

PCMA Regulatory Affairs Tracking

Last revised July 29, 2021

The table below provides the status of high-priority regulations and guidance documents that PCMA is following. It is not intended to be a comprehensive list of PBM-related regulatory activity. Hyperlinks go to the official documents or OMB page for rules under review. The table is generally in priority order. We will keep documents on this table until they are implemented, or new guidance or regulations are published that replace them. We will highlight in yellow any open comment periods. See the key at the bottom for other shading.

	Document Name & Agency or Entity	Description	PCMA Sub-Cmte. or WG	Comments Filed	Activity
1	Rebate Rule (RIN 0936-AA08) Agency: HHS/OIG	This rule removes existing safe harbors concerning rebates paid to PBMs in the Medicare Part D program and replaces it with two new safe harbors concerning up front discounts and fixed administrative fees.	Federal Drug Pricing, Part D, Legal	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Proposed rule <input checked="" type="checkbox"/> Executive Order <input checked="" type="checkbox"/> Final rule <input checked="" type="checkbox"/> Final rule; delay of effective date; correction <input checked="" type="checkbox"/> Final rule; notification of court-ordered delay of effective date
2	MCIT (CMS-3372) Agency: CMS	This proposed rule modifies the Medicare coverage process to streamline coverage of breakthrough technologies that have the potential to improve patient health outcomes and quality of care.	Federal Drug Pricing	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Proposed rule <input checked="" type="checkbox"/> Final rule <input checked="" type="checkbox"/> Interim final rule; delayed effective date; request for comments <input checked="" type="checkbox"/> Final rule
3	SUNSET (Docket No. HHS-OS-2020-0012) Agency: HHS	A rule requiring the Department to assess its regulations every 10 years and retire those that are no longer or relevant or needed.	Federal Drug Pricing	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Proposed rule <input checked="" type="checkbox"/> Final rule <input checked="" type="checkbox"/> Final rule; delay of effective date and correction
4	Good Guidance Practices (RIN 0991-AC17) Agency: HHS	This proposed rule outlines the Department's process through which it will review whether existing guidance should be subject to notice-and-comment rulemaking.	Federal Drug Pricing	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Proposed rule <input checked="" type="checkbox"/> Executive Order <input checked="" type="checkbox"/> Final rule <input checked="" type="checkbox"/> OGC Advisory Opinion
5	Nondiscrimination in Health Programs or Activities (RIN 0945-AA11) Agency: OCR	HHS proposes to revise its Section 1557 regulations to limit notice and tagline requirements.	1557	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Proposed rule <input checked="" type="checkbox"/> Final rule <input checked="" type="checkbox"/> Court proceedings ongoing

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6	ICR: PBM Transparency (CMS-10725) Agency: CMS	Implements SSA Section 1150A, specific to the QHP market, would require PBMs to disclose in the aggregate specific data.	Health Reform	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Notice <input checked="" type="checkbox"/> Notice (item 3)
7	2022 NBPP (CMS-9914) Agency: HHS/CMS	This rule updates annual benefit parameters for Qualified Health Plans sold in the exchanges and makes other revisions to ACA-regulated plans.	Health Reform	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Proposed rule <input checked="" type="checkbox"/> Final rule 1 <input checked="" type="checkbox"/> Final rule 2
8	2022 NBPP (2) (CMS-9906) Agency: HHS/CMS	This rule updates annual benefit parameters for Qualified Health Plans sold in the exchanges and makes other revisions to ACA-regulated plans.	Health Reform		<input checked="" type="checkbox"/> Proposed rule
9	ICR: Transparency in Coverage (CMS-10715) Agency: CMS	This document collection is provided to solicit public input on which data elements CMS will collect to bring issuers to compliance to the Transparency in Coverage final rule.	Federal Drug Pricing, Health Reform	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Notice
10	HIPAA Modifications (HHS-OCR-0945-AA00) Agency: HHS/OCR	This rule would modify provisions of the HIPAA Rules that may impede the transformation of the health care system to value-based health care, by limiting or discouraging care coordination and case management.	Privacy	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> RFI <input checked="" type="checkbox"/> Proposed rule
11	Info Blocking Extension (HHS-ONC-2020-0013) Agency: HHS/ONC	This rule will extend select compliance dates and timeframes of the May 2020 ONC Cures Final Rule .	Privacy	<input type="checkbox"/>	<input checked="" type="checkbox"/> Final rule <input checked="" type="checkbox"/> Interim final rule with comment period
12	Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements: (CMS-2482) Agency: HHS/CMS	Proposes minimum standards in DUR programs, increase oversight of opioid prescriptions in Medicaid, and modify rebate program regulations to support VBP arrangements.	Medicaid Federal Regulatory Drug Pricing Health Reform	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Proposed rule <input checked="" type="checkbox"/> Final rule <input checked="" type="checkbox"/> Proposed rule

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13	Requirements Related to Prescription Drug Reporting (CMS-9905-NC) Agency: DOL-EBSA	Proposes the development of rulemaking that would implement the prescription drug reporting requirements that apply to group health plans and health insurance issuers offering coverage in the group and individual markets under section 204 of title II of Division BB of the Consolidated Appropriations Act.	Health Reform	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> RFI
14	Requirements Related to Surprise Billing; Part I (CMS-9909-IFC) Agency: HHS/CMS	This interim final rule (IFR) with comment would implement certain protections against surprise medical bills under the No Surprises Act.	Health Reform	<input type="checkbox"/>	<input checked="" type="checkbox"/> Interim final rules with request for comments
15	Rescission of the Final Rule “Implementation of Executive Order on Access to Affordable Life-Saving Medications” (RIN: 0906-AB25) Agency: HHS-HRSA	This final rule will provide access to life-saving medications by low-income individuals who do not have access to affordable insulin and injectable epinephrine due to either lack of insurance or high cost sharing requirements. Based on comments in response to both the proposed rule published at 85 FR 60748 (September 28, 2020) and the proposed rule published at 86 FR 13872 (March 11, 2021), which indicated concerns that administrative costs and related burdens required by health centers to comply with the rule and the loss of 340B savings that would result from the rule taking effect would reduce resources available to support critical services for patients, HHS is considering a proposed rulemaking to rescind the final rule of December 23, 2020.	340B	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Proposed rule

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16	<p>Medicare Program; CY 2022 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-payment Medical Review Requirements (CMS-1751-P) Agency: CMS/HHS</p>	<p>This major proposed rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare provider enrollment policies; requirements for prepayment and postpayment medical review activities; requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan, or a Medicare Advantage Prescription Drug (MA-PD) plan;</p>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> Propose rule
17	<p>MFN Model (CMS-5528) Agency: HHS/CMS</p>	<p>This interim final rule with comment period (IFC) implements the Most Favored Nation (MFN) Model, a new Medicare payment model under section 1115A of the Social Security Act (the Act). The MFN Model tests whether more closely aligning payment for Medicare Part B drugs and biologicals (hereafter, referred to as drugs) with international prices and removing incentives to use higher-cost drugs can control unsustainable growth in Medicare Part B spending without adversely affecting quality of care for beneficiaries.</p>			<input checked="" type="checkbox"/> Interim final rule with comment period pending review by OMB

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