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Impact Health Policy Weekly

Framing the Week

Both the House and Senate are in session this week, for a busy two week stretch before recessing for the winter holidays. This week the House is set to take up a series of bills including the <u>TRANQ</u> <u>Research Act</u>, which would require the National Institute of Standards and Technology to coordinate science and research activities regarding illegal drugs containing the horse tranquilizer xylazine, new synthetic opioids and other substances of concern. The House unanimously passed a version of the bill in May but is now voting on minor tweaks made by the Senate. The House is also set to vote on the <u>Elizabeth Dole Home Care Act</u>, which would expand caregiver support for veterans outside of nursing homes.

In the Senate, Majority Leader Chuck Schumer (D-NY) has said he would bring the President's \$105 billion-plus supplemental foreign aid request to the floor this week. While most Senate Republicans agree that additional aid for Ukraine, Israel, and Taiwan is needed, they are also insisting on meaningful border policy changes. A bipartisan group negotiating border policy changes, however, have not come to a resolution yet, leaving the question if the bill will pass. House Republicans are insisting that H.R. 2, the House GOP's border security bill be a part of any package, which is a non-starter for the White House and Congressional Democrats. Time is ticking as the Administration conveyed in a <u>letter</u> from OMB Director Shalanda Young to Congressional leaders stating that if Congress does not pass a bill with additional funding, the Pentagon will run out of resources to provide funding and more weapons to Ukraine. The Senate could also bring up the National Defense Authorization Act this week, but timing is dependent upon the supplemental.

Hearings and Markups

<u>Senate Finance Committee</u>: The Senate Finance Committee will hold a <u>hearing</u> on Tuesday titled Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective. The hearing will examine drug shortages, focusing on supply challenges, impacts, and policy solutions from a federal health program perspective.

<u>Energy & Commerce Committee</u>: On Tuesday the House Energy & Commerce Committee will hold a markup of 44 various bills across the Committee's jurisdiction. The health-related bills being marked up include:

- <u>H.R. 2365</u>, National Plan to End Parkinson's Act
- <u>H.R. 5372</u>, Expanding Seniors' Access to Lower Cost Medicines Act of 2023 \
- <u>H.R. 2880</u>, Protecting Patients Against PBM Abuses Act
- <u>H.R. 5393</u>, To amend title XVIII of the Social Security Act to ensure fair assessment of pharmacy performance and quality under Medicare part D.
- <u>H.R. 5385</u>, Medicare PBM Accountability Act
- <u>H.R. 5386</u>, Cutting Copays Act
- <u>H.R. 4881</u>, To amend title XVIII of the Social Security Act to limit cost sharing for drugs under the Medicare program.
- <u>H.R. 5389</u>, National Coverage Determination Transparency Act, as amended.



- <u>H.R. 133</u>, Mandating Exclusive Review of Individual Treatments (MERIT) Act, as amended.
- <u>H.R. 5396</u>, Coverage Determination Clarity Act of 2023
- <u>H.R. 5371</u>, Choices for Increased Mobility Act of 2023
- <u>H.R. 5388</u>, Supporting Innovation for Seniors Act
- <u>H.R. 5380</u>, To amend title XVIII of the Social Security Act to increase data transparency for supplemental benefits under Medicare Advantage.
- <u>H.R. 3842</u>, Expanding Access to Diabetes Self-Management Training Act of 2023, as amended.
- H.R. 5397, Joe Fiandra Access to Home Infusion Act of 2023, as amended.
- <u>H.R. 6366</u>, To amend title XVIII of the Social Security Act with respect to the work geographic index for physician payments under the Medicare program and to revise the phase-in of clinical laboratory test payment changes under such program.
- <u>H.R. 6369</u>, To amend title XVIII of the Social Security Act to extend incentive payments for participation in eligible alternative payment models.
- H.R. 5555, DMEPOS Relief Act of 2023
- <u>H.R. 6545</u>, Physician Fee Schedule Update and Improvements Act
- H.R. 6364, Medicare Telehealth Privacy Act of 2023
- <u>H.R. 1352</u>, Increasing Access to Biosimilars Act of 2023

Regulatory Update

The Office of Management and Budget (OMB) completed reviewing an <u>interim final rule</u> that would establish rules regarding CMS enforcement of states' compliance with reporting requirements and renewal requirements during the period that begins on July 1, 2023 and ends on June 30, 2024. The interim final rule may codify <u>existing guidance</u> and provide more details on how CMS may enforce the requirements.

OMB is also reviewing the following rules:

Medicare, Medicaid, or Both:

- Appeals Process The propose rule, pursuant to a court order, would establish new appeals
 processes for Medicare beneficiaries who have an inpatient hospital admission changed to
 outpatient by a hospital.
- Healthcare System Resiliency and Modernization The proposed rule would establish culturally competent and person-centered requirements for all provider and supplier types that participate in Medicare and Medicaid programs.

Other Topics:

• **Conscience Rights in Health Care** – The <u>final rule</u> would safeguard the rights of federal conscience and religious nondiscrimination while protecting access to care, including abortion.



• Health Data Interoperability – The <u>final rule</u> would implement certain provisions of the 21st Century Cures Act and make several enhancements to the ONC Health IT Certification Program to advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information.

<u>OIG Report</u>

OIG Issues Semiannual Report to Congress With Summaries of Work From March Through September

The Department of Health and Human Services (HHS) Office of the Inspector General (OIG) released the <u>Semiannual Report to Congress</u> providing an overview of the Agency's activities from March 2023 through September 2023 including data on reports, audits, investigations, and other statistics. OIG highlights that HHS could recoup \$3.4 billion in recoveries from OIG audits and investigations.

The report describes OIG's work on identifying significant problems, abuses, deficiencies, remedies, and investigative outcomes relating to the administration of HHS programs and operations during the reporting period. Highlights include discussions on:

- Medicare payment for psychotherapy services during the COVID-19 public health emergency (PHE);
- Reporting of health, fire safety, and emergency preparedness in nursing homes;
- FDA enforcement against tobacco retailers with a history of violations;
- Program integrity risks from telehealth;
- Treatment of opioid use disorder among Medicaid enrollees; and
- Placement and transfer of unaccompanied refugee children.

This Week in Health Policy

Mon. (12/4)

- 2:00pm AEI Discussion: Tobacco Control/FDA Regulations The American Enterprise Institute for Public Policy Research holds a discussion titled "Rethinking Tobacco Control: Electronic Nicotine Delivery Systems and FDA Regulations." <u>Details</u>.
- 3:00pm Hearing: VA.gov Modernization The House Veterans' Affairs Subcommittee on Technology Modernization holds an oversight hearing titled "Reexamining VA.gov." <u>Details</u>.

<u>Tue. (12/5)</u>

- **10:00am Hearing: Drug Shortages –** The Senate Finance Committee holds a hearing to examine drug shortages, focusing on supply challenges, impacts, and policy solutions from a federal health program perspective. <u>Details</u>.
- 10:00am Markup: VA Economic Opportunity and Suicide Prevention The House Veterans' Affairs Committee holds a markup of legislation addressing economic opportunity and suicide prevention for Veterans. <u>Details</u>.



- 10:00am SAMHSA Meeting: Drug Testing The Substance Abuse and Mental Health Services Administration (SAMHSA) holds a virtual meeting of the Center for Substance Abuse Prevention's Drug Testing Advisory Board to hear federal Partner updates and presentations regarding National Laboratory Certification Program (NLCP) activities and other updates. <u>Details</u>.
- 10:30am Hearing: NTIA Oversight The House Energy and Commerce Subcommittee on Communications and Technology holds an oversight hearing of the National Telecommunications and Information Technology (NTIA) to ensure the agency has the right tools to improve broadband deployment and cybersecurity. NTIA Administrator Alan Davidson will be testifying. <u>Details</u>.
- 12:00pm HHS Event: Music and Mental Health The Department of Health and Human Services (HHS) holds the first-ever "Music is Medicine" event to spotlight the impact of music on mental health and well-being and featuring local musicians, including those who are also health workers, physicians, and first responders. <u>Details</u>.
- **2:00pm Markup: Health-Related Legislation –** The House Energy and Commerce Committee holds full Committee markup to consider 44 pieces of legislation. <u>Details</u>.

Wed. (12/6)

- 9:00am SAMHSA Meeting: Substance Abuse Harm Reduction Approaches SAMHSA holds a meeting of the Interdepartmental Substance Use Disorders Coordinating Committee (ISUDCC) on recommendations to HHS on how the federal government can further integrate and coordinate harm reduction approaches and strategies across the continuum of prevention, treatment, and recovery policies, programs, and practices. <u>Details</u>.
- 9:00am Member Day Hearing: Budget Process Reform The House Budget Committee holds a Member Day hearing on the budget process reform. <u>Details</u>.
- **11:00am HHS Meeting: HIV/AIDS Issues** HHS holds a meeting of the Presidential Advisory Council on HIV/AIDS to discuss reducing new HIV infections in the United States by 90% by 2030, addressing the needs of people aging with HIV, and other issues. <u>Details</u>.
- **11:00am A4H Discussion:** Accountable **Care** Accountable for Health (A4H) holds a discussion on state-based approaches to effective accountable care. <u>Details</u>.
- 2:00pm Hearing: White House Policy on AI The House Oversight and Accountability Subcommittee on Cybersecurity, Information Technology, and Government Innovations holds a hearing to examine the White House policy on artificial intelligence (AI). <u>Details</u>.
- 2:30pm Hearing: Fentanyl in Native Communities The Senate Indian Affairs Committee holds a hearing to examine fentanyl in Native communities, focusing on the federal response to the growing crisis. <u>Details</u>.

Thurs. (12/7)

• 8:30am – Hill Discussion: US Health Care Annual Checkup – The Hill holds a discussion on topics including the doctor shortage, rising health care costs, the consequences of an aging



population, new treatments for cancer and weight-loss drugs, and the role of AI in health care. Reps. Vern Buchanan (R-FL) and Robin Kelly (D-IL) will be attending. <u>Details</u>.

- 8:30am NIH Meeting: Reducing Cancer Care Inequities The National Institutes of Health (NIH) holds a meeting of the National Cancer Institute on reducing cancer care inequities, focusing on policy considerations at the intersection of technology and patient navigation. <u>Details</u>.
- 11:00am BPC Discussion: Direct Care Workforce Shortage The Bipartisan Policy Center (BPC) holds a discussion on the need for bipartisan policy reforms to address the shortage of direct care workers. <u>Details</u>.
- **12:00pm US News Discussion: Children's Hospitals –** The US News Hospital Data Insights and Research Triangle Institute (RTI) hold a discussion on the Best Children's Hospitals methodology's ongoing evolution and a preview of the 2024 survey cycle. <u>Details</u>.
- Meeting: MedPAC The Medicare Payment Advisory Commission (MedPAC) meets to discuss Medicare issues and policy questions. <u>Details</u>.

Fri. (12/8)

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Additional Multi-Day Events

- Dec. 5-Dec. 6 HRSA Meeting: Infant Mortality and Maternal Health The Health Resources and Services Administration (HRSA) holds a meeting of the Advisory Committee on Infant and Maternal Mortality (ACIMM) to discuss improving birth outcomes among American Indian/Alaska Native mothers and infants and updates on the federal Healthy Start program. <u>Details</u>.
- Dec. 6-Dec. 7 HRSA Meeting: Nurse Education/Practice HRSA holds a meeting of the National Advisory Council on Nurse Education and Practice to discuss program updates. <u>Details</u>.

Featured Analysis

- Impact Artificial Intelligence Policy Round Up In the Policy Hub Insight Bank here.
- Impact Regulatory Outlook: 2023 Unified Agenda In the Policy Hub Insight Bank here.
- Impact Updated Chart: PBM Legislation Under Consideration In the Policy Hub Insight Bank here.
- Impact Tracker of COVID-19 PHE Flexibilities In the Policy Hub Insight Bank here
- Impact Health Policy Guide to the 118th Congress In the Policy Hub Insight Bank <u>here.</u>

Congressional Lookback

Weds. (11/29)



- **The House Budget Committee** held a <u>hearing</u> to discuss legislative proposals that would establish a bipartisan, bicameral fiscal commission. <u>Details</u>.
- The House E&C Health Subcommittee convened a <u>hearing</u> to examine the potential benefits and risks of how AI being used in health care and how potential regulation could impact AI tools and algorithms. <u>Details</u>.

Regulatory Lookback

<u>Fri. (12/1)</u>

- **The GAO** released a <u>report</u> with updates on the CMS plan to include phosphate binders in the bundled payment for ESRD treatment. <u>Details</u>.
- The USDA FNS announced <u>two research-based funding opportunities</u> to develop a subgrant program related to the WIC Program. Applications are due February 14. <u>Details</u>.
- **The HHS OIG** released a <u>report</u> showing that some states made Medicaid capitation payments to MCOs on behalf of deceased enrollees. <u>Details</u>.

Weds. (11/29)

 HHS announced <u>measures</u> aimed at strengthening the nation's medical supply chain resilience. <u>Details</u>.

<u>Tues. (11/28)</u>

 The Tri-Departments released <u>Frequently Asked Questions (FAQs)</u> explaining how the batching requirements of the No Surprises Act (NSA) apply to the Federal Independent Dispute Resolution (IDR) process. <u>Details</u>.

<u>Mon. (11/27)</u>

• The FDA issued a <u>final rule</u> to amend its regulations regarding direct-to-consumer (DTC) advertisements for prescription drugs. <u>Details</u>.

Comment & Application Deadlines

- December 4: CMS released <u>new Medicaid information</u> and questions for public comment on mental health parity. <u>Details</u>.
- December 4: The Tri-Departments issued an <u>RFI</u> regarding commercial coverage of over-thecounter (OTC) preventive products. <u>Details</u>.
- December 11: The FDA announced the creation of the <u>Digital Health Advisory Committee</u>.
 <u>Details</u>.



- January 2: CMS and the ONC released a proposed rule to establish disincentives for providers who are determined to have committed information blocking. <u>Details</u>.
- January 5: CMS released the CY 2025 Policy and Technical Changes to the MA and Part D Programs proposed rule. Details.
- January 8: CMS released the HHS Notice of Benefit and Payment Parameters for <u>2025 proposed</u> rule. <u>Details</u>.
- January 12: The USDA announced <u>two new grant opportunities</u> and a training and technical assistance partnership to help schools continue to invest in nutritious school meals. <u>Details</u>.
- January 16: HHS announced the establishment of the Secretary's <u>Advisory Committee on Long</u> <u>COVID</u> and invites nominations for the Committee. <u>Details</u>.
- January 30: CMMI released an <u>RFA</u> for the GUIDE model. <u>Details</u>.
- February 5: CMMI released the <u>NOFO</u> for the Ahead Model. <u>Details.</u>
- **February 14:** The USDA FNS announced <u>two research-based funding opportunities</u> to develop a subgrant program related to the WIC Program. <u>Details</u>.
- March 6: CMMI announced the <u>State Advancing AHEAD Model</u> to address unsustainable health care cost growth, poor population health, and disparities in health outcomes. <u>Details</u>.

