TO: Medicaid Directors
FROM: NAMD Staff
DATE: December 20, 2021
RE: Fall 2021 Unified Regulatory Agenda

This memo provides a brief overview of the Fall 2021 update to the Office of Management and Budget's Unified Regulatory Agenda (URA), which outlines anticipated regulatory activities from CMS and other federal agencies for the remainder of 2021 and 2022. The Unified Regulatory Agenda is updated twice a year, in the Spring and Fall. In this memo, NAMD has focused on highlighting planned activities with direct or potential impact on the Medicaid program; you can view the URA for the Department of Health and Human Services here, or the full URA here.

In this document, we use ***"Target Date"*** to refer to the anticipated timeline for the agency to take the action described – whether it is issuing guidance, an RFI, a proposed rule, or a final rule – as indicated in the URA. This timeline information should not be considered a firm deadline for these activities, and instead indicates the relative prioritization of regulations and a general sense of when they can be expected. It is not uncommon for these published timelines to change in the Fall and Spring updates.

Please direct any questions to Jack Rollins and Hannah Maniates at NAMD.

Contents

CMS Regulatory Actions

Medicaid

- **Assuring Access to Medicaid Services (0938-AU68):** This rule proposes to assure and monitor equitable access in Medicaid and CHIP. These activities could include actions that support the implementation of a comprehensive access strategy as well as payment specific requirements related to particular delivery systems.
    - **Target Date:** October 2022

- **Interoperability and Prior Authorization for MA Organizations, Medicaid and CHIP Managed Care and State Agencies, FFE QHP Issuers, MIPS Eligible**

Clinicians, Eligible Hospitals and CAHs (0938-AU87): This proposed rule would place new requirements on certain entities to improve the electronic exchange of health care data and streamline processes related to prior authorization and would also add a new measure for eligible hospitals and critical access hospitals under the Medicare Promoting Interoperability Program and for Merit-based Incentive Payment System (MIPS) eligible clinicians under the Promoting Interoperability performance category of MIPS.

- **Target Date:** February 2022

- **Medicare, Medicaid and Health Insurance Exchanges Program Integrity (0938-AU90):** This proposed rule includes provisions that would promote payment accuracy and efficiency and help CMS identify and deter fraud, waste, and abuse.
    - **Target Date:** August 2022

- **Reassignment of Medicaid Provider Claims (0938-AU73):** This final rule reinterprets the scope of the general requirement that state payments for Medicaid services under a state plan must be made directly to the individual practitioner providing services, in the case of a class of practitioners for which the Medicaid program is the primary source of revenue.
    - **Target Date:** March 2022

- **Streamlining the Medicaid and CHIP Application, Eligibility Determination, Enrollment, and Renewal Processes (0938-AU00):** This proposed rule would streamline eligibility and enrollment processes for all Medicaid and CHIP populations, creating new enrollment pathways to maximize enrollment and retention of eligible individuals.
    - **Target Date:** April 2022

- **Medicaid Drug Misclassification, Beneficiary Access Protection, and Drug Program Administration (0938-AU28):** This proposed rule would implement section 6 of the Medicaid Services Investment and Accountability Act of 2019, which created new penalties related to manufacturers' misclassification of covered outpatient drug products under the Medicaid Drug Rebate Program (MDRP) including civil monetary penalties, suspension of a manufacturer's drug, and the ability of states to recover unpaid rebates.
    - **Target Date:** May 2022

- **Mandatory Medicaid and CHIP Core Set Reporting (0938-AU52):** This proposed rule would establish requirements for mandatory reporting of the Child Core Set, the Adult Core Set, and Health Home Core Set.
    - **Target Date**: April 2022

- **Improving Infection Prevention and Control in LTC Facilities (0938-AU58):** This proposed rule would revise the infection control requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs.
    - **Target Date:** September 2022

Medicare and Duals

- **Transitional Coverage for Emerging Technologies (0938-AU86):** This proposed rule would establish the criteria for an expedited coverage pathway to provide Medicare beneficiaries with faster access to innovative and beneficial technologies.
    - **Target Date:** October 2022

- **Contract Year 2023 Policy and Technical Changes to the MA and Medicare Prescription Drug Benefit Programs (0938-AU30):** This proposed rule would strengthen and improve the MA and Part D programs for contract year 2023.
    - **Target Date:** December 2021

- **Implementing Certain Provisions of the CAA and Other Revisions to Medicare Enrollment and Eligibility Rules (0938-AU85):** This proposed rule would implement certain Medicare-related provisions of the Consolidated Appropriations Act, including allowing Medicare coverage to take effect earlier for certain individuals and giving the Secretary the authority to establish special enrollment periods in extraordinary circumstances.
    - **Target Date:** October 2022

- **Medicare Advantage and Medicare Prescription Drug Benefit Program Payment Policy (0938-AU59):** This proposed rule would codify long-established Medicare Advantage (MA) and Part D payment policies that are outside the scope of the annual Advance Notice/Rate Announcement.
    - **Target Date:** May 2022

Other

- **Administrative Simplification: Adoption of Standards for Health Care Attachment Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Standard (0938-AT38):** This rule proposes new standards to support both health care claims and prior authorization transactions, and standards for electronic signatures to be used in conjunction with health care attachments transactions. This rule also proposes to adopt a modification to the standard for the referral certification and authorization transaction. Additionally, this rule proposes a regulatory change that would implement requirements of the Administrative Simplification subtitle of HIPAA and the ACA.
    - **Target Date:** January 2022

- **Requirements for Rural Emergency Hospitals (0938-AU92):** This proposed rule would establish health and safety requirements for a new provider type, Rural Emergency Hospitals, in accordance with section 125 of the CAA, 2021.
    - **Target Date:** January 2023

- **Mental Health Parity and Addiction Equity Act and the CAA, 2021 (0938-AU93):** This rule would propose amendments to the final rules implementing the Mental Health Parity and Addiction Equity Act, taking into account the amendments to the law enacted by the CAA, 2021.
    - **Target Date:** July 2022

Substance Abuse and Mental Health Services Administration (SAMHSA) Regulatory Actions

- **Treatment of Opioid Use Disorder with Buprenorphine Utilizing Telehealth (0930- AA38):** SAMHSA states that in the face of an escalating overdose crisis and an increasing need to reach remote and underserved communities, SAMHSA plans to permanently extend the buprenorphine telehealth flexibility among OTPs after the COVID-19 PHE.
    - **Target Date:** September 2022

- **Treatment of Opioid use Disorder with Extended Take Home Doses of Methadone (0930-AA39):** SAMHSA will revise 42 CFR part 8 to make permanent some regulatory flexibilities for opioid treatment programs to provide extended take home doses of methadone. To facilitate this new treatment paradigm, sections of 42 CFR part 8 will require updating to reflect current treatment practice.
    - **Target Date:** September 2022

Food and Drug Administration (FDA) Regulatory Actions

- **Medical Devices; Ear, Nose and Throat Devices; Establishing Over-the-Counter Hearing Aids and Aligning Other Regulations (0910-AI21):** FDA has proposed to establish aligning over-the-counter category of hearing aids to promote the availability of additional kinds of devices that address mild to moderate hearing loss, and proposing related amendments to the current hearing aid regulations, the regulations codifying FDA decisions on State applications for exemption from preemption, and the hearing aid classification regulations.
    - **Target Date:** January 18, 2022

Health Resources and Services Administration (HRSA) Regulatory Actions

- **340B Drug Pricing Program; Administration Dispute Resolution (ADR) (0906- AB28):** This proposed rule would replace the ADR final rule currently in

effect and apply to all drug manufacturers and covered entities that participate in the 340B Drug Pricing Program and would establish new requirements and procedures for the 340B Program's ADR process.
    - **Target Date:** January 2022

Office of Civil Rights (OCR) Regulatory Actions

- **HIPAA Privacy: Changes to Support, and Remove Barriers to, Coordinated Care and Individual Engagement (0945-AA00):** This rule will modify provisions of the HIPAA Privacy Rule to strengthen individuals' rights to access their own protected health information, including electronic information; improve information sharing for care coordination and case management for individuals; facilitate greater family and caregiver Page 8 involvement in the care of individuals experiencing emergencies or health crises; enhance flexibilities for disclosures in emergency or threatening circumstances; and reduce administrative burdens on HIPAA covered health care providers and health plans, while continuing to protect individuals' health information privacy interests.
    - **Target Date:** October 2022

- **Confidentiality of Substance Use Disorder Patient Records (0945-AA16):** This rulemaking would implement provisions of section 3221 of the CARES Act to better harmonize the confidentiality requirements with certain permissions and requirements of the HIPAA Rules and the HITECH Act. This rulemaking also would implement the requirement in section 3221 of the CARES Act to modify the HIPAA Privacy Rule NPP provisions so that HIPAA covered entities and part 2 programs provide notice to individuals regarding part 2 records, including patients' rights and uses and disclosures permitted or required without authorization.
    - **Target Date:** January 2022

- **ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing (0955-AA03):** The rulemaking implements certain provisions of the 21st Century Cures Act, including: the Electronic Health Record Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program; a process for health information networks that voluntarily adopt the Trusted Exchange Framework and Common Agreement to attest to such adoption of the framework and agreement; and enhancements to support information sharing under the information blocking regulations.
    - **Target Date:** September 2022