

Legislative/Regulatory Overview
Health Ethics Trust Compliance Conference

May 4, 2022

Congressional Update

- Congress returned last week following a two-week recess in the middle of April to a busy work period. The Senate is now in session until the Memorial Day recess week and the House will take another one week break next week followed by a work period through the end of the month as well.
- It will be a busy month on the health care front. Bipartisan negotiators in the Senate recently reached an agreement to provide roughly \$10 billion in supplemental funding for COVID tests, therapeutics and vaccines before the April recess, but have thus far been unsuccessful in passing it due to internal divisions over allowing an amendment addressing public health border powers (i.e. the Administration's decision to suspend Title 42).
- However, a new request from the Administration to provide supplemental funding for Ukraine may provide a vehicle for the COVID supplemental yet this month.

Congressional Update: Omnibus Appropriations Bill

- Funds government through September 30, 2022.
- Includes \$13.6B in aid to Ukraine.
- COVID relief was dropped from final package, but efforts underway to try to pass it separately.
- Does not include sequester relief so the Medicare cuts will kick in on April 1 at 1% and the full amount of 2% takes effect July 1.

Congressional Update: Omnibus Appropriations Bill

Telehealth Provisions

The legislation includes provisions to extend and expand telehealth flexibilities for 151 days after the end of the COVID-19 public health emergency. These include:

- Expanding originating site to include any site at which the patient is located, including the patient's home;
- Expanding eligible practitioners to furnish telehealth services to include occupational therapist, physical therapist, speech-language pathologist and audiologist;
- Extending the ability for federally qualified health centers (FQHCs) and rural health clinics (RHCs) to furnish telehealth services;
- Delaying the 6-month in-person requirement for mental health services furnished through telehealth until 152 days after the emergency, including the in-person requirements for FQHCs and RHCs;
- Extending coverage and payment for audio-only telehealth services;
- Extending the ability to use telehealth services to meet the face-to-face recertification requirement for hospice care; and
- Requiring the Medicare Payment Advisory Commission to conduct a study on the expansion of telehealth services and to require the Department of Health and Human Services (HHS) Secretary to publicly post data with respect to telemedicine utilization.

Congressional Update: Omnibus Appropriations Bill

Maternal Health Provisions

Maternal Health Quality Improvement

- The legislation would provide for Public Health Service Act grants to develop and disseminate best practices with authorization of \$45 million for 2023-2027;
- accredit health professional schools to train health care professionals about perceptions and biases with authorization of \$15 million for 2023-2027;
- support states and tribal organizations for integrated health care services with authorization of \$50 million for 2023-2027;
- and instruct HHS to include pregnant and postpartum women as part of their public awareness campaign.

Improving Rural Maternal and Obstetric Care Data

This provision would amend the Public Health Service Act to improve rural maternal and obstetric care data collection and care networks with authorization of \$15 million for 2023-2027, as well as establishes grants to support health care professional training and telehealth resources with authorization of \$25 million for 2023-2027.

Congressional Update: Omnibus Appropriations Bill

Medicaid Provisions

Extended Increased FMAP for Territories

- This provision would extend the increased Federal Medical Assistance Percentage (FMAP) for the five U.S. territories through Dec. 13, 2022. Historically, the territories FMAP was 55%. This provision would maintain Puerto Rico's increased FMAP at 76%, and maintain increased FMAP for the Virgin Islands, Guam, Northern Mariana Islands and American Samoa at 86%. The section also would increase Puerto Rico's federal allotment by \$200 million for fiscal year (FY) 2022.

Increasing State Flexibility with Respect to Third Party Liability

- This provision would provide state Medicaid programs with an enforcement mechanism to address third party liability for care provided to a Medicaid beneficiary. A large proportion of Medicaid beneficiaries have third party sources of insurance coverage and for these beneficiaries the third-party source of coverage must pay for care provided before the Medicaid program will pay. This provision strengthens the Medicaid program enforcement to seek recovery for issued Medicaid payments. In addition, this provision applies to all potential denials on the part of commercial plans, including prior authorization denials, by not allowing commercial health plans to avoid payment by saying that the service failed prior authorization if the state had waived prior authorization for the same service.

Congressional Update: Omnibus Appropriations Bill

340B Eligibility Exceptions due to COVID-19 Public Health Emergency

- The legislation would protect certain 340B hospitals that lost their 340B eligibility due to a drop in their disproportionate share hospitals (DSH) adjustment percentage below the required threshold for 340B eligibility to gain limited access to the program.
- Access to the 340B drug discounts would be available only from the date of the bill's enactment through the end of 2022 and not retrospectively.
- This exception would apply only to 340B hospitals actively participating in the 340B program from the day prior to the start of the COVID-19 public health emergency (Jan. 31, 2020) and who subsequently lost eligibility during the cost reporting periods of 2020, 2021, and ending Dec. 31, 2022.
- Hospitals qualifying for the exception would be required to attest to the HHS Secretary that the reason for their loss of 340B eligibility was the result of “any actions taken by or other impact on such hospital in response to or as a result of the COVID-19 public health emergency that may have impacted the ability to meet the applicable requirement for the disproportionate share adjustment percentage.”

Congressional Update: Omnibus Appropriations Bill

Cybersecurity

- The legislation would require critical infrastructure sectors, including hospitals and health systems, to report cyber incidents within 72 hours and any ransomware payments made within 24 hours to the Cybersecurity and Infrastructure Security Agency at the Department of Homeland Security. Currently, hospitals and health systems are required to report cyber breaches affecting more than 500 people to the Office of Civil Rights at HHS “without unreasonable delay” and “no later than 60 calendar days from the breach.”
- More time is provided for reporting incidents affecting less than 500 people. The legislation would allow for some exemptions for certain entities that already report similar information on a similar timeline.

Congressional Update: Omnibus Appropriations Bill

The omnibus appropriations bill would provide \$1.5 trillion in discretionary spending for FY 2022. The package would fund various health-related agencies at the following levels, many of which reflect new investments in areas of interest for hospitals and health systems:

HHS: \$108.3 billion in total spending, an increase of \$11.3 billion. As part of this appropriation, Congress would establish and/or fund the following agencies, among others:

- **Centers for Medicare & Medicaid Services:** \$4 billion in total spending, an increase of \$50 million.
- **Advanced Research Projects Agency for Health (ARPA-H):** \$1 billion to establish ARPA-H with the intent of accelerating the development of scientific breakthroughs for diseases such as ALS, Alzheimer's disease, diabetes and cancer.
- **National Institutes of Health:** \$45 billion, an increase of \$2.25 billion with a particular focus on investments in research to address cancer, HIV and dementia, among other conditions.
- **Centers for Disease Control and Prevention:** \$8.5 billion, an increase of \$582 million, with a particular emphasis on improving the nation's public health infrastructure, including data collection and monitoring.
- **Substance Abuse and Mental Health Services Administration:** \$6.5 billion, an increase of \$530 million to invest in a number of mental health programs, including those particularly targeted at children and youth.
- **Health Resources and Services Administration:** \$8.9 billion, an increase of \$1.4 billion, to improve access to care in underserved communities, develop the workforce, and improve maternal and child health outcomes.

Congressional Update: Omnibus Appropriations Bill

Separately, the legislation also would increase funding for the Food and Drug Administration (FDA) and the Federal Emergency Management Agency (FEMA):

- **FDA:** \$3.3 billion, representing an increase of \$102 million with new investments to address the opioid crisis, improve medical supply chain surveillance, facilitate the development of treatments for rare cancers and accelerate medical product development as authorized in the 21st Century Cures Act.
- **FEMA:** \$23.9 billion, representing an increase of \$2.19 billion with a particular focus on disaster response and recovery efforts.

Congressional Update: Committee Activity

- Key health care committees are continuing their work on the reauthorization of FDA user fees, behavioral and mental health, and the Administration's budget requests.
- The Senate HELP Committee and House Energy and Commerce Committee are working to produce a bipartisan package on user fees and are aiming to complete the legislative process sometime this summer.
- The Senate Finance Committee is engaged on mental and behavioral health, hoping to eventually produce a bipartisan work product.
- Insulin pricing also remains a legislative priority for many, with the House having passed a bill in April and Senate conversations continuing this month.

Congressional Update: Other Priorities

- **Build Back Better Act:** most Congressional Democrats, and the White House, would like to get an agreement on a piece of legislation that could pass before the reconciliation instruction (the legislative tool that Democrats would use to move the bill through the Senate by simple majority vote) expires on September 30, 2022.
- As the midterm election approaches, the political climate for legislating will become increasingly difficult, although there is an expectation that a final effort to reach an agreement will ensue.
- Senator Manchin continues to be in discussions with Senate leadership and the White House regarding what he is willing to agree to in terms of content. Right now, it is unclear what, if any health care provisions will be included.

Biden Administration Mental Health Initiative

On March 1, 2022, President Biden announced a [comprehensive mental health initiative](#)

- **Renewed commitment to mental health parity.** Biden's fiscal 2023 budget, expected later this month, will strengthen insurance network adequacy standards to enhance access to behavioral health professionals and require insurers to cover three visits a year without cost-sharing. This will build on the administration's ongoing efforts, including pending regulations stemming from existing mental health parity laws and stepped up enforcement against insurance companies not complying with those statutes.
- **Better integration of behavioral and physical health.** Biden proposed doubling the budget for programs that link primary care and behavioral health. The Health and Human Services Department will test behavioral health integration payment models and authorize Medicaid to pay for inter-professional consultations so primary care providers can coordinate with mental health specialists on patient care.

Biden Administration Mental Health Initiative

- **Bolstering the mental health workforce.** The budget will call for \$700 million to fund training, scholarships and loan repayment programs for clinicians committed to working in rural and underserved communities. Biden also will propose additional funds to develop provider capacity and support mental health transformation. The White House will ask Congress to make the Certified Community Behavioral Health Clinics program permanent and to extend funding for Community Mental Health Centers. Later this year, HHS will distribute more than \$225 million for training programs to build the workforce in underserved areas and continue grant programs to support burnout prevention.
- **Increased telehealth accessibility.** Biden will request legislation to promote insurance coverage of remote behavioral health services, including allowing providers to virtually practice across state lines. The Office of Personnel Management will encourage carriers covering federal employees to boost reimbursements and reduce out-of-pocket costs for telehealth visits with behavioral health professionals.
- **Continued focus on youth mental health.** The administration plans a series of initiatives to improve youth mental health, including removing barriers for providers to get Medicaid reimbursement. The 2023 budget will recommend \$1 billion to help schools hire more mental health staff, propose more than \$70 million for infant and early childhood mental health programs, and call for more funding for schools that provide wrap-around services including mental health support to families. Biden will request that Congress ban excessive data collection on and targeted online advertising for children.

Other Biden Administration Priorities

Nursing Home Reform

In his SOTU, President Biden also announced a [set of comprehensive nursing home reform measures](#). This includes:

- greater oversight of nursing home ownership, particularly the role of private equity
- minimum staffing requirements for nursing homes,
- reducing room crowding by promoting single-occupancy rooms, and
- reinforcing measures to limit unnecessary treatments and medications, including antipsychotics.

Other Biden Administration Priorities

Addressing Addiction and the Opioid Epidemic

Another SOTU priority included efforts to address [addiction and the overdose epidemic](#). This would be accomplished by:

- increased investments in prevention, treatment, harm reduction, and recovery programs,
- removing barriers for treatment, and
- eliminating the requirement that providers receive a waiver prior to prescribing buprenorphine. In 2021, a bipartisan group of lawmakers in both the House and Senate introduced the Mainstreaming Addiction Treatment Act of 2021 to eliminate the waiver requirement.

Other Biden Administration Priorities

Cancer Research

- The president also urged Congress to pass legislation to fund his proposed Advanced Research Projects Agency for Health to advance the administration's Cancer Moonshot Initiative goals of cutting the cancer death rate by at least 50% in the next 25 years, in addition to accelerating progress against Alzheimer's disease, diabetes, and other health threats.
- Creating a Cancer cabinet to advise on these issues.
- Encouraging Congress to pass additional funding to support these efforts.

Administration Update: Public Health Emergency (PHE)

- Current PHE extended for an additional 90 days effective April 16, 2022 ending July 15, 2022.
- Beginning to be discussions about the end of the PHE as early as July 15 assuming current PHE is extended another 90 days.
- Highly unlikely to end before then, but administration may choose to end it then to send a signal the pandemic is moving into endemic stage.
- Still expected to give providers at least 60 days notice prior to end of PHE.
- CMS issued [guidance to states](#) on March 3 regarding redeterminations of Medicaid beneficiary eligibility for when the public health emergency (PHE) ends. The new guidance provides planning and reporting tools to assist states as they transition back to pre-PHE Medicaid eligibility and enrollment operations at the end of the PHE. The guidance seeks to promote continuity of coverage and facilitate transitions between Medicaid, the Children's Health Insurance Program, the Basic Health Program, and the Health Insurance Marketplaces.
- The updated guidance will allow states to initiate, rather than complete, redeterminations during the 12-month unwinding period to reestablish a regular schedule of renewals. Additionally, states will be provided an extra two months before they initiate terminations to start the renewal process and until the end of the 14th month to complete all renewals, post-enrollment verifications, and redeterminations based on changes in circumstances.

Administration Update: Public Health Emergency

- CMS is already planning for education and outreach to providers to ensure there is ample lead time for them to prepare before the end of the PHE.
- PHE flexibilities end at midnight on the day the PHE expires.
- CMS and HHS-OIG will be performing a lot of post pandemic oversight to ensure that providers do not game the system. Expect lots of audits in the months following the end of the PHE.
- Providers are going to need to be very vigilant on compliance issues related to PHE flexibilities.
- CMS has [started to rescind](#) some of the 200 plus blanket Medicare waivers they issued with an eye to phasing out those that are no longer needed now that the pandemic is starting to wane. CMS has completed their review of all the existing waivers and has a plan for which ones will be grandfathered, phased out or continued either through regulation and/or statute.

Pandemic Oversight

In his SOTU, Biden announced that the Justice Department will name a chief prosecutor for pandemic fraud. The prosecutor will lead teams of specialized prosecutors and agents focusing on major targets of pandemic fraud, such as those committing large-scale identify theft, as well as investigate major cases of criminal fraud in programs like the Paycheck Protection Program and Unemployment Insurance. It is not clear when the Justice Department will appoint someone to the role.

Administration Update: Payment Rules

- All of the CMS Part A payment rules (Inpatient, Outpatient, ESRD, Hospice) are out in draft for comment.
- Part B payment rules (Physician Fee Schedule, Home Health) are starting to go to OMB for review.
- CMS last week released the 2023 Notice of Benefits and Payment Parameters Final Rule (final 2023 Payment Notice). The rule makes changes in the individual and small group health insurance markets and establishes parameters and requirements issuers need to design plans and set rates for the 2023 plan year. The rule also includes regulatory standards to help states, the Marketplaces, and health insurance companies in the individual and small group markets better serve consumers. A fact sheet on the rule can be found [here](#). Of particular note are the focus on network adequacy and the significant focus on health equity.
- All rules will include a health equity component.
- Also expect more of a focus toward a shift toward value based care.

Administration Update: CMMI Models

- Accountable Care Organization Realizing Equity, Access, and Community Health ([ACO REACH](#)) model officially replacing the direct contracting model.
- Goal is to better align the name with the purpose of the model: to improve the quality of care for people with Medicare through better care coordination, reaching and connecting health care providers and beneficiaries, including those beneficiaries who are underserved.
- Current version of program ends 12/31/22. New program starts 1/1/23 and [new applicants](#) for the program are now being solicited.
- A comparison chart of the new and old models can be found [here](#).

Administration Update

- CMS recently proposed a rule on [Medicare special enrollment periods](#), aiming to eliminate coverage gaps and improve Medicare access by allowing Medicare coverage to kick in the month after enrollment.
- CMS also [dropped its challenge](#) to the Texas Medicaid Waiver, allowing Texas hospitals to retain uncompensated care funds.
- Additionally, building on coverage and equity goals, CMS recently released an outline of its [health equity plan](#) seeking to address disparities.

Administration Update: CMS Vaccination Rule

How will CMS ensure compliance?

- CMS will work with state survey agencies to conduct on-site compliance reviews for the requirements via recertification surveys or complaint surveys.
- Accrediting organizations such as the Joint Commission will also assess facilities' compliance.
- Facilities found out of compliance with the regulation will be cited and have an opportunity to comply. If hospitals fail to comply, CMS may use enforcement remedies, including civil monetary penalties, denial of payment and termination from the Medicare and Medicaid programs, as a final measure.

CMS FAQs on Vaccine Mandate:

<https://www.cms.gov/files/document/cms-omnibus-covid-19-health-care-staff-vaccination-requirements-2021.pdf>

OSHA Emergency Temporary Standard Rule

- The U.S. Department of Labor's Occupational Safety and Health Administration is withdrawing the vaccination and testing emergency temporary standard issued on Nov. 5, 2021, to protect unvaccinated employees of large employers with 100 or more employees from workplace exposure to coronavirus. The [withdrawal](#) is effective January 26, 2022.
- Although OSHA is withdrawing the vaccination and testing ETS as an enforceable emergency temporary standard, the agency is not withdrawing the ETS as a proposed rule. The agency is prioritizing its resources to focus on finalizing a permanent COVID-19 Healthcare Standard.
- OSHA has stated it is strongly encouraging vaccination of workers against the continuing dangers posed by COVID-19 in the workplace. The official notice can be found here: [COVID-19 Vaccination and Testing ETS | Occupational Safety and Health Administration \(osha.gov\)](#).

Health Policy Priorities for 2022

- Telehealth services : audio only communications, geographic restrictions, site of service (home v office), state licensure requirements for providing Medicare services in states with similar requirements and also waiving Medicaid licensing requirements. Congressional and administrative efforts to extend all or some of these flexibilities post PHE.
- Health equity/improving data: Equity in health outcomes remains a top priority for the Administration and Congress driven by the pandemic's disproportionate impact on low income and historically marginalized groups. Continued push for racial and ethnic data for COVID-19 cases and data on social needs critical to understanding disparities. Several congressional bills to address disparities including maternal morbidity and mortality. CMMI has stated they will be creating new alternative payment models which will make equitable health outcomes a central pillar of its new strategy.

Health Policy Priorities for 2022

- **Mental Health:** CMS already made substantial changes to the provision of mental health services via telehealth in last year's physician fee schedule. Additional changes likely in the next round of payment rules to expand mental health coverage. Congress is actively pursuing new policies in mental health through the Senate Finance Committee.
- **Value-based care:** CMMI has made it clear they want ALL Medicare beneficiaries and the vast majority of Medicaid beneficiaries in an accountable care relationship with a provider by 2030. The current strategy released by CMMI indicates that new models will be simpler, fewer and mandatory. They have been publicly supportive of direct contracting and making improvements to that program. However, pushback from House Democrats of the direct contracting program will be an area to watch depending on how much traction that effort gains.

Health Policy Priorities for 2022

- **Medicare Advantage:** 1/1/22 enrollment numbers show that enrollment in MA has increased 8.8% since a year ago. Based on current projections, enrollment in 2022 will likely surpass the federal government's prediction of 29.5 million people. CBO has predicted that enrollment in MA is set to increase from 37% to 50% of Medicare eligible adults by 2029 or sooner. This means MA is fast becoming the program of choice for innovation by integrating social determinants of health more directly in care management. CMS will be watching closely how entities are doing in terms of ensuring appropriate care coordination and managing of MA enrollee medical risks. HHS OIG will also be watching as they recently identified over \$140 billion in systemic upcoding among MA plans. CMMI has said it will address risk adjustment in its future models.
- **Drug Pricing:** BBB has several proposals for addressing drug pricing. If BBB does not pass then CMMI will be looking to create models to address what they can do administratively to curb rising drug costs.

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