



## 2018 LEGISLATIVE & REGULATORY OUTLOOK

*Last updated 2.7.18*

**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	Merit-Based Incentive Payment System (MIPS) reporting year begins under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).	CMS <sup>1</sup>	
2/8	Deadline by which federal government funding expires under the most recent <a href="#">Continuing Resolution</a> (H.R. 195).	Congress	
2/12	Possible release of the President’s Fiscal Year (FY) 2019 budget priorities.	White House	
2/19-2/25	House and Senate in recess.	Congress	
2/1-2/28	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 ( <a href="#">CMS-3337-P</a> ).	CMS	Previously slated for December 2017.
2/1-2/28	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 ( <a href="#">CMS-3346-P</a> ).	CMS	Currently under OMB review.
2/1-2/28	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	Originally slated for December 2017.
2/1-2/28	Scheduled release of a proposal that defines “biological product” to conform to the statutory definition ( <a href="#">0910-AH57</a> ).	FDA <sup>2</sup>	
2/1-2/28	Timeframe for release of a proposed rule would make changes to the regulations for the Medicare Shared Savings Program for Accountable Care Organizations (ACOs) ( <a href="#">CMS-18701-P</a> ).	CMS	

<sup>1</sup> Centers for Medicare and Medicaid Services (CMS)

<sup>2</sup> Food and Drug Administration (FDA)



2/1-2/28	Timeframe for release of a proposed regulation amending the definition of short term, limited duration insurance (STLDI) for purposes of its exclusion from the definition of individual health insurance coverage ( <a href="#">CMS-9924-P</a> ).	CMS	Currently at OMB for review.
2/1-2/28	Slated release of a proposed a rule titled, “Updates to Part D E-Prescribing Standards and Part D HIPAA Electronic Standards” ( <a href="#">CMS-0055-P</a> ).	CMS	
2/1-2/28	Timeframe for the release of a final rule to update confidentiality requirements for patient records to, under certain circumstances, use and disclose part 2-covered data ( <a href="#">0930-AA26</a> ).	SAMHSA <sup>3</sup>	
3/12	Application deadline for the Center for Medicare and Medicaid Innovation’s (CMMI) Bundled Payments for Care Improvement (BPCI) Advanced <a href="#">model</a> .	CMS	
3/16	Approximate deadline by which the 115 <sup>th</sup> Congress will have to raise the <a href="#">debt limit</a> per the Congressional Budget Office’s (CBO) January 2018 projection.	Congress	
3/1-3/31	Timeframe on a final action to update FDA’s requirements for accepting clinical data for new medical devices ( <a href="#">0910-AG48</a> ).	FDA	
3/1-3/31	Timeframe for the release of the final CY 2019 Notice of Benefit and Payment Parameters final rule, a wide-ranging Exchange rule ( <a href="#">CMS-9930-E</a> ).	CCIIO	Currently under review at OMB.
3/1-3/31	Slated release of a proposed rule titled, “Food Labeling: Calorie Labeling of Articles of Food Sold from Certain Vending Machines; Front of Package Type Size” ( <a href="#">0910-AH83</a> ).	FDA	
3/1-3/31	Slated release of a proposed rule that would “remove redundant regulations applying to emergency response grants” ( <a href="#">0930-AA28</a> ).	SAMHSA	
3/1-3/31	Timeframe for release of a proposal to provide an exception to the requirements for documenting Medicaid fee-for-service (FFS) access to care for states with high managed care penetration rates ( <a href="#">CMS-2406-P</a> ).	CMS	
3/1-3/31	Timeframe for release of a proposed rule that would establish a Medicare benefit payment for home infusion therapy pursuant to the 21 <sup>st</sup> Century Cures Act ( <a href="#">CMS-3341-P</a> ).	CMS	

<sup>3</sup> Substance Abuse and Mental Health Services Administration (SAMHSA)



3/1-3/31	Possible timeframe for release of a proposal that would offer “improvements to Exchange program integrity” ( <a href="#">CMS-9922-P</a> ).	CMS	
3/23	Date by which the latest CR is set to expire.	Congress	
3/26-4/6	House and Senate in recess.	Congress	
Q1	Timeframe for release of a proposal that would amend the definition of ‘knowingly and intentionally’ under 340B and amend regulations regarding 340B ceiling price ( <a href="#">0906-AB12</a> ).	HRSA <sup>4</sup>	Previously slated for December 2017. Pending OMB review since October 2017.
Q1	Scheduled release of a final rule titled, “Medicaid Disproportionate Share Hospital (DSH) Allotment Reductions”, a rule finalizing the methodology to reduce the allotments for FY 2018-2025 ( <a href="#">CMS-2394-F</a> ).	CMS	Likely to account for any statutory delay of the DSH cuts for FYs 2018 and 2019 pursuant to the CR. Proposed rule out in July 2017; final rule previously targeted for November 2017.
Q1	Possible release of an FDA request for information (RFI) on kid-appealing flavors in tobacco products ( <a href="#">0910-AH60</a> ).	FDA	Previously targeted for November 2017 release. Pending OMB review since December 2017.
Q1	Timeframe for an interim final rule with comment period to extend the end of the transition period for phasing in adjustments to the fee schedule amounts for certain durable medical equipment (DME) and enteral nutrition not subject to competitive bidding ( <a href="#">CMS-1687-IFC</a> ).	CMS	Under review at OMB.
<i>Second Quarter</i>			
Q2	Potential release of a final rule pertaining to CY 2019 MA and Part D policy and technical changes ( <a href="#">CMS-4182-E</a> ).	CMS	

<sup>4</sup> Health Resources and Services Administration (HRSA)



4/2	Expected timeframe for the announcement of Calendar Year (CY) 2019 Medicare Advantage (MA) Capitation Rates and MA/Part D Payment Policies and Final Call Letter (see <a href="#">here</a> ).	CMS	
4/1-4/30	Timeframe for the release of an annual proposal to update the FY 2019 payment rate for skilled nursing facilities (SNFs) ( <a href="#">CMS-1696-P</a> ).	CMS	
4/1-4/30	Timeframe for the release of a proposal to update the Hospital Inpatient Prospective Payment System for Acute Care (IPPS) and the Long-Term Care Hospitals (LTCHs) for FY 2019 ( <a href="#">CMS-1694-P</a> ).	CMS	At OMB for review.
4/1-4/30	Timeframe for the release of the annual Inpatient Rehabilitation Facility (IRF) Prospective Payment System (PPS) update for FY 2019 (CMS-1688-P).	CMS	
4/1-4/30	Timeframe for the release of an annual proposal to update the hospice payment rates for FY 2019 ( <a href="#">CMS-1692-P</a> ).	CMS	
4/1-4/30	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) ( <a href="#">0910-AH50</a> ).	FDA	
5/28-6/3	House and Senate in recess (House begins recess 5/25 and ends 6/5).	Congress	
6/1-6/30	Slated release of an annual proposed home health payment rule that would update the 60-day national episode rate among other policies ( <a href="#">CMS-1689-P</a> ).	CMS	
6/1-6/30	Timeframe for release of a proposed rule to reform requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs ( <a href="#">CMS-3347-P</a> ).	CMS	
6/1-6/30	Slated release of a proposal specifying pediatric study requirements for new drug and biologics license applications ( <a href="#">0910-AG93</a> ).	FDA	
6/1-6/30	Timeframe for the release of an annual proposal titled, “CY 2019 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B” ( <a href="#">CMS-1676-P</a> ).	CMS	Likely vehicle for Medicare Access and CHIP Reauthorization Act (MACRA) Quality Payment Program (QPP) policies.



6/1-6/30	Timeframe for the release of a final rule to update requirements for state Medicaid Fraud Control Units (MFCU) ( <a href="#">0936-AA07</a> ).	OIG <sup>5</sup>	
6/1-6/30	Timeframe for the release of proposed rule delineating CY 2019 Hospital Outpatient PPS (OPPS) and Ambulatory Surgical Center (ASC) policy changes and payment rates” ( <a href="#">CMS-1695-P</a> ).	CMS	
6/1-6/30	Expected release of a proposal pertaining to CY 2019 changes to the End-Stage Renal Disease (ESRD) PPS ( <a href="#">CMS-1691-P</a> ).	CMS	
6/20	Proposed initial application deadline for Qualified Health Plans (QHPs) in Federally Facilitated Marketplaces	CMS	
<i>Third Quarter</i>			
7/1	Anticipated start date for CMS’ Episode Payment <a href="#">Models</a> .	CMS	
7/2-7/6	House and Senate in recess (House begins recess 6/29 and ends 7/10).	Congress	
7/25	Proposed initial application deadline for QHP application Rate Table Template in Federally Facilitated Marketplaces	CMS	
7/31	Statutory deadline for the release of the final SNF payment rate update.	CMS	
7/31	Statutory deadline for the release of the final IPPS/ASC payment rate update.	CMS	
8/1	Statutory deadline for the release of the final IRF PPS update.	CMS	
8/1	Statutory deadline for the release of the final hospice payment rate update.	CMS	
8/1-8/31	Anticipated release of a proposal regarding Medicaid and Children’s Health Insurance Program (CHIP) managed care programs ( <a href="#">CMS-2408-P</a> ).	CMS	
8/1-8/31	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	
8/1-9/3	House and Senate break for August recess (Senate in session first three days of August).	Congress	

<sup>5</sup> HHS Office of the Inspector General (OIG)

9/1-9/30	Timeframe for release of an annual proposed rule to set forth requirements for issuers offering plans on Federally-facilitated Exchanges and State-based Exchanges ( <a href="#">CMS-9926-P</a> ).	CMS	
9/15	Statutory deadline for the release of a final rule that announces the premiums for CY 2019 under Medicare Part A for the uninsured aged and for certain disabled individuals who have exhausted other entitlements ( <a href="#">CMS-8069-N</a> ).	CMS	
9/15	Statutory deadline for the released of a final rule that would provide the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2019 under Medicare Part A ( <a href="#">CMS-8068-N</a> ).	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 ( <a href="#">CMS-8070-N</a> ).	CMS	
<i>Fourth Quarter</i>			
10/1	The first cohort of Participants will start participation in the BPCI Advanced Model.	CMS	
10/29-11/12	House and Senate on recess.	Congress	
10/1-10/31	Anticipated release of a proposal to update outdated certification standards for and add new language permitting private, for-profit entities to serve as opioid treatment programs ( <a href="#">0930-AA27</a> ).	SAMHSA	
11/1	Open enrollment begins for 2019 plan year	CMS	
11/1	Statutory deadline for the release of the final home health payment rate update.	CMS	
11/1	Statutory deadline for the release of the final Medicare physician fee schedule update.	CMS	
11/1	Statutory deadline for the release of the final OPPS payment update.	CMS	
11/1	Statutory deadline for the release of the final ESRD/DMEPOS update.	CMS	
11/19-11/23	House and Senate on recess (Senate returns on 11/26; House on 11/27).	Congress	



11/1-11/30	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	Long-term regulatory <a href="#">agenda</a> item.
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) ( <a href="#">0910-AH81</a> ).	FDA	Long-term regulatory <a href="#">agenda</a> item.
11/1-11/30	Slated release of a second proposed rule pertaining to an extension of the compliance date for May 2016 final rules pertaining to “updated nutrition information on the label of food and dietary supplements; defining a single-serving container; requiring dual-column labeling for certain containers; updating, modifying, and establishing several reference amounts customarily consumed (RACCs)...” ( <a href="#">0910-AH92</a> ).	FDA	
12/17-12/31	Congress in recess (House recess begins 12/14)	Congress	