



## Health Policy Briefing

September 26, 2022

### UFA Reauthorization to be Attached to Stopgap Spending Bill

Congressional health committee leadership have reached a tentative agreement to reauthorize medical product user fees at the Food and Drug Administration for another five years. The reauthorization will be attached to a continuing resolution (CR) to fund the federal government beyond the end of the fiscal year on September 30. While Senate Health, Education, Labor, and Pensions Committee Ranking Member Richard Burr (R-N.C.) has characterized the deal as “practically clean,” Senate Minority Leader Mitch McConnell (R-Ky.) is reportedly seeking to block any policy riders from the bill. Specific reauthorization language has yet to be released. Measures to overhaul the regulation of diagnostics, dietary supplements, and cosmetics will likely be pushed for consideration in an end-of-the-year omnibus appropriations package.

### GOP Unveils “Commitment to America” Agenda

House Majority Leader Kevin McCarthy (R-Calif.) unveiled the Republican Party agenda – dubbed “Commitment to America” – during an event in suburban Pittsburgh last week. Should the GOP regain the majority in Congress this November, McCarthy stated that their focus would be on the economy, crime and safety, and individual and religious freedom. Republicans pledge to provide transparency, choice, and competition in health care. Their health platform includes making health savings accounts easier to use, allowing the creation of association health plans, and promoting domestic manufacturing of medicines. House Democratic leadership criticized the agenda for lacking details.

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## Cures 2.0 Pulled from E&C Markup Consideration

A House committee was scheduled to markup the biomedical innovation bill known as the **Cures 2.0 Act (H.R. 6000)**, but the legislation was pulled from consideration after Republicans indicated that they intended to attach poison pill riders to it, according to Democratic sponsor Diana DeGette (D-Colo.). DeGette stated that she was informed that Energy and Commerce Committee Republicans planned to attach amendments to the bill that would have changed the Democrats' landmark **Inflation Reduction Act**. Cures 2.0 – the follow-up legislation to the **21st Century Cures Act** passed in 2016 – aims to speed the availability of new treatments and technologies and increase access to telehealth services. Cures 2.0 currently has 100 cosponsors, including 13 Republicans. Energy and Commerce Committee Chair Frank Pallone (D-N.J.) has said that he will continue to push for a full House vote on the bill either this or next Congressional session.

## E&C, W&M Mark Up Health Legislation

The House Energy and Commerce Committee advanced five healthcare-related bills last week, including:

- H.R. 3655, the **Vaccine Injury Compensation Modernization Act of 2021**;
- H.R. 5141, the **Maximizing Outcomes through Better Investments in Lifesaving Equipment for (MOBILE) Health Care Act**;
- H.R. 8163, the **Improving Trauma Systems and Emergency Care Act**;
- H.R. 6737, the **Flint Registry Reauthorization Act**; and
- H.R. 5441, the **Prevent All Soring Tactics Act of 2021**.

During the markup, the committee also considered 19 resolutions of inquiry from panel Republicans seeking information from the Biden administration.

The House Ways and Means Committee also held a markup to consider home visiting and mental health legislation. The legislative proposals considered by the committee would strengthen coverage of Medicare outpatient mental health services, allow coverage of marriage and family therapist services and mental health counselor services under Medicare, and provide outreach and reporting on certain behavioral health integration services and opioid use disorder treatment services offered through Medicare. The following bills were passed out of the committee:

- H.R. 8876, **The Jackie Walorski Maternal and Child Home Visiting Reauthorization Act of 2022**;
- Committee Print 117-1. Improvements to Medicare Inpatient and Outpatient Mental Health Services;
- Committee Print 117-2. Improvements to the Medicare Program Related to Physician Services and Education;
- Committee Print 117-3. Requiring Coverage of Forensic Medical Exams with No Cost Sharing
- Committee Print 117-4. Improved Information in Provider Directories, Plan Definitions, and Crisis Services for Private Insurance Plans; and
- Committee Print 117-5. Improved Information for Network Coverage and Plan Documents in Private Insurance Plans.

## Finance Committee Releases Third Mental Health Discussion Draft

The Senate Finance Committee released its third [discussion draft](#) of legislation to address the nation's mental health care system last week. The bipartisan package includes [provisions](#) to support 400 new Medicare-funded residency slots per year to train psychiatrists, provide Medicare Part B coverage for family and marriage therapists and mental health counselors, and expand social worker services. The bill would also expand Medicare's Health Professional Shortage Area (HPSA) Physician Bonus Program and increase the number of mental health care providers in the Medicaid program. The Committee has previously released related discussion drafts on youth mental health and to address the role of telehealth in mental health care.

## COVID-19 Panel Releases Report on Nursing Home Neglect

The Select Subcommittee on the Coronavirus Crisis [released](#) a report last week detailing alleged neglect by five for-profit nursing home chains during the COVID-19 pandemic. According to the report, companies were short-staffed, failed to provide proper personal protective equipment, and encouraged employees to continue working with COVID-19 symptoms or confirmed cases of COVID-19. The report argues that these problems were exacerbated by opaque ownership structures that allowed the companies to avoid accountability. The panel's investigation examined 850 facilities that serve more than 80,000 residents across the country.

## Senate Confirms New OSTP Director

The Senate confirmed Arati Prabhakar, PhD as the next director of the White House Office of Science and Technology Policy (OSTP) in a 56-40 vote. Prabhakar will be the first woman, immigrant, and person of color to lead the White House's science office. She is an engineer and the former director of the Defense Advanced Research Projects Agency (DARPA). With her confirmation, Prabhakar also becomes Chief Advisor to the President for Science and Technology -- a cabinet-level position.

## NIH Dedicates New Alzheimer's Research Building to Retiring Sen. Roy Blunt

National Institutes of Health (NIH) Director Lawrence Tabak dedicated the new Roy Blunt Center for Alzheimer's Disease and Related Dementias, which is located on the main NIH campus in Bethesda, Md., last week. The building will house the NIH Intramural Research Program's Center for Alzheimer's and Related Dementias. The facility is named in honor of Senator Blunt (R-Mo.), who will be retiring from Congress when his current term ends, in recognition of his leadership and commitment to public health, research, and the NIH.

## FDA Releases Guidance to Increase Access to Naloxone

The Food and Drug Administration (FDA) issued an immediately-in-effect guidance last week regarding the distribution of approved naloxone products. ***Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act (DSCSA) for the Distribution of FDA-Approved Naloxone Products During the Opioid Public Health Emergency*** clarifies that the agency will not enforce certain ***Drug Supply Chain Security Act*** requirements, such as federal product tracing and verification requirements, for harm reduction programs distributing FDA-approved naloxone to underserved communities while an opioid public health emergency (PHE) declaration is in place. Wholesale distributor licensing requirements will also not apply to harm-reduction suppliers during the PHE. The guidance is intended to address obstacles to naloxone access but does not change the prescription-only status of naloxone products. It is a part of the agency's work on the FDA Overdose Prevention Framework to address the opioid PHE.

## IRS Releases Guidance on Improperly Forgiven PPP Loans

The Internal Revenue Service (IRS) has issued guidance regarding improper forgiveness of Paycheck Protection Program (PPP) loans. The guidance confirms that if a taxpayer's loan has been forgiven based upon misrepresentations or omissions, the taxpayer is not eligible to exclude the forgiveness from their income on their taxes. Under the terms of the PPP loan program, lenders can forgive the full amount of the loan if the recipient was eligible to receive the PPP loan, the loan had been used to pay eligible expenses, and the loan recipient applied for loan forgiveness.

## Upcoming Congressional Hearings and Markups

House Committee on Veterans' Affairs hearing "Veteran Suicide Prevention: Capitalizing on What Works and Increasing Innovative Approaches;" 10:00 a.m.; September 29

House Committee on Oversight and Reform hearing "Examining the Harm to Patients from Abortion Restrictions and the Threat of a National Abortion Ban;" 10:00 a.m.; September 29

House Committee on Science, Space, and Technology hearing "Trustworthy AI: Managing the Risks of Artificial Intelligence;" 10:30 a.m.; September 29

## Recently Introduced Health Legislation

S.Res.771 — A resolution supporting the designation of September 19, 2022, as "National Stillbirth Prevention Day", recognizing tens of thousands of American families that have endured a stillbirth, and seizing the opportunity to keep other families from experiencing the same tragedy; Sponsor: Merkley, Jeff [Sen.-D-OR]; Committees: Senate - Health, Education, Labor, and Pensions

S.Res.772 — A resolution recognizing the seriousness of myotonic dystrophy and expressing support for the designation of September 15, 2022, as "International Myotonic Dystrophy Awareness Day"; Sponsor: Kaine, Tim [Sen.-D-VA]; Committees: Senate - Health, Education, Labor, and Pensions

H.Res.1363 — Supporting the designation of September 19, 2022, as "National Stillbirth Prevention Day", recognizing tens of thousands of American families that have endured a stillbirth, and seizing the opportunity to keep other families from experiencing the same tragedy; Sponsor: Adams, Alma S. [Rep.-D-NC-12]; Committees: House - Energy and Commerce

H.Res.1370 — Supporting the goals and ideals of National HIV/AIDS and Aging Awareness Day; Sponsor: Lee, Barbara [Rep.-D-CA-13]; Committees: House - Energy and Commerce

H.R.8876 — ***The Jackie Walorski Maternal and Child Home Visiting Reauthorization Act of 2022***; Sponsor: Davis, Danny K. [Rep.-D-IL-7]; Committees: House - Ways and Means; Energy and Commerce

H.R.8877 — To direct the Secretary of Health and Human Services to evaluate the extent to which the substitution of interchangeable biological products may be impeded by differences between the system for determining a biological product to be interchangeable and the system for assigning therapeutic equivalence ratings to drugs, and for other purposes; Sponsor: Miller-Meeks, Mariannette [Rep.-R-IA-2]; Committees: House - Energy and Commerce

H.R.8878 — To amend title XVIII of the Social Security Act to ensure adequate coverage of outpatient mental health services under the Medicare program; Sponsor: Chu, Judy [Rep.-D-CA-27]; Committees: House - Energy and Commerce; Ways and Means

H.R.8879 — To amend title XVIII of the Social Security Act to provide for improvements to the Medicare prospective payment system for psychiatric hospitals and psychiatric units; Sponsor: Evans, Dwight [Rep.-D-PA-3]; Committees: House - Ways and Means

H.R.8881 — To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to require group health plans and health insurance issuers offering group or individual health insurance coverage to disclose the percentage of in-network participation for certain provider types, and for other purposes; Sponsor: Horsford, Steven [Rep.-D-NV-4]; Committees: House - Energy and Commerce; Ways and Means; Education and Labor

H.R.8884 — To direct the Secretary of Health and Human Services to provide outreach and reporting on opioid use disorder treatment services furnished by opioid treatment programs under the Medicare program; Sponsor: Kelly, Mike [Rep.-R-PA-16]; Committees: House - Energy and Commerce; Ways and Means

H.R.8885 — To amend the Public Health Service Act, Internal Revenue Code of 1986, and Employee Retirement Income Security Act of 1974 to provide for provider directory improvements to enhance enrollee, participant, and beneficiary access to care; Sponsor: Kildee, Daniel T. [Rep.-D-MI-5]; Committees: House - Energy and Commerce; Ways and Means; Education and Labor

H.R.8886 — To amend the Public Health Service Act, Internal Revenue Code of 1986, and Employee Retirement Income Security Act of 1974 to ensure mental health and substance use disorder benefits are defined pursuant to external benchmarks based on nationally recognized standards; Sponsor: Moore, Gwen [Rep.-D-WI-4]; Committees: House - Energy and Commerce; Education and Labor; Ways and Means

H.R.8887 — To direct the National Institute for Occupational Safety and Health to establish an occupational research program on mental health; Sponsor: Mrvan, Frank J. [Rep.-D-IN-1]; Committees: House - Education and Labor

H.R.8889 — To provide for improved access to group health plan and health insurance coverage summary of benefits and coverage explanation, require a joint report by the Secretaries of Health and Human Services, Treasury, and Labor relating to summaries of benefits and coverage, and for other purposes; Sponsor: Plaskett, Stacey E. [Del.-D-VI-At Large]; Committees: House - Energy and Commerce; Ways and Means; Education and Labor

H.R.8890 — To amend title XVIII of the Social Security Act to establish exceptions for certain physician wellness programs, and for other purposes; Sponsor: Ruiz, Raul [Rep.-D-CA-36]; Committees: House - Energy and Commerce; Ways and Means

H.R.8891 — To amend the Public Health Service Act, the Employee Retirement Income Security Act of 1974, and the Internal Revenue Code of 1986 to require group health plans and health insurance issuers offering group or individual health insurance coverage to provide coverage for forensic medical exams with no cost sharing, and for other purposes; Sponsor: Sánchez, Linda T. [Rep.-D-CA-38]; Committees: House - Energy and Commerce; Education and Labor; Ways and Means

H.R.8892 — To direct the Secretary of Health and Human Services to conduct a public outreach campaign to inform individuals covered under a group health plan or group or individual health insurance coverage of Federal requirements relating to mental health and substance use disorder crisis services, and for other purposes; Sponsor: Sewell, Terri A. [Rep.-D-AL-7]; Committees: House - Energy and Commerce; Ways and Means; Education and Labor

S.Res.776 — A resolution designating September 2022 as “National Prostate Cancer Awareness Month;” Sponsor: Menendez, Robert [Sen.-D-NJ]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Voice Vote.

S.Res.781 — A resolution recognizing the seriousness of polycystic ovary syndrome (PCOS) and expressing support for the designation of September 2022 as “PCOS Awareness Month;” Sponsor: Warren, Elizabeth [Sen.-D-MA]; Submitted in the Senate, considered, and agreed to without amendment and with a preamble by Unanimous Consent.

S.4899 — A bill to amend title XVIII of the Social Security Act to Remedy election revocations relating to administration of COVID-19 vaccines; Sponsor: Portman, Rob [Sen.-R-OH]; Introduced in the Senate, read twice, considered, read the third time, and passed without amendment by Voice Vote.

H.Res.1373 — Honoring the life of Dr. Paul Farmer by recognizing the duty of the Federal Government to adopt a 21st-century global health solidarity strategy and take actions to address past and ongoing harms that undermine the health



and well-being of people around the world; Sponsor: Schakowsky, Janice D. [Rep.-D-IL-9]; Committees: House - Foreign Affairs; Judiciary

H.Con.Res.107 — Designating the week of September 18 through September 24, 2022, as “National Fall Prevention Awareness Week” to raise awareness about, and encourage the prevention of, falls among older adults; Sponsor: Frankel, Lois [Rep.-D-FL-21]; Committees: House - Energy and Commerce

H.R.8908 — To amend title XI of the Social Security Act to require the Inspector General of the Department of Health and Human Services to review a safe harbor under the anti-kickback statute for certain contingency management interventions, and for other purposes; Sponsor: Estes, Ron [Rep.-R-KS-4]; Committees: House - Energy and Commerce; Ways and Means

H.R.8910 — To direct the Secretary of Health and Human Services to provide outreach and reporting on certain behavioral health integration services furnished under the Medicare program; Sponsor: Smith, Jason [Rep.-R-MO-8]; Committees: House - Ways and Means; Energy and Commerce

H.R.8914 — To authorize the Secretary of Health and Human Services and the Secretary of Education to make awards to increase or improve access to comprehensive mental and behavioral health services for individuals exposed to violent encounters involving law enforcement personnel, and for other purposes; Sponsor: Bush, Cori [Rep.-D-MO-1]; Committees: House - Energy and Commerce; Education and Labor; Judiciary

H.R.8917 — To amend the Controlled Substances Act with respect to the registration of opioid treatment programs to increase stakeholder input from relevant communities and to ensure such programs are treating patients in need, and for other purposes; Sponsor: Espaillat, Adriano [Rep.-D-NY-13]; Committees: House - Energy and Commerce; Judiciary

S.4905 — A bill to amend the Employee Retirement Income Security Act of 1974, title XXVII of the Public Health Service Act, and the Internal Revenue Code of 1986 to require group health plans and health insurance issuers offering group or individual health insurance coverage to provide for 3 primary care visits and 3 behavioral health care visits without application of any cost-sharing requirement; Sponsor: King, Angus S., Jr. [Sen.-I-ME]; Committees: Senate – Finance

S.4906 — A bill to amend the Public Health Service Act to reauthorize the National Neurological Conditions Surveillance System, and for other purposes; Sponsor: Murphy, Christopher [Sen.-D-CT]; Committees: Senate - Health, Education, Labor, and Pensions

S.4915 — A bill to amend the Indian Health Care Improvement Act to improve the recruitment and retention of employees in the Indian Health Service, restore accountability in the Indian Health Service, improve health services, and for other purposes; Sponsor: Barrasso, John [Sen.-R-WY]; Committees: Senate - Indian Affairs

H.Res.1379 — Of inquiry requesting the President and directing the Secretary of Veterans Affairs to transmit, respectively, certain documents to the House of Representatives relating to the wait times for veterans to receive primary care, mental health care, and specialty care appointments at medical centers of the Department of Veterans Affairs; Sponsor: Gosar, Paul A. [Rep.-R-AZ-4]; Committees: House - Veterans’ Affairs

H.R.8931 — To amend the Controlled Substances Act to require the Attorney General to remove a drug from scheduling within 180 days of a certain date pursuant to the recommendation of the Secretary of Health and Human Services, and for other purposes; Sponsor: Carter, Earl L. “Buddy” [Rep.-R-GA-1]; Committees: House - Energy and Commerce; Judiciary

H.R.8937 — To amend the Indian Health Care Improvement Act to improve the recruitment and retention of employees in the Indian Health Service, restore accountability in the Indian Health Service, improve health services, and for other purposes; Sponsor: Johnson, Dusty [Rep.-R-SD-At Large]; Committees: House - Natural Resources; Energy and Commerce; Ways and Means; Oversight and Reform

S.Res.792 — A resolution expressing support for the designation of November 2022 as “National Alpha-1 Antitrypsin Deficiency Awareness Month”; Sponsor: Scott, Rick [Sen.-R-FL]; Committees: Senate - Health, Education, Labor, and Pensions

S.J.Res.63 — A joint resolution relating to a national emergency declared by the President on March 13, 2020; Sponsor: Marshall, Roger [Sen.-R-KS]; Committees: Senate – Finance

S.4917 — A bill to amend title V of the Public Health Service Act to reauthorize the Minority Fellowship Program; Sponsor: Menendez, Robert [Sen.-D-NJ]; Committees: Senate - Health, Education, Labor, and Pensions

S.4918 — A bill to amend the Federal Food, Drug, and Cosmetic Act to prohibit the use of patents, trade secrets, or other intellectual property to inhibit competition; Sponsor: Hassan, Margaret Wood [Sen.-D-NH]; Committees: Senate - Health, Education, Labor, and Pensions

S.4929 — A bill to amend the Public Health Service Act to ensure the consensual donation and respectful disposition of human bodies and human body parts donated or transferred for education, research, or the advancement of medical, dental, or mortuary science and not for use in human transplantation, and for other purposes; Sponsor: Murphy, Christopher [Sen.-D-CT]; Committees: Senate - Health, Education, Labor, and Pensions

H.Res.1384 — Expressing support for the designation of September 2022 as “National Kinship Care Month”; Sponsor: Bass, Karen [Rep.-D-CA-37]; Committees: House - Ways and Means

H.Res.1390 — Expressing support for the protection of Medicare part D’s six protected classes; Sponsor: Napolitano, Grace F. [Rep.-D-CA-32]; Committees: House - Energy and Commerce; Ways and Means

H.Res.1391 — Expressing support of the designation of September 2022 as Peripheral Artery Disease Awareness Month; Sponsor: Payne, Donald M., Jr. [Rep.-D-NJ-10]; Committees: House - Oversight and Reform

H.R.8964 — To require the Secretary of Health and Human Services to issue to Federal agencies guidelines for developing procedures and requirements relating to certain primary care Federal health professionals completing continuing medical education on nutrition and to require Federal agencies to submit annual reports relating to such guidelines, and for other purposes; Sponsor: Grijalva, Raúl M. [Rep.-D-AZ-3]; Committees: House - Energy and Commerce

H.R.8968 — To allow States and local educational agencies to use unspent COVID-19 elementary and secondary school emergency relief funds to purchase life-saving opioid antagonists and to provide related training and education to students and teachers; Sponsor: Lamborn, Doug [Rep.-R-CO-5]; Committees: House - Education and Labor

H.R.8976 — To preempt State restrictions on dispensing mifepristone or misoprostol, and for other purposes; Sponsor: Ryan, Patrick [Rep.-D-NY-19]; Committees: House - Energy and Commerce

H.R.8979 — To direct the Secretary of Health and Human Services to award grants for the purpose of establishing, operating, or expanding one-stop crisis facilities, and for other purposes; Sponsor: Smith, Adam [Rep.-D-WA-9]; Committees: House - Energy and Commerce; Financial Services; Judiciary