

DEPARTMENT OF HEALTH AND HUMAN SERVICES**45 CFR Subtitle A****Policy on Redundant, Overlapping, or Inconsistent Regulations**

AGENCY: Immediate Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Policy statement.

SUMMARY: The Immediate Office of the Secretary (IOS) is issuing this policy regarding redundant, overlapping, or inconsistent regulations.

DATES: November 27, 2020.

SUPPLEMENTARY INFORMATION: The Department believes that its decision-making ought to be transparent, rational, and well-honed to achieve legitimate government objectives with minimum transaction costs to the affected sector. This policy furthers those objectives and the objectives of the Richardson Waiver (see 36 FR 2532 (Feb. 5, 1971)), and various Executive Orders by requiring that all regulations issued by this Department are necessary, understandable, and provide clear guidance to the public and regulated entities regarding the standards to be met and procedures to be followed. Redundant, overlapping, or inconsistent regulations undermine these goals by injecting uncertainty, creating potentially conflicting regulatory regimes, and increasing transactions costs with no discernible benefit to the public.

Effective immediately, all agencies and offices of the Department that prepare regulations must ensure that any rule is not inconsistent with, and does not overlap with, any regulation that has already been issued through an agency within the Department. In the event an agency proposing that the Secretary issue a rule discovers that such rule is inconsistent or overlaps with another Department rule, the proposing agency shall not recommend issuance until it also recommends to the Secretary the steps to be taken to avoid duplicative or overlapping regulations.

Collection of information requirements: This document does not impose information collection requirements.

Brian Harrison,

Chief of Staff, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of the Secretary****45 CFR Subtitle A****Public Access to Materials Underlying Impact Analyses; Statement of Policy**

The Department believes that its decision-making ought to be as transparent as appropriate to better enable the citizenry to comment on its proposed rules and demonstration projects. This document furthers that objective and the objectives of the Richardson Waiver (see 36 FR 2532 (Feb. 5, 1971)) by requiring that all assumptions, working papers, models, and other information used as part of any impact analysis (e.g., economic, actuarial) associated with a rule (including ratemakings) or demonstration project (hereinafter, “analyses”) are posted on the Department’s website at the time the results of the analysis are publicly disclosed, subject to the limitations set forth below. This document also applies to rules issued or demonstration projects approved by this Department jointly with one or more other Departments, but only after consultation with such other Departments and only with respect to the analyses performed by this Department.

The Department’s regulations and demonstration projects involving federal healthcare programs, the Affordable Care Act, the Food, Drug, and Cosmetic Act, or the Public Health Service Act are amongst the most economically significant actions undertaken by any Federal agency. The Office of the Assistant Secretary for Planning and Evaluation, the Office of Economics and Analysis within the Office of Policy, Legislation, and International Affairs at the Food and Drug Administration, the Office of the Actuary at the Centers for Medicare & Medicaid Services, and other applicable agencies and offices all undertake impact analyses that assess or seek to predict the wide range of economic and other impacts and burdens associated with each rule or demonstration project.

The Office of Management and Budget (“OMB”) Circular A-4 requires agencies to make their impact analyses reproducible by third-party evaluators. Disclosing the information underlying such analyses, to the extent permitted by law and consistent with robust privacy protections, will promote an informed public comment process that in turn advances both the quality and accountability of the Department’s

important programs. Implementing this policy will allow the public to review and evaluate the methodologies and assumptions that underlie the impact analysis. This transparency should enable a more accurate calculation of anticipated effects because the public will be better positioned to analyze and provide formal comment upon the models and data to identify and correct faulty assumptions or other errors.

Effective for any rulemaking or demonstration project proposed after November 30, 2020, all agencies and offices of the Department which issue analyses, whether economic, actuarial or otherwise, as part of a proposed or final rulemaking or demonstration project must post for public viewing on the Department’s website all data and assumptions underlying any such analysis, including all working papers, all calculations, all references, and all other information necessary to allow a third-party to replicate the agency’s analytic work. For purposes of this Notice, a rulemaking or demonstration project is deemed to have started with the publication in the **Federal Register** of a notice of proposed rulemaking or proposed demonstration projection, advanced notice of proposed rulemaking or final rule (whether interim or otherwise) or demonstration project, whichever occurs first.

The disclosure must occur no later than 3 days after the date when the results of such analyses are publicly released and are to be posted in-full on the Department’s website notwithstanding Exemption 5 of the Freedom of Information Act (5 U.S.C. 552(b)(5)), except as noted below. This Notice does not contemplate the release of information that would otherwise be exempt from disclosure under the Freedom of Information Act, other than Exemption 5 as noted in the preceding sentence, or the Privacy Act of 1974.

The disclosure requirements in this Notice do not apply to analyses undertaken for settlement or litigation purposes or to communications with the Executive Office of the President, OMB, or other departments or agencies that are not part of a published analysis for a rulemaking or demonstration project, or to information that is deemed to fall within the attorney-client privilege, or to privileges that inure to officials outside this Department. Whether an exception contained in this paragraph applies shall be determined by the Office of the General Counsel in consultation with the relevant division within the Department.

Nothing in this policy shall be construed to impair or otherwise affect the functions of the Director of OMB