

impracticable, unnecessary, or contrary to the public interest.

We determined that good cause exists for dispensing with the notice and public comment procedures. 5 U.S.C. 553(b)(B). This final rule only extends the date on which the four body system listings will no longer be effective. It makes no substantive changes to our rules. Our current regulations³ provide that we may extend, revise, or promulgate the body system listings again. Therefore, we determined that opportunity for prior comment is unnecessary, and we are issuing this regulation as a final rule.

In addition, for the reasons cited above, we find good cause for dispensing with the 30-day delay in the effective date of this final rule. 5 U.S.C. 553(d)(3). We are not making any substantive changes to the listings in these body systems. Without an extension of the expiration date for these listings, we will not have the criteria we need to assess medical impairments in these four body systems at step three of the sequential evaluation processes. We therefore find it is in the public interest to make this final rule effective on the publication date.

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this final rule does not meet the requirements for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB did not review it. We also determined that this final rule meets the plain language requirement of Executive Order 12866.

Regulatory Flexibility Act

We certify that this final rule does not have a significant economic impact on a substantial number of small entities because it affects only individuals. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

These rules do not create any new or affect any existing collections and, therefore, do not require OMB approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; 96.006, Supplemental Security Income)

³ See the first sentence of appendix 1 to subpart P of part 404 of 20 CFR.

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

The Acting Commissioner of the Social Security Administration, Kilolo Kijakazi, having reviewed and approved this document, is delegating the authority to electronically sign this document to Faye I. Lipsky, who is the primary Federal Register Liaison for SSA, for purposes of publication in the **Federal Register**.

Faye I. Lipsky,

Federal Register Liaison, Office of Legislation and Congressional Affairs, Social Security Administration.

For the reasons set out in the preamble, we are amending appendix 1 to subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

Subpart P—[Amended]

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a) and (h)–(j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a) and (h)–(j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend appendix 1 to subpart P of part 404 in the introductory text by revising items 5, 6, 9, and 15 to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

5. Cardiovascular System (4.00 and 104.00): February 6, 2026.

6. Digestive System (5.00 and 105.00): February 6, 2026.

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9. Skin Disorders (8.00 and 108.00): February 6, 2026.

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15. Immune System Disorders (14.00 and 114.00): February 6, 2026.

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[FR Doc. 2021–26884 Filed 12–10–21; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Parts 655 and 656

[Docket No. ETA–2020–0006]

RIN 1205–AC00

Strengthening Wage Protections for the Temporary and Permanent Employment of Certain Immigrants and Non-Immigrants in the United States, Implementation of Vacatur

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Final rule.

SUMMARY: This Final Rule effectuates a Federal district court order vacating a January 14, 2021 Final Rule.

DATES: This rule is effective December 13, 2021. As of December 13, 2021, the Final Rule published on January 14, 2021, at 86 FR 3608, delayed on March 12, 2021, at 86 FR 13995, and further delayed May 13, 2021, at 86 FR 26164, is withdrawn. The Final Rule published on May 13, 2021, at 86 FR 26164, is also withdrawn.

FOR FURTHER INFORMATION CONTACT:

Brian Pasternak, Administrator, Office of Foreign Labor Certification, Employment and Training Administration, Department of Labor, 200 Constitution Avenue NW, Room N–5311, Washington, DC 20210, telephone: (202) 693–8200 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone numbers above via TTY/TDD by calling the toll-free Federal Information Relay Service at 1 (877) 889–5627.

SUPPLEMENTARY INFORMATION:

I. Background and Basis for Removal of Regulations

On October 8, 2020, the Department of Labor (Department) published an Interim Final Rule¹ (IFR or October 2020 IFR), amending Employment and Training Administration (ETA) regulations governing the prevailing wages for employment opportunities that U.S. employers seek to fill with foreign workers on a permanent or temporary basis through certain employment-based immigrant visas or through H–1B, H–1B1, or E–3 nonimmigrant visas. The Department published the October 2020 IFR with an

¹ *Strengthening Wage Protections for the Temporary and Permanent Employment of Certain Aliens in the United States*, 85 FR 63872 (Oct. 8, 2020).

immediate effective date, bypassing pre-promulgation notice and comment, but requesting public input during a post-promulgation 30-day public comment period. Four groups of plaintiffs separately challenged the Department's IFR and, on December 1, 3, and 14, 2020, respectively, the IFR was set aside or enjoined by three district courts on procedural grounds.² Subsequently, on January 14, 2021, the Department published a Final Rule³ in the **Federal Register** (Final Rule or January 2021 Final Rule), which adopted changes to the IFR. Although the Final Rule contained an effective date of March 15, 2021, the Department also included two sets of transition periods under which adjustments to the new wage levels would not begin until July 1, 2021. The Department twice delayed the effective date of the Final Rule,⁴ and, on June 23, 2021, before the Final Rule took effect, the U.S. District Court for the Northern District of California entered an order vacating and remanding the Final Rule.⁵ In light of the court's order, the Department has already announced that the operative version of the Code of Federal Regulations (CFR) at 20 CFR 656.40 and 20 CFR 655.731 continues to be the text in place on October 7, 2020, prior to the publication of the IFR.⁶ However, changes to the regulatory text resulting from the now-vacated rulemaking are still reflected in the CFR at 20 CFR parts 655 and 656.

This rule removes from the CFR the regulatory text that the Department promulgated through the rulemaking in October 2020, and restores the regulatory text to appear as it did before the IFR's effective date.

The Department is not required to provide notice and comment or delay the effective date of this rule, because the changes made simply implement the courts' orders, including the vacatur of the January 2021 Final Rule, and restore the regulatory text so that it correctly reflects the operative regulatory text in place prior to publication of the now-vacated rulemaking. Moreover, good

cause exists here for bypassing any otherwise applicable requirements of notice and comment and a delayed effective date. Notice and comment and a delayed effective date are unnecessary for the implementation of the court's order vacating the rule and would be contrary to public interest in light of the agency's need to implement the final judgment. See 5 U.S.C. 533(b)(B), (d). The Department believes that delaying the ministerial act of restoring the regulatory text in the **Federal Register** is contrary to the public interest because it could lead to confusion, particularly among the regulated public, as to the applicable prevailing wage methodology. The Department has concluded that each of those three reasons—that notice and comment and a delayed effective date are unnecessary, impracticable, and contrary to the public interest—independently provides good cause to bypass any otherwise applicable requirements of notice and comment and a delayed effective date.

List of Subjects

20 CFR Part 655

Administrative practice and procedure, Australia, Chile, Employment, Employment and training, Immigration, Labor, Migrant labor, Wages.

20 CFR Part 656

Administrative practice and procedure, Employment, Foreign workers, Labor, Wages.

Department of Labor

Accordingly, for the reasons stated in the preamble, the Department of Labor amends parts 655 and 656 of chapter V, title 20, Code of Federal Regulations, as follows:

PART 655—TEMPORARY EMPLOYMENT OF FOREIGN WORKERS IN THE UNITED STATES

■ 1. The authority citation for part 655 is revised to read as follows:

Authority: Section 655.0 issued under 8 U.S.C. 1101(a)(15)(E)(iii), 1101(a)(15)(H)(i) and (ii), 8 U.S.C. 1103(a)(6), 1182(m), (n), and (t), 1184(c), (g), and (j), 1188, and 1288(c) and (d); sec. 3(c)(1), Pub. L. 101–238, 103 Stat. 2099, 2102 (8 U.S.C. 1182 note); sec. 221(a), Pub. L. 101–649, 104 Stat. 4978, 5027 (8 U.S.C. 1184 note); sec. 303(a)(8), Pub. L. 102–232, 105 Stat. 1733, 1748 (8 U.S.C. 1101 note); sec. 323(c), Pub. L. 103–206, 107 Stat. 2428; sec. 412(e), Pub. L. 105–277, 112 Stat. 2681 (8 U.S.C. 1182 note); sec. 2(d), Pub. L. 106–95, 113 Stat. 1312, 1316 (8 U.S.C. 1182 note); 29 U.S.C. 49k; Pub. L. 107–296, 116 Stat. 2135, as amended; Pub. L. 109–423, 120 Stat. 2900; 8 CFR 214.2(h)(4)(i); 8 CFR

214.2(h)(6)(iii); and sec. 6, Pub. L. 115–218, 132 Stat. 1547 (48 U.S.C. 1806).

Subpart A issued under 8 CFR 214.2(h).

Subpart B issued under 8 U.S.C. 1101(a)(15)(H)(ii)(a), 1184(c), and 1188; and 8 CFR 214.2(h).

Subpart E issued under 48 U.S.C. 1806.

Subparts F and G issued under 8 U.S.C. 1288(c) and (d); sec. 323(c), Pub. L. 103–206, 107 Stat. 2428; and 28 U.S.C. 2461 note, Pub. L. 114–74 at section 701.

Subparts H and I issued under 8 U.S.C. 1101(a)(15)(H)(i)(b) and (b)(1), 1182(n), and (t), and 1184(g) and (j); sec. 303(a)(8), Pub. L. 102–232, 105 Stat. 1733, 1748 (8 U.S.C. 1101 note); sec. 412(e), Pub. L. 105–277, 112 Stat. 2681; 8 CFR 214.2(h); and 28 U.S.C. 2461 note, Pub. L. 114–74 at section 701.

Subparts L and M issued under 8 U.S.C. 1101(a)(15)(H)(i)(c) and 1182(m); sec. 2(d), Pub. L. 106–95, 113 Stat. 1312, 1316 (8 U.S.C. 1182 note); Pub. L. 109–423, 120 Stat. 2900; and 8 CFR 214.2(h).

■ 2. Amend § 655.731 by revising paragraphs (a)(2)(ii) introductory text, (a)(2)(ii)(A) introductory text, and (a)(2)(ii)(A)(2) to read as follows:

§ 655.731 What is the first LCA requirement, regarding wages?

* * * * *
(a) * * *
(2) * * *

(ii) If the job opportunity is in an occupation which is not covered by paragraph (a)(2)(i) of this section, the prevailing wage shall be the arithmetic mean of the wages of workers similarly employed, except that the prevailing wage shall be the median when provided by paragraphs (a)(2)(ii)(A), (b)(3)(iii)(B)(2), and (b)(3)(iii)(C)(2) of this section. The prevailing wage rate shall be based on the best information available. The following prevailing wage sources may be used:

(A) *OFLC National Processing Center (NPC) determination.* Prior to January 1, 2010, the SWA having jurisdiction over the area of intended employment shall continue to receive and process prevailing wage determination requests, but shall do so in accordance with these regulatory provisions and Department guidance. On or after January 1, 2010, the NPC shall receive and process prevailing wage determination requests in accordance with these regulations and with Department guidance. Upon receipt of a written request for a PWD on or after January 1, 2010, the NPC will determine whether the occupation is covered by a collective bargaining agreement which was negotiated at arm's length, and, if not, determine the arithmetic mean of wages of workers similarly employed in the area of intended employment. The wage component of the Bureau of Labor Statistics Occupational Employment Statistics survey shall be used to

² *Strengthening Wage Protections for the Temporary and Permanent Employment of Certain Aliens in the United States*, 86 FR 3608, 3612 (Jan. 14, 2021) (discussing cases).

³ 86 FR 3608.

⁴ 86 FR 13995 (Mar. 12, 2021); 86 FR 26164 (May 13, 2021).

⁵ See Order Granting Defendants' Motion for Voluntary Remand with Vacatur, *Chamber of Commerce, et al. v. Dep't of Homeland Sec., et al.*, No. 20–cv–07331 (N.D. Cal. June 23, 2021), ECF No. 139.

⁶ Announcements, *OFLC Announces Updates to Implementation of the Final Rule Affecting Wages for H-1B and PERM Workers; District Court's Order Vacating Final Rule* (June 29, 2021), available at <https://www.dol.gov/agencies/eta/foreign-labor/news>.

determine the arithmetic mean, unless the employer provides an acceptable survey. The NPC shall determine the wage in accordance with secs. 212(n) and 212(t) of the INA. If an acceptable employer-provided wage survey provides a median and does not provide an arithmetic mean, the median shall be the prevailing wage applicable to the employer's job opportunity. In making a PWD, the Chicago NPC will follow 20 CFR 656.40 and other administrative guidelines or regulations issued by ETA. The Chicago NPC shall specify the validity period of the PWD, which in no event shall be for less than 90 days or more than 1 year from the date of the determination.

* * * * *

(2) If the employer is unable to wait for the NPC to produce the requested prevailing wage for the occupation in question, or for the CO and/or the BALCA to issue a decision, the employer may rely on other legitimate sources of available wage information as set forth in paragraphs (a)(2)(ii)(B) and (C) of this section. If the employer later discovers, upon receipt of the PWD from the NPC, that the information relied upon produced a wage below the final PWD and the employer was paying the NPC-determined wage, no wage violation will be found if the employer retroactively compensates the H-2B nonimmigrant(s) for the difference between the wage paid and the prevailing wage, within 30 days of the employer's receipt of the PWD.

* * * * *

PART 656—LABOR CERTIFICATION PROCESS FOR PERMANENT EMPLOYMENT OF ALIENS IN THE UNITED STATES

■ 3. The authority citation for part 656 is revised to read as follows:

Authority: 8 U.S.C. 1182(a)(5)(A), 1182(p)(1); sec.122, Public Law 101-649, 109 Stat. 4978; and Title IV, Public Law 105-277, 112 Stat. 2681.

■ 4. Amend § 656.40 by revising paragraphs (a) and (b)(2) and (3) to read as follows:

§ 656.40 Determination of prevailing wage for labor certification purposes.

(a) *Application process.* The employer must request a PWD from the NPC, on a form or in a manner prescribed by OFLC. Prior to January 1, 2010, the SWA having jurisdiction over the area of intended employment shall continue to receive and process prevailing wage determination requests in accordance with the regulatory provisions and Department guidance in effect prior to January 1, 2009. On or after January 1,

2010, the NPC shall receive and process prevailing wage determination requests in accordance with these regulations and with Department guidance. The NPC will provide the employer with an appropriate prevailing wage rate. The NPC shall determine the wage in accordance with sec. 212(t) of the INA. Unless the employer chooses to appeal the center's PWD under § 656.41(a) of this part, it files the Application for Permanent Employment Certification either electronically or by mail with the processing center of jurisdiction and maintains the PWD in its files. The determination shall be submitted to the CO, if requested.

(b) * * *

(2) If the job opportunity is not covered by a CBA, the prevailing wage for labor certification purposes shall be the arithmetic mean, except as provided in paragraph (b)(3) of this section, of the wages of workers similarly employed in the area of intended employment. The wage component of the DOL Occupational Employment Statistics Survey shall be used to determine the arithmetic mean, unless the employer provides an acceptable survey under paragraph (g) of this section.

(3) If the employer provides a survey acceptable under paragraph (g) of this section that provides a median and does not provide an arithmetic mean, the prevailing wage applicable to the employer's job opportunity shall be the median of the wages of workers similarly employed in the area of intended employment.

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Angela Hanks,
Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2021-26660 Filed 12-10-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA-2021-N-0575]

Medical Devices; Neurological Devices; Classification of the Temporary Coil Embolization Assist Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the temporary coil

embolization assist device into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the temporary coil embolization assist device's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective December 13, 2021. The classification was applicable on April 24, 2019.

FOR FURTHER INFORMATION CONTACT: Xiaolin Zheng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4224, Silver Spring, MD 20993-0002, 301-796-2823, Xiaolin.Zheng@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the temporary coil embolization assist device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section