



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Part 291

42 CFR Part 8

45 CFR Parts 86 and 92

Notification of HHS Documents Identified for Rescission

AGENCY: Department of Health and Human Services.

ACTION: Notification of rescissions.

SUMMARY: The Department of Health and Human Services (HHS or the Department) provides notice that it is rescinding four informal guidance documents. This action will reduce the burdens on regulated parties and allow HHS to refocus on its core mission to Make America Healthy Again.

DATES: [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Sean R. Keveney, Acting General Counsel, Office of the General Counsel, HHS. 200 Independence Avenue SW, Washington, DC 20201. 202-690-7741.

SUPPLEMENTARY INFORMATION: President Donald J. Trump has declared that the policy of the executive branch is to “alleviate unnecessary regulatory burdens placed on the American people.” *Unleashing Prosperity Through Deregulation*, Executive Order 14192, 90 FR 9065, 9065 (Jan. 31, 2025). This burden does not come from formal regulations alone, but also from “rules, memoranda, administrative orders, guidance documents, policy statements, and interagency agreements that are not subject to the Administrative Procedure Act.” *Id.* The President has accordingly directed every agency to review and rescind all such agency actions which are unlawful or impose greater burdens than benefits. *Ensuring Lawful Governance and Implementing the President’s*

“Department of Government Efficiency” Deregulatory Initiative, Executive Order 14219, 90 FR 10583, 10583 (Feb. 19, 2025).

Independently, I have instructed HHS to launch the most sweeping deregulatory initiative in the history of the Department. We are eliminating bureaucratic red tape and refocusing on our core mission to Make America Healthy Again. Across the Department, we are aggressively deregulating to return the freedoms eroded over decades by unnecessary and burdensome regulations.

As part of this Department-wide initiative, I have determined that the documents identified below have been superseded, are unduly burdensome, no longer represent the considered legal judgment of HHS, and/or are otherwise appropriate for rescission. To the extent one of these documents should have been promulgated with notice and comment, but was not, that provides another basis for rescission. Accordingly, all documents identified below are hereby rescinded, effective immediately.

Because HHS promulgated these documents without notice and comment, HHS may rescind them in the same manner. *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 101 (2015). Any effect on reliance interests could only be positive since these guidance documents have already largely been superseded. Thus, formal rescission will reduce the burdens on regulated parties. To the extent there are negative effects on reliance interests, those interests are unreasonable or unwarranted. The American public knew that these informal documents could be rescinded at any time, especially following a change of administration now that they are defunct.

This is the beginning of a new era for HHS and American health more broadly. In this new era, patient choice and individual freedom will predominate over burdensome federal regulations. In this document, we are taking the first step towards making that a reality.

I hereby order that the following documents be rescinded, effective immediately:

- * Extension of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures; Extension of Effective Date With Modifications, 86 FR 35810 (July 7, 2021).

- * Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Repeal of Current Regulations and Issuance of New Regulations: Delay of Effective Date and Resultant Amendments to the Final Rule, 66 FR 15347 (Mar. 19, 2001).

- * Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder, 86 FR 22439 (Apr. 28, 2021).

- * Notification of Interpretation and Enforcement of Section 1557 of the Affordable Care Act and Title IX of the Education Amendments of 1972, 86 FR 27984 (May 25, 2021).

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.