



## 2020 LEGISLATIVE & REGULATORY OUTLOOK

1.8.20

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

Date	Event	Responsible Party	Notes
<i>First Quarter</i>			
1/7	Opening day of the second session of the 116 <sup>th</sup> Congress.	Congress	
1/14	Final Democratic Presidential Debate in Des Moines, Iowa, hosted by CNN and Des Moines Register. <a href="#">Details</a> .	White House	
Q1	Potential release of a proposed rule titled, “HIPAA Privacy: Changes to Support, and Remove Barriers to, Coordinated Care and Individual Engagement,” which would amend HIPAA rules that currently limit care coordination ( <a href="#">0945-AA00</a> ).	OCR <sup>1</sup>	
Q1	Anticipated release of a proposed rule titled, “Civil Money Penalties (CMPs) and MSP Payer Reporting Requirements” ( <a href="#">CMS-6061-P</a> ).	CMS <sup>2</sup>	Previously slated for Sep. 2019.
Q1	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 ( <a href="#">0970-AC79</a> ).	ACF <sup>3</sup>	Currently at OMB for review.
Q1	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”) ( <a href="#">1125-AA84</a> ).	DOJ <sup>4</sup>	
Q1	Timeframe for release of a proposal to allow more flexibility in the availability of grandfathered health plans in the individual and small group markets ( <a href="#">CMS-9923-P</a> ).	CMS	Previously slated for Sep. 2019.

<sup>1</sup> HHS Office for Civil Rights

<sup>2</sup> Centers for Medicare & Medicaid Services

<sup>3</sup> HHS Administration for Children and Families

<sup>4</sup> U.S. Department of Justice



Q1	Slated release of a proposed rule titled, “Biologics Regulation Modernization” ( <a href="#">0910-AI14</a> ).	FDA <sup>5</sup>	Previously slated for July 2019.
Q1	Potential release of a proposed rule titled, “Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2021 ( <a href="#">CMS-4190-P</a> ).”	CMS	Currently at OMB for review.
Q1	Slated release of a proposed rule titled, “Medical Devices; Hematology and Pathology Devices; Classification of Human Leukocyte, Neutrophil and Platelet Antigen or Antibody Tests” ( <a href="#">0910-AI12</a> ).	FDA	Previously slated for June 2019.
Q1	Slated release of a proposed rule titled, “Revised Procedures for the Announcement of Approvals and Denials of Premarket Approval Applications and Humanitarian Device Exemptions” ( <a href="#">0910-AI10</a> ).	FDA	Previously slated for June 2019.
Q1	Anticipated release of a proposed rule titled, “Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value Based Payments (VBP) for Drugs Covered in Medicaid” ( <a href="#">CMS-2482-P</a> ).	CMS	Previously slated for June 2019.
Q1	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.” ( <a href="#">0938-AT81</a> ).	CMS	Originally expected as a proposed rule in May 2019.
Q1	Slated release of a proposed rule titled, “Nutrient Content Claims, Definition of Term: Healthy” ( <a href="#">0910-AI13</a> ).	FDA	
Q1	Slated release of a proposed rule titled, “Medicare Coverage of Innovative Technologies” ( <a href="#">CMS-3372-P</a> ).	CMS	Currently at OMB for review.
Q1	Planned release of International Pricing Index (IPI) model proposed rule ( <a href="#">CMS-5528-P</a> ).	CMS	Currently at OMB for review.
Q1	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 ( <a href="#">CMS-3337-P</a> ).	CMS	Currently at OMB for review.
Q1	Possible release of a rule that would “promote transparency” through “new reporting requirements for states to provide CMS with certain information on supplemental payments to Medicaid providers” ( <a href="#">CMS-2393-P</a> ).	CMS	

<sup>5</sup> Food and Drug Administration



Q1	Possible release of a proposed a rule titled, “Update of Retail Pharmacy Standards” ( <a href="#">CMS-0055-P</a> ).	CMS	Q1
Q1	Possible release of a proposed rule titled, “National Standards for the Licensure of Wholesale Drug Distributors and Third-Party Logistics Providers” ( <a href="#">0910-AH11</a> ).	FDA	Q1
Q1	Timeframe for release of the Calendar Year (CY) 2021 Notice of Benefit and Payment Parameters proposed rule, a wide-ranging Exchange rule ( <a href="#">CMS-9926-P</a> ).	CMS	Currently at OMB for review.
Q1	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) ( <a href="#">0910-AI08</a> ).	FDA	Previously slated for April 2019.
Q1	Potential release of a notice regarding the “Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program Eligibility” ( <a href="#">0906-ZA12</a> ).	HRSA <sup>6</sup>	Currently pending OMB review.
Q1	Potential release of a final rule implementing 21 <sup>st</sup> Century Cures Act-driven interoperability, information blocking, and health information technology (health IT) guidelines ( <a href="#">0955-AA01</a> ).	ONC <sup>7</sup>	Likely to be released in tandem with the related CMS final rule (below), both of which are currently pending OMB review.
Q1	Potential release of a final rule titled, “Interoperability and Patient Access ( <a href="#">CMS-9115-F</a> )”	CMS	Although the HHS regulatory agenda indicates a final action date of March 2022, it is likely the CMS rule will be released in tandem with the related ONC rule (above), given that both rules are currently pending OMB review.

<sup>6</sup> Health Resources and Services Administration

<sup>7</sup> Office of the National Coordinator for Health Information Technology



Q1	Possible release of a final rule that defines “biological product” to conform to the statutory definition ( <a href="#">0910-AH57</a> ).	FDA	Previously slated for Q3/Q4 2019.
Q1	Slated release of a final rule titled, “Civil Monetary Penalties Law Notice of Proposed Rule Making” implementing 21 <sup>st</sup> Century Cures Act-related provisions ( <a href="#">0936-AA09</a> ).	OIG <sup>8</sup>	Previously slated for Sep. 2019.
Q1	Anticipated release of a final rule regarding Medicaid and Children’s Health Insurance Program (CHIP) managed care programs ( <a href="#">CMS-2408-F</a> ).	CMS	Previously slated for mid-2019.
Q1	Possible release of a final rule titled, “Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies to be Allowed in Electronic Format” ( <a href="#">0910-AH48</a> ).	FDA	Previously slated for October 2018.
1/20-1/24	House and Senate in recess.	Congress	Due to uncertainty surrounding the impeachment trial, the Senate excluded January from its <a href="#">tentative 2020 legislative schedule</a> .
1/28-1/30	House Democratic Retreat.	Congress	
1/1-1/31	Possible release of a proposed rule titled, “Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)” ( <a href="#">0910-AH56</a> ).	FDA	Previously slated for Q1 2019.
January/February	Senate impeachment trial of President Trump.	Congress	
2/3-2/10	The President is required to submit his annual budget request to Congress on the first Monday in February pursuant to the Budget and Accounting Act. However, recent reports suggest the President will release his budget on February 10, 2020.	White House	
2/4	President’s State of the Union address to Congress.	Congress	
2/1-2/29	Anticipated release of a proposed rule titled, “Miscellaneous Medicare Secondary Payer (MSP) Clarifications and Updates” ( <a href="#">CMS-6047-P</a> ).	CMS	Previously slated for Sep. 2019.

<sup>8</sup> HHS Office of the Inspector General



2/1-2/29	Possible release of a final rule titled, “Biologics License Applications and Master Files” ( <a href="#">0910-AH50</a> ).	FDA	
2/1-2/29	Possible finalization of a deregulatory action to implement section 1557 of the ACA, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any health program ( <a href="#">0945-AA11</a> ).	OCR	
2/17-2/21	House and Senate in recess.	Congress	
3/1-3/31	Potential release of a proposed rule that would ban the characterization of flavors in cigars ( <a href="#">0910-AI28</a> ).	FDA	
3/1-3/31	Potential release of a final rule titled, “Premarket Tobacco Product Applications and Recordkeeping Requirements” ( <a href="#">0910-AH44</a> ).	FDA	Fall 2019 agenda does not provide a target date for final rule.
3/1-3/31	Slated release of a final rule titled, “Revision of Product Jurisdiction Regulations,” implementing 21 <sup>st</sup> Century Cures Act-related provisions ( <a href="#">0910-AH71</a> ).	FDA	Previously slated for Sep. 2019
3/1-3/31	Timeframe for release of a final rule titled, “Methods for Assuring Access to Covered Medicaid Services – Rescission” ( <a href="#">CMS-2406-F</a> ).	CMS	
3/1-3/31	Potential release of a final rule amending regulations for Veterans Care Agreements ( <a href="#">2900-AQ45</a> ).	VA <sup>9</sup>	Previously slated for June 2019.
3/16-3/20	House and Senate in recess.	Congress	
Q1/Q2	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” ( <a href="#">0936-AA10</a> ).	OIG	Fall 2019 agenda does not provide a target date for final rule.
<b><i>Second Quarter</i></b>			
4/1-4/30	Anticipated release of the FY 2021 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System proposed rule ( <a href="#">CMS-1735-P</a> ).	CMS	

<sup>9</sup> U.S. Department of Veterans Affairs



4/1-4/30	Anticipated release of the FY 2021 Skilled Nursing Facility (SNF) PPS Prospective Payment System Rate Update and Quality Reporting Requirements proposed rule ( <a href="#">CMS-1737-P</a> ).	CMS	
4/1-4/30	Anticipated release of the FY 2021 Inpatient Rehabilitation Facility (IRF) PPS Rate Update and Quality Reporting Requirements proposed rule ( <a href="#">CMS-1729-P</a> ).	CMS	
4/1-4/30	Anticipated release of the FY 2021 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements proposed rule ( <a href="#">CMS-1733-P</a> ).	CMS	
4/1-4/30	Anticipated release of the FY 2021 Inpatient Psychiatric Facilities (IPF) PPS Rate and Quality Reporting Updates proposed rule ( <a href="#">CMS-1731-P</a> ).	CMS	
4/1-4/30	Probable release of a final rule that would establish the format and content of reports intended to demonstrate substantial equivalence (SE) in tobacco products ( <a href="#">0910-AH89</a> ).	FDA	
4/6-4/17	House and Senate in recess.	Congress	
4/22-4/24	House Republican Retreat.	Congress	
4/20-5/8	Notice of Intent to Apply (NOIA) deadline for the January 1, 2021 start date of the Medicare Shared Savings Program (MSSP). <a href="#">Details.</a>	CMS	Final applications to participate are due by noon ET on June 11, 2020.
5/1-5/31	Possible release of a proposed rule implementing a 21 <sup>st</sup> Century Cures Act provision to “exclude certain medical software functions from the definition of device and therefore FDA’s jurisdiction” ( <a href="#">0910-AH67</a> ).	FDA	
5/1-5/31	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 ( <a href="#">CMS-0053-P</a> ).	CMS	
5/1-5/31	Potential timing of a final rule regarding Categorical Eligibility in the Supplemental Nutrition Assistance Program (SNAP) ( <a href="#">0584-AE62</a> ).	FNS <sup>10</sup>	

<sup>10</sup> USDA Food and Nutrition Service



5/1-5/31	Potential timing of a final rule titled, “Supplemental Nutrition Assistance Program (SNAP): Standardization of State Heating and Cooling Standard Utility Allowances” ( <a href="#">0584-AE69</a> ).	FNS	
5/1-5/31	Anticipated release of a final rule that would provide several meal pattern flexibilities in the National School Lunch Program (NSLP) and School Breakfast Program (SBP) “to make it easier for local program operators to administer the programs and to reduce the burden for state administering agencies that are responsible for conducting administrative reviews” ( <a href="#">0584-AE67</a> ).	FNS	
5/4-5/8	House in recess.	Congress	
5/22	Date by which “health extenders” – funding for community health centers (CHCs), teaching health centers, National Health Service Corps, Special Diabetes Program, certified community behavioral health clinics, National Quality Forum, outreach and assistance to low-income Medicare beneficiaries – are set to expire.	Congress	
5/23	Date by which Medicaid disproportionate share hospital (DSH) payment reductions go into effect, absent further congressional intervention.	Congress	
5/25-5/29	House and Senate in recess.	Congress	
6/1-6/30	Slated re-proposing of a rule that would amend the post marketing safety reporting regulations for human drugs and biological products in order to 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 ( <a href="#">0910-AA97</a> ).	FDA	Previously slated for release in May 2019 (as a then-final rule).
6/1-6/30	Anticipated release of a proposed rule titled, “Current Good Manufacturing Practice for Positron Emission Tomography [PET] Drugs” ( <a href="#">0910-AH58</a> ).	FDA	Previously slated for April 2019.



6/1-6/30	Anticipated release of the CY 2021 Medicare Physician Fee Schedule (PFS) proposed rule ( <a href="#">CMS-1734-P</a> ).	CMS	
6/1-6/30	Anticipated release of the CY 2021 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system proposed rule ( <a href="#">CMS-1736-P</a> ).	CMS	
6/1-6/30	Anticipated release of the CY 2021 Changes to the End-Stage Renal Disease (ESRD) PPS, Quality Incentive Program (QIP), Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) proposed rule ( <a href="#">CMS-1732-P</a> ).	CMS	
6/1-6/30	Anticipated release of a proposed rule titled, “Medication Guides; Patient Medication Information” ( <a href="#">0910-AH68</a> ).	FDA	Previously slated for July 2019.
6/1-6/30	Slated release of a proposed rule titled, “Nonprescription Drug Product with an Additional Condition for Nonprescription Use” ( <a href="#">0910-AH62</a> ).	FDA	Previously slated for August 2019.
6/1-6/30	Slated release of a proposed rule titled, “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> ).	FDA	Previously slated for September 2019.
6/1-6/30	Potential timing of a final rule that would establish criteria for imposing fines against schools, school food authorities, or state agencies that fail to correct severe mismanagement in the Summer Food Service Program, fail to correct repeat violations of program requirements, or disregard a program requirement of which they had been informed ( <a href="#">0584-AE72</a> ).	FNS	This would finalize a proposal originally promulgated in 2016 under the Obama Administration, and stemming from the Healthy, Hunger-Free Kids Act of 2010 (current iteration of Child Nutrition Reauthorization (CNR)).
6/1-6/30	Slated release of a final rule titled, “Direct-to-Consumer [DTC] Prescription Drug Advertisements: Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, Neutral Manner” ( <a href="#">0910-AG27</a> ).	FDA	Previously slated for July 23019.





6/1-6/30	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 ( <a href="#">0910-AH53</a> ).	FDA	Previously slated for mid-2019.
Q2/Q3	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” ( <a href="#">0910-AH81</a> ).	FDA	Fall 2019 regulatory agenda does not contain a target date for final rule release. However, the comment period for the proposed rule ended on Dec. 4, 2019.
Q2/Q3	Possible release of a final rule titled, “Modernizing and Clarifying the Physician Self-Referral Regulations” ( <a href="#">CMS-1720-P</a> ).	CMS	Fall 2019 regulatory agenda does not contain a target date for final rule release. However, the comment period for the proposed rule ended on Dec. 31, 2019.
6/29-7/3	House in recess.	Congress	
<i>Third Quarter</i>			
7/13-7/17	House and Senate in recess (Senate begins recess on 7/3).	Congress	
7/1-7/31	Slated release of a proposed rule titled, “Personnel, Proficiency Testing Referral, and Histocompatibility Requirement Updates,” updating Clinical Laboratory Improvement Amendments (CLIA) requirements ( <a href="#">CMS-3326-P</a> ).	CMS	Previously slated for July 2019.
7/1-7/31	Anticipated release of the FY 2021 Medicare SNF PPS final rule ( <a href="#">CMS-1737-F</a> ).	CMS	
7/1-7/31	Anticipated release of the FY 2021 Medicare IPPS and LTCH PPS final rule ( <a href="#">CMS-1735-F</a> ).	CMS	
7/1-7/31	Statutory deadline for the release of the FY 2021 Medicare IRF PPS final rule ( <a href="#">CMS-1729-F</a> ).	CMS	
7/1-7/31	Statutory deadline for the release of the FY 2021 Medicare IPF PPS final rule ( <a href="#">CMS-1731-F</a> ).	CMS	



7/1-7/31	Statutory deadline for the release of the FY 2021 Medicare Hospice final rule ( <a href="#">CMS-1733-F</a> ).	CMS	
8/1-8/31	Potential release of a proposed rule that would require state SNAP agencies to request reimbursement from a sponsored non-citizen's financial sponsor upon notification that the non-citizen has received any means tested public benefit ( <a href="#">0584-AE77</a> ).	FNS	This appears to be intended to bring SNAP program requirements into alignment with CMS guidance issued in August 2019 regarding the legal responsibilities of sponsors for immigrants who receive Medicaid or CHIP (WHG summary <a href="#">here</a> ).
8/3-9/4	House in recess.	Congress	
8/10-9/7	Senate in recess.	Congress	
9/1-9/30	Anticipated release of a proposed rule titled, "Pediatric Study Plan Requirements for New Drug and Biologics License Applications" ( <a href="#">0910-AG93</a> ).	FDA	Previously slated for April 2019.
9/1-9/30	Potential release of a proposed rule to implement statutory authority to permit states to require certain beneficiaries to share in the costs of providing medical assistance by charging premiums and cost-sharing in Medicaid ( <a href="#">CMS-2411-P</a> ).	CMS	
9/1-9/30	Slated release of a proposed rule titled, "Post Approval Changes to Approved Applications" ( <a href="#">0910-AH55</a> ).	FDA	
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" ( <a href="#">CMS-3359-P</a> ).	CMS	
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” ( <a href="#">0910-AH65</a> ).		
9/1-9/30	Possible release of a final rule titled, “Institutional Review Board [IRB] Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations” ( <a href="#">0910-AH52</a> ).	FDA	
9/1-9/30	Possible release of a final rule titled, “Mammography Quality Standards Act; Amendments to Part 900 Regulations” ( <a href="#">0910-AH04</a> ).	FDA	Previously slated for November 2018.
9/1-9/30	Slated release of a final rule addressing 42 CFR Part 2 regulations regarding changes to confidentiality of alcohol and drug abuse patient records to remove barriers to coordinated care and permit information-sharing for patients with substance use disorders (SUDs) ( <a href="#">0930-AA32</a> ).	SAMHSA <sup>11</sup>	
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” ( <a href="#">CMS-2334-F3</a> ).	CMS	Previously slated for September 2019.
9/28-9/29	Senate in recess.	Congress	
9/29	First Presidential Debate in Notre Dame, Indiana. Host pending ( <a href="#">details</a> ).	White House	
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	
<b><i>Fourth Quarter</i></b>			
10/5-11/13	House in recess.	Congress	
10/7	Vice Presidential Debate in Salt Lake City, Utah. Host pending ( <a href="#">details</a> ).	White House	
10/12-11/6	Senate in recess.	Congress	
10/1-10/31	Slated release of a proposed rule pertaining to CLIA fees ( <a href="#">CMS-3356-P</a> ).	CMS	
10/15	Medicare open enrollment begins for the 2021 plan year.	CMS	

<sup>11</sup> Substance Abuse and Mental Health Services Administration



10/15	Second Presidential Debate in Ann Arbor, Michigan. Host pending ( <a href="#">details</a> ).	White House	
10/22	Third Presidential Debate in Nashville, Tennessee. Host pending ( <a href="#">details</a> ).	White House	
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	
12/11-12/31	House and Senate in recess (Senate begins recess on 12/21).	Congress	