UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ASSOCIATION OF AMERICAN MEDICAL COLLEGES, *et al.*, Plaintiffs, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	Civil Action No. 25-CV-10340-AK

ORDER GRANTING PLAINTIFFS' EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER

ANGEL KELLEY, D.J.

For purposes of Federal Rule of Civil Procedure 65(b), the Plaintiffs have made a sufficient showing that, unless their Emergency Motion For Temporary Restraining Order ("TRO") [Dkt. 5] is granted, they will sustain immediate and irreparable injury before there is an opportunity to hear from all parties. Thus, a TRO is justified to preserve the status quo pending a hearing and the Plaintiffs' Motion 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 Cost Rates (NOT-OD-25-068), issued by the Office of the Director of the National Institutes of Health on February 7, 2025 (the "Rate Change Notice"), in any form with respect to institutions nationwide until further order is issued by this Court. This Court further orders that counsel for the Defendants shall file a status report with the Court within 48 hours of the entry of this Order, and at biweekly

intervals thereafter, confirming the regular disbursement and obligation of federal financial assistance funds and reporting all steps that Defendants and their officers, employees, servants, agents, appointees, and successors have taken to comply with the Court's TRO.

Defendants' opposition to the Motion is due by **Friday, February 14, 2025**. Plaintiffs may file a reply brief, limited to ten pages in length, by **Tuesday, February 18, 2025**. Counsel shall appear in-person for a hearing on the Motion at **10:00 AM** on **Friday, February 21, 2025**. Counsel for the Plaintiffs shall provide a copy of this Order, along with copies of the motion papers, to the following by **6:00 PM** on **Tuesday, February 11, 2025**: Brad P. Rosenberg, Special Counsel, Federal Programs Branch, Civil Division, U.S. Department of Justice; Leah Foley, U.S. Attorney for the District of Massachusetts; and the Chief of the Civil Division of the U.S. Attorneys Office for the District of Massachusetts. Electronic service suffices.

This TRO shall become effective immediately upon entry by this Court. It shall remain in effect until further order of this Court.

SO ORDERED.

Dated: February 10, 2025

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

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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 GREATER NEW YORK HOSPITAL ASSOCIATION.

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH; MATTHEW MEMOLI, M.D., M.S., in his official capacity as Acting Director of the National Institutes of Health; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and DOROTHY FINK, in her official capacity as Acting Secretary of the U.S. Department of Health and Human Services,

Defendants.

Case No. _____

COMPLAINT FOR DECLARATORY & INJUNCTIVE RELIEF

1. In the evening of Friday, February 7, 2025, the National Institutes of Health ("NIH") published a brief, eleven-paragraph Notice (the "Rate Change Notice") purporting fundamentally to upend, by the next business day, how the federal government has historically, over decades, reimbursed the nation's research institutions for federally sponsored, peer-reviewed scientific research it has asked them to conduct. There was no advance warning of the Rate Change Notice and no opportunity for research institutions to explain the flaws in logic and evidence underlying the Rate Change Notice, and no explanation in the Rate Change Notice of what evidence NIH had relied on to justify this shift. The only legal authority cited for this fundamental change implicating

$36 billion in federally funded research was a regulatory provision that, by its express terms, is limited to adopting principles for "deviating" from institution-specific negotiated rates for a limited set of grants. Yet, the Rate Change Notice swept aside the entire regulatory and financial structure underlying federal grants for scientific research, which has been premised on an institution-specific, evidence-based model, for a blanket, one-size-fits-all rule that would drastically cut the rate for reimbursing these costs for virtually every institution. Adding further injury, the Rate Change Notice purported to apply these cuts retroactively to grants already awarded using the existing, historic methodology, for research that is already underway. The numerous substantive and procedural defects in the Rate Change Notice are evident on its face. Because the Rate Change Notice purports to take effect today, the next business day after it was issued, and will jeopardize many critical research projects, the Court should set it aside as unlawful and, in the interim, enjoin its effect through a temporary restraining order.

2. Academic institutions in the United States conduct groundbreaking research that yields life-changing results. Researchers from the nation's federally funded institutions have discovered effective cancer treatments and targeted therapies, built semiconductors and microelectronics, advanced agriculture and farming techniques, and set the global standard for innovation. Many of these inventions are outlicensed to U.S. industry, such as biotechnology, pharmaceutical and information technology companies, thus driving innovation and U.S. economic developments in profound ways.

3. Those institutions rely on federal grants to conduct their world-class research effectively, efficiently, safely, and securely.

4. Grants reimburse research institutions for their costs in two equally important ways. First, costs that institutions can allocate to specific research projects and initiatives, such as project-

specific research salaries and supplies, are reimbursed as "direct costs." Second, costs that support the institutions' overall grant-funded research efforts but that cannot easily be assigned to a specific project—including, for example, facilities' maintenance of state-of-the-art research laboratories, high-speed data processing, data security and data storage, cutting edge laboratory equipment, radiation safety and hazardous waste disposal, and the personnel who support essential administrative and regulatory compliance work—are shared across the entirety of an institution's research programs and are reimbursed as Facilities & Administrative ("F&A") (sometimes called "indirect"), costs.

5. While these costs are "indirect" with respect to any one grant, they are real costs that the grant recipient must incur in order to carry out the research that the grant supports. Without support through F&A costs, research laboratories would literally go dark for lack of electricity and the needed safeguards within the physical and data infrastructure supporting this research.

6. For decades, the government has reimbursed research institutions for their F&A costs through periodically negotiated institution-specific rates. The negotiated rates vary based on where institutions are located and the non–project specific research equipment, facilities, and technology available to help scientists conduct their research. In higher-cost geographic areas with a high wage base, or for institutions with higher-tech laboratory equipment and technology, the institutions typically negotiate and receive higher F&A costs. In lower-cost areas, or for institutions whose research does not require extensive equipment and technology, the negotiated F&A costs tend to be lower. And for some standalone research institutions with state-of-the-art facilities, the costs of maintaining facilities and equipment might even exceed the direct grant amounts. In each case, however, the negotiated rates are tailored to the cost of conducting research

at each specific institution, based on evidence of each institution's actual expenditures to support its scientists' research.

7. Regulations require institutions to document and support their F&A rate proposals, and they require agencies to formalize their determination of negotiated F&A costs, including by describing adjustments. If an agency and institution cannot agree to a negotiated F&A cost rate, they must follow the agency's system for appeals. F&A costs are subject to audit, and institutions must certify that their F&A costs are allowable under relevant rules.

8. Existing regulations, promulgated through notice-and-comment rulemaking, require all Federal awarding agencies to accept those previously negotiated individualized rates. 45 C.F.R. 75.414(c)(1).

9. Although awarding agencies "may use a rate different from the negotiated rate . . . when required by Federal statute or regulation, or when approved by a Federal awarding agency head or delegate," *id.*, the existing regulations limit when and how an awarding agency can deviate from the negotiated rate, and they require the awarding agency to document and justify its deviation:

a. ***First***, the awarding agency can depart from the negotiated rate only for "a single Federal award" or "a class of Federal awards," *id.*, which existing regulations define 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. In other words, a funding agency must use the negotiated rates as a starting point, and the funding agency can deviate from those negotiated rates only for specific awards or groups of awards to specific entities or groups of entities.

b. ***Second***, the awarding agency "must implement, and make publicly available, the policies, procedures and general decision making criteria that [its] programs will follow to seek and justify deviations from negotiated rates." 45 C.F.R. 75.414(c)(3).

10. Under the existing regulations, negotiated rates promote predictability for budgeting and for planning and conducting research. Agencies generally "must use the negotiated rates for indirect (F&A) costs in effect at the time of the initial award throughout the life of the Federal award." Appendix III(C)(7) to 45 C.F.R. Part 75. Indeed, to help research institutions "facilitate the preparation of their budgets," when "cost experience and other pertinent facts" suggest that the agency and institution can "reach an informed judgment as to the probable level of [F&A] costs during [ ] ensuing accounting periods," "negotiation of predetermined rates for [F&A] costs ***for a period of two to four years should be the norm***." Appendix III(C)(4) to 45 C.F.R. Part 75.

11. Research institutions rely on that predictability and core cost support in accepting research grants, knowing that the required research activities can be conducted in reliance on continuity with which the federal funding agencies reimburse them at their individual negotiated indirect cost rates.

12. That all changed on Friday night, February 7, 2025. In an eleven-paragraph notice issued by Matthew J. Memoli, Acting Director of NIH, titled "Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates," NIH uniformly and unilaterally imposed a new cap, slashing reimbursements for facilities and infrastructure to 15 percent for ***all*** new grants issued to ***all*** institutions. That across-the-board 15 percent rate is well below the previously negotiated, institution-specific F&A rates many research institutions rely on to fund their research. At least

for institutions of higher education ("IHEs"),[1] the sudden change was even more dramatic: the Rate Change Notice purported to apply not just to new grants, but also to ***all*** existing grants to ***all*** IHEs. NIH issued the Rate Change Notice without any notice or warning and without giving research institutions any opportunity to comment or be heard. And it did so without adequately justifying its drastic changes, without considering the reliance interests of research institutions, and without establishing the reasonableness of its uniform, across-the-board approach.

13. The Rate Change Notice is invalid under the Administrative Procedure Act ("APA") many times over. It is contrary to HHS's existing regulations, which require NIH to accept the previously negotiated F&A rates and permit NIH to depart from those rates only with justification and only for a limited and defined group of recipients. It is contrary to the 2024 Further Consolidated Appropriations Act, which forbids HHS from using funds to "develop or implement a modified approach" to existing HHS regulations relating to F&A cost reimbursement. It is arbitrary and capricious because NIH failed adequately to account for reliance interests, failed to justify its switch from individualized, evidence-based negotiated rates to an across-the-board 15 percent cap, and failed to explain the factual basis for its 15 percent determination. The Rate Change Notice also failed to undergo required notice and comment rulemaking, and it retroactively deprives research institutions of receiving the negotiated F&A rates the agencies committed to provide.

14. The Court should set aside the Rate Change Notice and enjoin any actions taken to implement its directives.

[1] According to the regulations cited in the Rate Change Notice, this change must apply only to IHEs and not to non-IHEs. Plaintiffs reserve all rights to argue that the Rate Change Notice's affect on existing grants applies only to IHEs.

PARTIES

15. Plaintiff **The Association of American Medical Colleges ("AAMC")** is a not-for-profit membership association dedicated to transforming health through medical education, health care, medical research, and community collaborations.

16. AAMC represents medical schools, teaching hospitals and academic health systems, and academic and academic societies. Among these members are institutions of higher education ("IHEs"). Member institutions include 159 accredited U.S. medical schools, over 490 teaching hospitals and health systems, and more than 70 academic societies. Through these member institutions, AAMC serves and leads over 200,000 full-time faculty members, 158,000 resident physicians, and 97,000 medical students, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. AAMC member institutions educate medical students and resident physicians and treat patients in all 50 states. A list of AAMC's members is available at https://myengagement.aamc.org/memberdirectory.

17. AAMC's member institutions receive grants from the NIH to fund their research. Member institutions conduct approximately 60 percent of all NIH-funded extramural research, pioneering critical advances that enable the U.S. to maintain a leader in medical research, and improve health equity. These grants include significant payments for F&A costs.

18. Plaintiff **American Association of Colleges of Pharmacy ("AACP")** advances pharmacy education, research, scholarship, practice and service, in partnership with our institutional and individual members and stakeholders, to improve health for all. AACP is comprised of 143 accredited colleges and schools with pharmacy degree programs, including more than 6,400 faculty, 61,000 students enrolled in professional programs and 6,000 individuals pursuing graduate study. AACP currently has 143 member institutions across the country, and several in Massachusetts, including the Massachusetts College of Pharmacy and Health Sciences,

with campuses in Boston and Worcester, Northeastern University Bouvé College of Health Sciences School of Pharmacy in Boston, and Western New England University in Springfield

19. Plaintiff **Association of Schools and Programs of Public Health ("ASPPH")** represents more than 150 accredited schools and programs of public health, including a community of more than 103,000 deans, faculty, staff, and students. ASPPH is the voice of academic public health and trains the next generation of public health professionals, convenes leaders, generates evidence, and advocates for policies that improve the health and well-being of everyone, everywhere

20. Plaintiff **The Conference of Boston Teaching Hospitals, Inc. ("COBTH")** is a section 501(c)(6) nonprofit coalition of twelve Boston-area teaching hospitals incorporated and headquartered in Massachusetts. COBTH is dedicated to fostering collaboration among its member teaching hospitals and supporting the full mission of its member institutions by ensuring high quality, accessible, and affordable care; advocating for policies that advance the missions of education, research, and the provision of specialized services; and working with government and local communities to protect the public health.

21. Plaintiff **Greater New York Hospital Association ("GNYHA")** is a Section 501(c)(6) organization that represents the interests of approximately 200 hospitals and health systems primarily in New York State but also in New Jersey, Connecticut, and Rhode Island. All of GNYHA's members are either not-for-profit, charitable organizations or publicly sponsored institutions that provide services ranging from state-of-the art, acute quaternary services to basic primary care needed by their communities. Many GNYHA members conduct significant research studies funded by the NIH, in conjunction with and separately from affiliated medical schools. To assist its members, GNYHA engages in advocacy, policy analysis, education, research, and

communication services at the local State, and Federal levels. GNYHA also undertakes extensive activities in the health care regulatory area, participating actively in issues pertaining to hospitals and other health care entities, health planning, and requirements for establishing and operating health care facilities.

22. Defendant the **National Institutes of Health ("NIH")** is an agency of the United States Government, established pursuant to 42 U.S.C. § 281, and is housed within the U.S. Department of Health and Human Services.

23. Defendant **Matthew Memoli, M.D., M.S.**, is Acting Director of NIH. He is sued in his official capacity.

24. Defendant **U.S. Department of Human and Health Services ("HHS")** is a federal cabinet agency that houses NIH. HHS is a Department of the Executive Branch of the U.S. Government and is an agency within the meaning of 5 U.S.C. § 551.

25. Defendant **Dorothy Fink, M.D.**, is the Acting Secretary of HHS. She is sued in her official capacity.

JURISDICTION & VENUE

26. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331, because this action arises under federal law, including the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551 *et seq.*

27. Venue is proper in this district pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391(e)(1), because at least one of the Plaintiffs—COBTH—resides in this judicial district, and other Plaintiffs have members in Massachusetts.

LEGAL FRAMEWORK

A. HHS Regulations Require NIH to Generally Accept Negotiated F&A Cost Rates and Permit NIH to Deviate from Negotiated F&A Cost Rates Only on a Limited, Case-by-Case Basis.

28. As relevant here, two statutory provisions govern the negotiation of F&A cost rates. The Office of Management and Budget ("OMB") has statutory authority to issue "supplemental interpretive guidelines" to "promote consistent and efficient use" of grant agreements. 31 U.S.C. § 6307. A separate statute, 41 U.S.C. § 4708, allows "cost-type" research contracts, including grants, to "provide for payment of reimbursable indirect costs on the basis of predetermined fixed-percentage rates applied to the total of the reimbursable direct costs incurred or to an element of the total of the reimbursable direct costs incurred."

29. Pursuant to those statutes, OMB has promulgated regulations at 2 C.F.R. 200 *et seq*., referred to as the "Uniform Guidance," compiling and codifying its grant agreement guidelines. OMB Uniform Guidance includes provisions governing federal agency negotiation of F&A cost rates with grant awardees. 2 C.F.R. 200.414(c).

30. The Department of Health and Human Services ("HHS"), the parent department of the NIH, has codified its own regulations implementing the Uniform Guidance at 45 C.F.R. 75 *et seq*. ("HHS Uniform Guidance"). *See* 45 C.F.R. 75.106.

31. Consistent with OMB's Uniform Guidance, HHS Uniform Guidance generally requires that, once a research institution and an awarding agency have agreed to a negotiated rate, NIH "must [ ] accept[]" the previously agreed-to, institution-specific "negotiated rates." 45 C.F.R. 75.414(c)(1) (providing rules specifically for HHS); *accord* 2 C.F.R. 200.414 (providing framework for all federal agencies).

32. OMB and HHS Uniform Guidance also explain how F&A rates should be negotiated: by focusing on individualized, institution-specific characteristics. For example, HHS

Uniform Guidance notes the "diverse characteristics and accounting practices of nonprofit organizations," and accordingly, it provides extensive and detailed instructions for calculating F&A costs and apportioning the distribution of payments. 45 C.F.R. 75.414(b); *see generally* 2 C.F.R. Part 200 app. III. Individualized rates are thus established for "***an*** educational institution" through either "formal negotiations" or "other than formal negotiations." Appendix III(C)(11)(f) to Part 75 (emphasis added). If the negotiating agency is concerned about "systems deficiencies relating to accountability for Federal awards," those concerns "must" be addressed by "negotiating changes." Appendix III(C)(11)(c) to Part 75; see also Appendix III(C)(11)(d) to Part 75 (agency also "must" address "amounts questioned by audit that are due the Federal Government related to costs covered by a negotiated agreement" through "necessary negotiations"). If grant terms are changed related to noncompliance, the agency "must provide the non-Federal entity an opportunity to object and provide information and documentation challenging the suspension or termination action, in accordance with written processes and procedures published by the HHS awarding agency." 45 CFR 75.374. And if the agency is "unable to reach agreement with an education institution . . . the appeal system of the cognizant agency for indirect costs must be followed for resolution of the disagreement." Appendix III(C)(11)(h) to Part 75. Once the agency and the institution have settled on a negotiated rate for F&A costs, that rate generally applies to the institution's awards for two to four years. 2 C.F.R. Part 200 app. III § C.4 and C.11.a.

33. Several presidential administrations have considered across-the-board caps to F&A cost rates, but in those previous instances, neither Congress nor the agencies have chosen to implement caps.[2] Furthermore, since 2018, Congress has explicitly prohibited NIH from

[2] *See* Audrey Leath, *CRS Report: History of Indirect Cost Policies*, Am. Inst. Physics (November 22, 1994), https://ww2.aip.org/fyi/1994/crs-report-history-indirect-cost-policies; Alexis Wolfe,

implementing changes to the F&A cost rate program, noting in the 2024 Further Consolidated Appropriations Act (the "Appropriations Rider") that "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 historically, and "[n]one of the funds appropriated in this or prior Acts or otherwise made available to [HHS] may be used to develop or implement a modified approach to such provisions." Further Consolidated Appropriations Act of 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677 (2024). Because of continuing resolutions, the Appropriations Rider is still in effect. *See* Continuing Appropriations and Extensions Act, 2025, Pub. L. No 118-83, §§ 101, 106; Further Continuing Appropriations Act, 2025, Pub. L. No. 118-158, § 101.

34. HHS Uniform Guidance also provides for limited exceptions to the general rule that NIH "must" accept the previously negotiated, institution-specific F&A rates. NIH may "use a rate different from the negotiated rate," but "only when required by Federal statute or regulation, or when approved by a Federal awarding agency head or delegate *based on documented justifications*." 45 C.F.R. 75.414(c)(1) (emphasis added). If (as here) no statute or regulation requires a different rate, HHS Uniform Guidance requires NIH to "implement, and make publicly available," three separate forms of documented justification: "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). These "policies procedures, and general decision making criteria" must be disclosed and implemented ***before*** NIH "will follow" them to "seek and justify deviations from negotiated rates." *Id.*

Trump Budget Slashes NIH by 22%, Am. Inst. Physics (June 6, 2017), https://ww2.aip.org/fyi/2017/trump-budget-slashes-nih-22.

35. Crucially, NIH's ability to "use a rate different from the negotiated" is also limited ***only*** to "a class of Federal awards or a single Federal award." 45 C.F.R. 75.414(c)(1). HHS Uniform Guidance defines "a class of Federal awards" as "a group of Federal awards either awarded under a specific program or group of programs or to a specific type of recipient or group of recipients to which specific provisions or exceptions may apply." 45 C.F.R. 75.2. For example, awards to a specific type of entity, such as small businesses, or under the same program, such as NIH's small business Commercialization Readiness Program, would be considered a "group of Federal awards."

B. The Rate Change Notice Resets the F&A Cost Rate Across the Board, for All Grants to All Grant Recipients

36. Friday afternoon's Rate Change Notice upended that preexisting regulatory framework. The Rate Change Notice purports to impose a "standard indirect rate of 15% across all NIH grants . . . in lieu of a separately negotiated rate for indirect costs in every grant." Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates, NOT-OD-25-068 at 1 (Feb. 7, 2025).

37. The Guidance declared that ***all*** "award recipients are subject" to this across-the board rate for "any new grant issued." *Id.* at 3. In addition, the one-size-fits-all rate applies "retroactive to the date of issuance of this Supplemental Guidance" for "all existing grants to IHEs." *Id.* at 3.

38. NIH issued this document without giving the public or interested parties any notice and any opportunity to comment.

39. For authority to justify the Rate Change Notice, NIH pointed only to "45 CFR 75 and its accompanying appendices," which, NIH asserted, authorized replacing negotiated rates

with a standard indirect cost rate for all existing and future grants, which the Rate Change Notice characterized as being "a class of Federal awards." *Id.* at 1.

40. As the Rate Change Notice acknowledged, those regulations require NIH to implement and disclose "the policies, procedures and general decision making criteria that their programs will follow to seek and justify deviations from negotiated rates." *Id.* at 1 (quoting 45 C.F.R. 75.414(c)(3)). Despite that requirement, however, NIH claimed only that "private foundations provide substantially lower indirect costs than the federal government." *Id.* at 2. It claimed without documentation or evidence that "a recent study found that the most common rate of indirect reimbursement by foundations was 0%." *Id.* at 2. But NIH did not identify or disclose this study. *See id.* Instead, NIH provided a brief list of maximum F&A cost rates for a handful private organizations. All of these were more than 0 percent. *Id.* They ranged from 10 percent to 15 percent. *Id.* The Rate Change Notice also purported to rely on a "recent analysis" that "examined what level for indirect expenses research institutions were willing to accept from funders." *Id.* But NIH also did not identify or disclose this study. *See id.* In fact, NIH stated that several universities refuse to accept grants from private sources, precisely because the private sources do not fully cover the expenses of running the research projects the grants are intended to fund.

41. The Rate Change Notice also did not attempt to explain why a single rate would accurately cover indirect costs across the broad range of institutions and programs funded by Federal grants. Rather, NIH acknowledged that it chose to set an across-the-board 15 percent rate that is "50% higher than the 10% de minimis indirect cost rate provided in 45 F.F.R. 75.414(f)," which sets the floor for F&A cost rates. *Id.* at 2–3. The Rate Change Notice indicated this decision was, "among other things," designed to reflect "(1) the private sector indirect cost rates . . . and (2)

the de minimis cost rate of 15% in 2 C.F.R. 200.414(f) . . . " *Id.* NIH did not explain what these "other things" were or why the chosen rate should or must reflect these other figures. *See id.* NIH also stated its new rate provided a "reasonable and realistic recovery of indirect costs" but did not explain why the 15 percent rate, specifically, would represent a realistic and financially feasible F&A cost recovery or why an across-the-board rate for all recipients was realistic, regardless of unique features of an institution, including the cost of facilities for its fields of specialized research and the cost of salaries, benefits and facilities in its geographic area. *Id.* at 3. There was no "documented justification" for these assertions and determinations in the Rate Change Notice.

PLAINTIFFS' INJURIES

42. The Rate Change Notice will immediately and significantly harm Plaintiffs, their member institutions, and the communities that those member-institutions serve.

43. As just one example, as soon as AAMC's IHE members begin drawing down funds pursuant to grants affected by the Rate Change Notice, they will inevitably lose money. For research activities up to Friday, February 7th, 2025, the IHEs have been reimbursed for F&A costs at their individual negotiated rates. Beginning February 10th, 2025, these IHE members will be reimbursed at only 15 percent. This difference in funding between the previously negotiated rate and the new 15 percent rate constitutes an irreparable harm, as the IHEs will be unable to receive this money back from the government and will be faced with large financial shortfalls immediately.

44. That irreparable harm, repeated across Plaintiffs' member institutions, will ultimately hinder scientific progress and ultimately harm patients. It will impede progress on American medical, scientific, technical, and economic priorities; result in fewer jobs and slower economic growth; cede to other nations American companies' competitive advantage as a catalyst of new industries; and threaten the nation's long-term competitiveness against global adversaries.

45. The reduction of federal funds to support the research mission at academic institutions would cause irreparable harm, leaving institutions no choice but to scale back research activities. Without the funding to adequately support the facilities and infrastructure to conduct research and the personnel and offices that ensure the safety of human subjects and animals used in research, compliance with federal regulations, laboratory maintenance, and data storage and processing, institutions would be forced to stop some research activities. This could mean fewer clinical trials, less fundamental discovery research, and slower progress in delivering lifesaving advances to the patients and families that do not have time for delay.

46. Member institutions have communicated to the AAMC, for example, that they are intending to take immediate actions to respond to this sudden change in the funding that institutions expected and budgeted. These actions include implementing an immediate hiring freeze across all research programs.

CLAIMS FOR RELIEF

COUNT I: The Rate Change Notice is Contrary to Existing HHS Regulations for the Administration of Awards

47. Plaintiffs repeat the allegations in paragraphs 1 through 46 of this Complaint as if fully set forth herein.

48. The APA expressly prohibits agency actions that are "not in accordance with law" and "in excess of statutory . . . authority." 5 U.S.C. § 706(2)(A), (C). An agency action that conflicts with the plain language of the statute or regulation is "substantively invalid." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 104-05 (2015). Nor can an agency "'trump' the language of a regulation when the regulation is clear on its face." *Christensen v. Harris County.,* 529 U.S. 576, 588 (2000); *see also Gustavsen v. Alcon Laboratories, Inc.*, 903 F.3d 1, 13 (1st Cir. 2018) (an

agency's interpretation of its own regulations cannot "overcome the regulation's obvious meaning") (citation omitted).

49. The Rate Change Notice is contrary to existing HHS regulations.

50. Existing HHS regulations generally require awarding agencies to accept previously negotiated, institution-specific indirect cost rates. 45 C.F.R. 75.414(c)(1).

51. Awarding agencies "may use a rate different from the negotiated rate for a class of Federal awards or a single Federal award," but may do so "*only* when required by Federal statute or regulation" or based on an approved "documented justification" according to "publicly available … criteria" for "justify[ing] deviations from negotiated rates." 45 C.F.R. 75.414(c)(1), (3).

52. 45 C.F.R. 75.414(c)(1) and (3) do not authorize NIH to abandon negotiated rates on an undifferentiated, across-the-board basis for all recipients, as it has done through the Rate Change Notice.

a. There is no federal law or regulation requiring NIH's action.

b. Deviations pursuant to 45 C.F.R. 75.414(c)(1) and (3) are allowed only "for a class of Federal awards or a single Federal award." "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." 45 C.F.R. 75.2. The Rate Change Notice—which establishes a "***standard*** indirect rate" for ***all*** "new grant awards and existing grant awards" issued to ***all*** non-Federal entities—is inconsistent with the regulations because it does *not* establish "criteria" for a "***specific*** type of non-Federal entity or group of non-Federal entities ***to which specific provisions or exceptions may apply,***" but is instead a new rule of general applicability from which there are no exceptions.

c. The Rate Change Notice does not establish "criteria" for "deviations from negotiated rates," which presupposes that negotiated rates continue to exist and apply outside the deviations. By giving itself authority to justify specific "deviations," the agency's regulation did not purport to arrogate to itself a unilateral power to do away with negotiated rates altogether, including as to existing grants that applied the negotiated rate.

d. While the Rate Change Notice purports to apply to "any new grant issued," the authority cited by the Rate Change Notice for its drastic change, 45 C.F.R. 75.414, does not even apply to hospitals under 45 CFR 75.101(b)(1). For this reason as well, the Notice exceeds the agency's regulatory authority as to grants to hospitals.

e. The Rate Change Notice is thus contrary to existing regulations, including 45 C.F.R. 75.414(c)(1).

COUNT II: The Rate Change Notice Exceeds NIH's Statutory Authority

53. Plaintiffs repeat the allegations in paragraphs 1 through 46 of this Complaint as if fully set forth herein.

54. The APA expressly prohibits agency actions that are "not in accordance with law." 5 U.S.C. § 706(2)(A), (C).

55. Congress has twice explicitly considered, but did not adopt, an across-the-board cap on F&A costs. Rather than adopting a uniform cap, Congress affirmatively chose, in the Appropriations Rider, to maintain the status quo based on individually negotiated rates. The Appropriations Rider provides: "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 historically, and "[n]one of the funds appropriated in this or prior Acts or otherwise made available to [HHS] may be used to develop or implement a modified approach to such

provisions." Further Consolidated Appropriations Act of 2024, Pub. L. No. 118-47, § 224, 138 Stat. 460, 677 (2024).

56. Because of continuing resolutions, the Appropriations Rider is still in effect. *See* Continuing Appropriations and Extensions Act, 2025, Pub. L. No 118-83, §§ 101, 106; Further Continuing Appropriations Act, 2025, Pub. L. No. 118-158, § 101

57. The Rate Change Notice is inconsistent with and exceeds the authority granted by Congress to HHS to adopt revisions to the manner in which F&A rates are set. Through the Appropriations Rider, HHS was expressly forbidden by the appropriations rider to spend any funds to modify the F&A rate system. Rather than adhere to Congress's command, HHS and NIH expended funds to develop criteria to modify the F&A rate system by purporting to justify the new across-the-board cap.

COUNT III: The Rate Change Notice is Arbitrary & Capricious

58. Plaintiffs repeat the allegations in paragraphs 1 through 46 of this Complaint as if fully set forth herein.

59. Under the APA, a reviewing court must set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706; In making this inquiry, the reviewing court "must consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989) (citation omitted). At a minimum, the agency must have considered relevant data and articulated an explanation establishing a "rational connection between the facts found and the choice made." *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626 (1986) (citation omitted). When, as here, an agency is "not writing on a blank slate," it is "required to assess whether there [are] reliance interests, determine whether they [are] significant, and weigh any such interests against competing policy concerns." *Dept't of Homeland*

Sec. v. Regents of Univ. of Cal., 591 U.S. 1, 33 (2020). An agency's failure to consider those reliance interests is arbitrary and capricious.

60. The Rate Change Notice is arbitrary and capricious in at least three ways.

61. ***First***, NIH failed to adequately consider the reliance interests of grant recipients and especially of IHEs. In general, negotiated rates must be used "throughout the life of the Federal award." Appendix III(C)(7) to Part 75. That standard creates significant reliance interests by grant recipients who count on predictable, consistent rates to budget and plan ahead. Yet the Rate Change Notice does not adequately consider how an overnight change to the negotiated rate affects predictability, budgeting, and planning. Nor does the Rate Change Notice explain why an immediate, late Friday afternoon change effective on the next business was necessary or whether an alternative approach or different timing may have better accounted for reliance interests.

62. ***Second***, even on its own terms, the Rate Change Notice's rationale is contradictory and internally inconsistent. HHS's existing regulations contemplate that IDC rates will be based on evidence. The Guidance contains no record of having considered any evidence other than the IDC rates of certain private foundations. The Guidance does not reflect any consideration of evidence regarding the differences between how these types of grants are administered. Rather, the Guidance applies the same, blunt, across-the-board change for all institutions regardless of their F&A costs. As even the Guidance's own purported rationale makes clear, a uniform approach is unsupported. Different foundations offer *different* indirect cost rates, and different institutions have different policies with respect to accepting lower indirect cost rates from private foundations. Thus, even on its own terms, the Guidance is arbitrary and capricious.

63. ***Third***, the existing regulations require that any deviations from negotiated rates be according to publicly declared policies that are "***based on documented justifications.***" 45 C.F.R.

75.414(c)(1) (emphasis added). Yet, there was no discussion of any evidentiary basis or analysis of what the actual indirect costs are to grant recipients for administering grants. In stark contrast to the institution-specific negotiated rates, which are (as required by regulation), based in fact, the Rate Change Notice made no such effort to justify its radical departure from the system laid out in the regulations and utilized for decades, relying instead on a comparison to private foundations, without any record or analysis of whether the comparison is an apt one, or whether, for example, private foundations may permit a greater range of costs to be reimbursable as "direct" costs.

COUNT IV: The Rate Change Notice Was Adopted Without Observance of Procedures Required By Law and in Violation of the Due Process Clause

64. Plaintiffs repeat the allegations in paragraphs 1 through 46 of this Complaint as if fully set forth herein.

65. A court must set aside agency action that is "without observance of procedure required by law." 5 U.S.C. § 706(2). In particular, an agency must follow legally mandated procedures when issuing new rules, including issuing new legislative rules through notice and comment. NIH has violated these procedural requirements by adopting a legislative rule through the Rate Change Notice without going through the required notice-and-comment rulemaking.

66. Legislative rules have the "force and effect of law" and may be promulgated only after public notice and comment. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019) ("A key feature of [interpretive rules] is that (unlike legislative rules) they are not supposed to 'have the force and effect of law'—or, otherwise said, to bind private parties" (citation omitted)); *Perez*, 575 U.S. at 97 ("Interpretive rules 'do not have the force and effect of law and are not accorded that weight in the adjudicatory process.'" (quoting *Shalala v. Guernsey Mem'l Hosp.,* 514 U.S. 87, 99 (1995))). An agency action that purports to impose legally binding obligations or prohibitions on regulated

parties—and that could form the basis of an enforcement action for violations of those obligations or requirements—is a legislative rule. *Nat'l Mining Ass'n*, 758 F.3d at 251.

67. In determining whether an agency pronouncement is a legislative rule, and as such required to undergo notice-and-comment rulemaking, the most important factor concerns the actual legal effect (or lack thereof) of the agency action in question on regulated entities. *Id.* at 252. Whether a purported interpretive rule has "legal effect" is determined by asking "(1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule. If the answer to any of these questions is affirmative, we have a legislative rule." *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993); *see also Civitas Massachusetts Regional Ctr., LLC v Mayorkas*, 2022 US Dist LEXIS 44170, at *20-21 (D. Mass 2022) (applying that test).

68. The Rate Change Notice is a substantive rule and effectively rewrites 45 C.F.R. 75.411. Thus, it was required—but failed to—undergo notice and comment rulemaking.

69. In addition, the application of the Rate Change Notice to existing IEH grants violates basic principles of fair notice and due process. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 156 (2012). IEHs agreed to grants expecting their F&A costs would be reimbursed at their previously negotiated rates. By changing the terms of those grants without providing any warning to IEHs, NIH deprived IEHs of their due process rights.

COUNT V: The Rate Change Notice Violates Both the Statutory and Constitutional Prohibitions on Retroactivity

70. Plaintiffs repeat the allegations in paragraphs 1 through 46 of this Complaint as if fully set forth herein.

71. The Rate Change Notice violates the Due Process Clause and exceeds statutory authority because it retroactively alters existing grants without an express authorization from Congress to do so.

72. The presumption against retroactivity—"a legal doctrine centuries older than our Republic"—requires courts to protect fair notice and settled expectations by disfavoring government action that operates retroactively. *Landgraf v. USI Film Prods.*, 511 U.S. 244 (1994). This principle "serves as guardian of the Constitution's promise of due process and its ban on *ex post facto* laws," *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 435 n.5 (2024) (Gorsuch, J., concurring) (citing *id.*).

73. To implement this bedrock presumption, the Supreme Court applies a simple rule: if a law or action "would operate retroactively, our traditional presumption teaches that it does not govern absent clear congressional intent favoring such a result." *Landgraf,* 511 U.S. at 280. Such retroactive application includes when a rule "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.* Moreover, "a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988).

74. Here, the agency admits—indeed highlights—that its action operates "retroactive to the date of issuance of this Supplemental Guidance" for "all existing grants" to Institutes of

Higher Education. NOT-OD-25 at 3. That violates both the constitutional and statutory prohibitions on retroactivity.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request an Order from the Court that:

a. Declares unlawful and set aside the Rate Change Notice (NOT-OD-25-068) as arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under 5 U.S.C. § 706(2)(A), contrary to constitutional right, power, privilege, or immunity under 5 U.S.C. § 706(2)(B), in excess of statutory jurisdiction, authority, or limitations, or short of statutory right under 5 U.S.C. § 706(2)(C), and without observance of procedure required by law under 5 U.S.C. § 706(2)(D);

b. Issues a temporary restraining order and preliminary injunction barring the NIH, HHS and all of their officers, employees, and agents from taking any steps to implement, apply, or enforce the Rate Change Notice (NOT-OD-25-068);

c. Orders Defendants to file a status report with the Court within 24 hours of entry of a temporary restraining order, and at regular intervals thereafter, confirming the regular disbursement and obligation of federal financial assistance funds and reporting all steps that NIH, HHS and their officers, employees, and agents have taken to comply with the Court's temporary restraining order;

d. Issues a preliminary injunction barring the NIH, HHS and all of its officers, employees, and agents from taking any steps to implement, apply, or enforce the Rate Change Notice (NOT-OD-25-068) in any form or under any name;

e. Issues a permanent injunction barring the NIH, HHS and all of its officers, employees, and agents from taking any steps to implement, apply, or enforce the Rate Change Notice

(NOT-OD-25-068) in any form or under any name; and

f. Awards such additional relief as the interests of justice may require.

Dated: February 10, 2025

Respectfully submitted,

ROPES & GRAY LLP

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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 GREATER NEW YORK HOSPITAL ASSOCIATION,

Plaintiffs,

v.

NATIONAL INSTITUTES OF HEALTH; MATTHEW MEMOLI, M.D., M.S., in his official capacity as Acting Director of the National Institutes of Health; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; and DOROTHY FINK, in her official capacity as Acting Secretary of the U.S. Department of Health and Human Services,

Defendants.

C.A. No. _____

DECLARATION OF HEATHER H. PIERCE

I, Heather H. Pierce, declare as follows:

1. I am the Senior Director for Science Policy and Regulatory Counsel at the Association of American Medical Colleges ("AAMC"). I have held this position since October 2010. I make this declaration as a representative of AAMC based on my personal knowledge and experience. I serve as AAMC's leader for scientific regulatory issues including federal grant oversight, human subject protections, clinical research, conflicts of interest, research data sharing, and collaborations between industry, government, and academia in biomedical research. In my official capacity and based on my personal knowledge and

other sources of information which I have obtained and reviewed in that official capacity, I am familiar with, and if called upon to do so, would be competent to testify to the facts and circumstances set forth herein.

2. AAMC is a not-for-profit membership association dedicated to transforming health through medical education, health care, medical research, and community collaborations.

3. AAMC's members consist of medical schools, teaching hospitals and academic health systems, and academic and scientific societies. Among these members are institutions of higher education ("IHEs"). Member institutions include 159 accredited U.S. medical schools, over 490 teaching hospitals and health systems, and more than 70 academic societies. Through these member institutions, AAMC serves and leads 200,000 full-time faculty members, 158,000 resident physicians, 97,000 medical students, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. AAMC member institutions educate medical students and resident physicians and treat patients in all 50 states.

4. AAMC's member institutions receive grants from the NIH to fund peer-reviewed research deemed to have significant promise in advancing scientific knowledge and improving health. Member institutions conduct approximately 60% of all NIH-funded extramural research, pioneering critical life-saving advances in patient care. These grants include payments for Facilities and Administrative ("F&A") costs, which have been negotiated with the federal government based on the individual circumstances of the grantee and are routinely audited.

5. The "Supplemental Guidance to the 2024 NIH Grants Policy Statement: Indirect Cost Rates," Office of The Director, National Institutes of Health (February 7, 2025), would

significantly harm AAMC and the member institutions and communities AAMC serves who rely on the terms of their NIH grants, as stated above.

6. As soon as AAMC's IHE members begin drawing down funds pursuant to current grants affected by the Supplemental Guidance, they will lose money. Had they drawn down those funds on Friday, February 7th, 2025, they would have been reimbursed for F&A costs at their negotiated rate. Beginning February 10th, 2025, these IHE members will be reimbursed at only 15%. This difference in funding between the previously negotiated rate and the new 15% rate constitutes an irreparable harm, as they will be unable to receive this money back from the government.

7. The reduction of federal funds to support the research mission at academic institutions would cause irreparable harm, leaving institutions no choice but to scale back research activities. Without the funding to adequately support the facilities and infrastructure to conduct research and the personnel and offices that ensure the safety of human subjects and animals used in research, compliance with federal regulations, laboratory maintenance, and data storage and processing, institutions would be forced to stop some research activities. This could mean fewer clinical trials, less fundamental discovery research, and slower progress in delivering lifesaving advances to the patients and families that do not have time for delay.

8. Member institutions have communicated to the AAMC that they are intending to take immediate actions to respond to this sudden change in the funding that institutions expected and budgeted. These actions include implementing an immediate hiring freeze across all research programs.

9. This guidance will curb the research activities of hundreds of medical schools, teaching hospitals, and academic health systems, leading to devastating effects on the health of Americans.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 10th day of February, 2025 in Washington, D.C.

/s/ Heather H. Pierce

Heather H. Pierce
Senior Director
Association of American Medical Colleges