**Biden Administration Releases Fall 2021 Unified Agenda**

**Executive Summary**

Recently, the Office of Management and Budget (OMB) published the Fall 2021 [Unified Agenda](#) outlining the forthcoming regulatory priorities of the Biden administration. Sharon Block, the Associate Administrator of the Office of Information and Regulatory Affairs at OMB, wrote that the new Unified Agenda outlines “actions Federal agencies intend to take over the coming months to continue protecting public health, creating a stronger and fairer economy, addressing climate change, and advancing equity.” Further, she noted that the “regulatory plans and agendas... offer blueprints for how the administration will continue delivering on President Biden’s agenda as we build back better for everyone.”

- **Background.** Generally, OMB releases the Unified Agenda in the Spring and Fall, and the timelines included in the Unified Agenda tend to be aspirational but demonstrate the administration’s regulatory priorities. Through this, administrations seek to solidify their regulatory actions earlier in election cycles to ensure these actions are more difficult to overturn should control of Congress and/or the White House shift.

  Of note in the regulatory agenda are changes to the 340B Drug Pricing Program, which would replace the Administration Dispute Resolution (ADR) final rule currently in effect. This proposed rule would establish new requirements and procedures for the 340B Program’s ADR process, applicable to all drug manufacturers and covered entities that participate in the 340B Drug Pricing Program. Also of note is a forthcoming rollback to a Trump-era regulation which would have created procedures for the periodic review and sunset of Department of Health and Human Services’ (HHS) regulations. The [Securing Updated and Necessary Statutory Evaluations Timely](#) rule is currently under its second notice of proposed rulemaking (NPRM), and public comments on the rule are expected to close at the conclusion of December 2021.

  The Unified Agenda contains several proposals aimed at creating new, or modifying existing, regulations around prescription drugs. Specifically, the [Post Approval Changes to Approved Applications](#) proposed rule would make changes to approved new drug applications, abbreviated new drug applications, and biologics license applications, as well as regulations regarding certain post-approval reports. Additionally, the [Prescription Drug and Health Care Spending](#) interim final rule (IFR) would implement the prescription drug reporting requirements that apply to group health plans and health insurance issuers offering coverage in the group and individual markets.
The administration’s regulatory agenda also proposes a new, mandatory Medicare Alternative Payment Model which would assess ways to further the Centers for Medicare and Medicaid Services’ (CMS) goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries under the program. Regarding telehealth, the Unified Agenda includes plans to permanently extend the buprenorphine telehealth flexibility among opioid treatment programs (OTPs) after the conclusion of the COVID-19 public health emergency (PHE).

- **What’s Next?** Looking ahead, additional regulations may be added to the agenda in the Spring in the event of Build Back Better Act (BBBA) passage, as provisions contained within the measure would require regulatory action.

Below is a brief description of some of the most notable items related to HHS published in the Fall 2021 Unified Agenda.

**GLOSSARY**

- Office of the Secretary
- Centers for Medicare and Medicaid Services
- Office of Civil Rights
- Food and Drug Administration
- Health Resources and Services Administration
- Centers for Disease Control and Prevention
- Indian Health Service
- Substance Abuse and Mental Health Services Administration
- Office of the Inspector General
- Administration for Children and Families

**OFFICE OF THE SECRETARY (OS)**

- **Securing Updated and Necessary Statutory Evaluations Timely** (0991-AC24): HHS is proposing to withdraw or rescind regulations that were issued but have not yet become effective that would have created procedures for the periodic review and sunset of the Department's regulations.

- **Limiting the Effect of Exclusions Implemented Under the Social Security Act (SSA)** (0991-AC11): Exclusions implemented under the SSA prevent individuals convicted of certain crimes or individuals whose health care licenses have been revoked from participating in Federal health care programs. This rulemaking would remove the regulatory provisions at issue, in order to align the regulation with the intent of the SSA and current practice.

- **Health Resources Priority and Allocations System** (0991-AB95): This final rule would establish standards and procedures by which HHS may require that certain contracts or orders that promote the national defense be given priority over other contracts or orders. Final Action Target Date: April 2022.
• CY 2022 Civil Monetary Penalties Inflation Adjustment (0991-AC33).

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

• Alternative Payment Model (0938-AU51): This rule proposes to implement a new mandatory Medicare payment model under section 1115A of the SSA. This proposed model would test ways to further CMS' goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries. NPRM Target Date: August 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. NPRM Target Date: May 2022.

• HHS Notice of Benefit and Payment Parameters for 2023 (0938-AU65).

• Short-Term Limited Duration Insurance; Update (0938-AU67): 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. NPRM Target Date: October 2022.

• FY 2023 Skilled Nursing Facility (SNFs) Prospective Payment System (PPS) Rate Update and Quality Reporting Requirements (0938-AU76).

• CY 2023 Home Health PPS Rate Update and Home Infusion Therapy Services Payment Update (0938-AU77).

• FY 2023 Inpatient Rehabilitation Facility (IRF) PPS Rate Update and QRP (0938-AU78).

• CY 2023 Changes to the End-Stage Renal Disease (ESRD) PPS and Quality Incentive Program (0938-AU79).

• FY 2023 Inpatient Psychiatric Facilities PPS Rate and Quality Reporting Updates (0938-AU80).

• CY 2023 Revisions to Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Medicare Part B (0938-AU81).

• CY 2023 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (0938-AU82).

• FY 2023 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements (0938-AU83).

• Hospital Inpatient PPS for Acute Care Hospitals; the Long-Term Care (LTC) Hospital PPS; and FY 2023 Rates (0938-AU84).
• **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 CAA. Separately, this rule would address enrollment in Medicare Part A for applicants who are eligible for Social Security benefits, but are not yet receiving them, and make certain updates related to state payment of Medicare premiums. NPRM Target Date: October 2022.

• **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. NPRM 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. NPRM Target Date: February 2022.

• **Strengthening Oversight of Accrediting Organizations (AO) and Preventing AO Conflict of Interest, and Related Provisions** ([0938-AU88]): This proposed rule would set forth a number of provisions to strengthen the oversight of accrediting organizations (AO) by addressing conflicts of interest, establishing consistent standards, processes and definitions, and updating the validation and performance standards systems. NPRM Target Date: April 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. NPRM Target Date: August 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. NPRM 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. NPRM Target Date: July 2022.

• **Coverage of Certain Preventive Services** ([0938-AU94]): This rule would propose amendments to the final rules regarding religious and moral exemptions and accommodations regarding coverage of certain preventive services under title I of the ACA. NPRM Target Date: February 2022.

• **Durable Medical Equipment Fee Schedule, Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Non-Competitive Bidding Areas** ([0938-AT21]): This final rule responds to public comments on the IFR for phasing in adjustments to the fee
schedule amounts for certain durable medical equipment (DME) and enteral nutrition paid in areas not subject to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). Final Action Target Date: May 2022.

- **Accrediting Organizations--Changes to Change of Ownership (0938-AT83):** This final rule adds new requirements and a specified process to address changes of ownership in the sale, transfer, or purchase of assets of AOs for CMS approved accreditation programs. Final Action Target Date: May 2022.

- **Requirements Related to Air Ambulance Services, Agent and Broker Disclosures and Provider Enforcement (0938-AU61):** This final rule implements certain provisions of the CAA, 2021. This rule finalizes the form and manner in which group health plans, health insurance issuers offering group or individual health insurance coverage, and providers of air ambulance services report information regarding air ambulance services; requirements on health insurance issuers offering individual health insurance coverage or short-term limited duration insurance coverage to disclose and report information regarding direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage; and provisions related to enforcing requirements in the CAA on issuers, non-federal governmental group health plans, providers, facilities, and air ambulance providers. Final Action Target Date: December 2021.

- **Requirements Related to Surprise Billing; Part II (0938-AU62):** This IFR with comment would implement additional protections against surprise medical bills under the No Surprises Act, including provisions related to the independent dispute resolution processes.

- **Prescription Drug and Health Care Spending (0938-AU66):** This IFR implements the prescription drug reporting requirements that apply to group health plans and health insurance issuers offering coverage in the group and individual markets under section 204 of title II of Division BB of the CAA.

- **Provider Nondiscrimination Requirements for Group Health Plans and Health Insurance Issuers in the Group and Individual Markets (0938-AU64):** This proposed rule would implement section 108 of the No Surprises Act. NPRM Target Date: January 2022.

- **CY 2023 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts (0938-AU71).**

- **CY 2023 Part A Premiums for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (0938-AU72).**

- **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. Final Action Target Date: March 2022.

- **Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2023 (0938-AU74):** This notice announces the monthly actuarial rates for aged and disabled beneficiaries enrolled in part B of the Medicare Supplementary Medical Insurance (SMI) program beginning January 1, 2023. In addition, this notice announces the
monthly premium for aged and disabled beneficiaries, the deductible for 2023, and the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. Final Action Target Date: September 2022.

- **Omnibus COVID-19 Health Care Staff Vaccination** (0938-AU75): This IFR with comment period revises the infection control requirements that most Medicare- and Medicaid-participating providers and suppliers must meet to participate in the Medicare and Medicaid programs.

- **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. NPRM Target Date: April 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. NPRM Target Date: April 2022.

- **Request for Information: Transplant System Modernization** (0938-AU55): The request for information will seek public input on all aspects of the transplant ecosystem, from ESRD issues to transplant center issues to organ procurement issues.

- **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. NPRM Target Date: January 2022.

- **Reporting of Crimes Occurring in Federally Funded LTC Facilities and Enforcement Under Section 1150B of the SSA** (0938-AT60): This proposed rule would implement federal requirements requiring specific covered individuals in LTC facilities to report to the Secretary and law enforcement entities any reasonable suspicion that a crime has been committed against an individual who is receiving care from such facility. NPRM Target Date: March 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. NPRM Target Date: May 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. NPRM Target Date: December 2021.

• **Medicare Payment Policies for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) (0938-AU45):** This rule would include proposed changes related to Medicare payment and/or scope of benefit policies and programs for DMEPOS items and services. NPRM Target Date: September 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. NPRM 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. NPRM Target Date: September 2022.

**OFFICE OF CIVIL RIGHTS (OCR)**

• **Rulemaking on Discrimination on the Basis of Disability in Critical HHS Programs or Activities (0945-AA15):** This proposed rule would revise regulations under section 504 of the Rehabilitation Act of 1973 to address unlawful discrimination on the basis of disability in certain vital HHS-funded health and human services programs.

• **HIPAA Rules: Request for Information on Sharing Civil Money Penalties or Monetary Settlements With Harmed Individuals, and Recognized Security Practices Under HITECH (0945-AA04):** This Request for Information would solicit the public's views on establishing a methodology for the distribution of CMPs and monetary settlements to those harmed by an offense under the HIPAA Rules relating to privacy or security. The RFI also would seek comment on ways to implement in regulation the requirement for OCR to consider certain recognized security practices of covered entities and business associates when making certain HIPAA enforcement determinations.

• **Nondiscrimination in Health Programs and Activities (0945-AA17):** This proposed rulemaking would propose changes to the 2020 Final Rule implementing section 1557 of the ACA. NPRM Target Date: April 2022.

• **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
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. Final Action 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. NPRM 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. NPRM Target Date: September 2022.

**FOOD AND DRUG ADMINISTRATION (FDA)**

- **Amendments to the List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the FFDCA (0910-AH81):** FDA has finalized its proposed rule to amend the 503A Bulks List by placing five additional bulk drug substances on the list. FDA has also identified 26 bulk drug substances that FDA has considered and proposed not to include on the 503A Bulks List. Final Rule Target Date: March 2022.

- **Investigational New Drug Applications; Exemptions for Clinical Investigations to Evaluate a Drug Use of a Product Lawfully Marketed as a Conventional Food, Dietary Supplement, or Cosmetic (0910-AH07):** This proposed rule intends to broaden the regulatory criteria for studies exempt from IND requirements and provide clarity and consistency when studies evaluating drug uses of products that are lawfully marketed as conventional foods, dietary supplements, or cosmetics are subject to IND review. NPRM Target Date: February 2022.

- **National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers (0910-AH11):** The proposed rule will establish standards for State licensing (SL) of prescription drug wholesale distributors and third-party logistics providers, and will also establish a Federal system for wholesale drug distributor and third-party logistics provider licensing for use in the absence of a SL program. NPRM Target Date: December 2021.
• **Nicotine Toxicity Warnings** (**0910-AH24**): FDA has proposed to establish acute nicotine toxicity warning requirements for liquid nicotine and nicotine-containing e-liquid(s) that are made or derived from tobacco and intended for human consumption, and potentially for other tobacco products including, but not limited to, novel tobacco products such as dissolvables, lotions, gels, and drinks. NPRM Target Date: October 2022.

• **Post Approval Changes to Approved Applications** (**0910-AH55**): The proposed rule would update the existing regulations governing supplements and other changes to approved new drug applications, abbreviated new drug applications, and biologics license applications, as well as regulations regarding certain post-approval reports. NPRM Target Date: September 2022.

• **Certain Requirements Regarding Prescription Drug Marketing** (**0910-AH56**): FDA is amending the regulations at 21 CFR 203 to remove provisions no longer in effect and incorporate conforming changes following enactment of the Drug Supply Chain Security Act (DSCSA). This proposed rule amends the regulations to clarify provisions and avoid causing confusion with the new standards for wholesale distribution established by DSCSA. NPRM Target Date: January 2022.

• **Current Good Manufacturing Practice for Outsourcing Facilities** (**0910-AH61**): This proposed rule would set forth the minimum current good manufacturing practice requirements for human drug products compounded by an outsourcing facility. NPRM Target Date: July 2022.

• **Nonprescription Drug Product with an Additional Condition for Nonprescription Use** (**0910-AH62**): The proposed rule would establish requirements for a drug product that could be marketed as a nonprescription drug product with an additional condition that an applicant must implement to ensure appropriate self-selection, appropriate actual use, or both by consumers. NPRM Target Date: December 2021.

• **Medication Guide; Patient Medication Information** (**0910-AH68**): The proposed rule would amend FDA medication guide regulations to require a new form of patient labeling, Patient Medication Information, for submission to and review by the FDA for human prescription drug products and certain blood products used, dispensed, or administered on an outpatient basis. The proposed rule would include requirements for Patient Medication Information development and distribution and would require clear and concisely written prescription drug product information presented in a consistent and easily understood format to help patients use their prescription drug products safely and effectively. NPRM Target Date: February 2022.

• **Requirements for Tobacco Product Manufacturing Practice** (**0910-AH91**): The rule is proposing to establish tobacco product manufacturing practice (TPMP) requirements for manufacturers of finished and bulk tobacco products. This proposed rule, if finalized, would set forth requirements for the manufacture, pre-production design validation, packing, and storage of a tobacco product. NPRM Target Date: March 2022.

• **Harmonizing and Modernizing Regulation of Medical Device Quality Systems** (**0910-AH99**): The revisions will update the existing requirements with the specifications of an international consensus standard for medical device manufacturers. The revisions are intended to promote the use of more modern risk management principles and reduce
regulatory burdens on device manufacturers and importers by harmonizing domestic and international requirements. NPRM Target Date: December 2021.

- **Administrative Detention of Tobacco Products** *(0910-AL05)*: FDA is proposing regulations to establish requirements for the administrative detention of tobacco products. This proposal would allow FDA to administratively detain tobacco products encountered during inspections that an officer or employee conducting the inspection has reason to believe are adulterated or misbranded. NPRM Target Date: July 2022.

- **Biologics Regulation Modernization** *(0910-AL14)*: FDA’s biologics regulations will be updated to clarify existing requirements and procedures related to Biologic License Applications and to promote the goals associated with FDA’s implementation of the abbreviated licensure pathway created by the Biologics Price Competition and Innovation Act of 2009. NPRM Target Date: August 2022.

- **Clinical Holds in Medical Device Investigations** *(0910-AL20)*: The proposed rule would create procedures for suspending, i.e., imposing a hold (a "clinical hold") on, a clinical investigation of a medical device. The proposed rule would implement section 520(g)(8) of the FFDCA authorizing clinical holds for device investigations. NPRM Target Date: May 2022.

- **Medical Devices; Ear, Nose and Throat Devices; Establishing Over-the-Counter Hearing Aids and Aligning Other Regulations** *(0910-AL21)*: 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. NPRM Comment End Date: January 18, 2022.

- **Classification of Wound Dressings Containing Antimicrobials and/or Other Chemicals** *(0910-AL26)*: FDA proposed to classify the following three categories of unclassified, pre-amendments wound dressings that contain antimicrobials, and/or other chemicals currently grouped under product code FRO: Solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes. NPRM Target Date: August 2022.

- **Amendment to Records and Reports Concerning Adverse Drug Experiences on Marketed Prescription Drugs for Human Use Without Approved New Drug Applications** *(0910-AL30)*: FDA is proposing to amend the Adverse Event Reporting regulations for marketed prescription drug products that are not the subject of an approved new drug or abbreviated new drug application. The proposed amendment will provide clarity to industry regarding when adverse event reports should be submitted to the Agency.

- **Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A and 503B of the FFDCA** *(0910-AL31)*: FDA has proposed to establish the criteria by which drug products and categories of drug products will be evaluated for inclusion on the list of drug products and categories of drug products that present demonstrable difficulties for compounding under section 503A and the Difficult to Compound List for section 503B. FDA is also proposing to include certain categories of drug products on these lists. NPRM Target Date: June 2022.
• **Investigational New Drug Application Annual Reporting (0910-AI37):** This proposed rule, if finalized, would amend FDA’s requirements concerning annual reports submitted by sponsors to INDs by replacing FDA’s current annual reporting requirement with a new requirement for an FDA development safety update report. NPRM Target Date: February 2022.

• **Modified Risk Tobacco Product Applications (0910-AI38):** This proposed rule would establish content and format requirements to ensure that modified risk tobacco product applications contain sufficient information for FDA to determine whether it should permit the marketing of a modified risk tobacco product. Additionally, the proposed rule would set forth the basic procedures for modified risk tobacco product application review and require applicants receiving authorization to market a modified risk tobacco product to establish and maintain records, conduct postmarket surveillance and studies, and submit reports to FDA. NPRM Target Date: June 2022.

• **Prohibition of Sale of Tobacco Products to Persons Younger Than 21 Years of Age (0910-AI51):** As required by the section 603 of the CAA, 2020, FDA is issuing a final rule to make conforming changes to its regulations to: reflect the increased minimum age of sale for tobacco products from 18 to 21 years of age, increase the minimum age for verification from under the age of 27 to under the age of 30; and increase the minimum age for facilities that maintain vending machines or self-service displays that sell tobacco products from 18 years to 21 years of age. Final Rule Target Date: March 2022.

• **Revising the National Drug Code Format and Drug Labeling Barcode Requirements (0910-AI52):** This action, if finalized, will standardize the format of all NDCs. Additionally, this proposal revises drug product bar code label requirements to permit the use of linear or non-linear barcodes that meet certain standards. NPRM Target Date: April 2022.

• **Conduct of Analytical and Clinical Pharmacology, Bioavailability and Bioequivalence Studies (0910-AI57):** FDA proposed to amend 21 CFR 320, in certain parts, and establish a new 21 CFR 321 to clarify FDA's study conduct expectations for analytical and clinical pharmacology, bioavailability (BA) and bioequivalence (BE) studies that support marketing applications for human drug and biological products. NPRM Target Date: June 2022.

• **Additional Amendments to the Final Rule Regarding the List of Bulk Substances that can be used to Compound Drug Products in Accordance with Section 503A of the FFDCA (0910-AI70):** The proposed rule will identify certain bulk drug substances that FDA has proposed to place on the 503A Bulks List and certain bulk drug substances that FDA has proposed not to include on the 503A Bulks List. NPRM Target Date: November 2021.

• **Fixed-Combination and Co-Packaged Drugs: Applications for Approval and Combinations of Active Ingredients Under Consideration for Inclusion in an Over-the-Counter (OTC) Monograph (0910-AF89):** The final rule combines the combination drug requirements into a single set of regulations for both prescription and OTC combination drugs and codifies existing policy on what kinds of studies are needed to show that the combination drug requirements are met. The final rule also applies these regulations to combinations of biological drug products and to drug-biological product combinations; clarifies application of FDA’s requirements regarding fixed combinations to certain natural source drugs and certain synthetic drugs; establishes circumstances under which the Agency
might waive the combination requirements for a particular drug or biological product; and addresses the issue of co-packaging. Final Rule Target Date: May 2022.

- **Biologics License Applications and Master Files (0910-AH50):** The final rule will permit the continued use of DMFs for NDAs subject to the BPCI Act transition. The final rule will codify that a biological product that was originally approved as a new drug application under the FD&C Act can continue to reference a DMF for drug substance, a drug substance intermediate, or a drug product information after the application is deemed to be a license under the PHS Act. Final Rule Target Date: December 2021.

- **Updating Public Information Regulations (0910-AH69):** The amendments bring the agency’s regulations in line with statutory amendments to the FOIA, update cross references to other statutes and parts of the agency’s regulations, and clarify certain provisions with minor editorial updates. Additionally, the rule will update the current regulations to reflect changes to the organization, to make the FOIA process easier for the public to navigate, and to make certain provisions clearer. Final Rule Target Date: December 2021.

- **Revision of Product Jurisdiction Regulations (0910-AH71):** FDA is amending its regulation on classifying medical products as drugs, devices, biological products or combination products (products composed of two or more different types of medical products, e.g., a drug and device) and on Center assignment and regulation of combination products, in two respects. Final Rule Target Date: September 2022.

- **Revised Procedures for the Announcement of Approvals and Denials of Premarket Approval Applications (PMAs) and Humanitarian Device Exemption (HDEs) Applications (0910-AI10):** FDA is amending its medical device regulations regarding the procedures for the announcement of approvals and denials of PMAs and HDEs. Final Rule Target Date: November 2021.

- **Annual Summary Reporting Requirements Under the Right to Try Act (0910-AI36):** To facilitate implementation of the reporting requirements of the Right to Try Act, FDA is establishing requirements for the deadline and contents of submission of an annual summary. Final Rule Target Date: March 2022.

- **Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, and the Nation (0910-AI68):** FDA is amending its drug establishment registration and drug listing regulations via Direct Final Rule to extend the current exemption from drug establishment registration for certain manufacturers, repackers, relabelers, or salvagers of Type B or Type C medicated feeds to exempt all manufacturers, repackers, relabelers, or salvagers of Type B and C medicated feeds from drug establishment registration. Direct Final Rule Target Date: September 2022.

**HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)**

- **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. NPRM Target Date: January 2022.
CENTER FOR DISEASE CONTROL AND PREVENTION (CDC)

- **Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review** ([0920-AA71](#)): The Bioterrorism Preparedness Act requires that HHS Secretary review and republish the list of select agents and toxins on at least a biennial basis. This document begins the biennial review and republication of the list of biological agents and toxins regulated by HHS. NPRM Target Date: March 2022.

- **CDC and ATSDR User Fee Regulation** ([0920-AA73](#)): CDC proposes to amend its current regulation at 42 CFR 7, *Distribution of Reference Biological Standards and Biological Preparations*, to include the collection of user fees for services provided to requestors for both CDC and ATSDR. NPRM Target Date: May 2022.

- **Requirement for Proof of Vaccination or Other Proof of Immunity Against Quarantinable Communicable Diseases** ([0920-AA80](#)): This IFR will amend current regulations to permit CDC to require proof of vaccination or other proof of immunity against quarantinable communicable diseases. IFR Target Date: December 2021.

INDIAN HEALTH SERVICE (IHS)

- **Catastrophic Health Emergency Fund (CHEF)** ([0917-AA10](#)): The proposed rule establishes conditions and procedures for payment from the fund. NPRM Target Date: February 2022.

- **Medical Quality Assurance Records Regulations** ([0917-AA20](#)): To encourage thorough review and open discussion of the medical care provided by IHS, other Indian health programs and urban Indian organizations, Congress elected to make IHS medical quality assurance records and related testimony confidential and privileged. NPRM Target Date: May 2022.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

- **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. NPRM 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. NPRM Target Date: September 2022.

OFFICE OF THE INSPECTOR GENERAL (OIG)

- **Amendments to Civil Monetary Penalty Law Regarding Grants, Contracts, and Information Blocking** ([0936-AA09](#)): The final rule would implement the 21st Century Cures
Act provision that authorizes HHS to impose civil monetary penalties, assessments, and exclusions upon individuals and entities that engage in fraud and other misconduct related to HHS grants, contracts, and other agreements. Final Action Target Date: March 2022.

**ADMINISTRATION FOR CHILDREN AND FAMILIES (ACF)**

- **Standards for Data Exchange** (0970-AC58): This rule would designate data exchange standards for certain categories of information required to be shared under applicable Federal law for agencies operating the Temporary Assistance for Needy Families (TANF), child support enforcement, child welfare services, and foster care and adoption assistance programs. NPRM Target Date: June 2022.

- **Vaccine and Mask Requirements To Mitigate the Spread of COVID-19 in Head Start Programs** (0970-AC90): This regulation will propose to mandate a vaccine or regular testing for all staff in Head Start programs. IFR Effective Target Date: January 2022.