DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

20 CFR Part 10

RIN 1240–AA18

Claims for Compensation Under the Federal Employees' Compensation Act

AGENCY: Office of Workers' Compensation Programs, Department of Labor.

ACTION: Final rule.

SUMMARY: The Office of Workers' Compensation Programs (OWCP) is publishing this final rule to adjust the amount of time a claimant has to provide additional information when the evidence that has been submitted by the claimant is insufficient to meet their burden of proof and OWCP needs additional information. This change implements a requirement of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023, which requires OWCP to increase the minimum amount of time allowed from 30 days to 60 days.

DATES: This final rule is effective March 7, 2023.

FOR FURTHER INFORMATION CONTACT: Antonio Rios, Director, Division of Federal Employees' and Longshore and Harbor Workers' Compensation, Office of Workers' Compensation Programs, by mail at U.S. Department of Labor, Room C–3154, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210; by email at *DFECDirector@dol.gov;* or by telephone at 202–693–0040. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The Federal Employees' Compensation Act (FECA) provides compensation for wage loss, medical care, and vocational rehabilitation to Federal employees and certain other individuals who are injured in the performance of their duties, or who develop illnesses as a result of factors of their Federal employment.

Under Public Law 117–263, Congress directed OWCP to update 20 CFR 10.121 within 16 days of the law's enactment. Section 10.121 addresses situations when the evidence submitted by the claimant is insufficient to meet their burden of proof and OWCP needs additional information. Presently, it requires OWCP to give the claimant at least 30 days to submit the evidence required. At Congress' express direction, OWCP is changing this 30-day period to 60 days.

The Agency's implementation of this action without opportunity for public comment is based on the good cause exception in 5 U.S.C. 553(b)(B), in that seeking public comment is impracticable, unnecessary, and contrary to the public interest. Seeking public comment is unnecessary because the agency has no discretion to change the timeline for a claimant to submit additional evidence. In addition, given the 16-day deadline for amending the regulation that was prescribed by Congress, seeking prior public comment on this is impracticable and contrary to the public interest in the orderly promulgation and implementation of regulations.

Executive Order 12866

This regulatory action does not constitute a ''significant'' rule within the meaning of Executive Order 12866 in that it only changes the timeline to submit additional evidence by 30 days.

Regulatory Flexibility Act of 1980

An analysis under the Regulatory Flexibility Act of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (RFA), 5 U.S.C. 601–612, is not needed for this rule. The RFA imposes certain requirements on Federal agency rules that are subject to the notice and comment requirements of the APA, 5 U.S.C. 553(b). The Department is invoking the good cause exception to notice-and-comment procedures for this final rule. Accordingly, the Department is not required to either certify that the final rule would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Paperwork Reduction Act (PRA)

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the Department consider the impact of paperwork and other information collection burdens imposed on the public. The Department has determined that this final rule does not require any collection of information or alter any existing information collections.

Unfunded Mandates Reform Act of 1995 and Executive Order 13132

The Department has reviewed this proposed rule in accordance with the requirements of Exec. Order No. 13132, 64 FR 43,225 (Aug. 10, 1999), and the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.,* and has found no potential or 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. As there is no Federal mandate contained herein that could result in increased expenditures by State, local, or tribal governments or by the private sector, the Department has not prepared a budgetary impact statement.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

The Department has reviewed this proposed rule in accordance with Exec. Order 13,175, 65 FR 67249 (Nov. 9, 2000), and has determined that it does not have ''tribal implications.'' The proposed rule does not ''have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

Executive Order 12630: Governmental Actions and Interference With Constitutionally Protected Property Rights

The Department has reviewed this proposed rule in accordance with Exec. Order 12630, 53 FR 8859 (Mar. 15, 1988), and has determined that it does not contain any ''policies that have takings implications'' in regard to the ''licensing, permitting, or other condition requirements or limitations on private property use, or that require dedications or exactions from owners of private property.''

Executive Order 13211: Energy Supply, Distribution, or Use

The Department has reviewed this proposed regulation and has determined that the provisions of Exec. Order 13211, 66 FR 28355 (May 18, 2001), are not applicable as there are no direct or implied effects on energy supply, distribution, or use.

The Privacy Act of 1974, 5 U.S.C. 552a, as Amended

Claims filed under this regulation are subject to the current Privacy Act System of Records, DOL/GOVT–1, Office of Workers' Compensation Programs, Federal Employees' Compensation Act File, 67 FR 16826 (April 8, 2002).

List of Subjects in 20 CFR Part 10

Administrative practice and procedure, Federal Employees' Compensation Act, Federal employees, and other groups of employees and individuals who are injured or killed while performing their jobs.

For the reasons discussed in the preamble, the Office of Workers'

Compensation Programs amends 20 CFR part 10 as follows:

PART 10—CLAIMS FOR COMPENSATION UNDER THE FEDERAL EMPLOYEES' COMPENSATION ACT, AS AMENDED

■ 1. The authority citation for part 10 is amended to read as follows: 5 U.S.C. 301, 8102a, 8103, 8145 and 8149; 31 U.S.C. 3716 and 3717; Reorganization Plan No. 6 of 1950, 15 FR 3174, 64 Stat. 1263; Secretary of Labor's Order No. 10–2009, 74 FR 218; Pub. L. 117–263.

■ 2. Revise § 10.121 to read as follows:

§ 10.121 What happens if OWCP needs more evidence from the claimant?

If the claimant submits factual evidence, medical evidence, or both, but OWCP determines that this evidence is not sufficient to meet the burden of proof, OWCP will inform the claimant of the additional evidence needed. The claimant will be allowed at least 60 days to submit the evidence required. OWCP is not required to notify the claimant a second time if the evidence submitted in response to OWCP's first request for additional evidence is not sufficient to meet the burden of proof.

Signed at Washington, DC, on December 30, 2022.

Christopher Godfrey,

Director, Office of Workers' Compensation Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2022–N–3189]

Medical Devices; Cardiovascular Devices; Classification of the Hardware and Software for Optical Camera-Based Measurement of Pulse Rate, Heart Rate, Breathing Rate, and/or Respiratory Rate

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate 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 hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate'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 January 6, 2023. The classification was applicable on April 1, 2021.

FOR FURTHER INFORMATION CONTACT: Jennifer Kozen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2272, Silver Spring, MD 20993–0002, 307–796–5813, *Jennifer.Shih@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the hardware and software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate 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, in part 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 (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 12, 2020, FDA received ContinUse Biometrics Ltd.'s request for De Novo classification of the Gili Pro BioSensor. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.