

2022 LEGISLATIVE & REGULATORY OUTLOOK 1.24.22

Red = Congressional/Legislative Event; Blue = Proposed Executive/Regulatory Action; Green = Final Executive/Regulatory Action

Date	Event	Responsible Party	Notes
	First Quarter		
Q1	President Biden's State of the Union Address	Congress	Speaker Nancy Pelosi (D- CA) <u>invited</u> President Biden to deliver SOTU on 3/1
Q1	Potential release of an interim final rule to require proof of vaccination or other proof of immunity against quarantinable communicable diseases for persons arriving at a U.S. port of entry (<u>0920-AA80</u>).	CDC ¹	
Q1	Possible release of a proposed rule to harmonize and modernize regulation of medical device quality systems (0910-AH99).	FDA	Previously slated for December 2021
Q1	Potential release of proposal rule to classify Human Leukocyte Antigen (HLA), Human Platelet Antigen (HPA), and Human Neutrophil Antigen (HNA) devices into class II (0910-Al12).	FDA	Previously slated for December 2021
Q1	Aligns regulations under the Social Security Act so that agencies must exercise suspension and debarment authority to stop individuals from participating in all Federal procurement and non-procurement actions (0991-AC11).	OS	
Q1	Proposed rule to provide a more effective means to affirmatively further the purposes of the Fair Housing Act focused on advancing equity and providing access for underserved populations (2529-AB05).	HUD	
Q1	Implements section 108 of the No Surprises Act (P.L. 116-260) having to do with provider nondiscrimination (1210-AC06).	DOL	Enacted in the Consolidated Appropriations Act, 2021 (P.L. 116-260), statutory deadline for a proposed rule was 1/1/22

¹ Centers for Disease Control and Prevention



Q1	Amends regulations governing VA participating in State prescription drug monitoring programs (2900-AQ57).	VA	Implements the VA MISSION Act of 2019 (<u>P.L.</u> <u>115-182</u>)
Q1	Anticipated release of the Air Ambulance Services, Agent and Broker Disclosures and Provider Enforcement final rule (0938-AU61).	CMS	
Q1	Timeframe for the release of final rule to permit the continued use of drug master files (DMFs) for new drug applications (NDAs) subject to the Biologics Price Competition and Innovation Act (BPCI Act) transition (0910-AH50).	FDA	Previously slated for December 2021
Q1	Possible release of final rule to amend medical device regulations regarding the procedures for the announcement of approvals and denials for humanitarian device exemption (HDE) applications (0910-Al10).	FDA	Previously slated for November 2021
Q1	Determines the form and manner in which group health plans, health insurance issuers offering group or individual coverage, and providers of air ambulance services would report information regarding air ambulance services (<u>1210-AC08</u>).	DOL/IRS	
Q1	Implements protections against surprise medical bills under the No Surprises Act by cross-reference to temporary regulations (1545-BQ01).	IRS	Temporary rule
1/1	Surprise billing protections, prohibitions, and requirements take effect.	Congress	Enacted in the Consolidated Appropriations Act, 2021 (P.L. 116-260)
1/1	Expiration of Health Coverage Tax Credit.	Congress	Last reauthorized in the Consolidated Appropriations Act, 2021 (P.L. 116-260)
1/3-1/7	House in recess.	Congress	
1/15	Expiration of expedited procedures for considering an increase in the debt limit.	Congress	Established in the Protecting Medicare and American Farmers from Sequester Cuts Act (P.L. 117-71)
1/17-1/21	Senate in recess.	Congress	
1/24-1/31	House in recess.	Congress	
1/1-1/31	Anticipated release of the 340B Administrative Dispute Resolution proposed rule (0906-AB28).	HRSA	



1/1-1/31	Anticipated release of the Administrative Simplification of Health Care	CMS	
	Transactions proposed rule (0938-AT38).		
1/1-1/31	Anticipated release of the Confidentiality of Substance Use Disorder (SUD) Patient Records proposed rule (0945-AA16).	OCR	
1/1-1/31	Anticipated release of the Medicare Enrollment and Eligibility Rules proposed rule (0938-AU85).	CMS	
1/1-1/31	Anticipated release of a proposed rule that addresses certain requirements regarding prescription drug marketing by removing provisions no longer in effect and incorporating requirements of the Drug Supply Chain Security Act (0910-AH56).	FDA	Previously slated for September 2021
2/9-2/11	House Democratic Issues Conference	Congress	
2/14, 2/18-2/25	House in recess.	Congress	
2/21-2/25	Senate in recess.	Congress	
2/1-2/28	Anticipated release of the Medicare Secondary Payer (MSP) and Future Medicals proposed rule (0938-AT85).	CMS	
2/1-2/28	Anticipated release of the Coverage of Certain Preventive Services proposed rule (0938-AU94).	CMS	
2/1-2/28	Anticipated release of the Interoperability and Prior Authorization proposed rule (0938-AU87).	CMS	
2/1-2/28	Potential release of a proposed rule that would establish a new reporting requirement for an FDA development safety update report for investigational new drug applications (INDs) (0910-Al37)	FDA	Previously slated for October 2021
2/1-2/28	Timeframe for the release of a proposed rule to amend FDA medication guide regulations to require a new form of patient labeling, Patient Medication Information (0910-AH68).	FDA	
2/1-2/28	Possible release of proposed rule 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 (0910-Al30)	FDA	
2/1-2/28	Amends regulations that govern VA health care professionals who practice via telehealth (2900-AQ59).	VA	Implements the VA MISSION Act of 2019 (P.L. 115-182)
2/1-2/28	Establishes a pilot program on graduate medical education and residency that funds residents regardless of whether they are in VA facilities (2900- AR01)	VA	
2/1-2/28	Conforms regulations for the Housing Opportunity Through Modernization Act affecting Housing Quality Standards and the Project-Based Voucher	HUD	



	program that have already been implemented and implements remaining provisions (2577-AD06).		
3/1-3/31	Anticipated release of the National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards proposed rule (<u>0938-</u> AU19).	CMS	
3/1-3/31	Anticipated release of the Reporting of Crimes Occurring in Federally Funded Long Term Care Facilities proposed rule (0938-AT60).	CMS	
3/1-3/31	Anticipated release of the Clinical Laboratory Improvement Amendments (CLIA) Personnel, Histocompatibility, Alternative Sanctions for Certificate of Waiver Laboratories, and Fees proposed rule (<u>0938-AT47</u>).	CMS	0938-AT56 to be merged with this rule
3/1-3/31	Potential release of a proposed rule to amend its current good manufacturing practice regulations for positron emission tomography (PET) drugs to remove a reference to an outdated United States Pharmacopeia (USP) chapter (<u>0910-AH58</u>).	FDA	
3/1-3/31	Timeframe for the release of a proposed rule to establish tobacco product manufacturing practice requirements for manufacturers of finished and bulk tobacco products (0910-AH91)	FDA	Previously slated for October 2021
3/1-3/31	Amends the application process and guidelines for the Public Benefits Conveyance program to reduce the government's inventory of real property as guided by the Public Building Reform Board.	HUD	Revised to coincide with the Federal Assets Sales and Transfer Act of 2016 (P.L. 114-287)
3/1-3/31	Eliminates the option for State agencies to use visual observation to collect race and ethnicity data from program applicants (<u>0584-AE86</u>).	FNS	
3/1-3/31	Anticipated release of the Sharing Civil Money Penalties Request for Information (RFI) (0945-AA04).	OCR	
3/1-3/31	Anticipated release of the Reassignment of Medicaid Provider Claims final rule (0938-AU73).	CMS	
3/1-3/31	Possible release of a final rule that modifies 42 CFR 1003 and 1005, pursuant to the 21 st Century Cures Act, which would authorize HHS to impose civil monetary penalties upon individuals and entities that engage in fraud and other misconduct , as well as allow the HHS OIG to investigate claims of information blocking and provide HHS the authority to impose civil monetary penalties for information blocking, the penalties for which would be increased per the Civil Monetary Penalties Law (0936-AA09).	OIG ²	

² HHS Office of Inspector General



3/1-3/31	Potential release of a final rule to prohibit the sale of tobacco to individuals younger than 21 years of age (0910-Al51)	FDA	Previously slated for May 2021
3/1-3/31	Possible release of final rule to establish annual summary reporting requirements under the Right to Try Act (0910-Al36).	FDA	Previously slated for December 2021
3/1-3/31	Codifies changes from sections 102, 203, and 104 of the <u>Housing</u> <u>Opportunity Through Modernization Act</u> including income determinations and definitions of income and assets under the 8 Project-Based Rental Assistance, Housing Choice Voucher, and Public Housing programs (<u>2577-AD03</u>).	HUD	Final action after a comment period (<u>85 FR</u> <u>78295</u>)
3/1-3/31	Updates section 8 program regulations to include enhanced vouchers and codify existing policy (2577-AD00).	HUD	
3/1-3/31	Requires the establishment of an interstate data system to prevent multiple issuances of SNAP benefits.	FNS	Implements sections 4009 and 4011 of the 2018 Farm Bill (P.L. 115-334)
3/1-3/31	Implements sections 4009 and 4011 of the 2018 Farm Bill to require the establishment of the National Accuracy Clearinghouse (NAC) interstate data system.(0584-AE75)	FNS	
3/21-3/25	House in recess	Congress	
3/23-3/25	House Republican Issues Conference	Congress	
3/31	Expiration of 10 percent FMAP increase for Medicaid home and community- based services.	Congress	Authorized in the American Rescue Plan Act (<u>P.L. 117-</u> <u>2</u>)
3/31	Expiration of temporary suspension of 2 percent Medicare sequestration reductions, phase-in of sequestration payment reductions over time: 1 percent beginning 4/1/22, 2 percent beginning 7/1/22	Congress	Last extended in the Protecting Medicare and American Farmers from Sequester Cuts Act (<u>P.L.</u> <u>117-71</u>)
	Second Quarter		
Q2	House Appropriations Committee marks up FY 2023 appropriations legislation.	Congress	
4/11-4/22	House and Senate in recess.	Congress	
4/1-4/30	Anticipated release of the Medicaid and CHIP Eligibility and Enrollment Processes proposed rule (<u>0938-AU00</u>).	CMS	
4/1-4/30	Anticipated release of the Provider Nondiscrimination Requirements for Group Health Plans proposed rule (<u>0938-AU64</u>).	CMS	
4/1-4/30	Anticipated release of the FY 2023 Skilled Nursing Facility (SNF) PPS Update and Quality Reporting Requirements proposed rule (0938-AU76).	CMS	



d for
d for
1



4/1-4/30	Implements section 108 of the No Surprises Act which includes protections	IRS	
	against provider discrimination (<u>1545-BQ03</u>).		
5/2-5/6	House in recess.	Congress	
5/23, 5/27-6/3	House in recess.	Congress	
5/30-6/3	Senate in recess.	Congress	
5/1-5/31	Anticipated release of the Medicaid Drug Rebate Program (MDRP) proposed rule (0938-AU28).	CMS	
5/1-5/31	Anticipated release of the Rules Governing Organ Procurement Organizations proposed rule (<u>0938-AU54</u>).	CMS	
5/1-5/31	Anticipated release of the Medicare Advantage and Medicare Prescription Drug Benefit Program Payment proposed rule (0938-AU59).	CMS	
5/1-5/31	The timeframe for the release of a proposed rule to create procedures of imposing a hold on a clinical investigation of a medical device (0910-Al20).	FDA	
5/1-5/31	Potential release of a proposed rule to revise regulations applicable to establishments that collect blood or blood components, including blood or blood components intended solely for autologous use (0910-Al11).	FDA	
5/1-5/31	Potential release of a proposed rule to amend the FDA's Patent Term Restoration regulations to make the agency's regulations consistent with statutory amendments (<u>0910-AI29</u>)	FDA	Previously slated for September 2021
5/1-5/31	Revises regulations to the SNAP Quality Control system.	FNS	
5/1-5/31	Anticipated release of the Durable Medical Equipment Fee Schedule final rule (<u>0938-AT21</u>).	CMS	To be merged with <u>0938-</u> <u>AU38</u> and <u>0938-AU17</u> .
5/1-5/31	HUD will open the interim final rule for a comment period for proposed rules to establish the allocation formula and regulations that govern the Housing Trust Fund, with a focus on simplifying program regulations (2506-AC30)	HUD	Applies to <u>80 FR 5200</u>
5/1-5/31	Codifies several nationwide waivers and flexibilities for the Summer Food Service Program , and provisions to streamline program administration, enhance monitoring requirements, and provide clarity. (0584-AE72)	FNS	
6/1-6/30	Anticipated release of the CY 2023 Home Health PPS Rate Update and Home Infusion Therapy Services Payment Update proposed rule (<u>0938-</u> <u>AU77</u>).	CMS	
6/1-6/30	Anticipated release of the CY 2023 End-Stage Renal Disease (ESRD) PPS and Quality Incentive Program proposed rule (0938-AU79).	CMS	
6/1-6/30	Anticipated release of the CY 2023 Medicare Physician Fee Schedule (PFS) proposed rule (0938-AU81).	CMS	



6/1-6/30	Anticipated release of the CY 2023 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system proposed rule (0938-AU82).	CMS	
6/1-6/30	Possible release of a proposed rule to establish content and format requirements to ensure that modified risk assessments for tobacco products contain sufficient information (0910-AI38).	FDA	
6/1-6/30	The timeframe for the release of a proposed rule 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 (0910-Al31)	FDA	
6/1-6/30	The possible release of a proposed rule to clarify the FDA's study conduct expectation for analytical and clinical pharmacology, bioavailability (BA) and bioequivalence (BE) studies that support marketing applications (<u>0910-AI57</u>).	FDA	
6/1-6/30	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 (0970-AC58)	ACF	
6/1-6/30	Proposes several changes to the HOME program requirements including Community Housing Development Organization requirements, property standards, and changes related to community land trusts, evictions, and allowable gross rent (2506-AC50)	HUD	
6/1-6/30	Revises the Community Development Block Grant and Indian Community Development Block Grant programs to make it easier for recipients to promote economic development and recovery in low- and moderate-income areas and support investments in underserved areas (2506-AC52)	HUD	
6/1-6/30	Provides regulations to implement the Emergency Solutions Grant Program which places greater emphasis on homelessness prevention and rapid re-housing. (2506-AC47)	HUD	From the HEARTH Act, replaces the Emergency Shelter Grants Program
	Third Quarter		
6/27-7/8	House and Senate in recess.	Congress	
7/1-7/31	Anticipated release of the Mental Health Parity and Addiction Equity Act proposed rule (0938-AU93).	CMS	
7/1-7/31	Potential release of a proposed rule that would implement certain provisions of the 21 st Century Cures Act related to the Electronic Health Record	ONC	



	Reporting condition and maintenance of certification requirements under the ONC Health IT Certification Program, information blocking, the Trusted Exchange Framework and Common Agreement, and new standards for real-time benefit tools and electronic prior authorization (<u>0955-AA03</u>).		
7/1-7/31	The timeframe for the release of a proposed rule to set forth the minimum current good manufacturing practice requirements for human drug products compounded by an outsourcing facility (0910-AH61)	FDA	
7/1-7/31	The anticipated release of proposed regulations to establish requirements for the administrative detention of tobacco products (<u>0910-Al05</u>).	FDA	
7/1-7/31	Proposes amendments to the rules implementing the <u>Mental Health Parity</u> ad Addiction Equity Act to clarify requirements and incorporate amendments (<u>1545-BQ29</u>).	DOL/IRS	Incorporates amendments from the Consolidated Appropriations Act of 2021 (P.L. 116-260)
8/1-9/5, 9/9	House in recess.	Congress	
8/8-9/5	Senate in recess.	Congress	
8/1-8/31	Anticipated release of the Alternative Payment Model for Medicare proposed rule (<u>0938-AU51</u>).	CMS	May be a proposed mandatory demonstration since the agency is announcing it via rulemaking
8/1-8/31	Anticipated release of the Medicare, Medicaid, and Health Insurance Exchanges Program Integrity proposed rule (0938-AU90).	CMS	
8/1-8/31	The anticipated release of a proposed rule to update biologics regulations 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 (0910-Al14)	FDA	
8/1-8/31	Amends the definition of "short-term, limited-duration insurance" to ensure it does not undermine protections for people with pre-existing conditions, the Health Insurance Exchanges, or markets for health insurance (1210-AC12)	DOL	
8/1-8/31	Would change the procedures for affirmatively furthering fair housing to focus on advancing equity and providing access to opportunity in a manner that is more effective while avoiding unnecessary burden. (2529- AB05)	HUD	
9/1-9/30	Anticipated release of the Long-Term Facilities Infection Prevention and Control proposed rule (0938-AU58).	CMS	



9/1-9/30	Anticipated release of the Medicare Payment Policies for Durable Medical Equipment, Prosthetics, Orthotics and Supplies proposed rule (0938-AU45).	CMS	
9/1-9/30	Anticipated release of CY 2023 Inpatient Hospital Deductible and Coinsurance Amounts notice (0938-AU71).	CMS	
9/1-9/30	Anticipated release of CY 2023 Medicare Part A Premiums notice (0938- AU72).	CMS	
9/1-9/30	Anticipated release of CY 2023 Medicare Part B Premiums and Deductibles notice (<u>0938-AU74</u>).	CMS	
9/1-9/30	Expected release of a proposed rule that would permanently extend the buprenorphine telehealth flexibility beyond the COVID-19 public health emergency (0930-AA38).	SAMHSA ³	
9/1-9/30	Expected release of a proposed rule that would make permanent some regulatory flexibilities for opioid treatment programs to provide extended take home doses of methadone (0930-AA39).	SAMHSA	
9/1-9/30	The timeframe for the release of a proposed rule to update the existing regulations governing supplements and other changes to approved new drug applications (ANDAs) and biologics license applications (BLAs) (0910-AH55)	FDA	
9/1-9/30	Possible release of final rule to amend regulations concerning direct-to- consumer (DTC) advertisements of prescription drugs (0910-AG27)	FDA	
9/1-9/30	Finalizes the regulations governing the Continuum of Care program and planning process from two interim final rules (2506-AC51)	HUD	2012 interim final rule and 2016 interim final rule
9/30	End of FY 2022. FY 2023 appropriations bills or continuing resolution (CR) is needed to keep federal government open.	Congress	
9/30	Expiration of authority for the Prescription Drug User Fee Act (PDUFA) and Medical Device User Fee Act (MDUFA)	Congress	Last reauthorized in the Food and Drug Administration Reauthorization Act of 2017 (P.L. 115-52)
	Fourth Quarter		
10/1	Medicare open enrollment begins for the 2022 plan year.	CMS	

³ Substance Abuse and Mental Health Services Administration



10/1-10/31	Anticipated release of the Transitional Coverage for Emerging Technologies proposed rule (0938-AU86).	CMS	
10/1-10/31	Anticipated release of the Assuring Access to Medicaid Services proposed rule (0938-AU68).	CMS	
10/1-10/31	Possible release of a proposed rule to establish acute nicotine toxicity warning requirements for liquid nicotine that are made or derived from tobacco and intended for human consumption. (0910-AH24)	FDA	
10/1-10/31	Authorizes a Seamless Summer Option for public or private nonprofit school food authorities to participate in the National School Lunch Program and School Breakfast Program (<u>0584-AD70</u>).	FNS	Codifies section 116 of the Child Nutrition and WIC Reauthorization Act of 2004 (P.L. 108-265)
10/1-10/31	Revises the Child Nutrition Program meal patterns for meals and snacks to be consistent with the 2020 Dietary Guidelines for Americans (<u>0584-AE88</u>).	FNS	
10/1-10/31	Proposes the Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Food Delivery Modernization and Streamlining for Customer Service rule to increase program flexibility and ensure that electronic benefits transfer is considered in WIC regulations (0584-AE89).	FNS	
10/3-11/11	House in recess.	Congress	
10/3-10/10	Senate in recess.	Congress	
10/24-11/8	Senate in recess.	Congress	
11/8	Midterm elections.	Congress	
12/19-12/30	House in recess.	Congress	
12/22-12/31	Senate in recess.	Congress	
12/1-12/31	Timeframe for the release of a proposed rule aimed at increasing access to nonprescription drug products through the establishment of requirements for a drug product that could be marketed as a nonprescription drug product. (0910-AH62).	FDA	
12/1-12/31	Potential release of a final rule entitled " National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers. " The rule would also establish a federal system for wholesale drug distributor licensing in lieu of a state licensure program (<u>0910-AH11</u>)	FDA	



12/1-12/31	Would implement protections against surprise medical bills and provisions related to Title II of Division BB of the Consolidated Appropriations Act. (<u>1545-BQ02</u>).	IRS	From the No Surprises Act
12/31	Expiration of enhancements to ACA premium tax credits	Congress	Established in the American Rescue Plan Act (P.L. 117-2)
12/31	Expiration of 3 percent Medicare payment adjustment	Congress	Last extended in the Protecting Medicare and American Farmers from Sequester Cuts Act (<u>P.L.</u> <u>117-71</u>)
12/31	Expiration of waiver for 4 percent PAYGO cuts to Medicare	Congress	Last extended in the Protecting Medicare and American Farmers from Sequester Cuts Act (<u>P.L.</u> 117-71)
	2023 and Beyond		
1/1/2023	Delayed start date of the Radiation Oncology Model	CMS	Delayed per the Protecting Medicare and American Farmers from Sequester Cuts Act (P.L. 117-71)
Early 2023	Anticipated cliff of statutory debt limit.	Congress	Last increased in joint resolution (P.L. 117-73)
9/30/2023	Expiration of Pandemic and all Hazards Preparedness Act (PAHPA) authority.	Congress	Las reauthorized in Pandemic and All-Hazards Preparedness and Advancing Innovation Act (P.L. 116-22).
9/30/2023	Expiration of public health and health care extenders.	Congress	Last reauthorized in the Consolidated Appropriations Act, 2021 (P.L. 116-260).
9/30/2023	End of delay to Medicaid disproportionate share hospital (DSH) payment reductions.	Congress	Last delayed in the Consolidated Appropriations Act, 2021 (P.L. 116-260).



4/1/2024	Sunset of cap on Medicaid drug rebates.	Congress	Authorized in the American Rescue Plan Act (P.L. 117-2)
3/31/2027	Expiration of state option to extend coverage for pregnant and postpartum women under Medicaid/CHIP for an additional 12 months postpartum.	Congress	Authorized in the American Rescue Plan Act (P.L. 117-2)
3/31/2027	Expiration of state option to provide community-based mobile crisis intervention services.	Congress	Authorized in the American Rescue Plan Act (P.L. 117-2)