With the House on recess this week, the time to make a legislative deal on raising the debt ceiling continues to shrink, with the most recent financial projections stating that the U.S. could surpass the debt ceiling as early as June 1. President Biden is scheduled to meet with House and Senate leadership on May 9 to discuss the issue. Both chambers are back in session next week and will need to move quickly after the meeting to pass legislation avoiding financial disaster. While the debt ceiling hangs in the balance, House and Senate Appropriations Committees are pushing forward on fiscal year (FY) 2024 federal funding bills, with both Committees in the final stages of drafting their own bills before consideration by individual Subcommittees later this month and in June. Senate Majority Leader Chuck Schumer (D-NY) also announced a new initiative this week to pass additional legislation focused on competition with China. The legislation would follow up last year’s enacted CHIPS and Science Act and focus on increasing protection from Chinese military and economic threats. Schumer and other Senators are currently seeking engagement and ideas from relevant stakeholders, and hope to draft the legislation over the coming months.

The University of Minnesota Washington Update provides intelligence and analysis on recent federal activities. Contact Jackson Clark, Lewis-Burke Associates LLC, at jackson@lewis-burke.com with any questions or comments related to the Update’s content.

**Policy Updates and Funding, Engagement Opportunities**

**Policy Update: CMS Issues Proposed Medicaid Rules**

The Centers for Medicare and Medicaid Services (CMS) issued two proposed rules for the Medicaid program. The first, *Ensuring Access to Medicaid Services*, relates to improving access to care, health outcomes, quality, and equity in Medicaid fee-for-service, managed care plans, and home and community-based services programs. The second, *Medicaid and Children’s Health Insurance Program Managed Care Access, Finance, and Quality*, focuses primarily on standards for timely access to care, and state monitoring and enforcement efforts.

The proposed rules follow major changes in Medicaid policy, such as continuous enrollment, coinciding with the wind-down of the COVID-19 Public Health Emergency (PHE). CMS characterized the expiration of the continuous enrollment condition authorized by the *Families First Coronavirus Response Act* (FFCRA) as “the single largest health coverage transition event since the first open enrollment period of the *Affordable Care Act*.” As a condition of receiving a temporary 6.2 percentage point Federal Medical Assistance Percentage (FMAP) increase under the FFCRA, states have been required to maintain enrollment of nearly all Medicaid

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**Policy Update: FDA Issues Draft Guidance on Decentralized Clinical Trials**

**Funding Opportunity: AFOSR Releases FY 2024 Young Investigator Program (YIP)**

**Engagement Opportunity: NSF Releases RFI to Inform Development of a TIP Roadmap**

**Engagement Opportunity: NIST Seeks Feedback on Cybersecurity Resources for Federally-Funded Higher Ed R&D**
enrollees. This continuous enrollment condition expired on March 31, 2023, and states now have 12 months to initiate and 14 months to complete renewals for all individuals enrolled in Medicaid, the Children’s Health Insurance Program (CHIP) and the Basic Health Program.

**Ensuring Access to Medicaid Services**

CMS is proposing to implement two Executive Orders (EO) signed by the President. The first, **EO 14009**, “Strengthening Medicaid and the Affordable Care Act,” seeks to protect and strengthen Medicaid and the Affordable Care Act (ACA) and make high-quality health care accessible and affordable for all Americans. The second, **EO 14070**, “Continuing to Strengthen Americans’ Access to Affordable, Quality Health Coverage,” calls for a review of agency actions to identify ways to continue expanding the availability of affordable health coverage, improve the quality of coverage, strengthen benefits, and help individuals enroll in quality health coverage.

The proposed rule would rename and expand the scope and use of states’ Medical Care Advisory Committees (MCAC) and require states to establish and operate the newly named Medicaid Advisory Committee (MAC) and a Beneficiary Advisory Group (BAG), a standalone group that would meet separately from the MAC. The BAG would include Medicaid beneficiaries, their family members, and/or their caregivers. CMS makes clear it is attempting to respond to comments it has received over the years for greater cultural competency in promoting health equity in Medicaid. The proposed rule would also establish minimum requirements for representation on the MAC, including those from the BAG, consumer advocacy groups, clinical providers or administrators, Medicaid managed care plans, and other state agencies serving Medicaid beneficiaries. In addition, the state could also consider members representing or serving Medicaid beneficiaries in the following categories: children’s health care; behavioral health services; preventative care and reproductive health services; health or service issues pertaining to people over the age of 65; and health or service issues pertaining to people with disabilities. CMS is proposing to require 25 percent of the MAC membership to be reserved for BAG members. CMS is also seeking to promote transparency and accountability between the state and stakeholders by making public MAC and BAG activities.

According to the proposed rule, CMS argued that “current regulations lack specificity related to how MCACs can be used to benefit the Medicaid program more expressly by more fully promoting the beneficiary voice. MCACs need to provide a forum for beneficiaries and people with lived experience with the Medicaid program to share their experiences and challenges with accessing health care.” The MAC and its corresponding BAG would serve as vehicles for bi-directional feedback between interested parties and the State on matters related to the effective administration of the Medicaid program.

**Medicaid and Children's Health Insurance Program Managed Care Access, Finance, and Quality**

CMS issued an additional rule in response to EO 14009 and EO 14070 to improve beneficiary access to care in Medicaid. The proposed rule would establish new standards for appointment wait times, use secret shopper and enrollee experience surveys, and require states to submit a managed care plan analysis of payments made by plans to providers for specific services to monitor plans’ network adequacy more closely.

The proposed rule, if finalized, would implement policies to reduce burden for states that choose to direct managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) in ways to use their capitation payments to pay providers specified amounts, address impermissible redistribution of Medicaid payments, and add clarity to the requirements related to medical loss ratio (MLR) calculations. MLRs are a tool CMS and states can use to determine whether capitation rates are
appropriately set by analyzing how much is spent on claims and quality improvement activities as opposed to administrative expenses.

The proposed rule also seeks to enhance transparency for beneficiaries and providers on state Medicaid websites, establish state requirements for implementing a Medicaid and CHIP quality rating system aimed to monitor the performance of Medicaid and CHIP managed care plans, and empower beneficiary choice in managed care. In addition to enhanced quality measures, CMS is continuing to seek improvements to its health equity efforts by working with states to improve measurements of health disparities through the stratification of state reporting on certain measures. CMS would like to identify potential differences in access, quality, and outcomes based on demographic factors like race, ethnicity, age, rural/urban status, disability, language, sex, sexual orientation, and gender identity, as well as social determinants of health.

Comments on both proposed rules are due by July 3, 2023.

Sources and Additional Information:
- The proposed rule on “Medicaid and Children’s Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality” is available at https://public-inspection.federalregister.gov/2023-08961.pdf.

Policy Update: FDA Issues Draft Guidance on Decentralized Clinical Trials
The Food and Drug Administration (FDA) issued draft guidance for industry, investigators, and other stakeholders providing recommendations for implementing decentralized clinical trials (DCTs) for drugs, biological products, and devices. The guidance is in response to the Food and Drug Omnibus Reform Act of 2022, included as part of the Consolidated Appropriations Act of 2023, which required the FDA to “issue or revise draft guidance with recommendations related to using decentralized clinical studies to support the development of drugs and devices, including how decentralized trials can help improve the diversity of the clinical trial population.”

Under the guidance, FDA provides recommendations to trial sponsors on:
- DCT Design;
- Remote Clinical Trial Visits and Clinical Trial-Related Activities;
• The use of digital health technologies to remotely acquire data in a DCT;
• The roles and responsibilities of sponsors and investigators;
• Obtaining informed consent and institutional review board oversight of the informed consent process;
• The appropriateness of investigational products;
• Packaging and shipping of investigational products;
• Monitoring the safety of trial participants; and
• Software used in conducting a DCT.

FDA recognizes that many clinical trials already have elements that do not take place in one location, and decentralizing clinical trial activities can allow sponsors to grow the diversity of their participants. The agency also acknowledges that the use of telehealth, remote monitoring, and other digital health technologies can enhance participation, reduce the burden of caregivers, and provide incentives for research into rare diseases.

FDA believes fully decentralized trials are appropriate for investigational products that are simple to use, have well understood safety profiles, and do not require complex medical assessments. However, the agency believes hybrid decentralized trials may be more appropriate when the administration of the product requires a more complex medical assessment performed at a clinical trial site, with some follow-up assessments performed remotely through online patient-reported outcomes, via telehealth, or by a patient’s local health care provider.

Comments and suggestions regarding the draft guidance should be submitted to https://www.regulations.gov/ within 90 days.

Funding Opportunity: AFOSR Releases FY 2024 Young Investigator Program (YIP)

The Air Force Office of Scientific Research (AFOSR) released its fiscal year (FY) 2024 funding opportunity announcement (FOA) for the Young Investigator Program (YIP). This program provides early career university faculty, scientists, and engineers who have shown promise for conducting basic research the opportunity to work with the Air Force and Space Force to further its research and development mission. This popular program is also offered by other Department of Defense (DOD) agencies, such as the Army Research Office (ARO), the Office of Naval Research (ONR), and the Defense Advanced Research Projects Agency (DARPA) through their Young Faculty Program.

AFOSR will only accept proposals that pursue research in its outlined research interest areas. A full list of the areas of interest to AFOSR and the relevant Program Officer to contact for questions and inquiries can be found in AFOSR’s open broad agency announcement (BAA) here. YIP proposals can only be submitted for one research area.

Due Date: Technical and eligibility questions should be submitted no later than May 15, 2023. White papers must be submitted to the program in the applicant’s research area by June 12, 2023. Full proposals are due by August 14, 2023.

Total Funding and Award Size: Individual awards will be funded at a maximum of $150,000 per year for a three-year base period, for a total maximum of $450,000. Exceptional proposals will be considered for higher funding levels and longer durations. AFOSR anticipates making 36 awards.
Eligibility and Limitations: This FOA is for individual early career university faculty, scientists, and engineers who have received a Ph.D. or equivalent degree on or after April 1, 2016. Proposers must be a U.S. citizen, national, or permanent resident. The award associated with this FOA will be issued in the form of a grant to U.S. institutions of higher education. U.S. nonprofit research organizations, for-profit research organizations, and industrial laboratories are also eligible if the principal investigator (PI) is a full-time employee and holds a non-contractor position.

Sources and Additional Information:
- The Full FOA, with more information on eligibility, submission information, and contact information, is available on [www.grants.gov](http://www.grants.gov) under solicitation number “FOA-AFRL-AFOSR-2023-0011.”

Engagement Opportunity: NSF Releases RFI to Inform Development of a TIP Roadmap
The National Science Foundation (NSF) released a request for information (RFI) seeking input on a roadmap for the Technology, Innovation, and Partnerships (TIP) Directorate. The roadmap will focus on directions for the Directorate to make investments in use-inspired and translational research over a three-year period with the goal of securing U.S. competitiveness in the ten key technology focus areas identified for TIP in the CHIPS and Science Act of 2022:

- “Artificial intelligence, machine learning, autonomy, and related advances;
- High performance computing, semiconductors, and advanced computer hardware and software;
- Quantum information science and technology;
- Robotics, automation, and advanced manufacturing;
- Natural and anthropogenic disaster prevention or mitigation;
- Advanced communications technology and immersive technology;
- Biotechnology, medical technology, genomics, and synthetic biology;
- Data storage, data management, distributed ledger technologies, and cybersecurity, including biometrics;
- Advanced energy and industrial efficiency technologies, such as batteries and advanced nuclear technologies, including but not limited to for the purposes of electric generation; and
- Advanced materials science, including composites 2D materials, other next-generation materials, and related manufacturing technologies.”

Responses should also consider the related societal, national, and geostrategic challenges related to “national security, manufacturing and industrial productivity, workforce development and skill gaps, climate change and environmental sustainability, and inequitable access to education, opportunities, and services.”

The RFI is calling for input on the following topic areas in particular:

- Prioritization: What evidence is available to determine priorities across the key technology areas to advance U.S. competitiveness? Within each technology area, which use-inspired or translation topic areas should be prioritized by NSF and why?
- Suitability: Which technologies or related topics are best fit to be supported by TIP? What kind of funding mechanisms or processes would have the greatest impact on advancing such technology?
- Workforce: What key technologies will have the most pressing or urgent workforce needs within the next one to five years? How could TIP structure programs or pathways to meet growing workforce needs?
demands in the U.S.? How can TIP collaborate with other government organizations and industry to ensure efforts to meet workforce needs are actually addressing needs in the key technology areas and societal challenges, while broadening equity and inclusion?

- Addressing societal challenges: Which of the key technology areas should receive investment priority and why, especially when considering ways the key technology areas will impact societal, national, and geostrategic challenges?
- Additions: Are there technology areas that TIP should be prioritizing in the near term that is not included in the above key technologies list, and why should they be included?
- Crosscutting Investments: What investments in translational research should TIP make to meet critical needs that are commonly found across the key technology focus areas?
- Are there other relevant topics that should be considered to develop a TIP roadmap?

Responses are due by **July 27, 2023**, and can be sent to TIPRoadmap-RFI@nsf.gov. The full RFI can be found [here](#).

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**Engagement Opportunity: NIST Seeks Feedback on Cybersecurity Resources for Federally-Funded Higher Ed R&D**

The National Institute of Standards and Technology (NIST) issued a Request for Comment seeking information on cybersecurity risks related to conducting research at institutions of higher education. The *CHIPS and Science Act of 2022* included provisions that require NIST to “disseminate and make publicly available resources to help qualifying institutions of higher education identify, assess, manage, and reduce cybersecurity risks related to conducting research.” Following public comments, NIST will develop potential cybersecurity resources (e.g., white papers, quick start guides, etc.) that could address the identified challenges.

Specifically, NIST is seeking feedback on the following questions from institutions of higher education (and other interested organizations) related to potential cybersecurity resources and research areas:

1. “What common cybersecurity challenges and risks does your institution face when conducting research?
2. Does your institution face unique cybersecurity challenges and risks associated with certain types of research, for example, microelectronics or other areas of science and technology?
3. How is your institution identifying, assessing, managing, and reducing cybersecurity risks related to conducting research?
   a. How do NIST resources support cybersecurity risk management in your institution?
   b. What other resources does your institution leverage to support cybersecurity risk management?
4. Are existing resources sufficient and effective? If not, why?
5. What new resources or areas of further research might address common cybersecurity challenges and risks faced by faculty or researchers, students, academic or research affairs offices, and personnel with enterprise risk management responsibilities (e.g., Chief Information Officers, Chief Information Security Officers, Chief Privacy Officers, Chief Compliance Officers, Chief Risk Officers, and others)?
   a. What role might NIST play in providing resources and research to address common cybersecurity challenges and risks faced by these communities?
b. Who should be involved in the development of these resources and research (e.g., researchers with institutional affiliation, research cybersecurity subject matter experts, or other associations or groups)?

Feedback and comments, which will become part of public record, should be sent to cyber4R&D@nist.gov via this form by June 30, 2023. More information can be found at https://www.nist.gov/cybersecurity/cybersecurity-rd-request-comment and https://www.nist.gov/cybersecurity/cybersecurity-rd.

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