



Regulatory Update: Congressional Review Act and the Biden Administration Executive Actions

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Executive Summary

This document provides a brief overview of two avenues of regulatory change that are impacting the rulemaking efforts of the outgoing Trump Administration as well as those of the incoming Biden Administration:

- (1) The Congressional Review Act**
- (2) Use of Presidential Executive Authority**

Each section includes relevant background on the approaches and the rules they potentially impact, and other relevant analysis.

The Congressional Review Act (CRA) has a strict timeline and process for consideration of recent regulations and members interested in using its authorities may face challenges doing so given competing priorities such as COVID-19 relief legislation, the Senate’s impeachment trial, and Senate confirmation of President Biden’s appointees. However, the Biden Administration’s early regulatory moves may prove an alternate pathway for revisions to regulatory actions taken at the end of the Trump Administration.

Congressional Review Act

Every four to eight years, depending on when there is a transition of power in the Executive Branch, Congress may consider using a legislative strategy enabled by the Congressional Review Act (CRA) to undo last-minute regulations from the previous administration. While historic use of the CRA since its enactment in 1996 has been rare, more recent Executive branch reliance on regulatory pathways to advance policy interests has spurred interest in the CRA’s possibilities. Between 1996 and 2016, the Bush Administration used the CRA once – to revoke a Clinton-era regulation to combat stress injuries in the workplace. However, when President Trump came into office in 2017, Congress saw the opportunity to reverse some Obama-era policy and opted to use the CRA 15 times to overturn regulations released in the last days of that administration. With the Democrats holding a majority in Congress, the Biden Administration may look to the CRA as an opportunity to overturn last-minute Trump-era regulations that do not align with its policy agenda.

What Kind of Rules Apply for CRA Review?

CRA uses a broad definition of *rule* found in the Administrative Procedures Act Section 551:

“The whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency.”

However, there are three statutorily mandated exceptions to the definition of “rule” under the CRA:

- Any rule that approves or prescribes for the future rates, wages, prices, services, or allowances, corporate or financial structures, reorganizations, mergers, or acquisitions, or account practices or disclosures related to what was previously mentioned;
- Any rule relating to agency management or personnel; or
- Any rule of agency organization, procedure, or practice that does not substantially affect the rights or obligations of non-agency parties

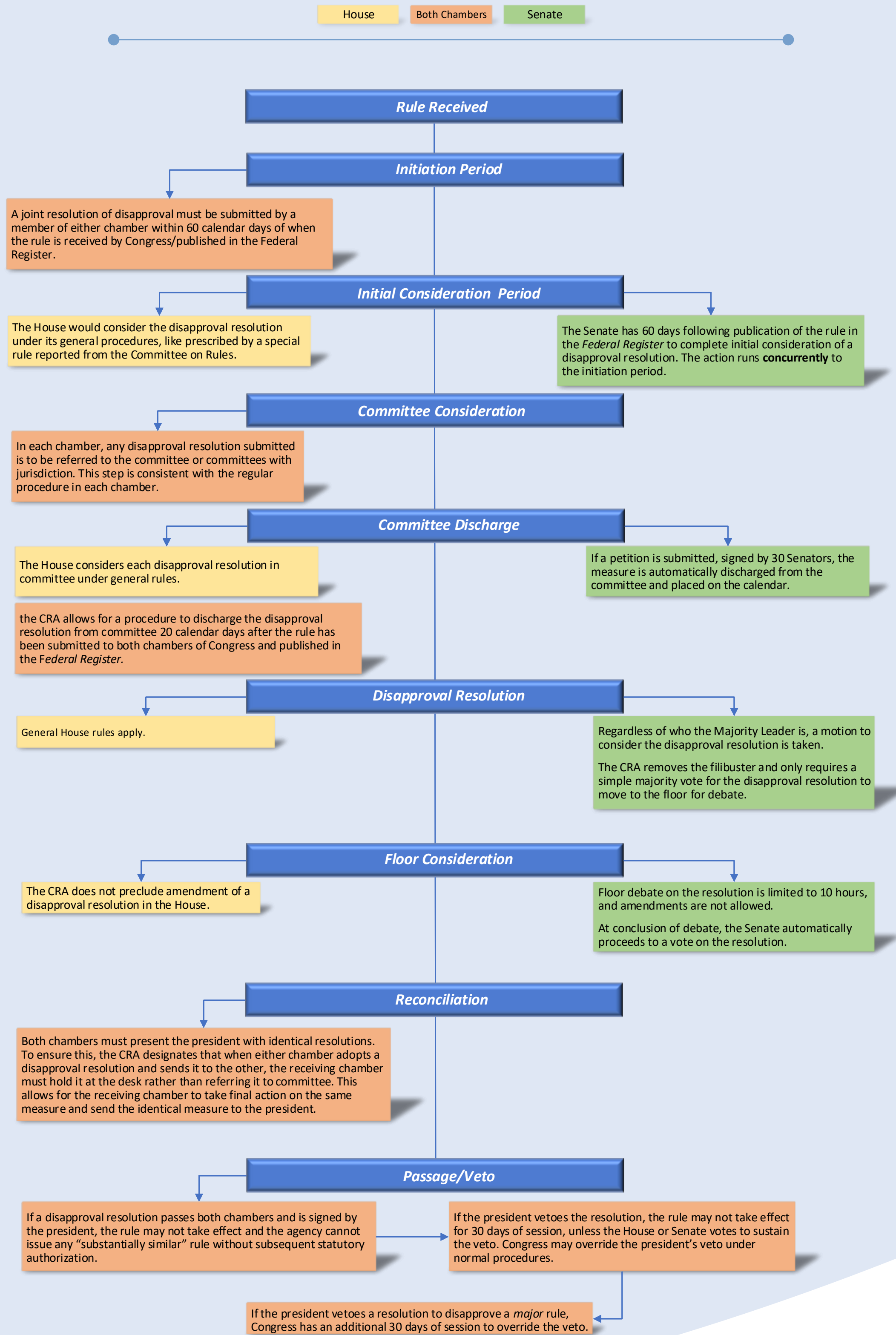
Additionally, certain agency action taken outside of the notice-and-comment rulemaking process may be considered a rule for the purposes of the CRA. The action must meet three requirements set out under the Administrative Procedures Act (APA):

1. The action is of general or particular applicability,
2. The action has future effect, and
3. The action is designed to implement, interpret, or prescribe law or policy

Agency Action	Rule/Not a Rule Under CRA?
Final Rule	Rule Under CRA
Proposed Rule	Not a Rule Under CRA
Interim Final Rule	Rule Under CRA
Agency Guidance or Other Agency Action Outside of Notice-and-Comment Rule Making	Depends (see explanation above)

In **Figure 1** of the Appendix, a list of pertinent rules that are subject to the CRA are listed.

CRA Congressional Procedure



Biden Administration Executive Action

The Biden Administration is pursuing executive action related to Trump Administration administrative actions and approach to the regulatory process. Notably, President Biden issued a [memorandum](#) which directs executive departments and agencies to freeze certain rules that are not yet finalized or rules that were recently finalized, but not effective. Second, President Biden issued an executive order revoking Trump Administration executive orders related to the regulatory process and issued a memorandum to the Director of the Office of Management and Budget to set a framework to “modernize the regulatory process”, a move that signals the administration plans to consider its own approach to the use of regulatory action in advancing its policy agenda. Details on those approaches are below:

Regulatory Freeze and Review

President Biden’s Chief of Staff Ronald Klain issued a [memorandum](#) for the heads of executive departments and agencies on freezing the implementation of rules pending review by President Biden’s appointees or designees.

The memorandum applies to both rules that were sent to the Office of the Federal Register (OFR) and those that have already recently been published in the Federal Register. Specifically, if a rule was sent to the OFR but not yet published, the departments and agencies are directed to withdraw the rule from OFR for review and approval by the department or agency head and the withdrawal must be conducted consistent with OFR procedures.

For rules that were already published in the Federal Register, or rules that were issued in any manner, but have not yet taken effect, departments and agencies must consider postponing the rules’ effective dates for 60 days from January 20, 2021. Klain explained that this is to review any questions of fact, law, and policy that the rules may raise. The memorandum also suggests reopening a 30-day comment period for rules that are postponed 60 days to allow for interested parties to comment on issues of fact, law, and policy raised by the rules and then consider pending petitions for reconsideration involving those rules.

In **Figure 2** of the Appendix, we list out pertinent rules that are subject to the Biden Administration regulatory freeze.

Executive Order Revoking Trump-Era Executive Orders

President Biden Issued an [Executive Order](#) revoking several Trump-era orders on the regulatory process, including:

- **Executive Order 13711 “Reducing Regulation and Controlling Regulatory Costs”**: Created the 2 for 1 rule requiring agencies to repeal two regulations for every new one regulation they issued.
- **Executive Order 13777 “Enforcing the Regulatory Reform Agenda”**: Required each agency to designate a Regulatory Reform Officer and establish a Regulatory Reform Task Force to oversee regulatory reform initiatives and recommend regulations to be repealed.
- **Executive Order 13875 “Evaluative and Improving the Utility of Federal Advisory Committees”**: Required each executive department and agency to review, reduce, and limit the number of federal advisory committees, terminating at least one-third of these committees. Capped government-wide total advisory committees at 350.

- **Executive Order 13891 “Promoting the Rule of Law Through Improved Agency Guidance Documents”**: Required agencies to treat guidance documents as “non-binding both in law and in practice,” maintain an online database of all guidance documents, rescind outdated guidance documents, and establish procedures for issuing new guidance documents, including a clear statement of their non-binding effect, opportunities for the public to petition for withdrawal or modification of documents, and a 30-day period of notice and comment for certain significant guidance documents.
- **Executive Order 13892 “Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication”**: Limited agencies’ ability to enforce standards of conduct that were not publicly stated or issued in formal rulemakings. It also provided that agencies issuing notices of noncompliance provide an affected party the opportunity to be heard, encouraged “self-reporting of regulatory violations in exchange for reductions or waivers of civil penalties,” and imposed requirements governing administrative inspections of certain statutory obligations.
- **Executive Order 13893 “Increasing Government Accountability for Administrative Actions by Reinventing administrative PAYGO”**: Sought to ensure compliance with the “pay-as-you-go” (PAYGO) requirement first adopted in 2005. PAYGO mandates that agencies propose ways to reduce mandatory spending whenever they undertake a discretionary action that would increase mandatory spending.

In sum, with the revocation of these Trump Administration executive orders the Biden Administration aims to give more flexibility to the executive departments and agencies to rely on a range of regulatory tools to advance its policy agenda and to develop its own approach to oversight and improvements in the regulatory process.

Regulatory Modernization Memorandum

The Biden Administration issued a [memorandum](#) intended to modernize regulatory review. This memorandum instructs the Director of the Office of Management and Budget (OMB) to make recommendations for improving and modernizing review of regulations, a process that would introduce new policy-related considerations to the regulatory process. Specifically, the memorandum asks OMB to provide “concrete suggestions on how the regulatory review process can promote public health and safety, economic growth, social welfare, racial justice, environmental stewardship, human dignity, equity, and the interests of future generations.

Appendix



Figure 1: Rules Subject to Congressional Review Act

Publication Date	Agency	Rule	Link
08/31/2020	CMS	Medicare Program; FY 2016 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements; Correcting Amendment	https://www.federalregister.gov/documents/2020/08/31/2020-18905/medicare-program-fy-2016-hospice-wage-index-and-payment-rate-update-and-hospice-quality-reporting
09/2/2020	CMS	Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to COVID-19 Public Health Emergency	https://www.federalregister.gov/documents/2020/09/02/2020-19150/medicare-and-medicaid-programs-clinical-laboratory-improvement-amendments-clia-and-patient
09/08/2020	CMS	Medicare and Medicaid Programs; Adjustment of Civil Monetary Penalties for Inflation; Continuation of Effectiveness Extension of Timeline for Publication of Final Rule	https://www.federalregister.gov/documents/2020/09/08/2020-19657/medicare-and-medicaid-programs-adjustment-of-civil-monetary-penalties-for-inflation-continuation-of
09/17/2020	CMS	Medicare Program; Alternative Payment Model (APM) Incentive Payment Advisory for Clinicians- Request for Current Billing Information for Qualifying APM Participants	https://www.federalregister.gov/documents/2020/09/17/2020-20488/medicare-program-alternative-payment-model-apm-incentive-payment-advisory-for-clinicians-request-for
09/18/2020	CMS	Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment System and Final Policy Changes and Fiscal year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals	https://www.federalregister.gov/documents/2020/09/18/2020-19637/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the
09/29/2020	CMS	Medicare Program; Specialty Care Models to Improve Quality of care and Reduce Expenditures	https://www.federalregister.gov/documents/2020/09/29/2020-20907/medicare-program-specialty-care-models-to-improve-quality-of-care-and-reduce-expenditures
10/01/2020	FDA	Importation of Prescription Drugs	https://www.federalregister.gov/documents/2020/10/01/2020-21522/importation-of-prescription-drugs



11/03/2020	CMS	Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update, Home Health Quality Reporting Program Requirements, and Home Infusion Therapy services and Supplier Enrollment Requirements; and Home Health Value-Based Purchasing Model Data Submission Requirements	https://www.federalregister.gov/documents/2020/11/04/2020-24146/medicare-and-medicaid-programs-cy-2021-home-health-prospective-payment-system-rate-update-home
11/09/2020	CMS	Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program	https://www.federalregister.gov/documents/2020/11/09/2020-24485/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis
11/13/2020	CMS	Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care	https://www.federalregister.gov/documents/2020/11/13/2020-24758/medicaid-program-medicare-and-childrens-health-insurance-program-chip-managed-care
11/27/2020	CMS	Most Favored Nation (MFN) Model	https://www.federalregister.gov/documents/2020/11/27/2020-26037/most-favored-nation-mfn-model
12/01/2020	CMS	Amendments to the HHS-Operated Risk Adjustment Data Validation (HHS-RADV) Under the Patient Protection and Affordable Care Act's HHS-Operated Risk Adjustment Program	https://www.federalregister.gov/documents/2020/12/01/2020-26338/amendments-to-the-hhs-operated-risk-adjustment-data-validation-hhs-radv-under-the-patient-protection
12/02/2020	OIG	Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements	https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the
12/02/2020	CMS	Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations	https://www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations
12/02/2020	CMS	Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations	https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicare-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to



12/07/2020	CMS	Medicare Program; Alternative Payment Model (APM) Incentive Payment Advisory for Clinicians- Request for Current Billing Information for Qualifying APM Participants-Update	https://www.federalregister.gov/documents/2020/12/07/2020-26776/medicare-program-alternative-payment-model-apm-incentive-payment-advisory-for-clinicians-request-for
12/28/2020	CMS	Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID-19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID-19	https://www.federalregister.gov/documents/2020/12/28/2020-26815/medicare-program-cy-2021-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part
12/29/2020	CMS	Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-	https://www.federalregister.gov/documents/2020/12/29/2020-26819/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment



		Owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID-19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19)	
12/31/2020		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	https://www.federalregister.gov/documents/2020/12/31/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and
12/31/2020	CMS	Medicare Program; Secure Electronic Prior Authorization for Medicare Part D	https://www.federalregister.gov/documents/2020/12/31/2020-28877/medicare-program-secure-electronic-prior-authorization-for-medicare-part-d
01/14/2021	CMS	Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of Reasonable and Necessary	https://www.federalregister.gov/documents/2021/01/14/2021-00707/medicare-program-medicare-coverage-of-innovative-technology-mcit-and-definition-of-reasonable-and
01/19/2021	CMS	Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly	https://www.federalregister.gov/documents/2021/01/19/2021-00538/medicare-and-medicaid-programs-contract-year-2022-policy-and-technical-changes-to-the-medicare

Figure 2: Regulatory Action Subject to Biden Regulatory Freeze

Publishing Date	Agency	Regulatory Action	Title of Regulatory Action	Effective Date	Link
01/19/2021	CMS	Request for Applications	Part D Payment Modernization Model Request for Applications for Calendar Year (CY) 2022	01/01/2022	https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa
12/31/2020	CMS	Final Rule	Secure Electronic Prior Authorization for Medicare Part D	02/01/2021	https://www.govinfo.gov/content/pkg/FR-2020-12-31/pdf/2020-28877.pdf
01/14/2021	CMS	Final Rule	Medicare Coverage of Innovative Technology (MCIT) and Definition	03/15/2021	https://www.govinfo.gov/content/pkg/FR-2021-01-14/pdf/2021-00707.pdf
12/23/2020	HRSA	Final Rule	Implementation of Executive Order on Access to Affordable Life-saving Medications	01/22/2021	https://www.govinfo.gov/content/pkg/FR-2020-12-23/pdf/2020-28483.pdf
12/31/2020	CMS	Final Rule	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	These regulations are effective 03/01/2021, except for amendatory instructions 7, 10a, 14, 16, and 17, which have effective 01/01/2022, and amendatory instructions 9 and 11, which are effective 01/01/2023	https://www.govinfo.gov/content/pkg/FR-2020-12-31/pdf/2020-28567.pdf
12/18/2020	CMS	Proposed Rule	Reducing Provider and patient Burden by Improving Prior Authorization Process, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care	N/A – Comment deadline was 01/04/2021	https://www.govinfo.gov/content/pkg/FR-2020-12-18/pdf/2020-27593.pdf



			Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on Federally-facilitated Exchanges; Health Information Technology Standards and Implementation specifications		
12/17/2020	HHS	Final Rule	Equal Protection of Faith-Based Organizations in Federal Agencies' Programs and Activities	01/19/2021	https://www.govinfo.gov/content/pkg/FR-2020-12-17/pdf/2020-27084.pdf
01/21/2021	HHS OCR	Notice of Proposed Rulemaking	Proposed Modifications to HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement	Comments due before March 22, 2021	https://www.govinfo.gov/content/pkg/FR-2021-01-21/pdf/2020-27157.pdf
01/15/2021	CMS	Rate Announcement	CY 2022 MA Capitation Rates and Part C and Part D Payment Policies	n/a	https://www.cms.gov/files/document/2022-announcement.pdf
12/28/2020	CMS	Final Rule & Interim Final Rule	CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid	01/01/2021	https://www.govinfo.gov/content/pkg/FR-2020-12-28/pdf/2020-26815.pdf

			<p>Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment of Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Service Interim Final Rule (IFR) Policy; Coding and Payment for Personal Protective Equipment (PPE) IFR; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID-19; and Finalization of Certain Provisions from March 31st, May 8th, and September 2nd IFR in Response to the PHE for COVID-19.</p>		
12/01/2020	CMS	Final Rule	<p>Amendments to the HHS-operated Risk Adjustment Data Validation (HHS-RADV) under the Patient Protection and Affordable Care Act's HHS-operated risk Adjustment Program</p>	12/31/2020	<p>https://www.govinfo.gov/content/pkg/FR-2020-12-01/pdf/2020-26338.pdf</p>



12/29/2020	CMS	Final Rule with Comment Period & IFR with Comment Period	Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule; Laboratory Date of service Policy Overall Hospital Quality Star Rating Methodology; Physician-Owned Hospitals; notice of Closures of Two Teaching Hospitals and Opportunity to Apply for Available slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID-19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19)	01/01/2021, except for amendatory instructions 21 and 23 and 25 through 31, which are effective 12/04/2021	https://www.govinfo.gov/content/pkg/FR-2020-12-29/pdf/2020-26819.pdf
12/15/2021	HHS/Treasury/Labor	Final Rule	Grandfathered Group Health Plans and Grandfathered Group Health Insurance Coverage	01/14/2021	https://www.govinfo.gov/content/pkg/FR-2020-12-15/pdf/2020-27498.pdf



12/04/2020	CMS	Proposed Rule	HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations	Comments due 12/30/2020	https://www.govinfo.gov/content/pkg/FR-2020-12-04/pdf/2020-26534.pdf
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