

1 Jennifer C. Pizer (CA Bar No. 152327)
2 Lambda Legal Defense and Education Fund
3 4221 Wilshire Blvd., Suite 280
4 Los Angeles, CA 90010
(213) 590-5903
jpizer@lambdalegal.org

5 M. Currey Cook (admitted *pro hac vice*)
6 Lambda Legal Defense and Education Fund
7 120 Wall St., 19th Fl.
8 New York, New York 10005
ccook@lambdalegal.org
Telephone: (212) 809-8585

9 Sasha Buchert (admitted *pro hac vice*)
10 Lambda Legal Defense and Education Fund
11 1776 K Street, N.W., 8th Floor
12 Washington, DC 20006-2304
Sbuchert@lambdalegal.org
Telephone: (202) 804-6245

13 *Counsel for Plaintiffs*

Kristen Miller (admitted *pro hac vice*)
Jeffrey B. Dubner (admitted *pro hac vice*)
Sean A. Lev (admitted *pro hac vice*)
Democracy Forward Foundation
P.O. Box 34553
Washington, DC 20043
jdubner@democracyforward.org
kmiller@democracyforward.org
slev@democracyforward.org
Telephone: (202) 448-9090

Kathryn E. Fort (admitted *pro hac vice*)
Michigan State University College of Law
Indian Law Clinic
648 N. Shaw Lane
East Lansing, M.I. 48824
fort@msu.edu
Telephone: (517) 432-6992

Counsel for Plaintiffs

14 UNITED STATES DISTRICT COURT
15 NORTHERN DISTRICT OF CALIFORNIA
16 SAN FRANCISCO DIVISION

17 CALIFORNIA TRIBAL FAMILIES COALITION,
18 *et al.*,

19 Plaintiffs,

20 v.

21 XAVIER BECERRA, in his official capacity as
22 Secretary of Health and Human Services, *et al.*,

23 Defendants.

Case No. 3:20-cv-6018-MMC

**PLAINTIFFS' NOTICE OF FILING
NUNC PRO TUNC**

24
25
26
27
28

1 On July 6, Plaintiffs filed a Motion for Leave to File a Notice of Supplementary Material.
2 ECF No. 113. Attached to the motion was the proposed Notice of Supplementary Material and an
3 attachment. ECF Nos. 113-1, 113-2. On July 8, the Court granted the motion and directed
4 Plaintiffs to file the notice no later than July 15, 2022. ECF No. 114.

5 Due to an internal miscommunication, Plaintiffs did not refile by the Notice of
6 Supplementary Material by July 15. Accordingly, Plaintiffs now file the Notice of Supplementary
7 Material and respectfully request that it be treated *nunc pro tunc* as having been filed on July 15.
8 Because the Notice of Supplementary Material and its attachment are identical to the ones filed on
9 July 6 as ECF Nos. 113-1 and 113-2, there is no prejudice to Defendants. Counsel for Plaintiffs
10 contacted counsel for Defendants, who indicated that they have no objections to this *nunc pro tunc*
11 filing.

12

13 Dated: July 19, 2022

Respectfully submitted,

14

By: /s/ Jeffrey B. Dubner
Jeffrey B. Dubner (admitted *pro hac vice*)
Kristen P. Miller (admitted *pro hac vice*)
Sean A. Lev (admitted *pro hac vice*)
Democracy Forward Foundation
P.O. Box 34553
Washington, DC 20043
jdubner@democracyforward.org
kmiller@democracyforward.org
slev@democracyforward.org
Telephone: (202) 448-9090

15

16

17

18

19

20

21

Jennifer C. Pizer (CA Bar. No. 152327)
Lambda Legal Defense and Education Fund
4221 Wilshire Blvd., Suite 280
Los Angeles, CA 90010
(213) 590-5903
jpizer@lambdalegal.org

22

23

24

25

M. Currey Cook (admitted *pro hac vice*)
Lambda Legal Defense and Education Fund
120 Wall St., 19th Fl.
New York, New York 10005
ccook@lambdalegal.org
Telephone: (212) 809-8585

26

27

28

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

Sasha Buchert (admitted *pro hac vice*)
Lambda Legal Defense and Education Fund
1776 K Street, N.W., 8th Floor
Washington, DC 20006-2304
Sbuchert@lambdalegal.org
Telephone: (202) 804-6245

Kathryn E. Fort (admitted *pro hac vice*)
Michigan State University College of Law
Indian Law Clinic
648 N. Shaw Lane
East Lansing, M.I. 48824
fort@msu.edu
Telephone: (517) 432-6992

Counsel for Plaintiffs

1 Jennifer C. Pizer (CA Bar No. 152327)
2 Lambda Legal Defense and Education Fund
3 4221 Wilshire Blvd., Suite 280
4 Los Angeles, CA 90010
(213) 590-5903
jpizer@lambdalegal.org

5 M. Currey Cook (admitted *pro hac vice*)
6 Lambda Legal Defense and Education Fund
7 120 Wall St., 19th Fl.
8 New York, New York 10005
ccook@lambdalegal.org
Telephone: (212) 809-8585

9 Sasha Buchert (admitted *pro hac vice*)
10 Lambda Legal Defense and Education Fund
11 1776 K Street, N.W., 8th Floor
12 Washington, DC 20006-2304
Sbuchert@lambdalegal.org
Telephone: (202) 804-6245

13 *Counsel for Plaintiffs*

Kristen Miller (admitted *pro hac vice*)
Jeffrey B. Dubner (admitted *pro hac vice*)
Sean A. Lev (admitted *pro hac vice*)
Democracy Forward Foundation
P.O. Box 34553
Washington, DC 20043
jdubner@democracyforward.org
kmiller@democracyforward.org
slev@democracyforward.org
Telephone: (202) 448-9090

Kathryn E. Fort (admitted *pro hac vice*)
Michigan State University College of Law
Indian Law Clinic
648 N. Shaw Lane
East Lansing, M.I. 48824
fort@msu.edu
Telephone: (517) 432-6992

Counsel for Plaintiffs

14 UNITED STATES DISTRICT COURT
15 NORTHERN DISTRICT OF CALIFORNIA
16 SAN FRANCISCO DIVISION

17 CALIFORNIA TRIBAL FAMILIES COALITION,
18 *et al.*,

18 Plaintiffs,

19 v.

20 XAVIER BECERRA, in his official capacity as
21 Secretary of Health and Human Services, *et al.*,

22 Defendants.

Case No. 3:20-cv-6018-MMC

**PLAINTIFFS' NOTICE OF
SUPPLEMENTARY MATERIAL**

1 Pursuant to Local Rule 7-3(d), Plaintiffs file this Notice of Supplemental Material to
2 update the Court on facts relevant to Defendants’ Motion for Voluntary Remand Without Vacatur,
3 ECF No. 102 (“Defs.’ Mot.”).

4 On June 21, 2022, Defendant Department of Health and Human Services (“HHS”) issued
5 its Spring 2022 Regulatory Agenda. Pursuant to Executive Order 12866 section 4(b), an agency’s
6 Regulatory Agenda must include “all regulations under development or review.” 58 Fed. Reg.
7 51,735, 51,738 (Oct. 4, 1993). Actions expected to be taken within 12 months are listed as
8 “Active,” and actions expected more than 12 months out are listed as “Long-Term Actions.” *See*
9 Office of Info. & Regulatory Affairs, Office of Mgmt. & Budget, *About the Unified Agenda*,
10 https://www.reginfo.gov/public/jsp/eAgenda/UA_About.myjsp. HHS’s Spring 2022 Regulatory
11 Agenda is attached as Attachment A.

12 Defendants have previously asserted that they “are seeking to adopt a new rule due to a
13 change in administration,” Defs.’ Reply in Support of Mot. for Voluntary Remand Without
14 Vacatur, ECF No. 109, at 1, and have “already begun to obtain the necessary departmental
15 clearance from agency leadership to move forward with the rulemaking process,” Defs.’ Mot. at 2.
16 However, the Spring 2022 Regulatory Agenda does not include any rulemaking related to the
17 Adoption and Foster Care Analysis and Reporting System (“AFCARS”). *See* Attachment A. This
18 means that no amendment to the challenged 2020 Final Rule is “under development.” 58 Fed.
19 Reg. at 51,738. Indeed, even the “Long-Term Actions” list does not contain any such rule,
20 meaning that Defendants do not expect to issue a proposed rule or take any other action on the
21 subject in the next two years, and consequently do not intend to issue a final rule in the current
22 presidential term.

23 Accordingly, and for the reasons stated in Plaintiffs’ Opposition to Defendants’ Motion for
24 Remand Without Vacatur, ECF No. 104, the equities do not support Defendants’ request to
25 remand the 2020 Final Rule so that Defendants can consider amending it, and the 2020 Final Rule
26 should be remanded *with vacatur*.

27
28

1 Dated: July 19, 2022

Respectfully submitted,

2

By: /s/ Jeffrey B. Dubner

3

Jeffrey B. Dubner (admitted *pro hac vice*)

4

Kristen P. Miller (admitted *pro hac vice*)

5

Sean A. Lev (admitted *pro hac vice*)

6

Democracy Forward Foundation

7

P.O. Box 34553

8

Washington, DC 20043

9

jdubner@democracyforward.org

10

kmiller@democracyforward.org

11

slev@democracyforward.org

12

Telephone: (202) 448-9090

13

Jennifer C. Pizer (CA Bar. No. 152327)

14

Lambda Legal Defense and Education Fund

15

4221 Wilshire Blvd., Suite 280

16

Los Angeles, CA 90010

17

(213) 590-5903

18

jpizer@lambdalegal.org

19

M. Currey Cook (admitted *pro hac vice*)

20

Lambda Legal Defense and Education Fund

21

120 Wall St., 19th Fl.

22

New York, New York 10005

23

ccook@lambdalegal.org

24

Telephone: (212) 809-8585

25

Sasha Buchert (admitted *pro hac vice*)

26

Lambda Legal Defense and Education Fund

27

1776 K Street, N.W., 8th Floor

28

Washington, DC 20006-2304

Sbuchert@lambdalegal.org

Telephone: (202) 804-6245

Kathryn E. Fort (admitted *pro hac vice*)

Michigan State University College of Law

Indian Law Clinic

648 N. Shaw Lane

East Lansing, M.I. 48824

fort@msu.edu

Telephone: (517) 432-6992

Counsel for Plaintiffs

- Home
- Unified Agenda
- Regulatory Review
- Information Collection Review
- FAQs / Resources
- Contact Us

Agency Rule List - Spring 2022

Department of Health and Human Services

Agency	Agenda Stage of Rulemaking	Title	RIN
HHS/HRSA	Proposed Rule Stage	340B Drug Pricing Program; Administrative Dispute Resolution	0906-AB28
HHS/FDA	Proposed Rule Stage	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
HHS/FDA	Proposed Rule Stage	National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers	0910-AH11
HHS/FDA	Proposed Rule Stage	Post Approval Changes to Approved Applications	0910-AH55
HHS/FDA	Proposed Rule Stage	Current Good Manufacturing Practice for Positron Emission Tomography Drugs	0910-AH58
HHS/FDA	Proposed Rule Stage	Current Good Manufacturing Practice for Outsourcing Facilities	0910-AH61
HHS/FDA	Proposed Rule Stage	Nonprescription Drug Product With an Additional Condition for Nonprescription Use	0910-AH62
HHS/FDA	Proposed Rule Stage	Medication Guide; Patient Medication Information	0910-AH68
HHS/FDA	Proposed Rule Stage	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food	0910-AH77
HHS/FDA	Proposed Rule Stage	Permanent Listing of Color Additive Lakes	0910-AH80
HHS/FDA	Proposed Rule Stage	Amendments to Registration of Food Facilities	0910-AH82
HHS/FDA	Proposed Rule Stage	Requirements for Tobacco Product Manufacturing Practice	0910-AH91
HHS/FDA	Proposed Rule Stage	Updated Regulations for Medical Gases	0910-AH96
HHS/FDA	Proposed Rule Stage	Administrative Detention of Tobacco Products	0910-AI05
HHS/FDA	Proposed Rule Stage	Protection of Human Subjects and Institutional Review Boards	0910-AI07
HHS/FDA	Proposed Rule Stage	Institutional Review Boards; Cooperative Research	0910-AI08
HHS/FDA	Proposed Rule Stage	Nutrient Content Claims, Definition of Term: Healthy	0910-AI13
HHS/FDA	Proposed Rule Stage	Biologics Regulation Modernization	0910-AI14
HHS/FDA	Proposed Rule Stage	Conditional Approval of New Animal Drugs for Minor Use and Minor Species	0910-AI18
HHS/FDA	Proposed Rule Stage	Clinical Holds in Medical Device Investigations	0910-AI20
HHS/FDA	Proposed Rule Stage	Streamlining Provisions Requiring Disclosure to and Receipt of Written Assurances From Commercial Customers in the Foreign Supplier Verification Programs Rule	0910-AI23
HHS/FDA	Proposed Rule Stage	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals	0910-AI24
HHS/FDA	Proposed Rule Stage	The FDA Food Safety Modernization Act: Amendments to Exemption Provisions in the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Regulation	0910-AI25
HHS/FDA	Proposed Rule Stage	Classification of Wound Dressings Containing Antimicrobials and/or Other Chemicals	0910-AI26
HHS/FDA	Proposed Rule Stage	Tobacco Product Standard for Characterizing Flavors in Cigars	0910-AI28
HHS/FDA	Proposed Rule Stage	Amendments to Patent Term Restoration	0910-AI29
HHS/FDA	Proposed Rule Stage	Amendment to Records and Reports Concerning Adverse Drug Experiences on Marketed Prescription Drugs for Human Use Without Approved New Drug Applications	0910-AI30
HHS/FDA	Proposed Rule Stage	Drug Products or Categories of Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act	0910-AI31
HHS/FDA	Proposed Rule Stage	Medical Devices; Cardiovascular Devices; Classification of More Than Minimally Manipulated Allograft Heart Valves	0910-AI33
HHS/FDA	Proposed Rule Stage	Phased Review of New Animal Drug Applications, Electronic Submission, and Master Files	0910-AI35
HHS/FDA	Proposed Rule Stage	Investigational New Drug Application Annual Reporting	0910-AI37
HHS/FDA	Proposed Rule Stage	Modified Risk Tobacco Product Applications	0910-AI38
HHS/FDA	Proposed Rule Stage	Labeling Requirements for Approved and Conditionally Approved New Animal Drugs	0910-AI43
HHS/FDA	Proposed Rule Stage	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	0910-AI49
HHS/FDA	Proposed Rule Stage	Amending Regulations That Require Multiple Copies Submissions	0910-AI50
HHS/FDA	Proposed Rule Stage	Revising the National Drug Code Format and Drug Labeling Barcode Requirements	0910-AI52
HHS/FDA	Proposed Rule Stage	Amendment of Procedural Requirements for Color Additive Petitions	0910-AI53
HHS/FDA	Proposed Rule Stage	Amendment of Procedural Requirements for Food Additive Petitions	0910-AI55
HHS/FDA	Proposed Rule Stage	Conduct of Analytical and Clinical Pharmacology, Bioavailability and Bioequivalence Studies	0910-AI57
HHS/FDA	Proposed Rule Stage	Contact Lens Devices; Designation of Special Controls for Daily Wear Contact Lenses	0910-AI58
HHS/FDA	Proposed Rule Stage	Administrative Destruction of Certain Devices Refused Admission to the United States	0910-AI59
HHS/FDA	Proposed Rule Stage	Tobacco Product Standard for Menthol in Cigarettes	0910-AI60
HHS/FDA	Proposed Rule Stage	Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Certain Tobacco Products	0910-AI64
HHS/FDA	Proposed Rule Stage	Revocation of Methods of Analysis Regulation	0910-AI65

HHS/FDA	Proposed Rule Stage	Certifications Concerning Imported Foods	0910-AI66
HHS/FDA	Proposed Rule Stage	Color Additive Certification; Increase in Fees for Certification Services	0910-AI69
HHS/FDA	Proposed Rule Stage	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 Federal Food, Drug and Cosmetic Act	0910-AI70
HHS/FDA	Proposed Rule Stage	Distribution of Compounded Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act	0910-AI71
HHS/FDA	Proposed Rule Stage	Use of Salt Substitutes to Reduce the Sodium Content in Standardized Foods	0910-AI72
HHS/FDA	Proposed Rule Stage	Fish and Shellfish; Amendments to the Canned Tuna Standard of Identity	0910-AI74
HHS/FDA	Proposed Rule Stage	Prior Notice of Imported Food	0910-AI75
HHS/FDA	Proposed Rule Stage	Tobacco Product Standard for Nicotine Level of Certain Tobacco Products	0910-AI76
HHS/FDA	Final Rule Stage	Fixed-Combination and Co-Packaged Drugs: Applications for Approval and Combinations of Active Ingredients Under Consideration for Inclusion in an Over-the-Counter Monograph	0910-AF89
HHS/FDA	Final Rule Stage	Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in a Clear, Conspicuous, Neutral Manner in Advertisements in Television and Radio Format	0910-AG27
HHS/FDA	Final Rule Stage	Sunlamp Products; Amendment to the Performance Standard	0910-AG30
HHS/FDA	Final Rule Stage	Mammography Quality Standards Act	0910-AH04
HHS/FDA	Final Rule Stage	Biologics License Applications and Master Files	0910-AH50
HHS/FDA	Final Rule Stage	Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations	0910-AH52
HHS/FDA	Final Rule Stage	Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic Products; Amendments to Performance Standards for Diagnostic X-ray, Laser, and Ultrasonic Products	0910-AH65
HHS/FDA	Final Rule Stage	Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Veterinary Devices	0910-AH66
HHS/FDA	Final Rule Stage	Updating Public Information Regulations	0910-AH69
HHS/FDA	Final Rule Stage	Revision of Product Jurisdiction Regulations	0910-AH71
HHS/FDA	Final Rule Stage	Amendments to the List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act	0910-AH81
HHS/FDA	Final Rule Stage	Food Additives: Food Contact Substance Notification That Is No Longer Effective	0910-AI01
HHS/FDA	Final Rule Stage	Medical Devices; Immunology and Microbiology Devices; Classification of Human Leukocyte, Neutrophil and Platelet Antigen and Antibody Tests	0910-AI12
HHS/FDA	Final Rule Stage	Revocation of Uses of Partially Hydrogenated Oils in Foods	0910-AI15
HHS/FDA	Final Rule Stage	Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a Standard of Quality	0910-AI17
HHS/FDA	Final Rule Stage	Medical Devices; Ear, Nose and Throat Devices; Establishing Over-the-Counter Hearing Aids and Aligning Other Regulations	0910-AI21
HHS/FDA	Final Rule Stage	Classification of Spinal Spheres For Use in Intervertebral Fusion Procedures	0910-AI32
HHS/FDA	Final Rule Stage	Annual Summary Reporting Requirements Under the Right to Try Act	0910-AI36
HHS/FDA	Final Rule Stage	Cheeses and Related Cheese Products; Proposal to Permit the Use of Ultrafiltered Milk	0910-AI42
HHS/FDA	Final Rule Stage	Requirements For Additional Traceability Records For Certain Foods	0910-AI44
HHS/FDA	Final Rule Stage	Defining "Small Number of Animals" for Minor Use Determination; Periodic Reassessment	0910-AI46
HHS/FDA	Final Rule Stage	Prohibition of Sale of Tobacco Products to Persons Younger Than 21 Years of Age	0910-AI51
HHS/FDA	Final Rule Stage	Revision of Requirements for the Establishment and Maintenance of Records Related to Medicated Animal Feed and Veterinary Feed Directive Drugs	0910-AI67
HHS/FDA	Final Rule Stage	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	0910-AI68
HHS/FDA	Final Rule Stage	Amendment to Device Registration and Listing Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products	0910-AI73
HHS/IHS	Prerule Stage	Calendar Year 2023 Reimbursement Rates Notice	0917-AA22
HHS/IHS	Proposed Rule Stage	Catastrophic Health Emergency Fund (CHEF)	0917-AA10
HHS/IHS	Proposed Rule Stage	Medical Quality Assurance Records Regulations	0917-AA20
HHS/IHS	Final Rule Stage	Removal of Suspended Regulations	0917-AA13
HHS/IHS	Final Rule Stage	Removal of Obsolete Portion of Regulation Relating to Care and Treatment of Ineligible Individuals	0917-AA14
HHS/CDC	Proposed Rule Stage	Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review	0920-AA71
HHS/CDC	Proposed Rule Stage	CDC and ATSDR User Fee Regulation	0920-AA73
HHS/CDC	Proposed Rule Stage	Development of Regulatory Requirements for Respirator Fit Capability Test Standards for Air-Purifying, Half-Facepiece, Particulate Respirators	0920-AA77
HHS/CDC	Proposed Rule Stage	World Trade Center Health Program; Addition of Uterine Cancer to the List of WTC-Related Health Conditions	0920-AA81
HHS/CDC	Proposed Rule Stage	Control of Communicable Diseases; Foreign Quarantine Importation of Dogs and Cats	0920-AA82
HHS/CDC	Final Rule Stage	Approval Tests and Standards for Air-Purifying Particulate Respirators	0920-AA69
HHS/CDC	Final Rule Stage	Control of Communicable Diseases; Foreign Quarantine	0920-AA75
HHS/CDC	Final Rule Stage	Possession, Use, and Transfer of Select Agents and Toxins; Addition of SARS-CoV/SARS-CoV-2 Chimeric Viruses	0920-AA79
HHS/NIH	Final Rule Stage	Conduct of Persons and Traffic on the National Institutes of Health Federal Enclave	0925-AA67
HHS/NIH	Final Rule Stage	National Institutes of Health Loan Repayment Programs	0925-AA68
HHS/SAMHSA	Proposed Rule Stage	Mandatory Guidelines for Federal Workplace Drug Testing Programs--Urine	0930-AA36
HHS/SAMHSA	Proposed Rule Stage	Mandatory Guidelines for Federal Workplace Drug Testing Programs--Oral/Fluid	0930-AA37
HHS/SAMHSA	Proposed Rule Stage	Treatment of Opioid Use Disorder With Buprenorphine Utilizing Telehealth	0930-AA38
HHS/SAMHSA	Proposed Rule Stage	Treatment of Opioid use Disorder With Extended Take Home Doses of Methadone	0930-AA39
HHS/SAMHSA	Final Rule Stage	Mandatory Guidelines for Federal Workplace Drug Testing Programs--Hair	0930-AA33
HHS/OIG	Final Rule Stage	Amendments to Civil Monetary Penalty Law Regarding Grants, Contracts, and Information Blocking	0936-AA09

HHS/OASH	Proposed Rule Stage	Federal Policy for the Protection of Human Subjects: Updates to Reduce Administrative Burdens	0937-AA10
HHS/OASH	Proposed Rule Stage	Public Health Service Policies on Research Misconduct	0937-AA12
HHS/OASH	Final Rule Stage	HHS Policy for the Protection of Human Research Subjects: Updates to the Additional Protections for Specific Populations (Subparts B, C, and D)	0937-AA09
HHS/CMS	Proposed Rule Stage	Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories (CMS-3326)	0938-AT47
HHS/CMS	Proposed Rule Stage	Clinical Laboratory Improvement Amendments (CLIA) Fees (CMS-3356)	0938-AT56
HHS/CMS	Proposed Rule Stage	Reporting of Crimes Occurring in Federally Funded Long Term Care Facilities and Enforcement Under Section 1150B of the Social Security Act (CMS-3359)	0938-AT60
HHS/CMS	Proposed Rule Stage	Medicare Secondary Payer and Future Medicals (CMS-6047)	0938-AT85
HHS/CMS	Proposed Rule Stage	Radiation Oncology (RO) Model (CMS-5527)	0938-AT89
HHS/CMS	Proposed Rule Stage	Streamlining the Medicaid and CHIP Application, Eligibility Determination, Enrollment, and Renewal Processes (CMS-2421)	0938-AU00
HHS/CMS	Proposed Rule Stage	Administrative Simplification: Modifications to NCPDP Retail Pharmacy Standards (CMS-0056)	0938-AU19
HHS/CMS	Proposed Rule Stage	Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (CMS-2434)	0938-AU28
HHS/CMS	Proposed Rule Stage	Medicare Payment Policies for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) (CMS-1756)	0938-AU45
HHS/CMS	Proposed Rule Stage	Alternative Payment Model (CMS-5535)	0938-AU51
HHS/CMS	Proposed Rule Stage	Mandatory Medicaid and Children's Health Insurance Plan (CHIP) Core Set Reporting (CMS-2440)	0938-AU52
HHS/CMS	Proposed Rule Stage	Amendments to Rules Governing Organ Procurement Organizations (CMS-3409)	0938-AU54
HHS/CMS	Proposed Rule Stage	Improving Infection Prevention and Control in Long Term Care Facilities (CMS-3405)	0938-AU58
HHS/CMS	Proposed Rule Stage	Medicare Advantage and Medicare Prescription Drug Benefit Program Payment Policy (CMS-4198)	0938-AU59
HHS/CMS	Proposed Rule Stage	Provider Nondiscrimination Requirements for Group Health Plans and Health Insurance Issuers in the Group and Individual Markets (CMS-9910)	0938-AU64
HHS/CMS	Proposed Rule Stage	Short-Term Limited Duration Insurance; Update (CMS-9904)	0938-AU67
HHS/CMS	Proposed Rule Stage	Assuring Access to Medicaid Services (CMS-2442)	0938-AU68
HHS/CMS	Proposed Rule Stage	FY 2023 Skilled Nursing Facility (SNFs) Prospective Payment System and Consolidated Billing and Updates to the Value-Based Purchasing and Quality Reporting Programs (CMS-1765)	0938-AU76
HHS/CMS	Proposed Rule Stage	CY 2023 Home Health Prospective Payment System Rate Update and Home Infusion Therapy Services Payment Update (CMS-1766)	0938-AU77
HHS/CMS	Proposed Rule Stage	CY 2023 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive Program (CMS-1768)	0938-AU79
HHS/CMS	Proposed Rule Stage	CY 2023 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1770)	0938-AU81
HHS/CMS	Proposed Rule Stage	CY 2023 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1772)	0938-AU82
HHS/CMS	Proposed Rule Stage	Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals; the Long-Term Care Hospital Prospective Payment System; and FY 2023 Rates (CMS-1771)	0938-AU84
HHS/CMS	Proposed Rule Stage	Implementing Certain Provisions of the Consolidated Appropriations Act and Other Revisions to Medicare Enrollment and Eligibility Rules (CMS-4199)	0938-AU85
HHS/CMS	Proposed Rule Stage	Transitional Coverage for Emerging Technologies (CMS-3421)	0938-AU86
HHS/CMS	Proposed Rule Stage	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 (CMS-0057)	0938-AU87
HHS/CMS	Proposed Rule Stage	Strengthening Oversight of Accrediting Organizations (AO) and Preventing AO Conflict of Interest, and Related Provisions (CMS-3367)	0938-AU88
HHS/CMS	Proposed Rule Stage	Basic Health Program; Federal Funding Methodology for Program Year 2023 and Proposed Changes to Basic Health Program Regulations (CMS-2441)	0938-AU89
HHS/CMS	Proposed Rule Stage	Medicare and Medicaid Program Integrity (CMS-6084)	0938-AU90
HHS/CMS	Proposed Rule Stage	Culturally Competent and Person-Centered Requirements to Increase Access to Care and Improve Quality for All (CMS-3418)	0938-AU91
HHS/CMS	Proposed Rule Stage	Conditions of Participation (CoPs) for Rural Emergency Hospitals (REHs) and Critical Access Hospital (CAH) COP Updates (CMS-3419)	0938-AU92
HHS/CMS	Proposed Rule Stage	Mental Health Parity and Addiction Equity Act and the Consolidated Appropriations Act, 2021 (CMS-9902)	0938-AU93
HHS/CMS	Proposed Rule Stage	Coverage of Certain Preventive Services Under the Affordable Care Act (CMS-9903)	0938-AU94
HHS/CMS	Proposed Rule Stage	Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024 (CMS-4201)	0938-AU96
HHS/CMS	Proposed Rule Stage	HHS Notice of Benefit and Payment Parameters for 2024 (CMS-9899)	0938-AU97
HHS/CMS	Proposed Rule Stage	Requirements Related to Advanced Explanation of Benefits and Other Provisions Under the Consolidated Appropriations Act 2021 (CMS-9900)	0938-AU98
HHS/CMS	Proposed Rule Stage	Medicaid Managed Care (CMS-2439)	0938-AU99
HHS/CMS	Proposed Rule Stage	Update of Calculation of the Hospital Specific Disproportionate Share Hospital (DSH) Limit Third Party Payer (CMS-2445)	0938-AV00
HHS/CMS	Final Rule Stage	Proficiency Testing Regulations Related to Analytes and Acceptable Performance (CMS-3355)	0938-AT55
HHS/CMS	Final Rule Stage	Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2020; Risk Adjustment Data Validation (CMS-4185)	0938-AT59
HHS/CMS	Final Rule Stage	Medicare Secondary Payer and Certain Civil Money Penalties (CMS-6061)	0938-AT86
HHS/CMS	Final Rule Stage	Requirements Related to Surprise Billing; Part II (CMS-9908)	0938-AU62
HHS/CMS	Final Rule Stage	CY 2023 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts (CMS-8080)	0938-AU71
HHS/CMS	Final Rule Stage	CY 2023 Part A Premiums for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8081)	0938-AU72
HHS/CMS	Final Rule Stage	Medicare Part B Monthly Actuarial Rates, Premium Rates, and Annual Deductible Beginning January 1, 2023 (CMS-8082)	0938-AU74

HHS/CMS	Final Rule Stage	FY 2023 Inpatient Rehabilitation Facility (IRF) Prospective Payment System Rate Update and Quality Reporting Program (CMS-1767)	0938-AU78
HHS/CMS	Final Rule Stage	FY 2023 Inpatient Psychiatric Facilities Prospective Payment System Rate (CMS-1769)	0938-AU80
HHS/CMS	Final Rule Stage	FY 2023 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements (CMS-1773)	0938-AU83
HHS/OCR	Prerule Stage	Considerations for Implementing the Health Information Technology for Economic and Clinical Health (HITECH) Act, as Amended	0945-AA04
HHS/OCR	Proposed Rule Stage	Rulemaking on Discrimination on the Basis of Disability in Critical Health and Human Services Programs or Activities	0945-AA15
HHS/OCR	Proposed Rule Stage	Confidentiality of Substance Use Disorder Patient Records	0945-AA16
HHS/OCR	Proposed Rule Stage	Nondiscrimination in Health Programs and Activities	0945-AA17
HHS/OCR	Proposed Rule Stage	Rescission of the Regulation Entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority"	0945-AA18
HHS/OCR	Final Rule Stage	HIPAA Privacy: Changes to Support, and Remove Barriers to, Coordinated Care and Individual Engagement	0945-AA00
HHS/ONC	Proposed Rule Stage	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
HHS/ACF	Proposed Rule Stage	Updating Native Employment Works Requirements	0970-AC83
HHS/ACF	Proposed Rule Stage	Native Hawaiian Revolving Loan Fund Eligibility Requirements	0970-AC84
HHS/ACF	Proposed Rule Stage	Foster Care Legal Representation	0970-AC89
HHS/ACF	Proposed Rule Stage	Separate Licensing Standards for Relative or Kinship Foster Family Homes	0970-AC91
HHS/ACF	Proposed Rule Stage	OCSE Federal Case Registry of Child Support Orders System of Records Exemption	0970-AC92
HHS/ACF	Proposed Rule Stage	Unaccompanied Children Program Foundational Rule	0970-AC93
HHS/ACF	Proposed Rule Stage	Federal Licensing of Office of Refugee Resettlement Facilities	0970-AC94
HHS/ACF	Proposed Rule Stage	Performance Requirements Modifications During Times of National Emergencies	0970-AC95
HHS/ACF	Proposed Rule Stage	Parentage Establishment in the Child Support Program	0970-AC96
HHS/ACF	Final Rule Stage	ANA Non-Federal Share Emergency Waivers	0970-AC88
HHS/ACF	Final Rule Stage	Vaccine and Mask Requirements To Mitigate the Spread of COVID-19 in Head Start Programs	0970-AC90
HHS/ACL	Proposed Rule Stage	Older Americans Act, Titles III, VI, and VII	0985-AA17
HHS/ACL	Final Rule Stage	National Institute for Disability, Independent Living, and Rehabilitation Research Notice of Proposed Rulemaking	0985-AA16
HHS/OS	Proposed Rule Stage	Privacy Act Regulations	0991-AC05
HHS/OS	Proposed Rule Stage	Limiting the Effect of Exclusions Implemented Under the Social Security Act	0991-AC11
HHS/OS	Proposed Rule Stage	Use of Federal Property to Assist the Homeless	0991-AC14
HHS/OS	Proposed Rule Stage	HHS Requirements for Grants and Agreements	0991-AC26
HHS/OS	Proposed Rule Stage	Partnerships With Faith-Based and Neighborhood Organizations	0991-AC31
HHS/OS	Final Rule Stage	Health Resources Priority and Allocations System (HRPAS)	0991-AB95
HHS/OS	Final Rule Stage	Health and Human Services Grants Regulation	0991-AC16
HHS/OS	Final Rule Stage	Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures	0991-AC29
HHS/OS	Final Rule Stage	CY 2023 Civil Monetary Penalties Inflation Adjustment	0991-AC34



Agency Rule List - Spring 2022

Department of Health and Human Services

Agency	Agenda Stage of Rulemaking	Title	RIN
HHS/FDA	Long-Term Actions	Food Standards: General Principles and Food Standards Modernization	0910-AC54
HHS/FDA	Long-Term Actions	Investigational Tobacco Product Applications	0910-AH06
HHS/FDA	Long-Term Actions	General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products	0910-AH14
HHS/FDA	Long-Term Actions	Nicotine Toxicity Warnings	0910-AH24
HHS/FDA	Long-Term Actions	Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease	0910-AH43
HHS/FDA	Long-Term Actions	Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)	0910-AH56
HHS/FDA	Long-Term Actions	Establishment Registration and Product Listing for Tobacco Products	0910-AH59
HHS/FDA	Long-Term Actions	Medical Devices; Quality System Regulation Amendments	0910-AH99
HHS/FDA	Long-Term Actions	ENDS Safety Standards, Including Standards for Toxicants and Impurities in Nicotine, Propylene Glycol, and Vegetable Glycerin Used in E-Liquids; Tobacco Product	0910-AI06
HHS/FDA	Long-Term Actions	Requirements for Determining Donor Eligibility and Donation Suitability of Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use	0910-AI11
HHS/FDA	Long-Term Actions	Abbreviated New Animal Drug Applications	0910-AI54
HHS/FDA	Long-Term Actions	Revisions to Regulation for Receiving an Abbreviated New Drug Application	0910-AI56
HHS/FDA	Long-Term Actions	Postmarketing Safety Reporting Requirements, Pharmacovigilance Plans, and Pharmacovigilance Quality Systems for Human Drug and Biological Products	0910-AI61
HHS/FDA	Long-Term Actions	Animal Cells, Tissues, and Cell- and Tissue-Based Products	0910-AI63
HHS/CDC	Long-Term Actions	Respirator Certification Fees; Fee Schedule Update	0920-AA70
HHS/CDC	Long-Term Actions	NIOSH Respirator Approval Program: Penalties for Fraud and Fraudulent Statements	0920-AA78
HHS/CMS	Long-Term Actions	Administrative Simplification: Adoption of Standards for Health Care Attachment Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Standard (CMS-0053)	0938-AT38
HHS/CMS	Long-Term Actions	Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage (CMS-1739)	0938-AU24
HHS/CMS	Long-Term Actions	Requirements Related to Air Ambulance Services, Agent and Broker Disclosures and Provider Enforcement (CMS-9907)	0938-AU61
HHS/CMS	Long-Term Actions	Omnibus COVID-19 Health Care Staff Vaccination (CMS-3415)	0938-AU75
HHS/ONC	Long-Term Actions	Request for Information Regarding Electronic Prior Authorization in the ONC Health IT Certification Program	0955-AA04
HHS/ACF	Long-Term Actions	Standards for Data Exchange	0970-AC58
HHS/ACF	Long-Term Actions	Standards To Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Children	0970-AC61
HHS/ACF	Long-Term Actions	Updating Refugee Resettlement Program Requirements	0970-AC74

