Nos. 25-1343, 25-1344, 25-1345

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

COMMONWEALTH OF MASSACHUSETTS; DANA NESSEL, on behalf of the people of the State of Michigan; STATE OF ILLINOIS; STATE OF ARIZONA; STATE OF CALIFORNIA; STATE OF CONNECTICUT; STATE OF COLORADO; STATE OF HAWAII; STATE OF MAINE; STATE OF MARYLAND; STATE OF MINNESOTA; STATE OF NEVADA; STATE OF NEW JERSEY; STATE OF DELAWARE; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OREGON; STATE OF RHODE ISLAND; STATE OF VERMONT; STATE OF WASHINGTON; STATE OF WISCONSIN,

Plaintiffs - Appellees,

v.

NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, M.D., Ph.D. in their official capacity as Director of the National Institutes of Health; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS); ROBERT F. KENNEDY, JR., in their official capacity as Secretary of the U.S. Department of Health and Human Services,

Defendants - Appellants.

ASSOCIATION OF AMERICAN MEDICAL COLLEGES; THE AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY; THE ASSOCIATION OF SCHOOLS AND PROGRAMS OF PUBLIC HEALTH; THE CONFERENCE OF BOSTON TEACHING HOSPITALS, INC.; GREATER NEW YORK HOSPITAL ASSOCIATION,

Plaintiffs - Appellees,

v.

NATIONAL INSTITUTES OF HEALTH; JAY BHATTACHARYA, M.D., Ph.D. in their official capacity as Director of the National Institutes of Health; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS); ROBERT F. KENNEDY, JR., in their official capacity as Secretary of the U.S. Department of Health and Human Services,

Defendants - Appellants.

ASSOCIATION OF AMERICAN UNIVERSITIES; AMERICAN COUNCIL ON EDUCATION; ASSOCIATION OF PUBLIC AND LAND-GRANT UNIVERSITIES; BRANDEIS UNIVERSITY; BROWN UNIVERSITY; CARNEGIE MELLON UNIVERSITY; THE REGENTS OF THE UNIVERSITY OF CALIFORNIA; THE UNIVERSITY OF CHICAGO; CORNELL UNIVERSITY; THE GEORGE WASHINGTON UNIVERSITY; JOHNS HOPKINS UNIVERSITY; MASSACHUSETTS INSTITUTE OF TECHNOLOGY; TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA; UNIVERSITY OF ROCHESTER; TRUSTEES OF TUFTS COLLEGE; THE CALIFORNIA INSTITUTE OF TECHNOLOGY,

Plaintiffs - Appellees,

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES; NATIONAL INSTITUTES OF HEALTH; ROBERT F. KENNEDY, JR., in their official capacity as Secretary of the U.S. Department of Health and Human Services; JAY BHATTACHARYA, M.D., Ph.D. in their official capacity as Director of the National Institutes of Health,

Defendants - Appellants.

On Appeal from the United States District Court for the District of Massachusetts

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OPENING BRIEF FOR DEFENDANTS-APPELLANTS

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INTRODUCTION

The National Institutes of Health (NIH) expends billions of dollars of taxpayer funds each year on research projects intended to enhance health, lengthen life, and reduce illness and disability. It provides those funds to recipient institutions via grant agreements, a form of federal contract.

In February 2025, NIH took steps to achieve a longstanding goal across Administrations: to establish new contract terms that rein in spending on administrative overhead, which has increasingly displaced NIH's ability to fund direct medical research. By limiting such overhead, known as "facilities and administrative" or "indirect" costs, NIH seeks to "ensure that as many funds as possible go towards direct scientific research costs." ADD.83. Specifically, as announced in a February 2025 Supplemental Guidance, NIH will apply "a standard indirect rate of 15%" for "any new grant issued[] and for all existing grants to IHEs [*i.e.*, institutions of higher education]," which will apply "for go forward expenses from February 10, 2025 forward." ADD.84.

Plaintiffs in these three cases are private research institutions, associations, and States (on behalf of public institutions) that receive NIH funding and historically have benefited from higher negotiated indirect-cost rates. They do not deny that NIH has express regulatory authority to deviate from negotiated rates, but maintain that the Supplemental Guidance is

unlawful for various reasons. They brought suit seeking to enjoin NIH from allegedly violating their grant agreements lest they suffer monetary harm.

The district court erred in crediting plaintiffs' challenges. As an initial matter, the court lacked jurisdiction because plaintiffs' Administrative Procedure Act (APA) claims are essentially contractual in nature. The APA's waiver of sovereign immunity for equitable relief, *see* 5 U.S.C. § 702, does not apply when another statute granting consent to sue impliedly precludes the relief sought. Here, the Tucker Act, 28 U.S.C. § 1491(a)(1), provides the relevant statutory waiver of immunity, and it allows only money damages, not injunctions to compel specific performance. For the same reasons that the Supreme Court recently disapproved a similar district-court injunction in another grant dispute, *Department of Education v. California*, 145 S. Ct. 966 (2025) (per curiam), the court likewise lacked jurisdiction here.

In all events, the district court erred in holding the Supplemental Guidance to be unlawful. Far from violating the governing Department of Health and Human Services (HHS) regulations or the annual appropriations riders reaffirming the same, NIH's action directly implements those regulations. The Supplemental Guidance is reasonably explained and accounts for plaintiffs' reliance interests. It did not require notice and comment because the APA expressly exempts matters relating to grants from

rulemaking requirements. And it is not impermissibly retroactive because it applies only to indirect costs on a "go forward" basis, not to costs previously incurred. For the reasons set forth below, this Court should reverse.

STATEMENT OF JURISDICTION

Plaintiffs asserted claims under the Administrative Procedure Act and invoked the district court's jurisdiction under 28 U.S.C. § 1331. J.A.25, 718, 860. As set forth below, defendants maintain that the district court lacked jurisdiction over plaintiffs' claims. The district court entered its final judgments on April 4, 2025, ADD.77-81, and defendants filed timely notices of appeal on April 8, 2025, J.A.696-98, 826-28, 1354-56; *see* Fed. R. App. P. 4(a)(1)(B). This Court has appellate jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether the district court lacked jurisdiction over plaintiffs' APA claims because they are precluded by the Tucker Act, 28 U.S.C. § 1491.

2. Whether the district court erred in finding the Supplemental Guidance to be (a) contrary to HHS regulations or annual appropriations riders; (b) arbitrary and capricious; (c) undertaken without required notice and comment; and (d) impermissibly retroactive.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

1. NIH Grants

The mission of NIH is to "'seek fundamental knowledge about the nature and behavior of living systems' in order to enhance health, lengthen life, and reduce illness and disability." ADD.83. To further that mission, in Fiscal Year (FY) 2023 alone, NIH spent more than $35 billion on almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions across all 50 States and the District of Columbia. *Id.* NIH is "responsible to Congress and the U.S. taxpayer for carrying out its mission in a manner that not only facilitates research but does so cost-effectively." J.A.486.

NIH grant funds are generally disbursed in installments. J.A.492. A grantee draws down its grants on a periodic, as-needed basis, based on costs it incurred or expects to incur during the relevant period. *Id.*

These grants generally cover two types of expenses: direct costs and indirect costs. *See* 45 C.F.R. § 75.400 *et seq*. "Direct costs" are costs "identified specifically with" a particular research project or activity—*i.e.*, the specific research that NIH intends to support with the grant. *Id.* § 75.413(a). For example, in a grant for cancer research, direct costs would include the

"compensation of employees who work on" that research, "their related fringe benefit costs," and "the costs of materials and other items of expense incurred" for that research. *Id.* § 75.413(b). They may also include more general costs "[i]f directly related to a specific award," such as "extraordinary utility consumption" or "the cost of materials supplied from stock or services rendered by specialized facilities or other institutional service operations." *Id.*

NIH grants may also cover certain "indirect costs," also known as "F&A" costs. 45 C.F.R. § 75.414(a). These costs are "classified within two broad categories: 'Facilities' and 'Administration.'" *Id.* "Facilities" costs include "depreciation on buildings, equipment and capital improvement, interest on debt associated with certain buildings, equipment and capital improvements, and operations and maintenance expenses" not associated with particular research. *Id.* "Administration" costs, in turn, include "general administration and general expenses such as the director's office, accounting, personnel and all other types of expenditures not listed" elsewhere. *Id.*

Generally, NIH has paid indirect costs based on an "indirect cost rate" periodically negotiated with each grantee institution pursuant to a negotiated indirect-cost rate agreement (NICRA). 45 C.F.R. § 75.414(c); *see* 2 C.F.R. pt. 200, subpart E & app. III. The higher the indirect-cost rate, the more NIH will reimburse. For example, at Harvard University, which has an indirect-cost

rate of 69% for on-campus research, NIH may pay up to $169,000 for a $100,000 grant: $100,000 in direct costs plus $69,000 in indirect costs.[1] For institutions that have not negotiated rates, a default "de minimis rate of 10%" applies (with further terms not at issue here). *See* 45 C.F.R. § 75.414(f).

As a starting point, HHS's regulations require NIH to use the NICRA rates. *See* 45 C.F.R. § 75.414(c)(1) ("The negotiated rates must be accepted by all Federal awarding agencies."). But those regulations also provide a path for NIH to depart from those rates. The next sentence of section 75.414(c)(1) states that "[a]n HHS awarding agency may use a rate different from the negotiated rate for a class of Federal awards or a single Federal award" in two instances: first, "when required by Federal statute or regulation," and second, "when approved by a Federal awarding agency head or delegate based on documented justification as described in paragraph (c)(3) of this section." *Id.*

These cases involve the latter provision, allowing NIH to "use a rate different from the negotiated rate … when approved by [NIH's] agency head … based on documented justification as described in paragraph (c)(3)." 45 C.F.R. § 75.414(c)(1). Paragraph (c)(3), in turn, provides that "the HHS awarding agency [*i.e.*, NIH] must implement, and make publicly available, the policies,

[1] *See* Harvard Univ., FAS Office of Research Admin., Indirect Costs, https://perma.cc/NU2R-N6XB.

procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates." *Id.* § 75.414(c)(3). Aside from that procedural requirement, the regulations impose no substantive constraint on the ability of NIH or other HHS grant-making components to deviate from negotiated indirect-costs rates, whether "for a class of Federal awards or a single Federal award." *Id.* § 75.414(c)(1).

Historically, indirect costs have consumed a substantial share of NIH grant funding, in accordance with NICRA rates that vary significantly from institution to institution. The indirect-cost rate applicable to NIH-funded institutions has averaged between 27% and 28% over time. ADD.83. But some organizations have indirect-cost rates of 50% or even higher. *Id.*

Universities that accept NIH funds also routinely accept grants from private foundations. ADD.83. Private foundations are not bound by NICRA rates and, indeed, generally provide much lower indirect-cost rates for the research they fund: some of the largest foundations use indirect-cost rates of 10% to 15%, while others do not fund indirect costs at all. *Id.* Nearly all universities accept grants from private foundations notwithstanding their more limited reimbursement of indirect costs. *Id.*

2. Appropriations Riders

In his 2017 annual budget submission to Congress, the President proposed certain steps for NIH to "improve agency management by reducing duplication[] and reducing both agency and grantee administrative costs." J.A.94. In particular, he "propose[d] to reduce reimbursement of grantee administrative and facilities costs, referred to as 'indirect costs,' so that available funding can be better targeted toward supporting the highest priority research on diseases that affect human health." *Id.* The budget specifically proposed an "indirect cost rate for NIH grants that will be capped at 10 percent." *Id.* This 10% cap would "bring NIH's reimbursement rate for indirect costs more in line with the reimbursement rate used by private foundations, such as the Gates Foundation, for biomedical research conducted at U.S. universities." *Id.*

After considering the President's proposal, Congress did not direct NIH to depart from negotiated indirect-cost rates by adopting the proposed 10% statutory cap on indirect costs. But neither did Congress prohibit NIH from deviating from negotiated indirect-cost rates. Instead, in a rider accompanying its appropriations measure for FY 2018, Congress provided:

> In making Federal financial assistance, the provisions relating to indirect costs in part 75 of title 45, Code of Federal Regulations, including with respect to the approval of deviations from negotiated rates, shall continue to apply to the National Institutes of Health to

> the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017. None of the funds appropriated in this or prior Acts or otherwise made available to the Department of Health and Human Services or to any department or agency may be used to develop or implement a modified approach to such provisions, or to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter.

Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, div. H, tit. II, § 226, 132 Stat. 348, 740.

To date, Congress has included this same rider in every subsequent appropriations enactment for HHS. *See, e.g.*, Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, div. D, tit. II, § 224, 148 Stat. 460, 677; ADD.7 (collecting additional citations).

3. NIH Grant Policy Guidance

NIH annually issues a Grants Policy Statement that collects policy requirements that serve as the terms and conditions of NIH grant awards. *See* J.A.434-530 (excerpts of 2024 Grants Policy Statement). "By accepting an award, recipients agree to comply with the requirements in the NIH Grants Policy Statement except where the notice of award states otherwise." NIH, *NIH Grants Policy Statement*, https://perma.cc/7GUY-PWFG.

In addition, throughout the year, NIH publishes ad hoc policy notices in its Guide for Grants and Contracts. *See* J.A.437 ("Changes in statutes, regulations, or policies that take effect before the next revision of the [Grants

Policy Statement] will be published separately in the *NIH Guide for Grants and Contracts*.”). These policy notices “supersede information in the NIH Grants Policy Statement,” and “[c]ompliance with these policy updates become[s] a term and condition of award.” NIH, *Notices of NIH Policy Changes*, https://perma.cc/7JFX-QT2B. NIH typically issues dozens of such policy updates over the course of each fiscal year. *See id.*

B. The February 2025 Supplemental Guidance

These cases concern one such ad hoc policy notice—the Supplemental Guidance—issued by NIH on February 7, 2025, addressing indirect-cost rates. *See* ADD.81-83 (NIH, Notice No. NOT-OD-25-068, *Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates* (Feb. 7, 2025)).[2]

1. The animating policy of the Supplemental Guidance is that “NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life.” ADD.83. It observes that, although many grant recipients “use grant funds to cover indirect costs like overhead,” those indirect costs are “difficult for NIH to oversee” and do not as directly further NIH’s mission. ADD.83-84. In order to ensure that the United States has “the best medical research in the

[2] The Supplemental Guidance’s number, “NOT-OD-25-068,” reflects it was the 68th update issued in FY 2025.

world," NIH reasoned, it is "vital to ensure that as many funds as possible go towards direct scientific research costs rather than administrative overhead." ADD.83.

The Supplemental Guidance explains that NIH's funding of indirect costs has grown markedly as a result of recipient institutions having negotiated particularly favorable rates in their NICRAs. For example, of the "more than $35 [b]illion" spent by NIH on grants in FY 2023, some $9 billion went not to direct research but rather was "allocated to overhead." ADD.83. Indeed, not only has the average indirect-cost rate by NIH "averaged between 27% and 28% over time," but the indirect-cost rates paid to major institutions have been substantially higher still, including "rates of over 50% and in some cases over 60%." *Id.* Those rates are significantly greater than the default 10% indirect-cost rate that would otherwise apply absent a NICRA. *Id.* (citing 45 C.F.R. § 75.414(f)).

The Supplemental Guidance explains that these negotiated rates greatly exceed private grantmaking standards. "Most private foundations that fund research provide substantially lower indirect costs than the federal government," yet "universities readily accept grants from these foundations" notwithstanding those lower rates. ADD.83. For example, the Bill and Melinda Gates Foundation—one of the Nation's largest funders of medical

research—has a "maximum indirect costs rate [of] 10% for institutions of higher education" (and a maximum rate of 15% for other recipients). *Id.* The Smith Richardson Foundation likewise has a maximum indirect-cost rate of 10%. *Id.* The Gordon and Betty Moore Foundation and Robert Wood Johnson Foundation have maximum indirect-cost rates of 12%. *Id.* At least five other leading funders—the Carnegie Corporation of New York; the Chan Zuckerberg Initiative; the John Templeton Foundation; the Packard Foundation; and the Rockefeller Foundation—have maximum indirect-cost rates of 15%, either in general or with respect to universities specifically. *Id.*

Those larger foundations' indirect-cost rates are not only much lower than NIH's indirect-cost rates, but also are at the upper end of the private spectrum. One study "found that the most common rate of indirect rate reimbursement by foundations was 0%, meaning many foundations do not fund indirect costs whatsoever." ADD.83. Universities have nonetheless accepted grants from such funders. According to one analysis, "[o]f 72 universities in the sample, 67 universities were willing to accept research grants that had 0% indirect cost coverage." *Id.* Two universities that did not accept such grants—Harvard and the California Institute of Technology—nonetheless accepted grants with indirect-cost rates of 15% and 20%, respectively. *Id.*

2. In light of these considerations, the Supplemental Guidance provides that "there will be a standard indirect rate of 15% across all NIH grants" to IHEs, which shall apply "in lieu of a separately negotiated rate for indirect costs in every grant." ADD.82. NIH noted that this standard 15% rate is "50% higher than the 10% de minimis indirect cost rate" that already applies by regulation in the absence of individually negotiated rates. ADD.83. And the standard 15% rate remains consistent, if not more generous than, "the private sector indirect cost rates" that NIH had surveyed. ADD.84.

The Supplemental Guidance states that "[t]his policy shall be applied to all current grants for go forward expenses from February 10, 2025 forward as well as for all new grants issued." ADD.84. As a result, "[f]or any new grant issued[] and for all existing grants to IHEs retroactive to the date of issuance of this Supplemental Guidance [*i.e.*, February 7, 2025], award recipients are subject to a 15 percent indirect cost rate." *Id.*

NIH explained that it was adopting this standard 15% rate pursuant to express regulatory authority. *See* ADD.82 (discussing 45 C.F.R. § 75.414(c)). Although, as noted (*supra* p. 6), section 75.414(c)(1) presumptively requires the use of NICRA rates, that provision also authorizes NIH to "use a rate different from the negotiated rate"—whether for "a single Federal award" or for "a class of Federal awards"—"when approved by a Federal awarding agency head or

delegate based on documented justification" setting forth "the policies, procedures and general decision-making criteria that [NIH] will follow to seek and justify deviations from negotiated rates." 45 C.F.R. § 75.414(c)(1), (3). The Supplemental Guidance thus "implements and makes publicly available NIH's updated policy deviating from the negotiated indirect cost rate for new grant awards and existing grant awards" for IHEs. ADD.82.

C. Procedural History

1. Plaintiffs in these three cases are various States, universities, medical schools, hospital groups, and related membership associations. Plaintiffs filed suit under the APA challenging the Supplemental Guidance on various grounds and, in the interim, demanded emergency relief.

At plaintiffs' request, the district court immediately entered temporary restraining orders against implementation of the Supplemental Guidance—initially only for the benefit of grantees in the plaintiff States (*i.e.*, plaintiffs in No. 25-1343), but later for the benefit of all grantees nationwide. J.A.406-07, 740-41. The court then extended those TROs while it considered the parties' arguments in a preliminary-injunction posture. J.A.18, 708, 853.

The government opposed plaintiffs' motions for preliminary relief. It explained that plaintiffs' claims were not actionable in district court because they seek to enforce contractual grant-making arrangements for which relief is

limited to that authorized by the Tucker Act. In all events, the government explained that the Supplemental Guidance was a permissible exercise of NIH's regulatory authority and was lawful and reasonable in all other respects.

2. On March 5, 2025, the district court entered a nationwide preliminary injunction against the Supplemental Guidance. ADD.1-76.

a. At the threshold, the district court rejected the government's argument that it lacked jurisdiction over plaintiffs' APA claims. ADD.8-16. The court acknowledged that courts lack subject-matter jurisdiction over claims against the United States absent a "waiver of sovereign immunity," ADD.9, and it did not dispute that the APA's waiver in 5 U.S.C. § 702 is inapplicable when "any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought," *see* ADD.10. The court further acknowledged that the Tucker Act contains a separate waiver of immunity against the United States applicable to claims sounding in contract, ADD.9, and it agreed with the government that "the Notice of Award" pursuant to which each recipient institution draws grant funding "operates as a contract," ADD.12. The court also recognized that a plaintiff cannot skirt Tucker Act jurisdiction simply by "converting complaints which at their essence seek money damages ... into complaints requesting injunctive relief or declaratory actions." ADD.11 (quotation marks omitted). And the court did not dispute

that plaintiffs effectively seek specific performance of NIH's preexisting grant obligations—an equitable remedy that, notably, the Tucker Act does not authorize against the government.

The district court nonetheless concluded that plaintiffs' claims here could proceed. Applying a "'rights and remedies' test" developed by other courts of appeals, ADD.11, the court reasoned that plaintiffs' claims should be construed as sounding under the APA. First, the court noted that plaintiffs' demands for adherence to existing contractual terms rested on allegations that the government's deviation from those terms would violate other law. Because plaintiffs' claims "ask[] this Court to review and interpret the governing federal statute and regulations," ADD.12-13, the court concluded that the "source in which Plaintiffs aim to vindicate their rights … is actually in the regulation that facilitates such grants," ADD.13, rather than the grants themselves. Second, the district court "turn[ed] to the type of relief sought by Plaintiffs." *Id.* The court recognized that plaintiffs brought "an equitable action for specific relief" to require the government to comply with the "negotiated rates for indirect costs" in the parties' contracts. ADD.13-14 (quotation marks omitted). The court concluded, however, that this favored plaintiffs' position because plaintiffs were not seeking "monetary relief" and their complaints did not "refer to compensatory damages." ADD.14.

b. On the merits, the district court determined that plaintiffs established a likelihood of success on their APA claims in several respects. ADD.17-56.

First, the district court concluded that the Supplemental Guidance likely exceeded NIH's regulatory authority. The court acknowledged that 45 C.F.R. § 75.414(c) authorizes NIH to "deviate" from individually negotiated indirect-cost rates, ADD.19, but it concluded that the Supplemental Guidance did not successfully invoke that authority. The court stated that, in its view, the Supplemental Guidance did not provide "any requisite *documented justification*" for the deviation. ADD.20. In particular, the court faulted the Supplemental Guidance for not "offer[ing] ... procedures and decision making criteria" that NIH "'will follow to seek and justify' the deviations from the negotiated rates," and for instead "purport[ing] to announce a single, uniform policy for all current and future grants" in "one fell swoop." *Id.* The court stated that, in its view, the regulation requires a "sequential process" under which NIH "'must'—present tense—make available the policies, procedures, and decision making criteria that the Agency 'will follow'—future tense—to seek and justify the deviation" at some later time. *Id.* Moreover, the court questioned NIH's ability to pursue a uniform policy. It acknowledged that the regulation allows NIH to "deviate ... for 'a *class of Federal awards*,'" ADD.21 (quoting 45 C.F.R.

§ 75.414(c)(1)), but suggested that that phrase must be interpreted as referring only "to a subset, as opposed to all, federal awards." *Id.*

The district court found "further assurances" for its regulatory interpretation in Congress's annual appropriations riders. ADD.22; *supra* pp. 8-9 (text of rider). The court deemed the rider's principal clause—which states that relevant provisions of 45 C.F.R. Part 75 "'shall continue to apply to [NIH] to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017'"—not merely to require adherence to NIH's regulations, but to "prevent the Administration from implementing" any uniform deviation. ADD.25. The court also deemed the rider's remaining clauses, which reinforce that NIH must adhere to "'such provisions,'" to similarly prohibit not only procedural departure from the regulations but also substantively to prohibit any "universal cap" on indirect costs. ADD.25-27.

Second, the district court concluded that the Supplemental Guidance was likely arbitrary and capricious. ADD.28-43. The court acknowledged that "[t]he scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." ADD.30 (alteration in original) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)). It nonetheless found the Supplemental Guidance to be unlawful on the basis that its reasoning was too "conclusory"

in certain respects. ADD.32. For example, although the Supplemental Guidance explained that capping indirect costs would free up more federal funding to "go to direct research," NIH does not "address how the money will actually be directed to cover direct costs." ADD.33. Similarly, though the Supplemental Guidance had explained that "indirect costs are difficult to oversee"—in that by definition they are not directly attributable to any particular project—the court found that NIH had not sufficiently demonstrated "the inadequacy of the existing audit system." ADD.34.

The district court also found that the Supplemental Guidance did not sufficiently account for grantees' reliance interests. It acknowledged that the Supplemental Guidance was "cognizant that grant recipients, particularly 'new or inexperienced organizations,' use grant funds to cover indirect costs like overhead." ADD.41. But it found NIH's discussion to be "plainly insufficient" because, among other things, it was not accompanied by any expressly stated judgment that "'other interests justifying the Supplemental Guidance outweighed [plaintiffs'] interest'" or that a 15% cap "'would not unduly upset their reliance interests.'" ADD.41-42. The court rejected the government's argument that such judgments were inferable from the face of the Supplemental Guidance, finding those arguments to be "'mere[] 'post hoc'

rationalizations'" and, in any event, insufficient to "consider the substantial and long-standing reliance interests" of grant recipients. ADD.42-43.

Third, the district court concluded that the Supplemental Guidance was likely procedurally invalid for lack of notice and comment. ADD.44-52. The court acknowledged that the APA expressly exempts from notice-and-comment rulemaking "matter[s] relating to agency … *grants*." ADD.45 (quoting 5 U.S.C. § 553(a)(2)). But the court concluded that HHS had waived the applicability of that statute through a 1971 policy statement. *Id*. The court concluded that once the agency had voluntarily adopted this policy, it was required to "follow" it, even though not statutorily required by the APA. ADD.46-49. And the court held that the Supplemental Guidance was a "legislative rule" that required notice-and-comment rulemaking. ADD.50.

Finally, the district court found that plaintiffs were likely to succeed in showing that the Supplemental Guidance was impermissibly retroactive as applied to existing grants. ADD.52-55. It concluded that, even though the 15% cap expressly applies only to "'go-forward' expenses" as of February 10, 2025, the Supplemental Guidance nonetheless "impair[s] the rights the institution[s] possessed" when they accepted the grant awards against the backdrop of previously negotiated NICRA rates. ADD.54.

The district court concluded that the remaining preliminary injunction factors favored plaintiffs. ADD.56-71. And addressing the scope of relief, the court found that the equities supported a nationwide injunction. ADD.71-75.

3. Because the court's preliminary-injunction order fully addressed the relevant record and decided the dispositive legal questions, the parties agreed that further proceedings in district court were unnecessary. The government accordingly moved for entry of final judgment, with plaintiffs' consent.

On April 4, 2025, the district court entered final judgment and a permanent injunction in each case. ADD.77-79. The court found that "[f]or reasons stated" in its prior opinion, it "has jurisdiction over Plaintiffs' claims" notwithstanding limitations on the APA's waiver of sovereign immunity. ADD.78. It also reaffirmed its earlier conclusions that the Supplemental Guidance "(1) violated 45 C.F.R. § 75.414 and [the appropriations rider]; (2) was arbitrary and capricious; (3) failed to follow notice-and-comment procedures; and (4) was impermissibly retroactive." *Id*. (footnotes omitted). The court vacated the Supplemental Guidance "in its entirety" and enjoined defendants from "taking any steps to implement, apply, or enforce [the Supplemental Guidance] in any form with respect to institutions nationwide." ADD.80.

SUMMARY OF ARGUMENT

NIH issued the Supplemental Guidance to address a longstanding policy concern: the substantial share of taxpayer funds that are annually expended on administrative overhead rather than on direct medical research. Although indirect costs can support related research functions, every dollar spent on indirect costs is one not spent on NIH's core mission. NIH determined, after considering its regulatory authority and surveying private-sector grantmaking practices, that a deviation from previously negotiated indirect-cost rates was warranted under 45 C.F.R. § 75.414(c) and that a standard rate of 15% for IHEs would best accommodate the competing policy concerns at stake. Plaintiffs, who prefer their higher NICRA rates, assert that the standard rate set forth in the Supplemental Guidance would breach NIH's grant agreements, and they sued to seek an injunction to prevent that breach.

I. The district court erred in assuming jurisdiction. Jurisdiction exists over claims against the United States only if sovereign immunity has been waived, and the APA waives immunity for nonmonetary relief only if another statute granting consent to sue does not impliedly forbid that relief. Here, plaintiffs' claims are in essence contractual and so governed by the Tucker Act, which authorizes money damages in the event of contract breach but does not allow courts to grant specific performance. 28 U.S.C. § 1491. The Supreme

Court recently recognized this point in a related grantmaking dispute, *see Department of Education v. California*, 145 S. Ct. 966 (2025) (per curiam), and its reasoning likewise counsels dismissal here. Plaintiffs cannot obtain an order directing the NIH to perform according to their preferred contractual terms.

II. In all events, the Supplemental Guidance is lawful.

A. NIH issued the Supplemental Guidance pursuant to express regulatory authority under 45 C.F.R. § 75.414(c). That regulation allows NIH to "use a rate different from the negotiated [indirect cost] rate for a class of Federal awards" when, as here, the deviation is "approved by a Federal awarding agency head … based on documented justification as described in paragraph (c)(3)." *Id.* § 75.414(c)(1). "[P]aragraph (c)(3)" in turn "describe[s]" the procedural requirement to "make publicly available[] the policies, procedures and general decision making criteria" governing those "deviations from negotiated rates." *Id.* § 75.414(c)(3). And the appropriations riders simply confirm that NIH must follow those regulations. The district court erred in construing the regulations and appropriations riders to impose further, atextual limitations on NIH's authority.

B. The Supplemental Guidance is both reasonable and reasonably explained. It concisely articulates in readily-understood fashion the basis for NIH's concerns about indirect rates and the reasons why it has chosen to

address those concerns by implementing a new uniform rate of 15%. And it expressly acknowledges the reliance interests of recipient institutions in the prior negotiated-cost regime. The district court's criticisms of the Supplemental Guidance amount to a policy disagreement with NIH's actions and do not identify any legal deficiency in NIH's explanation.

C. The Supplemental Guidance did not require notice and comment. The APA expressly exempts "matter[s] relating to ... grants" from its rulemaking requirements. 5 U.S.C. § 553(a)(2). HHS's former policy of voluntarily affording notice and comment for such matters cannot be judicially enforced against NIH. In all events, HHS has since rescinded that policy, so any error is now harmless: vacatur will not result in notice and comment.

D. The Supplemental Guidance is not retroactive. It applies only to "go forward" expenses as of February 10, 2025. ADD.84. Neither governing principles of retroactivity nor NIH regulations afford recipient institutions a blanket exemption from all future changes in NIH policy during the life of their grants. Plaintiffs' arguments are properly addressed under APA arbitrary-and-capricious review, not under retroactivity doctrine.

STANDARD OF REVIEW

All issues before this Court are questions of law reviewed de novo. *See Marasco & Nesselbush, LLP v. Collins*, 6 F.4th 150, 166 (1st Cir. 2021) ("whether a claim is justiciable under the APA"); *Jette v. United of Omaha Life Ins. Co.*, 18 F.4th 18, 26 (1st Cir. 2021) (regulatory interpretation); *Historic Bridge Found. v. Buttigieg*, 22 F.4th 275, 282 (1st Cir. 2022) (arbitrary-and-capricious review); *New Hampshire Hosp. Ass'n v. Azar*, 887 F.3d 62, 70 (1st Cir. 2018) (notice-and-comment); *Coskery v. Berryhill*, 892 F.3d 1, 4-5 (2018) (retroactivity).

ARGUMENT

I. THE DISTRICT COURT LACKED JURISDICTION OVER PLAINTIFFS' APA CLAIMS.

A. The APA Does Not Apply When Relief Is Impliedly Precluded By The Tucker Act.

"Absent a waiver, sovereign immunity shields the Federal Government and its agencies from suit." *FDIC v. Meyer*, 510 U.S. 471, 475 (1994). Sovereign immunity is jurisdictional: "the terms of the United States' consent to be sued in any court define that court's jurisdiction." *Id.* (brackets and quotation marks omitted).

APA Section 702 provides "a limited waiver of sovereign immunity for claims against the United States" that seek "'relief other than money damages.'" *Crowley Gov't Servs., Inc. v. GSA*, 38 F.4th 1099, 1105 (D.C. Cir.

2022) (quoting 5 U.S.C. § 702). But section 702's waiver of immunity facially "does not apply 'if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.'" *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 215 (2012) (quoting 5 U.S.C. § 702). That carve-out "prevents plaintiffs from exploiting the APA's waiver to evade limitations on suit contained in other statutes." *Id.*; *see, e.g.*, *Berman v. United States*, 264 F.3d 16, 21 (1st Cir. 2001) (holding that section 702 did not waive immunity where "other statute[]"—there, a tax statute—"expressly forbids" the relief sought).

When a party demands continued payment of funds it believes the federal government is obligated to pay by contract, the relevant "statute that grants consent to suit" is the Tucker Act. The Tucker Act vests the Court of Federal Claims with exclusive "jurisdiction to render judgment upon any claim against the United States founded ... upon any express or implied contract with the United States" for amounts over $10,000. 28 U.S.C. § 1491(a)(1).[3]

As the D.C. Circuit has explained, "the Tucker Act impliedly forbids" bringing "contract actions" against "the government in a federal district court." *Albrecht v. Committee on Emp. Benefits of the Fed. Reserve Emp. Benefits Sys.*,

[3] A parallel provision, the Little Tucker Act, authorizes concurrent district-court jurisdiction but only for claims "not exceeding $10,000 in amount." 28 U.S.C. § 1346(a)(2). That provision is not applicable here.

357 F.3d 62, 67-68 (D.C. Cir. 2004) (quotation marks omitted). This prohibition extends to claims founded on grants that are implemented through "contracts to set the terms of and receive commitments from recipients." *Boaz Hous. Auth. v. United States*, 994 F.3d 1359, 1368 (Fed. Cir. 2021). The proper recourse for asserted violations of such grant agreements is a "suit in the Claims Court for damages relating to [the] alleged breach." *Id.*

As this Court has long recognized, a plaintiff's own characterization of its claims does not control. If "the essence of the action is in contract," a plaintiff "cannot 'by the mystique of a different form of complaint' make it otherwise." *American Sci. & Eng'g, Inc. v. Califano*, 571 F.2d 58, 63 (1st Cir. 1978). In particular, "[a] plaintiff cannot transform a claim for damages into an equitable action by asking for an injunction that orders the payment of money." *Burgos v. Milton*, 709 F.2d 1, 3 (1st Cir. 1983) (quoting *Jaffee v. United States*, 592 F.2d 712, 715 (3d Cir. 1979)); *see Diaz v. Johnson*, No. 19-1501, 2020 WL 9437887, at *2 (1st Cir. Nov. 12, 2020) ("Because it seems clear that the injury [the plaintiff] is alleging is pecuniary in nature and at bottom what he seeks is monetary relief based on what he perceived as a contract ... [he] cannot manufacture an APA claim by asking the court to declare that the failure to fund his proposal was an arbitrary or capricious act."). Other courts of appeals, applying these same principles, have looked at both "the source of

the rights upon which the plaintiff bases its claims" and "the type of relief sought (or appropriate)." *Megapulse, Inc. v. Lewis*, 672 F.2d 959, 968 (D.C. Cir. 1982); *see also, e.g.*, *Cohen v. Postal Holdings, LLC*, 873 F.3d 394, 403 (2d Cir. 2017) (applying *Megapulse* test).

The Supreme Court recently confirmed the Tucker Act's substantial preclusive scope with respect to APA claims in *Department of Education v. California*, 145 S. Ct. 966, 968 (2025) (per curiam). There, this Court had initially declined to disturb a district court order requiring the government to fulfill certain grant agreements. *See California v. U.S. Dep't of Educ.*, 132 F.4th 92 (1st Cir. 2025). But the Supreme Court then stayed the district court's order, concluding that the government was likely to succeed in showing the court "lacked jurisdiction to order the payment of money under the APA." *Department of Educ.*, 145 S. Ct. at 968. The Court confirmed that "the APA's limited waiver of immunity does not extend to orders 'to enforce a contractual obligation to pay money' along the lines of what the District Court ordered." *Id.* (quoting *Great-West Life & Annuity Ins. Co.* v. *Knudson*, 534 U.S. 204, 212 (2002)).

B. Plaintiffs' Claims Are In Essence Contractual.

For much the same reasons given by the Supreme Court in *Department of Education*, the district court here likewise erred in assuming jurisdiction.

The "essence" of plaintiffs' claims is "in contract." *American Sci. & Eng'g*, 571 F.2d at 63. Notably, all agree that NIH grant agreements are contracts within the meaning of the Tucker Act. *Cf.* ADD.12 (acknowledging that "Notice of Award operates as a contract"). Those agreements bear all the hallmarks of a contract: they are written arrangements, agreed to by both NIH and the recipient institution, that set forth the maximum amount that NIH agrees to pay for specified research; the research that the recipient is to perform in exchange for the payment; the performance period for the project; and the applicable terms and conditions of the grant. *See* J.A.424-29 (sample Notice of Award); *see also, e.g.*, *Bennett v. New Jersey*, 470 U.S. 632, 638 (1985) (noting that "many ... federal grant programs" are "much in the nature of a contract") (quotation marks omitted); *Columbus Reg'l Hosp. v. United States*, 990 F.3d 1330, 1338 (Fed. Cir. 2021) (generally "treating federal grant agreements as contracts when the standard conditions for a contract are satisfied").

Plaintiffs frame their key allegations in contract language. They allege that they "have negotiated indirect cost rates with NIH" pursuant to NICRAs and, in turn "have executed agreements" for grant awards that incorporate the NICRA rates. J.A.38 (*Mass.* Compl. ¶ 86). They assert that "[o]nce the [Notice of Award] is signed or money is drawn, the [Notice of Award] and the

grant terms are binding on the grantee and the government." J.A.30 (*id.* ¶ 47) (citation omitted).

And plaintiffs allege that NIH's modification of indirect-cost rates fails "to comply with the terms" of their existing grant agreements and would, if implemented, "constitute a breach of the NIH's obligations." J.A.30-31 (*Mass.* Compl. ¶ 47). Notably, the grant terms relied upon by plaintiffs include 45 C.F.R. Part 75 and provisions therein, *see* J.A.65-66, 726-27, 869-70 (*Mass.* Compl. ¶¶ 188-196; *AAU* Compl. ¶¶ 109-114; *AAMC* Compl. ¶¶ 50-52), all of which are expressly "incorporated ... by reference" into their Notices of Award, J.A.426; *see* J.A.490 (reflecting that "grant program legislation and program regulation" are "terms and conditions" of the grant agreement itself); 2 C.F.R. § 200.300(a) (similar). At bottom, plaintiffs' actions are contractual, and they "cannot 'by the mystique of a different form of complaint' make it otherwise." *American Sci. & Eng'g*, 571 F.2d at 63.

The doctrinal framework applied by other courts of appeals leads to the same result. *Cf.* ADD.11 (observing that this Court has not "formally adopted" the D.C. Circuit's *Megapulse* framework). First, "the source of the rights upon which the plaintiff[s] base[] [their] claims," *Megapulse*, 672 F.2d at 968, is contractual. As discussed, plaintiffs' claimed harm is a feared reduction in the amount of their NIH research grants. And the central legal basis for

their claims—alleged violations of the federal regulations governing NIH grants—are terms incorporated into the contracts themselves.

Second, "the type of relief sought," *Megapulse*, 672 F.2d at 968, likewise weighs against plaintiffs here. The continued payment of grant funds at the higher NICRA rates, far from being merely incidental to or "hint[ed] at" by plaintiffs' request for relief, is the entire object of their suit. *Crowley*, 38 F.4th at 1112 (quotation marks omitted). As the district court recognized, plaintiffs seek to "requir[e] the government to respect negotiated rates for indirect costs" set forth in plaintiffs' grant agreements. ADD.13 (quotation marks omitted). In other words, plaintiffs seek specific performance of previously existing grant agreements—a prototypical contract remedy. *See* Restatement (Second) of Contracts § 357 cmt. a ("An order of specific performance .... orders a party to render the performance that he promised."). But that remedy is not available in a contract claim against the federal government: a plaintiff's remedy is damages for any underpayment, not an injunction to continue payments. *See Coggeshall Dev. Corp. v. Diamond*, 884 F.2d 1, 3 (1st Cir. 1989) ("Federal courts do not have the power to order specific performance by the United States of its alleged contractual obligations."); *Berman*, 264 F.3d at 21 (similar).

A grantee cannot obtain an impermissible contractual remedy by restyling its claim under the APA, thus circumventing the limitations designed

by Congress upon its waivers of sovereign immunity. "[T]he Tucker Act impliedly forbids—in APA terms—not only district court awards of money damages, which the Claims Court may grant, but also injunctive relief, which the Claims Court may not." *Albrecht*, 357 F.3d at 67-68 (quotation marks omitted).

C. The District Court Erred In Asserting Jurisdiction Over This Contractual Dispute.

As the district court recognized, NIH's "grants are treated as contracts," and plaintiffs allege that the Supplemental Guidance violates NIH's grant obligations. ADD.12. That should have led the court to decline jurisdiction.

The district court suggested that plaintiffs' claims sound not in contract, but rather in judicial review of administrative action, because plaintiffs focus on the Supplemental Guidance and ask the court to consider its consistency with "the governing federal statute and regulations." ADD.13. But as the court itself stated, in determining jurisdiction, courts must "look beyond the form of the pleadings to the substance of the claim." ADD.11 (quoting *Suburban Mortg. Assocs., Inc. v. U.S. Dep't of Hous. & Urban Dev.*, 480 F.3d 1116, 1124 (Fed. Cir. 2007)). Here the substance of the claim is contractual, as the Supplemental Guidance itself reflects: the very purpose of the Guidance is to set forth permissible contract terms.

Claimed violations of statutory or regulatory provisions do not oust a court from Tucker Act jurisdiction. On the contrary, the Tucker Act embraces monetary claims based on "any Act of Congress or any regulation of an executive department," 28 U.S.C. § 1491(a)(1), and plaintiffs in breach-of-contract suits often rely on statutes and regulations as sources of claimed rights. The fact that plaintiffs have identified an alleged final agency action (the Supplemental Guidance) purportedly infringing upon their contractual rights would not divest the Court of Federal Claims of jurisdiction to adjudicate their contractual claims. *Cf. Ingersoll-Rand Co. v. United States*, 780 F.2d 74, 77 (D.C. Cir. 1985) (reaffirming "the well-accepted proposition that a plaintiff may not avoid the jurisdictional bar of the [Contract Disputes Act] merely by alleging violations of regulatory or statutory provisions rather than breach of contract").

In all events, the district court's reasoning cannot be reconciled with the Supreme Court's intervening stay decision in *Department of Education*. The States there, like plaintiffs here, argued that their suit could proceed under the APA because their "claims are 'derived from' statutes and regulations, not contracts." Opposition to Application at 22, *Department of Educ.*, 145 S. Ct. 966 (No. 24A910), 2025 WL 963588. In initially crediting that argument, the district court in *Department of Education* had relied expressly on the district

court's opinion in this case, which it described as a "substantially similar" case involving "this precise issue." *See California v. U.S. Dep't of Educ.*, No. 25-cv-10548, 2025 WL 760825, at *1 (D. Mass. Mar. 10, 2025) ("agree[ing] with[] and adopt[ing]" the district court's reasoning here that plaintiffs' actions are "not contractual in nature since the source of the plaintiffs' rights [are] in federal statute and regulations and because the relief was injunctive"). But the Supreme Court, in staying that order, necessarily rejected the suggestion that a mere reliance on "statutes and regulations" can allow plaintiffs to escape the Tucker Act's preclusive scope, as other courts have since recognized.[4]

The district court's reliance on *Bowen v. Massachusetts*, 487 U.S. 879 (1988), was likewise misplaced. *Cf.* ADD.14-15. Critically, although *Bowen* recognized the ability of district courts in appropriate cases to provide equitable relief that may ultimately result in the payment of money, *Bowen* did not involve contracts or grant agreements with the government. Indeed, the Supreme Court expressly cited *Bowen* in its recent *Department of Education* stay decision but saw no conflict between *Bowen* and its conclusion that the

[4] *See, e.g.*, *Widakuswara v. Lake*, Nos. 25-5144 et al., 2025 WL 1288817, at *2-*5 (D.C. Cir. May 3, 2025) (per curiam) (granting stay where government would likely succeed in showing that district court lacked jurisdiction to "compel the agency to restore [plaintiffs'] FY 2025 grants"); *American Ass'n of Colls. for Teacher Educ. v. McMahon*, No. 25-1281, 2025 WL 1232337 (4th Cir. Apr. 10, 2025) (likewise granting stay in case where the district court had relied extensively on jurisdictional reasoning of district court here).

government was likely to succeed in showing that the district court lacked jurisdiction. *See Department of Educ.*, 145 S. Ct. at 968.

The district court also erred in its reliance on the fact that plaintiffs "seek equitable, not monetary, relief." ADD.15; *see* ADD.14 ("None of Plaintiffs' Complaints refer to compensatory damages."). That will be true any time a plaintiff attempts to plead around the Tucker Act by "requesting injunctive relief or declaratory actions." ADD.11 (quotation marks omitted). Thus, the controlling question is not whether plaintiffs expressly seek an award of damages but, rather, whether they are in "essence" seeking contract remedies. *American Sci. & Eng'g*, 571 F.2d at 63; *see also Megapulse*, 672 F.2d at 968 (similar). Here, plaintiffs seek specific performance of contractual obligations by the government; the Tucker Act "impliedly forbids" that relief under the APA. *Albrecht*, 357 F.3d at 67-68 (quotation marks omitted).

Finally, the district court erred in placing reliance on the fact that the Supplemental Guidance addresses "not just … current grants, but future ones as well." ADD.12-13. To the extent plaintiffs have established standing to sue, it is because they are recipients of current grants. Plaintiffs cannot use these suits as a vehicle to compel the payment of money at higher rates under hypothetical future contracts that do not yet exist. Again, the Tucker Act provides the relevant waiver of immunity for claims addressing contract

performance, and such claims require the alleged breach of an extant "binding agreement." *Anderson v. United States*, 344 F.3d 1343, 1353 (Fed. Cir. 2003). Plaintiffs cannot evade the Tucker Act by melding claims founded on existing grants with premature, foredoomed claims founded upon future grants.

Despite plaintiffs' "valiant effort to frame the suit as one for declaratory or injunctive relief," this litigation "should be understood for what it is": an effort to compel the government's performance of contractual obligations. *Suburban Mortg. Assocs.*, 480 F.3d at 1118. Because "the Court of Federal Claims can provide an adequate remedy" for breach of contract, these suits "belong[] in that court" instead. *Id.*; *accord, e.g.*, *U.S. Conference of Catholic Bishops v. U.S. Dep't of State*, No. 1:25-cv-465, 2025 WL 763738, at *5 (D.D.C. Mar. 11, 2025) (refusing jurisdiction where plaintiffs' APA claims, "[s]tripped of [their] equitable flair," in fact "seek[] one thing: ... the Court to order the Government to stop withholding the money due" under certain grants).

II. THE SUPPLEMENTAL GUIDANCE IS LAWFUL.

As explained, the district court lacked jurisdiction over plaintiffs' APA claims. But if this Court reaches the merits, it should reverse the district court's determination holding the Supplemental Guidance to be unlawful.

A. The Supplemental Guidance Is Authorized By Regulation And Consistent With Statute.

The district court held that the Supplemental Guidance contravened governing HHS regulations as well as a recurring annual appropriations rider requiring adherence to those regulations. Both rulings are in error.

1. The Supplemental Guidance Follows 45 C.F.R. § 75.414(c).

a. The Supplemental Guidance is consistent with, and indeed was promulgated expressly pursuant to, the HHS regulation governing indirect costs. That regulation provides that agencies generally will adhere to "negotiated rates" for indirect costs. 45 C.F.R. § 75.414(c)(1). But—like the government-wide provision it parallels, *see* 2 C.F.R. § 200.414(c)—the HHS regulation also provides an express path for NIH to depart from that approach. *See* 45 C.F.R. § 75.414(c)(1).

As relevant here, "[a]n HHS awarding agency may use a rate different from the negotiated rate for a class of Federal awards or a single Federal award … when approved by a Federal awarding agency head or delegate based on documented justification as described in paragraph (c)(3) of this section."

45 C.F.R. § 75.414(c)(1). Paragraph (c)(3), in turn, requires only that "[t]he HHS awarding agency [*i.e.*, NIH] must 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." *Id.* § 75.414(c)(3). Thus, the regulation expressly contemplates that NIH may deviate from negotiated indirect-cost rates for a "class of Federal awards" provided that NIH offers a "documented justification" and "make[s] publicly available[]" the "policies, procedures and general decision making criteria" that "justify deviations from negotiated rates." *Id.* § 75.414(c)(1), (3). Aside from that procedural requirement, the regulation imposes no substantive constraint on the ability of NIH to depart from negotiated rates.

NIH followed that regulatory path here, as the Supplemental Guidance itself explains. It recognizes that "[i]n issuing grants, NIH generally uses the indirect cost rate negotiated by [the] 'agency with cognizance for F&A/indirect cost rate (and other special rate) negotiation.'" ADD.82. But the regulation also authorizes NIH to "use 'a rate different from the negotiated rate for either a class of Federal awards or a single Federal award.'" *Id.* "In deviating from the negotiated indirect cost rate, NIH must '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.'" *Id.* (quoting 45 C.F.R. § 75.414(c)(3)).

The Supplemental Guidance fulfills those procedural obligations. It explains that "[i]n accordance with 45 CFR [Part] 75," NIH is making "publicly available" its "updated policy deviating from the negotiated indirect cost rate for new grant awards and existing grant awards, effective as of the date of this Guidance's issuance." ADD.82. And it proceeds to set forth a "documented justification" for adopting that updated policy—including that the updated policy would accord with private-sector funding practices; reduce taxpayer spending on costs that are "difficult ... to oversee"; and "ensure that as many funds as possible go towards direct scientific research costs rather than administrative overhead." ADD.83-84; *see also supra* pp. 10-13, *infra* pp. 46-51.

b. The district court erred in holding the Supplemental Guidance to be contrary to regulation. The court recognized that the regulation affords NIH express authority to "'deviate'" from negotiated indirect-cost rates, ADD.19, and the court did not deny that the agency may deviate from previously negotiated rates based on a policy judgment that negotiated indirect-cost rates have become excessive. In making that policy change here, the court concluded that the agency failed to follow procedural requirements set forth in

the regulation, but it misunderstood the regulatory requirements and the Supplemental Guidance.

First, the district court stated that NIH had "ignore[d]" the requirement that it "mak[e] publicly available the 'policies, procedures and general decision making criteria' that the Agency will use to then seek and justify deviations." ADD.20 (quoting 45 C.F.R. § 75.414(c)(3)). The court acknowledged that the Supplemental Guidance "announce[s] a single, uniform policy" for existing and future grants to institutions of higher education. *Id.* But it criticized NIH for "fail[ing] to provide or point to any announced procedure or decision making criteria" by which that policy would be applied. *Id.* Reading the regulation as requiring a "step-by-step process," the district court criticized NIH's effort to implement its policy in "one fell swoop." *Id.*

The district court's criticisms are unfounded. Nothing in the text of section 75.414(c)(1) and (3) expressly calls for a multi-stage adjudicative process. Its focus is instead on making publicly available NIH's explanation for any departure from negotiated rates. Section 75.414(c)(1) authorizes a deviation so long as NIH provides a sufficient "documented justification," and section 75.414(c)(3) in turn sets forth the contents of that justification. Although NIH could certainly choose to provide for a step-by-step rate

redetermination process, nothing in the regulation guarantees recipients any opportunity to litigate individual deviations.

On the contrary, the regulatory text actively contemplates that NIH may announce generally applicable "polic[y]." 45 C.F.R. § 75.414(c)(3). And the reason why the Supplemental Guidance does not set forth further "procedures and decision making criteria" for applying its policy, ADD.20, is because the policy does not contemplate any individualized redetermination of indirect-cost rates. Rather, as the Supplemental Guidance states, "there will be a standard indirect rate of 15% across all NIH grants for indirect costs in lieu of a separately negotiated rate for indirect costs in every grant." ADD.82. No further procedures or criteria are necessary to implement that uniform policy.

The district court apparently concluded that NIH lacked the authority to adopt a "uniform policy" at all. ADD.21. Again, however, the regulation expressly states that an "HHS awarding agency" may deviate from negotiated rates for "a single Federal award" or, at its option, for "a class of Federal awards." 45 C.F.R. § 75.414(c)(1). Here, NIH availed itself of the latter option, choosing to apply its new policy to all research grants for IHEs.

Contrary to the district court's suggestion, that phrasing readily encompasses the grants addressed by the Supplemental Guidance. A "[c]lass of Federal [a]wards," as defined in the governing regulations, includes "a

group of Federal awards either awarded under a specific program or group of programs or to a specific type of non-Federal entity or group of non-Federal entities to which specific provisions or exceptions may apply." 45 C.F.R. § 75.2; *cf.* 2 C.F.R. § 200.1 (similar). Here, the Supplemental Guidance applies to a "group of Federal awards" for a "specific type of recipient"—specifically, to NIH research grants made to IHEs. Nothing in the regulations limits the size of the group of awards that may be adjusted. But even accepting plaintiffs' theory that a "class" must be a subset of NIH awards, that is true here: the Supplemental Guidance applies only to research grants made to IHEs.

2. The Supplemental Guidance Does Not Contravene The Annual Appropriations Riders.

For substantially the same reasons, the Supplemental Guidance is consistent with the annual appropriations riders. At all relevant times, that rider's principal language has provided that "[i]n making Federal financial assistance, the provisions relating to indirect costs in part 75 of title 45, Code of Federal Regulations, including with respect to the approval of deviations from negotiated rates, shall continue to apply to [NIH] to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017." Pub. L. No. 118-47, div. D, tit. II, § 224, 148 Stat. at 677.

As its plain text reflects, that language reaffirms that HHS should adhere to its existing regulations: the "provisions relating to indirect costs in part 75

of [C.F.R.] title 45"—that is, the provisions of 45 C.F.R. § 75.414—"shall continue to apply" now as "such provisions" did in 2017. *Id.* As just discussed (*supra* pp. 37-42), the Supplemental Guidance invokes that regulation and operates within its regulatory framework. Nothing in the language of the rider purports to prohibit NIH from exercising its regulatory authority to deviate from negotiated rates to the extent and in the manner authorized by that regulation. On the contrary, the rider affirmatively guarantees NIH's ability to apply that regulation "to the same extent" as before.

The rider's second sentence likewise imposes no substantive impediment. That sentence states that "[n]one of the funds appropriated in this or prior Acts or otherwise made available to the Department of Health and Human Services or to any department or agency may be used to develop or implement a modified approach to such provisions, or to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter." Pub. L. No. 118-47, div. D, tit. II, § 224, 148 Stat. at 677.

Nothing in the Supplemental Guidance purports to "develop or implement a modified approach" to the aforementioned "such provisions," *i.e.*, 45 C.F.R. § 75.414. Rather, it invokes the "approach" for deviation already set forth in the regulations. And nothing in the Supplemental Guidance purports

to "expand the fiscal effect" of NIH's grants through deviations from negotiated rates; its purpose is to channel taxpayer funds toward direct research, not to spend less on medical research activities altogether.

In nonetheless deeming the Supplemental Guidance contrary to the rider, the district court relied principally on its understanding that Congress had enacted the rider against the backdrop of a prior Administration proposal for a uniform 10% indirect-cost rate. But that 10% cap had been a budgetary proposal for Congress's statutory consideration, not a proposed invocation of HHS's regulatory authority under 45 C.F.R. § 75.414. That certain committee reports expressed concern about cutting indirect costs, *see* ADD.23-24, reflects only that Congress did not see fit to mandate such reductions as a statutory matter. If Congress had intended to divest NIH of its own regulatory authority to act, it would have said so, rather than directing adherence to HHS regulations that expressly authorize deviations.

In all events, what controls is the text of the statute, not the court's assumptions about Congress's views on preferred policy. Statements in legislative history are helpful, if at all, only to the extent they shed light on ambiguous statutory text. *See, e.g.*, *Azar v. Allina Health Servs.*, 587 U.S. 566, 579-80 (2019). And here, as explained, the text of the rider enacted by Congress simply reaffirms the regulatory provisions at issue—provisions that

allow for "class"-wide deviations from negotiated rates, and on which NIH has expressly relied here.

B. The Supplemental Guidance Is Reasonable And Reasonably Explained.

The Supplemental Guidance also survives review under APA arbitrary-and-capricious standards.

1. The APA allows courts to "hold unlawful" agency actions when they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Sorreda Transp., LLC v. U.S. Dep't of Transp.*, 980 F.3d 1, 3 (1st Cir. 2020) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Indeed, a court must "uphold [even] a decision of less than ideal clarity if the agency's path may reasonably be discerned." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513-14 (2009) (quotation marks omitted). At bottom, the APA requires only that agency action be "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

Those deferential principles apply even where, as here and as is frequently the case, the agency action reflects a change in policy. An agency "need not demonstrate to a court's satisfaction that the reasons for the new

policy are *better* than the reasons for the old one." *Fox Television Stations*, 556 U.S. at 515. Rather, "it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates." *Id.* To the extent that the agency's change in course unsettles any "serious reliance interests," the agency need only acknowledge and address those interests and explain why it is nonetheless pursuing its chosen policy. *Id.*

2. NIH satisfied that burden here. The Supplemental Guidance clearly sets forth the factual basis and logic underpinning NIH's decision to avail itself of its regulatory authority to deviate from negotiated indirect-cost rates and, in so doing, acknowledges recipients' reliance upon the prior rates that NIH has determined it is appropriate to change.

As earlier described (*supra* pp. 10-13), the Supplemental Guidance sets out the reasons for its change in policy. *See* ADD.82-84. NIH explained that its substantive mission is to "'seek fundamental knowledge about the nature and behavior of living systems' in order to enhance health, lengthen life, and reduce illness and disability." ADD.83. And NIH recognized that its reason for awarding grants to "universities, medical schools, and other research institutions" is to further that mission. *Id.* Yet "administrative overhead" and other indirect costs have come to consume more than a quarter of NIH's

annual grantmaking budget (*i.e.*, $9 billion out of $35 billion). *Id.* The Supplemental Guidance explains that these indirect costs are "difficult for NIH to oversee" and harder to justify as a use of taxpayer funds, as "by their very nature" such costs are "not readily assignable" to the specific project that NIH seeks to fund. *Id.* (quotation marks omitted). Given its obligation to "carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life," NIH decided to "ensure that as many funds as possible go towards direct scientific research costs rather than administrative overhead." *Id.*; *accord* J.A.486 (April 2024 NIH Grants Policy Statement) (NIH is "responsible to … the U.S. taxpayer for carrying out its mission in a manner that not only facilitates research but does so cost-effectively.").

NIH explained that this change, though significant, would bring it more in line with other grantmaking institutions. "Most private foundations that fund research provide substantially lower indirect costs," and "universities readily accept grants from these foundations." ADD.83. Indeed, "the most common rate of indirect rate reimbursement by foundations was 0%," and the maximum indirect-cost rate identified among any of the major foundations surveyed by NIH was 15%. *Id.* NIH expressly stated that it had "elected to impose" a standard 15% indirect-cost rate—which it noted was "50% higher"

than NIH's own default rate—in order to better comport with these "private sector indirect cost rates." ADD.83-84.

In so doing, NIH recognized that it was changing policy and that this change would affect private interests. NIH was "cognizant that grant recipients, particularly 'new or inexperienced organizations,' use grant funds to cover indirect costs like overhead," ADD.83, and it cross-referenced the extensive discussion of such interests contained in an OMB final rule issued during the Biden Administration, *see id.* (citing *Guidance for Federal Financial Assistance*, 89 Fed. Reg. 30,046, 30,046-30,093 (Apr. 22, 2024)). Recipient institutions benefited from the fact that NIH's "average indirect cost rate ... has averaged between 27% and 28% over time," and has been even higher at many major institutions. *Id.* But the Supplemental Guidance reflects the considered policy judgment that it is preferable to "ensure that as many [taxpayer] funds as possible go towards direct scientific research costs" even at the cost of disrupting those private reliance interests. *Id.*

3. The district court erred in holding NIH's explanation to be arbitrary and capricious. The principal basis for the district court's ruling was that "NIH failed to provide any reasoning, rationale, or justification at all" and that its "explanations are conclusory." ADD.32-33. But those assertions are inaccurate; as just explained, the Supplemental Guidance identifies a concern

with indirect costs; describes how other grantmaking institutions seek to limit such costs; and explains that limiting such costs will allow NIH to enhance its funding of direct medical research.

The district court apparently considered that justification to be insufficient because NIH did not address certain matters that, as a matter of policy judgment, it would have been desirable for the agency to address at greater length. For example, the court suggested that NIH should have volunteered its views about specific steps that recipient institutions could or should take to respond to reductions in indirect-cost reimbursements in order to continue current operations. *Cf.* ADD.33. But it is a fundamental precept of APA review that "a court is not to substitute its judgment for that of the agency." *State Farm*, 463 U.S. at 43. Indeed, that NIH chose not to explain how "research will be conducted absent the [higher] indirect cost reimbursements," ADD.33, in turn reflects NIH's own understanding that it is the recipient institutions themselves that are best positioned to decide how to adjust their budgets or the structure of their research operations in light of changes in federal policy. Nothing in the APA requires NIH to assume recipients' responsibility for managing their own organizations, such as by "identifying a countervailing funding stream" to support the indirect costs that NIH is reasonably seeking to limit. ADD.35.

The district court also faulted NIH for "fail[ing] to explain the inadequacy of the existing audit system" for overseeing recipients' costs. ADD.34. But NIH did not conclude that the existing audit system is inadequate. It did not justify its cap based on concerns with problems of fraud or abuse at specific institutions that audit processes had failed to prevent. On the contrary, NIH explained that it was responding to the more fundamental concern that indirect costs are, as a definitional matter, "not readily assignable to" the particular "cost objectives" that NIH seeks to fund—*i.e.*, to a specifically identified medical research project. ADD.83 (quotation marks omitted). In that sense, as judged against NIH's core policy mission, indirect costs are "difficult for NIH to oversee." *Id.*

The district court also declared that the Supplemental Guidance "fails in its entirety to recognize or consider" grantees' "substantial reliance interests" in the higher negotiated indirect-cost rates. ADD.37-43. But as explained above, the Supplemental Guidance recognizes and considers reliance interests. It acknowledges that "grant recipients, particularly 'new or inexperienced organizations,' use grant funds to cover indirect costs like overhead," with indirect-cost rates having "averaged between 27% and 28% over time" and exceeded 50% or even 60% for particular institutions. ADD.83. At the same time, the Supplemental Guidance also considers "what level of indirect

expenses research institutions" have historically been "willing to accept from [other] funders of research." *Id.* It was against the backdrop of recipient institutions' reliance upon—and acceptance of—those private indirect-cost rates that NIH selected a (slightly higher) standard rate of 15% rather than universalizing the existing 10% regulatory default. ADD.84. And, as a further reflection of institutions' reliance interests, NIH decided against imposing its new rate "retroactively back to the initial date of issuance of current grants," and instead decided to apply it only on a "go forward" basis. *Id.*; *see also infra* pp. 56-59. In short, the agency took reliance interests "into account," and simply concluded that any reliance interests the institutions had in the negotiated rates did not overcome the significant policy benefits of a 15% cap. *See Fox Television Stations*, 556 U.S. at 515.

C. Notice And Comment Is Not Required.

1. "The APA generally requires that before a federal agency adopts a rule it must first publish the proposed rule in the Federal Register and provide interested parties with an opportunity to submit comments and information concerning the proposal." *New Hampshire Hosp. Ass'n v. Azar*, 887 F.3d 62, 70 (1st Cir. 2018). "In recognition of the potential burden posed by a blanket requirement for informal rulemaking, however, Congress expressly excepted several categories of rules from APA rulemaking requirements." *Baylor Univ.*

Med. Ctr. v. Heckler, 758 F.2d 1052, 1058 (5th Cir. 1985). "Thus, section 553(a)(2) of the [APA] exempts from those requirements any 'matter relating to agency management or personnel or to public property, loans, *grants*, benefits, or contracts." *Id.* (emphasis added) (quoting 5 U.S.C. § 553(a)(2)).

As no one disputes, the Supplemental Guidance expressly addresses "matter[s] relating to ... grants," which is a topic statutorily excluded from the APA's rulemaking requirements. That is sufficient to resolve plaintiffs' notice-and-comment rulemaking claim. "A court's role in reviewing an agency decision not to extend informal rulemaking procedures is to ascertain whether the APA required such procedures." *Baylor Univ. Med. Ctr.*, 758 F.2d at 1059. And where, as here, the Supplemental Guidance "clearly and directly relate[s] to ['grants'] as that word is used in section 553(a)(2)," a court is "unable to override Congress's choice not to require notice and an opportunity for comment under such circumstances." *Id.* at 1061.

2. In crediting plaintiffs' notice-and-comment claim, the district court did not deny that section 553(a)(2)'s statutory rulemaking exception would facially apply. Nor did the district court deny that NIH's regulations—which themselves previously went through notice and comment—do not call for further rounds of notice-and-comment rulemaking before the agency avails itself of its authority to deviate under 45 C.F.R. § 75.414(c)(1) and (3).

Instead, the district court relied on the fact that HHS's predecessor agency had in 1971 announced a voluntary policy of providing notice and comment even for matters within section 553(a)(2)'s scope (a policy known as the "Richardson Waiver"). *See* ADD.45-47. The district court thus held that plaintiffs were likely to succeed in claiming that HHS violated the APA by failing to afford procedures not required by the APA but that the agency had volunteered to follow as a matter of administrative grace.

That reasoning is incorrect. A deviation from voluntary procedures—procedures expressly made inapplicable by statute—cannot logically serve as a basis for invalidating agency action under that same statute. "[W]here Congress did not intend a statute to apply," there should be no basis "for the Judiciary to construe the Executive Branch's voluntary application of the statute" in a statement of policy "as a grant of judicial authority to enforce" that voluntary agency policy. *See Planned Parenthood of Wisc., Inc. v. Azar*, 316 F. Supp. 3d 291, 304 n.5 (D.D.C. 2018), *vacated on other grounds*, 942 F.3d 512 (D.C. Cir. 2019). Although the D.C. Circuit has concluded otherwise, *see, e.g.*, *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 356-67 (D.C. Cir. 2017) (citing cases), its belief that agency waivers of section 553(a)(2) can be judicially enforced is inconsistent with the principle that the APA sets forth the "maximum procedural requirements which Congress was willing to have the

courts impose upon agencies," *Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978). The district court erred in relying upon D.C. Circuit precedent that transgresses the APA's text. *Cf., e.g.*, *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92 (2015) (unanimously overturning D.C. Circuit precedents that imposed rulemaking requirement on agencies in circumstances not demanded by APA's text).[5]

In all events, HHS has since abrogated the voluntary policy on which the district court here relied. *See* ADD.94 (*Policy on Adhering to the Text of the Administrative Procedure Act*, 90 Fed. Reg. 11,029 (Mar. 3, 2025)). As the agency has explained, the "extra-statutory obligations" associated with that prior voluntary policy have "impose[d] costs on the Department and the public, are contrary to the efficient operation of the Department, and impede the Department's flexibility to adapt quickly to legal and policy mandates." *Id.* As a result, "[e]ffective immediately, the Richardson Waiver is rescinded and is no longer the policy of the Department." *Id.*

Any procedural error was therefore harmless. The district court concluded that if NIH wishes to impose a new policy governing indirect costs,

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[5] In *Cheshire Hospital v. New Hampshire-Vermont Hospitalization Service, Inc.*, 689 F.2d 1112 (1st Cir. 1982), this Court suggested that because "the Secretary has waived the so-called 'benefits exception,'" it "must still determine whether applicable procedures were violated." *Id.* at 1122 n.13. But that statement was dictum; the Court concluded rulemaking was not required. *Id.* at 1122-23.

it must proceed via notice-and-comment rulemaking, and it "vacate[d]" the Supplemental Guidance on that basis. But the purported legal obligation on which the district court relied no longer exists. The APA requires courts to take "due account" of "the rule of prejudicial error," 5 U.S.C. § 706; here, that means that a court should not vacate agency action based on non-compliance with an alleged procedural requirement that, even on plaintiffs' terms, concededly no longer applies.

3. Plaintiffs' section 553 rulemaking claim also fails because, in all events, the proper procedures governing a deviation from negotiated rates are those set forth in 45 C.F.R. § 75.414(c). HHS promulgated that regulation via notice and comment, *see* 79 Fed. Reg. 75,871, 75,923-24 (Dec. 19, 2014), thereby describing its regulatory mechanism for establishing and justifying future deviations from negotiated rates via informal adjudication. That mechanism itself provides for "public[]" notice as to the "policies, procedures and general decision making criteria that [the agency's] programs will follow to seek and justify deviations from negotiated rates." 45 C.F.R. § 75.414(c)(3). As explained above, *supra* pp. 37-42, that mechanism of informal adjudication was invoked here. Plaintiffs of course dispute whether that process was sufficiently followed, but assuming it was, APA section 553 can afford no further basis for setting aside NIH's actions.

D. The Supplemental Guidance Is Not Impermissibly Retroactive.

Finally, the district court's conclusion that the Supplemental Guidance is "impermissibly retroactive" as to existing grants, ADD.52, is in error because the Supplemental Guidance is not retroactive at all.

1. Because "[r]etroactivity is not favored in the law," neither statutes nor agency regulations are "construed to have retroactive effect unless their language requires this result." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). But not all changes that bear upon existing legal obligations are retroactive. An enactment "does not operate 'retrospectively' merely because it is applied in a case arising from conduct antedating the statute's enactment, or upsets expectations based in prior law." *Landgraf v. USI Film Prods., Inc.*, 511 U.S. 244, 269 (1994) (citation omitted). Rather, "the court must ask whether the new provision attaches new legal consequences to *events completed* before its enactment." *Id.* at 269-70 (emphasis added). A consequence is not "retroactive" unless it "affect[s] substantive rights, liabilities, or duties on the basis of conduct arising before its enactment." *Fernandez-Vargas v. Gonzales*, 548 U.S. 30, 37 (2006) (alterations and quotation marks omitted).

The Supreme Court's decision in *Martin v. Hadix*, 527 U.S. 343 (1999), provides a useful application of these principles. There, Congress had enacted a statute (the Prison Litigation Reform Act) that placed a new cap "on the fees

that may be awarded to attorneys who litigate prisoner lawsuits." *Id.* at 347. Specifically at issue was how the fee cap "applie[d] to cases that were [already] pending" on the statute's effective date in April 1996. *Id.* The Court concluded that, as to fees incurred prior to the statutory effective date, application of the fee cap would be retroactive because it would "attach new legal consequences to completed conduct," specifically, to "work performed before the [statute's] effective date" and undertaken "in reasonable reliance on th[e] [prior] fee schedule." *Id.* at 358 (alteration and quotation marks omitted). By contrast, as to fees incurred for work performed by attorneys in pending cases after the statutory effective date, no such retroactivity problem existed. That is because "[f]rom that point forward," the "plaintiffs' attorneys were on notice that their hourly rate had been adjusted" and they could conform their conduct accordingly. *Id.* at 360. That was true even though the attorneys had decided to file suit, and thus assume the duty of representation for ongoing cases, before the statute's effective date. *See id.* at 360-61.

2. The Supplemental Guidance is prospective in application. It applies only to "go forward expenses from February 10, 2025 forward as well as [to] all new grants issued" for IHEs. ADD.84. And it expressly disavows any change to indirect-cost rates for funds drawn prior to its effective date. *See id.* ("We will not be applying this cap retroactively back to the initial date of

issuance of current grants to IHEs, although we believe we would have the authority to do so under 45 CFR 75.414(c).”). Here, as in *Martin v. Hadix*, there is “no manifest injustice” in telling universities with taxpayer-funded NIH research grants “that, going forward, [they] will earn a lower [indirect-cost] rate than [they] had earned in the past.” 527 U.S. at 360.

That is true even though NIH grant recipients may well have assumed that negotiated indirect-cost rates would continue indefinitely. Although retroactivity principles generally prevent an agency from changing the *past* legal effects of past transactions, “the presumption against retroactivity is not violated by interpreting a statute to alter the *future* legal effect of past transactions.” *Landgraf*, 511 U.S. at 293 n.3 (Scalia, J., concurring in the judgment). Such “so-called secondary retroactivity,” *id.*, presents not a retroactivity problem but, rather, a question of reliance interests to be considered under APA arbitrary-and-capricious standards.

3. The district court’s contrary reasoning reflects its misunderstanding both of retroactivity principles and of the governing regulatory regime. The court concluded that the Supplemental Guidance “impair[s] the *rights* [an] institution possessed when accepting the Notice of Award—specifically, the negotiated [indirect-cost rate].” ADD.54 (emphasis added). But the governing regulations and policies make clear that institutions have no entitlement to any

particular indirect-cost rate, negotiated or otherwise. The very regulations on which all parties here seek to rely expressly authorize NIH to "use a rate different from the negotiated rate." 45 C.F.R. § 75.414(c)(1); *see also* J.A.497 ("F&A costs awarded may be subject to upward or downward adjustment").

More broadly, NIH routinely announces new policies governing research grants and applies them to existing grant agreements without any suggestion that doing so is impermissibly retroactive. *See NIH Grants Policy Statement*, *supra* (noting that policy notices, once published, "supersede information in the NIH Grants Policy Statement" and "[c]ompliance with these policy updates become[s] a term and condition of award"); *supra* p. 10 n.2 (noting that Supplemental Guidance was 68th policy notice in FY 2025 alone). And the recipient institutions expressly agreed to comply with such requirements when accepting their awards. Plaintiffs may well disagree about whether the Supplemental Guidance reflects sound policy, but they cannot dispute that they are required by law as a condition of receiving federal funding to adhere to NIH's policy views rather than their own.

CONCLUSION

The judgments of the district court should be vacated and remanded with instructions to dismiss for lack of jurisdiction. Alternatively, the judgments should be reversed on the merits.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 12,901 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2013 in Calisto MT 14-point font, a proportionally spaced typeface.

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2025, I electronically filed the foregoing opening brief with the Clerk of Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

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ADDENDUM

Addendum Contents

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUETTS, *et al.* Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	Case No. 25-CV-10338
ASSOCIATION OF AMERICAN MEDICAL COLLEGES, *et al.* Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	Case No. 25-CV-10340
ASSOCIATION OF AMERICAN UNIVERSITIES, *et al.*, Plaintiffs, v. DEPARTMENT OF HEALTH & HUMAN SERVICES, *et al.*, Defendants.	Case No. 25-CV-10346

MEMORANDUM AND ORDER
ON MOTION FOR PRELIMINARY INJUNCTION

ANGEL KELLEY, D.J.

These three cases came before the Court on an emergency basis on Monday, February 10, 2025.The National Institutes of Health ("NIH") issued a Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates (NOT-OD-25-068) ("Rate Change Notice") on Friday night, February 7, 2025, slashing and capping previously negotiated indirect cost rates on all existing and future grant awards for biomedical research, with an effective date of February 10. This Notice impacts thousands of existing grants, totaling billions of dollars across all 50 states—a unilateral change over a weekend, without regard for on-going research and clinical trials. The imminent risk of halting life-saving clinical trials, disrupting the development of innovative medical research and treatment, and shuttering of research facilities, without regard for current patient care, warranted the issuance of a nationwide temporary restraining order to maintain the status quo, until the matter could be fully addressed before the Court.

Following full briefing and oral argument by the parties, as well as review of accepted amicus briefs, the Court **GRANTS** a nationwide preliminary injunction.

I. BACKGROUND

Plaintiffs in action 25-CV-10338 are 22 attorneys general, who filed suit on behalf of their states, Massachusetts, Michigan, Illinois, Arizona, California, Connecticut, Colorado, Delaware, Hawaii, Maine, Maryland, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Rhode Island, Vermont, Washington, and Wisconsin ("Plaintiff States"). Plaintiffs in action 25-CV-10340 are five medical associations, including the Association of American Medical Colleges, the American Association of Colleges of Pharmacy, the Association for Schools and Programs of Public Health, the Conference of Boston Teaching

Hospitals, Inc., and the Greater New York Hospital Association ("AAMC"). Plaintiffs in action 25-CV-10346 are 17 associations and universities, including the Association of American Universities, the American Council on Education, the Association of Public and Land-grant Universities, Brandeis University, Brown University, the Regents of the University of California, Carnegie Mellon University, The University of Chicago, Cornell University, The George Washington University, John Hopkins University, Massachusetts Institute of Technology, the Trustees of the University of Pennsylvania, University of Rochester, the Trustees of Tufts College, and the California Institute of Technology ("AAU"). The Defendants[1] in each action are the National Institutes of Health and the Department of Health and Human Services ("HHS").

The National Institutes of Health is a federal agency created to support innovative medical research strategies to enhance health, lengthen life, and reduce illness and disability. This case concerns NIH's co-sharing method of funding biomedical and public health research. NIH is the primary source of federal funding for health research projects in the United States through grant awards. In fiscal year 2023, NIH grants totaled over $35 billion—giving out nearly 60,000 competitive grants to more than 300,000 researchers. The grants primarily go to public and private colleges and universities, and other non-governmental research institutions.

Congress has established a regulatory framework for how these grants are awarded, consisting of three primary actions. First, it has authorized NIH to "make grants-in-aid to universities" for research support. 42 U.S.C. § 241(a)(3). Second, it has instructed the Office of Management and Budget ("OMB") to issue general guidance on such grants. See 31 U.S.C. § 503(a), (b)(2)(C). Third, Congress passed an appropriations rider that prohibits HHS and, by

[1] The acting directors for each agency are also named as defendants in their official capacities.

extension, 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.

A. Grant Award Process

Under the structure of these Acts, NIH has set the regulations that govern the grant awarding process. As a general overview, the process begins with a notice from NIH that funding is available for a specific topic. Research institutions then submit applications for a grant on this specific topic. These applications are formally reviewed—including peer review by others working in the same field. If the application is approved, NIH will issue a Notice of Award ("NOA"), which is a legally binding decision indicating that funds can be withdrawn. This drawdown, or receipt of funds, is very rarely done as one lump sum withdrawal. Typically, the grantee will use a cost-based accounting system where they are reimbursed for their actual and documented costs connected to their research grant over the life of the grant.

The regulations proscribe two different categories of costs: direct costs and indirect costs. 45 C.F.R. § 75.412. Direct costs are costs that are attributed to one specific research project. For example: materials and supplies used in the research project, or a stipend for a graduate student working only on that one project. Indirect costs are research costs that cannot be attributed to one specific project but are incurred for common or joint objectives. 45 C.F.R. § 75.2. Indirect costs include expenses such as, building construction and maintenance, utilities, laboratory equipment maintenance, and faculty and staff employed across multiple research projects. Indirect costs are also referred to as facilities and administration ("F&A") costs. 45 C.F.R. § 75.414(a). All drawdowns for reimbursement of indirect expenses paid are subject to federal audit.

B. The Rate Change Notice

The acting director of the National Institutes of Health issued a Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates (NOT-OD-25-068) on Friday night, February 7, 2025. This Rate Change Notice relates to the administration of indirect costs. Before this Notice, each institution had negotiated its indirect cost rate ("ICR") with the appropriate federal agency, also known as the cognizant agency. Once negotiated, that rate became binding on every federal agency interacting with the institution. The ICR represents a percentage of the total grant—not a dollar amount. For example, if an organization has negotiated an ICR of 30%, and the grant award is $100,000, the total grant amount for the receiving institution is $130,000 ($100,000 (direct costs), plus $30,000 (indirect costs, or 30% of $100,000)). These negotiated rates are formalized in a Negotiated Indirect Cost Rate Agreement ("NICRA"). The varying rates of indirect costs are established so that each research institution can plan accordingly and facilitate the preparation of their budgets to fulfill their specific research needs. 45 C.F.R. pt. 75, appx. III § C(4).

After the ICR is agreed upon and the actual costs are incurred, federal agencies are authorized to conduct audits to ensure that the negotiated ICR conforms with actual costs and address any amounts questioned during the audit. 2 C.F.R. pt. 200, appx. III § C.11(2)(d). Funds are recouped and the ICR must be adjusted if the audit indicates that the institution recovered any unallowable costs. 2 C.F.R. § 200.411(a), (b).

Per federal regulations, the NICRA is binding on every federal agency throughout the life of the grant. 45 C.F.R. pt. 75, appx. III § C(7). There are limited exceptions through which the previously negotiated rate can be adjusted and only in particular circumstances, as their fixed nature is essential for institutions as they budget and plan for their research in the long term. As

an initial matter, a different-than-negotiated rate can only be used for a single federal award or a class of awards, defined as a "group of Federal awards either awarded under a specific program or group of programs or to a specific type of non-Federal entity or group of non-federal entities to which specific provisions or exceptions may apply." 45 C.F.R. §§ 75.2, 75.414(c)(1). The first circumstance under which an ICR can be adjusted is when "required by Federal statute or regulation." § 75.414(c)(1). The second circumstance, relevant to the cases before the Court, is when "approved by a Federal awarding agency head or delegate based on documented justification," as later described in Section (c)(3). Id. Turning to Section (c)(3), "[t]he HHS awarding agency must 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. § 75.414(c)(3).

The February 7 Rate Change Notice eliminates the individually negotiated rates to impose a flat rate of 15% across all grants. This usurps all currently existing NICRAs, impacting both all existing grants and all new grants going forward.

C. Prior Attempts to Limit Indirect Cost Rates Governing NIH Grants

Prior presidential administrations have made changes or attempted to make changes to the determination of F&A costs. The Clinton Administration limited indirect costs collectable by NIH grant recipients to 26% of modified total direct costs via the administrative rulemaking process. See Final Revision to Circular A-21, 56 Fed. Reg. 50224, 50228 (Oct. 3, 1991) (codified at 2 C.F.R. pt. 200, appx. III § C(8)(a)). A later budget proposal from the Clinton Administration related to the cutting of F&A funding was rejected out of hand by Congress. See H. Rep. 103-553 at 67 (1994); Genevieve J. Knezo, Cong. Rsch. Serv., Indirect Costs for R&D at Higher Education Institutions 32 (1994). The Obama Administration had some discussion

regarding a cap on all indirect costs, but later changed course after nearly universal institutional opposition.

In 2017, the first Trump Administration released a budget proposal that would have slashed the indirect cost rate to a uniform, across-the-board rate of 10%. In direct response, Congress passed the previously mentioned appropriations rider to prevent this change, deeply concerned for the resulting harm to the nation's research capability. Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 226, 132 Stat. 348. This rider has remained the law from its passage through the present day. Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677; see also Dept. of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, § 224, 132 Stat. 2981, 3094 (2018); Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 224, 133 Stat. 2534, 2582 (2019); Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, § 224, 134 Stat. 1182, 1594 (2020); Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, § 224, 136 Stat. 49, 470-71; Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 224, 136 Stat. 4459, 4883-84 (2022).

II. PROCEDURAL HISTORY

The Rate Change Notice was signed on the evening of February 7, 2025—and was set to go into effect on the following business day, February 10, 2025. On February 10, the three Plaintiff groups filed their cases seeking injunctive and declaratory relief, each alleging that the Rate Change Notice ignores existing regulations, is in excess of statutory authority, and violates the Administrative Procedure Act ("APA") because it is arbitrary and capricious, the Administration failed to follow proper procedure, and the Notice is impermissibly retroactive.

Each Plaintiff group requested an *ex parte* temporary restraining order ("TRO"), two of which were granted, and the third was denied as moot after the Court issued a nationwide injunction in the second action, AAMC, 25-CV-13460. Defendants subsequently filed reports confirming that they would not implement the Rate Change Notice until further notice from the Court. The Court then directed Defendants to submit a consolidated opposition to Plaintiffs' motions, and the Plaintiff groups to submit a consolidated reply brief.

On the eleventh day of the temporary restraining orders, February 21, 2025, the Court extended the temporary orders for good cause, pursuant to Fed. R. Civ. P. 65(b)(2), to resolve the fully briefed and argued motions for preliminary injunction, which both parties acknowledge is ripe for this Court.

III. SUBJECT MATTER JURISDICTION

As a threshold matter, the Court addresses Defendants' contention that this Court lacks subject matter jurisdiction to hear these cases. District courts are courts of limited jurisdiction and can only exercise jurisdiction when authorized by the Constitution or a federal statute. See, e.g., Exxon Mobil Corp. v. Allapattah Servs., Inc., 545 U.S. 546, 552 (2005). If a district court finds that it lacks subject matter jurisdiction, it shall transfer the case at issue to the appropriate district "if it is in the interest of justice." 28 U.S.C. § 1631. Thus, before moving onto the merits, the Court first addresses whether it can properly exercise jurisdiction.

Defendants contend that Plaintiffs' claims lie exclusively in the United States Court of Federal Claims, pursuant to the Tucker Act, 28 U.S.C. § 1491. Plaintiffs do not agree that the Tucker Act divests this Court of jurisdiction. For the reasons stated below, the Court rejects Defendants' characterization of Plaintiffs' claims as mere breach of contract claims meant for the Court of Federal Claims. The Court retains subject matter jurisdiction to hear these cases under

5 U.S.C. § 702. See Taydus v. Cisneros, 902 F. Supp. 278, 284 (D. Mass. 1995) (holding that the district court retains jurisdiction per the APA waiver of sovereign immunity).

A. The Tucker Act

The Tucker Act: (1) "confers jurisdiction upon the Court of Federal Claims over the specified categories of actions brought against the United States," and (2) "waives the Government's sovereign immunity for those actions."[2] Fisher v. United States, 402 F.3d 1167, 1172 (Fed. Cir. 2005). The Tucker Act vests jurisdiction in the United States Court of Federal Claims with respect to "any claim against the United States founded either upon the Constitution, or any Act of Congress or any regulation of an executive department, or upon any express or implied contract with the United States, or for liquidated or unliquidated damages in cases not sounding in tort." 28 U.S.C. § 1491(a)(1). In suits seeking more than $10,000 in damages, the Court of Federal Claims' jurisdiction is exclusive of the federal district courts. See, e.g., Burgos v. Milton, 709 F.2d 1, 3 (1st Cir. 1983).[3] Thus, plaintiffs wishing to file "a suit against the United States involving a contract" where the "relief [sought is] over $10,000" must do so in the Court of Federal Claims. Vill. W. Assocs. v. R.I. Hous. & Mortg. Fin. Corp., 618 F. Supp. 134, 138 (D.R.I. 2009), judgment entered, 641 F. Supp. 2d 135 (D.R.I. 2009).

Generally, claims brought in the Court of Federal Claims "must be for monetary relief; [they] cannot be for equitable relief, except in very limited circumstances[.]" Gonzales &

[2] The Tucker Act's waiver of sovereign immunity does not "create[] a substantive right enforceable against the Government by a claim for money damages." United States v. White Mountain Apache Tribe, 537 U.S. 465, 472 (2003). Rather, plaintiffs invoking the Tucker Act's waiver of sovereign immunity must point to "a statute" that "can fairly be interpreted as mandating compensation by the Federal Government for the damage[s] sustained." Id. (quoting United States v. Mitchell, 463 U.S. 206, 217 (1983)).

[3] For suits against the United States with claims for less than $10,000, the Court of Federal Claims and Federal District Courts have concurrent jurisdiction under 28 U.S.C. § 1346(a)(2), also known as the "Little Tucker Act."

Gonzales Bonds & Ins. Agency, Inc. v. Dep't of Homeland Sec., 490 F.3d 940, 943 (Fed. Cir. 2007). Such "limited circumstances" are found in cases in which the equitable relief requested is "an incident of and collateral to" monetary relief. James v. Caldera, 159 F.3d 573, 580 (Fed. Cir. 1998) (quoting 28 U.S.C. § 1491(a)(2) (1994)).

B. The Administrative Procedure Act

The Administrative Procedure Act entitles "a person suffering legal wrong because of any agency action" to seek "judicial review thereof." 5 U.S.C. § 702. Congress amended § 702 in 1976 to "broaden the avenues for judicial review of agency action by eliminating the defense of sovereign immunity" in suits "seeking relief other than money damages . . . ." Bowen v. Massachusetts, 487 U.S. 879, 891-92 (1988); see Act of Oct. 21, 1976, Pub. L. No. 94-574, 90 Stat. 2721. By clarifying that § 702's waiver of sovereign immunity applied "only to actions 'seeking relief other than money damages' and where 'there is no other adequate remedy in a court,'" Congress "sought to pull together the 'patchwork' of various statutory waivers of federal sovereign immunity" into one coherent scheme. Gregory C. Sisk, The Jurisdiction of the Court of Federal Claims and Forum Shopping in Money Claims Against the Federal Government, 88 Ind. L.J. 83, 90 (2013) (quoting 5 U.S.C. §§ 702, 704). Congress intended "the [1976 APA amendments] to complement[] . . . the Tucker Act[.]" Id. at 90 n.59 (citing H.R. Rep. No. 94-1656, at 11 (1976)).

C. Rights and Remedies Test

The "jurisdictional boundary" between the Tucker Act and Administrative Procedure Act is well-traversed by litigants seeking relief against the federal government. Suburban Mortg. Assocs., Inc. v. U.S. Dep't of Hous. & Urb. Dev., 480 F.3d 1116, 1117 (Fed. Cir. 2007). Still, the boundary's precise contours remain elusive. See, e.g., Id. at 1124 (listing cases treading the

jurisdictional line); Bublitz v. Brownlee, 309 F. Supp. 2d 1, 6 (D.D.C. 2004) (noting "[t]he bright-line rule" between monetary and equitable relief in the Tucker Act–APA context "turns out to be rather dim . . . ."). Plaintiffs often attempt to "avoid Tucker Act jurisdiction by 'converting complaints which "at their essence" seek money damages from the government into complaints requesting injunctive relief or declaratory actions.'" Martin v. Donley, 886 F. Supp. 2d 1, 8 (D.D.C. 2012) (quoting Kidwell v. Dep't of Army, Bd. for Correction of Mil. Recs., 56 F.3d 279, 284 (D.C. Cir. 1995)).

The Supreme Court has made clear that "[n]ot every claim invoking the Constitution, a federal statute, or a regulation is cognizable under the Tucker Act." United States v. Mitchell, 463 U.S. 206, 216 (1983). Indeed, not every "failure to perform an obligation" by the federal government "creates a right to monetary relief." United States v. Bormes, 568 U.S. 6, 16 (2012). When traversing the Tucker Act–APA jurisdictional boundary, courts "must look beyond the form of the pleadings to the substance of the claim[,]" Suburban Mortg., 480 F.3d at 1124, to determine whether "the essence of [an] action is in contract . . . ." Am. Sci. & Eng'g, Inc. v. Califano, 571 F.2d 58, 63 (1st Cir. 1978). The "essence" of an action encompasses two distinct aspects—the "source of the rights upon which the plaintiff bases its claim" and "the type of relief sought (or appropriate)." Piñeiro v. United States, No. 08-CV-2402, 2010 WL 11545698, at *5 (D.P.R. Jan. 26, 2010) (quoting Megapulse, Inc. v. Lewis, 672 F.2d 959, 968 (D.C. Cir. 1982)); see also R.I. Hous. & Mortg. Fin. Corp., 618 F. Supp. 2d at 138.

While the First Circuit has not formally adopted the "rights and remedies" test that is used by several other circuits,[4] courts in this Circuit have adopted the test to determine if the

[4] See, e.g., Cohen v. Postal Holdings, LLC, 873 F.3d 394, 403 (2nd Cir. 2017); RMI Titanium Co. v. Westinghouse Elec. Corp., 78 F.3d 1125, 1136 (6th Cir. 1996); Evers v. Astrue, 536 F.3d 651, 657-658 (7th Cir. 2008); United Aeronautical Corp. v. U.S. Air Force, 80 F.4th 1017, 1026

"essence" of an action is truly contractual in nature. See R.I. Hous. & Mortg. Fin. Corp., 618 F. Supp. 2d at 138; Piñeiro, 2010 WL 11545698, at *5. This Court adopts the Megapulse framework and discusses each element in turn.

1. Source of Right

The Defendants contend that Plaintiffs' source of rights stems from the legally binding Notice of Awards that are provided to selected grant recipients stating that funds may be requested. Defendants contend that, generally, grants are treated as contracts when all the necessary attributes are present and that "[a]ll elements [of a contract] are present in the Notices of Award," and the Court should look no further if this "contract" exists. States [Dkt. 73, at 8]. Plaintiffs, however, argue that their claims are not based on the contract. Rather, according to the Plaintiffs, their claims are rooted in "the Constitution, federal statutes, and federal regulations, not contract terms." States [Dkt. 81, at 3]. Plaintiffs explicitly ask this Court to interpret and enforce the federal regulations, not the grants in which the regulations are incorporated.

After examining the three Complaints in their entirety, the Court finds that the gravamen of Plaintiffs' Complaints does not turn on terms of a contract between the parties; it turns on federal statute and regulations put in place by Congress and NIH. See, e.g., K-Mar Indus., Inc. v. U.S. Dep't of Def., 752 F. Supp. 2d 1207, 1214 (W.D. Okla. 2010) ("The source of the rights alleged in this action is not contractual, it is the procedures put in place by the defendants."). While it is true that the Notice of Award operates as a contract, the claims in this case turn on how the regulations govern the provision of these awards. This is further underscored by the

(9th Cir. 2023); McKay v. United States, 516 F.3d 848, 851 (10th Cir. 2008); Begner v. United States, 428 F.3d 998, 1002 (11th Cir. 2005); cf. United States v. J&E Salvage Co., 55 F.3d 985, 988 (4th Cir. 1995) (applying Megapulse to a dispute arising under the Contract Disputes Act).

Rate Change Notice's impact not just on current grants, but future ones as well. It follows that the source in which Plaintiffs aim to vindicate their rights is not in contracts that are yet to exist (future grants) but is actually in the regulation that facilitates such grants.

Plaintiffs' contractual relationships with NIH do not automatically "convert a claim asserting rights based on federal regulations into one which is, 'at its essence,' a contract claim." Normandy Apartments, Ltd. v. U.S. Dep't of Hous. & Urb. Dev., 554 F.3d 1290, 1299 (10th Cir. 2009). This is especially the case since "[c]ontract issues may arise in various types of cases where the action itself is not founded on a contract." Megapulse, 672 F.2d at 968 (listing examples of tort theories that could require a court to dispose of contractual issues incidentally). This is not a request for "monetary relief" that is "dressed in equitable and declaratory garb." R.I. Hous. & Mortg. Fin. Corp., 618 F. Supp. 2d at 138 (D.R.I.). Plaintiffs are not seeking judicial review of a contract. In fact, Plaintiffs have not requested the Court to examine any contract or grant agreement created between the parties. Rather, they have asked this Court to review and interpret the governing federal statute and regulations. Accordingly, Plaintiffs have sufficiently established that the source of their rights is not rooted in any contract between them and the Defendants.

2. Relief Sought

This Court now turns to the type of relief sought by Plaintiffs. Defendants contend that Plaintiffs "seek monetary relief greater than $10,000 for NOA's reduction of the indirect cost rate to 15%." States [Dkt. 73, at 10]. Plaintiffs, on the other hand, contend that they are not seeking a money judgment at all. Instead, they only "seek declaratory and injunctive relief returning the parties to the pre-existing status quo by requiring the government to respect negotiated rates for indirect costs," States [Dkt. 81, at 5], with existing contracts establishing

ICR's for the next several years, underscoring the nature of the ongoing relationship between the Plaintiffs, other third-parties, and NIH. See, e.g., AAU [Dkt. 2-12, Declaration of Dr. David F. Kotz, of Dartmouth College] ("Direct negotiations and detailed audits with the federal government in 2022 resulted in the setting of a predetermined rate that Dartmouth had expected in good faith would be applicable through 2029."); Id. [Dkt. 2-20, Declaration of Anshuman Razdan, of the University of Oregon] ("UO's current negotiated rate for organized research is 49% (up from 47.5%), last negotiated August 2023 and valid through June 30, 2027."). None of Plaintiffs' Complaints refer to compensatory damages.[5]

It is now axiomatic that there is a "distinction between an action at law for damages," which provides monetary compensation, and "an equitable action for specific relief," which might nonetheless require monetary relief. Bowen, 487 U.S. at 893; see Great-West Life & Annuity Ins. Co. v. Knudson, 534 U.S. 204, 213 (2002) ("[W]hether [restitution] is legal or equitable depends on 'the basis for [the plaintiff's] claim' and the nature of the underlying remedies sought." (quoting Reich v. Continental Casualty Co., 33 F.3d 754, 756 (7th Cir. 1994) (Posner, J.))). Simply because "a judicial remedy may require one party to pay money to another" does not necessarily "characterize the relief as 'money damages.'" Bowen, 487 U.S. at 893. A hallmark of such equitable actions is the existence of prospective relief in ongoing relationships. Compare Bowen, 487 U.S. at 905 (holding the district court had jurisdiction because declaratory or injunctive relief was appropriate to clarify petitioner state's ongoing obligations under the Medicaid plan), with Me. Cmty. Health Options v. United States, 590 U.S. 296, 298 (2020) (holding that petitioners properly relied on the Tucker Act to sue for damages in

[5] All three Complaints request declaratory judgment and injunctive relief. The Complaint by AAU also requests vacatur of the Rate Change Notice.

the Court of Federal Claims because plaintiffs were strictly concerned with "specific sums already calculated, past due, and designed to compensate for completed labors"). Plaintiffs do not bring claims for past pecuniary harms. Rather, like the petitioners in Bowen, their claims are to preserve their ongoing and prospective agreements with NIH. The various harms identified by Plaintiffs properly correspond to the sought equitable relief. Plaintiffs indicate that the Rate Change Notice would result in the loss of jobs, the suspension of research, including clinical trials and infrastructure projects, and a reduction of teaching staff who are committed to cultivating medical students. See, e.g., States [Dkt. 6-34, Declaration of Dr. Greg Hirth, of Brown University] ("At a 15% indirect cost rate, many of Brown's current research projects and clinical trials will be forced to cease abruptly."); AAU [Dkt. 2-12, Declaration of Dr. David F. Kotz, of Dartmouth College] ("The world's best scientists will not move to (or stay at) universities where they are not able to conduct world-class research."); AAU [Dkt. 2-28, Declaration of Ishwar K. Puri, of the University of Southern California] (discussing the likely cutting of 73 staff members while also adding "slowdowns or halts in research by USC and other American universities will allow competitor nations that are maintaining their investments in research to surpass the United States on this front, threatening both our Nation's national security and its economic dominance."). Ultimately, it is these harms (among many others) for which Plaintiffs are pleading relief. It would be legal error to construe Plaintiffs' harms as couched pleas for monetary relief for which they never ask.

Plaintiffs' primary purpose in bringing their claims is to seek equitable, not monetary, relief. Since this Court finds that the proper source of Plaintiffs' rights is federal statute and regulations and because the relief sought is injunctive in nature, this Court determines that the "essence" of the action is not contractual in nature. R.I. Hous. & Mortg. Fin. Corp., 618 F. Supp.

2d at 138. Thus, Plaintiffs' claims cannot properly be brought under the Tucker Act in the Federal Claims Court and this Court retains jurisdiction.

IV. PRELIMINARY INJUNCTION LEGAL STANDARD

Courts apply the same standard in assessing motions for temporary restraining order— as the Plaintiffs originally requested—and motions for preliminary injunction, which follow full briefing and the opportunity to be heard by the Court. See Fed. R. Civ. P. 65; Wash. Tr. Advisors, Inc. v. Arnold, 646 F. Supp. 3d 210, 217 (D. Mass. 2022). Following the briefing and oral argument in this matter, the parties agree the request for a preliminary injunction, as opposed to a temporary restraining order, is ripe.

The "extraordinary and drastic" remedy of a preliminary injunction requires a showing of four elements: (1) substantial likelihood of success on the merits; (2) a high likelihood of irreparable harm if injunctive relief is not granted; (3) a balance of equities tips in the movant's favor; and (4) the injunctive relief is in the public interest. See Voice of the Arab World, Inc. v. MDTV Med. News Now, Inc., 645 F.3d 26, 32 (1st Cir. 2011) (citing Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7, 20 (2008)). The last two factors "merge when the Government is the party opposing the preliminary injunction." Nken v. Holder, 556 U.S. 418, 435 (2009). The most important of the four elements is the likelihood of success on the merits—which is considered the "sine qua non" of the inquiry. Ryan v. U.S. Immigr. & Customs Enf't, 974 F.3d 9, 18 (1st Cir. 2020) (quoting New Comm Wireless Servs., Inc. v. SprintCom, Inc., 287 F.3d 1, 9 (1st Cir. 2002)).

The evaluating court need not conclusively determine the merits of the movant's claim but should evaluate the likelihood or not that the movant will prevail on the merits. Id. (citing Ross-Simons of Warwick, Inc. v. Baccarat, Inc. (Ross-Simons I), 102 F.3d 12, 16 (1st Cir.

1996)). The court may accept as true well-pleaded allegations in the complaint and uncontroverted affidavits. Rohm & Haas Elec. Materials, LLC v. Elec. Circuits, 759 F. Supp. 2d 110, 114 n.2 (D. Mass. 2010) (quoting Elrod v. Burns, 427 U.S. 347, 350 n.1 (1976)). The court may also rely upon otherwise inadmissible evidence in deciding a motion for preliminary injunction. Howe v. U.S. Bank Nat'l Ass'n as Tr. for RMAC Tr. Series 2016-CTT, 440 F. Supp. 3d 99, 102 (D. Mass. 2020) (citing Asseo v. Pan Am. Grain Co., Inc., 805 F.2d 23, 26 (1st Cir. 1986)).

A. Likelihood of Success on the Merits

Turning to the likelihood of success on the merits, this Court considers three main categories as presented by the various Plaintiffs. First, Plaintiffs claim the February 7 Rate Change Notice violates the plain language of the regulations regarding the administration of indirect, or F&A, costs. See AAMC [Dkt. 1, at 16]. Second, Plaintiffs argue that absent compliance with said regulation, the Rate Change Notice is contrary to law. See [id. at 18]. Finally, Plaintiffs argue that the Rate Change Notice failed to follow administrative procedure, as required by the Administrative Procedure Act, including that the action was arbitrary and capricious, that it failed to abide by notice-and-comment requirements, and that it is impermissibly retroactive. See [id. at 19]. The Court addresses each claim in turn.

Before turning to these claims, the Court recognizes that the Plaintiffs made several other claims, including constitutional arguments, but it is cognizant of the doctrine of constitutional avoidance, which declares that "federal courts are not to reach constitutional issues where alternative grounds for resolution are available." Marasco & Nesselbush, LLP v. Collins, 6 F.4th 150, 178 (1st Cir. 2021) (quoting Vaquería Tres Monjitas, Inc. v. Pagan, 748 F.3d 21, 26 (1st Cir. 2014)). Although not resolving the merits of the instant cases, alternative grounds exist here

such that discussion of "the constitutional questions would be inconsistent with our obligation to avoid doing so where a non-constitutional disposition is possible." Id. at 179.

1. 45 C.F.R. § 75.414

45 C.F.R. § 75.414, the regulation that explains the provision of, and potential deviation from, indirect (F&A) costs, operates within a larger regulatory structure. This structure includes: (1) Appendix III to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs); and, (2) Appendix IV to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Nonprofit Organizations. The appendices expound upon the identification, negotiation, and administration of indirect costs, which also operate alongside policy statements provided by HHS and NIH in the effectuation of grants generally and indirect costs more specifically. See, e.g., States [Dkt. 82-1, NIH Grants Policy Statement].

These regulations and policies provide for a system in which the cognizant agency for indirect costs, or "the Federal agency responsible for reviewing, negotiating, and approving cost allocation plans or indirect cost proposals . . . on behalf of all Federal agencies," undertakes a lengthy negotiation process to establish a long-term ICR, memorialized in NICRAs, that complies with this strict regulatory framework. 45 C.F.R. §§ 75.2, 75.414; 45 C.F.R. pt. 75, appx. III; 45 C.F.R. pt. 75, appx. IV; States [Dkt. 82-1, NIH Grants Policy Statement]; see also AAU [Dkt. 2-12, Declaration of Dr. David F. Kotz, of Dartmouth College] ("Direct negotiations and detailed audits with the federal government in 2022 resulted in the setting of a predetermined rate that Dartmouth had expected in good faith would be applicable through 2029."); AAU [Dkt. 2-20, Declaration of Anshuman Razdan, of the University of Oregon] ("UO's current negotiated rate for organized research is 49% (up from 47.5%), last negotiated August 2023 and valid

through June 30, 2027."); States [Dkt. 6-41, Declaration of Dorota Grejner-Brzezinska, of the University of Wisconsin-Madison] ("The sense of whiplash is particularly acute, given that UW-Madison had finalized its most recent NICRA with DHHS less than three weeks prior.").

With this understanding of the larger regulatory structure, 45 C.F.R. § 75.414(c) prescribes the process by which HHS, and by extension NIH, can "deviate" from NICRAs in seemingly limited circumstances. According to the regulation:

> 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 when required by Federal statute or regulation, or when approved by a Federal awarding agency head or delegate based on documented justification as described in paragraph (c)(3) of this section.

45 C.F.R. § 75.414(c)(1). Turning to paragraph (c)(3),

> The HHS awarding agency must 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.

Id. § 75.414(c)(3).

According to Defendants, "[i]n issuing the Supplemental Guidance, NIH acted under authority expressly granted in 45 C.F.R. § 75.414(c)." States [Dkt. 73, at 11]. Defendants argue that the three-page Rate Change Notice provides a "documented justification," 45 C.F.R. § 75.414(c)(1), for "us[ing] a rate different from the negotiated rate for a class of Federal awards or a single Federal award," Id., by "implement[ing] and mak[ing] publicly available[] the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates." Id. § 75.414(c)(3). This Rate Change Notice, which at best provides a summary explanation of the government's policy to cut all ICRs to a standard 15% rate for *all* existing and future Federal grants, fails to fulfill the above regulatory mandates for several reasons.

First, the Rate Change Notice ignores the separate requirements of § 75.414(c)(3), which dictates that the Agency must provide a "documented justification" by making publicly available the "policies, procedures and general decision making criteria" that the Agency will use to then seek and justify deviations from negotiated rates. The Rate Change Notice purports to announce a single, uniform policy for all current and future grants, but fails to offer the procedures and decision making criteria it "will follow to seek and justify" the deviations from the negotiated rates. Defendants have failed to provide or point to any announced procedure or decision making criteria. At base, NIH failed to provide any requisite *documented justification*, which certainly was available to it through audits and other materials.

Even if the Rate Change Notice represented sufficient explanation of policy, procedures, and decision making criteria—of which it includes none—NIH did not comply with the step-by-step process mandated by the language of the regulation. The plain language is instructive, making clear NIH "must"—present tense—make available the policies, procedures, and decision making criteria that the Agency "will follow"—future tense—to seek and justify the deviation. The Federal Register notice discussing § 75.414 specifically recognizes this sequential process, stating:

> Language in paragraph (c) provides for the consistent application of negotiated indirect cost rates, and articulates the conditions under which a Federal awarding agency may use a different rate. These conditions include approval of the Federal awarding agency head (as delegated per standard delegations of authority) based on documented justification, the public availability of established policies for determinations to use other than negotiated rates, the inclusion of notice of such a decision in the announcement of funding opportunity, as well as in any pre-announcement outreach, and notification to OMB of the decision.

Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, 78 Fed. Reg. 78,590, 78,600 (Dec. 26, 2013). The three-page Rate Change Notice purported, but failed, to do all of these required steps in one fell swoop.

Second, by creating such a uniform policy, NIH molds the language of the regulation to fit its policy goals, rendering the text as written meaningless. As provided for in the regulation, the Agency may seek to deviate from the NICRA for "a *class of Federal awards* or a single Federal award." 45 C.F.R. § 75.414(c)(1) (emphasis added). A class of federal awards is defined as, "a group of Federal awards either awarded under a specific program or group of programs or to a specific type of non-Federal entity or group of non-Federal entities to which specific provisions or exceptions may apply." Id. § 75.2. Defendants argue that there is no limit to the size of the class, States [Dkt. 73, at 12], but fails to mention the definition of that term-of-art provided for in the regulation itself. If a "class of Federal awards" actually means *all* Federal awards, the definition provided for in § 75.2, and the inclusion of "a class of Federal awards" in § 75.414(c)(1), would be rendered entirely superfluous and meaningless. Pulsifer v. United States, 601 U.S. 124, 125 (2024) ("When a statutory construction 'render[s] an entire subparagraph meaningless,' this Court has noted, the canon against surplusage applies with special force." (quoting National Ass'n of Mfrs. v. Dep't of Def., 583 U.S. 109, 128 (2018)).

Even the dictionary definition of class—a "group, set, or kind sharing common attributes" —underscores that the plain meaning of the text refers to a subset, as opposed to all, federal awards. Class, The Merriam-Webster Dictionary (2025). In ignoring the plain meaning, Defendants are asking the Court to re-mold the text to meet the Administration's policy goals. See Fourstar v. Garden City Grp., Inc., 875 F.3d 1147, 1152 (D.C. Cir. 2017) (Kavanaugh, J.) ("It is not a judge's job to add to or otherwise re-mold statutory text to try to meet a statute's perceived policy objectives. Instead, we must apply the statute as written.").

In light of the above, the Rate Change Notice directly conflicts with the plain language of 45 C.F.R. § 75.414(c), disregarding an existing regulation and regulatory structure. FCC v. Fox

Television Stations, Inc., 556 U.S. 502, 515 (2009) ("An agency may not . . . simply disregard rules that are still on the books."); Nat'l Env't Dev. Ass'n's Clean Air Project v. EPA, 752 F.3d 999, 1009 (D.C. Cir. 2014) ("It is axiomatic . . . that an agency is bound by its own regulations." (internal quotation marks and citation omitted)). As a result, the Plaintiffs are likely to succeed in claiming the Rate Change Notice conflicts with existing regulation.

2. Section 224 Rider

If one is looking for further assurances that the Rate Change Notice violates 45 C.F.R. § 75.414(c), it was reiterated through the adoption of the § 224 Rider in 2018. The rider has been re-adopted by Congress in each year since. In 2017, the first Trump Administration released a budget proposal that would have slashed the indirect cost rate to a uniform, across-the-board rate of 10%. It stated, "[t]he Budget includes an indirect cost rate for NIH grants that will be capped at 10 percent of total research. This approach would be applied to all types of grants with a rate higher than 10 percent currently and will achieve significant savings in 2018. It would also bring NIH's reimbursement rate for indirect costs more in line with the reimbursement rate used by private foundations, such as the Gates Foundation, for biomedical research conducted at U.S. universities." Office of Management & Budget, Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2018, at 43 (2017).

Following its introduction, the House Subcommittee Labor, Health and Human Services, and Education of the Committee on Appropriations held a two-hour long hearing discussing concerns, on a bipartisan basis, relating to the cap of indirect costs. Hearing on the Role of Facilities and Administrative Costs in Supporting NIH-Funded Research Before the Subcomm. on Labor, Health and Human Services, Education, and Related Agencies of the H. Comm. on Appropriations, 115th Cong. (2017), available at:

https://www.youtube.com/watch?v=R3Eb7CjsjRE. Instead of solely declining to adopt the Administration's budget recommendation, Congress, again on a bipartisan basis, adopted the previously mentioned appropriations rider to prevent such a change through regulatory action. Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, § 226, 132 Stat. 348. This rider has remained the law from its passage through the present day. Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677; see also Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, § 224, 132 Stat. 2981, 3094 (2018); Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 224, 133 Stat. 2534, 2582 (2019); Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, § 224, 134 Stat. 1182, 1594 (2020); Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, § 224, 136 Stat. 49, 470-71 (2021); Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 224, 136 Stat. 4459, 4883-84 (2022). When enacting the rider, both the House and Senate Appropriations Committees specifically addressed the need for the rider in direct response to the Administration's proposal in their respective reports.

> According to the House Appropriations Committee,
>
> > While the Committee appreciates the Secretary's efforts to find efficiencies in NIH research spending, the Administration's proposal to drastically reduce and cap reimbursement of facilities and administrative (F&A) costs to research institutions is misguided and would have a devastating impact on biomedical research across the country. To ensure that NIH can continue supporting both direct and F&A costs as is their current practice, the bill includes a new general provision directing NIH to continue reimbursing institutions for F&A costs according to the rules and procedures described in 45 CFR 75 (with the exception of existing waivers for training grants). This provision also prohibits funds in this Act from being used to implement any further caps on F&A cost reimbursements.

H.R. Rep. No. 115-244, at 50 (2017). The Senate Appropriations Committee shared the same sentiment in adopting the rider:

> Central to the Administration's proposal to reduce Federal investments in biomedical research is its proposal to cap the F&A costs of grants, so-called "indirect costs," at 10 percent. The F&A cost of a grant is intended to cover the indirect costs of biomedical research, ranging from administration and facilities to the cost of equipment shared across multiple researchers. For example, at research facilities focused on making the next breakthrough in cancer treatment, indirect costs supply the air handlers that provide the precise conditions needed to generate therapeutic T cells for immunotherapy trials, complex data systems to analyze and protect patients' genomic data, and support for the next generation of scientific leaders. The methodology for negotiating indirect costs has been in place since 1965, and rates have remained largely stable across NIH grantees for decades. The Administration's proposal would radically change the nature of the Federal Government's relationship with the research community, abandoning the Government's long-established responsibility for underwriting much of the Nation's research infrastructure, and jeopardizing biomedical research nationwide. The Committee has not seen any details of the proposal that might explain how it could be accomplished without throwing research programs across the country into disarray. To avoid this possibility, the Committee has included bill language to prohibit HHS from developing or implementing a modified approach to funding F&A costs.

S. Rep. No. 115-150, at 109 (2017). Both committees across both chambers of Congress were clear. Not only would they not adopt the budget proposal as written, but they wanted to ensure any future, similar proposals would be contrary to law, not just regulation. Congress' rebuke of the first Trump Administration's proposal to slash and cap was patently clear.

Turning to the language of the rider itself, Congress provided:

> In making Federal financial assistance, the provisions relating to indirect costs in part 75 of title 45, Code of Federal Regulations, including with respect to the approval of deviations from negotiated rates, shall continue to apply to the National Institutes of Health to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017. None of the funds appropriated in this or prior Acts or otherwise made available to the Department of Health and Human Services or to any department or agency may be used to develop or implement a modified approach to such provisions, or to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter.

Further Consolidated Appropriations Act, 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677. This rider contains three, overlapping provisions meant to restrict NIH's ability to enact an across-the-board rate reduction.

Taking each in turn, Congress first mandated, "with respect to the approval of deviations from negotiated rates, [45 C.F.R. § 75] shall continue to apply to the National Institutes of Health to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017." As described above, the Rate Change Notice failed to comply with 45 C.F.R. § 75.414(c). If looking for further confirmation, Congress intended the rider to prevent the Administration from implementing the proposed 10% cap, or any similar cap, as violative of the provisions of 45 C.F.R. § 75. Otherwise, passing such a statute would be meaningless and ineffective in addressing congressional concerns regarding the Administration's efforts to cap ICRs. Congress does not pass meaningless statutes. See, e.g., Plaut v. Spendthrift Farm, Inc., 514 U.S. 211, 216 (1995); Rumsfeld v. FAIR, 547 U.S. 47, 57 (2006). The Trump Administration previously unequivocally agreed, including in its 2019 budget proposal:

> For the past two years, NIH has been prohibited by law from reducing grantee administrative costs and shifting these resources to support direct research on high impact areas, such as cancer, Alzheimer's disease, and heart disease. The Congress imposed this prohibition, which limits NIH's ability to maximize its support of direct biomedical research. The Budget proposes to eliminate the current prohibition, which would give NIH the flexibility to support more direct research while encouraging research institutions to improve the efficiency of operations

Office of Management & Budget, Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2020, at 43 (2019). Congress, the first Trump Administration, and this Court agree: A universal cap to ICRs is contrary to the first provision of the appropriations rider.

Turning to the second provision, "[n]one of the funds appropriated . . . may be used to develop or implement a modified approach to such provisions." Again, Congressional intent

makes clear that an across-the-board ICR cap was considered a modified approach to the existing regulations. At base, a single ICR capped at 15% is certainly a different approach than negotiating ICRs institution by institution with deviations allowed in limited, justified circumstances. As such, the Rate Change Notice is also contrary to the second provision of the appropriations rider.

Turning to the third provision of the rider, "[n]one of the funds appropriated . . . may be used . . . to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter." The Plaintiffs and Defendants put forth two interpretations of this provision. Plaintiffs claim the "fiscal effects" focus on the institution. As a result, "the 'fiscal effect' of [the Rate Change Notice]—which yields across-the-board 15% indirect cost rate, compared with the near 30% historical average—plainly goes beyond 'the proportional effect of such approvals' in the third quarter of Fiscal Year 2017." AAU [Dkt 16, at 18]. Should the fiscal effect refer to the institution, this Court agrees the Rate Change Notice plainly violates the provision.

The Defendants argue the "fiscal effect" refers to the government, and "because the [Rate Change Notice] does not seek to save the government money; rather, it takes the appropriations to NIH as a given and allocates the grants made with that money so that more of the money is spent on the direct costs[,] . . . the [Rate Change Notice] does not increase the 'fiscal effects.'" States [Dkt. 73, at 17]. Should the fiscal effect refer to the government, the Court disagrees with Defendants claim that the action does not "expand the fiscal effects" for two reasons.

First, as Plaintiffs argue, "[t]he rider focuses on [] 'the fiscal effect of the approval of such deviations from negotiated rates.' . . . Nothing in the rider suggests that the Executive may try to make up for that forbidden effect [of cutting ICRs across the board] through separate

grants." States [Dkt 81, at 10]. This is supported by the history of the 2017 proposed rate cut. Contrary to Defendants' assertion, the 2017 proposal did not only focus on savings. It also claimed that a cut to F&A (indirect) costs was necessary so "available funding can be better targeted toward supporting the highest priority research on diseases that affect human health . . . ." Office of Management & Budget, Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2018, at 43 (2017). In essence, the administration made the same claim that "available funding" would be redirected to direct costs. Again, Congress passed the rider to prevent any similar efforts following the 2017 proposal and any alternative interpretation would again render the rider meaningless and superfluous. Again, Congress does not pass meaningless statutes. See, e.g., Plaut, 514 U.S. at 216; FAIR, 547 U.S. at 57.

Second, Defendants argue, both in their briefing and at the February 21, 2025 motion hearing, this "fiscal effect" is different from the 2017 "fiscal effect" because in 2017, the focus was "saving," as opposed to the reallocation of indirect costs to direct costs. States [Dkt. 73, at 17]. This is unconvincing for two reasons. First, as described above, the Administration's 2017 proposal similarly claimed the "available funds" would be repurposed for direct costs. Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2018, at 43 (2017). This view is reinforced by the 2019 budget proposal, which stated that because of the rider, the "NIH has been prohibited by law from reducing grantee administrative costs and *shifting these resources to support direct research* on high impact areas, such as cancer, Alzheimer's disease, and heart disease . . . . The Budget proposes to eliminate the current prohibition, which would give NIH the flexibility *to support more direct research* while encouraging research institutions to improve the efficiency of operations." Major Savings and Reforms: Budget of the U.S. Government Fiscal Year 2020, at 43 (2019). This explanation echoes in the same reasoning as the current

proposed cap, particularly considering the Rate Change Notice offers no explanation as to how the newly available funding will be re-allocated to direct costs. Second, this Court is unconvinced the 15% ICR is unrelated to saving. NIH issued the Rate Change Notice on the evening of February 7, 2025. By 6:19 P.M., NIH had tweeted, "This change will save more than $4B a year effective immediately." States [Dkt. 6-5]. Considering the current explanation nearly mirrors that of the 2017 and 2019 budget proposals, the Court sees little reason to credit the Defendants' post-hoc explanation.

Considering the above, whether the fiscal effect is at the institution level or the government level is of little consequence because the Rate Change Notice violates the third provision of the appropriations rider under either interpretation.

Based on the plain language of the rider, reinforced by legislative history and acknowledged by the first Trump Administration, the Rate Change Notice is in direct contravention of Section 224. Again, the Plaintiffs are likely to succeed on the merits of their claim that the Rate Change Notice as issued is contrary to law.

3. The Administrative Procedure Act

While contrary to both statute and regulation, the Court must also consider the Rate Change Notice in light of the Administrative Procedure Act's substantive and procedural requirements. Generally speaking, the Federal government, absent its express consent, is immune from suit, also known as sovereign immunity. With that said, "[t]he APA 'sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts.'" Dep't of Homeland Sec. v. Regents of the Univ. of California, 591 U.S. 1, 16 (2020) (quoting Franklin v. Massachusetts, 505 U.S. 788, 796 (1992)). More specifically, and relevant to the claims in the current matter, the APA provides that a "reviewing court

shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be: [1] arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; [2] in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; [or, 3] without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (C), (D).

Before proceeding to judicial review, the court must ensure the agency action is considered "final" and thus ripe for review. See 5 U.S.C. § 704. "As a general matter, two conditions must be satisfied for agency action to be 'final': First, the action must mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" Bennett v. Spear, 520 U.S. 154, 177-78 (1997) (first quoting Chicago & Southern Air Lines, Inc. v. Waterman S.S. Corp., 333 U.S. 103, 113 (1948); and then quoting Port of Bos. Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic, 400 U.S. 62, 71 (1970)). Uncontested by either party, it appears clear that the Rate Change Notice is a "final" agency action ripe for judicial review. The Rate Change Notice, capping ICRs at 15%, is neither tentative nor interlocutory in nature. The Notice itself states that "[f]or any new grant issued, and for all existing grants to IHEs . . . , award recipients are subject to a 15 percent indirect cost rate . . . . This policy shall be applied to all current grants for go forward expenses from February 10, 2025 forward as well as for all new grants issued." Additionally, it is clear the action is one by which "rights or obligations" are determined—namely, the ICR applied to each grant recipient, which will determine the amount of indirect costs reimbursed to each institution.

As the Rate Change Notice is a final agency action, the Court turns to three of the claims put forth by plaintiffs and contemplated by the APA: (1) that the Rate Change Notice, as put

forth, is arbitrary and capricious; (2) that the Agency failed to comply with procedure required by law, specifically notice-and-comment rulemaking; and, (3) the Rate Change Notice is impermissibly retroactive.

a. Arbitrary & Capricious

It has long been recognized that "[t]he agency's action . . . may be set aside if found to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 41 (1983) (quoting 5 U.S.C. § 706(2)(A)); see also Regents, 519 U.S. at 16 (noting that the APA "requires agencies to engage in 'reasoned decisionmaking'" (quoting Michigan v. EPA, 576 U.S. 743, 750 (2015))). With that said, "[t]he scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." State Farm, 463 U.S. at 43; see also Regents, 591 U.S. at 16; Fox Television Stations, 556 U.S. 502, 513-14 (2009).

Although the scope of review is narrow, "the court must undertake 'a thorough, probing, in-depth review' and a 'searching and careful' inquiry into the record." Penobscot Air Servs., Ltd. v. FAA, 164 F.3d 713, 720 (1st Cir. 1999) (quoting Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 415-16 (1971)). "Only by 'carefully reviewing the record and satisfying [itself] that the agency has made a reasoned decision' can the court 'ensure that agency decisions are founded on a reasoned evaluation of the relevant factors.'" Id. (quoting Marsh v. Or. Nat. Res. Council, 490 U.S. 360, 378 (1989) (alteration in original)). To put a finer point on the issue, "[w]hile this is a highly deferential standard of review, it is not a rubber stamp." Penobscot, 164 F.3d at 720 (quoting Dubois v. U.S. Dep't of Agric., 102 F.3d 1237, 1285 (1st Cir. 1996)); see also Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc., 419 U.S. 281, 285 (1974).

There are several considerations that courts have found important when determining if an agency action is arbitrary and capricious, within the bounds of the standard described above. An agency has acted arbitrarily and capriciously if it has

> relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

State Farm, 463 U.S. at 43; see Penobscot, 164 F.3d at 719 (holding that courts must "determine whether the agency has examined the pertinent evidence, considered the relevant factors, and 'articulate[d] a satisfactory explanation for its action including a "rational connection between the facts found and the choice made"'") (quoting State Farm, 463 U.S. at 43); Associated Fisheries of Me., Inc. v. Daley, 127 F.3d 104, 109 (1st Cir. 1997).

Plaintiffs argue the Rate Change Notice is arbitrary in capricious for several reasons, including: (1) NIH failed to provide adequate reasoning, disregarding prior fact finding that supported the existing system of negotiation and failing to consider the relevant factors, and (2) NIH did not appropriately consider grant recipients' reliance interests. The Court will take each argument in turn.

1. Inadequate Reasoning

Agencies must provide sufficient reasoning to justify their rulemaking. "[A] 'fundamental requirement of administrative law is that an agency set forth its reasons for decision; an agency's failure to do so constitutes arbitrary and capricious agency action.'" Amerijet Int'l, Inc. v. Pistole, 753 F.3d 1343, 1350 (D.C. Cir. 2014) (quoting Tourus Records, Inc. v. Drug Enf't Admin., 259 F.3d 731, 737 (D.C. Cir. 2001)). As described above, agencies must provide reasons that both exhibit sufficient consideration of the relevant factors and

pertinent aspects of the problem and demonstrate a rational connection between the facts and choice that was made. See Regents, 591 U.S. at 16.

Defendants argue the Rate Change Notice supplies three independent reasons justifying the cap of ICRs at 15%, despite a header that solely claims that the rate notice "Provide[es] Indirect Cost Rates that Comport with Market Rates." First, in a single line, NIH claims, "[i]t is . . . vital to ensure that as many funds as possible go towards direct scientific research costs rather than administrative overhead." No additional explanation is provided. Second, again in a single line, NIH insists that "[i]ndirect costs are, by their very nature, 'not readily assignable to the cost objectives specifically benefitted' and are therefore difficult for NIH to oversee." Beyond the fact that the "not readily assignable" language refers to the ways in which indirect costs support more than one project, in contrast to the direct costs of a single grant award, see 75 C.F.R. § 75.2, no other explanation is provided in the Notice. Third, NIH purports to bring indirect costs in line with a random collection of private organizations. The Rate Change Notice offers no explanation as to why those organizations were selected, fails to consider both how private organizations calculate direct and indirect costs differently than the federal government (including many indirect costs in their direct costs calculation) and that private foundations are more likely to fund different types of research with lower F&A costs than the government, and finally, ignores private organizations' reliance on complementary federal funding.

These "explanations" are insufficient, and thus the Rate Change Notice is arbitrary and capricious, for two reasons. First, the explanations are conclusory. "[T]o this end, conclusory statements will not do; an 'agency's statement must be one of *reasoning*.'" Amerijet, 753 F.3d at 1350 (quoting Butte Cnty., Cal. v. Hogen, 613 F.3d 190, 194 (D.C. Cir. 2010)) (emphasis in original). As described above, NIH failed to provide any reasoning, rationale, or justification at

all. It claims that more funds will go to direct research but fails to address how the money will actually be directed to cover direct costs and how that research will be conducted absent the necessary indirect cost reimbursements provided by the federal government. This is particularly true considering the number of universities and associations that have made clear that research will have to be cut, as other funding sources will not be able to make up the shortfall. See, e.g., States [Dkt. 6-34, Declaration of Dr. Greg Hirth, of Brown University, at ¶ 24] ("Any further increases in the gap between Brown's current cost of research and federally sponsored funding cannot be recouped from other revenue sources."); AAU [Dkt. 2-1, Declaration of Barbara R. Snyder, of the Association of American Universities, at ¶ 17] ("AAU member universities' existing endowments cannot simply be redirected to pick up these losses. The vast majority of endowed funds often are restricted by the terms on which the funds were donated to the AAU member university and cannot legally be used to cover research infrastructure costs. Moreover, an AAU member university may only draw down the portion of the endowment that is unrestricted at a rate that complies with applicable law."); AAU [Dkt. 2-3, Declaration of Mark Becker, of the Association of Public & Land-grant Universities, at ¶ 14] ("Nor can APLU member institutions' endowments be simply redirected to make up for these losses . . . . Endowments are also complex assets with many legal requirements stipulating how they can be used. And not all universities have large endowments, or any endowment at all—in fact, of the public institutions that have endowments, nearly half are valued at less than $50 million."); AAU [Dkt. 2-8, Declaration of Theresa S. Mayer, of Carnegie Mellon University, at ¶ 18] ("CMU cannot cover the funding gap itself that would result from the reduction of the indirect cost rate. While CMU maintains an endowment, it is neither feasible nor sustainable for CMU funds or other revenue sources to offset shortfalls in indirect cost recovery[.]"); AAU [Dkt. 2-11,

Declaration of Robert A. Harrington, M.D., of Cornell University, at ¶ 17] ("Cornell's existing endowment cannot simply be redirected to pick up these losses. The vast majority of endowed funds are restricted by the terms on which the funds were donated to the University and cannot legally be used to cover research infrastructure costs. Moreover, Cornell may only draw down the portion of the endowment that is unrestricted at a rate that complies with New York State law.").

NIH then claims indirect costs are difficult to oversee but fails to explain the inadequacy of the existing audit system or how the auditing system differs from the tracing of direct costs. See 45 C.F.R. § 75.500 et seq. Defendants argument that Plaintiffs' "extensive citations to audit and calculation requirements for indirect costs confirm NIH's position" fails to address why the audit system is deficient. States [Dkt. 73, at 21]. Instead, the citations point to a fairly comprehensive regulatory regime that NIH seems to ignore in the Rate Change Notice altogether. See, e.g., 45 C.F.R. § 75.504 (frequence of audits); § 75.507(a) (noting availability of "program-specific audit guide[s]" maintained by HHS); § 75.508(a)-(d) (describing responsibilities of IHEs in preparing their audits). Finally, NIH asserts the Rate Change Notice will bring the ICRs in line with private foundations, providing no explanation for this choice in light of the fact that private organizations, like the Gates Foundation, are "more expansive than NIH in defining direct costs, meaning some overhead payments are wrapped in with the grant." Jocelyn Kaiser, NIH Plan to Reduce Overhead Payments Draws Fire, Science (June 2, 2017), https://www.science.org/content/article/nih-plan-reduce-overhead-payments-draws-fire; States [Dkt 81, at 17 n.14]; see also generally States [Dkt 82-2]. Instead, NIH simply makes a conclusory claim that "[m]ost private foundations that fund research provide substantially lower indirect costs than the federal government, and universities regularly accept grants from these

foundations." The Notice does not contemplate if bringing the federal government in line with private foundations is actually a good thing. NIH's conclusory statements hardly rise to the level of "reasoned decisionmaking" required by the APA. Regents, 591 U.S. at 16 (quoting Michigan, 576 U.S. at 750). It is this Court's obligation to hold NIH "accountable to the public." Franklin v. Massachusetts, 505 U.S. 788, 796 (1992). The failure to provide any type of *reasoning* renders the Rate Change Notice arbitrary and capricious.

Second, NIH's proffered "reasons" fail to grapple with the relevant factors or pertinent aspects of the problem and fails to demonstrate a rational connection between the facts and choice that was made. In cutting indirect costs without identifying a countervailing funding stream for such costs of research, the only reasonable outcome will be the discontinuing of research supported by the slashed F&A rates, including ongoing clinical trials. See, e.g., AAU [Dkt 2-5, Declaration of Greg Hirth, of Brown University, at ¶ 15] ("At a 15% indirect cost rate, many of Brown's current research projects and clinical trials will be forced to cease abruptly."); Id. [Dkt. 2-6, Declaration of Theresa A. Maldonado, of the University of California, at ¶ 15] ("[Indirect costs] not only support the infrastructure and buildings that house pioneering research teams, but also the personnel who assure the safety of adults and children enrolling in clinical trials for cancer and chronic disease, the ethics teams that assure those trials are done safely, and the data and privacy teams that protect research subjects' personal data."); Id. [Dkt. 2-15, Declaration of Laurent Heller, of Johns Hopkins University, at ¶¶ 5-6 ("NIH's reimbursement of its portion of indirect costs is essential for supporting . . . critical research" such as "clinical trials . . . focusing on innovative treatments for pediatric and young adult craniopharyngioma (a rare type of brain tumor)."]; Id. [Dkt. 2-18, Declaration of Arthur Lupia, of the University of Michigan, at ¶¶ 7-8 ("[T]here are currently 425 NIH-funded interventional clinical trials

underway and not yet completed at the University of Michigan . . . . The loss of [indirect cost coverage] will immediately impact the University of Michigan's ability to . . . pay expenses associated with these [clinical trials]."). The Rate Change Notice seems to have ignored the need for indirect funds in the administration of *any and all* research. In essence, by cutting indirect funds, NIH is cutting research. There also seems to be a limited rational connection between the facts, particularly the nature of private funding opportunities and their differences from federal funding grants, as well as the limitation on university endowments, and the decision to cut ICRs to bring them in line with private organizations.

This failure to grapple with relevant factors and facts is even more egregious in light of the drastic change from the existing ICR negotiation process. Although a change in policy does not result in a heightened standard of review, if an agency's "new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests" an agency's failure to consider such factors "would be arbitrary or capricious . . . ." Fox Television Stations, 566 U.S. at 515. "In such cases it is not that further justification is demanded by the mere fact of policy change; but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." Encino Motorcars, LLC v. Navarro, 579 U.S. 211, 222 (2016) (quoting Fox Television Stations, 556 U.S. at 515-16) (internal quotation marks omitted). Thus, "when an agency rescinds a prior policy[,] its reasoned analysis must consider the 'alternative[s]' that are 'within the ambit of the existing [policy].'" Regents, 591 U.S. at 30 (quoting State Farm, 463 U.S. at 51).

As described above, the NIH Rate Change Notice failed to provide even the most basic level of "reasoning," let alone recognize or justify the disregarded facts that underlay its existing

policy. NIH's existing ICR negotiation process contemplates the need for an individualized analysis at the institution level, as well as the dramatically different needs of those varying institutions. The Rate Change Notice failed to acknowledge those circumstances, nor provides any justification for that disregard.

As the reasons in the Rate Change Notice are both conclusory and fail to grapple with the necessary factors, facts, and pertinent aspects of the problem demanded by this change from the existing ICR negotiation process, the Plaintiffs are likely to succeed in their claims that the Rate Change Notice is arbitrary and capricious.

2. Substantial Reliance Interests

The justifications provided by the Rate Change Notice fails in an additional respect. Even if the reasons provided had been more thorough and sufficient, the Notice fails in its entirety to recognize or consider the substantial reliance interests at issue. Courts have long recognized that "[w]hen an agency changes course . . . it must 'be cognizant that longstanding policies may have "engendered serious reliance interests that must be taken into account."'" Regents, 591 U.S. at 30 (quoting Encino Motorcars, 579 U.S. at 222). "It would be arbitrary and capricious to ignore such matters." Regents, 591 U.S. at 1913 (quoting Fox Television Stations, 556 U.S. at 515); see also Perez v. Mortg. Bankers Ass'n, 575 U.S. 92, 106 (2015) ("[T]he APA requires an agency to provide more substantial justification when . . . its prior policy has engendered serious reliance interests that must be taken into account. It would be arbitrary and capricious to ignore such matters."); Smiley v. Citibank (South Dakota), N. A., 517 U.S. 735, 742 (1996) ("Sudden and unexplained change[s to prior policies] . . . may be 'arbitrary, capricious [or] an abuse of discretion.'" (quoting 5 U.S.C. § 706(2)(A)).

As a result, "because [NIH] was not writing on a blank slate, it was required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." Regents, 591 U.S. at 33 (internal quotation marks omitted). The reliance interests at play are many and acknowledged by all parties. Non-governmental organization have relied on the Federal provision of indirect costs for decades. E.g., AAU [Dkt. 2-7, Declaration of David A. Tirrell, of the California Institute of Technology, at ¶ 14]; Id. [Dkt. 2-8, Declaration of Theresa S. Mayer, of Carnegie Mellon University, at ¶ 15]; Id. [Dkt. 2-13, Declaration of David Paul Norton, of the University of Florida, at ¶ 15]; Id. [Dkt. 2-20, Declaration of Anshuman Razdan, of the University of Oregon, at ¶ 17]; Id. [Dkt. 2-21, Declaration of Elizabeth Duggins Peloso, of the University of Pennsylvania, at ¶ 18]; Id. [Dkt. 2-28, Declaration of Ishwar K. Puri, of the University of Southern California, at ¶ 15]; Id. [Dkt. 2-29, Declaration of C. Cybele Raver, of Vanderbilt University, at ¶ 14].

Indirect costs are taken into consideration when universities and associations formulate their overall operating budgets and consider improvements to research infrastructure. E.g., Id. [Dkt. 2-3, Declaration of Mark Becker, of the Association of Public & Land-grant Universities, at ¶ 11] ("For each NIH award, APLU member institutions necessarily rely on both the direct cost and indirect cost allocations in formulating their overall operating budgets for any given year. These allocations are used to plan for annual staffing needs, infrastructure support (e.g., IT networks, regulatory compliance, and grant management support), facility building and renovation, and equipment purchases to support a broad range of overlapping research activities."); Id. [Dkt. 2-6, Declaration of Theresa A. Maldonado, of the University of California, ¶ 17] ("UC campuses receive and expend hundreds of millions of dollars annually in multiyear awards for their projects, centers, and institutes, and can proceed with establishing budget

estimates for planning purposes in reliance on the facilities and administrative cost recovery rates periodically negotiated between individual campuses and the federal government (the Department of Health and Human Services) that set rates for three to five years."); Id. [Dkt. 2-12, Declaration of Dr. David F. Kotz, of Dartmouth College, at ¶ 9] ("Dartmouth spent $17 million of its own funds for the repair and renovation of research facilities in fiscal years 2022 and 2023, and anticipates spending another $14 million in institutional funds to maintain these existing facilities in fiscal years 2024 and 2025. These investments, to which Dartmouth has already committed, have been made specifically in reliance on our ability to recover a portion of these expenses through the negotiated indirect costs rate with federal agencies like the NIH."). Beyond the institutions, the reliance interests are plenty, ranging from the researchers who chose to conduct research at certain institutions with the understanding that they would be supported, to the students who will no longer be admitted to these institutions, to the local communities that will suffer from the loss of community-based programming. See, e.g., States [Dkt. 6-11, Declaration of Donald M. Elliman, Jr., of Colorado Anschutz Medical Campus, at ¶ 10] ("The drastic cuts to NIH F&A will bring the Institute's research and community-based programs to a virtual standstill due to the loss of shared administrative staff and the specialized computing infrastructure essential for the Institute's efforts."); AAU [Dkt. 2-7, Declaration of David A. Tirrell, of the California Institute of Technology] ("Caltech is currently making decisions regarding admission of graduate students who conduct much of our NIH-supported research. The number of graduate students – who are the future of biomedical research – who can be admitted will have to be reduced substantially. The impact on the future of research will be immediate and unrecoverable. [] Offers to new postdoctoral scholars also will be reduced, with similar impact on the quality of the research environment and on the future of biomedical research.").

In short, the Notice fails to consider the impact the Rate Change Notice would have on public health, which is the purpose of the entire regulatory regime. The Notice fails to contemplate the budgets of these institutions, formulated months and years before this Notice's sudden implementation. It fails to contemplate the risk to human life as research and clinical trials are suspended in response to the shortfall. It fails to contemplate the life, careers, and advancement that will be lost as these budgets are indiscriminately slashed. Although reticent to consider together, the Rate Change Notice fails to reflect on the health of those whose hopes rely on clinical trials and the financial investment that will be lost as research is disrupted. It fails to consider that public health will suffer.

As an initial matter, Defendants claim that Plaintiffs' reliance interests "relate[] only to existing grants, because Plaintiffs can have no legally protectible reliance interests in grants that they have not yet been awarded." States [Dkt. 73, at 23] (citing Lemon Bay Cove, LLC v. United States, 160 Fed. Cl. 593, 613 (2022) ("A property owner who acquires land with knowledge of a regulatory restraint could be said to have no reliance interest or to have assumed the risk of any economic loss.")). However, Defendants misunderstand the nature of the reliance interests. ICRs, memorialized in NICRAs, are negotiated for a period of several years, irrespective of any specific grant. Cf. 45 C.F.R. pt. 75, appx. III § C.1 et seq. (establishing procedures for the "[d]etermination and [a]pplication of [i]ndirect (F&A) [c]ost [r]ates"). At the very least, these reliance interests exist for the length of the NICRA, which institutions negotiated with the cognizant agency for the purpose of consistency until the conclusion of the agreement. See, e.g., AAU [Dkt. 2-12, Declaration of Dr. David F. Kotz, of Dartmouth College, at ¶ 10] ("Direct negotiations and detailed audits with the federal government in 2022 resulted in the setting of a predetermined rate that Dartmouth had expected in good faith would be

applicable through 2029."); Id. [Dkt. 2-20, Declaration of Anshuman Razdan, of the University of Oregon, at ¶ 12] ("UO's current negotiated rate for organized research is 49% (up from 47.5%), last negotiated August 2023 and valid through June 30, 2027."). As a result, the reliance interests concern both existing and future grants—at least those grants awarded within the timeframe contemplated by each institution's NICRA.

Nonetheless, Defendants claim to have addressed these substantial and long-standing reliance interests despite the Rate Change Notice, read generously, offering only a fleeting reference to reliance interests:

> Although cognizant that grant recipients, particularly "new or inexperienced organizations," use grant funds to cover indirect costs like overhead . . . , NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Indirect costs are, by their very nature, "not readily assignable to the cost objectives specifically benefitted" and are therefore difficult for NIH to oversee. . . . Yet the average indirect cost rate reported by NIH has averaged between 27% and 28% over time. And many organizations are much higher—charging indirect rates of over 50% and in some cases over 60%.

This explanation is plainly insufficient because it is conclusory and fails to address some, or any, of the reliance interests discussed above. "[S]ummary discussion may suffice in other circumstances, but here—in particular because of decades of industry reliance on [NIH]'s prior policy—the explanation fell short of the agency's duty to explain why it deemed it necessary to overrule its previous position." Encino Motorcars, 579 U.S. at 222. As stated in Encino Motorcars, and equally applicable here, "[i]n light of the serious reliance interests at stake, . . . conclusory statements do not suffice to explain [the agency] decision." 579 U.S. at 224 (citing Fox Television Stations, 556 U.S. at 515–16).

In both its opposition to the Temporary Restraining Order and at the motion hearing, Defendants attempted to supplement NIH's consideration of Plaintiffs' tremendous reliance

interests with additional arguments. In its opposition, Defendants stated, "NIH did note that 'grant recipients use grant funds to cover indirect costs.' It simply concluded that the other interests justifying the Supplemental Guidance outweighed that interest." States [Dkt. 73, at 23] (citation omitted). Defendants added, "NIH likewise considered that grantees often accept grants with lower indirect cost rates, demonstrating that those rates are generally acceptable to the grantees and would not unduly upset their reliance interests." [Id. at 24]. However convincing or unconvincing these arguments may be, the fact of the matter is that they did not appear in the Rate Change Notice. Defendants attempted to further supplement these claims at oral argument. After reciting the above quoted language from the Rate Change Notice, counsel for Defendants added, "[the Rate Change Notice] goes on to explain the various rationales that it thinks trump those reliance interests. So it was considered. And the idea that it's not . . . that's a policy disagreement . . . . [S]o they were considered here. And you can see the reasons that NIH put forward for not adhering to them."

The Court is prohibited from considering these additions to the brief explanation provided in the Rate Change Notice. "It is a 'foundational principle of administrative law' that judicial review of agency action is limited to 'the grounds that the agency invoked when it took the action.'" Regents, 591 U.S. at 20 (quoting Michigan, 576 U.S. at 758); see also State Farm, 463 U.S. at 50 (stating that it has long been recognized that an agency action may only be upheld "on the basis articulated by the agency itself"); Sec. & Exch. Comm'n v. Chenery Corp., 332 U.S. 194, 196 (1947) ("[It is] a simple but fundamental rule of administrative law . . . that a reviewing court . . . must judge the propriety of [an agency's] action solely by the grounds invoked by the agency."). Especially in light of Defendants' arguments in their papers and at the motion hearing, "[t]he functional reasons for requiring contemporaneous explanations apply with

equal force regardless whether post hoc justifications are raised in court by those appearing on behalf of the agency or by agency officials themselves." Regents, 591 U.S. at 23; see also Am. Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 539 (1981) ("[T]he post hoc rationalizations of the agency . . . cannot serve as a sufficient predicate for agency action."); Volpe, 401 U.S. at 419 (rejecting "litigation affidavits" from agency officials as "merely 'post hoc' rationalizations" (citation omitted)). Thus, with no additional explanation on top of what amounts to one sentence in the Rate Change Notice, NIH plainly failed to sufficiently consider the substantial reliance interests at stake. Of note, even had the Court considered these additional statements both in the opposition and at oral argument, NIH still failed to appropriately consider the substantial and long-standing reliance interests.

In summary, a "[s]udden and unexplained change . . . , or change that does not take account of legitimate reliance on prior interpretation may be 'arbitrary, capricious [or] an abuse of discretion.'" Smiley, 517 U.S. at 742 (1996) (quoting 5 U.S.C. § 706(2)(A)) (citing State Farm, 463 U.S. at 46-57; United States v. Pa. Indus. Chem. Corp., 411 U.S. 655, 670-75 (1973); NLRB v. Bell Aerospace Co., 416 U.S. 267, 295 (1974)). The Rate Change Notice was issued, without warning, on the evening of Friday, February 7, 2025. It was set to take effect on Monday, February 10, 2025. It would be difficult to mandate a more sudden change. The three-page Notice failed to provide basic reasoning for its decision, as described above, and failed to address the substantial reliance interests. Although empowered to make impactful policy decisions, "a new administration may not . . . ignore statutory standards in carrying out its regulatory functions." State Farm, 463 U.S. at 59 n.* (Rehnquist, J., concurring in part and dissenting in part). The Defendants have ignored those statutory standards here and the Plaintiffs are likely to succeed in their claim that the Rate Change Notice is arbitrary and capricious.

b. Failure to Follow Notice and Comment Procedures

According to the APA, before a federal agency adopts a rule a "[g]eneral notice of proposed rule making shall be published in the Federal Register." 5 U.S.C. § 553(b). After providing notice, "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." Id. at § 553(c). Taken together this process is known as notice-and-comment rulemaking and "[f]ailure to abide by these requirements renders a rule procedurally invalid." N.H. Hosp. Ass'n v. Azar, 887 F.3d 62, 70 (1st Cir. 2018) (citing Warder v. Shalala, 149 F.3d 73, 75 (1st Cir. 1998); Hoctor v. U.S. Dep't of Agric., 82 F.3d 165, 167 (7th Cir. 1996) (stating that, unless an exception applies, a "rule promulgated by an agency that is subject to the [APA] is invalid unless the agency" follows notice-and-comment procedures)).

Generally speaking, "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice" are exempted from notice-and-comment rulemaking. 5 U.S.C. § 553(b)(A). Interpretive rules are those "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." Perez, 575 U.S. at 97 (quoting Shalala v. Guernsey Mem'l Hosp., 514 U.S. 87, 99 (1995)). Conversely, so-called "legislative" or "substantive" rules are subject to the process described above, absent some other exception. N.H. Hosp. Ass'n, 887 F.3d at 70. Legislative rules are those that "create[] rights, assign[] duties, or impose[] obligations, the basic tenor of which is not already outlined in the law itself." La Casa Del Convaleciente v. Sullivan, 965 F.2d 1175, 1178 (1st Cir. 1992) (citation omitted). A legislative rule "'has the force of law,' while an interpretive rule is 'merely a clarification or explanation of an existing statute or rule' and is 'issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.'" Id.

(quoting Guardian Fed. Sav. & Loan Ass'n v. FSLIC, 589 F.2d 658, 664-65 (D.C. Cir. 1978); United States Department of Justice, Attorney General's Manual on the Administrative Procedures Act 30 n.3 (1947)).

1. Waiver of the Grant Exception

Before examining the boundary between interpretive and legislative rules, Defendants raise an alternative argument: The Rate Change Notice is exempt from notice-and-comment rulemaking because an alternative exception applies. The APA provides that notice-and-comment rulemaking applies "except to the extent that there is involved . . . a matter relating to agency management or personnel or to public property, loans, *grants*, benefits, or contracts." § 553(a)(2) (emphasis added). Although seemingly on point, the application of the exception is not nearly that straightforward. In 1971, the Secretary of the Department of Health, Education, and Wealth ("HEW"), the predecessor agency of HHS, voluntarily waived the grant exception found in § 553(a)(2). The Secretary's statement reads as follows:

> The APA exempts from [notice-and-comment rulemaking] matters relating to public property, loans, grants, benefits, or contracts. . . . The public benefit from such participation should outweigh any administrative inconvenience or delay which may result from use of the APA procedures in the five exempt categories. Effective Immediately, all agencies and offices of the Department which issue rules and regulations relating to public property, loans, grants, benefits, or contracts are directed to utilize the public participation procedures of the APA, 5 U.S.C. 553. Although the APA permits exceptions from these procedures when an agency for good cause finds that such procedures would be impracticable, unnecessary or contrary to the public interest, such exceptions should be used sparingly, as for example in emergenc[i]es and in instances where public participation would be useless or wasteful because proposed amendments to regulations cover minor technical matters.

Public Participation in Rule Making: Statement of Policy, 36 Fed. Reg. 2,532 (Feb. 5, 1971).

2. Binding Nature of the Grant Exception Waiver

In their papers and at oral argument, Defendants state that despite the Secretary's explicit statement otherwise, the grant exception in the APA continues to apply, and thus the Rate Change Notice is entirely exempt from notice-and-comment rulemaking. Defendants argue,

> [w]hile the Secretary [of] the Department of Health and Human Services predecessor department voluntarily agreed to follow notice and comment rulemaking, he did so 'as a matter of policy'—not in a binding regulation. See 36 Fed. Reg. 2,532 (Feb. 5, 1971). There is thus no binding requirement of notice-and-comment rulemaking here—and, in any event, no matter what the executive branch says as a matter of policy discretion, the Court should not extend the APA's notice-and-comment requirements to a context, i.e., grant making, that Congress expressly dictated they should not reach.

States, [Dkt. 73, at 19-20]. At oral argument, Defendants added that post-Loper Bright, courts "should not let an agency extend a statute to a context that Congress plainly didn't want it to go."

As an initial matter, Loper Bright is inapplicable to the matter at hand. In that case, the Supreme Court held that under the APA, courts need not defer to agency interpretation of ambiguous statutes. See generally Loper Bright Enters. v. Raimondo, 603 U.S. 369 (2024). That is not relevant here, where the head of HHS issued a policy statement that was not an interpretation of an ambiguous statute. The statute was clear. Instead, by adding a notice-and-comment requirement for exempted actions, the agency head was simply adding procedures on top of the minimum laid out by Congress.

Second, the Supreme Court has long held that agency heads are well within their function, contrary to Defendants' statements otherwise, to impose additional procedural and substantive requirements beyond those required by Congress. Serv. v. Dulles, 354 U.S. 363, 388 (1957) ("While it is of course true . . . the Secretary was not obligated to impose upon himself these more rigorous substantive and procedural standards, neither was he prohibited from doing so, . . . and having done so he could not . . . proceed without regard to them."). While an agency

cannot go below the floor set by Congress, it can certainly go above it. Once such procedural requirements have been put in place agencies must follow them, even when the internal procedures exceed the process otherwise required. See Morton v. Ruiz, 415 U.S. 199, 235 (1974) (citing Dulles, 354 U.S. at 388; Vitarelli v. Seaton, 359 U.S. 535, 539-40 (1959)) ("Where the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures. This is so even where the internal procedures are possibly more rigorous than otherwise would be required."); cf. Rotinsulu v. Mukasey, 515 F.3d 68, 72 (1st Cir. 2008) ("An agency has an obligation to abide by its own regulations. The failure to follow an applicable regulation may be a sufficient ground for vacation of an agency's decision, resulting in a remand." (citing Accardi v. Shaughnessy, 347 U.S. 260, 265-67 (1954); Picca v. Mukasey, 512 F.3d 75, 79-80 (2d Cir. 2008); Nelson v. INS, 232 F.3d 258, 262 (1st Cir. 2000))).

Courts across the country have not only found such self-imposed requirements binding on the agency by which they were issued: Courts have found HHS, and thus NIH, bound by *this* self-imposed waiver of the grant exception. Clarian Health W., LLC v. Hargan, 878 F.3d 346, 356-57 (D.C. Cir. 2017) ("The Government recognizes that, in 1971, the Secretary voluntarily waived the § 553(a)(2) exception and subjected itself to the statute's procedural requirements . . . . Yet, it appears to contest the assertion that this waiver binds the agency . . . . The Government provides no basis for this argument, however, and it fails to address this court's and the Supreme Court's cases treating this or other such waivers as binding." (citing Samaritan Health Serv. v. Bowen, 811 F.2d 1524, 1529 & n.14 (D.C. Cir. 1987); Humana of S.C., Inc. v. Califano, 590 F.2d 1070, 1084 (D.C. Cir. 1978); Rodway v. U.S. Dep't of Agric., 514 F.2d 809, 814 (D.C. Cir. 1975) ("[T]he regulation fully bound the Secretary to comply thereafter with the procedural demands of the APA."); Dulles, 354 U.S. at 388));

Buschmann v. Schweiker, 676 F.2d 352, 356 n.4 (9th Cir. 1982) ("The Administrative Procedures Act is applicable to rulemaking by the Secretary of Health and Human Services. Although 5 U.S.C. § 553(a)(2) would have exempted the rulemaking procedure now in dispute, the then Secretary of Health, Education and Welfare, in a policy statement dated January 28, 1971, (36 F.R. 2532), required all agencies and offices in his department to utilize the public participation procedures of § 553. The Secretary does not contest his legal obligation to comply with § 553 procedures."); Nat'l Welfare Rts. Org. v. Mathews, 533 F.2d 637, 646 (D.C. Cir. 1976) ("In addition to these substantive standards a regulation must be promulgated in accord with procedural requirements of the Administrative Procedure Act . . . and any further rules imposed by the department itself." (citing Rodway, 514 F.2d at 814; 36 Fed. Reg. 2532 (1971)); Herron v. Heckler, 576 F. Supp. 218, 229-30 (N.D. Cal. 1983) ("The APA contains a provision that ordinarily would exempt the Secretary from its rule-making procedures . . . . Notwithstanding this statutory exemption, the Secretary elected to abide by the provisions of the APA . . . . The Secretary asserts that her obligations under the APA remain discretionary, because 'statements of policy,' unlike rules or regulations, do not create binding legal obligations . . . . This Court perceives no reason to depart from [] authority. [T]he Court finds that the Secretary was bound by the provisions of the APA when she promulgated the claims manual limitations at issue."); Herron, 576 F. Supp. at 229 n.12 ("Defendants mistakenly rely solely on the January 1971 directive's label— 'statement of policy'—to argue that it carries no binding legal effect."); Lewis v. Weinberger, 415 F. Supp. 652, 661 (D.N.M. 1976) ("HEW, the agency of which the IHS [(Indian Health Service)] is a part, has placed itself under the procedural requirements of section 553 in all its rulemaking relating to 'public property, loans, grants, benefits or contracts.' 36 Fed. Reg. 2536 (Feb. 5, 1971). Thus, the IHS was bound to

comply with A.P.A. rulemaking procedures in this case despite the otherwise applicable exemption found at subsection (a)(2) of section 553." (citing Morton, 415 U.S. at 235 (1973); Rodway, 514 F.2d 809; Florida v. Weinberger, 401 F. Supp. 760 (D.D.C. 1975))).

Defendants cite to a single case that seems to state the opposite: "'[A]lthough it appears that no notice of proposed rule making was given when these regulations were issued, the requirement of notice in the Administrative Procedure Act, 5 U.S.C. § 553(b), is inapplicable when regulations concern matters relating to grants, as do the instant ones.' . . . Since the rule challenged by the plaintiffs falls within the 'grant' exception, it is not necessary for the purpose of procedural review to determine whether the rule is legislative or interpretative." Opelika Nursing Home, Inc. v. Richardson, 356 F. Supp. 1338, 1342 (M.D. Ala. 1973) (quoting Rodriguez v. Swank, 318 F. Supp. 289, 295 (N.D. Ill.1970)). Although the Court assumes it was not purposely misleading, the case cited by the Defendants is entirely inapplicable. The original Opelika Nursing Home case was decided on January 29, 1971. Opelika Nursing Home, Inc. v. Richardson, 323 F. Supp. 1206 (M.D. Ala. 1971), rev'd, 448 F.2d 658 (5th Cir. 1971). It concerned regulations from 1970, *before* the Secretary put the new procedural requirements in place on February 5, 1971. 36 Fed. Reg. 2,532. In short, the 1970 agency action at issue in the case cited by the Defendants was certainly not subject to the Secretary's February 1971 announcement. Conversely, seemingly every case that addressed the question *after* the policy was issued came to the opposite conclusion.

In light of the weight of precedent, the waiver of the grant exception is binding and cannot be summarily disregarded. Fox Television Stations, 556 U.S. at 515 ("An agency may not, for example, depart from a prior policy sub silentio."). The only remaining question is

whether the Rate Change Notice is the type of legislative rule that is subject to notice-and-comment rulemaking.

3. Legislative Rule

As described above, legislative rules are those that "create[] rights, assign[] duties, or impose[] obligations, the basic tenor of which is not already outlined in the law itself." N.H. Hosp. Ass'n, 887 F.3d at 70 (quoting La Casa Del Convaleciente, 965 F.2d at 1178). At its most basic level, the Rate Change Notice does just that. As opposed to honoring existing NICRAs and negotiating ICRs on a case-by-case basis as contemplated by the existing regulation, the Rate Change Notice provides that "there will be a standard indirect rate of 15% across all NIH grants for indirect costs in lieu of a separately negotiated rate for indirect costs in every grant." This is a two-fold overhaul of the existing regulatory regime.

First, courts consider if "the rule is 'inconsistent with another rule having the force of law,' or otherwise 'alter[s] or enlarg[es] obligations imposed by a preexisting regulation.'" N.H. Hosp. Ass'n, 887 F.3d at 73 (quoting Warder, 149 F.3d at 75; Aviators for Safe & Fairer Regulation, Inc. v. FAA, 221 F.3d 222, 226-27 (1st Cir. 2000)) (alterations in original). There is no question the Rate Change Notice is both inconsistent with an existing rule and alters existing obligations: The institutions currently dedicated to the good work of improving the lives and health of Americans do so in reliance on their negotiated indirect cost rates. Despite being dressed up as a simple deviation, which the Court addressed above, this Rate Change Notice imposes entirely different obligations, slashing ICRs that resulted from a lengthy negotiation process prescribed by the current regulation. Thus, this Rate Change Notice is inconsistent with a current rule having the force of law. In so doing, it alters the agency's and the institutions' obligations.

Second, courts "consider the manner in which the . . . action[] fit[s] within the statutory and regulatory scheme." N.H. Hosp. Ass'n, 887 F.3d at 73 (citing Warder, 149 F.3d at 81). As the Association of American Universities state, the Rate Change Notice is "manifest not only with respect to the rate itself, but also with respect to the reticulated process by which the rates were previously set on an individualized basis, which is not compatible with a single, across-the-board rate." AAU [Dkt. 16, at 37]. For decades, institutions have relied on the negotiation process, as laid out by the regulations. With the Rate Change Notice, this negotiation process would no longer exist. Such a change does not simply, "advise the public of the agency's construction of the statutes and rules which it administers," which would bring it within the gambit of an interpretive rule. Perez, 575 U.S. at 97. It changes the entire field of play, as legislative rules often do.

HHS and other agencies have recognized the need for notice-and-comment rulemaking in similar circumstances. For example, HHS submitted to notice and comment when it intended to restrict indirect costs for foreign organizations and foreign public entities, Health and Human Services Grants Regulation, 81 Fed. Reg. 45270 (proposed July 13, 2016) (to be codified at 45 C.F.R. pt. 75), while the Office of Management and Budget submitted to notice and comment when it planned to "establish a consistent policy for adjustment of indirect cost rates based on a proposal(s) subsequently found to have contained unallowable costs," Proposed Revisions to Circular A-21, 56 Fed. Reg. 29530 (proposed June 27, 1991). In both cases, the agencies recognized that rules even less substantive than the Rate Change Notice at issue were legislative, and thus subject to notice-and-comment. The Rate Change Notice does not simply restrict indirect costs for a subset of organizations, as did the rule submitted in 2016. It also does not simply adjust the policy for unallowable costs. It restricts indirect costs for every institution

accepting a grant from NIH and changes the process by which those indirect costs are determined on a wholesale basis. If notice-and-comment rulemaking was appropriate for the former proposed rules, it is certainly appropriate for the proposed Rate Change Notice.

On a final note, Defendants make an additional argument that because the Rate Change Notice purports to comply with an existing regulation, 45 C.F.R. § 75.414(c), which has already gone through notice-and-comment rulemaking, no additional notice-and-comment safeguards are required. States [Dkt. 73, at 22]. This plainly cannot be true. First, as described above, the Rate Change Notice is inapposite with § 75.414. Second, because the Rate Change Notice is a legislative rule, any existing regulation cannot excuse NIH from compliance with the APA's notice-and-comment rulemaking requirements. Simply claiming a legislative rule complies with some other regulation does not excuse compliance with administrative law altogether.

As the Rate Change Notice is a legislative rule and no exception is applicable, NIH was required to submit the Rate Change Notice to notice-and-comment rulemaking. Failure to comply with these requirements renders the rule procedurally invalid. Thus, the Plaintiffs are, again, likely to succeed on the merits of their claim.

c. Impermissibly Retroactive

In considering whether retroactive application of an agency regulation is permissible, the court conducts a two-step inquiry. First, it must determine if the enabling statute endorses retroactive rulemaking. Landgraf v. USI Film Prods., 511 U.S. 244, 280 (1994). If it does, the inquiry is complete. If it does not, the court must continue to the second step—determining if the regulation truly operates retroactively. Id. If it does, the regulation is impermissibly retroactive.

Turning to the first step, "[i]t is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress . . . .

Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result." Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988) (citing Greene v. United States, 376 U.S. 149, 160 (1964); Claridge Apartments Co. v. Commissioner, 323 U.S. 141, 164 (1944); Miller v. United States, 294 U.S. 435, 439 (1935); United States v. Magnolia Petroleum Co., 276 U.S. 160, 162-63 (1928)); see also Brimstone R. & Canal Co. v. United States, 276 U.S. 104, 122 (1928) ("The power to require readjustments for the past is drastic . . . . [I]t ought not to be extended so as to permit unreasonably harsh action without very plain words."). Thus, as a threshold matter, the Court must determine if the authority delegated by Congress explicitly empowers HHS, and therefore NIH, to issue retroactive regulations. The express language of the enabling statute does not appear—at least explicitly—to give NIH any such power. See 42 U.S.C. § 241.

Thereafter, the question for the Court becomes whether the Rate Change Notice does, in fact, operate retroactively. If so, the Rate Change has an impermissible retroactive effect. As an initial matter, both Plaintiffs and Defendants focus their arguments on the Rate Change Notice's application to existing grants, thus so too will the Court. AAU [Dkt. 16, at 32]; States [Dkt. 73, at 25]; States [Dkt. 81, at 15].

Defendants argue that this case is unlike prior cases that found legislative action to be impermissibly retroactive, as in those cases, "an agency attempted to claw back money that already had been paid out." States [Dkt. 73, at 25]. Defendants argue, instead, that the Rate Change Notice only applies to existing grants' "go forward expenses," and that, therefore, the Rate Change Notice is not retroactive. However, the Supreme Court has specifically rejected this view. "[T]he ban on retrospective legislation embrace[s] 'all statutes, which, though

operating only from their passage, affect vested rights and past transactions . . . . Upon principle . . . every statute, which takes away or impairs vested rights acquired under existing laws, or creates a new obligation, imposes a new duty, or attaches a new disability, in respect to transactions or considerations already past, must be deemed retrospective.'" Landgraf, 511 U.S. at 268-69 (quoting Soc'y for Propagation of the Gospel v. Wheeler, 22 F. Cas. 756 (No. 13,156) (CCNH 1814)). Thus, the Supreme Court held in Landgraf that a regulation has retroactive effect when "it would impair rights a party possessed when he acted, increase a party's liability for past conduct, or impose new duties with respect to transactions already completed." Id. at 280. Important to the matter before the Court, "[t]he largest category of cases in which we have applied the presumption against statutory retroactivity has involved new provisions affecting *contractual or property rights*, matters in which predictability and stability are of prime importance." Id. at 271 (emphasis added).

Although not a contract, the Notice of Award and NICRA are both legally binding and have many of the key hallmarks of a contract. When receiving a grant from NIH, institutions are subject to a Notice of Award, which integrates the previously settled-upon NICRA. In adopting the Rate Change Notice, even as to "go-forward" expenses, the ICR cap would impair the rights the institution possessed when accepting the Notice of Award—specifically, the negotiated ICR at the time of the NOA. The Rate Change Notice imposes a new, lower rate, displacing the institutions' right to the previously negotiated—and legally binding—ICR. Additionally, the institutions will now be liable for more expenses with respect to the Notices of Award already executed, imposing new duties for transactions already completed. As a result, there is little

question the Rate Change Notice is retroactive as to its application to existing grants.[6] Thus, again, Plaintiffs are likely to succeed on the merits as to the retroactive application of the Rate Change Notice on existing grants.

4. Other Claims

Plaintiffs make a series of additional statutory and constitutional claims, including violations of the Public Health Service Act and the Appropriations Clause. Without commenting on the substance, the Court finds its unnecessary to address those claims at this stage of the litigation, as the likelihood of success on the merits on each claim addressed above is independently sufficient to support the issuance of a preliminary injunction. Specifically as to the constitutional claim(s), the Court "find[s] it unnecessary and, indeed, inappropriate . . . to reach these claims. Under the doctrine of constitutional avoidance, 'federal courts are not to reach constitutional issues where alternative grounds for resolution are available.'" Marasco & Nesselbush, 6 F.4th at 178 (quoting Vaquería Tres Monjitas, Inc. v. Pagan, 748 F.3d 21, 26 (1st Cir. 2014)) (citing Nw. Austin Mun. Util. Dist. No. One v. Holder, 557 U.S. 193, 205 (stating that the court ordinarily "will not decide a constitutional question if there is some other ground upon which to dispose of the case")). As in Marasco & Nesselbush, the Court finds discussion of the merits of the above claims "adequately addresses [Plaintiffs'] remedial requests and that,

[6] This Court finds the retroactivity concerns as to new grants that are otherwise still subject to an existing NICRA to be a closer question. While the Rate Change Notice does not appear to impose new duties with respect to transactions already completed, as no institution is forced to undertake new or additional research, the NICRA itself is still its own contractual relationship. The Rate Change Notice could thus foreseeably impair rights protected by institutions' NICRAs. Because all parties limit the retroactivity discussion to existing grants, and success on the merits is likely for both existing and new grants on several other grounds, the Court finds it unnecessary to rule on the issue of retroactivity as it applies to future grants, particularly without additional briefing.

hence, resolving the constitutional questions would be inconsistent with our obligation to avoid doing so where a non-constitutional disposition is possible." 6 F.4th at 179.

B. IRREPARABLE HARM

The second element that Plaintiffs must show to justify a preliminary injunction is that they are "likely to suffer irreparable harm in the absence of preliminary relief." Voice of the Arab World, 645 F.3d at 32 (quoting Winter v. Nat. Res. Def. Council, Inc., 555 U.S. at 20); see also Winter, 555 U.S. at 22 ("Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction." (first citing Los Angeles v. Lyons, 461 U.S. 95, 103 (1983); then Granny Goose Foods, Inc. v. Teamsters, 415 U.S. 423, 441 (1974)); and then O'Shea v. Littleton, 414 U.S. 488, 502 (1974)). Importantly, "[d]istrict courts have broad discretion to evaluate the irreparability of alleged harm and to make determinations regarding the propriety of injunctive relief." K-Mart Corp. v. Oriental Plaza, Inc., 875 F.2d 907, 915 (1st Cir. 1989) (quoting Wagner v. Taylor, 836 F.2d 566, 575-76 (D.C. Cir.1987)).

1. Standard

"Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with [the Supreme Court's] characterization of injunctive relief as an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." Winter, 555 U.S. at 22 (citing Mazurek v. Armstrong, 520 U.S. 968, 972 (1997) (per curiam)). The burden falls directly on the moving party to demonstrate the likely irreparable harm. See Fed. R. Civ. P. 65(a); Narragansett Indian Tribe v. Guilbert, 934 F.2d 4, 6 (1st Cir.1991) ("[I]rreparable harm is not assumed; it must be demonstrated."); Ross-Simons I, 102 F.3d at 18 ("[T]he burden of demonstrating that a denial of interim injunctive relief would cause

irreparable harm [rests] squarely upon the movant."). Although "[t]he burden is substantial . . . it is possible to overstate its dimensions." Ross-Simons I, 102 F.3d at 18. Additionally, when, as here, "the likelihood of success on the merits is great, a movant can show somewhat less in the way of irreparable harm and still garner preliminary injunctive relief." Vaqeria Tres Monjitas, Inc. v. Irizarry, 587 F.3d 464, 485 (1st Cir. 2009) (quoting E.E.O.C. v. Astra U.S.A., Inc., 94 F.3d 738, 743-44 (1st Cir. 1996)); Ross-Simons I, 102 F.3d at 19 ("[A]n attempt to show irreparable harm cannot be evaluated in a vacuum; the predicted harm and the likelihood of success on the merits must be juxtaposed and weighed in tandem."); Gately v. Massachusetts, 2 F.3d 1221, 1232 (1st Cir. 1993) (noting a "general principle" of equity "that irreparable harm is subject to a sliding scale analysis").

In determining if the harm is irreparable, "[i]t is settled beyond peradventure that irreparable harm can consist of 'a substantial injury that is not accurately measurable or adequately compensable by money damages.'" Ross-Simons of Warwick, Inc. v. Baccarat, Inc. (Ross-Simons II), 217 F.3d 8, 13 (1st Cir. 2000) (quoting Ross-Simons I, 102 F.3d at 19); see also e.g., Weinberger v. Romero-Barcelo, 456 U.S. 305, 312 (1982) ("The Court has repeatedly held that the basis for injunctive relief in the federal courts has always been irreparable injury and the inadequacy of legal remedies."); K-Mart Corp., 875 F.2d at 915 (noting "injuries to real estate interests" along with "harm to goodwill" are types of irreparable harm that "frequently come within the ken of the chancellor"); Danielson v. Local 275, Laborers Int'l Union, 479 F.2d 1033, 1037 (2d Cir. 1973) ("Irreparable injury is suffered where monetary damages are difficult to ascertain or are inadequate.").

As made clear by the declarations in support of a preliminary injunction against the implementation of the Rate Change Notice, the risk of harm to research institutions and beyond is immediate, devastating, and irreparable.

2. Imminent, Dangerous, and Irreparable Harms

Although the harms resulting from the Rate Change Notice are many, not all harms are irreparable. With that said, Plaintiffs identify several irreparable harms in their declarations. First, the suspension of ongoing clinical trials and the resulting threats to patients' lives represents a dire risk of a quintessentially irreparable nature. Second, the threats to non-human, yet still essential, research subjects similarly rings in irreparability. Finally, the potential loss of human capital and talent to virtually every Plaintiff poses yet another harm incapable of run-of-the-mill legal relief. Because each of these harms, discussed in detail below, cannot be adequately remedied once inflicted the Court finds Plaintiffs have met their burden of demonstrating irreparable harm.

The first, and most pressing, irreparable harm is the suspension of ongoing research and risk to patients' lives. Institutions across the country described the immediate suspension of research, and more specifically, clinical trials, should the Court fail to grant a preliminary injunction in this case. E.g., States [Dkt. 6-34, Declaration of Dr. Greg Hirth, of Brown University] ("There is no simpler way to put it: At a 15% indirect cost rate, many of Brown's current research projects and clinical trials will be forced to cease abruptly. . . . Even a temporary interruption of work would threaten clinical trials that supply lifesaving medicine and risk derailing years of careful progress and efforts directed towards major health challenges."); States [Dkt. 6-36, Declaration of Bharat Ramratnam, M.D., of Lifespan Corporation d/b/a Brown University Health] ("Additionally, [the Rate Change Notice] will hinder the purchase of supplies

for clinical trials from national and local vendors. As [a] result, this will lead to the premature closure of clinical trials leading to layoffs in nursing staff. The overall impact will be the greatest on patient care with potentially life-saving treatments withdrawn from individuals who have failed all other treatments." (emphasis removed)); States [Dkt. 82-8, Declaration of Dr. Penny Gordon-Larsen, PhD, of the University of North Carolina at Chapel Hill] ("In the event the Supplemental Guidance is implemented, UNC also anticipates, and is planning for, paused or canceled clinical trials due to an inability to maintain the facilities and regulatory support necessary for proper trial execution. This would directly impact patient care in North Carolina."); AAU [Dkt. 2-13, Declaration of David P. Norton, of the University of Florida in Gainesville] ("The NIH's proposal to cut indirect cost rates to 15% would end or seriously jeopardize[:] . . . the University of Florida['s] . . . cancer research[] . . . , clinical research aimed at providing better outcomes for persons stricken with [Parkinson's] disease . . . , [and] cutting edge genetics research [into the cause and treatment of ALS]."); AAU [Dkt. 2-21, Declaration of Elizabeth Duggins Peloso, of the University of Pennsylvania] ("A 15 percent cap on F&A costs would disrupt numerous ongoing clinical trials in cancer treatment, immunotherapy and bone marrow transplant therapy with enrolled patients, including those who have already started but not yet completed treatment."); AAU [Dkt. 2-28, Declaration of Ishwar K. Puri, of the University of Southern California] ("USC anticipates the following immediate consequences of cutting the indirect cost rate to 15%: [1] Stopping/curbing clinical trials[; 2] Closing critical [biomedical] research programs[; and, 3] Cancell[ation of] Research Symposia . . . [on] Alzheimer's disease, diabetes . . . , prostate cancer, addiction, and many other issues."). The lives that will certainly be lost from a pause in these trials cannot be replaced. That is not an opinion of the Court—that

is the belief put forth by dozens of declarants who represent universities, research institutions, and associations whose very goals are to protect the sanctity of human life and science.

Even a temporary halt in clinical trials would be catastrophic, as "clinical trials must generally be continuous to be effective, due to concerns for both patient care and trial validity." States [Dkt. 6-34, Declaration of Dr. Greg Hirth, of Brown University]. Because clinical "trials take years to set up, create, and perform[,]" a freeze in F&A costs would make it "difficult, if not impossible, to restart" ongoing clinical trials. [Id.] And even if trials were to resume, "the lack of continuity [would] compromise[] the scientific results . . . ." [Id.]; see also, e.g., States [Dkt. 6-40, Declaration of Leslie Anne Brunelli, of Washington State University] ("[T]he Sharma lab has already developed nanotherapeutics and is actively testing them on prostate cancer cells and organoids. This is time-sensitive work, and any disruption would result in immediate and potentially irreplaceable data loss on these active tests, which would delay and could ultimately eliminate the viability of the treatment they are researching."). Existing NIH-funded clinical trials represent not only significant capital investments in research equipment and animal specimens, but also an incalculable commitment to patients, who by the very nature of their condition have nowhere else to turn. Human safety and scientific integrity are immeasurably compromised by NIH's slash-and-cap approach. The Court is hard pressed to think of a loss more irreparable than the loss of a life, let alone the thousands of people who are counting on clinical trials as their last hope. There is no question, "there can be no do over and no redress." League of Women Voters of U.S. v. Newby, 838 F.3d 1, 9 (D.C. Cir. 2016) (quoting League of Women Voters of N.C. v. North Carolina, 769 F.3d 224, 247 (4th Cir. 2014)); see also States [Dkt. 6-7, Declaration of Ken A. Dill, Ph.D., of the State University of New York] ("It is not an

exaggeration to say that the true cost of the NIH's decision may be that thousands of American lives are needlessly degraded or sacrificed.").

The Court not only considers the harm to research, and by extension, to human life; the lives of animals that are essential to research in advance of human trials are also put at risk by the indirect rate cut. For example, at Washington State University,

> [w]ithout funds for animal care through the Office of the Campus Veterinarian, combined with the loss of indirect[costs] for the research projects themselves within CVM, research animal colonies will have to be severely reduced or eliminated. The loss of life would be massive: in 2023, WSU accounted for use of 90,000 animals of which 50% were fish and 39% were mice. The remaining 11% include amphibians, reptiles, birds and other mammals. The results would be horrific. . . . WSU cares for valuable *gene-edited strains of cattle, rodents and fish which are irreplaceable*, and elimination of animal colonies will take potentially years to replace even the ones that are capable of replacement. Even if some funding could be later restored, *the massive loss of animal life cannot be easily replaced, and some projects are unlikely to restart*. Moreover, the loss of the animal population would require layoffs of professional animal care and veterinary staff that are nearly impossible to replace, given the current disparity in opportunities in veterinary medicine that are available in the private sector.

States [Dkt. 6-40, Declaration of Leslie Anne Brunelli, of Washington State University] (emphasis added). At the University of Washington, which operates one of only seven National Primate Research Centers, "[t]he cut in IDC rates will cripple [the Research Center]'s life-saving research," as it is "required to shut down facilities, directly impacting the 170 individuals employed by the Center. In addition, with other NPRCs impacted, there will be animals that cannot be sold or relocated to other research facilities. There is limited sanctuary space available, and the UW would not be able to cover the high costs associated with lifetime sanctuary care, so these animals would have to be euthanized." States [Dkt. 6-39, Declaration of Mari Ostendorf, of the University of Washington]. As a result, the Center's "pioneering biomedical advances that benefit human health . . . will be crippled from loss of NIH funding." Id. Several other institutions also identified the need to euthanize animals, including those that are currently key to

on-going research, as an immediate consequence. See, e.g., AAU [Dkt. 2-21, Declaration of Elizabeth Duggins Peloso, of the University of Pennsylvania] ("F&A costs are crucial in clinical trials with live subjects. In one of the studies mentioned [], where researchers are developing therapies for HIV, autoimmune disease, and cancer, researchers utilize F&A funds to support 16,000 mice, which includes the cost of 5,333 cages, 11 mice caretakers, 4 cage wash technicians, 3 veterinary technicians, 1 veterinarian, cage equipment costs, feed, bedding, enrichment, water bottles for all animals, and regulatory and facility support."); id. [Dkt. 2-28, Declaration of Ishwar K. Puri, of the University of Southern California] ("NIH's proposal to cut indirect cost rates to 15% would seriously jeopardize" "Aging and Alzheimer's disease research . . . [conducted with] genetically engineered mice . . . .").

For essentially all of the Plaintiff institutions, there are myriad other immediate consequences that will make it harder to fulfill their purpose. "[O]bstacles [that] unquestionably make it more difficult for the [plaintiff] to accomplish [its] primary mission . . . provide injury for purposes . . . [of] irreparable harm." Newby, 838 F.3d at 9 (citing Nat'l Treasury Emps. Union v. United States, 101 F.3d 1423, 1430 (D.C. Cir. 1996)). These consequences include the degradation of vital infrastructure, the loss of imperative staff necessary for research to be conducted, the loss of human capital resulting from leading scientists choosing to work elsewhere and universities admitting fewer students, and finally, the uncertainty around the ability to sustain future grant applications, resulting in the loss of direct research. See, e.g., States [Dkt. 6-11, Declaration of Donald M. Elliman, Jr., of Colorado Anschutz Medical Campus] ("The drastic cuts to NIH F&A will bring the Institute's research and community-based programs to a virtual standstill due to the loss of shared administrative staff and the specialized computing infrastructure essential for the Institute's efforts."); States [Dkt. 6-15, Declaration of

Dr. Tony Allen, of Delaware State University] ("[T]he loss of these funds will necessitate laying-off three or more research support personnel, and reductions in or elimination of stipends for institutionally-supported doctoral students in DSU's neuroscience PhD program, the only such program offered at an Historically-Black university."); States [Dkt. 6-19, Declaration of Denise Barton, of the University of Massachusetts] ("Loss of IDC will curtail the ability of UMass Chan Medical School to provide and keep necessary equipment in good shape. Malfunctioning equipment can produce faulty data and loss of equipment would bring research relying on that equipment to a halt, which could erase several years of progress on a project or grant."); States [Dkt. 6-24, Declaration of Douglas A. Gage, Ph.D., of Michigan State University] ("MSU next anticipates to draw funds on or around Friday, February 14, 2025. At that time, the reduced IDC rate will reduce reimbursement for actual expenditures incurred, and MSU must begin to reduce staffing and identify other reductions, which will be detrimental to attaining committed research goals."); States [Dkt. 6-41, Declaration of Dorota Grejner-Brzezinska, of the University of Wisconsin-Madison] ("NIH's eleventh-hour change in available funding forces researchers and university administrators to reconsider whether to submit grant applications, many of which they have been fine-tuning for months, given uncertainty about whether the institution can afford to sustain these projects at a 15% IDC rate. The sense of whiplash is particularly acute, given that UW-Madison had finalized its most recent NICRA with DHHS less than three weeks prior."); States [Dkt. 82-8, Declaration of Dr. Penny Gordon-Larsen, PhD, of the University of North Carolina at Chapel Hill] ("[T]he loss of these funds will immediately impact UNC's ability to cover expenses associated with, among other items: facilities operations and maintenance, facilities debt service and rent, research equipment purchases, federally-mandated regulatory compliance and grant administration functions, research-specific IT services, and research-

specific student support."); AAU [Dkt. 2-7, Declaration of David A. Tirrell, of the California Institute of Technology] ("This reduction will have deeply damaging effects on Caltech's ability to conduct research from day one. For example: . . . [1] The number of graduate students – who are the future of biomedical research – who can be admitted will have to be reduced substantially. The impact on the future of research will be immediate and unrecoverable. [2] Offers to new postdoctoral scholars also will be reduced, with similar impact on the quality of the research environment and on the future of biomedical research. [3] Support for our shared biomedical research facilities will have to be reduced immediately. The viability of these facilities will be compromised."); [id.] ("Caltech is in the process of submitting 11 applications for NIH research support. The uncertainty regarding NIH indirect cost policy makes it impossible to complete submission of these applications, which are intended to support research related to nicotine addiction, congenital birth defects, aging, neuromodulation, Parkinson's disease, and biomedical measurement technologies."); AAU [Dkt. 2-12, Declaration of David F. Kotz, of Dartmouth College] ("Such cuts would certainly result in a hiring freeze on faculty, postdoctoral associates, and graduate students, directly impacting our ability to conduct advanced research in the public interest and train the next generation of research scientists. . . . The world's best scientists will not move to (or stay at) universities where they are not able to conduct world-class research. The reality of this shortfall and the cuts it would necessitate would reduce the amount available for new faculty "start-up" packages, which are required for junior investigators to set up their laboratories and jump start their own new research programs."); AAU [Dkt. 2-13, Declaration of David Paul Norton, of the University of Florida] ("The University of Florida Research Integrity, Security & Compliance (RISC) unit . . . would have to reduce staffing within RISC by an estimated 5 individuals, which would immediately

impact its ability to ensure university compliance with federal regulations. The University of Florida's Division of Sponsored Programs (DSP) . . . would have to reduce staffing within DSP by an estimated 18 individuals, thus crippling [] its ability to submit proposals, negotiate awards, and setting up subcontracts such as to be consistent with the funding agency's accountability requirements. The University of Florida's Research Division of Contracts & Grants . . . would have to reduce staffing within Contracts & Grants by an estimated 22 individuals, thus crippling the University of Florida's ability to meet its obligations to manage federally-funded grants, including grants from the NIH, so as to meet the funding agency's accountability requirements."); AAU [Dkt. 2-28, Declaration of Ishwar K. Puri, of the University of Southern California] (discussing the likely cutting of 73 staff members).

These harms are particularly irreparable, as the losses are compounding. Most institutions draw funds multiple times per month. Each time there is a draw, the immediate cap on ICRs is felt anew, exacerbating the harms identified more and more over time. See, e.g., States [Dkt. 6-13, Declaration of Dr. Pamir Alpay, of the University of Connecticut] ("UConn and UCH anticipate this will reduce its draw to recover these costs by about $673,000 per week."); States [Dkt. 6-32, Declaration of Peter Barr-Gillespie, Ph.D., of Oregon Health and Science University] ("OHSU's next anticipated draw of funds is on or around February 10, 2025. At that time, the reduction in the IDC rate will result in the loss of $1.6M per week in reimbursement that supports the salaries, facility costs, and research infrastructure that allows OHSU to conduct research."); AAU [Dkt. 2-31, Declaration of Dorota Grejner-Brzezinska, of the University of Wisconsin-Madison] ("UW-Madison typically draws down funds for NIH-funded projects twice per month and next anticipates drawing funds on or around February 17, 2025. At that time, if allowed to be implemented, the reduced IDC rate will result in UW-

Madison experiencing a $3.9 million loss in IDC recovery for this upcoming draw."). Additionally, despite NIH's claims, institutions' endowments, which vary from institution to institution, will be unable to make up the shortfall—a majority of the funds in endowments are legally bound for specific purposes based on the gift. See, e.g., States [Dkt. 6-34, Declaration of Dr. Greg Hirth, of Brown University] ("Brown's endowment, which provides an essential source of support for the University's financial aid, faculty salaries, and academic and co-curricular programs, consists of over 3,800 unique funds that are legal contracts given as charitable gifts by alumni, parents, students, and friends of the University."); AAU [Dkt. 2-8, Declaration of Theresa S. Mayer, of Carnegie Mellon University] ("While CMU maintains an endowment, it is neither feasible nor sustainable for CMU funds or other revenue sources to offset shortfalls in indirect cost recovery. . . ."); [id.] (noting 83.3% "of CMU's endowment . . . is restricted to specific donor-designated purposes . . . ."); AAU [Dkt. 2-11, Declaration of Robert A. Harrington, M.D., of Cornell University] ("Cornell's existing endowment cannot simply be redirected to pick up these losses."). Further, even the funds that are unrestricted are generally subject to a managed annual payout, often further restricted by applicable state laws. See, e.g., AAU [Dkt. 2-1, Declaration of Barbara R. Snyder, of the Association of American Universities] ("The vast majority of endowed funds often are restricted by the terms on which the funds were donated to the AAU member university and cannot legally be used to cover research infrastructure costs."); AAU [Dkt. 2-8, Declaration of Theresa S. Mayer, of Carnegie Mellon University] ("Even the portion of the endowment that is unrestricted is subject to a carefully managed annual payout, typically around 5%, to ensure long-term financial stability for the institution."); AAU [Dkt. 2-11, Declaration of Robert A. Harrington, M.D., of Cornell

University] ("Cornell may only draw down the portion of the endowment that is unrestricted at a rate that complies with New York State law.").

As most universities are non-profit institutions, almost all revenue is re-invested in an effort to advance the universities' mission and enhance student life, leaving little option to redirect funds. See, e.g., AAU [Dkt. 2-8, Declaration of Theresa S. Mayer, of Carnegie Mellon University] ("As a non-profit institution, CMU reinvests nearly all of its revenue into mission-critical activities, leaving little margin to absorb unexpected funding gaps . . . . CMU does not generate significant surpluses that could be redirected without impacting core academic priorities such as educational programs and financial aid support for students."). These harms, and many more, do not only impact the Plaintiff states and institutions, but the communities and people they serve. See generally States [Dkt. 91, Amicus Brief by Cities, Counties, and Mayors, at 4-12] (discussing harms in local communities including staffing cuts for some localities' largest employer, slowing job creation and economic growth, and increasing disparities in health outcomes for rural and urban communities). The ripples are profound and have the potential to reverberate around the world.

Finally, "[b]y its very nature injury to goodwill and reputation is not easily measured or fully compensable in damages. Accordingly, this kind of harm is often held to be irreparable." Ross-Simons I, 102 F.3d at 20. This reputational harm will operate on an institutional, local, and national basis. For example, clinical trial patients have "placed their trust in [the] U[niversity of] W[ashington] for what is in many cases their last option at lifesaving care" and the "scaling back in their level of care[,]" an inevitable result of capping indirect costs at 15%, "would be a devastating breach of trust." States [Dkt. 6-39, Declaration of Mari Ostendorf, of the University of Washington]. "The damage to these patients' lives and their relationship with their care team

at UW would be nearly impossible to rectify." [Id.]. No dollar amount can be placed on patient trust. On an institutional level, "any limit on [UW's] ability to start new trials will delay lifesaving treatments that rely on decades of research and development." [Id.]. More broadly, the United States leads the world in the health sciences. The cut proposed immediately hinders the medical research industries, which will jeopardize the United States' standing as a global leader in discovery, innovation, and technological advancement. The cut undermines the universities' and institutions' ability to drive medical breakthrough that benefits public health and contributes to national advancement in science. Once that is lost, it can almost certainly never be regained. No dollar amount can be placed on the value of the United States remaining the world leader in research and medical advancement.

As Plaintiffs have demonstrated their collective harm "is not accurately measurable or adequately compensable by money damages, irreparable harm is a natural sequel." Ross-Simons I, 102 F.3d at 19. Even though, as established above, the likelihood of success on the merits is great, which would allow "a movant [to] show somewhat less in the way of irreparable harm and still garner preliminary injunctive relief," the allowance is unnecessary. Astra U.S.A., 94 F.3d at 743-44 (1st Cir. 1996). It is impossible to accurately measure or compensate humans who lose their lives from a pause in research. It is impossible to measure the value of lost research animals—representing years of study central to medical breakthrough—that will be euthanized. It is impossible to measure the value of discovery from scientists who choose to leave, or of the potential students who now never become scientists at all. Even for those harms than can be measured in dollars and cents, the losses are compounding and will result in even greater disruption to ongoing research and clinical trials. As a result, failure to grant a preliminary injunction would certainly result in irreparable harm.

C. BALANCE OF EQUITIES AND PUBLIC INTEREST

Finally, the Court must balance the parties' relative hardships and consider the public interest. These factors merge because government parties oppose the preliminary injunction. Nken, 556 U.S. at 435.

Courts have consistently held there is a strong public interest in health and safety. See World Gym, Inc. v. Baker, 474 F. Supp. 3d 426, 434 (D. Mass. 2020) (noting a "great" public interest in public health); see also Grand River Enters. Six Nations, Ltd. v. Pryor, 425 F.3d 158, 169 (2d Cir. 2005) (writing that public health is a "significant public interest"); Jones v. Wolf, 467 F. Supp. 3d 74, 94 (W.D.N.Y. 2020) (confirming there is a public interest in "public health and safety"). The Plaintiffs' hardship absent a preliminary injunction, as described above, is substantial and ranges from the halting of research and clinical trials, resulting in the loss of life for those of whom are relying on clinical trials as their last hope, to a negative impact on patient health and outcomes, the death of animals that represent years of research, the degradation of infrastructure, the loss of staff who are central to patient care and research activities, brain drain in the healthcare industry, and the delay and potential suspension of future grant applications as institutions are unable to support additional research projects. Thus, in light of these hardships, a preliminary injunction would preserve public health, and by extension, serve the public interest. Additionally, there is "substantial public interest 'in having governmental agencies abide by the federal laws.'" Newby, 838 F.3d at 12 (D.C. Cir. 2016) (quoting Washington v. Reno, 35 F.3d 1093, 1103 (6th Cir. 1994)). As described above, it is likely Plaintiffs will succeed on the merits, rendering the Notice unlawful. Therefore, the preliminary injunction would serve the public interest as NIH is forced to abide by existing law and regulations.

Conversely, Defendants do not specifically address the hardship or public interest factors and thus waive arguments as to their balancing. Doe v. Trump, No. 25-CV-10135-LTS, 2025 WL 485070, at *14 (D. Mass. Feb. 13, 2025); see also United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990). Despite this waiver, the Court will consider the three government interests asserted in the Rate Change Notice: First, NIH seeks to maximize funding toward "direct scientific research costs rather than administrative overhead"; second, "indirect costs are . . . difficult for NIH to oversee"; and third, NIH hopes to make indirect costs "reflect . . . the private sector indirect cost rates." Despite these interests, the scales remain tipped in Plaintiffs' favor because the government "cannot suffer harm from an injunction that merely ends an unlawful practice." Rodriguez v. Robbins, 715 F.3d 1127, 1145 (9th Cir. 2013); see also R.I.L-R v. Johnson, 80 F. Supp. 3d 164, 191 (D.D.C. 2015) (finding that the government "cannot suffer harm from an injunction that merely ends an unlawful practice"). Further, there is no public interest in upholding unlawful agency action. Newby, 838 F.3d at 12.

Nonetheless, even if promulgation of the Rate Change Notice is ultimately vindicated, the temporary halting of the rate change cannot create hardship if it does not frustrate Defendants' policy choices. Defendants indicate they seek to maximize direct funding but neither the Rate Change Notice nor their filings demonstrate how that is accomplished under the proposed regulation. Instead, Plaintiffs' declarations show repeatedly that the overall volume of research will necessarily decrease. Defendants also state an oversight goal but fail to explain how the Rate Change Notice increases or simplifies grant supervision beyond the accountability already required by Appendix III § (C)(11)(c)-(d) to 45 C.F.R. § 75. Finally, as described above, NIH failed to explain how bringing ICRs in line with private institutions, which not only serve different roles in supporting institutions that conduct research but also follow entirely different

procedures in defining direct versus indirect costs, would serve the public interest. In fact, it only seems to diminish institutions' ability to support both existing and potential research.

Because Plaintiffs are likely to prevail in their argument that the Rate Change Notice is counter to statute and regulation, an injunction supports the public interest in having agencies abide by federal law. Further, an injunction also pauses cuts in grant funding that would adversely and immediately affect public health. Thus, the public interest factors weigh in favor of a preliminary injunction.

V. SCOPE OF INJUNCTION

Having concluded that Plaintiffs have met their burden under the preliminary injunction standard, the Court must craft the appropriate relief. The AAMC and AAU Plaintiffs urge the Court to preliminarily enjoin the Defendants from taking any steps to further implement the Rate Change Notice in its entirety for all grant recipients, while Plaintiff States seek preliminary injunctive relief for the 22 named Plaintiff States. AAMC and AAU assert there are compelling reasons to enjoin the implementation of Rate Change Notice, namely the breadth of the impact on the victims in these suits, but also similarly situated states, associations, universities, and research institutions. The Plaintiffs represent an excess of 1,400 medical institutions across all 50 states and territories, including Puerto Rico and the District of Columbia. NIH issues nearly 60,000 grants, involving 300,000 researchers at 2,500 universities, medical schools, and research institutions.

While federal district courts have issued nationwide or "universal" injunctions and they have been acknowledged by the circuit courts, the Supreme Court has not directly addressed the issue despite concerns expressed by some justices over their use. See Trump v. Hawaii, 585 U.S. 667, 713 (2018) (Thomas, J., concurring) (expressing skepticism of the use of such authority by

the district courts.); Dep't. of Homeland Sec. v. New York, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring). With that said, there are appropriate circumstances during which nationwide injunctions are not only appropriate, but necessary. Florida. v. Dep't of Health & Hum. Servs., 19 F.4th 1271, 1281-82 (11th Cir. 2021). Such appropriate circumstances include the need "to protect similarly situated nonparties, [] to avoid the 'chaos and confusion' of a patchwork of injunctions, . . . [or] where the plaintiffs are dispersed throughout the United States." Id. (citing Chicago v. Barr, 961 F.3d 882, 916-17 (7th Cir. 2020)). To this end, in drafting equitable relief, courts must consider "what is necessary, what is fair, and what is workable." North Carolina v. Covington, 581 U.S. 486, 488 (2017) (quoting New York v. Cathedral Acad., 434 U.S. 125, 129 (1977)).

As to the similarly situated nonparties, the need here is particularly acute. The Rate Change Notice was signed on Friday, February 7, 2025 and was set to go into effect on the following business day, Monday, February 10, 2025. Plaintiffs here were moving with great speed to file this suit, as the change was announced after business hours on a Friday and its implementation was set for that following Monday, resulting in immediate harm. As discussed at oral argument, there are certainly other similarly situated nonparties who likely would have joined the suits had there been time ahead of the Rate Change Notice's implementation. These nonparties should not be forced to suffer the harm just because there was not enough time and resources for them to join the suit because of the agency's rush to implement the Rate Change Notice. "[N]ationwide injunctions provide a mechanism for courts to protect all those who could be harmed by a federal policy when only a few have the ability to quickly bring their case before a court." Amanda Frost, In Defense of Nationwide Injunctions, 93 N.Y.U. L. Rev. 1065, 1094-95 (2018) ("Nationwide injunctions are at times the only way to prevent irreparable injury to

individuals who cannot easily or quickly join in litigation."). Further, this Court agrees with Plaintiffs that "[c]ourts should also avoid issuing an injunction that 'lop[s] a state off' thereby 'entirely undercut[ting] that injunction's effectiveness.'" States [Dkt 81, at 26] (quoting DraftKings Inc. v. Hermalyn, 118 F.4th 416, 424 (1st Cir. 2024)) (modifications in original).

Turning to the "chaos and confusion" of a patchwork of injunctions, the concern is certainly present in this case. Should an injunction be limited to the named Plaintiffs, institutions both within and outside the scope of the injunction will need to operate with concern for the future sustainability of their research. The Massachusetts Institute of Technology ("MIT") provides an enlightening example:

> As a direct result of real and threatened federal cost-cutting in fundamental research and potential increased levies on universities, including this attempted reduction in F&A cost reimbursement rate, MIT is being forced to take immediate and contemporaneous action to reduce its financial exposure. The Institute is implementing operating budget reductions and curtailing its capital investments. At the Institute level, MIT is deferring capital projects, notably including research infrastructure and space renewals, lab equipment installations, ventilation air capacity improvements, and energy efficiency upgrades. MIT also expects to implement a partial hiring freeze across the Institute this week. In addition, this week MIT is issuing central budgets to its internal units that mandate cuts from current resource levels.

AAU [Dkt. 2-17, Declaration of Ian A. Waitz, of the Massachusetts Institute of Technology]. Absent a nationwide injunction, institutions across the country will be forced to operate with the same uncertainty, resulting in the types of irreparable harm that a preliminary injunction is meant to prevent. In the face of this uncertainty, institutions would almost certainly file many additional lawsuits. The potential patchwork of injunctions would cause administrability problems, not only for the institutions relying on consistency to prevent the harm discussed above but also for NIH as it attempts to comply with varying injunctions across the country.

As to the third point, Plaintiff States, institutions, associations, and association members are plainly dispersed across the country. There are 22 states, university declarations from 32 states, and association membership in all 50 states. There is no doubt the Plaintiffs are dispersed across the country, which weighs in favor of a nationwide injunction.

In addition to the considerations discussed above, the nature of the action itself supports a nationwide injunction. The normal remedy for a successful APA challenge is vacatur of the rule and its applicability to all who would have been subject to it. Victim Rts. L. Ctr. v. Cardona, 20-CV-11104-WGY, 2021 WL 3516475, at *1 (D. Mass. Aug. 10, 2021) (citing 5 U.S.C. § 706(2)(A) ("The reviewing court shall hold unlawful and set aside agency action . . . found to be . . . arbitrary [and] capricious . . . ."); William Baude et. al., The Federal Courts and the Federal System 1354 (8th ed. 2025) (describing how "the Administrative Procedure Act's provision for the vacatur of federal agency action may confer" a power analogous to universal injunction "by statute"); see also Gailius v. INS, 147 F.3d 34, 47 (1st Cir.1998) (finding that vacation and remand is appropriate when an agency has failed to give adequate explanation for its conclusions); Nw. Env't Advocs. v. EPA, 537 F.3d 1006, 1026 (9th Cir. 2008) ("We affirm the district court's decision to vacate the regulation and to remand for further proceedings as a valid exercise of its remedial powers."); Lovely v. FEC, 307 F. Supp. 2d 294, 301 (D. Mass. 2004) ("[V]acation is a proper remedy when an agency fails to explain its reasoning adequately." (quoting Harrington v. Chao, 280 F.3d 50, 60 (1st Cir. 2002) (internal quotation marks omitted)). It would be anathema to reasonable jurisprudence that only the named Plaintiffs should be protected from the irreparable harms of an unlawful regulation. Thus, "when a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed." Nat'l Min. Ass'n

v. U.S. Army Corps of Eng'rs, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (quotation marks and citation omitted); see also Griffin v. HM Fla.-ORL, LLC, 144 S. Ct. 1, 2 n.1 (2023) (explaining that "[u]nlike judicial review of statutes, in which courts enter judgments and decrees only against litigants, the APA . . . go[es] further by empowering the judiciary to act directly against the challenged agency action. This statutory power to 'set aside' agency action is more than a mere non-enforcement remedy. . . . In these situations, the courts do hold the power to 'strike down' an agency's work, and the disapproved agency action is treated as though it had never happened." (quoting Jonathan F. Mitchell, The Writ-of-Erasure Fallacy, 104 Va. L. Rev. 933, 1012-13 (2018))). Thus, particularly in light of the likelihood of success on the merits as to the unlawfulness of the Rate Change Notice and the APA claims, the nature of these suits counsel in favor of a nationwide injunction.

On a final note, there is a noteworthy factor of judicial economy and efficiency that likewise favors a universal solution to the current dilemma. Plaintiffs' challenge to the lawfulness of NIH's action and the unique nature of the broad impact of the Rate Change Notice warrants a broad response until final judgment or appellate review, whichever occurs first, resolves the question of the lawfulness of NIH's actions. Considering the irreparable harm likely to befall similarly situated nonparties, the chaos that would result both for institutions and NIH from a patchwork of injunctions, the diffuse nature of the Plaintiffs, and the nature of the suit, a nationwide preliminary injunction is the appropriate and reasonable remedy.

VI. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Preliminary Injunction is **GRANTED**.

The Defendants and their officers, employees, servants, agents, appointees, and successors are hereby enjoined from taking any steps to implement, apply, or enforce the

Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Costs Rates (NOT-OD-25-068), issued by the Office of the Director of the National Institutes of Health on February 7, 2025, above referred to as the Rate Change Notice, in any form with respect to institutions nationwide until further order issued by this Court.

SO ORDERED.

Dated: March 5, 2025

/s/ Angel Kelley
Hon. Angel Kelley
United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

COMMONWEALTH OF MASSACHUSETTS, *et al.* Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	Case No. 1:25-cv-10338
ASSOCIATION OF AMERICAN MEDICAL COLLEGES, *et al.* Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, et al., Defendants.	Case No. 1:25-cv-10340
ASSOCIATION OF AMERICAN UNIVERSITIES, *et al.* Plaintiffs, v. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	Case No. 1:25-cv-10346

FINAL JUDGMENT AND PERMANENT INJUNCTION

Pending before the Court is the Defendant's Assented-to Motion to Convert Order on Preliminary Injunction into Order on Permanent Injunction and Enter Final Judgment. After

reviewing the motion, the record, and the applicable law, the Court is of the opinion that the motion should be **GRANTED**.

For reasons stated in this Court's Memorandum and Order on Plaintiffs' Motion for Preliminary Injunction, *see Massachusetts v. NIH*, Case No. 1:25-cv-10338, Doc. No. 105, the Court finds that this Court has jurisdiction over Plaintiffs' claims, and that the Court of Federal Claims does not have exclusive jurisdiction over Plaintiffs' claims under the Tucker Act, 28 U.S.C. § 1491(a)(1). The Court concludes that Plaintiffs in the above-captioned cases have demonstrated success on the merits of their Administrative Procedure Act claims that the issuance of the 2024 National Institutes of Health (NIH) Notice Number NOT-OD-25-068 (hereinafter, "Notice Number NOT-OD-25-068"): (1) violated 45 C.F.R. § 75.414 and Section 224 of the Further Consolidated Appropriations Act, 2024, Public Law 118-47;[1] (2) was arbitrary and capricious;[2] (3) failed to follow notice-and-comment procedures;[3] and (4) was impermissibly retroactive.[4]

Accordingly, the Court concludes that entry of a permanent injunction is appropriate. *See Caroline T. v. Hudson Sch. Dist.*, 915 F.2d 752, 755 (1st Cir. 1990) ("Where a plaintiff seeks

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[1] *See* Doc. No. 1 in *Mass. v. NIH*, Case No. 1:25-cv-10338 (Counts II and III); Doc. 1 in *AAMC v. NIH*, Case No. 1:25-cv-10340 (Count 1 and II); Doc. 1 in *AAU v. HHS*, Case No. 1:25-cv-10346 (Counts I, III, and V).

[2] *See* Doc. No. 1 in *Mass. v. NIH*, Case No. 1:25-cv-10338 (Count I); Doc. 1 in *AAMC v. NIH*, Case No. 1:25-cv-10340 (Count III); Doc. 1 in *AAU v. HHS*, Case No. 1:25-cv-10346 (Count IV).

[3] *See* Doc. No. 1 in *Mass. v. NIH*, Case No. 1:25-cv-10338 (Count V); Doc. 1 in *AAMC v. NIH*, Case No. 1:25-cv-10340 (Count IV); Doc. 1 in *AAU v. HHS*, Case No. 1:25-cv-10346 (Count VI).

[4] *See* Doc. No. 1 in *Mass. v. NIH*, Case No. 1:25-cv-10338 (Count III); Doc. 1 in *AAMC v. NIH*, Case No. 1:25-cv-10340 (Count V); Doc. 1 in *AAU v. HHS*, Case No. 1:25-cv-10346 (Count VIII).

permanent injunctive relief, the test is the same, except that 'the movant must show actual success on the merits of the claim, rather than a mere likelihood of such success.'") (quoting *K-Mart Corp. v. Oriental Plaza, Inc.*, 875 F.2d 907, 915 (1st Cir. 1989)).

Therefore, it is hereby **ORDERED**:

1. The Court has subject matter and personal jurisdiction over this action and the Parties.

2. Venue is proper before this District.

3. For the reasons stated in this Court's Memorandum and Order on Plaintiffs' Motion for Preliminary Injunction, *see Massachusetts v. NIH*, Case No. 1:25-cv-10338, Doc. No. 105, in *Massachusetts, et al. v. NIH, et al.*, Case No. 1:25-cv-10338, judgment is entered in favor of the Plaintiffs in that action on the following claims brought against the National Institutes of Health; Jay Bhattacharya, M.D., Ph.D., in his official capacity as Director of the National Institutes of Health; the United States Department of Health and Human Services; and Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services: Count I; Count II; Count III; Count IV; and Count V.

4. For the reasons stated in this Court's Memorandum and Order on Plaintiffs' Motion for Preliminary Injunction, *see Massachusetts v. NIH*, Case No. 1:25-cv-10338, Doc. No. 105, in *Association of American Medical Colleges, et al. v. NIH, et al.*, Case No. 1:25-cv-10340, judgment is entered in favor of the Plaintiffs in that action on the following claims brought against the National Institutes of Health; Jay Bhattacharya, M.D., Ph.D., in his official capacity as Director of the National Institutes of Health; the United States Department of Health and Human Services; and Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and

Human Services: Count I; Count II; Count III; Count IV; and Count V, as to the claim of a violation of the statutory prohibition on retroactivity.

5. For the reasons stated in this Court's Memorandum and Order on Plaintiffs' Motion for Preliminary Injunction, *see Massachusetts v. NIH*, Case No. 1:25-cv-10338, Doc. No. 105, in *Association of American Universities, et al. v. NIH*, Case No. 1:25-cv-10346, judgment is entered in favor of the Plaintiffs in that action on the following claims brought against the United States Department of Health and Human Services; the National Institutes of Health; Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services; and Jay Bhattacharya, M.D., Ph.D., in his official capacity as Director of the National Institutes of Health: Count I; Count III; Count IV; Count V; Count VI; and Count VIII.

6. Defendants and their officers, employees, servants, agents, appointees, and successors are hereby **ENJOINED** from taking any steps to implement, apply, or enforce Notice Number NOT-OD-25-068, issued by the Office of the Director of the National Institutes of Health on February 7, 2025, in any form with respect to institutions nationwide.

7. Pursuant to 5 U.S.C. § 706(2), the Court **VACATES**, in its entirety, Notice Number NOT-OD-25-068, issued by the Office of the Director of the National Institutes of Health on February 7, 2025.

8. The following claim in *Association of American Medical Colleges, et al. v. NIH, et al.*, Case No. 1:25-cv-10340, is dismissed without prejudice: Count V, as to the claim of a violation of the constitutional prohibition on retroactivity.

9. The following claims in *Association of American Universities, et al. v. NIH*, Case No. 1:25-cv-10346, are dismissed without prejudice: Count II and Count VII.

This is a Final Judgment. It is **SO ORDERED**.

Dated: April 4, 2025

/s/ Angel Kelley
Hon. Angel Kelley
United States District Judge

Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates
Notice Number:
NOT-OD-25-068

Key Dates

Release Date:

February 7, 2025

Related Announcements

None

Issued by

Office of The Director, National Institutes of Health (OD)

Purpose

Purpose

The National Institutes of Health (NIH) awards a large number of grants providing substantial federal funding for research purposes. These grants include significant payments for "indirect costs," defined as "facilities" and "administration." 45 CFR 75.414(a). The "facilities" category is "defined as depreciation on buildings, equipment and capital improvements, interest on debt associated with certain buildings, equipment and capital improvements, and operations and maintenance expenses." *Id.* And the "administration" category is defined as "general administration and general expenses such as the director's office, accounting, personnel, and all other types of expenditures not listed specifically under one of the subcategories of 'Facilities"' (including cross allocations from other pools, where applicable). *Id.*

In issuing grants, NIH generally uses the indirect cost rate negotiated by an "agency with cognizance for F&A/indirect cost rate (and other special rate) negotiation." Grants Policy Statement at IIA-68; *see* 45 C.F.R. 75.414(c)(1). NIH may, however, use "a rate different from the negotiated rate for either a class of Federal awards or a single Federal award." 45 C.F.R. 75.414(c)(1). NIH may deviate from the negotiated rate both for future grant awards and, in the case of grants to institutions of higher education ("IHEs"), for existing grant awards. *See* 45 CFR Appendix III to Part 75, § C.7.a; *see* 45 C.F.R. 75.414(c)(1).

In deviating from the negotiated indirect cost rate, NIH must "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 § 75.414(c)(3).

In accordance with 45 CFR 75 and its accompanying appendices, this Guidance implements and makes publicly available NIH's updated policy deviating from the negotiated indirect cost rate for new grant awards and existing grant awards, effective as of the date of this Guidance's issuance. Pursuant to this Supplemental Guidance, there will be a standard indirect rate of 15% across all NIH grants for indirect costs in lieu of a separately negotiated rate for indirect costs in every grant.

Providing Indirect Cost Rates that Comport with Market Rates

NIH's mission is to "seek fundamental knowledge about the nature and behavior of living systems" in order to enhance health, lengthen life, and reduce illness and disability. In furtherance of this mission, NIH spent more than $35 Billion in Fiscal Year 2023 on almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions across all 50 states and the District of Columbia.[1] Of this funding, approximately $26 billion went to direct costs for research, while $9 billion was allocated to overhead through NIH's indirect cost rate.

Although cognizant that grant recipients, particularly "new or inexperienced organizations," use grant funds to cover indirect costs like overhead, *see* 89 FR 30046–30093, NIH is obligated to carefully steward grant awards to ensure taxpayer dollars are used in ways that benefit the American people and improve their quality of life. Indirect costs are, by their very nature, "not readily assignable to the cost objectives specifically benefitted" and are therefore difficult for NIH to oversee. *See* Grants Policy Statement at I-20. Yet the average indirect cost rate reported by NIH has averaged between 27% and 28% over time.[2] And many organizations are much higher—charging indirect rates of over 50% and in some cases over 60%.

Most private foundations that fund research provide substantially lower indirect costs than the federal government, and universities readily accept grants from these foundations. For example, a recent study found that the most common rate of indirect rate reimbursement by foundations was 0%, meaning many foundations do not fund indirect costs whatsoever. In addition, many of the nation's largest funders of research—such as the Bill and Melinda Gates Foundation—have a maximum indirect rate of 15%. And in the case of the Gates Foundation, the maximum indirect costs rate is 10% for institutions of higher education.

A sample list of foundations that provide indirect cost funding and their respective maximum indirect rate is below:[3]

Maximum Indirect Cost Rate	**Organizations**
10%	• Gates Foundation (for institutions of higher education) • Smith Richardson Foundation
12%	• Gordon and Betty Moore Foundation • Robert Wood Johnson Foundation
15%	• Carnegie Corporation of New York • Chan Zuckerberg Initiative • John Templeton Foundation • Packard Foundation • Rockefeller Foundation (for institutions of higher education)

Indeed, one recent analysis examined what level of indirect expenses research institutions were willing to accept from funders of research. Of 72 universities in the sample, 67 universities were willing to accept research grants that had 0% indirect cost coverage. One university (Harvard University) required 15% indirect cost coverage, while a second (California Institute of Technology) required 20% indirect cost coverage. Only three universities in the sample refused to accept indirect cost rates lower than their federal indirect rate. These universities were the Massachusetts Institute of Technology, the University of Michigan, and the University of Alabama at Birmingham.

The United States should have the best medical research in the world. It is accordingly vital to ensure that as many funds as possible go towards direct scientific research costs rather than administrative overhead. NIH is accordingly imposing a standard indirect cost rate on all grants of 15% pursuant to its 45 C.F.R. 75.414(c) authority. We note in doing so that this rate is 50% higher than the 10% de minimis indirect cost rate provided in 45 C.F.R. 75.414(f) for NIH grants. We have elected to impose a higher standard indirect cost rate to reflect,

among other things, both (1) the private sector indirect cost rates noted above, and (2) the de minimis cost rate of 15% in 2 C.F.R. 200.414(f) used for IHEs and nonprofits receiving grants from other agencies.

NIH Implementation

For any new grant issued, and for all existing grants to IHEs retroactive to the date of issuance of this Supplemental Guidance, award recipients are subject to a 15 percent indirect cost rate. This rate will allow grant recipients a reasonable and realistic recovery of indirect costs while helping NIH ensure that grant funds are, to the maximum extent possible, spent on furthering its mission. This policy shall be applied to all current grants for go forward expenses from February 10, 2025 forward as well as for all new grants issued. We will not be applying this cap retroactively back to the initial date of issuance of current grants to IHEs, although we believe we would have the authority to do so under 45 CFR 75.414(c).

[1] NIH, *Budget* (Oct. 3, 2024), https://www.nih.gov/ABOUT-NIH/WHAT-WE-DO/BUDGET.

[2] NIH, Fiscal Year 2021 Overview Supplementary Tables at 87, https://officeofbudget.od.nih.gov/pdfs/FY21/br/5-SupplementaryTables.pdf.

[3] *See* Bill & Melinda Gates Found., Indirect Cost Policy (Feb. 2017), https://docs.gatesfoundation.org/Documents/Indirect_Cost_Policy.pdf; Smith Richardson Found., Strategy and Policy Fellows Program, https://www.srf.org/wp-content/uploads/2014/04/2021-SPFP-Application-Requirements-and-Proposal-Template.pdf; Gordon & Betty Moore Found., Moore Inventor Fellows: 2024-2025 FAQ, https://www.moore.org/docs/default-source/moore-inventor-fellows/moore-inventor-fellows-faq.pdf; Robert Wood Johnson Found., Policies for Action:Grants FAQs, https://anr.rwjf.org/templates/external/P4A_FAQS.pdf; Carnegie Corp. of New York, Grantee FAQs, https://www.carnegie.org/grants/grantee-faqs/#:~:text=What%20is%20your%20indirect%20cost,think%20tanks%2C%20and%20government%20entities; Chan Zuckerberg Initiative, Application Instructions, https://chanzuckerberg.com/wp-content/uploads/2020/06/CZI_Imaging_Scientists_2_Detailed_Instructions.pdf; John Templeton Found., Grant FAQ, https://www.templeton.org/grants/grant-faq;The Packard Found., Fostering Equitable Grantmaking through Indirect Cost Coverage, https://www.packard.org/insights/perspective/fostering-equitable-grantmaking-through-indirect-cost-coverage/; The Rockefeller Found., Guidance: Preparing a Project Grant Budget for the Rockefeller Foundation, https://www.rockefellerfoundation.org/wp-content/uploads/2024/06/The-Rockefeller-Foundation-Project-Budget-Guidance-v2024.pdf.

Inquiries

Please direct all inquiries to:

NIH Office of Policy for Extramural Research Administration (OPERA)

Division of Grants Policy

grantspolicy@nih.gov

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

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§75.413 Direct costs.

(a) *General.* Direct costs are those costs that can be identified specifically with a particular final cost objective, such as a Federal award, or other internally or externally funded activity, or that can be directly assigned to such activities relatively easily with a high degree of accuracy. Costs incurred for the same purpose in like circumstances must be treated consistently as either direct or indirect (F&A) costs. See also §75.405.

(b) *Application to Federal awards.* Identification with the Federal award rather than the nature of the goods and services involved is the determining factor in distinguishing direct from indirect (F&A) costs of Federal awards. Typical costs charged directly to a Federal award are the compensation of employees who work on that award, their related fringe benefit costs, the costs of materials and other items of expense incurred for the Federal award. If directly related to a specific award, certain costs that otherwise would be treated as indirect costs may also include extraordinary utility consumption, the cost of materials supplied from stock or services rendered by specialized facilities or other institutional service operations.

(c) The salaries of administrative and clerical staff should normally be treated as indirect (F&A) costs. Direct charging of these costs may be appropriate only if all of the following conditions are met:

(1) Administrative or clerical services are integral to a project or activity;

(2) Individuals involved can be specifically identified with the project or activity;

(3) Such costs are explicitly included in the budget or have the prior written approval of the Federal awarding agency; and

(4) The costs are not also recovered as indirect costs.

(d) *Minor items.* Any direct cost of minor amount may be treated as an indirect (F&A) cost for reasons of practicality where such accounting treatment for that item of cost is consistently applied to all Federal and non-Federal cost objectives.

(e) The costs of certain activities are not allowable as charges to Federal awards. However, even though these costs are unallowable for purposes of computing charges to Federal awards, they nonetheless must be treated as direct costs for purposes of determining indirect (F&A) cost rates and be allocated their equitable share of the non-Federal entity's indirect costs if they represent activities which:

(1) Include the salaries of personnel,

(2) Occupy space, and

(3) Benefit from the non-Federal entity's indirect (F&A) costs.

(f) For nonprofit organizations, the costs of activities performed by the non-Federal entity primarily as a service to members, clients, or the general public when significant and necessary to the non-Federal entity's mission must be treated as direct costs whether or not allowable, and be allocated an equitable share of indirect (F&A) costs. Some examples of these types of activities include:

(1) Maintenance of membership rolls, subscriptions, publications, and related functions. See also §75.454.

(2) Providing services and information to members, legislative or administrative bodies, or the public. See also §§75.454 and 75.450.

(3) Promotion, lobbying, and other forms of public relations. See also §§75.421 and 75.450.

(4) Conferences except those held to conduct the general administration of the non-Federal entity. See also §75.432.

(5) Maintenance, protection, and investment of special funds not used in operation of the non-Federal entity. See also §75.442.

(6) Administration of group benefits on behalf of members or clients, including life and hospital insurance, annuity or retirement plans, and financial aid. See also §75.431.

§75.414 Indirect (F&A) costs.

(a) *Facilities and Administration Classification.* For major IHEs and major nonprofit organizations, indirect (F&A) costs must be classified within two broad categories: ''Facilities'' and ''Administration.'' ''Facilities'' is defined as depreciation on buildings, equipment and capital improvement,

interest on debt associated with certain buildings, equipment and capital improvements, and operations and maintenance expenses. ''Administration'' is defined as general administration and general expenses such as the director's office, accounting, personnel and all other types of expenditures not listed specifically under one of the subcategories of ''Facilities'' (including cross allocations from other pools, where applicable). For nonprofit organizations, library expenses are included in the ''Administration'' category; for institutions of higher education, they are included in the ''Facilities'' category. Major IHEs are defined as those required to use the Standard Format for Submission as noted in appendix III to part 75.C. 11. Major nonprofit organizations are those which receive more than $10 million dollars in direct Federal funding.

(b) *Diversity of nonprofit organizations.* Because of the diverse characteristics and accounting practices of nonprofit organizations, it is not possible to specify the types of cost which may be classified as indirect (F&A) cost in all situations. Identification with a Federal award rather than the nature of the goods and services involved is the determining factor in distinguishing direct from indirect (F&A) costs of Federal awards. However, typical examples of indirect (F&A) cost for many nonprofit organizations may include depreciation on buildings and equipment, the costs of operating and maintaining facilities, and general administration and general expenses, such as the salaries and expenses of executive officers, personnel administration, and accounting.

(c) *Federal Agency Acceptance of Negotiated Indirect Cost Rates.* (See also § 75.306.)

(1) The negotiated 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 when required by Federal statute or regulation, or when approved by a Federal awarding agency head or delegate based on documented justification as described in paragraph (c)(3) of this section.

(i) Indirect costs on Federal awards for training are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000;

(ii) Indirect costs on Federal awards to foreign organizations and foreign public entities performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000; and

(iii) Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.

(2) The HHS awarding agency head or delegate must notify OMB of any approved deviations.

(3) The HHS awarding agency must 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.

(4) As required under § 75.203(c), the HHS awarding agency must include in the notice of funding opportunity the policies relating to indirect cost rate reimbursement, matching, or cost share as approved. See also appendix I.C.2 and D.6 of this part. As appropriate, the HHS agency should incorporate discussion of these policies into their outreach activities with non-Federal entities prior to the posting of a notice of funding opportunity.

(d) Pass-through entities are subject to the requirements in § 75.352(a)(4).

(e) Requirements for development and submission of indirect (F&A) cost rate proposals and cost allocation plans are contained in appendices III–VII, and appendix IX as follows:

(1) Appendix III to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs);

(2) Appendix IV to Part 75—Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Nonprofit Organizations;

(3) Appendix V to Part 75—State/Local Governmentwide Central Service Cost Allocation Plans;

(4) Appendix VI to Part 75—Public Assistance Cost Allocation Plans;

(5) Appendix VII to Part 75—States and Local Government and Indian Tribe Indirect Cost Proposals; and

(6) Appendix IX to Part 75—Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals.

(f) In addition to the procedures outlined in the appendices in paragraph (e) of this section, any non-Federal entity that has never received a negotiated indirect cost rate, except for those non-Federal entities described in paragraphs (c)(1)(i) and (ii) of this section and section (D)(1)(b) of appendix VII to this part, may elect to charge a de minimis rate of 10% of modified total direct costs (MTDC) which may be used indefinitely. As described in §75.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as a non-Federal entity chooses to negotiate for a rate, which the non-Federal entity may apply to do at any time.

(g) Any non-Federal entity that has a current federally negotiated indirect cost rate may apply for a one-time extension of the rates in that agreement for a period of up to four years. This extension will be subject to the review and approval of the cognizant agency for indirect costs. If an extension is granted the non-Federal entity may not request a rate review until the extension period ends. At the end of the 4-year extension, the non-Federal entity must re-apply to negotiate a rate. Subsequent one-time extensions (up to four years) are permitted if a renegotiation is completed between each extension request.

[79 FR 75889, Dec. 19, 2014, as amended at 81 FR 3017, Jan. 20, 2016; 81 FR 89395, Dec. 12, 2016; 86 FR 2278, Jan. 12, 2021]

§ 75.415 Required certifications.

Required certifications include:

(a) To assure that expenditures are proper and in accordance with the terms and conditions of the Federal award and approved project budgets, the annual and final fiscal reports or vouchers requesting payment under the agreements must include a certification, signed by an official who is authorized to legally bind the non-Federal entity, which reads as follows: ''By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729–3730 and 3801–3812).''

(b) Certification of cost allocation plan or indirect (F&A) cost rate proposal. Each cost allocation plan or indirect (F&A) cost rate proposal must comply with the following:

(1) A proposal to establish a cost allocation plan or an indirect (F&A) cost rate, whether submitted to a Federal cognizant agency for indirect costs or maintained on file by the non-Federal entity, must be certified by the non-Federal entity using the Certificate of Cost Allocation Plan or Certificate of Indirect Costs as set forth in appendices III through VII, and appendix IX. The certificate must be signed on behalf of the non-Federal entity by an individual at a level no lower than vice president or chief financial officer of the non-Federal entity that submits the proposal.

(2) Unless the non-Federal entity has elected the option under §75.414(f), the Federal Government may either disallow all indirect (F&A) costs or unilaterally establish such a plan or rate when the non-Federal entity fails to submit a certified proposal for establishing such a plan or rate in accordance with the requirements. Such a plan or rate may be based upon audited historical data or such other data that have been furnished to the cognizant agency for indirect costs and for which

FURTHER CONSOLIDATED APPROPRIATIONS ACT, 2024

Public Law 118–47
118th Congress

An Act

Mar. 23, 2024
[H.R. 2882]

Making further consolidated appropriations for the fiscal year ending September 30, 2024, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Further Consolidated Appropriations Act, 2024.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Further Consolidated Appropriations Act, 2024".

SEC. 2. TABLE OF CONTENTS.

SEC. 3. REFERENCES. 1 USC 1 note.

Except as expressly provided otherwise, any reference to "this Act" contained in any division of this Act shall be treated as referring only to the provisions of that division.

SEC. 4. EXPLANATORY STATEMENT.

The explanatory statement regarding this Act, printed in the House section of the Congressional Record on or about March 22, 2024, and submitted by the chair of the Committee on Appropriations of the House, shall have the same effect with respect to the allocation of funds and implementation of divisions A through F of this Act as if it were a joint explanatory statement of a committee of conference.

SEC. 5. STATEMENT OF APPROPRIATIONS.

The following sums in this Act are appropriated, out of any money in the Treasury not otherwise appropriated, for the fiscal year ending September 30, 2024.

SEC. 6. AVAILABILITY OF FUNDS. President.

Each amount designated in this Act by the Congress as an emergency requirement pursuant to section 251(b)(2)(A)(i) of the Balanced Budget and Emergency Deficit Control Act of 1985 shall be available (or repurposed, rescinded, or transferred, if applicable) only if the President subsequently so designates all such amounts and transmits such designations to the Congress.

SEC. 7. ADJUSTMENTS TO COMPENSATION. 2 USC 4501 note.

Notwithstanding any other provision of law, no adjustment shall be made under section 601(a) of the Legislative Reorganization Act of 1946 (2 U.S.C. 4501) (relating to cost of living adjustments for Members of Congress) during fiscal year 2024.

explanatory statement described in section 4 in the matter preceding division A of such consolidated Act.

(b) The matter under the heading "Transit Infrastructure Grants" in title I of division F of Public Law 118–42 is amended—

Ante, p. 322.

(1) in the matter preceding the first proviso, by striking "$252,386,844" and inserting "$253,386,844"; and

(2) in paragraph (1), by striking "$20,000,000" and inserting "$21,000,000".

SEC. 550. (a) In the table of projects entitled "Community Project Funding/Congressionally Directed Spending" in the explanatory statement for division L of the Consolidated Appropriations Act, 2023 (Public Law 117–328) described in section 4 in the matter preceding division A of such Act, the item relating to "The Veterans' Place Renovation" is deemed to be amended by striking "Renovation" and inserting "New Construction".

(b) In the table of projects entitled "Community Project Funding/Congressionally Directed Spending" in the explanatory statement for division F of the Consolidated Appropriations Act, 2024 (Public Law 118–42) described in section 4 in the matter preceding division A of such Act, the item relating to "Kingfield Multi-Family Housing" is deemed to be amended by striking "Kingfield".

SEC. 551. The table entitled "Community Project Funding/Congressionally Directed Spending" in the explanatory statement for division F of the Consolidated Appropriations Act, 2024 (Public Law 118–42) described in section 4 in the matter preceding division A of such Act is deemed to be amended by adding at the end the items in the table entitled "THUD Addendum" in the explanatory statement for this division described in section 4 (in the matter preceding division A of this consolidated Act).

This division may be cited as the "Department of Homeland Security Appropriations Act, 2024".

Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2024.

DIVISION D—DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES APPROPRIATIONS ACT, 2024

TITLE I

DEPARTMENT OF LABOR

EMPLOYMENT AND TRAINING ADMINISTRATION

TRAINING AND EMPLOYMENT SERVICES

Department of Labor Appropriations Act, 2024.

Time periods.

For necessary expenses of the Workforce Innovation and Opportunity Act (referred to in this Act as "WIOA") and the National Apprenticeship Act, $4,006,421,000 plus reimbursements, shall be available. Of the amounts provided:

(1) for grants to States for adult employment and training activities, youth activities, and dislocated worker employment and training activities, $2,929,332,000 as follows:

(A) $885,649,000 for adult employment and training activities, of which $173,649,000 shall be available for the period July 1, 2024 through June 30, 2025, and of which $712,000,000 shall be available for the period October 1, 2024 through June 30, 2025;

TITLE II

Department of Health and Human Services Appropriations Act, 2024.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH RESOURCES AND SERVICES ADMINISTRATION

PRIMARY HEALTH CARE

For carrying out titles II and III of the Public Health Service Act (referred to in this Act as the "PHS Act") with respect to primary health care and the Native Hawaiian Health Care Act of 1988, $1,858,772,000: *Provided,* That no more than $1,000,000 shall be available until expended for carrying out the provisions of section 224(o) of the PHS Act: *Provided further,* That no more than $120,000,000 shall be available until expended for carrying out subsections (g) through (n) and (q) of section 224 of the PHS Act, and for expenses incurred by the Department of Health and Human Services (referred to in this Act as "HHS") pertaining to administrative claims made under such law.

HEALTH WORKFORCE

For carrying out titles III, VII, and VIII of the PHS Act with respect to the health workforce, sections 1128E and 1921 of the Social Security Act, and the Health Care Quality Improvement Act of 1986, $1,404,376,000: *Provided,* That section 751(j)(2) of the PHS Act and the proportional funding amounts in paragraphs (1) through (4) of section 756(f) of the PHS Act shall not apply to funds made available under this heading: *Provided further,* That for any program operating under section 751 of the PHS Act on or before January 1, 2009, the Secretary of Health and Human Services (referred to in this title as the "Secretary") may hereafter waive any of the requirements contained in sections 751(d)(2)(A) and 751(d)(2)(B) of such Act for the full project period of a grant under such section: *Provided further,* That section 756(c) of the PHS Act shall apply to paragraphs (1) through (4) of section 756(a) of such Act: *Provided further,* That no funds shall be available for section 340G–1 of the PHS Act: *Provided further,* That fees collected for the disclosure of information under section 427(b) of the Health Care Quality Improvement Act of 1986 and sections 1128E(d)(2) and 1921 of the Social Security Act shall be sufficient to recover the full costs of operating the programs authorized by such sections and shall remain available until expended for the National Practitioner Data Bank: *Provided further,* That funds transferred to this account to carry out section 846 and subpart 3 of part D of title III of the PHS Act may be used to make prior year adjustments to awards made under such section and subpart: *Provided further,* That $128,600,000 shall remain available until expended for the purposes of providing primary health services, assigning National Health Service Corps ("NHSC") participants to expand the delivery of substance use disorder treatment services, notwithstanding the assignment priorities and limitations under sections 333(a)(1)(D), 333(b), and 333A(a)(1)(B)(ii) of the PHS Act, and making payments under the NHSC Loan Repayment Program under section 338B of such Act: *Provided further,* That, within the amount made available in the previous proviso, $16,000,000 shall remain available until expended for the purposes of making payments under the NHSC Loan Repayment Program under section

Waiver authority. 42 USC 294a note.

SEC. 221. None of the funds made available by this Act from the Federal Hospital Insurance Trust Fund or the Federal Supplemental Medical Insurance Trust Fund, or transferred from other accounts funded by this Act to the "Centers for Medicare & Medicaid Services—Program Management" account, may be used for payments under section 1342(b)(1) of Public Law 111–148 (relating to risk corridors).

(TRANSFER OF FUNDS)

SEC. 222. (a) Within 45 days of enactment of this Act, the Secretary shall transfer funds appropriated under section 4002 of the ACA to the accounts specified, in the amounts specified, and for the activities specified under the heading "Prevention and Public Health Fund" in the explanatory statement described in section 4 (in the matter preceding division A of this consolidated Act). Deadline.

(b) Notwithstanding section 4002(c) of the ACA, the Secretary may not further transfer these amounts.

(c) Funds transferred for activities authorized under section 2821 of the PHS Act shall be made available without reference to section 2821(b) of such Act.

SEC. 223. Effective during the period beginning on November 1, 2015 and ending January 1, 2026, any provision of law that refers (including through cross-reference to another provision of law) to the current recommendations of the United States Preventive Services Task Force with respect to breast cancer screening, mammography, and prevention shall be administered by the Secretary involved as if— Time period.

(1) such reference to such current recommendations were a reference to the recommendations of such Task Force with respect to breast cancer screening, mammography, and prevention last issued before 2009; and

(2) such recommendations last issued before 2009 applied to any screening mammography modality under section 1861(jj) of the Social Security Act (42 U.S.C. 1395x(jj)).

SEC. 224. In making Federal financial assistance, the provisions relating to indirect costs in part 75 of title 45, Code of Federal Regulations, including with respect to the approval of deviations from negotiated rates, shall continue to apply to the National Institutes of Health to the same extent and in the same manner as such provisions were applied in the third quarter of fiscal year 2017. None of the funds appropriated in this or prior Acts or otherwise made available to the Department of Health and Human Services or to any department or agency may be used to develop or implement a modified approach to such provisions, or to intentionally or substantially expand the fiscal effect of the approval of such deviations from negotiated rates beyond the proportional effect of such approvals in such quarter. Applicability.

(TRANSFER OF FUNDS)

SEC. 225. The NIH Director may transfer funds for opioid addiction, opioid alternatives, stimulant misuse and addiction, pain management, and addiction treatment to other Institutes and Centers of the NIH to be used for the same purpose 15 days after notifying the Committees on Appropriations of the House of Representatives and the Senate: *Provided,* That the transfer authority Opioids. Time period. Notifications.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Subtitle A

Policy on Adhering to the Text of the Administrative Procedure Act

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Policy statement.

SUMMARY: The Department of Health and Human Services' (the Department) Immediate Office of the Secretary is rescinding the policy on Public Participation in Rule Making (Richardson Waiver) and re-aligning the Department's rule-making procedures with the Administrative Procedure Act.

DATES: March 3, 2025.

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: The Administrative Procedure Act (APA) establishes procedures for the issuance of rules and regulations. 5 U.S.C. 553. An agency generally is required to publish a notice of proposed rulemaking in the **Federal Register**; give interested persons an opportunity to participate in the rulemaking through the submission of written data, views, or arguments; and publish a final rule that is accompanied by a statement of the rule's basis and purpose. 5 U.S.C. 553. The APA exempts from these requirements ''matter(s) relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.'' 5 U.S.C. 553(a)(2). The APA also permits an agency to forgo these requirements for ''good cause'' when the agency finds that the procedures are ''impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(B).

In a 1971 **Federal Register** document, the Department adopted a policy that waived the APA's statutory exemption from procedural rulemaking requirements for rules and regulations relating to public property, loans, grants, benefits, or contracts (Richardson Waiver). 36 FR 2532 (Feb. 5, 1971). The Richardson Waiver thus required the Department to use the APA's notice and comment rulemaking procedures for these types of matters. The policy also instructed the Department to use the good cause exception ''sparingly.'' *Id.* The Department later proposed a rule to formally confirm the policy regarding the Department's use of rulemaking procedures for rules and regulations relating to public property, loans, grants, benefits, or contracts. 47 FR 26860 (June 22, 1982). The proposed rule was never adopted.

The policy waiving the statutory exemption for rules relating to public property, loans, grants, benefits, or contracts is contrary to the clear text of the APA and imposes on the Department obligations beyond the maximum procedural requirements specified in the APA. *See Perez* v. *Mortgage Bankers Ass'n,* 575 U.S. 92, 100 (2015) (finding that courts lack authority to impose obligations ''beyond the 'maximum procedural requirements' specified in the APA''). The text of the APA recognizes that it is necessary and appropriate to issue rules relating to agency management or personnel or to public property, loans, grants, benefits, or contracts without notice and comment procedures. It also is contrary to the clear text of the APA to use the good cause exception ''sparingly.'' The extra-statutory obligations of the Richardson Waiver impose costs on the Department and the public, are contrary to the efficient operation of the Department, and impede the Department's flexibility to adapt quickly to legal and policy mandates.

Effective immediately, the Richardson Waiver is rescinded and is no longer the policy of the Department. In accordance with the APA, ''matters relating to agency management or personnel or to public property, loans, grants, benefits, or contracts,'' are exempt from the notice and comment procedures of 5 U.S.C. 553, except as otherwise required by law. Agencies and offices of the Department have discretion to apply notice and comment procedures to these matters but are not required to do so, except as otherwise required by law. Additionally, the good cause exception should be used in appropriate circumstances in accordance with the requirements of the APA. The Department will continue to follow notice and comment rulemaking procedures in all instances in which it is required to do so by the statutory text of the APA.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–03300 Filed 2–28–25; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 513

[Docket No. NHTSA–2023–0014]

RIN 2127–AL85

Implementing the Whistleblower Provisions of the Vehicle Safety Act

AGENCY: National Highway Traffic Safety Administration, U.S. Department of Transportation (DOT).

ACTION: Notification of enforcement discretion.

SUMMARY: This notice announces that the National Highway Traffic Safety Administration will not enforce the requirements of the final rule titled ''Implementing the Whistleblower Provisions of the Vehicle Safety Act'' until March 20, 2025.

DATES: This notice of enforcement discretion is effective from March 3, 2025 to March 20, 2025.

FOR FURTHER INFORMATION CONTACT: Dylan Voneiff, Office of the Chief Counsel, National Highway Traffic Safety Administration (telephone: (202) 763–8536), email: *dylan.voneiff@dot.gov;* or Daniel Rabinovitz, Office of the Chief Counsel, National Highway Traffic Safety Administration (telephone: (202) 366–5263), email: *daniel.rabinovitz@dot.gov.*

Electronic Access and Filing: This document, the notice of proposed rulemaking (NPRM), all comments received, the final rule (including Form WB–INFO (Appendix A), Form WB–RELEASE (Appendix B), Form WB–AWARD (Appendix C)), and all background material may be viewed online at *www.regulations.gov* using the docket number listed above. Electronic retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at *www.federalregister.gov* and the Government Publishing Office's website at *www.GovInfo.gov.*

SUPPLEMENTARY INFORMATION: In December 2024, the National Highway Traffic Safety Administration issued a final rule titled, ''Implementing the Whistleblower Provisions of the Vehicle Safety Act,'' 89 FR 101952 (Dec. 17, 2024). This final rule fulfills a requirement in the Motor Vehicle Safety Whistleblower Act (Whistleblower Act), 49 U.S.C. 30172(i), that NHTSA promulgate regulations on the