



Health Policy Briefing

April 22, 2024

E&C Schedule Hearing on Change Healthcare Cyberattack

Bipartisan leadership of the House Energy and Commerce Committee sent a [letter](#) to UnitedHealth Group, Inc. last week seeking information about the Change Healthcare cyberattack. “The health care system is rapidly consolidating at virtually every level, creating fewer redundancies and more vulnerability to the entire system if an entity with significant market share at any level of the system is compromised,” the committee leaders wrote. “In order to understand better the steps UnitedHealth has taken to address this situation, we request information about the impact of the cyberattack, the actions the company is taking to secure its systems, and the outreach to the health care community in the aftermath.” UnitedHealth’s CEO Andrew Witty will testify before Energy and Commerce’s Oversight and Investigations Subcommittee in a hearing scheduled for May 1 to discuss the cyberattack and how it has impacted patients and providers.

Cassidy Questions FDA Oversight of Clinical Decision Support Software

Senate Health, Education, Labor, and Pensions Committee Ranking Member Bill Cassidy (R-La.) has sent a [letter](#) to the Food and Drug Administration (FDA) criticizing the agency’s decision in a September 2022 guidance to classify clinical decision support (CDS) software as a medical device and to subject software developers to the FDA’s regulatory process. Cassidy argues that the move is not aligned with the agency’s statutory authority, highlighting that Congress excluded CDS software from being categorized as a medical device in the **21st Century Cures Act**. He expresses concerns about the implications of increased oversight of CDS on patient access to innovative medical technology, and notes that the FDA made the change without providing stakeholders an opportunity to submit feedback on the potential impacts of the policy. “This guidance unnecessarily calls into question the safety of these tools and expands the universe of entities regulated by FDA, many of which are small provider practices who have developed their own CDS tools...FDA’s guidance not only runs contrary to an explicit congressional directive but may jeopardize access to advanced tools that improve patient care,” the letter argues.

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Buchanan Asks MedPAC to Rethink Approach to Digital Health Tools

Rep. Vern Buchanan (R-Fla.), Chair of the Ways and Means Subcommittee on Health, has sent a [letter](#) to the Medicare Payment Advisory Commission (MedPAC) encouraging the commission to rethink its approach to evaluating digital health tools and the use of artificial intelligence in the Medicare program. Buchanan expresses concerns that MedPAC's current approach could punish providers for using, and innovators for developing, digital health tools that improve health outcomes and control costs. Buchanan argues that "for Medicare to meaningfully transition to value-based care, payment policies need to maximize efficiencies in care delivery and enhance patient safety using digital health tools." The letter highlights the "quadruple aim" of digital health tools, and strongly encourages MedPAC to "incorporate digital health tools into future evaluations of Medicare policy recommendations and, in partnership with all stakeholders impacted by Medicare policy, ensure that its evaluations and recommendations related to digital health are inclusive of each of the quadruple aims."

Democratic Senators Raise Concerns With Levemir Discontinuation

Sens. Jeanne Shaheen (D-N.H.), Raphael Warnock (D-Ga.), and Elizabeth Warren (D-Mass.) have sent a [letter](#) to the President and CEO of Novo Nordisk regarding the company's recent decision to discontinue production of Levemir, one of three long-acting insulin products on the market. The letter highlights that access to affordable, in-demand biosimilar insulins will be further restricted by the discontinuation and the creation of significant barriers to demonstrating biosimilarity without a reference sample. The lawmakers ask Novo Nordisk about the supply chain constraints and issues related to formulary placement that led to the discontinuation of Levemir, and about how the company plans to ensure patient access to similar long-acting insulin products at similar cost-sharing without gaps in coverage.

GAO Releases New Report on State PBM Regulations

The Government Accountability Office (GAO) released a new [report](#) last week examining five states' regulation of pharmacy benefit managers (PBMs). Each of the five states selected for review—Arkansas, California, Louisiana, Maine, and New York—have enacted a variety of laws to regulate PBMs, including fiduciary or duty of care requirements, drug pricing and pharmacy reimbursement requirements, transparency requirements, and pharmacy network and access requirements. The regulators interviewed by GAO generally agreed that broad regulatory authority was more effective than enacting specific statutory provisions, and also stressed the need for robust enforcement of PBM laws and effective penalties to enforce them.

CBO Releases Analysis of Medicare ACOs' Past Performance and Future Directions

The Congressional Budget Office has released a new [report](#) summarizing recent research findings about accountable care organizations (ACOs) and the factors that have contributed to or limited their ability to achieve net budgetary savings for the Medicare program. The analysis found that certain types of ACOs are associated with greater savings, including ACOs led by independent physician groups, ACOs with a larger proportion of primary care providers, and ACOs whose initial baseline spending was higher than the regional average. CBO also outlines the factors that limit the savings from Medicare ACOs, including weak incentives for ACOs to reduce spending, a lack of the resources necessary for providers to participate in ACO models, and providers' ability to selectively enter and exit the program on the basis of the financial benefits or losses they anticipate from participating.

PAs in Oregon to Rebrand as Physician Associates

Oregon has become the first state in the nation to legally allow physician assistants to use the title physician associate on their license. Other states, including Michigan and South Carolina, are considering similar measures. The change is opposed by the American Medical Association and other physician groups, who have expressed concerns about patient confusion around scope of practice. Oregon's new law will take effect on June 6, 2024.

Congressional Retirements and Resignations

Rep. Jake LaTurner (R-Kan.) has announced that he will not seek re-election this November. LaTurner has served in Congress since 2021 and currently sits on the Homeland Security, Oversight and Reform, and Science, Space, and Technology committees.

A running list of members of Congress who are retiring or seeking other office can be found below.

| SENATE | |
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| Stabenow (D), MI | Braun (R), IN |
| Cardin (D), MD | Romney (R), UT |
| Carper (D), DE | |
| Butler (D), CA | |
| Manchin (D), WV | |
| Sinema (I), AZ | |
| HOUSE OF REPRESENTATIVES | |
| Porter (D), CA | Mooney (R), WV |
| Lee (D), CA | Banks (R), IN |
| Gallego (D), AZ | Bishop (R), NC |
| Schiff (D), CA | Lesko (R), AZ |
| Slotkin (D), MI | Granger (R), TX |
| Allred (D), TX | Buck (R), CO (effective March 22, 2024) |
| Trone (D), MD | Burgess, MD (R), TX |
| Blunt Rochester (D), DE | Wenstrup, DPM (R), OH |
| Napolitano (D), CA | McHenry (R), NC |
| Wexton (D), VA | McCarthy (R), CA (effective Dec. 31, 2023) |
| Kim, Andy (D), NJ | Johnson (R), OH (effective Jan. 21, 2024) |
| Jackson, Jeff (D), NC | Ferguson, IV, DMD, PC (R), GA |
| Sarbanes (D), MD | Curtis (R), UT |
| Blumenauer (D), OR | Luetkemeyer (R), MO |
| Kilmer (D), WA | Lamborn (R), CO |
| Spanberger (D), VA | Bucshon, MD (R), IN |
| Kildee (D), MI | Pence (R), IN |
| Phillips (D), MN | Duncan (R), SC |
| Cardenas (D), CA | Armstrong (R), ND |
| Eshoo (D), CA | McMorris Rodgers (R), WA |
| Manning (D), NC | Gallagher (R), WI (effective April 19, 2024) |
| Higgins (D), NY (effective Feb. 2, 2024) | LaTurner (R), KS |
| Nickel (D), NC | |
| Ruppersberger (D), MD | |
| Sablan (D), MP | |
| Kuster (D), NH | |

Upcoming Congressional Hearings and Markups

House Appropriations Subcommittee on Labor, Health and Human Services, and Education Member Day Hearing; 10:30 a.m.; April 30

House Energy and Commerce Subcommittee on Oversight and Investigation and Subcommittee on Health hearing to discuss gain-of-function research with EcoHealth Alliance President Dr. Peter Daszak; time TBD; May 1

House Energy and Commerce Subcommittee on Oversight and Investigations hearing to discuss the Change Healthcare Cyberattack with Andrew Witty, CEO, UnitedHealth Group Inc.; 2:00 p.m.; May 1

Recently Introduced Health Legislation

H.R.7974 — To amend the Federal Food, Drug, and Cosmetic Act to require labeling of food products containing insects, and for other purposes; Sponsor: Miller, Mary E. [Rep.-R-IL-15]; Committees: House - Energy and Commerce

H.R.7994 — To support the direct care professional workforce, and for other purposes; Sponsor: Dingell, Debbie [Rep.-D-MI-6]; Committees: House - Energy and Commerce; Education and the Workforce; Ways and Means; Judiciary; House Administration; Oversight and Accountability

H.R.7996 — To amend title XIX of the Social Security Act to ensure Medicaid coverage of mental health services and primary care services furnished on the same day; Sponsor: Dunn, Neal P. [Rep.-R-FL-2]; Committees: House - Energy and Commerce

S.Res.647 — A resolution recognizing the designation of the week of April 11 through April 17, 2024, as the seventh annual “Black Maternal Health Week”; Sponsor: Booker, Cory A. [Sen.-D-NJ]; Committees: Senate - Health, Education, Labor, and Pensions

S.4131 — A bill to reform Federal firearms laws, and for other purposes; Sponsor: Kaine, Tim [Sen.-D-VA]; Committees: Senate - Judiciary

S.4137 — A bill to amend title XVIII of the Social Security Act to count a period of receipt of outpatient observation services in a hospital toward satisfying the 3-day inpatient hospital requirement for coverage of skilled nursing facility services under Medicare; Sponsor: Brown, Sherrod [Sen.-D-OH]; Committees: Senate - Finance

S.4147 — A bill to continue to fund the IMPROVE initiative through the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and for other purposes; Sponsor: Butler, Laphonza R. [Sen.-D-CA]; Committees: Senate - Health, Education, Labor, and Pensions

S.Res.654 — A resolution expressing concern about the elevated levels of lead in one-third of the world’s children and the global causes of lead exposure, and calling for the inclusion of lead exposure prevention in global health, education, and environment programs abroad; Sponsor: Cardin, Benjamin L. [Sen.-D-MD]; Committees: Senate - Foreign Relations

S.4159 — A bill to amend the Public Health Service Act to encourage qualified individuals to enter the forensic pathology workforce, and for other purposes; Sponsor: Cornyn, John [Sen.-R-TX]; Committees: Senate - Health, Education, Labor, and Pensions

S.4169 — A bill to establish and support primary care team education centers, and for other purposes; Sponsor: Kaine, Tim [Sen.-D-VA]; Committees: Senate - Health, Education, Labor, and Pensions

S.4174 — A bill to amend title IV of the Public Health Service Act to direct the Secretary of Health and Human Services to establish a clearinghouse on intellectual disabilities, and for other purposes; Sponsor: Schmitt, Eric [Sen.-R-MO]; Committees: Senate - Health, Education, Labor, and Pensions

S.4178 — A bill to establish artificial intelligence standards, metrics, and evaluation tools, to support artificial intelligence research, development, and capacity building activities, to promote innovation in the artificial intelligence industry by ensuring companies of all sizes can succeed and thrive, and for other purposes; Sponsor: Cantwell, Maria [Sen.-D-WA]; Committees: Senate - Commerce, Science, and Transportation

H.Res.1153 — Recognizing the designation of the week of April 11 through April 17, 2024, as the seventh annual “Black Maternal Health Week”; Sponsor: Adams, Alma S. [Rep.-D-NC-12]; Committees: House - Energy and Commerce

H.R.8018 — To require the Administrator of the Centers for Medicare & Medicaid Services and the Commissioner of Social Security to review and simplify the processes, procedures, forms, and communications for family caregivers to assist individuals in establishing eligibility for, enrolling in, and maintaining and utilizing coverage and benefits under the Medicare, Medicaid, CHIP, and Social Security programs respectively, and for other purposes. Sponsor: Cammack, Kat [Rep.-R-FL-3]; Committees: House - Energy and Commerce; Ways and Means

H.R.8025 — To amend title 10, United States Code, to clarify roles and responsibilities within the Department of Defense relating to subconcussive and concussive brain injuries and to improve brain health initiatives of the Department of Defense, and for other purposes. Sponsor: Khanna, Ro [Rep.-D-CA-17]; Committees: House - Armed Services

H.R.8037 — To continue to fund the IMPROVE initiative through the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and for other purposes; Sponsor: Underwood, Lauren [Rep.-D-IL-14]; Committees: House - Energy and Commerce

H.R.8042 — To authorize the Secretary of Health and Human Services to award grants to qualified entities to support community paramedicine programs, and for other purposes; Sponsor: Cleaver, Emanuel [Rep.-D-MO-5]; Committees: House - Energy and Commerce

H.R.8049 — To amend the Internal Revenue Code of 1986 to prohibit treatment of certain distributions and reimbursements for certain abortions as qualified medical expenses; Sponsor: Mooney, Alexander X. [Rep.-R-WV-2]; Committees: House - Ways and Means

H.J.Res.129 — Providing for congressional disapproval under chapter 8 of title 5, United States Code, of the rule submitted by the Departments of Labor, the Treasury, and Health and Human Services relating to “Short-Term, Limited-Duration Insurance and Independent, Noncoordinated Excepted Benefits Coverage”; Sponsor: Self, Keith [Rep.-R-TX-3]; Committees: House - Energy and Commerce; Education and the Workforce; Ways and Means

H.R.8064 — To amend title XVIII of the Social Security Act to provide for coverage under the Medicare program of hearing aids and related hearing services; Sponsor: Cartwright, Matt [Rep.-D-PA-8]; Committees: House - Energy and Commerce; Ways and Means

H.R.8065 — To require the Secretary of Health and Human Services, acting through the Assistant Secretary for Preparedness and Response, to carry out a program under which the Secretary requires each regulated seller of a highly infectious agent to comply with certain logbook requirements, and for other purposes; Sponsor: Costa, Jim [Rep.-D-CA-21]; Committees: House - Energy and Commerce

H.R.8069 — To amend the Public Health Service Act to encourage qualified individuals to enter the forensic pathology workforce, and for other purposes; Sponsor: Guest, Michael [Rep.-R-MS-3]; Committees: House - Energy and Commerce; Ways and Means

H.R.8075 — To amend title XVIII of the Social Security Act to provide for Medicare coverage of staff-assisted home dialysis for certain hemodialysis and peritoneal dialysis patients and to ensure all patients are educated on modality options and receive the resources, information, and support to succeed on the modality of their choice, and for other purposes; Sponsor: Miller, Carol D. [Rep.-R-WV-1]; Committees: House - Energy and Commerce; Ways and Means

H.R.8078 — To authorize Federal support of States in piloting interoperable State-based repositories of sepsis cases, and for other purposes; Sponsor: Sherrill, Mikie [Rep.-D-NJ-11]; Committees: House - Energy and Commerce

H.R.8080 — To amend the Public Health Service Act to direct the Secretary of Health and Human Services to establish and implement a department-wide after-action program and a risk communication strategy, and for other purposes; Sponsor: Torres, Ritchie [Rep.-D-NY-15]; Committees: House - Energy and Commerce