

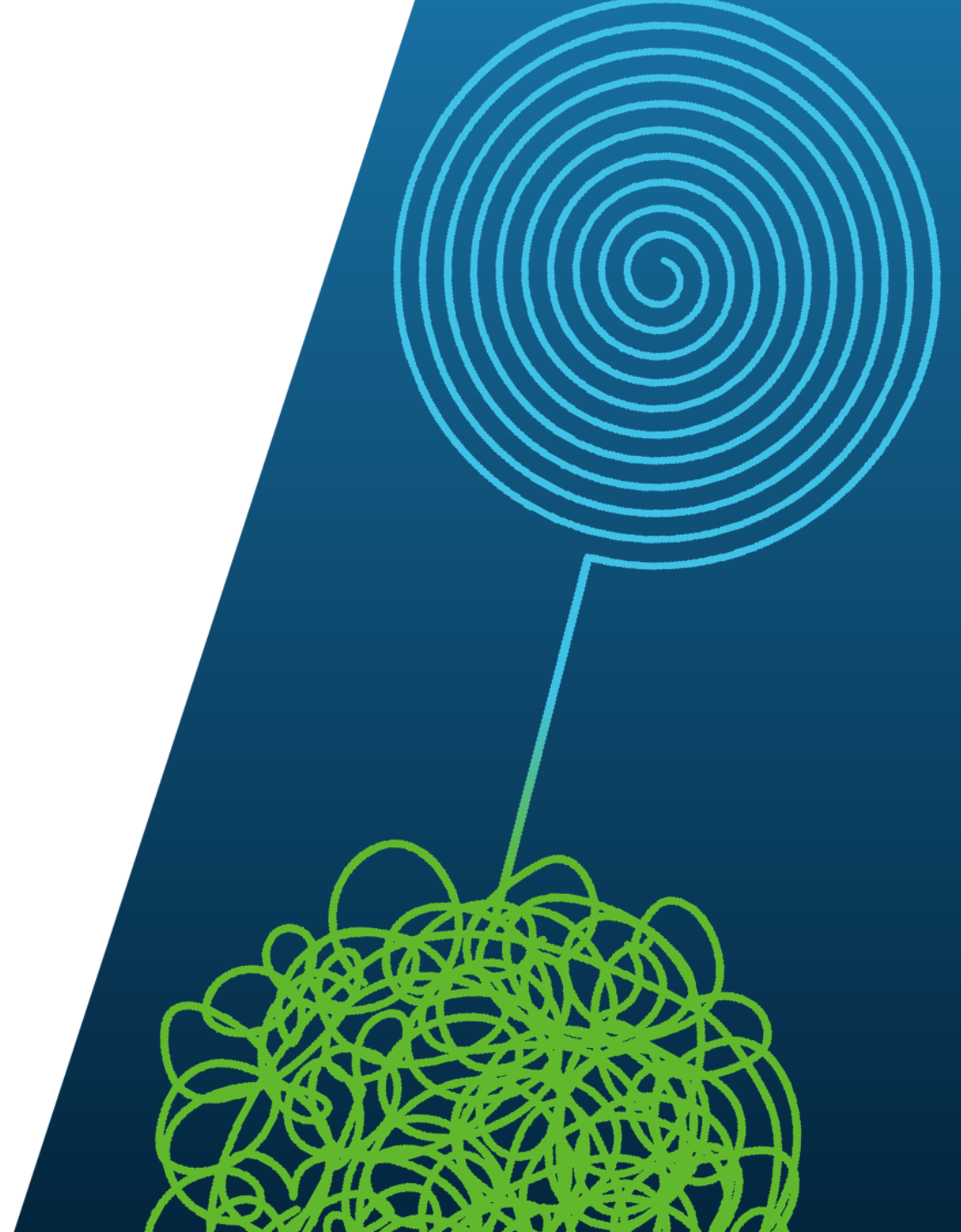


## Healthcare Regulatory Roundup #93

# Washington Updates: Deregulation-O-Rama!

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April 30, 2025



# Housekeeping



- Slides, handouts, and forms available in **Resources Panel**
- Enter questions in **Q&A Panel**
  - If question not addressed during webinar, will follow-up via e-mail
- Enlarge, rearrange, or close panels as you prefer

# Introductions

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# Today's Agenda



1. Repeal of Unlawful Regulations
2. Repeal of Burdensome Regulations
3. Update on Budget Reconciliation Process

# 1. Repeal of Unlawful Regulations

# January 31 Executive Order 14192



- Unleashing Prosperity Through Deregulation
  - Whenever agency publicly proposes for notice and comment or otherwise promulgates new regulation, agency shall identify at least 10 existing regulations to be repealed
    - Follow-up to prior Trump Administration executive order requiring repeal of 2 regulations for each new regulation
  - Any new incremental costs associated with new regulations shall, to extent permitted by law, be offset by elimination of existing costs associated with at least 10 prior regulations
  - Agency must provide its best approximation of total costs or savings associated with each new regulation or repealed regulation
- March 26 OMB FAQs
  - Identify 10 existing regulatory actions agency plans to eliminate/propose for elimination by 9/30/2025
  - Ensure total incremental cost of regulatory and deregulatory actions is significantly less than zero as of 9/30/2025
  - Agency may issue statutorily or judicially required regulations even if agency cannot meet requirements at time of issuance, but must offset as soon as practical

<https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-20-Guidance-Implementing-Section-3-of-Executive-Order-14192-Titled-Unleashing-Prosperity-Through-Deregulation.pdf>

# February 19 Executive Order 14219



- Directs agency heads, in coordination with DOGE and OMB, to review all regulations and create list of those that are:
  - Unconstitutional or constitutionally difficult
  - Unlawful delegations of power
  - Unclear on statutory authority
  - Imposing significant costs to private businesses that are not outweighed by public benefits
  - Harmful to national interests (e.g., impending technological innovation, inflation reduction)
  - Imposing undue burden to small and private businesses
- Within 60 days, generate lists of regulations and consult with Office of Information and Regulatory Affairs (OIRA) on Unified Regulatory Agenda to rescind/modify identified regulations
- De-prioritize enforcing regulations beyond their “best read” of statute or that exceed federal government’s constitutional powers

# April 19 Presidential Memorandum



- Beginning April 19, “agencies shall immediately take steps to effectuate the repeal of any regulation, or the portion of any regulation, that clearly exceeds the agency’s statutory authority or is otherwise unlawful”.
  - “[A]gency heads shall finalize rules without notice and comment, where doing so is consistent with the ‘good cause’ exception in the Administrative Procedure Act.”
  - “Retaining and enforcing facially unlawful regulations is clearly contrary to the public interest....Agencies thus have ample cause and the legal authority to immediately repeal unlawful regulations....The repeal of each unlawful regulation shall be accompanied by a brief statement of the reasons that the ‘good cause’ exception applies.”
- By May 19, agencies must submit written explanation why any regulation identified under Executive Order 14219 has not been repealed.



# Administrative Procedures Act



- 30-day notice-and-comment rulemaking not required in two circumstances
  - For matters related to “agency management or personnel or to public property, loans, grants, benefits, or contracts”
  - If agency “for good cause” determines “that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest”
    - Split among federal courts of appeal on evaluation of “good cause” claims (de novo vs. arbitrary and capricious)
- Richardson Waiver (HHS policy since 1971)
  - HHS will engage in notice-and-comment rulemaking even for exempted matters because “public benefit from such participation should outweigh any administrative inconvenience or delay which may result from use of the APA procedures....”
  - “Good cause” exception should be used only during emergencies or circumstances where “public participation would be useless or wasteful because proposed amendments to regulations cover minor technical matters”
- February 28 HHS Policy Statement rescinded Richardson Waiver
  - Good cause exception should be used in appropriate circumstances in accordance with APA requirements

<https://www.federalregister.gov/documents/2025/03/03/2025-03300/policy-on-adhering-to-the-text-of-the-administrative-procedure-act>

# Social Security Act



- Section 1871(42 USC 1395hh) requires notice-and-comment rulemaking for any Medicare “rule, requirement, or statement of policy” that “establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive benefits....”
  - Only applies to Medicare; not all federal healthcare programs
  - No “good cause” exception
- Supreme Court affirmed “Medicare APA” in *Azar v. Allina Health Services* (2019), invalidating DSH payment recalculations for CMS’ failure to engage in notice-and-comment rulemaking
- February 28 Policy Statement did not reference Medicare APA

# What Makes a Regulation Illegal?



- “[P]rioritize ... evaluating each existing regulation’s lawfulness under the following [U.S.] Supreme Court decisions”
  1. *Loper Bright Enterprises v. Raimondo* (2024): end of *Chevron* deference
  2. *West Virginia v. EPA* (2022): major questions doctrine
  3. *SEC v. Jarkesy* (2024): imposition of civil money penalties through administrative procedures
  4. *Michigan v. EPA* (2015): agency consideration of cost when formulating ‘appropriate and necessary’ regulations
  5. *Sackett v. EPA* (2023): authority to regulate wetlands under Clean Water Act
  6. *Ohio v. EPA* (2024): regulation is arbitrary and capricious if agency failed to respond to significant comment
  7. *Cedar Point Nursery v. Hassid* (2021): regulatory right of access is per se taking requiring owner compensation
  8. *Students for Fair Admissions v. Harvard* (2023): race-conscious admissions violates Equal Protection Clause
  9. *Carson v. Makin* (2022): state’s nonsectarian requirement for tuition assistance violates Free Exercise Clause
  10. *Roman Cath. Diocese of Brooklyn v. Cuomo* (2020): COVID-19 limits on church attendance unconstitutional

# Chevron Deference



- Agencies derive authority to make/enforce regulations from statutes
  - E.g., CMS' authority derived from Social Security Act
  - If regulated don't like regulation, file lawsuit challenging agency's authority
- *Chevron*: If statute ambiguous (2 or more reasonable interpretations), court defers to agency interpretation, provided it is permissible construction
  - Assume Congress delegated authority to agency to interpret ambiguous statute (vs. requiring agency to follow 'most reasonable' interpretation)
- Since 1984, federal courts applied *Chevron* deference in 18,000+ cases challenging regulations based on ambiguous statute
  - Agency prevailed in ~90% of cases (i.e., court found regulation based on permissible construction of ambiguous statute)
  - Regulated entities more successful when court determines statute is unambiguous

# *Loper Bright Enterprises: End of Chevron Deference*



- Courts, not agencies, are final authority in interpreting statutes
  - “Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority... Careful attention to the judgment of the Executive Branch may help inform that inquiry. And when a particular statute delegates authority to an agency consistent with constitutional limits, courts must respect the delegation, while ensuring that they agency acts within it. **But courts need not and may not defer to an agency interpretation of the law simply because a statute is ambiguous.**”
  - “The statute still has a best meaning, necessarily discernible by a court deploying its full interpretive toolkit.”
  - Regulations previously upheld applying *Chevron* deference remain in effect

## 2. Repeal of Burdensome Regulations

# Omnibus Burden Reduction Final Rule (2019)



- Repealed/revised Medicare regulations identified as unnecessary, obsolete, or excessively burdensome at projected savings to providers of \$800 million/year
- Examples:
  - Emergency preparedness – change from annual to biennial review of emergency program (except LTCs)
  - Hospitals – no longer require medical staff to attempt to secure autopsies in specified circumstances
  - Critical access hospitals – reduce frequency of policy & procedure reviews
  - ASCs – remove requirement to have written transfer agreement with hospital
  - Transplant centers – reduce re-approval data submission requirements
  - Home health agencies – reduce requirements for verbal notifications
  - Hospices – defer to State licensure requirements for qualification of their hospice aide

<https://www.cms.gov/newsroom/fact-sheets/omnibus-burden-reduction-conditions-participation-final-rule-cms-3346-f>

# DOJ Anticompetitive Regulations Task Force



- Per March 27 press release, task force “will bring together attorneys, economists, and other staff from across the Division, together with interagency partners, to identify state and federal laws and regulations that unnecessarily harm competition. The Antitrust Division will then take appropriate action, including helping agencies revise or eliminate these regulations.”
- Healthcare included as one of five target areas:
  - “Laws and regulations in healthcare markets too often discourage doctors and hospitals from providing low-cost, high-quality healthcare and instead encourage overbilling and consolidation. These kinds of unnecessary anticompetitive regulations put affordable healthcare out of reach for millions of American families.”
- **Invite public comment through May 27** at <https://www.regulations.gov/document/ATR-2025-0001-0002>



# Office of Management and Budget RFI



- Published in Federal Register on April 11
  - “OMB seeks proposals to rescind or replace regulations that stifle American businesses and American ingenuity. We seek comment from the public on regulations that are unnecessary, unlawful, unduly burdensome, or unsound.”
  - “Comments should address the background of the rule and the reasons for the proposed rescission, with particular attention to regulations that are inconsistent with statutory text or the Constitution, where costs exceed benefits, where the regulation is outdated or unnecessary, or where regulation is burdening American businesses in unforeseen ways.”
- **Submit proposals by May 12** at <https://www.regulations.gov/commenton/OMB-2025-0003-0001>

# CMS Request for Information – Unleashing Prosperity Through Deregulation of the Medicare Program



- Included in all five proposed FY2026 payment rules released April 11 + CMS press release
  - In response to Executive Order 14219's requirement that agency promulgating new rule must identify at least 10 existing regulations for appeal
- CMS “seeks public input on approaches and opportunities to streamline regulations and reduce administrative burdens on...stakeholders participating in the Medicare program”
  - Streamline regulatory requirements
  - Opportunities to reduce administrative burden of reporting and documentation
  - Identification of duplicative requirements
  - Additional recommendations
- **Responses due June 10**; submitted via <https://www.cms.gov/medicare-regulatory-relief-rfi> (vs. submission via Federal Register site)

# Streamline Regulatory Requirements



- Are there existing regulatory requirements that could be waived, modified, or streamlined to reduce administrative burdens without compromising patient safety or the integrity of Medicare program?
  - Including regulations, rules, memoranda, administrative orders, guidance documents, policy statements
- Which specific Medicare administrative processes or quality and data reporting requirements create most significant burdens for providers?
- Are there specific Medicare administrative processes, quality, or data reporting requirements that could be automated or simplified to reduce administrative burden?

# Opportunities to Reduce Administrative Burden of Reporting and Documentation



- What changes can be made to simplify Medicare reporting and documentation requirements without affecting program integrity?
- Are there opportunities to reduce frequency or complexity of reporting for Medicare providers?
- Are there documentation or reporting requirements that are overly complex or redundant? If so, which ones?
  - Provide specific OMB Control Number or CMS form number
    - OMB Control Number consists of two groups of four digits joined by hyphen; generally appears on top right of first page of Medicare form and the
    - CMS form number generally appears on bottom left of page of Medicare form

# Identification of Duplicative Requirements



- Which specific Medicare requirements or processes do you consider duplicative, either within program itself, or with other healthcare programs (including Medicaid, private insurance, and state or local requirements)?
- How can cross-agency collaboration be enhanced to reduce duplicative efforts in auditing, reporting, or compliance monitoring?
- How can Medicare better align its requirements with best practices and industry standards without imposing additional regulatory requirements, particularly in areas such as telemedicine, transparency, digital health, and integrated care systems?

# Burden Without Benefit?



- HIPAA Privacy Rule
  - New reproductive healthcare provisions
  - Administrative requirements (e.g., Notice of Privacy Practices)
- Conditions of Participation/Certification
  - New hospital maternal health CoPs
  - New hospital reporting on respiratory conditions requirements
  - Hospital physical plant requirements
- CoP Interpretive Guidelines (appendices to State Operations Manual)
  - EMTALA Interpretive Guidelines (Appendix V)
- Fraud and abuse
  - Anti-kickback statute safe harbors
  - Stark Law exceptions
  - Prohibition on patient inducements

# Burden Without Benefit?



- Medicare-specific patient notification requirements
  - Important Message from Medicare
  - Advance Beneficiary Notice of Noncoverage
  - Notice of Medicare Non-Coverage and Detailed Explanation of Non-Coverage
  - Medicare Outpatient Observation Notice (MOON)
  - Medicare Change of Status Notice
- No Surprises Act notice requirements (surprise billing and GFE notices)
- Cost report forms
- Section 1557 anti-discrimination regulations (administrative requirements)
- Section 504 requirements (accessible medical diagnostic equipment, digital accessibility)

# Burden Without Benefit?



- Quality reporting programs
    - Eliminate measures that do not provide meaningful/actionable information
    - Eliminate duplication and inconsistency (e.g., definitions, reporting methodology) across programs
  - Hospital and CAH meaningful use requirements
  - Hospital and SNF value-based purchasing programs
  - Merit-Based Incentive Payment Program (including meaningful use)
- ‘Incident to’ requirements
  - Virtual services
    - Consent requirement
    - Existing patient relationship requirement
  - Telehealth
    - Tele-prescribing of controlled substances
    - List of telehealth services
    - Limits on audio-only services



### 3. Update on Budget Reconciliation Process

# How We Got Here



- Reconciliation process starts with budget resolution
  - Establish revenue and spending targets over ten-year period; authorize increases in federal deficit
  - Committee instructions for drafting implementing legislation
- Getting to go:
  - **Senate budget resolution passed February 21**
    - Did not address tax cuts
  - **House budget resolution passed February 25**
    - Authorized \$2.3T increase in deficit (\$1.5T in mandatory spending cuts to offset \$4.5T in tax cuts)
  - **Senate amended budget resolution passed April 5**
    - Authorizes \$2T increase in deficit (uses “current policy” baseline assuming expiring tax cuts extended in perpetuity; otherwise, \$5.7T increase)
    - Requires House committees to offset tax cuts by at least \$1.7T in mandatory spending cuts (or tax cuts reduced dollar-for-dollar); Senate committees to identify \$4B in spending cuts
  - **House adopted Senate amended budget resolution April 10**

# Where We Go From Here?



- House and Senate committees markup legislation consistent with instructions in budget resolution
  - Multiple ‘behind-the-scenes’ meetings to stake out positions, build consensus
    - “Current baseline” debate (to what degree will tax cuts be funded by spending cuts or deficit spending)
    - Additional tax cuts beyond renewal of 2017 cuts (e.g., taxes on tips, Social Security benefits; SALT deduction)
    - Medicaid benefit cuts vs. provider payment cuts
  - Stated goal is to complete markup by May 9
- House debates, potentially amends, and votes on bill
- Senate debates, potentially amends, and votes on House-passed version of bill
  - Simple majority vote (vs. usual 60 votes to close debate)
- If Senate changes bill, move to conference committee to resolve differences
- President signs bill

# Cuts to Benefits vs. Cuts to Provider Payments



April 28, 2025 05:00 AM | 6 HOURS AGO

## Provider taxes under fire as Congress looks for Medicaid cuts

MICHAEL MCAULIFF [X](#) [in](#) [✉](#)

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## GOP Rep says Trump 'does not want' agenda bill 'to be a health care bill'

BY TARA SUTER - 04/27/25 1:19 PM ET

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