and 52 of this chapter for regulations related to the imposition of tax.

* * * * *

(e) *Applicability dates*—(1) *Paragraph (a).* Paragraph (a) of this section applies to returns required to be filed under § 40.6011(a)–1 for calendar quarters beginning on or after October 1, 2023. For rules that apply before October 1, 2023, see 26 CFR part 40, revised as of April 1, 2024.

(2) *Paragraphs (b) and (c).* Paragraphs (b) and (c) of this section apply to returns for calendar quarters beginning after March 31, 2013. For rules that apply before March 31, 2013, see 26 CFR part 40, revised as of April 1, 2012.

(3) *Paragraph (d).* Paragraph (d) of this section applies to returns for calendar quarters beginning on or after January 19, 2021. For rules that apply before January 19, 2021, see 26 CFR part 40, revised as of April 1, 2020.

■ **Par. 3.** Section 40.6011(a)-1 is amended by:

■ 1. Revising the first sentence of paragraph (a)(2)(i).

■ 2. Adding paragraphs (d) and (e).

The revision and additions read as follows:

§ 40.6011(a)–1 Returns.

(a) * * *

(2) * * *

(i) * * * Except as provided in paragraphs (b) through (d) of this section, the return must be made for a period of one calendar quarter. * * *

* * * * *

(d) *Tax on the sale of designated drugs.* A return that reports liability imposed by section 5000D of the Internal Revenue Code must be made for a period of one calendar quarter. A return must be filed for each calendar quarter in which liability for the tax imposed by section 5000D is incurred. There is no requirement that a return be filed for a calendar quarter in which there is no liability imposed by section 5000D.

(e) *Applicability dates*—(1) *Paragraph (a)(2)(i).* Paragraph (a)(2)(i) of this section applies to returns filed for calendar quarters beginning on or after October 1, 2023. For rules that apply before October 1, 2023, see 26 CFR part 40, revised as of April 1, 2024.

(2) *Paragraph (c). See* paragraph (c)(2) of this section.

(3) *Paragraph (d).* Paragraph (d) of this section applies to returns filed for calendar quarters beginning on and after October 1, 2023.

■ **Par. 4.** Section 40.6302(c)–1 is amended by:

■ 1. Revising paragraphs (e)(1)(iv) and (v).

■ 2. Adding paragraph (e)(1)(vi).

■ 3. Revising paragraph (f).

The revisions and addition read as follows:

§ 40.6302(c)–1 Deposits.

* * * * *

(e) * * *

(1) * * *

(iv) Sections 4375 and 4376 (relating to fees on health insurance policies and self-insured insurance plans);

(v) Section 5000B (relating to indoor tanning services); and

(vi) Section 5000D (relating to the sale of designated drugs).

* * * * *

(f) *Applicability dates*—(1) *Paragraphs (a) through (d).* Paragraphs (a) through (d) of this section apply to deposits and payments made after March 31, 2013. For rules that apply before March 31, 2013, see 26 CFR part 40, revised as of April 1, 2013.

(2) *Paragraph (e).* Paragraph (e) of this section applies to calendar quarters beginning on or after October 1, 2023. For rules that apply before October 1, 2023, *see* 26 CFR part 40, revised as of April 1, 2024.

■ **Par. 5.** Add part 47 to read as follows:

PART 47—DESIGNATED DRUGS EXCISE TAX REGULATIONS

Sec.

Authority: 26 U.S.C. 7805.

Section 47.5000D–1 also issued under 26 U.S.C. 5000D.

§ 47.5000D–0 Table of contents.

This section lists the table of contents for §§ 47.5000D–1 through 47.5000D–4.

§§ 47.5000D–2—47.5000D–4 [Reserved]

§ 47.5000D–1 Introduction.

(a) *In general.* The regulations in this part are designated the *Designated Drugs Excise Tax Regulations.* The regulations in this part relate to the tax imposed by section 5000D of the Internal Revenue Code. See part 40 of this chapter for regulations relating to returns, payments, and other procedural rules applicable to this part.

(b) *Applicability date.* This section applies to returns filed for calendar quarters beginning on or after October 1, 2023.

§§ 47.5000D–2—47.5000D–4 [Reserved]

Douglas W. O'Donnell,

Deputy Commissioner.

Approved: June 24, 2024.

Aviva R. Aron-Dine,

Acting Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2024–14706 Filed 7–3–24; 8:45 am]

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DEPARTMENT OF JUSTICE

28 CFR Part 15

[Docket No. CIV 150; AG Order No. 5968–2024]

RIN 1105–AB37

Process for Determining That an Individual Shall Not Be Deemed an Employee of the Public Health Service

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: This rule sets forth a process by which the Attorney General or a designee may determine that an individual shall not be deemed an employee of the Public Health Service for purposes of medical malpractice coverage under the Public Health Service Act. The process described in this rule applies to individuals who are deemed to be Public Health Service employees, as well as any other individuals deemed to be Public Health Service employees under different statutory provisions to which the procedures set out in the Public Health Service Act have been made applicable.

DATES: This rule is effective on August 5, 2024.

FOR FURTHER INFORMATION CONTACT: James G. Touhey, Jr., Director, Torts Branch, Civil Division, Department of Justice, Washington, DC 20530, (202) 616–4400.

SUPPLEMENTARY INFORMATION: This rule finalizes, with some changes, a proposed rule that the Department of Justice (''Department'') published on this subject on March 6, 2015, at 80 FR 12104. In brief, the following changes were made to the text of the proposed rule:

In § 15.11, a sentence was added to clarify that an individual who is no longer ''deemed'' to be an employee of the Public Health Service pursuant to section 224(i) of the Public Health Service Act, 42 U.S.C. 233(i), is excluded from medical malpractice protections otherwise available to individuals ''deemed'' to be Public Health Service employees under the

statute that conferred the ''deemed'' employee status.

In § 15.12, the definition of ''Attorney General'' for purposes of the rule was deleted as vague and unnecessary in light of the more specifically defined roles and responsibilities of the initiating official, the adjudicating official, and the administrative law judge involved in proceedings under this subpart.

In § 15.13, a change was made to clarify that the initiating official's notice to an individual is intended to comply with the Administrative Procedure Act (''APA''), 5 U.S.C. 551, *et seq.,* by furnishing a statement of the factual allegations and law asserted in support of the proposed action.

In § 15.14, a change was made to clarify that the administrative law judge assigned to conduct a hearing under this subpart must, consistent with the APA, conduct proceedings in an impartial manner. In addition, § 15.14 now incorporates the grounds and procedure for seeking disqualification of an administrative law judge set forth in 5 U.S.C. 556(b).

In §§ 15.16 and 15.20, a change was made to clarify that the administrative law judge, consistent with the APA, must certify the record to the adjudicating official for a final determination.

A change was made to § 15.17 to clarify that the adjudicating official will consult with the Secretary of Health and Human Services (''Secretary'') in making a final determination. A subsection (d) was added to clarify that the Attorney General, consistent with the traditional authority of agency heads, possesses discretion to review any final determination within 30 days of its issuance.

In addition, minor clarifications were made to § 15.19 to make clear that final determinations, whether upholding or rejecting the initiating official's proposed action, will be distributed to the parties in the same way.

Changes were also made to the reinstatement procedures in § 15.20. Petitions for reinstatement must be submitted to the initiating official, who is responsible for forwarding the petition, along with a recommendation on whether the petition makes a prima facie case for reinstatement, to the adjudicating official. The adjudicating official is responsible for determining whether a prima facie case for reinstatement has been made. If the adjudicating official determines that a prima facie case has been made for reinstatement, an administrative law judge is appointed to conduct such proceedings as are deemed necessary to make a formal recommendation to the adjudicating official. This procedure was revised to avoid having the initiating official—who might be viewed as the adverse party in an original proceeding to de-deem an individual—exercise an unfettered gatekeeping role in determining whether that same individual's petition for reinstatement should receive a hearing.

Finally, the Department notes that since the date of publication of the proposed rule on March 6, 2015, the Supreme Court held in *Lucia* v. *SEC,* 138 S. Ct. 2044 (2018), that administrative law judges assigned by the Securities and Exchange Commission to preside over enforcement proceedings are inferior officers of the United States who must, consistent with Article II, sec. 2, cl. 2 of the United States Constitution, be appointed by the President, a court of law, or a department head. Administrative law judges appointed to preside over proceedings under this rule are to be appointed pursuant to 5 U.S.C. 3105, which authorizes each agency to appoint as many administrative law judges as are necessary for proceedings to be conducted in accordance with 5 U.S.C. 556 and 557. Administrative law judges appointed to preside over proceedings under this rule will be appointed in a manner consistent with *Lucia,* that is, appointed by an agency head.

Discussion

The Federally Supported Health Centers Assistance Acts of 1992 (Pub. L. 102–501) (''FSHCAA'') and 1995 (Pub. L. 104–73) amended section 224 of the Public Health Service Act (42 U.S.C. 233) to make the Federal Tort Claims Act (''FTCA'') (28 U.S.C. 1346(b), 2672) the exclusive remedy for medical malpractice claims for personal injury or death brought against qualifying federally supported health centers and certain statutorily identified categories of individuals, to the extent that the centers and these individuals, as the case may be, have been ''deemed'' by the Department of Health and Human Services to be eligible for FTCA coverage and the conditions for such coverage have been satisfied. 42 U.S.C. 233(g).

In 1996, the Health Insurance Portability and Accountability Act (Pub. L. 104–191) amended section 224 of the Public Health Service Act to provide that, subject to certain conditions, a ''free clinic health professional'' providing ''a qualifying health service'' for the free clinic may be ''deemed'' to be a Public Health Service employee eligible for FTCA coverage to the same extent as persons ''deemed'' to be Public Health Service employees under 42 U.S.C. 233(g). In 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) further amended section 224 of the Public Health Service Act to add ''an officer, governing board member, employee, or contractor of a free clinic . . . in providing services for the free clinic'' to the statutorily identified categories of eligible individuals for this purpose. 42 U.S.C. 233(o)(1).

And in 2016, the 21st Century Cures Act (Pub. L. 114–225) amended section 224 of the Public Health Service Act to provide that, subject to certain conditions, a ''health professional volunteer'' at an entity ''deemed'' to be a Public Health Service employee by virtue of 42 U.S.C. 233(g) may be ''deemed'' to be a Public Health Service employee eligible for FTCA coverage to the same extent as persons ''deemed'' to be Public Health Service employees under 42 U.S.C. 233(g). 42 U.S.C. 233(q).

This rule will apply to any individual ''deemed'' to be a Public Health Service employee, regardless of the statutory provision under which the deemed status is obtained, provided that Congress has made the individual's ''deemed'' Public Health Service employee status subject to the procedures set out in 42 U.S.C. 233(i).

Section 233(i) of title 42 provides that the Attorney General, in consultation with the Secretary, may, on the record, determine, after notice and an opportunity for a full and fair hearing, that an individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of an entity described in 42 U.S.C. 233(g)(4) shall not be deemed to be an employee of the Public Health Service for purposes of 42 U.S.C. 233 if ''treating such individual as such an employee would expose the Government to an unreasonably high degree of risk of loss'' based on one or more of the following enumerated statutory criteria: (1) the individual does not comply with the policies and procedures that the entity has implemented pursuant to 42 U.S.C. 233(h)(1); (2) the individual has a history of claims filed against him or her as provided for under 42 U.S.C. 233 that is outside the norm for licensed or certified health care practitioners within the same specialty; (3) the individual refused to reasonably cooperate with the Attorney General in defending against any such claim; (4) the individual provided false information relevant to the individual's performance of his or her duties to the Secretary, the Attorney General, or an applicant for or recipient

of funds under chapter 6A of title 42; or (5) the individual was the subject of disciplinary action taken by a State medical licensing authority or a State or national professional society. 42 U.S.C. 233(i)(1).

A final determination by the Attorney General under 42 U.S.C. 233(i) that an individual physician or other licensed or certified health care professional shall not be deemed to be an employee of the Public Health Service is effective when the entity employing such individual receives notice of such determination, and the determination applies only to acts or omissions occurring after the date such notice is received. 42 U.S.C. 233(i)(2).

This rule establishes a process for creating the record and providing the full and fair hearing before the Attorney General makes a final determination under 42 U.S.C. 233(i).

The first step, pursuant to § 15.13(a), is a finding by the ''initiating official,'' in consultation with the Secretary, that treating an individual as an employee of the Public Health Service may expose the Government to an unreasonably high degree of risk of loss for one or more of the statutorily enumerated reasons in 42 U.S.C. 233(i). Under § 15.12(d), the initiating official is a Deputy Assistant Attorney General of the Department of Justice's Civil Division or a designee of a Deputy Assistant Attorney General.

Section 15.13(a) requires the initiating official to provide notice to the individual in question that an administrative hearing will be held to determine whether treating the individual as an employee of the Public Health Service would expose the Government to an unreasonably high degree of risk of loss based upon one or more of the statutory criteria enumerated in 42 U.S.C. 233(i). Following a period for discovery and depositions, to the extent determined appropriate by an administrative law judge under § 15.15, the hearing is then conducted by the administrative law judge in the manner prescribed in § 15.14. After the hearing is conducted and the record is closed, § 15.16 requires the administrative law judge to certify the record and submit written findings of fact, conclusions of law, and a recommended decision to the ''adjudicating official,'' who is the Assistant Attorney General for the Department of Justice's Civil Division or a designee of the Assistant Attorney General. Section 15.16 provides that copies of the findings of fact, conclusions of law, and recommended decision are made available to the parties and to the Secretary. Section 15.17(b) then gives the parties 30 days to submit certain additional materials, including exceptions to the administrative law judge's recommended decision, to the adjudicating official, who then must, in consultation with the Secretary, make a final determination whether treating the individual as an employee of the Public Health Service for purposes of 42 U.S.C. 233 would expose the Government to an unreasonably high degree of risk of loss based on one or more of the criteria specified in 42 U.S.C. 233(i). The Attorney General may exercise discretion to review any final determination within 30 days of its issuance.

Section 15.18 provides that an individual who is dissatisfied with the final determination may seek rehearing within 30 days after notice of the determination is sent, and § 15.20 allows individuals who have been determined to expose the United States to an unreasonably high degree of risk of loss to apply for reinstatement after a period of time. Consistent with 42 U.S.C. 1320a-7e(a) and 45 CFR 60.3, 60.5(h) and 60.16, the rule also provides that the Department will notify the National Practitioner Data Bank (''NPDB'') of the issuance of the Attorney General's final determination that an individual provider shall not be deemed to be an employee of the Public Health Service under this rule. The NPDB, which is maintained by the Health Resources and Services Administration within the Department of Health and Human Services, is a confidential information clearinghouse created by Congress with primary goals of improving health care quality and protecting the public.

Discussion of Comments

The Department received ten public comments on the proposed rule during the comment period, which closed on May 6, 2015. Several commenters generally supported the proposed rule as providing adequate notice and process to reach fair decisions on whether to de-deem individual practitioners who pose an unreasonably high degree of risk of loss to the Government. The Department is grateful for the feedback.

Several comments were received from membership organizations of federally supported health centers that receive Federal grant money under 42 U.S.C. 254b, as well as one federally supported health center that offered comments on its own behalf. These comments generally sought additional guidance on how the rules and criteria set forth in 42 U.S.C. 233(i)(1) would be applied. A few other commenters expressed more general concerns about the consequences of de-deeming determinations. Summaries of these comments and the Department's responses to them are set forth below.

1. Some commenters requested that the Department provide additional guidance on how the statutory criteria for determining whether treating an individual physician or certified health care provider as a Public Health Service employee exposes the Government to an ''unreasonably high degree of risk of loss'' will be applied. These commenters requested that clearer definitions be adopted and that specific examples be provided for how each of the criteria set forth in 42 U.S.C. 233(i)(A)–(E) will be weighed and considered.

Response: The Department does not adopt the changes suggested in these comments. The purpose of these regulations is procedural: to establish the process and procedures used to create a record and provide an individual medical provider the opportunity for the ''full and fair hearing'' required by section 233(i)(1) before the Attorney General makes a ''final determination'' that an individual ''shall not be deemed to be'' an employee of the Public Health Service for purposes of 42 U.S.C. 233. The Department is not undertaking, at this time, a regulatory effort to interpret or re-interpret the statutory criteria that Congress established more than 20 years ago to govern such determinations.

Section 233(i) requires a full and fair hearing to determine whether any one of these factors or combination of factors supports a determination that treating an individual physician or certified health care provider as a Public Health Service employee poses an ''unreasonably high degree of risk of loss'' to the Government.

The commenters recognized that ''strict definitions'' for these criteria would be impracticable. The Department agrees with the commenters. In addition to the impracticality of adopting strict definitions, the Department also observes that the application of the criteria set forth in the statute will necessarily depend on the specific facts and circumstances of each individual case.

2. Some commenters requested that the Department expand the scope of the regulations to specify the form and substance of the consultation that the Attorney General undertakes with the Secretary before finding that an individual should be provided notice of a hearing to determine whether treating

that individual as an employee of the Public Health Service poses an unreasonable risk of loss to the Government.

Response: The Department does not adopt the change suggested in these comments. The statute does not require that the Department's regulations specify the form and substance of the Attorney General's consultation with the Secretary. Moreover, a requirement for public disclosure of such consultations would not be warranted given the predecisional, deliberative nature of the consultation process between agencies.

3. Some commenters requested that the Department, when notifying an individual that a proceeding has been initiated under 42 U.S.C. 233(i), be required to provide both the specific information upon which the Department will rely and the standards that will apply for evaluating the criteria set forth in 42 U.S.C. 233(i). The commenters suggested that providing such information in the hearing notice would reduce discovery costs and increase efficiency of the hearing process.

Response: In response to these comments, the Department has added language in § 15.13(c) to clarify that the notice provided to individuals will set forth the factual allegations supporting the initiating official's proposed action, consistent with the requirements for notice under 5 U.S.C. 554(b). Thus, in addition to providing a statement of the nature and purpose of the hearing, the name of the administrative law judge who will preside, a statement of the nature of the action proposed to be taken, and a statement of the time, date, and location of the hearing for the individual to be heard, the notice will also provide a statement of the facts and, where appropriate, the law asserted in support of the proposed action. 28 CFR 15.13(c). The administrative law judge is vested with all powers necessary to reduce discovery costs and increase the efficiency of the process through exchanges of information and narrowing of issues. 28 CFR 15.14–.15. As for the further comment requesting additional information about the standards that will apply for evaluating the criteria set forth in 42 U.S.C. 233(i), the Department does not adopt the change requested in this comment for the reasons already expressed above.

4. One commenter requested that the Department state the period of time after which a de-deemed practitioner may apply for reinstatement.

Response: The final rule provides that a de-deemed practitioner may apply for reinstatement not sooner than five years after the time for seeking rehearing of the initial determination to de-deem a practitioner has expired. 28 CFR 15.20(a).

5. One commenter requested that the Department clarify the events and informational exchanges that will or could set into the motion the de-deeming process.

Response: The statute and final rule provide this information. When the Department's initiating official, in consultation with the Secretary, finds, based upon a review of available information, that treating an individual as an employee of the Public Health Service may expose the Government to an unreasonably high degree of risk of loss based on one or more of the criteria enumerated in 42 U.S.C. 233(i), the de-deeming process is initiated by issuing a notice for an administrative hearing to determine whether that individual should be de-deemed. 42 U.S.C. 233(i)(1); 28 CFR 15.13. The notice will set forth the facts, and where applicable, the law upon which the proposed action is based.

6. A few commenters expressed concern that the de-deeming process could be initiated to rescind FTCA coverage while a lawsuit was pending and requested that the rule allow only for prospective de-deeming. Another commenter suggested adoption of a ''safety period''—a designated period of time during which a ''deemed'' employee cannot be subject to ''de-deeming''—that would apply where litigation is anticipated involving acts or omissions of a practitioner who has been deemed to be an employee of the Public Health Service.

Response: The Department agrees that de-deeming should be prospective only (as the statute requires) but does not adopt the ''safety period'' suggestion. The statute provides that the Attorney General's decision to de-deem an individual shall apply only to acts or omissions occurring after the date that notice of the Attorney General's final determination that an individual not be deemed to be a Public Health Service employee is received. 42 U.S.C. 233(i)(2). The final regulations therefore provide in § 15.19(c) that a final agency determination that an individual provider shall not be deemed to be an employee of the Public Health Service shall apply to all acts or omissions of the individual occurring after the date the adverse final determination is received by the relevant entity or free clinic. The final regulations similarly provide in § 15.20(f) that a determination that an individual is reinstated pursuant to this section . . . shall apply only to acts or omissions of the individual occurring after the date of the final reinstatement determination. There is no need to adopt the suggested ''safety period.'' If a lawsuit is pending, or even anticipated, then the acts or omissions giving rise to that pending or anticipated suit will already have occurred. The Attorney General's ''de-deeming'' determination does not apply to acts or omissions that occurred before the de-deeming determination becomes final, and reinstatement determinations similarly apply only to acts or omissions that occur after reinstatement.

7. One commenter expressed concern that the proposed rule might have untoward consequences, such as difficulty in securing quality replacement personnel or loss of liability coverage while a lawsuit is pending.

Response: The Department does not adopt further changes in response to these comments. There should be no loss of liability coverage while a lawsuit is pending, as the Attorney General's final determination that a practitioner is de-deemed is effective only as to acts or omissions that occur after such a determination is received by the entity employing that practitioner. 42 U.S.C. 233(i)(2). Moreover, a final de-deeming determination is applicable only to the individual who was subject to the hearing and final determination.

The Attorney General's de-deeming determination does not require or compel a health center to terminate a practitioner. Entities may choose to employ ''de-deemed'' practitioners, but they can no longer rely on the protections of 42 U.S.C. 233(g) or similar statutes, as the case may be, as a substitute for medical malpractice liability coverage for that practitioner if that practitioner is subject to a medical malpractice claim for acts or omissions occurring after receipt of a final de-deeming determination, for so long as the final determination remains effective. Congress's decision to authorize the Attorney General to de-deem individual practitioners reflects a policy judgment that, if an individual practitioner exposes the Government to an unreasonably high degree of risk of loss based on any of the statutory criteria enumerated in 42 U.S.C. 233(i), insuring against that risk or finding a suitable replacement should fall upon the entity responsible for hiring and retaining the practitioners or the sponsoring free clinic, not the United States. Qualifying health centers that receive Federal grants pursuant to 42 U.S.C. 254b may purchase ''tail,'' ''gap,'' or ''wrap-around'' insurance to cover claims for which liability protections under 42 U.S.C. 233(g) or similar

statutes, as the case may be, are inapplicable.

8. One commenter expressed concern that final determinations are vested in the Attorney General or the Attorney General's designee and suggested that the recommendations of the presiding administrative law judge be binding or that three-judge panels be established for purposes of making final determinations.

Response: The Department does not adopt the changes requested in this comment. Under 42 U.S.C. 233(i), the ''final determination'' on whether to de-deem an individual ''under this subsection'' is vested in the ''Attorney General.'' The Department is not free to re-write the statute. Moreover, because section 233(i) provides that the Attorney General's final determination shall be made ''on the record'' ''after notice and an opportunity for a full and fair hearing,'' the provisions of sections 554, 556, and 557 of the APA are applicable to these hearings. *See* 5 U.S.C. 554(a), (c)(2) (section 554 applies ''in every case of adjudication required by statute to be determined on the record after opportunity for an agency hearing''; such hearings and decisions on contested issues are to be conducted ''in accordance with sections 556 and 557''). This rule provides for a hearing and recommended decision by an administrative law judge and a final determination by the agency, consistent with the foregoing provisions of the APA. Any review of the Attorney General's ''final determination'' is governed by the APA, so further review of that final determination by an Article III court is possible. The Department also declines to render the presiding administrative law judge's decision binding. Providing for a recommended decision that is further reviewed by the adjudicating official, with discretionary review by the Attorney General, adds further layers of review and therefore reduces the risk of an erroneous determination.

Regulatory Flexibility Act

The Attorney General, in accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), has reviewed this final rule and, by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities because it pertains to personnel and administrative matters affecting the Department. This rule merely sets forth the process for a hearing used to determine whether certain individual health care providers should no longer be ''deemed'' to be ''employees of the Public Health Service,'' thus excluding such individual health care providers from eligibility for the medical malpractice liability protections under 42 U.S.C. 233(g), (o), or (q). The rule does not adopt substantive standards and therefore will not have a significant impact on regulated parties.

Executive Orders 12866, 13563, and 14094: Regulatory Planning and Review

This final rule has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review,'' Executive Order 13563, ''Improving Regulation and Regulatory Review,'' and Executive Order 14094, ''Modernizing Regulatory Review.'' The Office of Management and Budget has determined that this final rule is a ''significant regulatory action'' under Executive Order 12866, section 3(f), and accordingly this final rule has been reviewed by the Office of Management and Budget. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

The Department has assessed the costs and benefits of this final rule and believes that its benefits justify its costs.

As an initial matter, this final rule only establishes a process for removing a statutorily conferred deemed status applicable to an individual provider who is determined to expose the Government to an unreasonably high degree of risk of loss for one or more statutorily enumerated reasons. As further explained below, Congress expressly granted the Attorney General the authority to de-deem certain individual physicians or other licensed or certified health care practitioners, provided that certain procedural safeguards were in place. This rule establishes those safeguards. The process will impose some costs on both the government and the individuals who are subject to proceedings under 42 U.S.C. 233(i). But the net benefit is to reduce the potential for incorrect de-deeming decisions, to ensure that a de-deeming decision is based upon a developed record, and to provide the individual provider an opportunity to participate in the process. On balance, the Department believes these benefits outweigh the costs and will contribute to just decisions.

Congress expressly provided the Attorney General with the authority to exclude individuals who expose the Government to an unreasonably high degree of risk of loss based upon one or more statutory criteria from the malpractice protections afforded under 42 U.S.C. 233(g) and similar statutes. A statutory provision granting the Attorney General authority to exclude an individual provider has existed since the FSHCAA was first enacted in 1992. This provision was specifically designed to ''assure that FTCA coverage is not extended to individual practitioners that do not provide care of acceptable quality'' when the Attorney General determines that such individuals ''expose the U.S. to an unreasonably high degree of risk of loss.'' H.R. Rep. No. 102–823, pt. 2, at 8 (1992).

When the FSHCAA was amended and extended in 1995, Congress continued to include the provision authorizing the Attorney General to exclude an individual provider, adding language to clarify that an individual provider's ''coverage'' under the FSHCAA would be removed only after receiving notice and an opportunity for a full and fair hearing, with all decisions to be made ''on the record.'' H.R. Rep. No. 104–398, at 13 (1995); Public Law 104–73, sec. 9, 109 Stat. 777, 781 (1995).

In light of the foregoing, this final rule assures the procedural protections Congress intended, without altering Congress's objective that certain individual providers be subject to exclusion from the malpractice liability protections under 42 U.S.C. 233 if they expose the Government to an unreasonably high degree of risk of loss based on the enumerated statutory criteria. Congress already has established that the benefits of excluding certain providers outweigh the costs if procedural protections are afforded and the final decision is supported by one or more of the criteria specified in 42 U.S.C. 233(i).

The Department does not expect that the process created by the final rule will have systemic or large-scale costs because it is only the rare individual provider who would be subject to the procedures under this rule based on the statutory criteria of 42 U.S.C. 233(i); proceedings against an individual provider under this rule are expected to be infrequent and will, therefore, affect only a small fraction of providers, health centers, or, potentially, their patients.

The majority of costs associated with the final rule, then, would come in the individual instances of its application, which are not feasible to predict. The

administrative process will impose some defense costs on the particular individual who is the subject of the hearing, but §§ 15.14 and 15.15 provide flexibility that may enable the parties and administrative law judges to avoid unduly burdensome costs when those costs are unnecessary.

While it is not feasible to estimate these costs with precision, the Department notes that the litigation costs incurred in defending medical malpractice suits in court frequently exceed $100,000 per case. The potential costs associated with a section 233(i) proceeding, by contrast, are expected to be a small fraction of the cost of litigating malpractice actions brought against individual providers. If even one provider is excluded from malpractice protections under 42 U.S.C. 233(g) or similar statutes, potentially resulting in at least one fewer malpractice action that the United States otherwise might have been required to defend, the potential cost savings to the United States will be tens of thousands of dollars on litigation expenses alone.

The Department also observes that losses in covered medical malpractice actions against deemed centers and their personnel are borne by the public fisc through the payment of judgments and settlements and other expenses. Each year, the Department transmits to the Secretary and Congress an estimate of the dollar amount of claims and litigation for which payments are expected to be made during the upcoming fiscal year, along with related fees and expenses. Although in 1996, it was estimated that only 14,234 individual providers were deemed to be Public Health Service employees for purposes of malpractice claims, that number has steadily risen, reaching in excess of 250,000 ''deemed'' providers as of April 2022.

In addition to the increasing numbers of providers eligible for malpractice protections under 42 U.S.C. 233(g) and similar statutes, the amount of money paid by the United States as a result of judgments and settlements and litigation expenses has steadily increased as well. Since fiscal year 2014, the average annual amount sought by claimants in malpractice losses against deemed providers has been approximately $35 billion. To be sure, the United States pays substantially less than the amount claimed in the majority of cases, but it still paid in excess of $100 million in fiscal years 2017, 2018, and 2019, respectively, including a then-record amount of $135,047,091 in 2019 alone. Fiscal years 2020 and 2021 saw a slight downturn in the number of claims paid, likely the result of delays in court proceedings during the COVID–19 pandemic and related restrictions. In fiscal year 2022, with restrictions largely lifted, the United States paid $158,338,182.79 in judgments and settlements, a new record amount.

Neither the criteria set forth in 42 U.S.C. 233(i) nor the final rule contemplates that an individual provider subjects the Government to an unreasonably high degree of risk of loss merely by subjecting the United States to suit on malpractice claims that result in losses. That is a potential basis for de-deeming only to the extent that a single provider's care has resulted in claims outside the norm for a licensed or certified practitioner in the same specialty. If a single provider, for example, exposed the United States to several meritorious claims, each costing the United States $1 million, and that provider's history of claims was outside the norm for a practitioner in the same specialty, then excluding that provider from the malpractice liability protections of 42 U.S.C. 233(g) or another statute, as the case may be, may result in substantial savings to the United States in the future. That is because de-deeming the provider will reduce the number of claims and the amount of losses the United States would otherwise have incurred as a result of that provider's care and treatment.

The Department further notes that, unlike with actual Federal employees, over whom Federal agencies exercise plenary control and have various means of addressing risk through disciplinary action or termination, individual providers deemed to be Public Health Service employees for purposes of covered malpractice claims remain under the exclusive control and supervision of the public or non-profit private entity that employs them. The Government has no role in the day-to-day operations of health centers or free clinics and no involvement in the employment or disciplinary decisions of such entities.

The Attorney General's authority to exclude an individual provider who poses an unreasonably high degree of risk of loss through a section 233(i) proceeding provides the United States some small measure of risk control. Moreover, the authority granted to the Attorney General under section 233(i) is, in practice, no different from the authority that a private insurance carrier could exercise to refuse to insure an individual provider who poses an unreasonably high degree of risk of loss. A section 233(i) proceeding to exclude an individual provider from coverage under 42 U.S.C. 233(g) or similar statutes, if it is determined that the individual provider poses an unreasonably high degree or risk of loss, is similar to the ability that a private insurer possesses to exclude from coverage individual providers for the same reasons.

In the event that treating an individual provider as a Public Health Service employee is ultimately determined to expose the United States to an unreasonably high degree of risk of loss, the Department acknowledges that there will be certain costs to that provider. An individual provider who is no longer deemed to be an employee of the Public Health Service for purposes of malpractice claims may, for example, be required to obtain personal medical malpractice insurance to continue practicing. The provider may also experience negative employment consequences as a result of the Attorney General's determination.

For several reasons, it is not feasible to estimate the costs to specific, individual providers of having to procure malpractice insurance in lieu of relying on deemed Public Health Service employee status for malpractice protection. Malpractice insurance rates vary greatly depending on factors like specialty and location, insurance provider, loss history, coverage requirements, policy limits, and policy type.[1] Even within States, coverage costs can vary from county to county depending on factors like population density and the density of the physician population in a given area.

For example, State-filed malpractice premiums, before applied insurer discounts, average between roughly $2,486 and $15,949 in Nebraska, but between roughly $10,560 and $161,942 in New York, with higher premiums for higher-risk specialties.[2] Compared to the average *loss* to the United States in malpractice actions brought under 42 U.S.C. 233(g) and related statutes, which in the first half of fiscal year 2022 averaged $1,064,767 per claim paid, the net benefit to the United States of excluding an individual provider who poses an unreasonably high degree of risk of loss to the United States justifies

[1] *See* Gallagher Healthcare, *How Much Does Medical Malpractice Insurance Cost?* (March 19, 2020), *https://www.gallaghermalpractice.com/blog/post/how-much-does-medical-malpractice-insurance-cost.*

[2] *Compare* Gallagher Health Care, *Nebraska Medical Malpractice Insurance, https://www.gallaghermalpractice.com/state-resources/nebraska-medical-malpractice-insurance* (last visited January 26, 2024), *with New York Medical Malpractice Insurance, www.gallaghermalpractice.com/state-resources/new-york-medical-malpractice-insurance* (last visited January 26, 2024).

the potential costs to that provider of procuring personal insurance.

The Department further observes that, while premiums may vary by location or specialty, an individual provider subject to a proceeding governed by this rule could come from any location or specialty; the only factor common to a provider subject to a proceeding under this rule will be a threshold finding, triggering the process under this rule, that the provider may expose the United States to an unreasonably high degree of risk of loss. Any provider who is excluded from coverage by a final determination made under 42 U.S.C. 233(i) would merely be placed in the position that provider would have occupied but for the existence of these statutes—that of a provider who must procure personal insurance. If a provider turns out to be uninsurable in the private insurance market, that provider's inability to procure insurance merely underscores that the provider poses an unreasonably high degree of risk of loss. Congress conferred upon the Attorney General the authority to de-deem certain individuals in order to protect against such an unreasonably high risk of loss. 42 U.S.C. 233(i); H.R. Rep. No. 102–823, pt. 2, at 8 (1992).

The Department acknowledges as well that if an individual provider is no longer deemed to be an employee of the Public Health Service and leaves the practice, the health center or free clinic may incur costs to find a new provider. Replacing providers, however, may occur even absent this final rule establishing a process for de-deeming individual providers, and the costs to entities of filling positions may not be readily traceable to the process established by this final rule.

In any event, the Department expects that substantial benefits will justify any costs incurred in finding replacements, as any individual who is replaced after being excluded from coverage following a proceeding under this rule will be one who has been determined to create an unreasonably high degree of risk of loss on claims for malpractice. It is anticipated that, in the usual case, the individual's replacement will provide reduced risk of loss for the United States and better care for patients. While there may be instances in which an individual who presented such a risk of loss cannot be replaced, the Department believes that these costs are justified by the benefits of implementing this rule to carry out Congress's stated objectives. Congress enacted 42 U.S.C. 233(i) ''to assure that FTCA coverage is not extended to individual practitioners that do not provide care of acceptable quality'' by providing a process whereby the Attorney General may exclude individuals based on a determination that such individuals ''expose the U.S. to an unreasonably high degree of risk of loss.'' H.R. Rep. No. 102–823, pt. 2, at 8 (1992). Implementing the process for section 233(i) proceedings through this final rule is a procedural step toward effectuating Congress's purpose in enacting section 233(i).

Based on the expectation that the process will be used sparingly and only for an individual provider who exposes the United States to an unreasonably high degree of risk of loss on medical malpractice claims for personal injury or death, the Department has concluded that the net benefits of improved patient care and reduced losses to the United States traceable to malpractice claims justify the potential costs of implementing a process to carry out 42 U.S.C. 233(i).

Executive Order 13132: Federalism

This final rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, the Department of Justice has determined that this final rule will not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Executive Order 12988: Civil Justice Reform

This final rule meets the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988.

Unfunded Mandates Reform Act of 1995

This final 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, and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

Small Business Regulatory Enforcement Fairness Act of 1996

This final rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 804. This final rule will not result in an annual effect on the economy of $100 million or more; a major increase in cost or prices; significant adverse effects on competition, employment, investment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

List of Subjects in 28 CFR Part 15

Claims, Government contracts, Government employees, Health care, Immunization, Nuclear energy.

For the reasons set forth in the preamble, the Attorney General amends part 15 of title 28 of the Code of Federal Regulations as follows:

PART 15—CERTIFICATIONS, DECERTIFICATIONS, AND NON-DEEMING DETERMINATIONS FOR PURPOSES OF THE FEDERAL TORT CLAIMS ACT

■ 1. The authority citation for part 15 is revised to read as follows:

Authority: 5 U.S.C. 301, 554, 556, 557, and 8477(e)(4); 10 U.S.C. 1054, 1089; 22 U.S.C. 2702, 28 U.S.C. 509, 510, and 2679; 38 U.S.C. 7316; 42 U.S.C. 233, 2212, 2458a, and 5055(f); and sec. 2, Pub. L. 94–380, 90 Stat. 1113 (1976).

■ 2. The heading for part 15 is revised to read as set forth above.

■ 3. Designate §§ 15.1 through 15.4 as subpart A under the following heading:

Subpart A—Certification and Decertification in Connection With Certain Suits Based Upon Acts or Omissions of Federal Employees and Other Persons

§§ 15.5 through 15.10 [Reserved]

■ 4. Add reserved §§ 15.5 through 15.10 to newly designated subpart A.

■ 5. Add subpart B to read as follows:

Subpart B—Determination of Individuals Deemed Not To Be Employees of the Public Health Service

Sec.

Subpart B—Determination of Individuals Deemed Not To Be Employees of the Public Health Service

§ 15.11 Purpose.

(a) The purpose of this subpart is to implement the notice and hearing

procedures applicable to a determination by the Attorney General or the Attorney General's designee under 42 U.S.C. 233(i) that an individual health care provider shall not be deemed an employee of the Public Health Service for purposes of 42 U.S.C. 233(g) or any other statute that confers deemed Public Health Service employee status to which 42 U.S.C. 233(i) has been made applicable. Under 42 U.S.C. 233(i), an individual health care provider who is no longer deemed to be an employee of the Public Health Service is excluded from any malpractice protections otherwise made statutorily available to individuals deemed to be Public Health Service employees.

(b) Section 233(i) of title 42 provides that the Attorney General, in consultation with the Secretary of Health and Human Services, may on the record determine, after notice and an opportunity for a full and fair hearing, that an individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of an entity described in 42 U.S.C. 233(g)(4) shall not be deemed to be an employee of the Public Health Service for purposes of 42 U.S.C. 233 if treating such individual as such an employee would expose the Government to an unreasonably high degree of risk of loss.

§ 15.12 Definitions.

As used in this subpart:

Adjudicating official means the Assistant Attorney General for the Civil Division of the Department of Justice or a designee of the Assistant Attorney General.

Entity means an entity described in 42 U.S.C. 233(g)(4).

Individual means an individual physician or other licensed or certified health care practitioner who is or was an officer, employee, or contractor of an entity described in 42 U.S.C. 233(g)(4); a health professional, officer, employee, or contractor of a free clinic as described in 42 U.S.C. 233(o); or a health professional volunteer as described in 42 U.S.C. 233(q).

Initiating official means a Deputy Assistant Attorney General of the Civil Division of the Department of Justice or a designee of a Deputy Assistant Attorney General.

Parties means an individual, as defined in paragraph (c) of this section, and the initiating official, as defined in paragraph (d) of this section.

Public Health Service means the Public Health Service or an operating division or component of the Public Health Service.

Secretary means the Secretary of Health and Human Services or the Secretary's designee.

Unreasonably high degree of risk of loss is a determination based on consideration of one or more of the following statutory criteria—

(1) The individual does not comply with the policies and procedures that the entity or the sponsoring free clinic has implemented pursuant to 42 U.S.C. 233(h)(1);

(2) The individual has a history of claims filed against him or her as provided for under 42 U.S.C. 233 that is outside the norm for licensed or certified health care practitioners within the same specialty;

(3) The individual refused to reasonably cooperate with the Attorney General in defending against any such claim;

(4) The individual provided false information relevant to the individual's performance of his or her duties to the Secretary, the Attorney General, or an applicant for or recipient of funds under title 42, chapter 6A, United States Code; or

(5) The individual was the subject of disciplinary action taken by a State medical licensing authority or a State or national professional society.

§ 15.13 Notice of hearing.

(a) Whenever the initiating official, in consultation with the Secretary, finds, based upon available information gathered or provided, that treating an individual as an employee of the Public Health Service may expose the Government to an unreasonably high degree of risk of loss, the initiating official shall notify the individual that an administrative hearing will be conducted for the purpose of determining whether treating the individual as an employee of the Public Health Service for purposes of 42 U.S.C. 233 would expose the United States to an unreasonably high degree of risk of loss.

(b) The notice of hearing shall be in writing and shall be sent by registered or certified mail to the individual at the individual's last known address, or to the individual's attorney in the event the Attorney General has received written notice that the individual has retained counsel.

(c) The notice shall contain:

(1) A statement of the nature and purpose of the hearing;

(2) The factual allegations and, where appropriate, the law asserted in support of the proposed action;

(3) The name of the administrative law judge;

(4) A statement of the nature of the action proposed to be taken; and

(5) A statement of the time, date, and location of the hearing.

(d) The hearing shall be initiated not sooner than 60 days of the date on the written notice of hearing.

§ 15.14 Conduct of hearing.

(a) An administrative law judge appointed in accordance with 5 U.S.C. 3105 shall preside over the hearing.

(b) Pursuant to 5 U.S.C. 556(b), the administrative law judge is to conduct all proceedings in an impartial manner. The administrative law judge may disqualify himself at any time. An individual may move to disqualify the appointed administrative law judge only upon the filing, in good faith, of a timely and sufficient affidavit of personal bias or other ground for disqualification of the administrative law judge, such as conflict of interest or financial interest. If such affidavit is timely filed, the adjudicating official shall determine the matter as part of the record and final determination in the case.

(c) The administrative law judge shall have the following powers:

(1) Administer oaths and affirmations;

(2) Issue subpoenas authorized by law;

(3) Rule on offers of proof and receive relevant evidence;

(4) Take depositions or have depositions taken when the ends of justice would be served;

(5) Regulate the course of the hearing;

(6) Hold conferences for the settlement or simplification of the issues by consent of the parties or by the use of alternative means of dispute resolution;

(7) Inform the parties as to the availability of one or more alternative means of dispute resolution, and encourage use of such methods;

(8) Dispose of procedural requests or similar matters;

(9) Make or recommend decisions;

(10) Require and, in the discretion of the administrative law judge, adopt proposed findings of fact, conclusions of law, and orders;

(11) Take any other action that administrative law judges are authorized by statute to take; and

(12) All powers and duties reasonably necessary to perform the functions enumerated in paragraphs (c)(1) through (11) of this section.

(d) The administrative law judge may call upon the parties to consider:

(1) Simplification or clarification of the issues;

(2) Stipulations, admissions, agreements on documents, or other understandings that will expedite conduct of the hearing;

(3) Limitation of the number of witnesses and of cumulative evidence; and

(4) Such other matters as may aid in the disposition of the case.

(e) At the discretion of the administrative law judge, parties or witnesses may participate in hearings by video conference.

(f) All hearings under this subpart shall be public unless otherwise ordered by the administrative law judge.

(g) The hearing shall be conducted in conformity with 5 U.S.C. 554–557 (sections 5–8 of the Administrative Procedure Act).

(h) The initiating official shall have the burden of going forward with the evidence and shall generally present the Government's evidence first.

(i) Technical rules of evidence shall not apply to hearings conducted pursuant to this subpart, but rules designed to assure production of the most credible evidence available and to subject testimony to cross-examination shall be applied where reasonably necessary by the administrative law judge. The administrative law judge may exclude irrelevant, immaterial, or unduly repetitious evidence. All documents and other evidence offered or taken for the record shall be open to examination by the parties, and opportunity shall be given to refute facts and arguments advanced on either side of the issues. A transcript shall be made of the oral evidence except to the extent the substance thereof is stipulated for the record.

(j) During the time a proceeding is pending before an administrative law judge, all motions shall be addressed to the administrative law judge and, if within the administrative law judge's delegated authority, shall be ruled upon. Any motion upon which the administrative law judge has no authority to rule shall be certified to the adjudicating official with a recommendation. The opposing party may answer within such time as may be designated by the administrative law judge. The administrative law judge may permit further replies by both parties.

§ 15.15 Discovery.

(a) At any time after the initiation of the proceeding, the administrative law judge may order, by subpoena if necessary, the taking of a deposition and the production of relevant documents by the deponent. Such order may be entered upon a showing that the deposition is necessary for discovery purposes and that such discovery could not be accomplished by voluntary methods. Such an order may also be entered in extraordinary circumstances to preserve relevant evidence upon a showing that there is substantial reason to believe that such evidence could not be presented through a witness at the hearing. The decisive factors for a determination under this subsection, however, shall be fairness to all parties and the requirements of due process. A deposition may be taken orally or upon written questions before any person who has the power to administer oaths and shall not exceed one day of seven hours.

(b) Each deponent shall be duly sworn, and any adverse party shall have the right to cross-examine. Objections to questions or documents shall be in short form, stating the grounds upon which objections are made. The questions propounded and the answers thereto, together with all objections made (but not including argument or debate), shall be reduced to writing and certified by the person before whom the deposition was taken. Thereafter, the person taking the deposition shall forward the deposition and one copy thereof to the party at whose instance the deposition was taken and shall forward one copy to the representative of the other party.

(c) A deposition may be admitted into evidence as against any party who was present or represented at the taking of the deposition, or who had due notice thereof, if the administrative law judge finds that there are sufficient reasons for admission and that the admission of the evidence would be fair to all parties and comport with the requirements of due process.

§ 15.16 Recommended decision.

Within a reasonable time after the close of the record of the hearings conducted under § 15.14, the administrative law judge shall certify the record to the adjudicating official and shall submit to the adjudicating official written findings of fact, conclusions of law, and a recommended decision. The administrative law judge shall promptly make copies of the findings of fact, conclusions of law, and recommended decision available to the parties and the Secretary.

§ 15.17 Final determination.

(a) In hearings conducted under § 15.14, the adjudicating official shall, subject to subsection (d), make the final determination on the basis of the certified record, findings, conclusions, and recommendations presented by the administrative law judge.

(b) Prior to making a final determination, the adjudicating official shall give the parties an opportunity to submit the following, within thirty days after the submission of the administrative law judge's recommendations:

(1) Proposed findings and determinations;

(2) Exceptions to the recommendations of the administrative law judge;

(3) Supporting reasons for the exceptions or proposed findings or determinations; and

(4) Final briefs summarizing the arguments presented at the hearing.

(c) The adjudicating official shall, within a reasonable time after receiving the parties' submissions, consult with the Secretary and then make a final determination. Copies of the final determination shall be served upon each party to the proceeding. Subject to paragraph (d) of this section, the final determination made by the adjudicating official under this rule shall constitute the final agency action.

(d) Within 30 days of any final determination made by the adjudicating official, the Attorney General may exercise discretion to review the final determination. In the event the Attorney General exercises discretion to review a decision, the Attorney General's final determination shall constitute the final agency action.

§ 15.18 Rehearing.

(a) An individual dissatisfied with a final determination under § 15.17 may, within 30 days after the notice of the final determination is sent, request the adjudicating official to re-review the record.

(b) The adjudicating official may require that another oral hearing be held on one or more of the issues in controversy, or permit the dissatisfied party to present further evidence or argument in writing, if the adjudicating official finds that the individual has:

(1) Presented evidence or argument that is sufficiently significant to require the conduct of further proceedings; or

(2) Shown some defect in the conduct of the adjudication under this subpart sufficient to cause substantial unfairness or an erroneous finding in that adjudication.

(c) Any rehearing ordered by the adjudicating official shall be conducted pursuant to § § 15.14 through 15.16.

§ 15.19 Effective date of a final determination.

(a) A final determination under § 15.17 shall be provided to the Department of Health and Human Services and sent by certified or registered mail to the individual and to the entity employing or sponsoring such individual if the individual is currently

an officer, employee, contractor, or health professional volunteer of an entity described in 42 U.S.C. 233(g)(4) or a health professional, officer, employee, or contractor of a free clinic described in 42 U.S.C. 233(o). In the event the individual is no longer an officer, employee, contractor, or health professional volunteer of an entity described in 42 U.S.C. 233(g)(4), or a health professional, officer, employee, or contractor of a free clinic described in 42 U.S.C. 233(o), the determination shall be sent by certified or registered mail to the individual and to the last entity described in 42 U.S.C. 233(g)(4) or free clinic described in 42 U.S.C. 233(o) at which such individual was an officer, employee, contractor, health professional volunteer, or health professional.

(b) A final determination shall be effective upon the date the written determination is received by such entity or free clinic.

(c) A final determination that an individual provider shall not be deemed to be an employee of the Public Health Service shall apply to all acts or omissions of the individual occurring after the date the adverse final determination is received by such entity or free clinic.

(d) The Attorney General will inform the National Practitioner Data Bank of any final determination under § 15.17 that an individual shall not be deemed to be an employee of the Public Health Service for purposes of 42 U.S.C. 233.

§ 15.20 Reinstatement.

(a) Not sooner than five years after the time for rehearing has expired, and no more often than once every five years thereafter, an individual who has been the subject of a final determination under § 15.17 may petition the initiating official for reconsideration of that determination and for reinstatement. The individual bears the burden of proof and persuasion.

(b) In support of the petition for reinstatement, the individual shall submit relevant evidence relating to the period since the original proceedings under this subpart and a statement demonstrating and explaining why treating the individual as an employee of the Public Health Service for purposes of 42 U.S.C. 233 would no longer expose the United States to an unreasonably high degree of risk of loss.

(c) Upon receiving a petition for reinstatement, the initiating official shall forward the petition, together with an evaluation and recommendation on whether the petition makes a prima facie case for reinstatement, to the adjudicating official. The adjudicating official shall determine, in the adjudicating official's discretion, whether the petition makes a prima facie case that the individual provider no longer would expose the United States to an unreasonably high degree of risk of loss. The adjudicating official's determination that a petition does not make a prima facie case for reinstatement is not subject to further review.

(d) If the adjudicating official determines that a prima facie case has been made for reinstatement, an administrative law judge shall be appointed in accordance with 5 U.S.C. 3105 and shall conduct such proceedings pursuant to §§ 15.14 through 15.16 as the administrative law judge deems necessary, in the administrative law judge's discretion, to determine whether the individual has established that treating the individual as an employee of the Public Health Service for purposes of 42 U.S.C. 233 would no longer expose the United States to an unreasonably high degree of risk of loss. After conducting such proceedings as the administrative law judge deems necessary, the administrative law judge shall certify the record to the adjudicating official and shall submit written findings of fact, conclusions of law, and a recommended decision to the adjudicating official pursuant to § 15.16.

(e) Following proceedings conducted under paragraph (d) of this section, the adjudicating official shall make the final determination on the basis of the record, findings, conclusions, and recommendations presented by the administrative law judge, which shall include the record from the original determination and any petition for rehearing. Copies of the adjudicating official's final determination shall be furnished to the parties. The adjudicating official's final determination shall constitute the final agency action.

(f) A determination that an individual is reinstated pursuant to this section shall be distributed in the same manner as provided in § 15.19 and shall apply only to acts or omissions of the individual occurring after the date of the final reinstatement determination.

Dated: June 28, 2024.

Merrick B. Garland,

Attorney General.

[FR Doc. 2024–14696 Filed 7–3–24; 8:45 am]

BILLING CODE 4410–12–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1630

RIN 3046–AB33

Removal of ADA Appendix Sections Related to Removal of Final ADA Wellness Rule Vacated by Court

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final rule.

SUMMARY: The Equal Employment Opportunity Commission is issuing a final rule supplementing a final rule it published on December 20, 2018, entitled ''Removal of Final ADA Wellness Rule Vacated by Court,'' which removed the incentive section in ADA regulations. This rule removes the discussion about the incentive section from the ADA appendix.

DATES: This final rule is effective as of July 5, 2024.

FOR FURTHER INFORMATION CONTACT: Sarah DeCosse, Assistant Legal Counsel, (202) 921–3240 (voice); (800) 669–6820 (TTY), Office of Legal Counsel, 131 M Street NE, Washington, DC 20507. Requests for this document in an alternative format should be made to the Office of Communications and Legislative Affairs at (202) 921–3191 (voice), (800) 669–6820 (TTY), or (844) 234–5122 (ASL).

SUPPLEMENTARY INFORMATION: On May 17, 2016, the Equal Employment Opportunity Commission (EEOC or Commission) published a final rule under the authority of title I of the Americans with Disabilities Act (ADA), 42 U.S.C. 12101–12117, ''provid[ing] guidance on the extent to which employers may use incentives to encourage employees to participate in wellness programs that ask them to respond to disability-related inquiries and/or undergo medical examinations.'' 81 FR 31126 (May 17, 2016). This 2016 rule also discussed the incentive provisions in the ADA appendix.

On October 24, 2016, AARP filed a complaint in the U.S. District Court for the District of Columbia challenging the incentive section of the ADA rule. On August 22, 2017, the District Court concluded that the Commission did not provide sufficient reasoning to justify the incentive limit adopted in the ADA rule and remanded the rule to the EEOC for reconsideration without vacating it. Following a motion by AARP to alter or amend the court's summary judgment order, the court issued an order vacating the incentive section of the rule, which was 29 CFR 1630.14(d)(3), effective