

The Congressional Review Act: Recent Regulations Eligible for Consideration

Included below is a list of every rule released under the Department of Health and Human Services (HHS), broken down by the Centers for Medicare and Medicaid Services (CMS) and non-CMS actions during the relevant 60-legislative day lookback period. Democratic lawmakers and their staff may review this universe of HHS rules with an eye toward whether the rule advances or impedes the health policy agenda for the party and President-elect Biden.

In reverse chronological order

Non-CMS Health and Human Services Regulations

1. **Implementation of Executive Order on Access to Affordable Life-Saving Medications**
 - a. **Rule.** [Link](#)
 - b. **Policy:** This final rule implements a Trump administration Executive Order requiring HRSA-funded community health centers that also participate in the 340B Drug Pricing Program (340B Program) to establish practices to provide access to insulin and injectable epinephrine to low-income health center patients at the price the health center purchased these two drugs through the 340B Program.
 - c. **Publication:** 12/23/2020
2. **Equal Participation of Faith-Based Organizations in the Federal Agencies' Programs and Activities**
 - a. **Rule.** [Link](#)
 - b. **Policy:** This final rule implements a 2018 Trump administration Executive Order and provides clarity about the rights and obligations of faith-based organizations participating in the Agencies' Federal financial assistance programs and activities. This rulemaking is intended to ensure that the Agencies' Federal financial assistance programs and activities are implemented in a manner consistent with the requirements of Federal law, including the First Amendment to the Constitution and the Religious Freedom Restoration Act.
 - c. **Publication:** 12/17/2020
3. **Confidentiality of Substance Use Disorder Patient Records**
 - a. **Rule.** [Link](#)
 - b. **Policy:** This final rule amends the Substance Abuse and Mental Health Services Administration's (SAMHSA) regulation governing the Confidentiality of Substance Use Disorder Patient Records (42 CFR Part 2), to clarify one of the conditions under which a court may authorize disclosure of confidential communications made by a patient to a Part 2 program as defined in this regulation.
 - c. **Publication:** 12/14/2020
4. **340B Drug Pricing Program; Administrative Dispute Resolution Regulation**
 - a. **Rule.** [Link](#)
 - b. **Policy:** This final rule finalizes a proposed rule issued during the Obama Administration and sets forth the requirements and procedures for the 340B Program's administrative dispute resolution (ADR) process establishing ADR process for two types of disputes: claims by covered entities that may have been overcharged for covered outpatient

drugs purchased from manufacturers; and claims by manufacturers after a manufacturer has conducted an audit of a covered entity.

- c. **Publication:** 12/14/2020
5. **Department of Health and Human Services Good Guidance Practices**
 - a. **Rule.** [Link](#)
 - b. **Policy:** This final rule implements a Trump administration Executive Order and requires all guidance documents issued after the rule's effective date to self-identify as "guidance," carry a disclaimer indicating that the contents of the document generally cannot impose binding new obligations that exceed requirements set forth in statutes or regulations, and include certain information designed to ensure transparency and uniformity across guidance documents, including citations to any statutory and/or regulatory provisions that the guidance document is interpreting or applying. Guidance documents that qualify as "significant guidance documents" can only be issued after a public notice-and-comment period.
 - c. **Publication:** 12/07/2020
6. **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**
 - a. **Rule.** [Link](#)
 - b. **Policy:** This final rule amends the safe harbors to the federal anti-kickback statute by adding new safe harbors and modifying existing safe harbors that protect certain payment practices and business arrangements from sanctions under the anti-kickback statute. The rule finalizes significant new flexibilities for value-based arrangements and modernization of the safe harbor regulations to account for the ongoing evolution of the health care delivery system.
 - c. **Publication:** 12/02/2020
7. **Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees**
 - a. **Rule.** [Link](#)
 - b. **Policy:** This final rule implements a Trump administration Executive Order and clarifies and amends the discount safe harbor under the federal Anti-kickback statute (AKS) such that rebates paid from drug manufacturers to Medicare Part D prescription drug plan sponsors or their pharmacy benefit managers (PBMs) are not protected from liability under the discount safe harbor. The rule also adds two new safe harbors.
 - c. **Publication:** 11/30/2020
8. **Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency**
 - a. **Interim Final Rule.** [Link](#)
 - b. **Policy:** This interim final rule extends certain compliance dates and timeframes adopted in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule). Actors subject to the information blocking provisions must come into compliance by April 5, 2021; Conditions of Certification requirements are enforceable December 31, 2023.
 - c. **Publication:** 11/04/2020
9. **Importation of Prescription Drugs**

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- a. **Rule.** [Link](#)
 - b. **Policy:** The final rule will look to implement a provision of the Food, Drug, and Cosmetic Act to allow importation of certain prescription drugs from Canada. Under this final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the Food and Drug Administration (FDA, the Agency, or we) for review and authorization. An importation program may be cosponsored by a State, Indian Tribe, pharmacist or wholesaler.
 - c. **Publication:** 10/01/2020
10. **Removing Financial Disincentives to Living Organ Donation**
- a. **Rule.** [Link](#)
 - b. **Policy:** This final rule implements a Trump administration Executive Order and amends the regulations implementing the National Organ Transplant Act of 1984, as amended (NOTA), to remove financial barriers to organ donation by expanding the scope of reimbursable expenses incurred by living organ donors to include lost wages, and child-care and elder-care expenses incurred by a caregiver.
 - c. **Publication:** 9/22/2020
11. **Control of Communicable Diseases; Foreign Quarantine: Suspension of the Right to Introduce and Prohibition of Introduction of Persons into United States from Designated Foreign Countries or Places for Public Health Purposes**
- a. **Rule.** [Link](#)
 - b. **Policy:** This final rule provides a procedure for the CDC Director to suspend the right to introduce and prohibit introduction, in whole or in part, of persons from such foreign countries or places as the Director shall designate in order to avert the danger of the introduction of a quarantinable communicable disease into the United States, and for such period of time as the Director may deem necessary for such purpose.
 - c. **Publication:** 9/11/2020

Center for Medicare and Medicaid Services (CMS) Regulations

1. **Medicare Program: Secure Electronic Prior Authorization for Medicare Part D**
 - a. **Rule.** [Link](#)
 - b. **Policy:** This final rule names a new transaction standard for the Medicare Prescription Drug Benefit program's (Part D) e-prescribing program as required by the "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" or the "SUPPORT Act." This new electronic prior authorization standard is intended to allow prescribers to see that a drug is subject to prior authorization while they are prescribing it.
 - c. **Publication:** 12/31/2020
2. **Medicaid Program: Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability Requirements**
 - a. **Rule.** [Link](#)
 - b. **Policy:** This final rule establishes minimum standards in Medicaid State Drug Utilization Review, providing additional flexibility for states and commercial payers to enter value-based purchasing arrangements with drug manufacturers. It also addresses drug manufacturer copay assistance programs.
 - c. **Publication:** 12/31/2020

3. **Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs**
 - a. **Rule.** [Link](#)
 - b. **Policy:** This final annual payment rule finalizes the agency's proposal to phase out over three years its inpatient-only list, among several other changes.
 - c. **Publication:** 12/29/2020
4. **Medicare Program: CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies. Etc.**
 - a. **Rule.** [Link](#)
 - b. **Policy:** This final annual payment rule reforms Medicare payments under the Physician Fee Schedule and other Medicare Part B issues. One of the most important set of changes makes time-limited or permanent telehealth changes even if the public health emergency period ends during 2021.
 - c. **Publication:** 12/28/2020
5. **Grandfathered Group Health Plans and Grandfathered Group Health Insurance Coverage**
 - a. **Rule.** [Link](#)
 - b. **Policy:** This final rule, citing the objectives of a Trump administration Executive Order, relaxes requirements that group plans and insurers must follow to maintain their status as a "grandfathered" plan under the Affordable Care Act (ACA). The new rule will enable such plans to impose higher cost-sharing requirements without losing their legacy status.
 - c. **Publication:** 12/15/2020
6. **Medicare Program; Modernizing and Clarifying the Physician Self-Referral (Stark) Regulations**
 - a. **Rule.** [Link](#)
 - b. **Policy:** The final rule provides guidance on exceptions to the Stark Law, including protections for non-abusive, beneficial arrangements such as donations of cybersecurity technology. The rule also establishes a permanent exception for value-based arrangements to permit physicians and other health care providers to enter into such arrangements to better coordinate and improve the quality of care for patients and lower costs.
 - c. **Publication:** 12/02/2020
7. **Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations**
 - a. **Rule.** [Link](#)
 - b. **Policy:** The final rule seeks to increase the supply of organs available for transplant in the United States by revising outcome measures for assessing the performance of Organ Procurement Organizations (OPOs) in order to increase transparency and competition. The revised measures include a donation rate measure, which measures the number of organs an OPO procures from all eligible donors in its donation service area, as well as an organ transplantation rate measure designed to incentivize OPOs to transplant and use all viable organs.
 - c. **Publication:** 12/02/2020
8. **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**
 - a. **Rule.** [Link](#)

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- b. **Policy:** This final rule finalizes changes to the HHS-RADV error estimation methodology, which is used to calculate adjusted risk scores and risk adjustment transfers for small group and individual health insurers, beginning with the 2019 benefit year of HHS-RADV.
 - c. **Publication:** 12/01/2020
- 9. Most Favored Nation (MFN) Model—currently under a temporary restraining order by a federal court**
- a. **Rule.** [Link](#)
 - b. **Policy:** The final rule establishes a new drug payment model aimed at lowering Medicare Part B payments for certain drugs. Under the new innovation model, the Part B drug payment amount for the top 50 physician administered Part B drugs (based on CMS 2019 reimbursement data) will be set according to the lowest price available in another Organization for Economic Co-operation and Development (OECD) country with a GDP of 60% of the U.S. GDP per capita.
 - c. **Publication:** 11/27/2020
- 10. Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care**
- a. **Rule.** [Link](#)
 - b. **Policy:** This final rule modifies certain changes made in a 2016 final rule and seeks to reduce federal regulatory barriers, support flexibility, and promote transparency and innovation when states develop and implement managed care programs for their Medicaid and CHIP beneficiaries.
 - c. **Publication:** 11/13/2020
- 11. Transparency in Coverage**
- a. **Rule.** [Link](#)
 - b. **Policy:** The final rules implement an Affordable Care Act requirement and Trump administration Executive Order and set forth requirements for group health plans and health insurance issuers to make negotiated rates available through machine-readable files and to disclose cost-sharing information upon request to a participant, beneficiary or enrollee (or his or her authorized representative), including an estimate of the individual's cost-sharing liability for covered items or services furnished by a particular provider.
 - c. **Publication:** 11/12/2020
- 12. 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**
- a. **Rule.** [Link](#)
 - b. **Policy:** This final annual payment rule updates the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2021. The rule proposes to update the acute kidney injury (AKI) dialysis payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI and proposes changes to the ESRD Quality Incentive Program.
 - c. **Publication:** 11/09/2020
- 13. Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency**
- a. **Interim Final Rule.** [Link](#)
 - b. **Policy:** This interim final rule implements section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which established Medicare Part B coverage and

payment for the Coronavirus Disease 2019 (COVID-19) vaccine and its administration. It also clarifies providers' obligations to post cash pay prices for COVID-19 testing.

c. **Publication:** 11/06/2020

14. 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

a. **Rule.** [Link](#)

b. **Policy:** This final annual payment rule updates the home health prospective payment system (HH PPS) payment rates and wage index for calendar year (CY) 2021. The final rule sets an increased national, standardized 30-day period payment for HHAs in 2021 by applying a wage index budget neutrality factor and a payment update of 2%.

c. **Publication:** 11/04/2020

15. Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures

a. **Rule.** [Link](#)

b. **Policy:** This final rule implements two new mandatory Medicare payment models under section 1115A of the Social Security Act—the Radiation Oncology Model (RO Model) and the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model).

c. **Markets Affected:** Medicare

d. **Publication:** 9/29/2020

16. Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the 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

a. **Rule.** [Link](#)

b. **Policy:** This final annual payment rule sets up payment policies for inpatient hospitals and long-term acute care hospitals for FY 2021 including requiring hospitals to include within their cost reports the median payer-specific negotiated charges by MS-DRG for all of the hospital's Medicare Advantage (MA) payers.

c. **Publication:** 9/18/2020

17. Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

a. **Rule.** [Link](#)

b. **Policy:** This interim final rule revises regulations to strengthen CMS' ability to enforce compliance with Medicare and Medicaid long-term care (LTC) facility requirements for reporting information related to Coronavirus Disease 2019 (COVID-19) and requiring testing of residents and staff.

c. **Publication:** 9/02/2020