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HHS Reverses Its Longstanding Policy and Limits Public Participation in Rulemaking

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On March 3, 2025, the Secretary of Health and Human Services published a policy statement in the Federal Register that reverses a policy adopted over 50 years ago that was intended to expand public participation in the process of rulemaking at the Department of Health and Human Services (the "Department"). 90 Fed. Reg. 11029 (2025).

This action is at odds with the "radical transparency" that Secretary Kennedy had promised previously, and may affect many programs and financial relationships between individuals, organizations, and others that interact with Health and Human Services ("HHS").

Regulatory agencies such as HHS and its components, including the Centers for Medicare and Medicaid Services ("CMS"), the Food and Drug Administration ("FDA"), and the National Institutes of Health ("NIH") must follow rulemaking procedures set out in the Administrative Procedure Act ("APA") when they formulate and publish regulations that are intended to implement a statute and have the force of law. Those procedures include offering the public an opportunity to be notified of proposed regulations and to submit comments to the agency. The APA also contains several exceptions to the notice and comment requirement, including one for matters relating to "public property, loans, grants, benefits, or contracts." Nevertheless, HHS and several other federal departments adopted policies that voluntarily waived these exceptions.

In 1971, then-Secretary of Health, Education, and Welfare Elliot Richardson issued a policy statement announcing that the Department would voluntarily follow notice and comment procedures for regulations relating to public property, loans, grants, benefits, or contracts (the "Richardson Waiver"). That notice explained that the waiver would allow for greater participation by the public in the rulemaking process, and that the additional burden on the Department was outweighed by the public benefit. The policy also instructed that although the APA allows for rulemaking procedures to be waived when good cause exists, that exception should be used "sparingly."

HHS's New Policy Limiting Rulemaking and Potential Safeguards

The new HHS policy statement sweeps away the 1971 policy. Its impact may vary depending on the issue and component of HHS. For example, for research funded by the NIH or other projects funded by agencies within HHS, the new policy could allow a granting or contracting agency to amend financial terms without public participation. This exact issue is currently in the spotlight as courts actively evaluate the legality of the NIH's recent Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates (NOT-OD-25-068))("Supplemental Guidance"), issued by the Office of the Director of the National Institutes of Health on February 7, 2025, which attempted to impose an across-the-board 15% cap on Indirect Cost ("IDC') rates for all new grants as well as for existing grants awarded to Institutions of Higher Education. The District Court of Massachusetts has imposed a nationwide preliminary injunction ("PI") prohibiting the Secretary and NIH from taking any steps to implement or enforce the Supplemental Guidance. *Commonwealth of Massachusetts, et al. v. National Institutes of Health, et al.*, No. 25-CV-10338 (D. Mass. Mar. 5, 2025). The court concluded that the plaintiffs would be irreparably harmed by the Supplemental Guidance and agreed that the Supplemental Guidance was a legislative rule that failed to comply with the notice and comment requirements of the APA. It relied in part on the argument that under the Richardson Waiver, the Secretary could not change the IDC rate unilaterally. The timing of the Department's policy reversing the Richardson Waiver might be viewed as directly responsive to this disputed point in the ongoing litigation.

In other areas, the policy statement may have little or no impact if there is a separate statutory requirement for rulemaking. In the Medicare statute, for example, Congress mandated in Section 1871(a)(2) of the Social Security Act that HHS must engage in notice and comment rulemaking for any "substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits . . . ." Should Congress decide to limit the scope of the new HHS policy, this statute could be a template for legislation.

The impact of the new policy on the Medicaid program is less clear. While there is no similar statutory requirement for rulemaking under the Medicaid program as there is for Medicare, the federal government also has more limited control over the direction of each individual State's Medicaid program offering. However, there are areas where HHS has sought public comment on changes to state Medicaid program requirements in the past, such as changes proposed by States through Medicaid program waivers that the federal government has to approve. This new policy may be signaling that HHS will choose not to seek comments on those proposed changes in the future.

Returning to the IDC rate litigation, there arguably exists both statutory and regulatory grounding for applying grantees' existing negotiated indirect cost rates, documented in the negotiated indirect cost rate agreement ("NICRA") entered into between the government and grantee institutions. First, a provision in the annual appropriations act since 2018 has limited Congress' ability to impose any type of across-the-board cap. *See* Further Consolidated Appropriations Act, 2024, P.L. 118-47, Title II, § 224. This was adopted in response to the first Trump administration's attempt to impose an across-the-board cap of 10% in 2017. Second, in the HHS regulations applicable to IDC rates, there is an explicit requirement that the negotiated rates must be "accepted by all Federal awarding agencies." 45 C.F.R. § 75.414(c)(1). This regulatory exception, and alleged noncompliance with the APA's rulemaking requirement, is at the core of the ongoing IDC rate litigation. As such, there are arguably continued bases for the objection to the NIH Supplemental Guidance notwithstanding the recent reversal of the Richardson Waiver.

Does HHS's New Policy Signal a Wider Use of the "Good Cause" Exception?

Another part of the new HHS policy to watch carefully involves the exception in the APA that allows agencies to dispense with notice and comment rulemaking when there is good cause that a notice and comment period is impractical or contrary to the public interest. The new HHS policy states that agencies may rely on the good cause exception “in appropriate circumstances” rather than “sparingly” but provides no further clarification.

Courts have interpreted this exception narrowly; for example, they have upheld good cause exceptions when agencies have responded to epidemics and natural disasters, but have rejected exceptions claimed by agencies due to statutory deadlines, economic concerns, or a need to implement a political goal rapidly. In addition, a 2012 report published by the General Accountability Office criticized the frequent use of the good cause exception to avoid public comments on rules. Therefore, it remains to be seen how and when HHS relies on this exception, and whether the reasons offered justify the exception or would stand up to judicial review.

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