



Health Policy Briefing

July 3, 2023

Debate on Drug Shortages Continues Amidst PAHPA Reauthorization

The House Energy and Commerce Subcommittee on Health plans to move forward with a markup of legislation to reauthorize the **Pandemic and All-Hazards Preparedness Act** (PAHPA) on July 13 despite an unresolved dispute over the exclusion of provisions to address the nation’s ongoing drug shortages in the must-pass package. On Friday, Rep. Richard Hudson (R-N.C.), a senior member of the House Energy and Commerce Committee who had taken the lead on soliciting stakeholder comments in preparation for the PAHPA reauthorization, introduced three separate bills (H.R. 4419, H.R. 4420, and H.R. 4421) which seek to reauthorize PAHPA-related programs. Democrats on the panel continue to push for the inclusion of drug shortage measures as a part of the reauthorization bill. Ranking Member Frank Pallone (D-N.J.) supports giving the Food and Drug Administration (FDA) new authorities to combat the shortages, arguing in a statement last week that the “initial PAHPA included a provision requiring FDA to prepare for shortage issues that might arise, and all previous reauthorizations have included FDA-related policy.” Republicans support a narrower reauthorization package, saying that it will ease the chances of passing a reauthorization bill before the current all-hazards and public health security programs expire on September 30. Committee Chair Cathy McMorris Rodgers (R-Wash.) is requesting information from stakeholders on current drug shortages as a separate matter, while Democrats are seeking assurance that any drug shortages bill be considered in must-pass legislation if it is not included in PAHPA reauthorization. Subcommittee Republicans are expected to attach a measure to reauthorize and expand the **SUPPORT Act**, passed in 2018 to combat the opioid crisis, as a part of the PAHPA reauthorization bill. According to Politico, lawmakers hope to then consider the reauthorization package before the full committee on either July 19 or July 27.

Inside

- PEPFAR Reauthorization Complicated by Abortion Dispute.....2
- SCOTUS Issues Ruling Reversing Affirmative Action.....2
- CBO Releases Score of Telehealth Expansion Act.....2
- CMS Releases Final Drug Price Negotiation Guidance.....2
- ARPA-H Office Director Discusses Health Science Futures Work.....3
- HHS Releases Smoking Cessation Framework.....3
- Upcoming Congressional Hearings and Markups.....3
- Recently Introduced Health Legislation.....4

PEPFAR Reauthorization Complicated by Abortion Dispute

The issue of abortion is complicating congressional efforts to reauthorize the President's Emergency Plan for AIDS Relief (PEPFAR). The program, created in 2003 under the George W. Bush administration, is credited with saving more than 25 million lives through its support of antiretroviral treatments and efforts to prevent HIV infections and strengthen health care systems across the globe. PEPFAR has historically enjoyed bipartisan support on Capitol Hill, but Democrats and Republicans are currently at odds about federal funding for HIV/AIDS prevention groups that also support access to abortion. Chair of the House Foreign Affairs Subcommittee on Global Health, Global Human Rights, and International Organizations Chris Smith (R-N.J.), who led the last PEPFAR reauthorization in 2018, has stated that he will not write another update for PEPFAR programs unless it includes a prohibition on funding for organizations that back abortion services. Democrats have characterized the inclusion of such a provision as a poison pill and argue that there is no evidence that PEPFAR funding has gone to providing or promoting abortion.

SCOTUS Issues Ruling Reversing Affirmative Action

The Supreme Court issued a decision last week to effectively end the use of affirmative action in the college admissions process. Justices ruled that these programs violate the Constitution's equal protection clause, which bars racial discrimination by government entities. Justices Clarence Thomas, Samuel Alito, Neil Gorsuch, Brett Kavanaugh, and Amy Coney Barrett joined the majority opinion written by Chief Justice John Roberts. In response to the historic ruling, U.S. Department of Health and Human Services Secretary Xavier Becerra issued a statement highlighting the impact of the court's decision on the health care workforce. Becerra argues that people of color have been historically excluded from attending medical school, noting that there is still a "significant deficit" in the number of Black and Latino doctors and medical students. "We need more health workers, especially those who look like and share the experiences of the people they serve," Becerra stated. "This ruling will make it even more difficult for the nation's colleges and universities to help create future health experts and workers that reflect the diversity of our great nation. The health and wellbeing of Americans will suffer as a result."

CBO Releases Score of Telehealth Expansion Act

The Congressional Budget Office [estimates](#) that the *Telehealth Expansion Act* (S. 1001/H.R. 1843) has a 10-year price tag of \$5.05 billion, driven by lost revenue from income and payroll taxes associated with increased contributions to Health Savings Accounts. The bill would permanently allow high-deductible health plans to offer telehealth before enrollees hit their deductible. Plans are currently only able to do so through the end of 2024 under a COVID-era statute. While the legislation, which was advanced by the House Ways and Means Committee earlier this year, has some bipartisan support, many Democrats have argued against strengthening high deductible health plans and undermining Affordable Care Act patient protections. Democrats have also raised concerns about the bill's potential cost.

CMS Releases Final Drug Price Negotiation Guidance

The Centers for Medicare and Medicaid Services (CMS) released its revised [guidance](#) on Friday detailing the rules of the road for implementation of the *Inflation Reduction Act's* "Medicare Drug Price Negotiation Program." The final guidance relaxes the proposed requirement that pharmaceutical manufacturers not disclose information about price negotiations. It also removes the confidentiality policy's data destruction requirements. These changes will result in the government no longer considering such materials as confidential.

ARPA-H Office Director Discusses Health Science Futures Work

The Advanced Research Projects Agency for Health's (ARPA-H) Health Science Futures Director Amy Jenkins previewed her office's work in an interview with Politico last week. In describing the foundational breakthroughs the Health Science Futures Office aims to accomplish, Jenkins stressed that the work of ARPA-H will be disease agnostic and will focus on developing, scaling, and applying different types of solutions to any disease state. She also discussed ARPA's goal of de-risking innovation through the exploration of multiple approaches to a problem. Jenkins anticipates that ARPA-H will eventually have around 80 program managers that issue frequent research solicitations – once every year and a half – with 20 or more solicitations expected in the next calendar year. ARPA-H is currently soliciting research proposals for its first program, Novel Innovations for Tissue Regeneration in Osteoarthritis. Proposals are due on July 28, 2023.

HHS Releases Smoking Cessation Framework

The U.S. Department of Health and Human Services (HHS) [released](#) a draft framework last week to support and accelerate smoking cessation efforts. The framework is intended to serve as a roadmap for strengthening collaboration both amongst federal agencies and with nonfederal stakeholders. HHS highlights the framework as a part of the Biden administration's Cancer Moonshot, which aims to reduce cancer mortality by 50% within 25 years. Smoking is the largest single driver of cancer mortality, causing approximately 30% of all cancer deaths. The draft framework is organized around six goals:

- Eliminate smoking-related and cessation-related disparities;
- Increase awareness and knowledge of smoking and cessation;
- Strengthen and sustain cessation services and supports;
- Increase access to and coverage of comprehensive, evidence-based cessation treatment;
- Expand public health surveillance of smoking and cessation behaviors and strengthen performance measurement and evaluation; and
- Promote ongoing and innovative research to support and accelerate smoking cessation.

HHS is seeking public input on the framework by July 30.

Upcoming Congressional Hearings and Markups

Senate HELP Subcommittee on Primary Health & Retirement Security hearing “Superbugs: The Impact of Antimicrobial Resistance on Modern Medicine;” 10:00 a.m.; July 11

House Oversight and Accountability Select Subcommittee on the Coronavirus Pandemic hearing “Investigating the Proximal Origin of a Cover Up;” 10:00 a.m.; July 11

Senate Appropriations Committee hearing “Accelerating Breakthroughs: How the Special Diabetes Program Is Creating Hope for those Living with Type 1 Diabetes;” 10:00 a.m.; July 11

House Small Business Subcommittee on Oversight, Investigations, and Regulations hearing “Burdensome Red Tape: Overregulation in Health Care and the Impact on Small Businesses;” 10:00 a.m.; July 19

H.Res.550 — Expressing the sense of the House of Representatives regarding the Centers for Medicare & Medicaid Services developing a mobility metric to guide providers in preventing mobility loss among hospitalized older adults. Sponsor: Houchin, Erin [Rep.-R-IN-9]; Committees: House - Energy and Commerce

H.Res.555 — Recognizing the importance of intersectionality for abortion access. Sponsor: Watson Coleman, Bonnie [Rep.-D-NJ-12]; Committees: House - Energy and Commerce

H.R.4315 — To amend title XVIII of the Social Security Act to protect beneficiaries with limb loss and other orthopedic conditions by providing access to appropriate, safe, effective, patient-centered orthotic and prosthetic care; to reduce fraud, waste, and abuse with respect to orthotics and prosthetics; and for other purposes. Sponsor: Thompson, Glenn [Rep.-R-PA-15]; Committees: House - Energy and Commerce; Ways and Means

H.R.4324 — To amend the Federal Trade Commission Act to provide the Commission with notice and comment rulemaking authority respecting unfair or deceptive acts or practices and to provide for civil penalties for violations of such Act respecting unfair or deceptive acts or practices, and for other purposes. Sponsor: Castor, Kathy [Rep.-D-FL-14]; Committees: House - Energy and Commerce

H.R.4328 — To provide for establishment of the National Task Force on the Nursing Shortage. Sponsor: Costa, Jim [Rep.-D-CA-21]; Committees: House - Energy and Commerce

H.R.4329 — To provide enhanced funding for family planning services. Sponsor: Davids, Sharice [Rep.-D-KS-3]; Committees: House - Energy and Commerce

H.R.4330 — To amend title 18, United States Code, to require serial numbers to be engraved on ammunition, and for other purposes. Sponsor: Davis, Danny K. [Rep.-D-IL-7]; Committees: House - Judiciary

H.R.4331 — To amend title XIX of the Social Security Act to increase Federal Medicaid funding for States that provide intensive community-based services for adults with serious mental illness, and for other purposes. Sponsor: Goldman, Daniel S. [Rep.-D-NY-10]; Committees: House - Energy and Commerce

H.R.4334 — To amend chapter 171 of title 28, United States Code, to allow suit against the United States for injuries and deaths of members of the Armed Forces caused by improper medical care, and for other purposes. Sponsor: Issa, Darrell E. [Rep.-R-CA-48]; Committees: House - Judiciary

H.R.4339 — To amend title XIX of the Social Security Act to ensure enhanced Federal funding made available to States under the Medicaid program is equitably distributed to political subdivisions. Sponsor: Lawler, Michael [Rep.-R-NY-17]; Committees: House - Energy and Commerce

H.R.4343 — To amend the National Organ Transplant Act to clarify the definition of valuable consideration, to clarify that pilot programs that honor and promote organ donation do not violate that Act, and for other purposes. Sponsor: Matsui, Doris O. [Rep.-D-CA-7]; Committees: House - Energy and Commerce

H.R.4345 — To protect the dignity of fetal remains, and for other purposes. Sponsor: Miller, Mary E. [Rep.-R-IL-15]; Committees: House - Energy and Commerce

H.R.4347 — To amend title 18, United States Code, to provide increased penalties for mass killings involving machineguns or certain semiautomatic weapons, and for other purposes. Sponsor: Moulton, Seth [Rep.-D-MA-6]; Committees: House - Judiciary

H.R.4358 — To provide lawful permanent resident status and authorized dual intent for certain doctoral degree holders. Sponsor: Thanedar, Shri [Rep.-D-MI-13]; Committees: House – Judiciary

H.R.4363 — To address the health of cancer survivors and unmet needs that survivors face through the entire continuum of care from diagnosis through active treatment and posttreatment, in order to improve survivorship, treatment, transition to recovery and beyond, quality of life and palliative care, and long-term health outcomes, including by developing a minimum standard of care for cancer survivorship, irrespective of the type of cancer, a survivor's background, or forthcoming survivorship needs, and for other purposes. Sponsor: Wasserman Schultz, Debbie [Rep.-D-FL-25]; Committees: House - Energy and Commerce; Ways and Means; Education and the Workforce

H.Res.561 — Expressing opposition to the use of State power against people in the United States seeking essential health care, including criminalization of the full range of sexual and reproductive health care such as abortion, gender-affirming care, and contraceptive care, and disapproving of State punishment of people for their pregnancy outcomes; Sponsor: Williams, Nikema [Rep.-D-GA-5]; Committees: House - Energy and Commerce; Judiciary

H.R.4368 — Making appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies programs for the fiscal year ending September 30, 2024, and for other purposes; Sponsor: Harris, Andy [Rep.-R-MD-1]; Committees: House – Appropriations

H.R.4371 — To direct the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, and in consultation with the Secretary of Education and the President's Council on Fitness, Sports, and Nutrition, to conduct a study on the causes of deaths and catastrophic injuries related to high school and collegiate sports and formulate recommendations to prevent such deaths and catastrophic injuries, and for other purposes; Sponsor: Carter, Troy [Rep.-D-LA-2]; Committees: House - Energy and Commerce; Education and the Workforce

H.R.4375 — To amend title XVIII of the Social Security Act to provide coverage of medically necessary home resiliency services under Medicare; Sponsor: Frost, Maxwell [Rep.-D-FL-10]; Committees: House - Energy and Commerce; Ways and Means

H.R.4381 — To amend the Public Health Service Act with respect to the determination, termination, and renewal of public health emergencies, and for other purposes; Sponsor: Murphy, Gregory [Rep.-R-NC-3]; Committees: House - Energy and Commerce; Rules

H.R.4382 — To require the Secretary of Agriculture to conduct a study on the accessibility of addiction and mental health care providers and services for farmers and ranchers who have been impacted by severe and persistent drought, extreme weather events, instability in the commodities market, misinformation targeting consumers, and for other purposes; Sponsor: Neguse, Joe [Rep.-D-CO-2]; Committees: House – Agriculture

H.R.4383 — To amend title 10, United States Code, to waive cost-sharing under the TRICARE program for three mental health outpatient visits per year for certain beneficiaries, and for other purposes; Sponsor: Neguse, Joe [Rep.-D-CO-2]; Committees: House - Armed Services

H.R.4391 — To amend the Internal Revenue Code of 1986 to treat certain assisted reproduction expenses as medical expenses of the taxpayer; Sponsor: Schiff, Adam B. [Rep.-D-CA-30]; Committees: House - Ways and Means

H.R.4392 — To increase access to pre-exposure prophylaxis to reduce the transmission of HIV; Sponsor: Schiff, Adam B. [Rep.-D-CA-30]; Committees: House - Energy and Commerce; Oversight and Accountability; Ways and Means; Veterans' Affairs; Armed Services; Natural Resources; Financial Services; Education and the Workforce