

March 29, 2018

## 2018 Calendar of Key Anticipated Health Care Rules

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This regulatory calendar provides an overview of select Department of Health and Human Services (HHS) rules – and one Department of Homeland Security (DHS) rule – that the Administration anticipates releasing over the course of 2018. The calendar is based on the Fall “Unified Agenda of Regulatory and Deregulatory Actions” (or, the “Unified Agenda”),<sup>1</sup> and advancements in rule-making since the Unified Agenda’s release.

The Unified Agenda provides a useful overview of rules that agencies anticipate issuing over the next year – including a very high-level summary of the topic of the rule – but it is neither all-encompassing nor an exact calendar of how rule making will unfold. Inevitably, promulgation of certain rules will follow a timeline that departs from the Unified Agenda, and rules that were not indicated in the Unified Agenda will be released. Outside of the rule-making process, agencies will advance certain priorities via guidance that is neither subject to the rule-making process nor indicated in the Unified Agenda (and therefore not reflected in this calendar).

Rules that raise significant policy issues or that exceed a certain economic threshold must be reviewed by the Office of Management and Budget (OMB) prior to their publication. OMB’s website reflects rules that are under review (but not the content of the rules) and can be a tool to estimate timing of public release, although review times vary significantly.<sup>2</sup>

Manatt will update this calendar to reflect adjustments to timelines that agencies make in the Spring Unified Agenda, which is typically released in late May.

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<sup>1</sup> Agencies are required to publish a “Regulatory Plan” once a year in the fall, and a “Unified Agenda of Regulatory and Deregulatory Actions” in the spring and fall. The latest Unified Agenda was released in Fall 2017 and is available at: <https://www.reginfo.gov/public/do/eAgendaMain>.

<sup>2</sup> A more detailed summary of the rule-making process is available at: [https://www.federalregister.gov/uploads/2011/01/the\\_rulemaking\\_process.pdf](https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf), and the “Reg Map” that provides a one-page overview of the process is available at: <https://reginfo.gov/public/reginfo/Regmap/regmap.pdf>.



## 2018 Calendar of Key Anticipated Health Care Rules

Rule (Issuing Agency; Regulatory Information Number <sup>3</sup> )	Description	Next Stage <sup>4</sup>
<b>Proposed Rules Issued in FY 2018 For Which Further Action is Imminent</b>		
Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2019 (CMS; RIN <a href="#">0938-AT08</a> )	This proposed rule was published on November 16, 2017, and technical and typographical errors were corrected in a December 28, 2017 <a href="#">version</a> . The rule would make policy and technical changes for Medicare Advantage plans and Part D prescription drug plans. For additional information, see Manatt's <a href="#">summary</a> . <i>Note: the final rule is currently pending review at OMB.</i>	Final Rule
CY 2019 Notice of Benefit and Payment Parameters (CMS; RIN <a href="#">0938-AT12</a> )	This <a href="#">proposed rule</a> was published on November 2, 2017, and contains proposed changes to regulation of the individual and small group health insurance markets for 2019 and beyond (and in some cases, sooner). For additional detail, see Manatt's <a href="#">summary</a> . <i>Note: the final rule is currently pending review at OMB.</i>	Final Rule
<b>Proposed Rules Issued in FY 2018 For Which Further Action is Anticipated This Year</b>		
Short Term Limited Duration Insurance (CMS; RIN <a href="#">0938-AT48</a> )	This <a href="#">proposed rule</a> was published on February 21, 2018 and contains proposed regulations amending the definition of short term, limited duration insurance for purposes of its exclusion from the definition of individual health insurance coverage. For additional information, see Manatt's <a href="#">summary</a> .	Final Rule
Methods for Assuring Access to Care; Exceptions for High Managed Care Penetration and Rate Reduction Threshold (CMS; RIN <a href="#">0938-AT41</a> )	This <a href="#">proposed rule</a> was published on March 23, 2018 and would provide an exception to the requirements for documenting Medicaid fee-for-service access to care for states with high managed care penetration rates, set a threshold for rate reductions and restructuring that are not subject to analysis, and alter monitoring and public processes required for larger reductions. For additional detail, see	Final Rule

<sup>3</sup> A Regulatory Information Number (RIN) must be assigned to each new regulation requested by an agency and can be used to track regulations at every stage of the public rule-making process.

<sup>4</sup> "Next Stage" indicates the next rule-making step that will take place; for example, if a proposed rule has already been published, the next anticipated action will be shown as "Final Rule."

*The rules and timelines in this chart are based on the Unified Agenda and are neither all-encompassing nor an exact calendar of how rule-making will unfold.*

### COLOR-CODING LEGEND

Green = Medicare; Blue = Medicaid; Orange = Insurance and Marketplaces; Yellow = Mental Health/Substance Abuse; Purple = Privacy; Pink = 340B Drug Pricing Program; White = Several and/or Other Areas



Rule (Issuing Agency; Regulatory Information Number <sup>3</sup> )	Description	Next Stage <sup>4</sup>
Manatt's <a href="#">summary</a> .		
<b>Rules Originally Anticipated Prior to March 2018 That Have Not Yet Been Released</b>		
Durable Medical Equipment Fee Schedule, Adjustments to Resume the Transitional 50/50 Blended Rates to Provide Relief in Non-Competitive Bidding Areas (CMS; RIN <a href="#">0938-AT21</a> )	This interim final rule with comment period extends the end of the transition period for phasing in adjustments to the fee schedule amounts for certain durable medical equipment (DME) and enteral nutrition paid in areas not subject to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP); addresses the transition period for certain items furnished within specified time periods; makes technical amendments to existing regulations for DMEPOS items and services to exclude infusion drugs used with DME from the DMEPOS CBP; and requests information on issues related to adjustments to DMEPOS fee schedules, alternatives for ensuring budget neutrality of oxygen payment classes, and current rules under the DMEPOS CBP.	Interim Final Rule
Medicare Shared Savings Program; Accountable Care Organizations (CMS; RIN <a href="#">0938-AT45</a> )	This rule would make changes to the regulations for the Medicare Shared Savings Program for Accountable Care Organizations (ACOs), including facilitating transition to performance-based risk and other program flexibilities, additional waivers for patients and doctors, and policies for ensuring program integrity and sustainability. <i>Note: this proposed rule was received by OMB on August 24, 2017 and is pending review.</i>	Proposed Rule
Updates to Part D E-Prescribing Standards and Part D HIPAA Electronic Standards (CMS; RIN <a href="#">0938-AT52</a> )	This rule would propose certain e-prescribing standards for the Medicare Part D e-prescribing program and modifications to the National Council for Prescription Drug Programs (NCPDC) Telecommunication Standard Implementation Guide.	Proposed Rule
Covered Outpatient Drug; Finalization of Line Extension Definition and Delay in Including U.S. Territories in the Definitions of States and United State (CMS; RIN <a href="#">0938-AT09</a> )	This final rule responds to comments on the definition and identification of line extension drugs for which comments were requested in the Covered Outpatient Drug <a href="#">final rule with comment period</a> published on February 1, 2016. This rule also finalizes the <a href="#">interim final rule with comment period</a> published on November 15, 2016 that delayed the inclusion of the territories in the definitions of States and United States until April 1, 2020.	Final Rule
Medicaid Disproportionate Share Hospital (DSH) Hospital Allotment Reductions	This final rule would delineate a methodology to implement annual DSH allotment reductions beginning with FY 2018. However, the February -passed Bipartisan	Final Rule

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Rule (Issuing Agency; Regulatory Information Number <sup>3</sup> )	Description	Next Stage <sup>4</sup>
(CMS; RIN <a href="#">0938-AS63</a> )	Budget Act of 2018 postponed DSH reductions for two years; as a result, CMS likely will not finalize the rule in the near term. For additional detail regarding changes to the DSH reductions, see pages 2-3 of Manatt’s <a href="#">summary</a> of the Bipartisan Budget Act of 2018.	
Grandfathered Health Plans in the Individual and Small Group Markets (CMS; RIN <a href="#">0938-AT49</a> )	This proposed rule is intended to allow more flexibility in the availability of grandfathered health plans in the individual and small group markets, as well as carry out the instructions in the October 12, 2017 Executive Order to consider expanding the use of health reimbursement accounts (HRAs), health savings accounts (HSAs), and association health plans (AHPs).	Proposed Rule
Privacy Act Regulations (OS; RIN <a href="#">0991-AC05</a> )	45 CFR Part 5b details how HHS implements its Privacy Act program to comply with federal law as specified in the Privacy Act of 1974. The regulations contained within this proposed rule govern how HHS collects, maintains, uses, and disseminates personally identifiable information about individuals that is maintained in Systems of Records.	Proposed Rule
Privacy Act – Exempt Record System for Insider Threat Records (OS; RIN <a href="#">0991-AC10</a> )	This rule would exempt a new HHS law enforcement system of records from certain access and reporting requirements of the Privacy Act, to prevent interference with law enforcement investigations.	Proposed Rule
340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (HRSA; RIN <a href="#">0906-AB11</a> )	This proposed rule would delay the effective date of the <a href="#">final rule</a> that sets forth the calculation of the 340B ceiling price and application of civil monetary penalties to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. The final rule is required under the Affordable Care Act and amends section 340B of the Public Health Service Act to impose monetary sanctions (not to exceed \$5,000 per instance) on drug manufacturers who intentionally charge a covered entity a price above the ceiling price established under the procedures of the 340B Program and also define standards and methodology for the calculation of ceiling prices for purposes of the 340B Program.	Proposed Rule
340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation (HRSA; RIN <a href="#">0906-AB12</a> )	This statutorily required rule would define the standards and methodology for the calculation of ceiling prices within the 340B program and would impose civil monetary penalties on drug manufacturers who knowingly and intentionally charge	Proposed Rule

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Rule (Issuing Agency; Regulatory Information Number <sup>3</sup> )	Description	Next Stage <sup>4</sup>
	<p>a covered entity a price above the 340B ceiling price.  <i>Note: this proposed rule was received by OMB on October 6, 2017 and is pending review.</i></p>	
Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS; RIN <a href="#">0938-AT23</a> )	<p>This proposed rule would reform Medicare regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on healthcare providers and suppliers.  <i>Note: this proposed rule was received by OMB on February 1, 2018 and is pending review.</i></p>	Proposed Rule
<b>March 2018</b>		
Medicare Coverage of Infusion Therapy (CMS; RIN <a href="#">0938-AT39</a> )	This proposed rule would establish a Medicare benefit payment for home infusion therapy, as required by the 21st Century Cures Act.	Proposed Rule
Exchange Program Integrity (CMS; RIN <a href="#">0938-AT53</a> )	This rule proposes improvements to Exchange program integrity.	Proposed Rule
Mental Health and Substance Abuse Emergency Response Procedures (CMS; RIN <a href="#">0930-AA28</a> )	This proposed rule will remove redundant regulations applying to emergency response grants.	Proposed Rule
Substance Abuse and Mental Health Services Administration Mandatory Guidelines for Federal Workplace Drug Testing Programs (CMS; RIN <a href="#">0930-AA24</a> )	<p>These guidelines will establish the scientific and technical guidelines for the inclusion of oral fluid specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs and establishes standards for certification of laboratories engaged in drug testing for Federal agencies.  <i>Note: this rule has been submitted to and withdrawn from OMB twice (first, in August 2016 and again in January 2017).</i></p>	Final Rule
<b>April 2018</b>		
FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements (CMS; RIN <a href="#">0938-AT26</a> )	<p>These annual proposed rules will make payment updates for FY 2019 in the areas indicated in their title.  <i>Note: all four rules were received by OMB between March 14 and March 26, 2018 and are pending review.</i></p>	Proposed Rule
FY 2019 Inpatient Psychiatric Facilities Prospective Payment System – Rate Update		

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(CMS; RIN <a href="#">0938-AT32</a> )		
Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2019 (CMS; RIN <a href="#">0938-AT25</a> )		
FY 2019 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNFs) (CMS; RIN <a href="#">0938-AT24</a> )		
Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2019 Rates (CMS; RIN <a href="#">0938-AT27</a> )	This annual proposed rule would revise the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This proposed rule would implement changes arising from our continuing experience with these systems. <i>Note: this proposed rule was received by OMB on January 18, 2018 and is pending review; CMS indicated in the reg agenda its intent to finalize the rule in August 2018.</i>	Proposed Rule
Health Information Technology: Interoperability and Certification Enhancements (ONC; RIN <a href="#">0955-AA01</a> )	The proposed rule would update certain provisions of the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) and implement certain provisions of the 21st Century Cures Act ("Cures" Act).	Proposed Rule
<b>May 2018</b>		
Changes to the Requirements for Part D Prescribers (CMS; RIN <a href="#">0938-AS60</a> )	This rule finalizes an <a href="#">interim final rule</a> that revises requirements related to beneficiary access to covered Part D drugs.	Final Rule
HIPAA Privacy Rule: Presumption of Good Faith of HealthCare Providers (CMS; RIN <a href="#">0945-AA09</a> )	The proposed rule would modify the <a href="#">HIPAA Privacy Rule</a> to clarify that healthcare providers are presumed to be acting in the individual's best interest when they share information with an incapacitated patient's family members unless there is evidence that a provider was acted in bad faith.	Proposed Rule
<b>June 2018</b>		
CY 2019 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates	These annual proposed rules will make payment and policy updates for CY 2019 in the areas indicated in their respective titles.	Proposed Rule

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(CMS; RIN <a href="#">0938-AT30</a> )		
CY 2019 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS; RIN <a href="#">0938-AT31</a> )		
CY 2019 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System (CMS; RIN <a href="#">0938-AT28</a> )		
CY 2019 Home Health Prospective Payment System Rate Update (CMS; RIN <a href="#">0938-AT29</a> )		
Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid, and Other Provisions Related to Eligibility and Enrollment for Medicaid and CHIP (CMS; RIN <a href="#">0938-AS55</a> )	This final rule implements provisions of the Medicaid statute pertaining to Medicaid eligibility and appeals. This rule continues the agency's efforts to provide guidance to assist States in implementing Medicaid and CHIP eligibility, appeals, and enrollment changes required by the Affordable Care Act.	Final Rule
Medicaid, Revisions to State Medicaid Fraud Control Unit Rules (CMS; RIN <a href="#">0936-AA07</a> )	This final rule would amend the regulation governing State Medicaid Fraud Control Units (MFCUs). It would: (1) make it easier for MFCUs to understand their authorities and responsibilities under the grant program; (2) clarify the flexibilities MFCUs have to operate their programs; and (3) reduce administrative burden by eliminating duplicative and unnecessary reporting requirements.	Final Rule
Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS; RIN <a href="#">0938-AT36</a> )	This proposed rule would reform the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs, that CMS has identified as unnecessary, obsolete, or excessively burdensome on facilities.	Proposed Rule
<b>July 2018</b>		
Inadmissibility and Deportability on Public Charge Grounds (DHS, United States Citizenship and Immigration)	This DHS proposed rule would propose new rules regarding how the agency will determine whether an immigrant should be denied entry or denied adjustment of status to legal permanent resident ("LPR") on the grounds that the immigrant is	Proposed Rule

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Services; RIN <a href="#">1615-AA22</a> )	likely to become a “public charge” under Section 212(a)(4) of the Immigration and Nationality Act. Currently, public charge is not defined in law but by longstanding practice, using Medicaid, CHIP, and other subsidized health insurance (other than long-term care services) does not contribute to a determination that someone may become a public charge; the proposed rule is expected to change that.	
Rural Physician Training Grant Program, Definition of "Underserved Rural Community" (HRSA; RIN <a href="#">0906-AB17</a> )	This rule will remove 42 CFR Part 5a defining "underserved rural communities" for the Rural Physician Training Grant Program. This regulation is no longer relevant as the corresponding grant program was not funded.	Final Rule
<b>August 2018</b>		
Medicaid and CHIP Managed Care (CMS; RIN <a href="#">0938-AT40</a> )	This proposed rule would make changes to <a href="#">Medicaid and CHIP managed care rules</a> , finalized in May 2016. Manatt’s summary of the final rule is available <a href="#">here</a> .	Proposed Rule
Adoption of a Standard for a Unique Health Plan Identifier Repeal (CMS; RIN <a href="#">0938-AT42</a> )	This proposed rule would repeal the Health Plan Identifier regulations of the September 2012 administrative simplification <a href="#">final rule</a> .	Proposed Rule
Administrative Simplification; Health Care Claims Attachments (CMS; RIN <a href="#">0938-AT38</a> )	This proposed rule would adopt standards and operating rules for attachments based on statutory requirements introduced in the Health Insurance Portability and Accountability Act (HIPAA) and reinforced in the Affordable Care Act. In general, it would apply to circumstances in which a provider attaches clinical information to a transaction that it is being transmitted to a health plan.	Proposed Rule
<b>September 2018</b>		
Part A Premiums for CY 2019 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS; RIN <a href="#">0938-AT34</a> )	This annual notice announces the premiums for CY 2019 under Medicare's Hospital Insurance program (Medicare Part A) for individuals noted in the title.	Final Rule
CY 2019 Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible (CMS; RIN <a href="#">0938-AT35</a> )	This annual notice announces 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.	Final Rule
CY 2020 Notice of Benefit and Payment Parameters	This annual proposed rule would set forth payment parameters and provisions	Proposed

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Rule (Issuing Agency; Regulatory Information Number <sup>3</sup> )	Description	Next Stage <sup>4</sup>
(CMS; RIN <a href="#">0938-AT37</a> )	related to the risk adjustment programs; cost-sharing parameters and cost-sharing reductions; and user fees for issuers offering plans on Federally-facilitated Exchanges and State-based Exchanges using the Federal platform. It would also provide additional standards for several other Affordable Care Act programs.	Rule
HIPAA Privacy Rule: Changing Requirement to Obtain Acknowledgment of Receipt of the Notice of Privacy Practices (OCR; <a href="#">0945-AA08</a> )	The proposed rule would change the requirement that health care providers make a good faith effort to obtain from individuals a written acknowledgment of receipt of the provider's notice of privacy practices, and if not obtained, to document its good faith efforts and the reason the acknowledgment was not obtained.	Proposed Rule
National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table (HRSA; RIN <a href="#">0906-AB14</a> )	This statutorily required regulation revises the Vaccine Injury Table to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women. This category of vaccines must be added to the Table for such injury claims to be eligible for adjudication through the Vaccine Injury Compensation Program.	Proposed Rule
<b>October 2018</b>		
Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2019 (CMS; RIN <a href="#">0938-AT33</a> )	This annual notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2019 under Medicare Part A. The Medicare statute specifies the formula used to determine these amounts.	Final Rule
Certification of Opioid Treatment Programs (SAMHSA; RIN <a href="#">0930-AA27</a> )	This proposed rule would remove requirements for transitional certification and add new language permitting private, for-profit entities to serve as opioid treatment programs.	Proposed Rule
Medical Devices; Amendments to Medical Software Regulations (FDA; RIN <a href="#">0910-AH67</a> )	The 21st Century Cures Act amended the definition of device under the Federal Food, Drug, and Cosmetic Act to exclude certain medical software functions from the definition of device and therefore FDA's jurisdiction. FDA will revise its regulations to be consistent with this statutory change.	Final Rule
Medical Devices; Medical Device Classification Procedures (FDA; <a href="#">0910-AH75</a> )	The final rule implements Section 608 of the Food and Drug Administration Safety and Innovation Act (FDASIA) requiring FDA to use administrative orders to announce or to change the classification of devices, instead of taking action by regulation.	Final Rule

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	Where feasible, FDA is also amending its regulations to authorize the use of administrative orders in other FDA reclassification proceedings and to update and to clarify its Part 860 regulations. FDA expects this rulemaking to be in part a deregulatory action under Executive Order 13771 because two FDA forms (FDA 3427 and FDA 3429) would be eliminated and our existing procedures would be streamlined by shifting to the use of administrative orders instead of regulations to propose and to finalize reclassification actions in response to petitions and at FDA initiative.	
<b>December 2018</b>		
Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program Methodology in Determining Single Payment Amounts (CMS; RIN <a href="#">0938-AT43</a> )	This rule amends the methodology for establishing single payment amounts for items furnished under the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Competitive Bidding Program.	Proposed Rule

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