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Insights This Week: Administration Unveils Inflation Reduction Act Implementation Timeline and Renews the Public Health Emergency

This Week's Content:

Congress

House Elects Speaker, Completes Organizing Activities

After 15 ballots and widespread GOP intraparty conflicts to kick off the new session of Congress, Rep. Kevin McCarthy (R-CA) was elected Speaker of the House of Representatives for the 118th Congress. The issues that Speaker McCarthy faced in winning support from his caucus foreshadow the challenges that the new Republican House majority will likely face in this Congress—namely, garnering cohesive, reliable support from a razor-thin majority with opinionated and vocal factions within his caucus.

This week the House finalized its rules for this session of Congress. Notably, the new rules (H. Res. 5) establish a new investigative subcommittee—the "Select Subcommittee on the Coronavirus Pandemic." This subcommittee is tasked with conducting a "full and complete investigation" into the pandemic, including its origins; effectiveness and transparency of the use of taxpayer funds; "societal impact of decisions to close schools"; and "executive branch policies, deliberations, decisions, activities, and internal and external communications related to the coronavirus pandemic." The House rules dictate that the Speaker will appoint 12 members, of whom "not more than 5 shall be appointed in consultation with the Minority Leader," and require the subcommittee to submit a report by January 2, 2025.

In addition to finalizing the House rules, House Republicans concluded committee leadership appointments this week. Rep. Jason Smith (R-MO) was appointed the new chair of the powerful House Ways & Means Committee (responsible for tax policy, Social Security, Medicare, and other topics). The outcome of the race for this post was largely seen as part of Speaker McCarthy's concessions to conservative members of his party. Though Rep. Smith is not a member of the Freedom Caucus himself, he leans more conservative than some of the other members who were in contention for the position.

Executive Branch

Biden Administration Releases Updated Regulatory Agenda, Signaling 2023 Priority Areas

Last week, the Administration released the Fall 2022 Unified Agenda (the regulatory agenda),[1] which provides an overview of rulemaking activity that the Administration intends to pursue over the course of the next year, providing an update on still outstanding rules included in previous agendas, while outlining new priorities for the year ahead.

The Department of Health and Human Services (HHS) agenda and plan are organized around the same policy priorities that have guided HHS and the Centers for Medicare & Medicaid Services (CMS) thus far under President Biden, such as expanding access to affordable health

[1] Agencies are required to publish a "Regulatory Plan" once a year in the fall and a "Unified Agenda of Regulatory and Deregulatory Actions" in the spring and fall.

care coverage, promoting health equity, mitigating health disparities, enhancing the affordability of prescription drugs, and extending flexibilities to continue to improve access to behavioral health treatment. The agenda updates timelines for release of certain rules that were included in previous agendas, such as a proposed rule to advance CMS' goals of improving access to both coverage and care in Medicaid and the Children's Health Insurance Program (CHIP) and a proposed rule to amend the regulatory definition of "short-term, limited-duration insurance," aiming to ensure that this type of coverage does not undermine the Affordable Care Act (ACA) protections (both now slated for April 2023). The agenda also includes new rulemaking, such as a forthcoming proposal to resolve Medicare payments retroactively owed to hospitals for drugs acquired through the 340B program in light of the Supreme Court's decision in *American Hospital Association v. Becerra*.

Manatt on Health will provide additional detail on the fall regulatory agenda in the coming days.

HHS Unveils Timeline for First Year of the Inflation Reduction Act's Medicare Drug Price Negotiation Program

HHS unveiled an implementation timeline and related materials for the Inflation Reduction Act's (IRA) first season of drug price negotiations. These materials do not fully detail how CMS will select and negotiate the prices for ten drugs under IRA's Medicare Drug Price Negotiation Program, and instead lay out a timeline for the development of policies leading up to the statute's mandated September 1, 2023 selected drug publication date.

The timeline sheds some light on CMS' thinking with regard to IRA implementation. CMS is permitted to implement the negotiation program through program instruction, and the agency confirms that it will be releasing such program guidance this spring. In a nod to requests for transparency and public engagement, CMS notes that it is committed to releasing this guidance in draft form and allowing a 30-day public comment period before revising and finalizing the guidance, even though these steps are not required under IRA.

CMS' materials also detail that the agency will be publishing three new information collection requests (ICRs) in order to implement the law. The first is a mechanism for collecting information from manufacturers to determine which manufacturers qualify for IRA's exemption from negotiation for small biotech companies; the information must be submitted to CMS in summer of 2023 by companies wishing to claim exempt status. The second is an ICR for negotiation data elements, pursuant to which manufacturers selected for negotiation will submit information CMS is required to consider in the course of its negotiation. This ICR will also allow the public to voluntarily submit data for consideration in the negotiation process when "related to evidence about alternative treatments." Finally, CMS will be creating a process for the exchange of offers and counteroffers between CMS and manufacturers of selected drugs. Each of these ICRs will be published in advance draft form by CMS with a 60-day

comment period, then revised, released again with a 30-day comment period, and finally approved by the Office of Management and Budget pursuant to the Paperwork Reduction Act.

The timeline itself is generally high-level, categorizing the implementation steps that are projected to occur in winter, spring, and summer of this year, rather than setting forth clear dates. As currently planned by CMS, the timeline leading up to September 1, 2023, is as follows:

- **Winter 2023:** ICR for small biotech exception published with a 60-day notice and public comment period
- **Spring 2023:**
    - Initial guidance for the Medicare Drug Price Negotiation Program initial price applicability year 2026 with a 30-day comment period
    - ICR on negotiation data elements published with a 60-day notice and public comment period
    - ICR for negotiation offer and counteroffer exchange published with a 60-day notice and public comment period
- **Summer 2023:**
    - Revised guidance for the Medicare Drug Price Negotiation Program initial price applicability year 2026 published
    - Deadline for request by a manufacturer of a biosimilar biological product for a delay in the selection of the reference biological product for negotiation due to high likelihood of biosimilar market entry
    - Deadline for submission to qualify for small biotech exception for initial price applicability year 2026

HHS Extends Public Health Emergency Declaration

Effective January 11, HHS has once again extended the public health emergency (PHE) declaration for COVID-19. While the Consolidated Appropriations Act, 2023, unlinked several policies from the PHE's end date—including the Medicaid continuous coverage requirements and the telehealth flexibilities[2]—a number of temporary regulatory flexibilities remain associated with the PHE's timeline, including emergency use authorizations (EUAs) authorized by the Food and Drug Administration (FDA); Section 1135 waivers that relax federal

[2] For more on the policies in the Consolidated Appropriations Act, 2023, please see the *Manatt on Health* analysis of the legislation.

requirements for health care providers and state Medicaid programs; and several flexibilities for skilled nursing facilities and swing beds. For more details on the federal flexibilities associated with the PHE, see *Manatt on Health*'s latest update to Expiration Timelines for Key Federal Emergency Measures Implemented During the COVID-19 Pandemic.

Despite speculation, HHS did not provide any indication in the renewal notice about the potential end of the PHE. Many stakeholders believe that this will be the final renewal, in which case HHS would notify providers and states of its intent to terminate the PHE in February, in accord with repeated promises to provide 60 days' notice ahead of the PHE's end date.

HHS OIG Publishes Reports and Recommendations on Improvements to Calculating Average Sales Price

In December, HHS Office of the Inspector General (OIG) published two reports regarding needed improvements to pharmaceutical manufacturer calculation of average sales price (ASP). Manufacturers report ASP to CMS, and those reported amounts are used to calculate the reimbursement rates for many drugs under Medicare Part B. Total reimbursement for Part B drugs, which are typically injected or infused in doctors' offices and hospital outpatient settings, totaled more than $40 billion in 2020.

In one report, OIG surveyed manufacturers of the 30 highest-spend drugs under Part B about how they calculate ASP for those drugs. OIG noted that CMS guidance for calculation of ASP has been significantly more limited than the agency's guidance for two other pricing metrics—best price and average manufacturer price (AMP). OIG said CMS guidance could help address confusion on various price reporting issues that were uncovered by the survey, such as whether sales to the TRICARE retail pharmacy program should be included in ASP calculations, the definition of bona fide service fees, how to calculate ASP for sales made to the U.S. territories, how value-based purchasing agreements impact the calculation of ASP, and whether rebates paid to CMS for drug wastage would impact ASP. The report separately found that the relationship between wholesale acquisition cost (WAC) and ASP varies significantly among the 30 highest-expenditure drugs, with ASPs ranging from .5% to 68% below WAC.

In a separate report, OIG concluded that gaps in CMS' oversight of the ASP system have resulted in millions of dollars in additional costs to the Medicare program. For example, CMS failed to timely identify that several drugs should have been paid based on 103% of AMP, lower than the typical amount of 106% of ASP. OIG also noted that nearly one-quarter of drugs code payment amounts were associated with a missing National Drug Code and that CMS does not indicate whether the lack of data is based on valid or invalid reasons. OIG indicated that in some instances the missing data may result in an inflated ASP, resulting in higher costs to both the Medicare program and Medicare beneficiaries. OIG recommended that CMS strengthen its internal controls to improve the accuracy of Part B drug payments.

CMS Issues New Guidance to Support Unwinding in Light of the CAA

On January 5, CMS released guidance to states on Section 5131 of the recently enacted Consolidated Appropriations Act, 2023 (CAA) that provides a fixed end date of March 31, 2023, for the Medicaid continuous coverage requirement; gradually phases down the enhanced federal match; and establishes new guardrails for mitigating coverage loss for individuals who continue to be eligible (see the *Manatt on Health* analysis of the CAA health policy provisions for additional detail). As the first in a series of guidance responding to unwinding changes in light of the CAA, the Center for Medicaid and CHIP Services (CMCS) Informational Bulletin (CIB):

- Clarifies that states may begin initiating renewals as early as February 1, 2023, though states may not terminate Medicaid enrollment until April 1, 2023.
- Maintains the unwinding timeline of 12 months to initiate and 14 months to complete renewals (consistent with earlier CMS guidance).
- Revises due dates for existing unwinding reports and documentation required of states:

Submission[3]	Date Due to CMS
Renewal Redistribution Plan	• February 1, 2023, for states initiating renewals in February • February 15, 2023, for all other states
Systems Readiness Artifacts	
Baseline Unwinding Data Report[4]	• The eighth day of the month in which a state begins renewals (i.e., February 8, 2023, March 8, 2023, or April 8, 2023)

- Articulates CMS' plan to issue additional guidance related to its interpretation and state implementation of the enhanced Federal Medical Assistance Percentage (FMAP) conditions, as well as the CAA reporting requirements—including the intersection with existing reporting requirements (e.g., CMS' Unwinding Data Report). CMS has also offered technical assistance and is planning to meet with state Medicaid directors and systems leads as states prepare for the end of the continuous coverage guarantee.

Building on the CIB, CMS released a refresher on the Systems Readiness Artifacts (referenced above), which refers to the documentation that states will be required to submit to CMS to demonstrate system readiness prior to initiating renewals. CMS recognizes that the type and degree of system changes adopted during the PHE and in response to the continuous coverage requirement vary by state and that system change processes are state-specific. States,

[3] Where a submission due date falls on a weekend or public holiday, states may submit the required document(s) on the following business day.
[4] Note that the Monthly Unwinding Data Report is subsequently due the eighth day of each month during the unwinding period.

therefore, will have some discretion in the development of their Configuration Plan, Test Plan, and Test Results—all of which comprise the Systems Readiness Artifacts—while maintaining alignment with Medicaid Enterprise Systems (MES) testing guidance. The refresher includes frequently asked questions further outlining CMS' expectations of states.

Last week, CMS also updated its guidance on strategic approaches that states can deploy to engage Medicaid managed care plans in unwinding efforts. The slide deck provides additional examples of ways in which states can work with their managed care plans to help individuals complete the renewal process, assist individuals found ineligible for Medicaid/CHIP, support reenrollment when the reason for termination is unclear, facilitate qualified health plan enrollment, and leverage Marketplace agents and brokers (see slides 20–30).

CMS Releases Guidance on Coverage of Interprofessional Consultants

On January 5, CMS released a State Health Official letter on Medicaid and CHIP coverage and payment of interprofessional consultants (e.g., a qualified practitioner who provides opinion and/or treatment advice to a treating practitioner without patient face-to-face contact). The updated guidance allows for direct payment to the consulting practitioner as long as the consultation is for the direct benefit of the patient. Under this new guidance, states have broad flexibility in how they choose to furnish interprofessional consultations (including synchronous and asynchronous) and cover such consultations in their state plan (including as a physician service or rehabilitative service) as well as in their payment methodologies.

This guidance replaces previously issued policy that prohibited direct payment to an interprofessional consultant if the patient was not present, and instead allowed for an indirect payment arrangement between the treating and consulting providers. CMS believes this update in guidance will reduce administrative burdens and barriers created in the previously issued guidance and will improve timely access to specialty care, specifically for behavioral health treatment.

FDA Approves New Treatment for Alzheimer's Disease, Raising Questions About Future Coverage

Eisai Co. and Biogen, Inc., recently requested that the FDA grant full approval for their Alzheimer's drug Lequimbi, raising the possibility that Medicare patients could soon have expanded access to monoclonal antibodies for the treatment of Alzheimer's.

There are currently two FDA-approved monoclonal antibody treatments. The first, aducanumab (marketed as Aduhelm), received FDA approval through an accelerated pathway in June 2021, but soon fell under criticism for its high cost and questionable effectiveness. That episode prompted CMS to issue a National Coverage Determination (NCD), under which CMS limited Medicare payment for Alzheimer's monoclonals with accelerated approvals to coverage in a randomized controlled trial conducted under an investigational new drug application. (For more

on CMS' Aduhelm NCD, see the *Manatt on Health* analysis.) Lequimbi, granted accelerated approval on January 6, is currently the second drug to fall within this category and faces the same coverage restrictions.

Eisai has now submitted additional data to the FDA and seeks approval of Lequimbi under a traditional pathway. If approved, Lequimbi would fall into a different category of coverage under CMS' NCD, with Medicare paying for the drug more broadly in CMS-approved prospective comparative studies.

The high costs of monoclonal antibody treatments for Alzheimer's as well as the widespread prevalence of the disease and related conditions in the Medicare program and questions about the drugs' effectiveness have all combined to create a fraught position for CMS. The agency must seek a balance between patient access to medications and a desire to limit coverage of therapies, particularly costly ones, until they are proven effective. Further complicating matters is the bureaucratic gray area created by the FDA's accelerated approvals, and the question of whether CMS can independently determine a drug's effectiveness in the face of an FDA approval. These issues will be further compounded as the FDA makes its decision on Lequimbi and other pipeline drugs reach the market.

Judiciary

Supreme Court Declines to Hear Appeal on Medicare Drug Manufacturer Cost Sharing Assistance

The Supreme Court declined to take up an appeal seeking to overturn the HHS OIG's long-standing prohibition on pharmaceutical manufacturer cost sharing assistance for federal health care program beneficiaries. The decision leaves in place an opinion of a federal appeals court denying a challenge by Pfizer to the prohibition, which rejected Pfizer's theory that the court should limit the reach of the federal Anti-Kickback Statute (AKS) "to payments that seek to corrupt the recipient's medical decision-making." A second similar challenge to the OIG's position, brought by the Pharmaceutical Coalition for Patient Access in a Virginia district court, is still pending.

States

First State Bill Referencing IRA Introduced in Virginia Legislature

With state legislative sessions now convening for the first time since the enactment of the federal Inflation Reduction Act, state legislators considering prescription drug pricing legislation are likely to incorporate elements of the IRA in their proposals. Virginia House Bill No. 1596 appears to be the first such state pricing proposal referencing the IRA. H.B. 1596 would create the Prescription Drug Affordability Board and Fund, and permits the Prescription Drug Affordability Board to set a state upper payment limit for drugs identified as presenting an

"affordability challenge." The upper payment limit cannot exceed the IRA's Medicare "maximum fair price," when a maximum fair price has been set for a particular drug. The IRA permits the federal government to set the "maximum fair price" for certain Medicare Part B and Part D drugs, but does not directly regulate the launch price of drugs purchased by Medicare, or any prices paid by commercial insurance (for more on the IRA's provisions, see the *Manatt on Health* analysis). Several states have already created Prescription Drug Affordability Boards or enacted similar measures to limit the prices state-regulated health plans and programs will reimburse for drugs.

On Our Radar

- HHS awarded $245 million in Bipartisan Safer Communities Act funding to support youth mental health, help the health care workforce address mental health needs, and fund other critical mental health supports. Specifically, $185.7 million was awarded to Substance Abuse and Mental Health Services Administration (SAMHSA) programs and $60 million to Health Resources and Services Administration (HRSA) mental health training programs. Awardee programming activities include developing school-based mental health programs and services; improving treatment and services for children, adolescents, and families; and preparing primary care providers to treat the mental health needs of children and adolescents.

- The Medicare and Payment Advisory Commission (MedPAC) held its first public meeting of the year on January 12 and 13. *Manatt on Health* will provide a summary of the meeting next week; the next public meeting is scheduled for March 2 and 3.

- New York released its *2023 State of the State*, with plans to invest broadly in infrastructure, health care, transportation, and the economy. Health-related investments include, among others, investing in efforts to increase provider capacity statewide for mental and behavioral health care; increasing subsidies to hospitals and nursing homes; and developing a comprehensive, evidence-based strategy for transforming how New York pays for health care.

- Several states recently submitted amendments to or extension requests for their 1115 waivers, as described below:

    - New York submitted an 1115 waiver amendment to authorize federal Medicaid matching funds for reimbursement for services provided to enrollees residing in Institutions for Mental Diseases (IMD) with serious mental illness, serious emotional disturbance, and substance use disorder (SUD) diagnoses. Additionally, the waiver seeks to provide coverage for a targeted set of in-reach services up to 30 days before discharge from in-patient psychiatric centers, including care management, clinical consultants, peer services, and

pharmaceutical management for individuals who do not fall into the 30-day average length of stay cohort outlined in the waiver request.

- Oklahoma submitted a request for a five-year extension with no program changes of the SoonerCare Section 1115 Demonstration to be effective from January 1, 2024, through December 31, 2028.

- Kansas submitted a request for a five-year renewal of the KanCare Section 1115 Demonstration. The waiver proposes to transition some features of the current program—including managed care, managed care for home and community-based services, the state's employment support pilot program, and tribal member opt out—out of the 1115 demonstration and into more permanent federal authorities, such as state plan amendments or 1915(b) waivers. The renewal request seeks to continue 12-month continuous eligibility for select populations, specific SUD services and the SUD IMD exclusion, and continuous eligibility for children in the state's CHIP program who turned 19 during the PHE.

- Rhode Island submitted a request for a five-year renewal to extend the Rhode Island Comprehensive Section 1115 Demonstration. The waiver requests to extend programs and services currently offered under the 1115 demonstration and requests new authority to expand home stabilization services; provide pre-release services for justice-involved individuals 30 days prior to release; launch a restorative and recuperative care pilot; and allow parents of disabled children to act as service providers.

- On January 1, Massachusetts' released voluntary recommendations to establish a health equity measure accountability framework and data standards went into effect. The standards, developed by the Massachusetts Quality Alignment Task Force, outline principles for developing and implementing key contractual measures, data standards, data points, and data collection methods for payors and providers in global risk-based contracts. The task force also endorsed implementation of race, ethnicity, and language standards by January 1, 2024, and implementation of disability, sexual orientation, gender identity, and sex data standards by January 1, 2025.

- New Jersey announced children under 19 may apply for NJ Familycare, the state's Medicaid and CHIP program, regardless of their immigration status. Covered services included physician visits, prescriptions, vision and dental services, mental health and substance use services, and hospitalizations.

- Upcoming webinars:

  - On February 1, Manatt Health will host "Reimagining Medicine: Can Policy Keep Pace With Scientific Advances?" In this webinar, Manatt, NYU Law, NYU Wagner,

and a panel of experts will examine the promise and challenges of medical innovation. Key topics include a review of current policies and regulations governing medical innovation, practical and ethical issues involved in the clinical trial process, and the balance between safety and innovation. *Click here to register for free.*

- On February 8, Manatt Health will host "Protecting Consumer Health Data: FTC and State Actions to Close the Privacy Gap." In this webinar, Manatt will examine the current data privacy landscape and actions on the horizon. Key topics will include types of data being collected and stored outside the health care system, the under-protection of consumer data, and actions being taken at the federal level to advance the privacy of consumers. *Click here to register for free*.

- On February 16, Manatt Health will host "No Surprises Act Update: The Latest Litigation, Enforcement, and Implementation Challenges." In this webinar, Manatt will provide an update on the NSA, including new and ongoing litigation, enforcement, and execution challenges. Topics will include guidance on regulatory and operational risk and compliance, review of federal vs. state enforcement, and current state of independent dispute resolution arbitration and its complex challenges. *Click here to register for free.*

Editorial Team

Michael Kolber
Partner
mkolber@manatt.com

Katie Rubinger
Senior Manager
krubinger@manatt.com

Emily Polk
Manager
epolk@manatt.com

Virginia Morgan
Manager
vmorgan@manatt.com

Editorial Board

Melinda Dutton
Partner
mdutton@manatt.com

Joel Ario
Managing Director
jario@manatt.com

Jared Augenstein
Director
jaugenstein@manatt.com

Brian Bewley
Partner
bbewley@manatt.com

Patti Boozang
Sr. Managing Director
pboozang@manatt.com

Blair Cantfil
Partner
bcantfil@manatt.com

Alex Dworkowitz
Partner
adworkowitz@manatt.com

Linda Elam
Managing Director
lelam@manatt.com

Adam Finkelstein
Counsel
afinkelstein@manatt.com

Alice Lam
Managing Director
alam@manatt.com

Cindy Mann
Partner
cmann@manatt.com

Helen Pfister
Partner
hpfister@manatt.com

Julian Polaris
Associate
jpolaris@manatt.com

Ian Spatz
Senior Advisor
ispatz@manatt.com

Tara Straw
Senior Advisor
tstraw@manatt.com

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