

regulation have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR parts 801 and 809, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 862

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 862.1092 to subpart B to read as follows:

§ 862.1092 Anti-mullerian hormone test system.

(a) *Identification.* An anti-mullerian hormone test system is an in vitro diagnostic device intended to measure anti-mullerian hormone in human serum and plasma. An anti-mullerian hormone test system is intended to be used for assessing ovarian reserve in women.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Design verification and validation must include:

(i) An adequate traceability plan to minimize the risk of drift in anti-mullerian hormone test system results over time.

(ii) Detailed documentation of a prospective clinical study to demonstrate clinical performance or, if appropriate, results from an equivalent sample set. This detailed documentation must include the following information:

(A) Results must demonstrate adequate clinical performance relative to a well-accepted comparator.

(B) Clinical sample results must demonstrate consistency of device output throughout the device measuring range that is appropriate for the intended use population.

(C) Clinical study documentation must include the original study protocol (including predefined statistical analysis plan), study report documenting support for the proposed indications for use(s), and results of all statistical analyses.

(iii) Reference intervals generated by testing an adequate number of samples from apparently healthy normal

individuals in the intended use population.

(2) The labeling required under § 809.10(b) of this chapter must include a warning statement that the device is intended to be used for assessing the ovarian reserve in conjunction with other clinical and laboratory findings before starting any fertility therapy, and that the device should be used in conjunction with the antral follicle count.

Dated: May 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09776 Filed 5–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 230

[FHWA Docket No. FHWA–2019–0026]

RIN 2125–AF87

State Highway Agency Equal Employment Opportunity Programs

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FHWA is removing outdated and duplicative regulations requiring State highway agencies to submit to FHWA, on an annual basis, Equal Employment Opportunity (EEO) Program plans for FHWA approval. Currently, FHWA is responsible for oversight of State highway agencies' EEO programs, which include collection and analysis of internal employment data, development of an internal affirmative action hiring plan, and contractor compliance reporting. These regulations overlap with, and are duplicative of, other Federal requirements enforced by other Federal agencies. In addition, an Executive order (E.O.) issued by President Donald J. Trump repealed a previous E.O. that was relied on to initially promulgate the regulation. Elimination of these regulations will reduce administrative and monetary burdens on Federal-aid recipients.

DATES: This final rule is effective June 30, 2025.

FOR FURTHER INFORMATION CONTACT: Nichole McWhorter, Acting Associate Administrator, Office of Civil Rights, Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC

20590, (202) 366–1396, Nichole.McWhorter@dot.gov; or James Esselman, Office of the Chief Counsel, Federal Highway Administration, 1200 New Jersey Avenue SE, Room E82–322, Washington, DC 20590, (202) 366–6181, James.Esselman@dot.gov. Office hours are from 8 a.m. to 4:30 p.m. e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document, as well as the notice of proposed rulemaking (NPRM) and all comments received, may be viewed online through the Federal eRulemaking portal at www.regulations.gov. The website is available 24 hours each day, 365 days each year. An electronic copy of this document may also be downloaded by accessing the Office of the Federal Register's website at: www.federalregister.gov and the Government Publishing Office's website at: www.GovInfo.gov.

Background

On November 30, 2020, at 85 FR 76500, FHWA published a notice of proposed rulemaking (NPRM) proposing to remove its State Highway Administration Equal Employment Opportunity Programs regulations at 23 Code of Federal Regulations (CFR) part 230, subpart C. These regulations require State highway agencies to submit to FHWA, on an annual basis, EEO Program plans, which include collection and analysis of internal employment data, development of an internal affirmative action hiring plan, and contractor compliance reporting. The NPRM described how these regulations overlap with, and are duplicative of, other Federal requirements ensuring nondiscrimination in employment that are enforced by other Federal agencies. The NPRM further outlined how elimination of FHWA's regulations would reduce administrative and monetary burdens on FHWA recipients.

The FHWA received four public comment submissions in response to the NPRM. Commenters included two State highway agencies and two individuals. One of the individuals supported the proposed rule. The second individual's comments did not address the NPRM at all. One State highway agency did not express an opinion in favor of or against the proposed regulatory rescission, but commented that it was not concerned by the duplicative nature of FHWA's EEO regulations, noting that while other authorities require the submission of data, no other authorities require the submission of EEO program plans. The second State highway agency

commented that it would continue to implement an EEO plan even if FHWA rescinds its EEO regulations. It noted that FHWA's rescission of the regulations would reduce the credibility of FHWA's EEO program activities. After carefully considering the comments received in response to the NPRM, along with changes in Federal EEO authorities since FHWA issued the NPRM, FHWA is promulgating final regulations without changes to the proposed regulatory text.

FHWA Response to Comments and Discussion of Regulatory Changes

As discussed in the NPRM, FHWA's regulations at 23 CFR part 230, subpart C, currently require that all State highway agencies submit to FHWA for approval, on an annual basis, an EEO Program, which must include provisions for reporting on contractor compliance and internal State highway agency employment. The internal employment provisions require submission of an affirmative action plan and an analysis of employment statistical data. The NPRM explained why these requirements are outdated and duplicative of other employment nondiscrimination authorities enforced by other Federal agencies, including the Equal Employment Opportunity Commission (EEOC) and the Department of Justice (DOJ). None of the comments received in response to the NPRM disputed the existence of this overlap among employment nondiscrimination authorities and Federal enforcement agencies. The only point of difference noted by one of the State highway agency commenters is that FHWA's regulations require submission of an EEO program plan, not just the submission of employment data.

The FHWA acknowledges that its regulations require that State highway agencies submit formal EEO program plans addressing contractor compliance and State internal employment, which other authorities do not require. This distinction, however, is not a justification for retaining FHWA's regulations.

As an initial matter, FHWA's regulatory requirement that State highway agencies submit reports on their own internal employment EEO programs is not directly required by statute. In issuing the regulation in 1976, FHWA cited authority at title 23 United States Code (U.S.C.), 140(a). *See* 41 FR 28270 (July 9, 1976). That authority directs the Department to require State highway agencies provide assurances that employment in connection with proposed Federal-aid highway projects will be provided

without regard to race, color, creed, national origin, or sex. Providing assurances that Federal-aid project employment will be provided in a nondiscriminatory manner does not mandate the submission of an internal EEO report. The assurance of complying with nondiscrimination requirements overlaps with requirements under title VII of the Civil Rights Act, enforced by EEOC and DOJ. There is no separate need for FHWA to conduct such oversight.

To the extent that FHWA issued its regulations based on the direction provided under E.O. 11246, regarding EEO responsibilities of Federal and Federal-aid contractors, implementation of EEO requirements under that authority was consolidated under the Office of Federal Contract Compliance Programs (OFCCP) in 1978 through E.O. 12086, Consolidation of Contract Compliance Functions for Equal Employment Opportunity, issued by President Carter. That action, coupled with the issuance of OFCCP's EEO regulations at 41 CFR part 60 in 1978, rendered FHWA's Federal-aid contractor EEO provisions under subpart C duplicative of the OFCCP framework.

The overlap with OFCCP authority was reason enough to support FHWA's rescission of its Subpart C regulations. More significantly, however, through E.O. 14173, Ending Illegal Discrimination and Restoring Merit-Based Opportunity, issued January 21, 2025, President Donald J. Trump revoked E.O. 11246. Without E.O. 11246 FHWA's Subpart C regulations addressing Federal-aid highway EEO requirements, such requirements can longer be justified.

Given that other authorities at both the State and Federal level provide coverage of employment discrimination applicable to State highway agencies and Federal-aid contractors, and given that Congress never expressly directed FHWA to require State highway agencies to create and submit affirmative action plans, FHWA is proceeding with removing the regulatory requirements at 23 CFR part 230, subpart C.

The elimination of this regulation at 23 CFR part 230, subpart C, will reduce the reporting and compliance burdens on State highway agencies by eliminating duplicative requirements that will ultimately result in a cost savings to the State agencies and to FHWA, without diminishing Federal oversight of Federal employment nondiscrimination requirements.

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review) and DOT Rulemaking Policies and Procedures

The Office of Management and Budget (OMB) has not designated this rule a significant action under section 3(f) of Executive Order (E.O.) 12866.

Accordingly, OMB has not reviewed it. It is anticipated that the economic impact of this rulemaking would be minimal. This rulemaking eliminates required reporting and analysis that is currently required under the regulation; therefore, eliminating this portion of the regulation would achieve cost savings.

Although this rulemaking to revise 23 CFR part 230, subpart C would not be a significant regulatory action, it does generate cost savings resulting from reduced administrative burden associated with the efforts by the States and FHWA related to the collecting and analyzing of State internal employment data leading to creation of an affirmative action plan.

Executive Order 14192 (Unleashing Prosperity Through Deregulation)

This final rule is an E.O. 14192 deregulatory action. The annualized cost savings are estimated to be \$832,116 per year, measured in 2024 dollars. For the 20-year period from 2026 through 2045 the estimated cost savings are roughly \$8.8 million in net present value when discounted at 7 percent to 2024. A summary of the results of the analysis and the assumptions underlying the calculations are included in the docket for this rulemaking.

These changes would not adversely affect, in a material way, any sector of the economy. In addition, these changes would not interfere with any action taken or planned by another Agency and would not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs. Consequently, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601-612), FHWA has evaluated the effects of this action on small entities. Because the regulations are applicable primarily to States, FHWA has determined that the action is not anticipated to have a significant economic impact on a substantial number of small entities. States are not included in the definition of small entity set forth in 5 U.S.C. 601. Therefore, FHWA certifies that the action will not have a significant

economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

The FHWA has determined that this rule does not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, March 22, 1995, 109 Stat. 48). This rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year (when adjusted for inflation) (2 U.S.C. 1532). In addition, the definition of “Federal Mandate” in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or Tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility.

Executive Order 13132 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in E.O. 13132. The FHWA has determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment. The FHWA has also determined that this action does not preempt any State law or State regulation or affect the States’ ability to discharge traditional State governmental functions.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget for each collection of information they conduct, sponsor, or require through regulations. The FHWA has determined that this action does not contain collection of information requirements for the purposes of the PRA and there was no PRA number associated with this regulation. However, the elimination of this regulatory section will alleviate current burdens imposed on the States by reducing the need to file lengthy Affirmative Action Plans along with filing duplicative EEO–4 documents to FHWA.

National Environmental Policy Act

The Agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321) and has determined that it qualifies for a categorical exclusion under 23 CFR 771.117(c)(20), which

applies to the promulgation of regulations, and that no unusual circumstances are present under 23 CFR 771.117(b). Categorically excluded actions meet the criteria for categorical exclusions under 23 CFR 771.117(a) and normally do not require any further NEPA approvals by FHWA.

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this action under E.O. 13175 and believes that it would not have substantial direct effects on one or more Indian tribes; would not impose substantial direct compliance costs on Tribal governments; and, would not preempt Tribal law. Therefore, a Tribal summary impact statement is not required.

Rulemaking Summary, 5 U.S.C. 553(b)(4)

As required by 5 U.S.C. 553(b)(4), a summary of this rule can be found in the Abstract section of the Department’s Unified Agenda entry for this rulemaking at <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202410&RIN=2125-AF87>.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in the spring and fall of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 230

Equal employment opportunity, Federal-aid construction contracts, Grant programs—transportation, Highways and roads, Reporting and recordkeeping requirements.

Issued in Washington, DC, under authority delegated in 49 CFR 1.85(a)(1).

Gloria M. Shepherd,

Executive Director, Federal Highway Administration.

In consideration of the foregoing, FHWA amends 23 CFR part 230 as set forth below:

PART 230—EXTERNAL PROGRAMS

■ 1. The authority citation for part 230 is revised to read as follows:

Authority: 23 U.S.C. 101, 140, and 315; 42 U.S.C. 2000d *et seq.*; and 49 CFR 1.81.

Subpart C—[Removed and Reserved]

■ 2. Remove and reserve subpart C, consisting of § 230.301 through appendix A to subpart C of part 230.

[FR Doc. 2025–09753 Filed 5–27–25; 4:15 pm]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 490

RIN 2125–AG27

National Performance Management Measures; Rescinding Requirements for the First Performance Period

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule rescinds the requirements pertaining to the performance targets established by State departments of transportation (State DOTs) and Metropolitan Planning Organizations (MPOs) for the first performance period (Calendar Years 2018 through 2021), as originally promulgated in the regulations issued on January 18, 2017, National Performance Management Measures; Assessing Performance of the National Highway System, Freight Movement on the Interstate System, and Congestion Mitigation and Air Quality Improvement Program.

DATES: This final rule is effective May 30, 2025.

FOR FURTHER INFORMATION CONTACT: For questions about this final rule, please contact Ms. LaToya Johnson, FHWA Office of Infrastructure, 202–366–0479, or via email at latoya.johnson@dot.gov. For legal questions, please contact Mr. David Serody, FHWA Office of Chief Counsel, 202–366–4241, or via email at David.Serody@dot.gov. Office hours for FHWA are from 8 a.m. to 4:30 p.m., eastern time (E.T.), Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

An electronic copy of this document may also be downloaded from the Office of Federal Register’s website at www.federalregister.gov and the U.S. Government Publishing Office’s website at www.GovInfo.gov.

I. General Discussion

Through this final rule, FHWA is rescinding part of the rule issued on January 18, 2017, National Performance