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I G H **Policy Bri** ealth

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Congressional Negotiations for End of Year Package Wrapping Up

ongress continues to negotiate policies to be included in an end of year package with a short-term continuing resolution. To avoid a government shutdown, Congress must act no later than December 20. Congress expects to release language soon. A number of policies are still under discussion, including prior authorization reforms for Medicare Advantage plans. Key health provisions that are reported to be in the end of year package include:

2-year extension of telehealth flexibilities;

The House of L Representatives

passed the fiscal year (FY) 2025 National Defense Authorization Act (NDAA) last week. The \$884 billion

- 2.5% adjustment to the Medicare Physician Fee Schedule conversion factor for 2025;
- 2-year reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA);
- 5-year reauthorization of the SUPPORT Act programs for opioid response;
- Pharmacy Benefit Manager (PBM) reforms, including delinking and prohibiting spread pricing; and

Medicare coverage of Multi-Cancer Early Diagnosis (MCED) screening tests. Once agreement is reached, the language will be made public and the House plans to vote first. Currently, the House is scheduled to be in session until Thursday, December 19. After House passage, the package will require approval by the Senate before it can be sent to the president to be signed into law.

House Passes FY 2025 NDAA

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bill also requires the Director of National Intelligence to develop a plan to secure those U.S. biotechnology supply chains deemed critical to national security. The Senate is expected to vote on the must-pass legislation before the end of the week.

Senate Passes OAA Reauthorization, HEARTS Act

The Senate passed several health-related bills last week, including the **Older Americans Act Reauthorization Act** (S. 4776). The bill, which was unanimously approved by the chamber, would reauthorize the Older Americans Act for five years, increasing funding from \$2.3 billion to \$2.76 billion in fiscal year 2025. The **HEARTS Act** (H.R. 6829) also passed unanimously. The bill, which passed the House of Representatives by voice vote in September, will now be sent to the President to be signed into law. The legislation aims to combat sudden cardiac arrest in young people and student athletes by increasing access to CPR training and automated external defibrillators in schools.

GOP Steering Committee Makes Leadership, Membership Picks for the 119th Congress

The House GOP Steering Committee made its committee leadership picks for the 119th Congress in private votes last week. Committee leadership will be comprised entirely of male members of Congress for the first time in almost a decade. Rep. Ann Wagner (R-Mo.), the only woman running for a competitive gavel, lost the Foreign Affairs Committee chairmanship to Rep. Brian Mast (R-Fla.).

Rep. Brett Guthrie (R-Ky.) was chosen to serve as the Chairman of the House Energy and Commerce Committee. Guthrie beat Rep. Bob Latta (R-Ohio) to succeed retiring Chair Cathy McMorris Rodgers (R-Wash.). As the leader of a top congressional committee with health policy jurisdiction, Guthrie will play a key role in advancing the GOP's health care agenda next year. Efforts to overhaul regulation of the pharmacy benefit manager industry are expected to continue under Guthrie's leadership. Guthrie has also been a proponent of shoring up medical supply chains, increasing transparency around drug pricing, and improving the nation's response to the opioid epidemic through the reauthorization of the SUPPORT Act. He has introduced legislation (H.R. 7174) that would exempt small molecule drugs from the Inflation Reduction Act's (IRA) drug price negotiation program for a longer period of time after coming to market, and has also pushed to strengthen oversight of the IRA. Guthrie is a supporter of per capita allotments for state Medicaid programs and of expanding access to association health plans. He currently chairs the Energy and Commerce Health Subcommittee. Reps. Gus Bilirakis (R-Fla.), Buddy Carter (R-Ga.), and Morgan Griffith (R-Va.) are seeking to fill that now-open position.

Rep. Tim Walberg was selected to chair the House Committee on Education and the Workforce next year, beating Rep. Burgess Owens (R-Utah) for the role. Walberg will replace term-limited Chair Virginia Foxx (R-N.C.). During the 118th Congress, the committee has considered reforms to ERISA and employer-sponsored health benefits, as well as ways to lower health care costs while increasing access to care. Walberg has been a strong supporter of maintaining access to telehealth, introducing legislation (H.R. 824) that would permanently allow employers to offer telehealth as a tax-free benefit separate from group health insurance plans. He has also expressed support for restoring Trump-era regulations expanding the availability of association health plans.

House GOP and Democratic leadership also reached an agreement on the standing committee ratios for the 119th Congress. The committees on Appropriations, Energy and Commerce, Financial Services, Transportation and Infrastructure, and Ways and Means will grow by one seat on both sides of the aisle. The Committee on Armed Services will decrease proportionally by one seat, and the Committee on Education and the Workforce will decrease proportionally by four seats on both sides of the aisle. With that agreement having been reached, the GOP Steering Committee selected Reps. Rudy Yakym (R-Ind.), Max Miller (R-Ohio), Nathaniel Moran (R-Texas), and Aaron Bean (R-Fla.) to join the Ways and Means Committee next year. The new members will replace the retiring Reps. Brad Wenstrup (R-Ohio) and Drew Ferguson (R-Ga.), as well as Rep. Michelle Steel (R-Calif.), who lost her race for re-election. The Ways and Means Committee is expected to play a key role in Republicans' attempt to extend the 2017 tax law before it expires at the end of 2025. The Steering Committee's picks must all be ratified by the full House Republican Conference, which is expected to take place without controversy early next year.

Rep. Robin Kelly to Co-Chair Democratic Steering Committee

House Democratic Leader Hakeem Jeffries (D-N.Y.) announced last week that Rep. Robin Kelly (D-Ill.) will co-chair the House Democratic Steering and Policy Committee in the 119th Congress. Kelly will serve alongside co-chairs Debbie Wasserman Schultz (D-Fla.) and Nanette Barragán (D-Calif.). The Committee is responsible for determining which Democratic lawmakers lead and serve on standing committees in the House of Representatives.

Bipartisan Bill Introduced to Prohibit Joint Ownership of PBMs, Pharmacies

A bipartisan, bicameral group of lawmakers have introduced legislation to prohibit joint ownership of pharmacy benefit managers (PBMs) and pharmacies. The *Patients Before Monopolies (PBM) Act* was introduced in the Senate (S. 5503) by Sens. Elizabeth Warren (D-Mass.) and Josh Hawley (R-Mo.) and in the House of Representatives (H.R. 10362) by Reps. Diana Harshbarger (R-Tenn.) and Jake Auchincloss (D-Mass.). The legislation would prohibit a parent company of a PBM or a health insurer from owning a pharmacy business. A one pager on the legislation can be found <u>here</u> and the bill text can be found <u>here</u>.

Lawmakers Urge House Leadership to Avert DSH Cuts

A bipartisan group of more than 150 lawmakers in the House of Representatives have sent a <u>letter</u> urging leadership to stop a nearly \$8 billion cut to safety-net hospitals set to take effect January 1. The Affordable Care Act included a phased in reduction of Medicare Disproportionate Share Hospital (DSH) payments beginning in 2014. Congress has since delayed the statutory cuts from going into effect for more than a decade. "Our nation's Medicaid DSH hospitals, many of which are the backbone of rural and urban communities alike, simply cannot absorb losses of this magnitude," the letter states. "We ask that you work to prevent these DSH cuts, to ensure our hospitals can continue their mission of providing care for the most vulnerable among us."

Markey, Braun Question Private Equity Investments in Opioid Treatment Programs

Sens. Ed Markey (D-Mass.) and Mike Braun (R-Ind.) are raising concerns about private equity investment in opioid treatment programs (OTPs) and the role that private equity plays in access to, and the availability of, medication for opioid use disorder (OUD) and methadone in particular. The lawmakers have sent a series of <u>letters</u> to private equity firms requesting details about their investments along with data on patient outcomes specifically related to methadone treatment. The letter highlights Markey's *Modernizing Opioid Treatment Access Act* (S. 644), which would allow board-certified addiction psychiatry and addiction medicine physicians registered with the Drug Enforcement Administration to prescribe methadone for OUD to patients and allow U.S. pharmacies to dispense it. The bill is opposed by many for-profit and private equity-owned and affiliated OTPs. "We are concerned that there is incompatibility manifesting itself in private-equity-backed OTPs seeking to maintain their monopoly on methadone access, not because it is good for the patient, but because it is good for the bottom line," the lawmakers write.

Pelosi Has Hip Surgery Following Injury While Abroad

Former House Speaker Nancy Pelosi (D-Calif.), 84, has been hospitalized following an injury while on a congressional trip to Luxembourg. Pelosi fractured her hip and received hip replacement surgery at a U.S. military hospital in Germany. Her office has stated that she is "well on the mend" and continues to work while in the hospital.

Nobel Laureates Oppose RFK Confirmation

A group of 77 Nobel laureates have sent a <u>letter</u> to the Senate urging lawmakers to oppose the confirmation of Robert F. Kennedy Jr. as Secretary of the U.S. Department of Health and Human Services (DHHS). The letter expresses concerns about RFK's lack of relevant experience in medicine, science, public health, or administration and specifically condemns the nominee's opposition to many vaccines, promotion of conspiracy theories, and criticism of government agencies. "In view of his record," the letter states, "placing Mr. Kennedy in charge of DHHS would put the public's health in jeopardy and undermine America's global leadership in the health sciences, in both the public and commercial sectors."

Doctors for America Suggest Qualifications for Next FDA Commissioner

Doctors for America, a Food and Drug Administration (FDA) watchdog group, is <u>urging</u> the Senate Health, Education, Labor, and Pensions Committee to carefully vet Marty Makary, MD, MPH, who has been nominated by Presidentelect Donald Trump to serve as FDA Commissioner. The group shares its criteria for a qualified FDA commissioner, and their expectations for the vetting and confirmation process. The letter suggests the following baseline qualities for the next leader of the FDA:

- 1) Have meaningful clinical experience;
- 2) Be free from financial conflicts of interest and associations with any industries regulated by the agency;

3) Staunchly support the need for robust clinical trials to support agency decision-making around medical product approvals that measure both safety and efficacy;

4) Maintain the integrity and independence of the agency by transparently following the science in making regulatory decisions;

5) Commit to weighing, considering, and deferring, when necessary, to the scientific view of the multitude of scientific and technical experts within the FDA over their and others' personal opinions or motives;

6) Be willing to uphold, enforce, and defend existing regulations despite political pressures;

7) Commit to enhancing transparency to instill public trust in the FDA.

Upcoming Congressional Hearings and Markups

House Veterans' Affairs Subcommittee on Health legislative hearing on H.R. 214, Veterans' True Choice Act of 2023; H.R. 3176, Veterans Health Care Freedom Act; H.R. 5287, Veterans Access to Direct Primary Care Act; H.R. 8481, Emergency Community Care Notification Time Adjustment Act of 2024; H.R. 10012, To amend title 38, United States Code, to include eyeglass lens fittings in the category of medical services authorized to be furnished to veterans under the Veterans Community Care Program, and for other purposes; H.R. 9924, What Works for Preventing Veteran Suicide Act; H.R. 8347, Improving Menopause Care for Veterans Act; H.R. 6333, Veterans Emergency Care Reimbursement Act; Discussion Draft Supporting Medical Students and VA Workforce Act; and H.R. 10267, Complete the Mission Act of 2024; 2:30 p.m.; December 17

Recently Introduced Health Legislation

H.R.10317 — To amend title XIX of the Social Security Act to establish a community engagement requirement for certain individuals under the Medicaid program; Sponsor: Bean, Aaron [Rep.-R-FL-4]; Committees: House - Energy and Commerce

S.5453 — A bill to amend title 18, United States Code, to provide Tribal courts and law enforcement with more tools to combat the opioid epidemic; Sponsor: Daines, Steve [Sen.-R-MT]; Committees: Senate - Indian Affairs

S.5456 — A bill to amend the Public Health Service Act to authorize rural residency planning and development grant programs, and for other purposes; Sponsor: Smith, Tina [Sen.-D-MN]; Committees: Senate - Health, Education, Labor, and Pensions

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S.5459 — A bill to amend title XI of the Social Security Act to alter when biosimilar biological products are eligible for price negotiations under the Medicare program; Sponsor: Blackburn, Marsha [Sen.-R-TN]; Committees: Senate – Finance

H.R.10331 — To prohibit health insurers, including Medicaid managed care organizations and other private health plans, from imposing arbitrary time caps on reimbursement for anesthesia services and for other purposes; Sponsor: Torres, Ritchie [Rep.-D-NY-15]; Committees: House - Energy and Commerce

S.5460 — A bill to modify the Precision Medicine for Veterans Initiative of the Department of Veterans Affairs; Sponsor: Moran, Jerry [Sen.-R-KS]; Committees: Senate - Veterans' Affairs

S.5464 — A bill to amend title XVIII of the Social Security Act to require the collection of data regarding graduate medical education; Sponsor: Booker, Cory A. [Sen.-D-NJ]; Committees: Senate – Finance

H.Res.1613 — Recognizing the importance of a continued commitment to ending pediatric HIV/AIDS worldwide; Sponsor: McClellan, Jennifer L. [Rep.-D-VA-4]; Committees: House - Foreign Affairs; Energy and Commerce

H.R.10337 — To amend the Public Health Service Act to establish a demonstration project to make grants to eligible hospitals for the purpose of promoting work-based learning in health care, and for other purposes; Sponsor: Brown, Shontel M. [Rep.-D-OH-11]; Committees: House - Energy and Commerce

H.R.10346 — To amend title 38, United States Code, to direct the Secretary of Veterans Affairs to reimburse State homes for the cost of, or to furnish to State homes, certain costly medications provided to veterans who receive nursing home care in such State homes, and for other purposes; Sponsor: Miller-Meeks, Mariannette [Rep.-R-IA-1]; Committees: House - Veterans' Affairs

S.5474 — A bill to amend title XI of the Social Security Act to establish an interagency council on social determinants of health, and for other purposes; Sponsor: Young, Todd [Sen.-R-IN]; Committees: Senate – Finance

S.5481 — A bill to clarify that agencies of the Department of Health and Human Services do not have the authority to regulate the practice of medicine; Sponsor: Johnson, Ron [Sen.-R-WI]; Committees: Senate - Health, Education, Labor, and Pensions

S.5492 — A bill to amend title XVIII of the Social Security Act to provide for payment for services of radiologist assistants under the Medicare program, and for other purposes; Sponsor: Boozman, John [Sen.-R-AR]; Committees: Senate – Finance

H.R.10362 — To prohibit pharmacy benefit managers and pharmacies from being under common ownership, and for other purposes; Sponsor: Harshbarger, Diana [Rep.-R-TN-1]; Committees: House – Judiciary

H.R.10365 — To extend certain authorities relating to United States efforts to combat HIV/AIDS, tuberculosis, and malaria globally, and for other purposes; Sponsor: James, John [Rep.-R-MI-10]; Committees: House - Foreign Affairs

H.R.10373 — To amend the Internal Revenue Code of 1986 to create a tax credit for nurse preceptors; Sponsor: Tenney, Claudia [Rep.-R-NY-24]; Committees: House - Ways and Means; Appropriations

H.R.10374 — To require the Director of the Office of Science and Technology Policy to develop a consistent set of policy guidelines for Federal research agencies to address mental health and mentoring of graduate researchers and postdoctoral researchers, and for other purposes; Sponsor: Tonko, Paul [Rep.-D-NY-20]; Committees: House - Science, Space, and Technology

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S.5502 — A bill to ensure continued access to diabetes technology upon Medicare enrollment, and for other purposes; Sponsor: Shaheen, Jeanne [Sen.-D-NH]; Committees: Senate – Finance

S.5503 — A bill to prohibit pharmacy benefit managers and pharmacies from being under common ownership, and for other purposes; Sponsor: Warren, Elizabeth [Sen.-D-MA]; Committees: Senate – Judiciary

S.5504 — A bill to amend the Public Health Service Act to eliminate consideration of the income of organ recipients in providing reimbursement of expenses to donating individuals, and for other purposes; Sponsor: Lujan, Ben Ray [Sen.-D-NM]; Committees: Senate - Health, Education, Labor, and Pensions

S.5510 — A bill to amend title XI of the Social Security Act to require pharmaceutical and device manufacturers to publicly disclose covered payments made to patient advocacy organizations; Sponsor: Grassley, Chuck [Sen.-R-IA]; Committees: Senate – Finance

S.5511 — A bill to amend the Older Americans Act of 1965 to provide additional opportunities for older individuals to volunteer at facilities that serve older individuals or individuals in younger generations, and for other purposes; Sponsor: Hassan, Margaret Wood [Sen.-D-NH]; Committees: Senate - Health, Education, Labor, and Pensions

S.5517 — A bill to provide for the establishment, within the Food and Drug Administration, of an Abraham Accords Office to promote and facilitate cooperation between the Food and Drug Administration and entities in Abraham Accords countries wishing to work with the agency in order to develop and sell products in the United States, and for other purposes; Sponsor: Budd, Ted [Sen.-R-NC]; Committees: Senate - Foreign Relations

S.5524 — A bill to provide for civil monetary penalties for violations of mental health parity requirements; Sponsor: Murphy, Christopher [Sen.-D-CT]; Committees: Senate - Health, Education, Labor, and Pensions

H.R.10381 — To amend title 38, United States Code, to authorize a joint scholarship program under which the Secretary of Veterans Affairs pays for medical education of an officer of the commissioned corps of the Public Health Service at the Uniformed Services University in return for a period of obligated service by such officer at a medical facility of the Department of Veterans Affairs, and for other purposes; Sponsor: Takano, Mark [Rep.-D-CA-39]; Committees: House - Veterans' Affairs; Armed Services; Energy and Commerce

H.R.10396 — To amend title 38, United States Code, to ensure that the Secretary of Veterans Affairs furnishes certain non-opioid pain medications to veterans, and for other purposes; Sponsor: Landsman, Greg [Rep.-D-OH-1]; Committees: House - Veterans' Affairs

H.R.10406 — To amend the Federal Food, Drug, and Cosmetic Act to authorize requiring the manufacturers of a covered device to disclose to a patient all patient-specific data that is recorded or transmitted by the device and accessible to the manufacturer, and for other purposes; Sponsor: Sherrill, Mikie [Rep.-D-NJ-11]; Committees: House - Energy and Commerce

H.R.10409 — To address the high costs of health care services, prescription drugs, and health insurance coverage in the United States, and for other purposes; Sponsor: Westerman, Bruce [Rep.-R-AR-4]; Committees: House - Energy and Commerce; Ways and Means; Education and the Workforce; Judiciary; Oversight and Accountability; Rules; Budget; Armed Services; House Administration