retirement Income and Security Act of 1974, and the Internal Revenue Code of 1986 to treat benefits for telehealth services offered under a group health plan or group health insurance coverage as excepted benefits; Sponsor: Rep. Walorski, Jackie [R-IN-2]; Committees: House - Energy and Commerce; Education and Labor; Ways and Means