

**§ 1217.2 Requirements for toddler beds.**

Each toddler bed shall comply with all applicable provisions of ASTM F1821–19<sup>e1</sup>, Standard Consumer Safety Specification for Toddler Beds, approved June 1, 2019. The Director of the Federal Register approves the incorporation by reference listed in this section in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of this ASTM standard from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA; phone: 610–832–9585; [www.astm.org](http://www.astm.org). You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov), or go to: [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html).

**Alberta E. Mills,**

*Secretary, U.S. Consumer Product Safety Commission.*

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**SOCIAL SECURITY ADMINISTRATION****20 CFR Parts 404, 408, and 416**

[Docket No. SSA–2015–0006]

RIN 0960–AH78

**Prohibiting Persons With Certain Criminal Convictions From Serving as Representative Payees; Correction**

**AGENCY:** Social Security Administration.

**ACTION:** Correcting amendment.

**SUMMARY:** On February 15, 2019, we published final rules in the **Federal Register** to prohibit persons convicted of certain crimes from serving as representative payees under the Social Security Act (Act), as required by the Strengthening Protections for Social Security Beneficiaries Act of 2018. Those final rules inadvertently included two words in three places that should not have been there, and omitted one word in two sections of the rules. This document corrects the inadvertent inclusions and omissions in the final rules.

**DATES:** Effective October 25, 2019, and applicable beginning March 18, 2019.

**FOR FURTHER INFORMATION CONTACT:** Kevin Salamone, Office of Income

Security Programs, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 966–0854. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our internet site, Social Security Online, at <http://www.socialsecurity.gov>.

**SUPPLEMENTARY INFORMATION:** We published final rules in the **Federal Register** on February 15, 2019 (83 FR 4323), that prohibit persons with certain criminal convictions from serving as representative payees. Those rules codified our responsibilities under the Strengthening Protections for Social Security Beneficiaries Act of 2018,<sup>1</sup> which prohibits the selection of certain representative payee applicants who have a specified felony conviction of committing, attempting, or conspiring to commit certain crimes. The law also requires us to review each individual currently serving as a representative payee (who does not meet one of the exceptions set out in the law) to determine whether the individual has been convicted of a specified crime, and continue to do so at least once every five years. The final rules inadvertently included the words “or organization” in §§ 404.2026, 408.626, and 416.626. They also inadvertently omitted the word “individual” from §§ 404.2024(a)(10) and 416.624(a)(10).

Although a representative payee may be an organization such as a social service agency, or an individual such as a parent, relative, or friend of the beneficiary, the final rules concerning a criminal background check and criminal history apply only to individuals applying to serve as representative payee and individuals currently serving as a representative payee. Accordingly, this correction removes the words “or organization” from the affected sections and clarifies our regulations. They also clarify in §§ 404.2024(a)(10) and 416.624(a)(10) that the criminal background check requirement applies to individual representative payee applicants.

(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; and 96.020—Special Benefits for Certain World War II Veterans)

<sup>1</sup>Public Law 115–165, 132 Stat. 1257.

**List of Subjects***20 CFR Part 404*

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

*20 CFR Part 408*

Administrative practice and procedure, Aged, Reporting and recordkeeping requirements, Social Security, Supplemental Security Income (SSI), Veterans.

*20 CFR Part 416*

Administrative practice and procedure, Reporting and recordkeeping requirements, Supplemental Security Income (SSI).

**Andrew Saul,**

*Commissioner of Social Security.*

Accordingly, 20 CFR parts 404, 408, and 416 are amended by making the following correcting amendments:

**PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950– )****Subpart U—Representative Payment**

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

**Authority:** Secs. 205(a), (j), and (k), and 702(a)(5) of the Social Security Act (42 U.S.C. 405(a), (j), and (k), and 902(a)(5)).

■ 2. Amend § 404.2024 by revising paragraph (a)(10) to read as follows:

**§ 404.2024 How do we investigate a representative payee applicant?**

\* \* \* \* \*

(a) \* \* \*

(10) Conduct a criminal background check on the individual payee applicant.

\* \* \* \* \*

**§ 404.2026 [Amended]**

■ 3. Amend § 404.2026 to by removing the words “or organization”.

**PART 408—SPECIAL BENEFITS FOR CERTAIN WORLD WAR II VETERANS****Subpart F—Representative Payment**

■ 4. The authority citation for subpart F of part 408 continues to read as follows:

**Authority:** Secs. 702(a)(5), 807, and 810 of the Social Security Act (42 U.S.C. 902(a)(5), 1007, and 1010).

**§ 408.626 [Amended]**

■ 5. Amend § 408.626 by removing the words “or organization”.

**PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED**

**Subpart F—Representative Payment**

■ 6. The authority citation for subpart F of part 416 continues to read as follows:

**Authority:** Secs. 702(a)(5), 1631(a)(2) and (d)(1) of the Social Security Act (42 U.S.C. 902(a)(5), 1383(a)(2) and (d)(1)).

■ 7. Amend § 416.624 by revising paragraph (a)(10) to read as follows:

**§ 416.624 How do we investigate a representative payee applicant?**

\* \* \* \* \*

(a) \* \* \*

(10) Conduct a criminal background check on the individual payee applicant.

\* \* \* \* \*

**§ 416.626 [Amended]**

■ 8. Amend § 416.626 by removing the words “or organization”.

[FR Doc. 2019–23235 Filed 10–24–19; 8:45 am]

**BILLING CODE P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 888**

[Docket No. FDA–2019–N–2711]

**Medical Devices; Orthopedic Devices; Classification of Orthopedic Surgical Instrumentation Designed for Osteochondral Implants With Press-Fit Fixation**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation 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 orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation’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, in part by reducing regulatory burdens.

**DATES:** This order is effective October 25, 2019. The classification was applicable on April 26, 2018.

**FOR FURTHER INFORMATION CONTACT:** Pooja Panigrahi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1449, Silver Spring, MD 20993–0002, 240–402–1090, [Pooja.Panigrahi@fda.hhs.gov](mailto:Pooja.Panigrahi@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Upon request, FDA has classified the orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness for its intended use. In addition, we believe this action will enhance patients’ access to beneficial innovation, in part by reducing regulatory burdens by placing the device into the appropriate device class based on risk and the regulatory controls sufficient to provide reasonable assurance of safety and effectiveness.

FDA may classify a device through an accessory classification request under section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(6)), established by section 707 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52). The provision allows manufacturers or importers to request classification of an accessory distinct from another device upon written request. The classification is based upon the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016, will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request appropriate classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the **Federal Register** within 30 days announcing the classification.

Alternatively, under section 513(f)(6)(C), a person filing a PMA or 510(k) may include a written request for

the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to the PMA or 510(k). Upon granting, FDA will publish a notice in the **Federal Register** within 30 days announcing the classification.

**II. Accessory Classification**

On January 31, 2018, Cartiva, Inc., submitted a request for accessory classification of the Reusable Implantation Instruments for the Cartiva Synthetic Cartilage Implant. 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.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 26, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 888.4505. We have named the generic type of device orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation, and it is identified as hand-held devices intended to manipulate bone and cartilage tissue or the implant for the positioning, alignment, defect creation, and placement of press-fit osteochondral implants that utilize no additional means of fixation (e.g., suture fixation, adhesives). This type of device includes instruments specific to the geometry of the implant.