



2018 LEGISLATIVE & REGULATORY OUTLOOK

Last updated 9.12.18

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

Date	Event	Responsible Party	Notes
<i>Third Quarter</i>			
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 (CMS-0053-P).	CMS ¹	
9/1-9/30	Anticipated release of a proposed rule to rescind the standard unique identifier for health plans (HPID) and the implementation specifications and requirements for its use (CMS-0054-P).	CMS	
9/1-9/30	Scheduled release of a proposed rule to set forth programmatic and operational changes to the Medicare Advantage (MA) and prescription drug benefit programs for contract year 2020 (CMS-4185-P).	CMS	Pending OMB ² review.
9/1-9/30	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 ³	
9/1-9/30	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 Affordable Care Act (ACA) health insurance plans (CMS-3337-P).	CMS	
9/1-9/30	Timeframe for release of a proposed rule that would reform Medicare regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on healthcare providers and suppliers (CMS-3346-P).	CMS	Cleared by OMB.

¹ Centers for Medicare and Medicaid Services (CMS)

² Office of Management and Budget (OMB)

³ Food and Drug Administration (FDA)



9/1-9/30	Anticipated release of a proposal regarding Medicaid and Children’s Health Insurance Program (CHIP) managed care programs (CMS-2408-P).	CMS	Pending OMB review.
9/1-9/30	Timeframe for release of the Calendar Year 2020 Notice of Benefit and Payment Parameters proposed rule, a wide-ranging Exchange rule (CMS-9926-P).	CMS	
9/1-9/30	Possible release of a proposed rule titled “Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency” (CMS-4187-P).	CMS	Pending OMB review.
9/1-9/30	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 ⁴	Pending OMB review.
9/15	Statutory deadline for the release of a final rule that announces the premiums for calendar year (CY) 2019 under Medicare Part A for the uninsured aged and for certain disabled individuals who have exhausted other entitlements (0938-ATM).	CMS	
9/15	Statutory deadline for the release of a final rule that would provide the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in CY 2019 under Medicare Part A (CMS-8068-N).	CMS	
9/30	Statutory deadline for the release of a CMS annual notice for the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) enrollees in Part B of Medicare for CY 2019. It also announces the monthly Part B premiums and the Part B deductible during CY 2019 (CMS-8070-N).	CMS	
9/30	Lapse in Federal government funding absent enacted appropriations measures and/or Continuing Resolution.	Congress	
Q3	Timeframe for possible release of Executive Order-driven proposed rule addressing expansion of Health Reimbursement Arrangements (HRAs) (1545-BO46).	Treasury	

⁴ Health and Human Services (HHS) Office of Inspector General (OIG)



Q3	Timeframe for possible release of a proposed rule revising the definition of a “public charge,” which affects legal residency and visa status (1615-AA22).	DHS	Pending OMB review.
Q3	Timeframe for a proposed rule that would streamline the claims appeals process in MA to reduce associated burden on providers, beneficiaries, and appeals adjudicators (CMS-4174-P).	CMS	Previously slated for August 2018.
Q3	Scheduled release of a proposal that defines “biological product” to conform to the statutory definition (0910-AH57).	FDA ⁵	Previously slated for May 2018.
Q3	Possible timeframe for release of a proposal that would offer “improvements to Exchange program integrity” (CMS-9922-P).	CMS	Pending OMB review.
Q3	Timeframe for the 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 May 2018.
Q3	Timeframe for the release of a final rule to update requirements for state Medicaid Fraud Control Units (MFCU) (0936-AA07).	OIG ⁶	Previously slated for June 2018.
Q3	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 ⁷	Under review at OMB
Q3	Timeframe for the release of a proposed rule to establish procedures and criteria for the medical device de novo classification process and would make it more transparent and predictable for manufacturers.	FDA	

⁵ Food and Drug Administration (FDA)

⁶ HHS Office of the Inspector General (OIG)

⁷ Office of Civil Rights (OCR)



Q3	Possible release of a final rule that would expand exemptions to protect moral convictions for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Affordable Care Act (ACA) (CMS-9925-P).	CMS	
Q3	Possible release of a final rule that would expand exemptions to protect religious beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA (CMS-9940-F2).	CMS	
<i>Fourth Quarter</i>			
10/1	The first cohort of participants are slated to begin participation in the Bundled Payments for Care Improvement (BPCI) Advanced Model. (Details).	CMS	
10/1-10/31	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	
10/1-10/31	Slated release of a proposed a rule titled, “Update of Retail Pharmacy Standards” (CMS-0055-P).	CMS	
10/1-10/31	Anticipated release of a proposal to update outdated certification standards and add new language permitting private, for-profit entities to serve as opioid treatment programs (0930-AA27).	SAMHSA ⁸	
10/16	Date by which comments are due on CMS’ proposed rule overhauling the Medicare Shared Savings Program (MSSP) for Accountable Care Organizations (ACOs).	CMS	
10/26	Comment deadline on a request for information (RFI) that seeks input on addressing regulatory provisions pursuant to the anti-kickback statute that may act as barriers to coordinated care or value-based care.	OIG	
10/29-11/12	House and Senate on recess.	Congress	
11/1	Open enrollment begins for 2019 Marketplace plan year. The open enrollment period generally runs to Dec. 15, 2018. (Details).	CMS	
11/1	Statutory deadline for the release of the final CY 2019 home health payment rate update.	CMS	

⁸ Substance Abuse and Mental Health Services Administration (SAMHSA)



11/1	Statutory deadline for the release of the final CY 2019 Medicare physician fee schedule (MPFS) update.	CMS	
11/1	Statutory deadline for the release of the final CY 2019 Medicare hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment update.	CMS	
11/1	Statutory deadline for the release of the final End-stage Renal Disease (ESRD)/ Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) update.	CMS	
11/6	Election Day.		
11/19-11/23	House and Senate on recess (Senate returns on 11/26; House on 11/27).	Congress	
11/1-11/31	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	
11/1-11/30	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-3394-E).	CMS	Likely to account for any statutory delay of the DSH cuts for FYs 2018 and 2019 pursuant to the 2018 Bipartisan Budget Act (BBA). Proposed rule out in July 2017; final rule previously targeted for November 2017.
11/1-11/30	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	
11/1-11/30	Timeframe for final action on a rule to implement statutory requirements for FDA to use administrative orders to announce or to change the classification of devices, instead of taking action by regulation (0910-AH75).	FDA	
11/1-11/30	Scheduled released 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),	CMS	



	and critical access hospitals (CAHs), must meet to participate in the Medicare and Medicaid programs (CMS-3317-P).		
12/1-12/31	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	
12/1-12/31	Proposal 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	
12/1-12/31	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	
12/17-12/31	Congress in recess (House recess begins 12/14).	Congress	