



UPDATED: 2020 LEGISLATIVE & REGULATORY OUTLOOK

7.24.20

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

Date	Event	Responsible Party	Notes
<i>Third Quarter</i>			
7/3-7/17	Senate in recess.	Congress	
7/6-7/17	House Appropriations Committee marks up FY 2021 appropriations legislation.	Congress	
7/20-7/31	House expected to vote on FY 2021 appropriations legislation.	Congress	
7/20-7/31	Congress expected to negotiate phase four of coronavirus relief package.	Congress	Size and scope of the package, as well as passage, are unclear.
Q3	Anticipated release of the CY 2021 Medicare Physician Fee Schedule (PFS) proposed rule (0938-AU10).	CMS	
Q3	Anticipated release of the CY 2021 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system proposed rule (0938-AU12).	CMS	
Q3	Anticipated release of the CY 2021 Payment Policies for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies proposed rule (0938-AU17).		New for 2020, this rule is now bifurcated from the end stage renal disease (ESRD) prospective payment system (PPS) proposed rule, which has already been released.
Q3	Potential release of a proposed rule titled, "HIPAA Privacy: Changes to Support, and Remove Barriers to, Coordinated Care and Individual	OCR ¹	Previously slated for Q1 2020

¹ HHS Office for Civil Rights



	Engagement,” which would amend HIPAA rules that currently limit care coordination (0945-AA00).		
Q3	Potential release of a proposed rule titled, “Strengthening Work in TANF,” which would strengthen work requirements in the Temporary Assistance for Needy Families (TANF) program (0970-AC79).	ACF ²	Currently at OMB for review; Previously slated for Q1 2020
Q3	Timeframe for release of a proposal to allow more flexibility in the availability of grandfathered health plans in the individual and small group markets (0938-AT49).	CMS ³	Previously slated for Q1 2020
Q3	Anticipated release of a request for information “seeking public input on whether the Assurance of Transportation in the Medicaid program remains administratively necessary given the delivery of healthcare both in terms of technological advances and the commercial market design.” (0938-AT81).	CMS	Previously slated for Q1 2020
Q3	Slated release of a proposed rule titled, “Nutrient Content Claims, Definition of Term: Healthy” (0910-AI13).	FDA ⁴	Previously slated for Q1 2020
Q3	Slated release of a proposed rule titled, “Medicare Coverage of Innovative Technologies” (0938-AT88).	CMS	Currently at OMB for review; Previously slated for Q1 2020
Q3	Potential release of a proposed rule addressing whether an immigrant is admissible to the country and whether they may be deported based on the use of public benefits (i.e., their designation as a “public charge”) (1125-AA84).	DOJ ⁵	Previously slated for Q1 2020
Q3	Potential release of a proposed rule to implement changes to grandfathered group health plans and grandfathered group health insurance coverage under section 1251 of the Patient Protection and Affordable Care Act (1545-BP67).	DOT ⁶	
Q3	Potential release of a proposed rule to revise its regulations for various Quality Control (QC) provisions in subpart C of 7 CFR part 275 to reflect	FNS ⁷	

² HHS Administration for Children and Families

³ Centers for Medicare & Medicaid Services

⁴ Food and Drug Administration

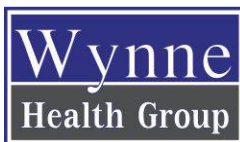
⁵ U.S. Department of Justice

⁶ U.S. Department of the Treasury

⁷ U.S. Department of Agriculture’s Food and Nutrition Service



	numerous changes to the Supplemental Nutrition Assistance Program’s (SNAP) Quality Control system (0584-AE79).		
Q3	Planned release of International Pricing Index (IPI) model proposed rule (0938-AT91).	CMS	Currently at OMB for review; Previously slated for Q1 2020
Q3	Timeframe for release of a proposed rule that would replace current FDA requirements for cooperative research such that any institution located in the US participating in multisite cooperative research would need to rely on approval by a single Institutional Review Board (IRB) (0910-AI08).	FDA	Previously slated for Q1 2020
Q3	Possible release of a proposed rule titled, “Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)” (0910-AH56).	FDA	Previously slated for Q1 2020
Q3	Possible release of a proposed rule implementing a 21 st Century Cures Act provision to “exclude certain medical software functions from the definition of device and therefore FDA’s jurisdiction” (0910-AH67).	FDA	Originally slated for May 2020.
Q3	Potential release of a request for information (RFI) to seek input on how best to implement section 2003 of the SUPPORT Act, which pertains to the electronic prescribing of controlled substances (0938-AU25).	CMS	
7/1-7/31	Timeframe for release of a proposed rule that would establish requirements for third parties that provide financial assistance to end-stage renal disease (ESRD) patients for premiums to enroll in Affordable Care Act (ACA) Marketplace plans (0938-AT11).	CMS	Currently at OMB for review; Previously slated for Q1 2020
7/1-7/31	Possible release of a proposed rule that would “strengthen the integrity of the Medicaid and CHIP eligibility determination process including verification, changes in circumstance, and redetermination” (0938-AU00).	CMS	
7/1-7/31	Possible release of a proposed rule titled, “National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers” (0910-AH11).	FDA	Previously slated for Q1 2020
8/1-8/31	Anticipated release of a proposed rule titled, “Miscellaneous Medicare Secondary Payer (MSP) Clarifications and Updates” (0938-AT85).	CMS	Previously slated for Q1 2020
8/1-8/31	Slated release of a proposed rule titled, “Personnel, Proficiency Testing Referral, and Histocompatibility Requirement Updates,” updating Clinical Laboratory Improvement Amendments (CLIA) requirements (CMS-3326-P).	CMS	Previously slated for July 2020



8/1-8/31	Potential release of a proposed rule to add changes to grandfathered group health plans and grandfathered group health insurance coverage under section 1251 of the Patient Protection and Affordable Care Act (1210-AB89).	DOL ⁸	
8/3-9/4	House in recess.	Congress	
8/10-9/7	Senate in recess.	Congress	
9/1-9/30	Scheduled release of a proposed rule to adopt standards to facilitate the electronic exchange of clinical information pursuant to HIPAA as amended by the ACA (0938-AT38).	CMS	Previously slated for May 2020.
9/1-9/30	Slated release of a proposed rule titled, “Civil Money Penalties and Exclusion Authority to Enforce 1150B Requirements” pertaining to reporting crimes to nursing home residents” (0938-AT60).	CMS	
9/1-9/30	Potential release of a proposed rule to update HUD’s 24 CFR part 581 on use of Federal properties to assist the homeless pursuant to the Federal Assets Sale and Transfer Act of 2016, Public Law 114-287, and would make other clarifications (2506-AC49).	HUD ⁹	
9/1-9/30	Pursuant to Executive Order 13890, the potential release of a proposed rule to advance changes to Medicare and Medicaid provider enrollment, the Medicare Advantage risk adjustment data validation program, certain documentation requirements, along with proposals to “modernize state payment of Medicare premiums” (0938-AU21).	CMS	
Q3	Anticipated release of a final rule regarding Medicaid and Children’s Health Insurance Program (CHIP) managed care programs (0938-AT40).	CMS	Previously slated for Q1 2020
Q3	Possible release of a final rule titled, “Biologics License Applications and Master Files” (0910-AH50).	FDA	Previously slated for Q1 2020
Q3	Potential timing of a final rule to codify Supplemental Nutrition Assistance Program (SNAP) issuance provisions of the Food, Conservation and Energy Act of 2008, Public Law 110-234 (0584-AE02).	FNS	
Q3	Potential timing of a temporary final rule to prevent the hoarding of certain health and medical resources, or any of their essential components, needed	FEMA ¹⁰	Joint rule with HHS and DHS

⁸ U.S. Department of Labor

⁹ U.S. Department of Housing and Urban Development

¹⁰ Federal Emergency Management Agency



	to respond to the Coronavirus Disease 2019 (COVID-19) pandemic and which are, or are likely to be, in short supply (scarce materials) or the supply of which would be threatened by excessive accumulation (threatened materials) (1660-AB05).		
Q3	Potential timing of an interim final rule to meet the provisions of Section 4011 of the 2018 Farm Bill, requiring the establishment of an interstate data system, to be known as the National Accuracy Clearinghouse (NAC), that State agencies will use to prevent multiple issuances of SNAP benefits to an individual by more than one State agency simultaneously (0584-AE75).	FNS	
Q3	Proposed timing of a final rule to revise regulations for various Quality Control (QC) provisions in subpart C of 7 CFR part 275 to reflect numerous changes to the Supplemental Nutrition Assistance Program's (SNAP) Quality Control system (0584-AE64).	FNS	
7/1-7/31	Probable release of a final rule that would establish the format and content of reports intended to demonstrate substantial equivalence (SE) in tobacco products (0910-AH89).	FDA	Previously slated for April 2020.
7/1-7/31	Anticipated release of the FY 2021 Medicare SNF PPS final rule (0938-AU13).	CMS	
8/1-8/31	Statutory deadline for the release of the FY 2021 Medicare IRF PPS final rule (0938-AU05).	CMS	
8/1-8/31	Statutory deadline for the release of the FY 2021 Medicare IPF PPS final rule (0938-AU07).	CMS	
8/1-8/31	Statutory deadline for the release of the FY 2021 Medicare Hospice payment rate update final rule (0938-1733).	CMS	
8/1-8/31	Potential timeframe for release of a final rule titled, "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalties Rules Regarding Beneficiary Inducement" (0936-AA10).	OIG ¹¹	Currently at OMB for review
8/1-8/31	Possible release of a final rule titled, "Modernizing and Clarifying the Physician Self-Referral Regulations" (0938-AT64).	CMS	Currently at OMB for review
8/1-8/31	Timeframe for release of a final rule titled, "Methods for Assuring Access to Covered Medicaid Services – Rescission," which would remove	CMS	Previously slated for March 2020

¹¹ HHS Office of the Inspector General



	regulatory text that established certain access monitoring review plan processes (0938-AT41).		
8/1-8/31	Proposed timing of a final rule to codify several nationwide waivers and flexibilities that have supported State agencies and program operators by increasing efficiencies, reducing burden and redundancy, and strengthening program compliance and integrity (0584-AE72).	FNS	
8/1-8/31	Proposed timing of a final rule to implement targeted flexibilities and regulatory changes to simplify meal pattern and monitoring requirements in the National School Lunch and School Breakfast Programs (0584-AE67).	FNS	
8/1-8/31	Proposed timing of a final rule standardizing the methodology to calculate State heating and cooling standard utility allowances (HCSUA) used in determining a SNAP applicant household's shelter expenses as part of the certification process (0584-AE69).	FNS	
8/1-8/31	Proposed timing of a final rule this proposal would change the regulations at 7 CFR 273.2(j)(2) pertaining to categorically eligible TANF households by limiting categorical eligibility to households that receive cash TANF or other substantial assistance from TANF (0584-AE62).	FNS	
9/1-9/31	Potential timing of a final rule that would require health insurers to facilitate access to information about expected health care costs for patients before they receive care (0938-AU04).	CMS	Joint rule with DOT and DOL
9/1-9/30	Anticipated release of the FY 2021 Medicare IPPS and LTCH PPS final rule (0938-AU11).	CMS	
9/1-9/30	Possible release of a final rule on Medicaid Fiscal Accountability (otherwise known as MFAR), which seeks to “increase accountability, transparency, and clarity through improved reporting of Medicaid payments.” (0938-AT50).	CMS	
9/1-9/30	Potential release of a final rule titled, “Premarket Tobacco Product Applications and Recordkeeping Requirements” (0910-AH44).	FDA	Previously slated for Q1 2020
9/1-9/30	Possible release of a final rule to establish procedures and criteria for the medical device de novo classification process and would make it more transparent and predictable for manufacturers (0910-AH53).	FDA	Previously slated for June 2020
9/1-9/30	Possible release of a final rule titled, “Radiological Health Regulations; Amendments to Records and Reports for Radiation Emitting Electronic	FDA	



	Products; Amendments to Performance Standards for Diagnostic X-ray, Laser and Ultrasonic Products” (0910-AH65).		
9/1-9/30	Possible release of a final rule titled, “Mammography Quality Standards Act; Amendments to Part 900 Regulations” (0910-AH04).	FDA	
9/1-9/30	Anticipated release of an ACA-related final rule titled, “Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid, and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP” (0938-AS55).	CMS	
9/1-9/30	Potential timing of a final rule to make several changes to regulations for the Program of Comprehensive Assistance for Family Caregivers (PCAFC). Changes would be made to comply with the recent enactment of the VA MISSION Act of 2018, which made several changes to the PCAFC at Section 161 to expand eligibility, establish new benefits for primary family caregivers, and other changes. (2900-AQ48).	VA ¹²	
9/1-9/31	Potential timing of a final rule to codify three provisions of the Healthy, Hunger-Free Kids Act of 2010 (the 2010 Child Nutrition Reauthorization). Sections 303, 322, and 362 establish criteria for imposing fines against schools or State agencies that fail to correct severe mismanagement of the program; establish procedures for the termination and disqualification of organizations participating in the Summer Food Service Program (SFSP); and require that any school, institution, service institution, facility, or individual that has been terminated from any Child Nutrition Program appears on either the SFSP or the Child and Adult Care Food Program's (CACFP's) disqualified list. (0584-AE08).	FNS	
9/28-9/29	Senate in recess.	Congress	
9/29	First Presidential Debate in Notre Dame, Indiana. Host pending (details).	White House	
9/30	Expiration of the National Highway Trust Fund	Congress	Last reauthorized under the Fixing America’s Surface Transportation (FAST) Act (P.L. 114-94).
9/30	End of the Federal Fiscal Year. Likely need for FY 2021 appropriations bills or continuing resolution (CR) to keep federal government open.	Congress	

¹² U.S. Department of Veterans Affairs



<i>Fourth Quarter</i>			
10/5-11/13	House in recess.	Congress	
10/7	Vice Presidential Debate in Salt Lake City, Utah. Host pending (details).	White House	
10/12-11/6	Senate in recess.	Congress	
10/15	Second Presidential Debate in Ann Arbor, Michigan. Host pending (details).	White House	
10/22	Third Presidential Debate in Nashville, Tennessee. Host pending (details).	White House	
10/1-10/31	Potential release of proposed rule which would implement statutory provisions of the Food, Conservation, and Energy Act of 2008 (the 2008 Farm Bill), the Agriculture Improvement Act of 2018 (the 2018 Farm Bill), and other language intended to deter retailer fraud, abuse, and non-compliance in the Supplemental Nutrition Assistance Program (SNAP) (0584-AE71).	FNS	
11/1-11/30	Slated release of a proposed rule titled, “Medical Devices; Hematology and Pathology Devices; Classification of Human Leukocyte, Neutrophil and Platelet Antigen or Antibody Tests” (0910-AI12).	FDA	Previously slated for Q1 2020
11/1-11/30	Potential release of a proposed rule that would ban the characterization of flavors in cigars (0910-AI28).	FDA	Previously slated for Q1 2020
11/1-11/30	Possible release of a proposed rule that would place new requirements on Medicare Advantage, Medicaid, and CHIP managed care plans, Qualified Health Plans, and other plan types that would seek to improve the exchange of health care data and streamline the prior authorization process (0938-AT99).	CMS	
11/1-11/30	Anticipated release of a proposed rule titled, “Medication Guides; Patient Medication Information” (0910-AH68).	FDA	Previously slated for June 2020
11/1-11/30	Potential release of proposed changes to promote timely and accurate reporting of changes in household circumstances and income that might affect household benefit amounts (0584-AE76).	FNS	
12/1-12/31	Slated release of a proposed rule titled, “Biologics Regulation Modernization” (0910-AI14).	FDA	Previously slated for Q1 2020
12/1-12/31	Slated re-proposing of a rule that would amend the post marketing safety reporting regulations for human drugs and biological products in order to	FDA	Previously slated for release in June 2020



	better align FDA requirements with guidelines of the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and update reporting requirements in light of current pharmacovigilance practice and safety information sources and enhance the quality of safety reports received by FDA (0910-AA97).		
12/1-12/31	Slated release of a proposed rule that would “modify the existing Medicaid Payment Error Rate Measurement (PERM) to address limitations, including any methodological limitations, on the ability to recoup eligibility-related improper payments” (0938-AU03).	CMS	
12/1-12/31	Slated release of a proposed rule titled, “Nonprescription Drug Product with an Additional Condition for Nonprescription Use” (0910-AH62).	FDA	Previously slated for June 2020
12/1-12/31	Slated release of a proposed rule pertaining to CLIA fees (0938-AT56).	CMS	
11/1	Statutory deadline for the release of the final CY 2021 HHA payment rate update.	CMS	
11/1	Statutory deadline for the release of the final CY 2021 Medicare PFS update.	CMS	
11/1	Statutory deadline for the release of the final CY 2021 Medicare OPPS/ASC payment update.	CMS	
11/1	Statutory deadline for the release of the final CY 2021 ESRD/DEMPOS update.	CMS	
11/1	Exchange open enrollment begins for 2021 plan year.	CMS	
11/3	Presidential election	White House	
11/23-11/27	House and Senate in recess.	Congress	
11/30	Date by which “health extenders” are set to expire. This includes funding for the following: <ul style="list-style-type: none"> • Medicare: National Quality Forum, Outreach and Assistance for Low-Income Programs, floor on work geographic practice cost indices • Medicaid: Money Follows the Person program, spousal impoverishment protections, certified community behavioral health clinics 	Congress	Last reauthorized under the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136).



	<ul style="list-style-type: none"> Public Health: Community health centers (CHCs), teaching health centers, National Health Service Corps, Special Diabetes Program Human Services and Other Health Programs: Sexual Risk Avoidance Education Program, Personal Responsibility Education Program (PREP), demonstration projects to address health professions workforce needs, Temporary Assistance for Needy Families (TANF). 		
12/1-12/31	Possible release of a final rule establishing a drug importation program that would allow participating states to re-import U.S. drugs intended for international sale in Canada back to the United States (0910-AI45).	FDA	
12/1-12/31	Slated release of a final rule titled, “Revision of Product Jurisdiction Regulations,” implementing 21 st Century Cures Act-related provisions (0910-AH71).	FDA	Previously slated for March 2020
12/1-12/31	Possible release of a final rule titled, “Amendments Regarding 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).	FDA	Previously slated for mid-2020
12/1-12/31	Possible release of a final rule titled, “Institutional Review Board [IRB] Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations” (0910-AH52).	FDA	Previously slated for September 2020
12/1	Date by which the Medicaid disproportionate share hospital (DSH) payment reductions delay expires.	Congress	
12/11-12/31	House and Senate in recess (Senate begins recess on 12/21).	Congress	
12/31	Medicare Home health prospective systems rural add-on for high utilization counties expires	Congress	Last reauthorized under the Bipartisan Budget Act of 2018 (P.L. 115-123).
12/31	Health Coverage Tax Credit expires.	Congress	Last reauthorized under the Further Consolidated Appropriations Act, 2020 (P.L. 116-94).