

NIH Announces New Antidiscrimination Certification Heightening FCA Risk for Some Life Sciences Companies

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On April 21, 2025, the National Institutes of Health (NIH) announced a new civil rights term and condition of award for NIH grants, cooperative agreements and other transaction awards. The new term states that recipients of such awards, by accepting them, certify that they have no diversity, equity and inclusion DEI programs that violate federal antidiscrimination law. Life sciences companies with NIH funding should take note of this new award term, as it is likely to begin appearing immediately in new NIH awards and in renewals, supplements and modifications of existing NIH awards, and it could foreshadow increased risk of False Claims Act (FCA) enforcement activity targeting funding recipients with DEI programs

NIH's Notice NOT-OD-25-090 announcing the new civil rights term provides that, effective as of the date of publication, the revised term applies to all new NIH funding actions and to renewal, supplement or continuation awards. The most important elements of the new award term are:

1. All NIH funding recipients must comply with federal antidiscrimination laws, as applicable, that are “material to the government’s payment decisions for purposes of” the FCA.
2. By accepting NIH funding through an award, the recipient is certifying that it does not and will not during the award term “operate any programs that advance or promote DEI [diversity, equity, inclusion and accessibility], or discriminatory equity ideology in violation of” such laws, and that it does not and will not during the award term take part in any “discriminatory prohibited boycott.” “Discriminatory equity ideology” is defined in President Donald Trump’s Executive Order (EO) 14190, dated January 29, 2025. A “discriminatory prohibited boycott” is one that entails “refusing to deal, cutting commercial relations, or otherwise limiting commercial relations specifically with Israeli companies or with companies doing business in or with Israel or authorized by, licensed by, or organized under the laws of Israel to do business.”
3. NIH is authorized to terminate awards and seek to recover funds expended if a recipient operates a program that runs afoul of these legal requirements during the term of the applicable award.

The reference in the new term to the FCA and labeling the requirement as a certification is particularly important because it may signal increased risk of government inquiries and investigations focused on the DEI programs of federal funding recipients, adding to the uncertainty companies face as they seek to maintain compliance with the evolving interpretation of the underlying legal regimes. The FCA provides for treble damages plus penalties as a consequence of, among other things, directly or indirectly submitting a false claim for payment to the government. A government contractor that falsely certifies compliance with a condition of an award material to the government’s decision to pay the contractor’s requests for payment may face outsized liability under the FCA, which also permits whistleblowers to enforce the statute through provisions that allow “*qui tam* relators” to keep up to 30% of amounts recovered. FCA settlements and judgments reached nearly \$3 billion in fiscal year 2024, the same year the industry saw the highest number of whistleblower *qui tam* lawsuits ever filed.

Relatedly, the US Department of Justice (DOJ) issued a memorandum on May 19 announcing a Civil Rights Fraud Initiative specifically targeting grant recipients with DEI programs. It points to the FCA as the government’s primary enforcement mechanism when a recipient of federal funds knowingly violates applicable civil rights law while falsely certifying compliance: “The False Claims Act is [] implicated whenever federal-funding recipients or contractors certify compliance with civil rights laws while knowingly engaging in racist preferences, mandates, policies, programs, and activities, including through diversity, equity, and inclusion (DEI) programs that assign benefits or burdens on race, ethnicity, or national origin.” The Civil Rights Fraud Initiative – co-led by the DOJ’s Civil Rights Division and Civil Fraud Section with assistance from the 93 US attorney’s offices across the country – will focus on pursuing FCA investigations and claims against such recipients.

The revised NIH provision, which will apply to new, renewal, supplement or continuation awards issued on or after the date the notice was published, supersedes the current NIH Grant Policy Statement (GPS) Section 4.1.2,

Civil Rights Protections. The superseded section stated that NIH funding recipients must comply with federal civil rights laws prohibiting discrimination based on race, color, national origin, disability, age and sex (including gender identity, sexual orientation and pregnancy), and take meaningful steps to ensure individuals with limited English proficiency can nevertheless effectively access health and social services. NIH stated that it will update its GPS accordingly.

While it remains to be seen how the applicable federal antidiscrimination laws will be interpreted in the current environment and what the government's enforcement efforts in this area will entail, the new certifications may invite increased whistleblower activity under the FCA, which DOJ's May 19 memorandum "strongly encourages." Contractors should closely monitor changes to their contractual requirements, the terms of new awards and developments in the relevant landscape through further notice announcements from customer agencies, additional EOs and litigation related to enforcement of the administration's policies – including judicial decisions interpreting the applicable requirements under federal law. In addition, current and prospective funding recipients should consider retaining counsel to review their internal policies and programs, document their efforts to ensure compliance with applicable law, and be prepared to respond to and adequately investigate reports from employees raising concerns about DEI programs or potential discrimination.

The landscape on these issues continues to shift, but given the potential reputational and monetary consequences of an FCA investigation, related litigation and liability, this latest notice from NIH (and the corresponding commentary in DOJ's May 19 memorandum) reminds life sciences companies receiving funds from NIH (either directly or as subrecipients) that they must remain vigilant. Cooley's government contracts and employment teams continue to monitor developments and can advise clients in these areas.

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