



2019 LEGISLATIVE & REGULATORY OUTLOOK

F 1.16.19

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

Date	Event	Responsible Party	Notes
<i>First Quarter</i>			
1/1-1/31	Anticipated release of a proposed rule titled, “HIPAA Privacy Rule: Presumption of Good Faith of Health Care Providers” (0945-AA09). The rule is in response to the opioid epidemic with the goal of “eas[ing] the burden on and potential risks to covered entities that may want to disclose PHI [protected health information] in such circumstances.”	OCR ¹	
1/1-1/31	Slated release of a Request for Information (RFI) titled, “HIPAA Enforcement: Sharing Civil Money Penalties or Monetary Settlements” (0945-AA04).	OCR	
1/3	Opening day of the 116 th Congress.	Congress	
1/18	Notices of Intent to Apply (NOIA) for participation in the July 1, 2019 cycle of the Medicare Shared Savings Program (MSSP) are due. Details .	CMS ²	
1/21-1/27	House and Senate in recess (House begins recess on 1/18).	Congress	
1/25	Comments due on Medicare Advantage (MA) and Part D proposed rule re: loosening restrictions for the six protected classes (CMS-4180-P).	CMS	Once finalized, the proposal is slated to apply to Contract Year 2020.
1/29	President’s State of the Union address to the Congress.	Congress	Note that House Speaker Nancy Pelosi (D-CA) requested the President reschedule the State of the Union address in light of

¹ Office of Civil Rights (OCR)

² Centers for Medicare and Medicaid Services (CMS)



			the partial federal government shutdown.
2/1	Likely release of the Advance Notice of Methodological Changes for CY 2020 MA Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter (Part II) (0938-ZB52).	CMS	Pending OMB review.
2/1-2/28	Scheduled release of a final rule titled, “Medicaid Disproportionate Share Hospital (DSH) Allotment Reductions,” a rule finalizing the methodology to reduce the allotments for fiscal years (FYs) 2020-2025 (CMS-2394-F).	CMS	
2/1-2/28	Slated release of a proposed rule pertaining to CLIA fees (CMS-3356-P).	CMS	
2/1-2/28	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” (CMS-3359-P).	CMS	
2/4	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, though that date has slipped in previous years.	White House	
2/13	Contract Year 2020 Medicare Advantage (MA), Prescription Drug Plan (PDP) Employer/Union-Only Group Waiver Plan, and Medicare-Medicaid Plan applications due. Details .	CMS	Applications due at 8:00 p.m. ET.
2/18-2/24	House and Senate in recess (House begins recess on 2/15).	Congress	
2/19	Applications for participation in the July 1, 2019 cycle of MSSP are due. Details .	CMS	
3/2	Technical date of expiration of the existing debt limit suspension. Action not likely necessary until the summer to avoid adverse implications.	Congress	
3/18-3/22	House and Senate in recess (House begins recess on 3/15).	Congress	
3/1-3/31	Possible release of a final rule titled, “Program Integrity Enhancements to the Provider Enrollment Process” (CMS-6058-F).	CMS	Pending OMB review.
3/1-3/31	Timeframe for release of a final rule titled, “Methods for Assuring Access to Covered Medicaid Services – Rescission” (CMS-2406-P2).	CMS	Pending OMB review. Note that final action on the underlying proposal



			was slated for March 2019.
3/1-3/31	Slated release of a proposed rule titled, “Premarket Tobacco Product Applications and Recordkeeping Requirements” (0910-AH44).	FDA	
3/1-3/31	Slated release of a proposed rule titled, “Post Approval Changes to Approved Applications” (0910-AH55).	FDA	
3/1-3/31	Slated release of a proposed rule titled, “Nutrient Content Claims, Definition of Term: Healthy” (0910-AI13).	FDA	
3/1-3/31	Slated release of a proposed rule titled, “Mental Health and Substance Abuse Emergency Response Procedures” (0930-AA28).	SAMHSA	
3/1-3/31	Slated release of a proposed 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)” (0930-AA32).	SAMHSA	
3/1-3/31	Slated release of a proposed rule titled, “Medicare Coverage of Innovative Technologies” (CMS-3372-P).	CMS	
Winter/Spring 2019	Approximate deadline by which the 116 th Congress will have to raise budget caps to begin the fiscal year (FY) 2020 appropriations process.	Congress	
Spring 2019	Planned release of International Pricing Index (IPI) model proposed rule pursuant to the timeline put forth in the Advanced Notice of Proposed Rule Making (ANPRM) (CMS-5528-ANPRM).	CMS	
Spring 2019	Applications to participate in the second cohort of the Bundled Payments for Care Improvement (BPCI) Advanced demonstration open. Details .	CMS	Second round set to begin January 1, 2020.
Q1	Scheduled release of a proposed rule to adopt standards to facilitate the electronic exchange of clinical information pursuant to HIPAA as amended by the Affordable Care Act (ACA) (CMS-0053-P).	CMS	Previously slated for December 2018.



Q1	Potential release of a proposed rule titled, “Interoperability and Patient Access” (CMS-9115-P).	CMS	Previously slated for December 2018. Pending OMB ³ review.
Q1	Possible release of a proposed rule titled, “Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction” (CMS-3347-P).	CMS	Previously slated for November 2018. Pending OMB review.
Q1	Probable release of a proposed rule that would establish the format and content of reports intended to demonstrate substantial equivalence (SE) in tobacco products (0910-AH89).	FDA ⁴	Previously slated for November 2018. Pending OMB review.
Q1	Timeframe for release of a proposed rule that would establish requirements for third parties that provide financial assistance to patients for premiums to enroll in ACA health insurance plans (CMS-3337-P).	CMS	Previously slated for November 2018.
Q1	Possible release of a proposed rule titled, “21 st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” (0955-AA01).	ONC ⁵	Previously slated for November 2018. Pending OMB review.
Q1	Possible release of a proposed rule titled “Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection” (0936-AA08).	OIG ⁶	Previously slated for October 2018. Pending OMB review.
Q1	Possible release of a proposed rule titled, “Mammography Quality Standards Act; Amendments to Part 900 Regulations” (0910-AH04).	FDA	Previously slated for November 2018. Pending OMB review.
Q1	Timeframe for release of the Calendar Year (CY) 2020 Notice of Benefit and Payment Parameters proposed rule, a wide-ranging Exchange rule (CMS-9926-P).	CMS	Previously slated for October 2018. Pending OMB review.

³ Office of Management and Budget (OMB)

⁴ Food and Drug Administration (FDA)

⁵ Office of the National Coordinator for Health Information Technology (ONC)

⁶ Health and Human Services (HHS) Office of Inspector General (OIG)



Q1	Possible release of a final rule titled, “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority” (0945-AA10).	OCR	Previously slated for November 2018.
Q1	Possible release 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 (0945-AA11).	OCR	Previously slated for July 2018. Pending OMB 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” (CMS-2393-P).	CMS	
Q1	Possible release of a proposed a rule titled, “Update of Retail Pharmacy Standards” (CMS-0055-P).	CMS	Previously slated for November 2018.
Q1	Possible release of a proposal to update outdated certification standards and add new language permitting private, for-profit entities to serve as opioid treatment programs (OTPs) (0930-AA27).	SAMHSA ⁷	Previously slated for October 2018.
Q1	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 (CMS-2411-P).	CMS	Previously slated for December 2018.
Q1	Possible timeframe for the release of a rule titled, “Amendments to the Proposed Rule 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 November 2018.
Q1	Approximate timeframe for parties involved in the federal D.C. district court case regarding 340B reimbursement to submit supplemental briefings on suggested next steps.	DOJ ⁸ /HHS ⁹	Supplemental briefings were originally due by Jan. 26; timeframe now disrupted by the federal government shutdown.

⁷ Substance Abuse and Mental Health Services Administration (SAMHSA)

⁸ Department of Justice (DOJ)

⁹ Department of Health and Human Services (HHS)



Q1	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 November 2018.
Q1	Possible release of a notice titled, “Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2019” (CMS-8068-N).	CMS	
Q1	Possible release of a proposed rule titled, “Institutional Review Board [IRB] Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations” (0910-AH52).	FDA	Previously slated for October 2018.
Q1	Possible release of a proposed rule titled, “Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies to be Allowed in Electronic Format” (0910-AH48).	FDA	Previously slated for October 2018.
Q1	Possible release of a proposed rule titled, “Biologics License Applications and Master Files” (0910-AH50).	FDA	Previously slated for October 2018.
Q1	Possible release of a proposed rule titled, “Certain Requirements Regarding Prescription Drug Marketing (203 Amendment)” (0910-AH56).	FDA	Previously slated for November 2018.
Q1	Possible release of a proposed rule related to CLIA titled, “Proficiency Testing Regulations Related to Analytes and Acceptable Performance” (CMS-3355-P).	CMS	Previously slated for November 2018.
Q1	Possible release of a proposed rule titled, “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” (0910-AH65).	FDA	Previously slated for October 2018.
Q1	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	Previously slated for November 2018.



Q1	Possible release of a proposed rule titled, “Modernizing and Clarifying the Physician Self-Referral Regulations” (CMS-1720-P).	CMS	Previously slated for December 2018.
Q1	Possible release of a proposed rule titled, “Potential Model Updates” (CMS-5527-P).	CMS	
Q1	Possible release of a final rule titled, “Covered Outpatient Drug; Line Extension Definition and Delay in Including U.S. Territories in Definitions of States and U.S.; Changes to the Rebate Calculation for Line Extension Drugs” (CMS-2345-F2).	CMS	Slated for January 2019. Pending OMB review.
Q1	Possible release of a final rule to update requirements for state Medicaid Fraud Control Units (MFCU) (0936-AA07).	OIG	Previously slated for December 2018.
Q1	Anticipated release of Notice of Funding Opportunities (NOFO) for the Integrated Care for Kids (InCK) and Maternal Opioid Misuse (MoM) models.	CMS	InCK Model NOFO release previously slated for fall 2018.
Q1	Possible release of a final rule titled, “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-AH29).	FDA	Previously slated for October 2018.
Q1	Possible release of a final rule that “would amend the regulation regarding the list of drug products that may not be compounded under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, because the drug products have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective” (0910-AH35).	FDA	Previously slated for December 2018.
Q1	Possible release of a final rule titled, “Medical Devices; Medical Device Classification Procedures: Incorporating FDA Safety and Innovation Act Procedures” (0910-AH75).	FDA	Previously slated for November 2018.
<i>Second Quarter</i>			
4/1-4/30	Anticipated release of the FY 2020 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System proposed rule (CMS-1716P).	CMS	



4/1-4/30	Timeframe for 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	
4/1-4/30	Anticipated release of the FY 2020 Skilled Nursing Facility (SNF) PPS Prospective Payment System Rate Update and Quality Reporting Requirements proposed rule (CMS-1718-P).	CMS	
4/1-4/30	Anticipated release of the FY 2020 Inpatient Rehabilitation Facility (IRF) PPS Rate Update and Quality Reporting Requirements proposed rule (CMS-1710-P).	CMS	
4/1-4/30	Anticipated release of the FY 2020 Hospice Wage Index, Payment Rate Update, and Quality Reporting Requirements proposed rule (CMS-1714-P).	CMS	
4/1-4/30	Anticipated release of the FY 2020 Inpatient Psychiatric Facilities (IPF) PPS Rate and Quality Reporting Updates proposed rule (CMS-1712-P).	CMS	
4/1-4/30	Anticipated release of a proposed rule titled, “Pediatric Study Plan Requirements for New Drug and Biologics License Applications” (0910-AG93).	FDA	
4/1-4/30	Anticipated release of a proposed rule titled, “Current Good Manufacturing Practice for Positron Emission Tomography [PET] Drugs” (0910-AH58).	FDA	
4/15-4/28	House and Senate in recess.	Congress	
5/1-5/31	Slated release of a final rule titled, “Health Insurance Providers Fee,” which aims to “clarify the definition of ‘net premiums written’” for purpose of section 9010 of the ACA.	Treasury	
5/1-5/31	Slated release of a final 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 (0910-AA97).	FDA	



5/1-5/31	Anticipated release of a proposed rule titled, “Non-Emergency Medical Transportation in Medicaid” (CMS-2481-P).	CMS	
5/27-6/2	House and Senate in recess (House begins recess on 5/24 and ends 6/4).	Congress	
June	Kick-off of at least a dozen Democratic Presidential primary debates. Democratic National Committee (DNC) Chairman Tom Perez said that six debates will be held in 2019, with six more in 2020.	White House	
6/1-6/30	Anticipated release of the CY 2020 Medicare Physician Fee Schedule (PFS) proposed rule (CMS-1715-P).	CMS	
6/1-6/30	Anticipated release of the CY 2020 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system proposed rule (CMS-1717-P).	CMS	
6/1-6/30	Anticipated release of the CY 2020 Changes to the End-Stage Renal Disease (ESRD) PPS, Quality Incentive Program (QIP), Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) proposed rule (CMS-1713-P).	CMS	
6/1-6/30	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” (CMS-2482-P).	CMS	
6/1-6/30	Anticipated release of the CY 2020 Home Health Agency (HHA) PPS Rate Update and Quality Reporting Requirements proposed rule (CMS-1711-P).	CMS	
6/1-6/30	Slated release of a proposed rule titled, “Revised Procedures for the Announcement of Approvals and Denials of Premarket Approval Applications and Humanitarian Device Exemptions” (0910-AI10).	FDA	
6/1-6/30	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	
6/1-6/30	Slated release of a final rule titled, “Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care” (CMS-3295-F).	CMS	



Q2/Q3	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	
Q2/Q3	Anticipated release of a final rule regarding Medicaid and Children’s Health Insurance Program (CHIP) managed care programs (CMS-2408-F).	CMS	
Q2/Q3	Possible release of a final rule titled “Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency” (CMS-4187-F).	CMS	
Q2/Q3	Timeframe for possible release of Executive Order-driven final rule addressing expansion of Health Reimbursement Arrangements (HRAs) (1545-BO46).	Treasury	
Q2/Q3	Possible timeframe for release of a final rule that would offer “improvements to Exchange program integrity” (CMS-9922-F).	CMS	
Q2-Q3	Possible release of a final rule to set forth programmatic and operational changes to the Medicare Advantage (MA) and prescription drug benefit programs for contract year 2020 (CMS-4185-F).	CMS	
<i>Third Quarter</i>			
7/1-7/5	House and Senate in recess (House begins recess on 6/28 and ends 7/9).	Congress	
7/1-7/31	Anticipated release of the FY 2020 Medicare SNF PPS final rule (CMS-1718-F).	CMS	
7/1-7/31	Anticipated release of a proposed rule titled, “Medication Guides; Patient Medication Information” (0910-AH68).	FDA	
7/1-7/31	Anticipated release of the FY 2020 Medicare IPPS and LTCH PPS final rule (CMS-1716-F).	CMS	
7/1-7/31	Statutory deadline for the release of the FY 2020 Medicare IRF PPS final rule (CMS-1710-F).	CMS	
7/1-7/31	Statutory deadline for the release of the FY 2020 Medicare IPF PPS final rule (CMS-1712-F).	CMS	
7/1-7/31	Statutory deadline for the release of the FY 2020 Medicare Hospice final rule (CMS-1714-F).	CMS	
7/1-7/31	Slated release of a proposed rule titled, “Biologics Regulation Modernization” (0910-AI14).	FDA	



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 (CMS-3326-P).	CMS	
7/1-7/31	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” (0910-AG27).	FDA	
8/1-8/31	Slated release of a proposed rule titled, “Nonprescription Drug Product with an Additional Condition for Nonprescription Use” (0910-AH62).	FDA	
8/1-8/31	Anticipated release of a proposed rule titled, “Programs of All-Inclusive Care for the Elderly (PACE) Update” (CMS-4168-F).	CMS	
July-August	Likely timeframe Congress must act to raise or suspend the debt limit to avoid adverse implications to US financial system.	Congress	
8/5-9/6	House and Senate in recess (House begins recess on 7/29).	Congress	
9/1-9/30	Timeframe for release of a proposal to allow more flexibility in the availability of grandfathered health plans in the individual and small group markets (CMS-9923-P).	CMS	
9/1-9/30	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” (0910-AI11).	FDA	
9/1-9/30	Slated release of a final rule titled, “Revision of Product Jurisdiction Regulations,” implementing 21 st Century Cures Act-related provisions (0910-AH71).	FDA	
9/1-9/30	Slated release of a final rule titled, “Civil Monetary Penalties Law Notice of Proposed Rule Making” implementing 21 st Century Cures Act-related provisions (0936-AA09).	OIG	
9/1-9/30	Anticipated release of a proposed rule titled, “Excise Tax on High Cost Employer-Sponsored Health Coverage.” The rule “contains proposed regulations on the excise tax on high cost employer-sponsored health coverage under section 4980(I) for taxable years beginning after 2021, enacted by the Affordable Care Act [ACA]” (1545-BN21).	Treasury	



9/1-9/30	Anticipated release of a proposed rule titled, “Shared Responsibility for Employers Regarding Health Coverage” (1545-BO36).	Treasury	
9/1-9/30	Anticipated release of a proposed rule titled, “Application of Various Provisions of Section 2711 of the Public Health Service Act, the Affordable Care Act [ACA], and the Internal Revenue Code to Health Reimbursement Arrangements [HRAs]” (1545-BO46).	Treasury	
9/1-9/30	Anticipated release of a proposed rule titled, “Miscellaneous Medicare Secondary Payer (MSP) Clarifications and Updates” (CMS-6047-P).	CMS	
9/1-9/30	Anticipated release of a proposed rule titled, “Civil Money Penalties (CMPs) and MSP Payer Reporting Requirements (CMS-6061-P).	CMS	
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” (CMS-2334-F3).	CMS	
9/1-9/30	Slated release of a notice delineating CY 2020 Medicare Part A premiums (CMS-8072-N).	CMS	
9/1-9/30	Slated release of a notice delineating CY 2020 Medicare Part B premiums and deductibles (CMS-8073-N).	CMS	
9/30	End of Federal Fiscal Year. Likely need for FY 2020 appropriations bills or continuing resolution (CR) to keep federal government open.	Congress	
9/30	Date by which “health extenders” – funding for community health centers (CHCs) and teaching health centers, National Health Service Corps (NHSC), as well as Medicaid disproportionate share hospital (DSH) cut delays – are set to expire.	Congress	
9/30-10/14	House and Senate in recess.	Congress	
Q3	Potential release of a proposal to permit the contained use of drug master files for biologics approved in a new drug application (NDA) (0910-AH50).	FDA	Previously slated for October 2018.



Q3	Potential release of a final rule that revises the discharge planning requirements that hospitals – including long-term care hospitals (LTCHs) and inpatient rehabilitation facilities (IRFs), home health agencies (HHAs), and critical access hospitals (CAHs), must meet to participate in the Medicare and Medicaid programs (CMS-3317-F).	CMS	Latest notice extends timeframe to promulgate final regulation to Nov. 3, 2019.
Q3/Q4	Possible release of a final rule that defines “biological product” to conform to the statutory definition (0910-AH57).	FDA	
<i>Fourth Quarter</i>			
10/15	Medicare open enrollment begins for the 2020 plan year.	CMS	
11/1	Statutory deadline for the release of the final CY 2020 HHA payment rate update.	CMS	
11/1	Statutory deadline for the release of the final CY 2020 Medicare PFS update.	CMS	
11/1	Statutory deadline for the release of the final CY 2020 Medicare OPPS/ASC payment update.	CMS	
11/1	Statutory deadline for the release of the final CY 2020 ESRD/DEMPOS update.	CMS	
11/1	Exchange open enrollment begins for 2020 plan year.	CMS	
11/25-11/29	House and Senate in recess (House begins recess on 11/22 and ends 12/3).	Congress	
12/16-12/31	House and Senate in recess (House begins recess on 12/13).	Congress	
12/31/19	Date by which delays to the health insurance tax and the medical device tax expire.	Congress	