for export clearance purposes; however, when necessary, the symbol ''AVS'' may be used.

* * * * *

(d) * * *

(6) *Cuba, eligible vessels and purposes.* Only the types of vessels listed in this paragraph (d)(6) departing for Cuba for the purposes listed in this paragraph (d)(6) may depart for Cuba pursuant to this paragraph (d). Vessels used to transport both passengers and items to Cuba may transport automobiles only if the export or reexport of the automobiles to Cuba has been authorized by a separate license issued by BIS (*i.e.,* not authorized by license exception).

(i) Cargo vessels for hire for use in the transportation of items;

(ii) Passenger vessels for hire for use in the transportation of passengers and/or items; and

(iii) Recreational vessels that are used in connection with travel authorized by the Department of the Treasury, Office of Foreign Assets Control (OFAC).

Note to paragraph (d)(6)(iii): Readers should also consult U.S. Coast Guard regulations at 33 CFR part 107 Subpart B—Unauthorized Entry into Cuban Territorial Waters.

* * * * *

(e) *Intransit cargo.* Cargo laden on board an aircraft or vessel may transit Cuba provided:

(1) The aircraft or vessel is exported or reexported on temporary sojourn to Cuba pursuant to paragraph (a) or (d) of this section or a license from BIS; and

(2) The cargo departs with the aircraft or vessel at the end of its temporary sojourn to Cuba, is not removed from the aircraft or vessel for use in Cuba and is not transferred to another aircraft or vessel while in Cuba.

* * * * *

■ 4. Section 740.19 is amended by revising paragraphs (c)(2)(i) and (ii) to read as follows:

§ 740.19 Consumer communications devices (CCD).

* * * * *

(c) * * *

(2) * * *

(i) *Ineligible Cuban Government Officials.* Members of the Council of Ministers and flag officers of the Revolutionary Armed Forces.

(ii) *Ineligible Cuban Communist Party Officials.* Members of the Politburo.

■ 5. Section 740.21 is amended by:

■ a. Removing the word ''or'' from the end of paragraph (b)(2);

■ b. Removing the period from the end of paragraph (b)(3) and adding in its place ''; or'';

■ c. Adding paragraph (b)(4) and;

■ d. Revising paragraphs (d)(4)(ii) and (iii).

The addition and revisions read as follows:

§ 740.21 Support for the Cuban People (SCP).

* * * * *

(b) * * *

(4) Items sold directly to individuals in Cuba for their personal use or their immediate family's personal use, other than officials identified in paragraphs (d)(4)(ii) or (iii) of this section.

* * * * *

(d) * * *

(4) * * *

(ii) Members of the Council of Ministers and flag officers of the Revolutionary Armed Forces; and

(iii) Members of the Politburo.

* * * * *

PART 746—[AMENDED]

■ 6. The authority citation for part 746 continues to read:

Authority: 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 287c; Sec 1503, Pub. L. 108–11, 117 Stat. 559; 22 U.S.C. 6004; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p 168; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Presidential Determination 2007–7, 72 FR 1899, 3 CFR, 2006 Comp., p. 325; Notice of May 3, 2016, 81 FR 27293 (May 5, 2016); Notice of August 4, 2016, 81 FR 52587 (August 8, 2016).

■ 7. Section 746.2 is amended by revising paragraph (a)(1)(x) to read as follows:

§ 746.2 Cuba.

(a) * * *

(1) * * *

(x) Aircraft, vessels and spacecraft (AVS) for certain aircraft on temporary sojourn; equipment and spare parts for permanent use on a vessel or aircraft, and ship and plane stores; vessels on temporary sojourn; or cargo transiting Cuba on aircraft or vessels on temporary sojourn (*see* § 740.15(a), (b), (d), and (e) of the EAR).

* * * * *

Dated: October 11, 2016.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2016–25034 Filed 10–14–16; 8:45 am]

BILLING CODE 3510–33–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Docket No. SSA–2014–0016]

RIN 0960–AH66

Unsuccessful Work Attempts and Expedited Reinstatement Eligibility

AGENCY: Social Security Administration.

ACTION: Final rules.

SUMMARY: These rules finalize the rules we proposed in our notice of proposed rulemaking (NPRM), published on May 11, 2016. In these rules, we remove some of the requirements for evaluation of an unsuccessful work attempt (UWA) that lasts between 3 and 6 months, allow previously entitled beneficiaries to apply for expedited reinstatement (EXR) in the same month they stop performing substantial gainful activity (SGA), and provide that provisional benefits will begin the month after the request for EXR if the beneficiary stops performing SGA in the month of the EXR request. These changes will simplify our policies and make them easier for the public to understand.

DATES: These final rules will be effective November 16, 2016, except for the amendments to §§ 404.1592c and 416.999a, which will be effective April 17, 2017.

FOR FURTHER INFORMATION CONTACT: Kristine Erwin-Tribbitt, Office of Retirement and Disability Policy, Office of Research, Demonstration, and Employment Support, Social Security Administration, 6401 Security Boulevard, Robert Ball Building 3–A–26, Baltimore, MD 21235–6401, (410) 965–3353. 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: On May 11, 2016, we published an NPRM in the **Federal Register** at 81 FR 29212 in which we proposed to revise our rules to simplify certain aspects of our UWA and EXR policies and make them easier for the public to understand. We are adopting the proposed rules as final rules.

The final rules at 20 CFR 404.1574(c), 404.1575(d), 416.974(c), and 416.975(d) remove the additional conditions that we used when we evaluated a work attempt in employment or self-employment that lasted between 3 and 6 months and use the current 3-month standard for all work attempts that are 6 months or less. Under these rules, ordinarily, work you have done will not

show that you are able to do substantial gainful activity if, after you worked for a period of 6 months or less, your impairment forced you to stop working or to reduce the amount of work you do so that your earnings from such work fall below the substantial gainful activity earnings level. The new rules at 20 CFR 404.1592c and 416.999a allow a previously entitled individual to request EXR in the same month they stop performing SGA. These new rules apply to Social Security Disability Insurance (SSDI) and Supplemental Security Income (SSI) claimants and beneficiaries. We expect these changes will result in simplified case processing and faster and better determinations and decisions.

You can find additional information and discussion regarding these changes in the preamble to our proposed rule.

Public Comments and Discussion

We received eight timely submitted comments that addressed issues within the scope of our proposed rules. Below, we present the views we received and address all of the relevant and significant issues raised by the commenters. We carefully considered their concerns, but did not make any changes to our rules because of the comments.

Of these eight comments, six were from disability advocacy organizations, all of whom supported our proposed rules. The organizations expressed that the proposed changes will have a positive impact on beneficiaries by supporting their attempts to work and helping them understand and use the rules. They asserted that this, in turn, would provide greater assurance to beneficiaries who want to attempt a return to work and would result in increased program participation.

Comment: One commenter asked if it would be easier for an individual to temporarily and voluntarily suspend benefits when trying to rejoin the work force instead of terminating his or her benefits and then requesting EXR following an UWA.

Response: Under the Social Security Act, we are required to terminate an individual's disability benefits if he or she no longer meets the eligibility requirements and are therefore prohibited from simply suspending benefits.[1]

To be entitled to disability benefits, an individual must be unable to engage in any SGA by reason of any medically determinable physical or mental impairment that can be expected to result in death, or has lasted or can be expected to last for a continuous period of not less than 12 months.[2] An individual may be determined not to be entitled to benefits if there is substantial evidence demonstrating that the individual is able to engage in SGA.[3] Generally, a period of disability ends and benefits cease following a finding that the physical or mental impairment on the basis of which the benefits are provided has not been disabling for 36 months, as demonstrated by SGA.[4]

Because we are required to terminate benefits, we established EXR in order to facilitate benefit reinstatement to individuals whose benefits terminated as a result of SGA. Previously entitled individuals may request EXR within 60 months of their prior termination of benefits if their medical condition no longer permits them to perform SGA. To qualify for EXR, a previously entitled individual must be unable to perform SGA due to an impairment that is the same as, or related to, an impairment that was the basis for the previous entitlement.[5]

Comment: One commenter indicated that the proposed rules were unclear, stating that ''the rules for UWA, as proposed are in direct conflict with the definition of disability, which requires, in part, the inability to engage in SGA for 12 consecutive months.'' He went on to ask if our proposed rule changed the definition of disability or if it ''merely appl[ies] after the initial 12 month period?''

Response: The new rules do not conflict with the definition of disability nor do they change our policy or definition of disability. By applying the current 3-month conditions to all work attempts that are 6 months or less, the new rules simply remove the additional documentation previously required of an individual with a work attempt lasting between 3 and 6 months.

To be eligible for disability benefits, an individual must be unable to engage in any SGA by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.[6] As we explained in our NPRM, disability evaluation is generally concerned with the ability to work over an extended period rather than in short, isolated periods.

Disability claimants and beneficiaries may attempt to return to work and engage in SGA following a break in the continuity of their work. For SGA determination purposes, we may disregard work in employment or self-employment if a claimant or beneficiary, after working for a period of 6 months or less, stops working or reduces the amount of work so that the earnings fall below the SGA level because of the original impairment or the removal of special conditions that were essential to the performance of his or her work, and if there was a significant break in the continuity of work before this work attempt.[7]

Regulatory Procedures

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that these rules do not meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB has not reviewed them.

Regulatory Flexibility Act

We certify that these rules will not have a significant economic impact on a substantial number of small entities because they affect individuals only. 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 Office of Management and Budget approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 9601, Social Security—Disability Insurance; 96.006, Supplemental Security Income; 96.008, Social Security—Work Incentives Planning and Assistance Program.)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Reporting and recordkeeping requirements, Social security, Vocational rehabilitation.

20 CFR Part 416

Administrative practice and procedure, Medicaid, Reporting and recordkeeping requirements,

[1] 42 U.S.C. 416(i)(2)(D)(ii)(II).

[2] 42 U.S.C. 423(d)(1)(A), 42 U.S.C. 1382c(a)(3)(A).

[3] 42 U.S.C. 423(f)(2)(A)(ii), 42 U.S.C. 1382c(a)(4)(A)(i)(II).

[4] 42 U.S.C. 416(i)(2)(D)(ii)(II).

[5] 20 CFR 404.1592c and 416.999a.

[6] 42 U.S.C. 423(d)(1)(A); 42 U.S.C. 1382c(a)(3)(A).

[7] 20 CFR 404.1574(c) and 416.974(c).

Supplemental Security Income (SSI), Vocational rehabilitation.

Carolyn W. Colvin,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, we amend 20 CFR part 404 subpart P and 20 CFR part 416 subpart I as set forth below:

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

Subpart P—Determining Disability and Blindness

■ 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), (i), and (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), (i), and (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 § 404.1574 by revising the first sentence of paragraph (c)(1), revising paragraph (c)(3), removing paragraph (c)(4), and redesignating paragraph (c)(5) as (c)(4) to read as follows:

§ 404.1574 Evaluation guides if you are an employee.

* * * * *

(c) * * *

(1) *General.* Ordinarily, work you have done will not show that you are able to do substantial gainful activity if, after you worked for a period of 6 months or less, your impairment forced you to stop working or to reduce the amount of work you do so that your earnings from such work fall below the substantial gainful activity earnings level in paragraph (b)(2) of this section, and you meet the conditions described in paragraphs (c)(2), (3), and (4) of this section. * * *

* * * * *

(3) *If you worked 6 months or less.* We will consider work of 6 months or less to be an unsuccessful work attempt if you stopped working or you reduced your work and earnings below the substantial gainful activity earnings level because of your impairment or because of the removal of special conditions that took into account your impairment and permitted you to work.

* * * * *

■ 3. Amend § 404.1575 by revising the first sentence of paragraph (d)(1), revising paragraph (d)(3), removing paragraph (d)(4), and redesignating paragraph (d)(5) as (d)(4) to read as follows:

§ 404.1575 Evaluation guides if you are self-employed.

* * * * *

(d) * * *

(1) *General.* Ordinarily, work you have done will not show that you are able to do substantial gainful activity if, after working for a period of 6 months or less, you were forced by your impairment to stop working or to reduce the amount of work you do so that you are no longer performing substantial gainful activity and you meet the conditions described in paragraphs (d)(2), (3), and (4) of this section. * * *

* * * * *

(3) *If you worked 6 months or less.* We will consider work of 6 months or less to be an unsuccessful work attempt if you stopped working or you reduced your work and earnings below the substantial gainful activity earnings level because of your impairment or because of the removal of special conditions that took into account your impairment and permitted you to work.

* * * * *

■ 4. Amend § 404.1592c by revising paragraph (a)(4)(i) and (c)(2) to read as follows:

§ 404.1592c Who is entitled to expedited reinstatement?

(a) * * *

(4) * * *

(i) You are not able or become unable to do substantial gainful activity because of your medical condition as determined under paragraph (c) of this section;

* * * * *

(c) * * *

(2) You are not able or become unable to do substantial gainful activity in the month you file your request for reinstatement; and

* * * * *

■ 5. Amend § 404.1592e by revising paragraph (a)(1) to read as follows:

§ 404.1592e How do we determine provisional benefits?

(a) * * *

(1) We will pay you provisional benefits, and reinstate your Medicare if you are not already entitled to Medicare, beginning with the month you file your request for reinstatement under § 404.1592c(a) if you do not perform substantial gainful activity in that month. We will pay you provisional benefits, and reinstate your Medicare if you are not already entitled to Medicare, beginning with the month after you file your request for reinstatement under § 404.1592c(a) if you perform substantial gainful activity in the month in which you file your request for reinstatement.

* * * * *

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

Subpart I—Determining Disability and Blindness

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

Authority: Secs. 221(m), 702(a)(5), 1611, 1614, 1619, 1631(a), (c), (d)(1), and (p), and 1633 of the Social Security Act (42 U.S.C. 421(m), 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), (d)(1), and (p), and 1383b; secs. 4(c) and 5, 6(c)–(e), 14(a), and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, and 1382h note).

■ 7. Amend § 416.974 by revising paragraph (c)(3), removing paragraph (c)(4), and redesignating paragraph (c)(5) as (c)(4) to read as follows:

§ 416.974 Evaluation guides if you are an employee.

* * * * *

(c) * * *

(3) *If you worked 6 months or less.* We will consider work of 6 months or less to be an unsuccessful work attempt if you stopped working or you reduced your work and earnings below the substantial gainful activity earnings level because of your impairment or because of the removal of special conditions that took into account your impairment and permitted you to work.

* * * * *

■ 8. Amend § 416.975 by revising paragraph (d)(1) and (3), removing paragraph (d)(4), and redesignating paragraph (d)(5) as (d)(4) to read as follows:

§ 416.975 Evaluation guides if you are self-employed.

* * * * *

(d) * * *

(1) *General.* Ordinarily, work you have done will not show that you are able to do substantial gainful activity if, after working for a period of 6 months or less, you were forced by your impairment to stop working or to reduce the amount of work you do so that you are no longer performing substantial gainful activity and you meet the conditions described in paragraphs (d)(2), (3), and (4) of this section.

* * * * *

(3) *If you worked 6 months or less.* We will consider work of 6 months or less to be an unsuccessful work attempt if you stopped working or you reduced your work and earnings below the substantial gainful activity earnings

level because of your impairment or because of the removal of special conditions that took into account your impairment and permitted you to work.

* * * * *

■ 9. Amend § 416.999a by revising paragraph (a)(4)(i) and (c)(2) to read as follows:

§ 416.999a Who is eligible for expedited reinstatement?

(a) * * *

(4) * * *

(i) You are not able or become unable to do substantial gainful activity because of your medical condition as determined under paragraph (c) of this section.

* * * * *

(c) * * *

(2) You are not able or become unable to do substantial gainful activity in the month you file your request for reinstatement; and

* * * * *

[FR Doc. 2016–24873 Filed 10–14–16; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2016–N–2766]

Medical Devices; Cardiovascular Devices; Classification of the Apical Closure Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the apical closure device into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the apical closure device's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective October 17, 2016. The classification was applicable on July 27, 2016.

FOR FURTHER INFORMATION CONTACT: Jennifer Piselli, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 1561, Silver Spring, MD, 20993–0002, 240–402–6646, *jennifer.piselli@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On June 25, 2015, Micro Interventional Devices, Inc. submitted a request for classification of the Permaseal Device under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies 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 to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on July 27, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 870.4510.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an apical closure device will need to comply with the special controls named in this final administrative order.

The device is assigned the generic name apical closure device, and it is identified as a prescription device consisting of a delivery system and implant component that is used for soft tissue approximation of cardiac apical tissue during transcatheter valve replacement procedures.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1: