



2021 LEGISLATIVE & REGULATORY OUTLOOK
7.7.21

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

Date	Event	Responsible Party	Notes
<i>Third Quarter</i>			
6/28-7/9	Senate in recess.	Congress	
6/24-7/16	Fiscal year (FY) 2022 appropriations markup schedule	Congress	
Q3	Possible release of a proposed rule to harmonize and modernize regulation of medical device quality systems (0910-AH99).	FDA	Previously slated for April 2021
Q3	Anticipated release of the Medicaid Managed Care Risk-Sharing proposed rule (0938-AU69).	CMS	
Q3	Anticipated release of the Electronic Prescribing for Controlled Substances proposed rule, merged with CY 2022 Physician Fee Schedule (0938-AU25)	CMS	
Q3	Would set the Treasury's rules for implementing section 504 of the Rehabilitation Act of 1973 prohibiting discrimination on the basis of disability for programs offering federal financial assistance. (1505-AC54)	Treasury	Fulfills the obligation of the Treasury to issue agency-specific rules but no substantial changes.
Q3	The timeframe for the release of a final rule that would make the De Novo medical device classification process more transparent and predictable for manufacturers (0910-AH53).	FDA	
Q3	Possible release of a final rule to establish content and format for premarket tobacco product applications to ensure the agency has sufficient information on whether to authorize a new tobacco product (0910-AH44).	FDA	Previously slated for May 2021
Q3	Potential release of a final rule to prohibit the sale of tobacco to individuals younger than 21 years of age (0910-AI51)	FDA	Previously slated for May 2021
7/5-7/9	House in recess.	Congress	
7/31	Expiration of public health emergency (PHE) declaration; expected to be renewed through the end of 2021	WH	The end of the PHE would trigger current emergency waiver authorities to expire



			(e.g., expanded telehealth under Medicare) absent further congressional action
7/1-7/31	Anticipated release of the CY 2022 Medicare Physician Fee Schedule (PFS) proposed rule (0938-AU42).	CMS	
7/1-7/31	Anticipated release of the CY 2022 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system proposed rule (0938-AU43).	CMS	
7/1-7/31	Anticipated release of Request for Information (RFI) seeking input on the organ transplant system (0938-AU55).	CMS	
7/1-7/31	Anticipated release of the Medicare Coverage of Innovative Technology (MCIT) proposed rule (0938-AT88).	CMS	
7/1-7/31	Regulation revisions to reflect changes in the SNAP Quality Control System. (0584-AE64)	FNS	
8/1	Expiration of statutory debt limit.	Congress	Discretionary spending limits last modified in the Bipartisan Budget Act of 2019 (P.L. 116-37).
8/2-8/27	House in recess.	Congress	
8/9-9/10	Senate in recess.	Congress	
8/15	End of ACA Special Enrollment Period	HHS	
8/1-8/31	The timeframe for the release of a proposed rule that would ban characterizing flavors in all cigars (0910-AI28).	FDA	
8/1-8/31	Anticipated release of the Transplant System Modernization proposed rule (0938-AT38).	CMS	
8/1-8/31	Proposes to rescind regulations governing HHS release and maintenance of guidance documents . (0991-AC29)	HHS	
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	
8/1-8/31	Anticipated release of the Requirements for Surprise Billing Part 2 interim final rule (0938-AU62).	CMS	



8/1-8/31	Anticipated release of the Temporary Federal Medical Assistance Percentage (FMAP) Increase final rule (0938-AU70).	CMS	
8/1-8/31	Codifies changes sections 102, 103, and 104 of the Housing Opportunity Through Modernization Act of 2016 made to the US Housing Act of 1937. (2577-AD03)	HUD	Also affects HUD programs with provisions that mirror US Housing Act of 1937
8/1-8/31	Anticipated release of the FY 2022 Skilled Nursing Facility (SNF) PPS Update and Quality Reporting Requirements final rule (0938-AU36).	CMS	
8/1-8/31	Anticipated release of the FY 2022 Inpatient Rehabilitation Facility (IRF) PPS Rate Update and Quality Reporting Requirements final rule (0938-AU38).	CMS	
8/1-8/31	Anticipated release of the FY 2022 Inpatient Psychiatric Facilities (IPF) PPS Rate and Quality Reporting Updates final rule (0938-AU40).	CMS	
8/1-8/31	Anticipated Release of the FY 2022 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements final rule (0938-AU41).	CMS	
8/1-8/31	Anticipated release of the FY 2022 Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System final rule (0938-AU44).	CMS	
9/1-9/30	Anticipated release of the National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards proposed rule (0938-AU19).	CMS	
9/1-9/30	Anticipated release of the CY 2023 Medicare Advantage (MA or Part C) and Medicare Prescription Drug Benefit Programs (Part D) proposed rule (0938-AU30).	CMS	
9/1-9/30	Anticipated release of the Alternative Payment Model for Medicare proposed rule (0938-AU51).	CMS	May be a proposed mandatory demonstration since the agency is announcing it via rulemaking
9/1-9/30	Potential release of a proposed 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 (0910-AH11)	FDA	
9/1-9/30	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	



9/1-9/30	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 (0910-AI29)	FDA	
9/1-9/30	Anticipated release of a proposed rule that would standardize the format of all National Drug Codes (NDCs) (0910-AI52).	FDA	
9/1-9/30	Anticipated release of CY 2022 Inpatient Hospital Deductible and Coinsurance Amounts notice (0938-AU46).	CMS	
9/1-9/30	Anticipated release of CY 2022 Medicare Part A Premiums notice (0938-AU47).	CMS	
9/1-9/30	Anticipated release of CY 2022 Medicare Part B Monthly Actuarial Rates notice (0938-AU48).	CMS	
9/1-9/30	Anticipated release of the Discrimination in HHS Programs or Services proposed rule (0945-AA15).	OCR	
9/1-9/30	Anticipated release of National Vaccine Injury Compensation Program final rule revising recommendations for pregnant women (0906-AB27).	HRSA	
9/1-9/30	Final regulations regarding the employer shared responsibility provisions to HRAs and other account-based group health plans. (1545-BP17)	IRS	
9/1-9/30	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	
9/6-9/8	House in recess.	Congress	
9/15-9/17	House in recess.	Congress	
9/16-9/17	Senate in recess.	Congress	
9/30	End of Fiscal Year (FY) 2021. FY 2022 appropriations bills or continuing resolution (CR) is needed to keep federal government open.	Congress	
9/30	Expiration of COBRA premium assistance via American Rescue Plan Act of 2021 (ARP) (P.L. 117-2)	Congress	
Q3/Q4	Introduction and markup of Senate HELP bipartisan legislation to improve public health and medical preparedness and response	Congress	
Q3/Q4	Possible introduction of Murray/Pallone legislation to establish a public option, following RFI deadline on July 31	Congress	
Fourth Quarter			
10/1	Medicare open enrollment begins for the 2022 plan year.	CMS	



10/13-10/19	Due date for phase 2 of application to participate in the Medicare Shared Savings Program (MSSP).	CMS	Phase 1 applications were due between June 8 and June 28.
10/11-10/15	Senate in recess.	Congress	
10/1-10/31	Anticipated release of the Clinical Laboratory Improvement Amendments (CLIA) Fees proposed rule (0938-AT56).	CMS	
10/1-10/31	Anticipated release of the Medicare Secondary Payer (MSP) and Future Medicals proposed rule (0938-AT85).	CMS	
10/1-10/31	Anticipated release of Reporting Requirements for Air Ambulance, Agent or Broker Services, and HHS Enforcement proposed rule (0938-AU61).	CMS	
10/1-10/31	Anticipated release of the Benefits and Payment Parameters proposed rule (0938-AU65).	CMS	
10/1-10/31	Anticipated release of the Confidentiality of Substance Use Disorder (SUD) Patient Records proposed rule (0945-AA16).	OCR	
10/1-10/31	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	
10/1/10/31	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-AI37)	FDA	
10/1-10/31	Implements protections against surprise medical bills related to the independent dispute resolution processes. (1210-AC00).	OSHA	From the No Surprises Act
10/1-10/31	Would implement protections against surprise medical bills and provisions related to Title II of Division BB of the Consolidated Appropriations Act. (1545-BQ02).	IRS	From the No Surprises Act
11/1-11/30	Anticipated release of a proposed rule that would ban the use of menthol as a characterizing flavor in cigarettes (0910-AI60).	FDA	11/1-11/30
11/1-11/30	Anticipated release of the Medicaid and CHIP Eligibility and Enrollment Processes proposed rule (0938-AU00).	CMS	
11/1-11/30	Anticipated release of the Medicaid Drug Rebate Program (MDRP) proposed rule (0938-AU28).	CMS	
11/1-11/30	Anticipated release of the Long-Term Facilities Infection Prevention and Control proposed rule (0938-AU58).	CMS	
11/1	Exchange open enrollment begins for 2022 plan year.	CMS	
11/19	Final application dispositions for MSSP	CMS	



11/1-11/30	Anticipated release of the Sharing Civil Money Penalties Request for Information (RFI) (0945-AA04).	OCR	
11/1-11/30	Anticipated release of the CY 2020 Medicare Advantage and Prescription Drug Benefit Programs final rule's risk adjustment data validation (0938-AT59).	CMS	
11/1-11/30	Anticipated release of the CY 2022 Medicare Physician Fee Schedule (PFS) final rule (0938-AU42).	CMS	
11/1-11/30	Anticipated release of the CY 2022 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system final rule (0938-AU43).	CMS	
11/1-11/30	Anticipated release of the CY 2022 Changes to the End-Stage Renal Disease (ESRD) PPS and Quality Incentive Program (QIP), final rule (0938-AU39).	CMS	
11/1-11/30	Anticipated release of the CY 2022 Home Health PPS Rate Update , Quality Reporting Requirements, and Home Infusion Therapy Service Requirements final rule (0938-AU37).	CMS	
11/1-11/30	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	
11/1-11/30	Codifies HUD's policy regarding enhanced vouchers available for tenants when the owner leaves one of HUD's project-based programs. (2577-AD00)	HUD	
12/15	Effective date of the Medicare Coverage of Innovative Technology (MCIT) final rule (0938-AT88).	CMS	
11/8-11/12	Senate in recess.	Congress	
11/22-11/26	Senate and House in recess.	Congress	
12/13-12/31	Senate and House in recess.	Congress	
12/1-12/31	Anticipated release of the Provider Nondiscrimination Requirements for Group Health Plans proposed rule (0938-AU64).	CMS	
12/1-12/31	Would amend regulations governing WIC food packages to 1) incorporate recommendations of 2017 Review of WIC Food Packages: Improving Balance and Choice report 2) align with 2020 Dietary Guidelines for Americans 3) other revisions or clarifications. (0584-AE82)	FNS	



12/1-12/31	Would implement control measures to protect high-risk employees from infectious disease exposures to pathogens that can cause significant disease. (1218-AC46)	OSHA	
12/1-12/31	Would update the Treasury's regulations concerning enforcement of nondiscrimination on the basis of disability in programs or activities conducted by the Treasury. (1505-AC56)	DO	
12/1-12/31	Would make changes to the Community Development Block Grant to allow greater flexibility for economic development and recovery. (2506-AC52)	CPD	
12/1-12/31	Possible release of final rule to establish annual summary reporting requirements under the Right to Try Act (0910-AI36) .	FDA	
12/1-12/31	Establishes the parameters of agreements to provide care or services through non-contractual agreements defining the eligibility of providers to furnish such care or services, establishing a methodology to calculate rates for payment of care or services, and establishing a process for the submission of claims payment. (2900-AQ45)	VA	Veteran's Care Agreement
12/1-12/31	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
12/1-12/31	Regulations to implement the Continuum of Care program . (2506-AC51)	HUD	Following a request for comments on this and a related interim rule
12/31	End of 2% Medicare payment sequester	Dec. 31	
12/31	Deadline to address "Statutory PAYGO" stemming from ARP to avoid sequestration (exempts Medicaid and SNAP)	Dec. 31	
2022 and Beyond			
1/1/2022	Surprise billing protections, prohibitions, and requirements take effect.	Congress	Enacted in the Consolidated Appropriations Act, 2021 (P.L. 116-260)
1/1/2022	Expiration of Health Coverage Tax Credit.	Congress	Last reauthorized in the Consolidated Appropriations Act, 2021 (P.L. 116-260)



1/2022	Would implement section 108 of the No Surprises Act provider nondiscrimination requirements for Group Health Plans and health insurance issuers. (1210-AC06)	OSHA	
2/2022	Would amend medical regulations that govern VA health care professionals who practice via telehealth . (2900-AQ59)	VA	Would implement the authorities of the MISSION Act
3/2022	Would eliminate the option for State agencies to use visual observation to collect race and ethnicity data from SNAP applicants that do not provide it. (0584-AE86)	FNS	Will align SNAP regulation with current Federal policy.
4/2022	Anticipated release of a proposed rule that would ban the use of menthol as a characterizing flavor in cigarettes (0910-AI60).	FDA	
3/2022	The rule would implement statutory provisions of the 2008 and 2018 Farm Bills , and other language to deter fraud, abuse, and non-compliance in SNAP. (0584-AE71)	FNS	
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).