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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' MOTION FOR  
LEAVE TO FILE NOTICE OF  
SUPPLEMENTARY MATERIAL**

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1 Pursuant to Local Rule 7-3(d), Plaintiffs respectfully request leave to file the attached  
 2 Notice of Supplementary Material to update the Court on facts relevant to Defendants' Motion for  
 3 Voluntary Remand Without Vacatur, ECF No. 102 ("Defs.' Mot."). The proposed Notice of  
 4 Subsequent Factual Development will update the Court regarding the Spring 2022 Regulatory  
 5 Agenda recently published by Defendant Department of Health and Human Services, which shows  
 6 that Defendants are not developing a proposed rule to replace the 2020 Final Rule challenged in  
 7 this case. *See* Notice Attachment A. The fact that Defendants do not expect to issue even a  
 8 *proposed* rule within the next 24 months is relevant to their request for this Court to exercise  
 9 equitable discretion by remanding the rule to the agency without vacatur, as it confirms that the  
 10 undisputed harm to Plaintiffs will persist for years to come. *See* Pls.' Opp'n to Defs.' Mot. for  
 11 Remand Without Vacatur, ECF No. 104, at 13-17.

12 Under Local Rule 7-3(d), a party may file supplementary material after a motion's hearing  
 13 date only with "prior Court approval." The hearing date for Defendants' Motion (as well as the  
 14 parties' cross-motions for summary judgment) was December 3, 2021. Accordingly, Plaintiffs  
 15 require leave of the Court to file supplementary material. Plaintiffs contacted Defendants on  
 16 Thursday, June 30, 2022 to request their position on this motion, but Defendants have not  
 17 provided their position as of this July 6, 2022 filing.

18  
 19 Dated: July 6, 2022

Respectfully submitted,

20 By: /s/ Jeffrey B. Dubner  
 21 Jeffrey B. Dubner (admitted *pro hac vice*)  
 22 Kristen P. Miller (admitted *pro hac vice*)  
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14 UNITED STATES DISTRICT COURT  
15 NORTHERN DISTRICT OF CALIFORNIA  
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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 12,866 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 (Sept. 30, 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 *Off. of Info. & Regul. Affs., Off. of Mgmt. & Budget, About the Unified Agenda,*  
10 [https://www.reginfo.gov/public/jsp/eAgenda/UA\\_About.myjsp](https://www.reginfo.gov/public/jsp/eAgenda/UA_About.myjsp) (last accessed July 6, 2022).  
11 HHS’s Spring 2022 Regulatory 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 Supp. of Mot. for Voluntary Remand Without Vacatur,  
14 ECF No. 109, at 1, and have “already begun to obtain the necessary departmental clearance from  
15 agency leadership to move forward with the rulemaking process,” Defs.’ Mot. at 2. However, the  
16 Spring 2022 Regulatory Agenda does not include any rulemaking related to the Adoption and  
17 Foster Care Analysis and Reporting System (“AFCARS”). *See* Attachment A. This means that no  
18 amendment to the challenged 2020 Final Rule is “under development.” 58 Fed. Reg. at 51,738.  
19 Indeed, even the “Long-Term Actions” list does not contain any such rule, meaning that  
20 Defendants do not expect to issue a proposed rule or take any other action on the subject in the  
21 next two years, and consequently do not intend to issue a final rule in the current presidential term.

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

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1 Dated: July 6, 2022

Respectfully submitted,

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## 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	<a href="#">0906-AB28</a>
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	<a href="#">0910-AH07</a>
HHS/FDA	Proposed Rule Stage	National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers	<a href="#">0910-AH11</a>
HHS/FDA	Proposed Rule Stage	Post Approval Changes to Approved Applications	<a href="#">0910-AH55</a>
HHS/FDA	Proposed Rule Stage	Current Good Manufacturing Practice for Positron Emission Tomography Drugs	<a href="#">0910-AH58</a>
HHS/FDA	Proposed Rule Stage	Current Good Manufacturing Practice for Outsourcing Facilities	<a href="#">0910-AH61</a>
HHS/FDA	Proposed Rule Stage	Nonprescription Drug Product With an Additional Condition for Nonprescription Use	<a href="#">0910-AH62</a>
HHS/FDA	Proposed Rule Stage	Medication Guide; Patient Medication Information	<a href="#">0910-AH68</a>
HHS/FDA	Proposed Rule Stage	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food	<a href="#">0910-AH77</a>
HHS/FDA	Proposed Rule Stage	Permanent Listing of Color Additive Lakes	<a href="#">0910-AH80</a>
HHS/FDA	Proposed Rule Stage	Amendments to Registration of Food Facilities	<a href="#">0910-AH82</a>
HHS/FDA	Proposed Rule Stage	Requirements for Tobacco Product Manufacturing Practice	<a href="#">0910-AH91</a>
HHS/FDA	Proposed Rule Stage	Updated Regulations for Medical Gases	<a href="#">0910-AH96</a>
HHS/FDA	Proposed Rule Stage	Administrative Detention of Tobacco Products	<a href="#">0910-AI05</a>
HHS/FDA	Proposed Rule Stage	Protection of Human Subjects and Institutional Review Boards	<a href="#">0910-AI07</a>
HHS/FDA	Proposed Rule Stage	Institutional Review Boards; Cooperative Research	<a href="#">0910-AI08</a>
HHS/FDA	Proposed Rule Stage	Nutrient Content Claims, Definition of Term: Healthy	<a href="#">0910-AI13</a>
HHS/FDA	Proposed Rule Stage	Biologics Regulation Modernization	<a href="#">0910-AI14</a>
HHS/FDA	Proposed Rule Stage	Conditional Approval of New Animal Drugs for Minor Use and Minor Species	<a href="#">0910-AI18</a>
HHS/FDA	Proposed Rule Stage	Clinical Holds in Medical Device Investigations	<a href="#">0910-AI20</a>
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	<a href="#">0910-AI23</a>
HHS/FDA	Proposed Rule Stage	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals	<a href="#">0910-AI24</a>
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	<a href="#">0910-AI25</a>
HHS/FDA	Proposed Rule Stage	Classification of Wound Dressings Containing Antimicrobials and/or Other Chemicals	<a href="#">0910-AI26</a>
HHS/FDA	Proposed Rule Stage	Tobacco Product Standard for Characterizing Flavors in Cigars	<a href="#">0910-AI28</a>
HHS/FDA	Proposed Rule Stage	Amendments to Patent Term Restoration	<a href="#">0910-AI29</a>
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	<a href="#">0910-AI30</a>
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	<a href="#">0910-AI31</a>
HHS/FDA	Proposed Rule Stage	Medical Devices; Cardiovascular Devices; Classification of More Than Minimally Manipulated Allograft Heart Valves	<a href="#">0910-AI33</a>
HHS/FDA	Proposed Rule Stage	Phased Review of New Animal Drug Applications, Electronic Submission, and Master Files	<a href="#">0910-AI35</a>
HHS/FDA	Proposed Rule Stage	Investigational New Drug Application Annual Reporting	<a href="#">0910-AI37</a>
HHS/FDA	Proposed Rule Stage	Modified Risk Tobacco Product Applications	<a href="#">0910-AI38</a>
HHS/FDA	Proposed Rule Stage	Labeling Requirements for Approved and Conditionally Approved New Animal Drugs	<a href="#">0910-AI43</a>
HHS/FDA	Proposed Rule Stage	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption	<a href="#">0910-AI49</a>
HHS/FDA	Proposed Rule Stage	Amending Regulations That Require Multiple Copies Submissions	<a href="#">0910-AI50</a>
HHS/FDA	Proposed Rule Stage	Revising the National Drug Code Format and Drug Labeling Barcode Requirements	<a href="#">0910-AI52</a>
HHS/FDA	Proposed Rule Stage	Amendment of Procedural Requirements for Color Additive Petitions	<a href="#">0910-AI53</a>
HHS/FDA	Proposed Rule Stage	Amendment of Procedural Requirements for Food Additive Petitions	<a href="#">0910-AI55</a>
HHS/FDA	Proposed Rule Stage	Conduct of Analytical and Clinical Pharmacology, Bioavailability and Bioequivalence Studies	<a href="#">0910-AI57</a>
HHS/FDA	Proposed Rule Stage	Contact Lens Devices; Designation of Special Controls for Daily Wear Contact Lenses	<a href="#">0910-AI58</a>
HHS/FDA	Proposed Rule Stage	Administrative Destruction of Certain Devices Refused Admission to the United States	<a href="#">0910-AI59</a>
HHS/FDA	Proposed Rule Stage	Tobacco Product Standard for Menthol in Cigarettes	<a href="#">0910-AI60</a>
HHS/FDA	Proposed Rule Stage	Submission of Food and Drug Administration Import Data in the Automated Commercial Environment for Certain Tobacco Products	<a href="#">0910-AI64</a>
HHS/FDA	Proposed Rule Stage	Revocation of Methods of Analysis Regulation	<a href="#">0910-AI65</a>

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

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

HHS/CMS	Final Rule Stage	FY 2023 Inpatient Rehabilitation Facility (IRF) Prospective Payment System Rate Update and Quality Reporting Program (CMS-1767)	<a href="#">0938-AU78</a>
HHS/CMS	Final Rule Stage	FY 2023 Inpatient Psychiatric Facilities Prospective Payment System Rate (CMS-1769)	<a href="#">0938-AU80</a>
HHS/CMS	Final Rule Stage	FY 2023 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements (CMS-1773)	<a href="#">0938-AU83</a>
HHS/OCR	Prerule Stage	Considerations for Implementing the Health Information Technology for Economic and Clinical Health (HITECH) Act, as Amended	<a href="#">0945-AA04</a>
HHS/OCR	Proposed Rule Stage	Rulemaking on Discrimination on the Basis of Disability in Critical Health and Human Services Programs or Activities	<a href="#">0945-AA15</a>
HHS/OCR	Proposed Rule Stage	Confidentiality of Substance Use Disorder Patient Records	<a href="#">0945-AA16</a>
HHS/OCR	Proposed Rule Stage	Nondiscrimination in Health Programs and Activities	<a href="#">0945-AA17</a>
HHS/OCR	Proposed Rule Stage	Rescission of the Regulation Entitled "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority"	<a href="#">0945-AA18</a>
HHS/OCR	Final Rule Stage	HIPAA Privacy: Changes to Support, and Remove Barriers to, Coordinated Care and Individual Engagement	<a href="#">0945-AA00</a>
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	<a href="#">0955-AA03</a>
HHS/ACF	Proposed Rule Stage	Updating Native Employment Works Requirements	<a href="#">0970-AC83</a>
HHS/ACF	Proposed Rule Stage	Native Hawaiian Revolving Loan Fund Eligibility Requirements	<a href="#">0970-AC84</a>
HHS/ACF	Proposed Rule Stage	Foster Care Legal Representation	<a href="#">0970-AC89</a>
HHS/ACF	Proposed Rule Stage	Separate Licensing Standards for Relative or Kinship Foster Family Homes	<a href="#">0970-AC91</a>
HHS/ACF	Proposed Rule Stage	OCSE Federal Case Registry of Child Support Orders System of Records Exemption	<a href="#">0970-AC92</a>
HHS/ACF	Proposed Rule Stage	Unaccompanied Children Program Foundational Rule	<a href="#">0970-AC93</a>
HHS/ACF	Proposed Rule Stage	Federal Licensing of Office of Refugee Resettlement Facilities	<a href="#">0970-AC94</a>
HHS/ACF	Proposed Rule Stage	Performance Requirements Modifications During Times of National Emergencies	<a href="#">0970-AC95</a>
HHS/ACF	Proposed Rule Stage	Parentage Establishment in the Child Support Program	<a href="#">0970-AC96</a>
HHS/ACF	Final Rule Stage	ANA Non-Federal Share Emergency Waivers	<a href="#">0970-AC88</a>
HHS/ACF	Final Rule Stage	Vaccine and Mask Requirements To Mitigate the Spread of COVID-19 in Head Start Programs	<a href="#">0970-AC90</a>
HHS/ACL	Proposed Rule Stage	Older Americans Act, Titles III, VI, and VII	<a href="#">0985-AA17</a>
HHS/ACL	Final Rule Stage	National Institute for Disability, Independent Living, and Rehabilitation Research Notice of Proposed Rulemaking	<a href="#">0985-AA16</a>
HHS/OS	Proposed Rule Stage	Privacy Act Regulations	<a href="#">0991-AC05</a>
HHS/OS	Proposed Rule Stage	Limiting the Effect of Exclusions Implemented Under the Social Security Act	<a href="#">0991-AC11</a>
HHS/OS	Proposed Rule Stage	Use of Federal Property to Assist the Homeless	<a href="#">0991-AC14</a>
HHS/OS	Proposed Rule Stage	HHS Requirements for Grants and Agreements	<a href="#">0991-AC26</a>
HHS/OS	Proposed Rule Stage	Partnerships With Faith-Based and Neighborhood Organizations	<a href="#">0991-AC31</a>
HHS/OS	Final Rule Stage	Health Resources Priority and Allocations System (HRPAS)	<a href="#">0991-AB95</a>
HHS/OS	Final Rule Stage	Health and Human Services Grants Regulation	<a href="#">0991-AC16</a>
HHS/OS	Final Rule Stage	Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures	<a href="#">0991-AC29</a>
HHS/OS	Final Rule Stage	CY 2023 Civil Monetary Penalties Inflation Adjustment	<a href="#">0991-AC34</a>



## 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	<a href="#">0910-AC54</a>
HHS/FDA	Long-Term Actions	Investigational Tobacco Product Applications	<a href="#">0910-AH06</a>
HHS/FDA	Long-Term Actions	General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products	<a href="#">0910-AH14</a>
HHS/FDA	Long-Term Actions	Nicotine Toxicity Warnings	<a href="#">0910-AH24</a>
HHS/FDA	Long-Term Actions	Food Labeling: Health Claims; Soy Protein and Coronary Heart Disease	<a href="#">0910-AH43</a>
HHS/FDA	Long-Term Actions	Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)	<a href="#">0910-AH56</a>
HHS/FDA	Long-Term Actions	Establishment Registration and Product Listing for Tobacco Products	<a href="#">0910-AH59</a>
HHS/FDA	Long-Term Actions	Medical Devices; Quality System Regulation Amendments	<a href="#">0910-AH99</a>
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	<a href="#">0910-AI06</a>
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	<a href="#">0910-AI11</a>
HHS/FDA	Long-Term Actions	Abbreviated New Animal Drug Applications	<a href="#">0910-AI54</a>
HHS/FDA	Long-Term Actions	Revisions to Regulation for Receiving an Abbreviated New Drug Application	<a href="#">0910-AI56</a>
HHS/FDA	Long-Term Actions	Postmarketing Safety Reporting Requirements, Pharmacovigilance Plans, and Pharmacovigilance Quality Systems for Human Drug and Biological Products	<a href="#">0910-AI61</a>
HHS/FDA	Long-Term Actions	Animal Cells, Tissues, and Cell- and Tissue-Based Products	<a href="#">0910-AI63</a>
HHS/CDC	Long-Term Actions	Respirator Certification Fees; Fee Schedule Update	<a href="#">0920-AA70</a>
HHS/CDC	Long-Term Actions	NIOSH Respirator Approval Program: Penalties for Fraud and Fraudulent Statements	<a href="#">0920-AA78</a>
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)	<a href="#">0938-AT38</a>
HHS/CMS	Long-Term Actions	Treatment of Medicare Part C Days in the Calculation of a Hospital's Medicare Disproportionate Patient Percentage (CMS-1739)	<a href="#">0938-AU24</a>
HHS/CMS	Long-Term Actions	Requirements Related to Air Ambulance Services, Agent and Broker Disclosures and Provider Enforcement (CMS-9907)	<a href="#">0938-AU61</a>
HHS/CMS	Long-Term Actions	Omnibus COVID-19 Health Care Staff Vaccination (CMS-3415)	<a href="#">0938-AU75</a>
HHS/ONC	Long-Term Actions	Request for Information Regarding Electronic Prior Authorization in the ONC Health IT Certification Program	<a href="#">0955-AA04</a>
HHS/ACF	Long-Term Actions	Standards for Data Exchange	<a href="#">0970-AC58</a>
HHS/ACF	Long-Term Actions	Standards To Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Children	<a href="#">0970-AC61</a>
HHS/ACF	Long-Term Actions	Updating Refugee Resettlement Program Requirements	<a href="#">0970-AC74</a>

