NIH Issues Guidance Capping Grant Indirect Cost Rates at 15%, Drawing Multiple Legal Challenges Affecting Research-Based Organizations and R&D Innovation

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The National Institutes of Health (NIH) issued *NIH Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates*, Notice Number NOT-OD-25-068 (Feb. 7, 2025) (NIH Guidance or Guidance), which establishes a standard indirect cost rate (also known as a Facilities and Administration or F&A rate) of 15% across all NIH grants, regardless of existing negotiated indirect cost rates. The standard rate, which operates as a cap on indirect costs, applies to all future NIH grant awards and, specifically for Institutions of Higher Education (IHEs), even applies to existing awards. The Guidance acknowledges that most organizations have F&A rates averaging 27-28%, nearly double the new cap, and that many organizations have rates upwards of 50-60%.

The NIH Guidance was effective for new NIH awards as of the date it was issued, Feb. 7, 2025, and stated it applied to existing grants to IHEs "for go forward expenses from Feb. 10, 2025." Three groups of plaintiffs have brought actions challenging the Guidance, however, and a court issued two Temporary Restraining Orders (TROs) delaying implementation for many (if not all) recipients pending further proceedings.

1. Authority and Rationale for Cap Asserted in NIH Guidance

NIH cites the Health and Human Services grant and agreement regulations as the source of the agency's authority to impose this cap, specifically 45 C.F.R. § 75.414(c)(1) and 45 C.F.R. Appendix III to Part 75, C.7.a.

45 C.F.R. § 75.414, "Indirect (F&A) costs," states at (c)(1): "[N]egotiated rates must be accepted by all Federal awarding agencies. An HHS awarding agency may use a rate different from the negotiated rate for a class of Federal awards or a single Federal award only [1] when required by Federal statute or regulation, or [2] when approved by a Federal awarding agency head or delegate based on documented justification." (Numbering added).

NIH appears to assert a right to use a different rate based on agency head or delegate approval (No. 2), as it does not cite any statute or regulation. Elaborating on that requirement, 45 C.F.R. § 75.414(c)(3) requires the agency to "implement, and make publicly available, the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates."

45 C.F.R. Appendix III to Part 75, "Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs)" states at C.7.a: *"Except as provided in paragraph (c)(1) of 200.414,* Federal agencies must use the negotiated rates in effect at the time of the initial award throughout the life of the Federal award." 2 C.F.R. § 200.414(c) is the section of the OMB Uniform Guidance that corresponds to 45 C.F.R. § 75.414(c) in the HHS regulations. NIH's position seems to be that, with respect to IHEs, the Appendix III language allows the agency to

deviate from negotiated rates even for existing grants, i.e., grants awarded based on the IHE's negotiated rates before the NIH Guidance went into effect.

By way of justification, NIH states that a 15% indirect cost rate is comparable to indirect rates paid by private research foundations (many of which, NIH reports, do not reimburse any indirect costs). NIH states that the change is intended "to ensure as many funds as possible go towards direct scientific research rather than administrative overhead." NIH also cites a study that apparently found that 67 of 72 universities in a sample were willing to accept research grants that had a 0% indirect cost rate and that only three universities refused to accept rates lower than their federal indirect cost rates.

The NIH Guidance states that the 15% standard indirect cost rate "will allow grant recipients a reasonable and realistic recovery of indirect costs." The NIH Guidance also indicates that, for many recipients, the cap will not permit reimbursement for a substantial proportion of their audited indirect costs allocable to their federal awards.

2. Legal Challenges to the NIH Guidance

The NIH Guidance promptly drew three lawsuits, all filed Monday, Feb. 10, 2025, in federal district court in Massachusetts. For discussion below, we number the suits as follows:

1) 22 state attorneys general filed an action seeking to set aside the NIH Guidance (*Commonwealth of Massachusetts et al.* v. NIH et al., Case No. 1:25-cv-10338);

2) The Association of American Medical Colleges (AAMC) and several other medical institutions also challenged the Guidance (*Association of American Medical Colleges, et al. v. NIH et al.*, Civil Action No. 25-CV-10340-AK); and

3) The Association of American Universities (AAMU) and various individual universities and other university groups filed suit as well (*Association of American Universities et al v. Department of Health & Human Services et al.*, Case No. 1:25-cv-10346-AK).

The States assert in the first lawsuit that the indirect cost rate cap would "devastate critical public health research at universities and research institutions in the United States." In the third suit, the universities similarly assert that the rate cap will adversely affect "institutions' ability to contribute to medical and scientific breakthroughs," contending that the rate cap jeopardizes "lifesaving research and innovation."

a. Legal Arguments

The three groups of plaintiffs advance similar primary legal arguments. The lawsuits argue that, while the agency has authority to deviate from a negotiated indirect cost rate for an individual award or class of awards, HHS grant regulations do not allow NIH to impose a blanket cap for all agency grants and assistance agreements and that the agency's justification for the deviation is inadequate.

The plaintiffs also contend that statutory language included in annual appropriations acts, which Congress enacted in response to similar efforts made in President Trump's first term, specifically bars an across-the-board indirect cost rate cap. As the state attorneys general explained in their Complaint (at ¶ 6) in the first suit:

In 2017, during his first administration, President Trump made a budget proposal that would have reduced the indirect cost rate for research institutions to an across-the-board, categorical rate of 10%. Congress unequivocally responded to ward off such a change to the calculation of indirect cost rates. In 2018, Congress enacted an appropriations rider prohibiting HHS or NIH from spending appropriated funds "to develop or implement a modified approach to" the reimbursement of "indirect costs" and "deviations from negotiated rates." Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, 132 Stat 348, § 226. That rider has remained in effect through every appropriations law governing HHS to this day. See Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224.

The lawsuits thus assert that the NIH Guidance violates the Administrative Procedure Act (APA) because (i) the Guidance is arbitrary and capricious; (ii) it is contrary to law, including HHS grant regulations and the Consolidated Appropriations Acts; and (iii) it bypassed required notice and comment rulemaking. The suits also argue that the NIH Guidance exceeds the agency's statutory authority by imposing retroactive changes affecting existing grants, among other issues.[1]

b. Relief Sought

Despite the similar entitlement theories, the scope of temporary and permanent relief sought in the three cases, if granted, may apply differently to different groups of NIH recipients.

As far as immediate-term relief, all three plaintiff groups filed emergency motions for Temporary Restraining Orders (TROs). In the first suit, the states sought a TRO barring the NIH and HHS and the agencies' officers, employees and agents from "implementing, applying or enforcing" the Guidance ***within the plaintiff states***. Judge Kelley accordingly granted the states a TRO that only precludes the agencies from carrying out the Guidance within the 22 states that brought the lawsuit.

The medical institution plaintiffs in the second suit framed their TRO request to bar the agencies from applying the Guidance to "impacted institutions nationwide." The judge also granted that TRO, barring implementation of the Guidance "***with respect to institutions nationwide*** until further order is issued by this Court." Neither the medical institutions' complaint nor the TRO clearly defines which organizations qualify as "institutions" under the TRO, apart from "impacted institutions" and "nationwide."

In the third suit, the universities and university associations filed for a TRO as well, but the judge denied the motion as moot, referencing the TRO granted in the medical institution suit earlier in the day. That seems to reflect that the TRO in the second suit applies broadly to affected institutions that engage in research under NIH grants or at least engage in medical research under NIH grants. Based on either interpretation, various universities as well as public and private research institutions appear to fall into this implied scope of the second suit's TRO. At a minimum, this TRO must be broader than merely the plaintiff medical institutions or members of the plaintiff medical associations in the second suit, because the universities and university associations are presumably not all members of the medical organizations that are the plaintiffs in the second suit.

Permanent relief sought in the three lawsuits follows a similar track, at least as far as injunctive relief. The plaintiff states in the first lawsuit are asking for a permanent injunction barring the agencies from implementing, applying or enforcing the Guidance within their state boundaries, whereas the medical institutions and universities are asking for a similar bar for similar institutions without any geographic or other limitations except possibly that they must all be within the U.S. and its territories and possessions, given the "nationwide" limit. But all three actions, including the states' suit, ask the Court to declare the Guidance unlawful and set it aside. If the Court grants that

relief in any one of the cases, that would likely prevent NIH from imposing the rate cap on any of its recipients. In addition to the ongoing APA challenges, grant recipients typically can also bring contract claims, which are subject to judicial review under the Tucker Act at the Court of Federal Claims. If the cap were permitted to go into effect while litigation is still ongoing (including any appeals), recipients would need to pursue their own contract actions to recover money damages associated with the cap. Recipients' contract rights may vary depending on the type of assistance agreement and the terms of the award.[2]

3. Practical Suggestions and Concluding Thoughts

The current Presidential Administration has moved quickly to implement its policy priorities in the federal grant arena. The NIH Guidance has created uncertainty for recipients as it could jeopardize recovery of indirect costs if it survives legal challenges. In the meantime, various personnel of all such institutions may be distracted from mission-critical research to addressing these concerns, potentially hindering innovation and scientific advances.

Other funding agencies may follow NIH's lead and impose similar caps on indirect costs. Recipients should monitor developments and consider strategy with counsel on how to respond to government actions that affect them and their awards. That assessment should include developing an approach to any new grant requests to ensure the appropriate F&A rate can be applied if the NIH Guidance is further revised or overturned by judicial decision or further legislative action.

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[1] The government may face a higher bar to uphold the NIH Guidance under *Loper Bright Enters. v. Raimondo*, 603 U.S. 369 (2024). Loper Bright overruled *Chevron U.S.A. Inc. v. Nat. Res. Def. Council,* Inc., 467, U.S. 837 (1984), which had required courts to resolve ambiguities in a statute by deferring to the reasonable interpretation of the agency that administers the statute. By contrast, in *Loper Bright* the Supreme Court stressed that the courts "must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires." *Id.* at 412.

[2] Federal grants are contracts and, as with other contracts, money damages are the presumptive remedy for breach. *Sanders v. United States*, 252 F.3d 1329, 1334 (Fed. Cir. 2001). Money damages may not be available, however, for breach of certain federal assistance agreements. In *Rick's Mushroom Serv., Inc. v. United States*, 521 F.3d 1338 (Fed. Cir. 2008), the Federal Circuit held that money damages were not available under the cost-share agreement at issue. As a result, the Circuit held that the Court of Federal Claims lacked contract jurisdiction under the Tucker Act. For a more detailed discussion of jurisdictional issues in grant disputes, *see* Shaffer, Brent, and Ramish, *Threading the Needle: Navigating Jurisdictional Challenges to Resolve Disputes with the Government Under Federal Assistance Agreements*, Briefing Papers, Volume 2020, Issue 20-12 (Nov. 2020).