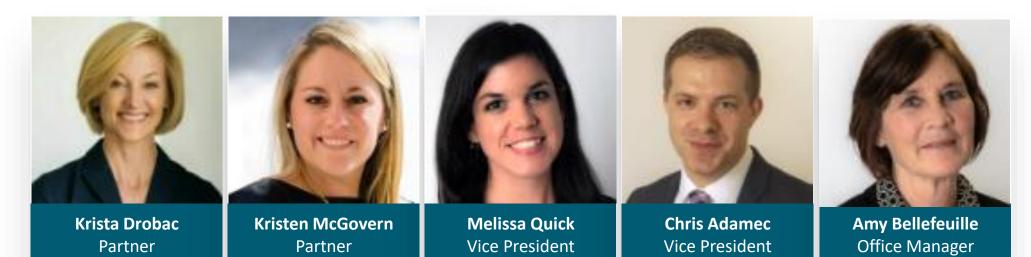
# 2023 Health Policy Summer Recap

September 18, 2023



Strategic Consulting at the Intersection of Health Care Policy, Politics and Business

# **SIRONA TEAM**





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# AGENDA



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# MEDICARE



# Congress

- Sen. Cassidy (R-LA) solicited feedback on discussion draft legislation to improve care for dually eligible Medicare and Medicaid beneficiaries.
- Nearly 300 members of Congress sent a <u>letter</u> to HHS urging **prior authorization reform** in Medicare Advantage.
- The Medicare Payment Advisory Commission (MedPAC) released its June 2023 <u>Report to Congress</u>; contemplates standardized benefit design and alternatives to FFS for determining Medicare Advantage payment rates.
- Concerns around Medicare Advantage overpayments raised in House <u>Energy & Commerce</u> and <u>Ways & Means</u> hearings.
  - Progressive House Democrats also held a <u>press conference</u> highlighting these concerns and urging more transparency.
  - E&C passed the <u>PATIENT Act</u>, which includes reporting requirements for MA plans.
- MedPAC announced upcoming Medicare Advantage work focused on: D-SNP quality; standardizing benefits; access and quality; and encounter data.

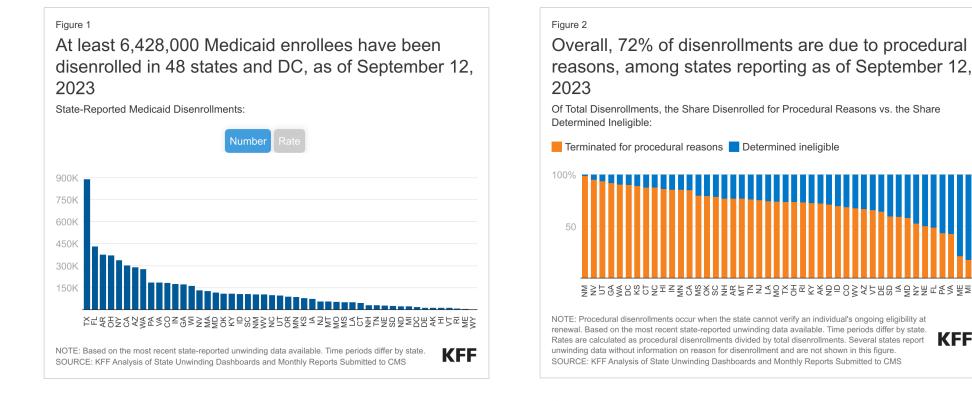
# Administration

- CY 2024 Physician Fee Schedule proposes a 3.34% decrease in the Conversion Factor.
- HHS OIG released a <u>strategic plan</u> for Managed Care oversight.
- CY 2025 MA and Part D Proposed Rule is under review at the Office of Management and Budget (OMB).
- CMS is facing a <u>lawsuit</u> over the Risk Adjustment Data Validation (RADV) Rule, finalized earlier this year.
- CMS issued draft <u>guidance</u> that outlines requirements and procedures for the new Medicare Prescription Payment Plan, created by the Inflation Reduction Act, which will allow Medicare Part D beneficiaries to spread out cost sharing over the year.
- CMS <u>announced</u> the first 10 drugs covered under Medicare Part D selected for negotiation. The negotiations with participating drug companies will occur in 2023 and 2024, with negotiated prices becoming effective beginning in 2026.



# MEDICAID

# **Medicaid Unwinding**



# **Proposed and Final Rules**

- Ensuring Access to Medicaid Services and the Medicaid Managed Care proposed rules released.
- Mandatory Medicaid and Children's Health Insurance Program Set Reporting final rule released; effective January 1, 2024.
- Streamlining the Medicaid, CHIP, and BHP Application, Eligibility Determination, Enrollment, and Renewal Processes final rule cleared OMB review, and its release is imminent.



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# **VALUE-BASED CARE**

Senior leaders from CMS released a blog on their <u>primary care strategy</u> in June; and an update on their <u>vision for accountable</u> <u>care</u> in *Health Affairs* in July.

#### MSSP

- CY 2024 proposed Physician Fee Schedule included adjustments intended to encourage more providers to participate in the MSSP and an RFI on the future of the program (incl. a full-risk track).
- 2022 results announced in August; \$1.8 billion in savings.

#### ACO REACH

- CMMI released PY2024 updates for the model in August, which included adjustments in response to stakeholder feedback.
- 2022 GPDC results are expected to be announced in November.

#### Requests for Information

• CMS issued a Request for Information (<u>RFI</u>) on a new episode-based payment model.

### CMMI announced 3 new models.

#### Making Care Primary (MCP) Model

• The new primary care model will launch in 8 states on July 1, 2024 and run 10.5 years.

#### *Guiding an Improved Dementia Experience* (*GUIDE*) <u>Model</u>

 The model aims to support people living with dementia and their unpaid caregivers. It will launch on July 1, 2024 and run 8 years.

#### States Advancing All-Payer Health Equity Approaches and Development (AHEAD) <u>Model</u>

• This total cost of care model, will support up to 8 states. It is scheduled to launch in 2024 and run for 11 years.

#### **Upcoming CMMI announcements:**

- Primary care capitation model within MSSP.
- Guide Model RFA.
- AHEAD Model RFA.

# Stakeholders continue to push Congress to extend APM bonus, which is currently at 3.5% and set to expire at the end of 2023.

#### Value in Healthcare Act of 2023

 Reps. LaHood (R-IL), DelBene (D-WA), Wenstrup (D-OH), Schrier (D-WA), Bucshon (R-IN), and Blumenauer (D-OR) reintroduced the Value in Health Care Act.

#### MACRA Reform

- Over 90 members of Congress signed a <u>letter</u> to Congressional leadership emphasizing the urgent need for MACRA reform.
- House Energy & Commerce Committee held a <u>hearing</u>, "MACRA Checkup: Assessing Implementation and Challenges that Remain for Patients and Doctors."



# **SOCIAL DETERMINANTS OF HEALTH & HEALTH EQUITY**

# CMS CY2024 Physician Fee Schedule proposed rule

- *SDOH Risk Assessment* as an optional element in the Annual Wellness Visit (AWV).
- New G-codes would provide funding for SDOH Risk Assessments and allow community health workers (CHW) and others to provide *Community Health Integration (CHI) and* Principal Illness Navigation (PIN) Services.

#### **CMMI Spotlight**

- CMMI's <u>"Assessing Equity to Drive Health</u> <u>Care Improvements: Learnings from the</u> <u>CMS Innovation Center</u>" highlighted gaps in evaluating health equity.
- CMMI launched a new voluntary, state total cost of care model called the <u>"All-Payer</u> <u>Health Equity Approaches and Development</u> <u>(AHEAD) Model.</u>"
- CMMI announced the <u>Making Care Primary</u> (MCP) model, which focuses on personcentered care.



**Other Administration Actions** 

**SDOH Funding Opportunities** 

- <u>CDC Social Determinants of Health</u> <u>Accelerator Plans</u>
- <u>CDC Addressing Conditions to</u> Improve Population Health (ACTion)
- NIH <u>awarded</u> \$50 million to launch an initiative to address poverty as a SDOH in cancer patients.
- HUD <u>issued</u> over \$3.1 billion for homelessness interventions, with a focus on equity.

### **CMS & Other Agencies**

- In June, CMS held its first annual Health Equity <u>conference</u>.
- CMS <u>announced</u> Dr. Aditi Mallick as Acting Director of the Office of Minority Health.
- Medicaid issued a toolkit for states entitled "<u>Increasing Access, Quality,</u> <u>and Equity in Postpartum Care in</u> Medicaid and CHIP."

## COMING SOON: SDOH PLAYBOOK

A soon-to-be-released White House SDOH Action Plan will describe the White House's approach to the SDOH narrative, including stakeholder feedback on the impacts of housing, transportation, and interpersonal violence on health outcomes.

It will touch on integration of community-based organizations and funding, collecting SDOH data, and sharing SDOH data.



# **HEALTH IT**

## Interoperability & Information Blocking

- ONC issued a <u>proposed rule</u> on Health Data, Technology and Interoperability.
- ONC released <u>United States Core Data for</u> <u>Interoperability (USCDI) Version 4</u>.
- OIG <u>enforcement</u> of information blocking penalties for health IT entities began.

### Trusted Exchange Framework and Common Agreement (TEFCA)

- There are seven organizations with approved QHIN applications – Health Gorilla, Kno2, KONZA, Epic, eHealth Exchange, CommonWell Health Alliance, and MedAllies.
- The Sequoia Project is drafting version two of the Common Agreement and QHIN Technical Framework.

# Privacy

• FTC proposed amendments to the <u>Health</u> <u>Breach Notification Rule</u>.

# Artificial Intelligence (AI) – Congressional Activity

#### **SAFE Innovation Framework**

• Senate Majority Leader Schumer (D-NY) released the SAFE Innovation Framework.

### Fall 2023 AI Insights Forums

- Sens. Schumer, Rounds (R-SD), Heinrich (D-NM), and Young (R-IN) <u>announced</u> intentions to hold "AI Insights Forums" throughout the fall.
- Sen. Schumer announced the <u>first forum</u> would be held September 13 and feature CEOs from leading AI and tech companies.

### Legislation and Hearings

- Legislation has mainly focused on oversight and establishment of commissions and task forces to assess the impact of AI or improve government understanding.
- Hearings have focused on overarching areas of opportunity for AI, as well as concerns on the societal impacts of AI.

### **AI Congressional Caucus**

• Reps. Eshoo (D-CA), McCaul (R-TX), Beyer (D-VA), and Obernolte (R-CA) introduced the CREATE AI Act.

#### White Papers and RFIs

 Senate HELP Ranking Member Cassidy (R-LA) issued a <u>white paper and RFI</u> on AI and released another <u>RFI</u> on health data privacy, with AI-related questions.

# Artificial Intelligence (AI) – Administration Activity

#### 2023 Actions to Promote Responsible AI Innovation

- The Biden Administration <u>announced</u> that it had secured voluntary commitments from leading AI companies to manage the risks posed by AI.
- The White House is currently developing an additional executive order and will pursue bipartisan legislation.



# **BEHAVIORAL HEALTH**

# **Administration**

#### Mental Health Parity and Addiction Equity Act Proposed Rule

• DOL, HHS, Treasury issued proposed Requirements Related to the Mental Health Parity and Addiction Equity Act.

#### **CMS Coverage of Intensive Outpatient Programs**

• New Coverage of Intensive Outpatient Programs in the CY2024 Medicare Outpatient Payment Rule.

### **Drug Enforcement Administration (DEA)**

• New developments on DEA proposed telemedicine rules (after more than 38,000 public comments and 6-month extension).

#### SAMHSA

- <u>988 Lifeline</u> developments
- Published <u>National Model Standards</u> for Peer Support Certification for substance use, mental health and family peer workers.
- Released the <u>2023–2026 Strategic Plan</u> with five priority areas to better meet the behavioral health needs of individuals, communities, and service providers.
- HHS <u>Report to Congress</u> on Certified Community Behavioral Health Clinics (CCBHC).

#### **Child Mental Health and School Based Programs**

• Activities to expand access to mental health services for children and in schools.

# Congress

#### **SUPPORT Act Reauthorization**

• September 30 deadline.

#### House E&C Health Subcommittee

 The Subcommittee held a hearing on remote opioid monitoring, reauthorizing mental and behavioral health education and training grants, and extending Medicaid coverage for inmates 30 days preceding release.

#### Senate HELP Committee

 The Committee held a hearing, which highlighted kids' worsening mental health as a public health issue and Congress' significant action in recent years to improve mental health care.



# WORKFORCE

## **SPOTLIGHT: Senate HELP Workforce Proposal**

On July 19, Senate HELP Committee Chair Sanders released a proposal to expand the health care workforce.



Community Health Centers/National Health Service Corps



Expanding the Number of Doctors, Nurses, Dentists in America



Expanding the Behavioral Health Workforce; Direct Care Workforce and Caregivers

Pilot Programs in States



**Requirements for Health Plans and Hospitals** 

### **Practitioner Expansion**

- CMS proposed adding marriage and family therapists and mental health counselors to enroll in Medicare and bill for their services starting in January 2024.
- There are policy developments around expanding the abilities of pharmacists and recognizing them as a Medicare provider.

### **Expanding Care in the Home**

 Reps. Smith (R-NE) and Dingell (D-MI) introduced the Expanding Care in the Home Act (<u>H.R. 2853</u>).

### **Telehealth Workforce**

- Expiring temporary extension of virtual direct supervision (2024) and ongoing debate.
- Extension of permanent virtual supervision of residents in teaching settings and ongoing debate.
- Policy developments related to a remote health workforce, such as home-address reporting requirements.



# **DRUG PRICING REFORMS**



# Congress

Committees have been working on bipartisan legislation to address drug pricing.

Proposals largely focus on PBMs and include transparency, rebate passthrough, reducing beneficiaries' out-of-pocket costs, and delinking PBM fees from a drug's price.

#### Senate

- Senate Finance Committee advanced by 26-1 a <u>bill</u> to bring more transparency, accountability and competition to PBM practices
- Senate HELP Committee advanced several bills to address generic drugs, increase generic competition, and address issues with PBMs.
- Senate Majority Leader Schumer has also called for legislation to reduce out of pocket costs for insulin.

#### House

- Most recently, House Energy and Commerce, Ways and Means, and Education and the Workforce Committees introduced the Lower Costs, More Transparency Act
- House Oversight Held a hearing examining the role of PBMs in pharmaceutical markets and how they affect patients.
- House Energy & Commerce held a hearing on challenges in pharmaceutical drug supply chains.



#### **IRA Implementation**

- The Administration released a <u>list</u> of the first 10 drugs selected for Medicare price negotiation.
- CMS <u>announced</u> the list of 43 prescription drugs for which Medicare Part B beneficiaries' coinsurances may be lower between July 1 – September 30, 2023. HHS also released a report analyzing growth in Part B spending.

**FTC & PBMs** – The Federal Trade Commission (FTC) voted to issue a <u>statement</u> rescinding previous advocacy statements and studies related to PBMs.

**340B** – <u>CMS</u> Proposed a Remedy for 340B-Acquired Drugs Purchased in Cost Years 2018-2022 – June 2023

**MDRP** – <u>CMS</u> Released a Proposed Rule on Misclassification of Drugs, Program Administration & Program Integrity Updates under the MDRP – May 2023.



# QUALITY

# Joint Commission Absorbed National Quality Forum

 Partnership for Quality Measurement (<u>PQM</u>), a CMS certified consensus-based entity (CBE), requested nominations for the PQM Committees.

### CMS CY2024 Physician Fee Schedule Proposed Rule

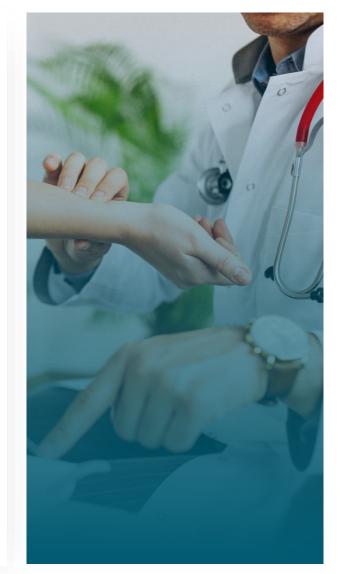
 Proposal to establish a Medicare clinical quality measure (CQM) for Accountable Care Organizations (ACO) Participating in the Medicare Shared Savings Program (MSSP) to algin future MIPs APP measure set for MSSP ACOs with the quality measures under Universal Foundation beginning performance year 2025.



**Other Administration Actions** 

# CMS 2024 OPPS Proposed Rule

- Requested comments on potential measures for implementing quality reporting for rural emergency hospitals (REH).
- CMS <u>released</u> the Mandatory Medicaid and Children's Health Insurance Program (CHIP) Core Set Report final rule. The rule establishes quality measures for Medicaid and CHIP, behavioral health of adults, and Medicaid home health.
- CMS released detailed quality measure information for 12 Innovation Center models. The quality measure information can be found on the CMS Measures Inventory Tool (<u>CMIT</u>), and shows the measures that CMS uses to promote health care quality and improvement.





# PUBLIC HEALTH UPDATES – ADMINISTRATION & AGENCY CHANGES

# Dr. Mandy Cohen as CDC Director



Dr. Cohen previously served as Secretary of North Carolina's Department of Health and Human Services, where she developed nationally recognized programs. She led the state through COVID-19 and transformation of North Carolina's Medicaid program. She has also served as Chief Operating Officer and Chief of Staff for CMS, and Acting Director of CCIIO.



COVID-19 vaccines have been at the forefront so far, with Dr. Cohen authoring a New York Times Op-Ed last week



Delayed launch of the Bridge Vaccine Program, meant to ensure coverage for vaccines for unand under-insured individuals.

# **CDC OCIO**



In July, HHS announced plans to modify CDC's structure by reorganizing the Office of the Chief Information Officer (OCIO). The restructuring is purposed to optimize support for the CDC Moving Forward reorganization and Data Modernization Initiatives.

# **OPPR**



In July, the Administration announced creation of a new office housed in the Executive Office of the President.



# **PUBLIC HEALTH UPDATES – COVID & PREPAREDNESS**



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### Public Health Emergency Officially Ended on May 11

- A number of COVID-19 PHE flexibilities and policies are now permanent, or have been extended, including telehealth flexibility.
- Coverage for testing with no cost sharing continues for those with Medicare and certain Medicare Advantage plans. State Medicaid programs must continue to provide testing until September 30, 2024.

#### **COVID-19 Vaccines**

- On September 11, the Food and Drug Administration approved updated COVID-19 vaccines. Officials believe that the COVID-19 vaccines will be updated every fall to account for virus variants, similar to annual flu vaccines.
- On September 12, the CDC recommended that everyone six months and older get an updated COVID-19 vaccine for protection through the fall and winter.



#### **ARPA-H Announcements**

- In July, the White House announced the launch of a new ARPA-H program, the Precision Surgical Interventions program, to develop novel technologies for more precise and accurate cancer tumor removal.
- ARPA-H also announced CUREIT, a project focused on the immune system and one on digital health security.
- On September 13, ARPA-H announced \$240 million in new funding for innovation to prevent, detect, treat and survive cancer. ARPA-H also announced a new biomedical data fabric toolbox to advance cancer research.



### Pandemic and All-Hazards Preparedness and Response Act (PAHPA)

 In July, the Senate HELP and House Energy & Commerce Committees passed their versions of PAHPA, which helps to fund public health programs and promote information sharing and new research.









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