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**Matthew S. Borman,**  
Deputy Assistant Secretary for Export  
Administration.

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## DEPARTMENT OF LABOR

### Employment and Training Administration

#### 20 CFR Part 641

[Docket No. ETA-2022-0002]

RIN 1205-AC04

#### Senior Community Service Employment Program Conforming Changes to the Supporting Older Americans Act of 2020—Updated Guidance on Priority of Service, Durational Limits and State Plan Submissions

**AGENCY:** Employment and Training  
Administration, Labor.

**ACTION:** Direct final rule; technical  
amendments.

**SUMMARY:** The Employment and Training Administration (ETA) of the Department of Labor (Department) is issuing this direct final rule (DFR) amending the Senior Community Service Employment Program (SCSEP) regulations to conform with changes in the Supporting Older Americans Act of 2020 regarding individuals who have been incarcerated within the last 5 years. Consistent with the Act, the rule adds this category of individuals to the priority groups; adds this category of individuals to the list of categories grantees may choose from to make eligible for increased periods of participation; includes people in this category within the definition of the term "individuals with barriers to employment"; and requires that grantees identify and report on the relative distribution of these individuals in the State Plan.

**DATES:** This DFR is effective April 15, 2022 without further action unless significant adverse comment is submitted by March 16, 2022. If the Department receives significant adverse comment, the Agency will publish a timely withdrawal in the **Federal Register** informing the public that this

DFR will not take effect. Comments to this DFR must be submitted by March 16, 2022. All submissions must be made by the close of the comment period.

**ADDRESSES:** You may submit comments electronically identified by Regulatory Identification Number (RIN) 1205-AC04 by the following method:

*Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions on the website for submitting comments.

*Instructions:* Include the agency's name and docket number ETA-2022-0002 in your comments. All comments received will become a matter of public record and will be posted without change to <https://www.regulations.gov>. Please do not include any personally identifiable or confidential business information that you do not want publicly disclosed.

**FOR FURTHER INFORMATION CONTACT:** Steven Rietzke, Chief, Division of National Programs, Tools and Technical Assistance, Office of Workforce Investment, at 202-693-3980. (This is not a toll-free number.)

#### SUPPLEMENTARY INFORMATION:

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##### I. Background

The SCSEP, authorized by title V of the Older Americans Act of 1965 (OAA) and most recently reauthorized in 2020, is the only federally sponsored employment and training program targeted specifically to low-income, older individuals who want to enter or reenter the workforce. The program provides subsidized work experience training for low-income persons 55 years or older who are unemployed and have poor employment prospects. The dual goals of the program are to promote useful community service employment activities and to move SCSEP participants into unsubsidized employment so that they can achieve economic self-sufficiency.

In the Supporting Older Americans Act of 2020, Public Law 116-131 (the Act), Congress amended title V of the OAA to make certain changes to the

SCSEP that would take effect 1 year from the March 25, 2020, enactment of the Act, *i.e.*, March 25, 2021. First, the Act makes an individual who "has been incarcerated within the last 5 years or is under supervision following release from prison or jail within the last 5 years" eligible for priority of service over those individuals who meet only the basic SCSEP eligibility criteria related to age, income, and employment. Public Law 116-131, sec. 401(a)(3)(B)(iii); 42 U.S.C. 3056p(b)(2)(H). Second, the Act adds individuals who "have been incarcerated within the last 5 years or are under supervision following release from prison or jail within the last 5 years," to the list of categories for which the Department is required to authorize any SCSEP grantee to provide an increased period of participation if the relevant SCSEP grantee has made such a request. Public Law 116-131, sec. 401(a)(3)(A)(iii); 42 U.S.C. 3056p(a)(3)(B)(ii)(VI). Third, the Act revises the definition of "individuals with barriers to employment" to include "eligible individuals who have been incarcerated or are under supervision following release from prison or jail." Public Law 116-131, sec. 401(a)(2); 42 U.S.C. 3056l(e)(1). Finally, the Act requires State Plans to identify and address the relative distribution of "eligible individuals who have been incarcerated within the last 5 years or are under supervision following release from prison or jail within the last 5 years." Public Law 116-131, sec. 401(a)(1)(C); 42 U.S.C. 3056a(a)(4)(C)(v).

In this DFR, the Department is incorporating the statutory changes described above into the SCSEP program regulations at 20 CFR part 641.

##### II. Consideration of Comments

The Department will consider comment on issues related to this action. If the Department receives no significant adverse comment, the Department will publish a **Federal Register** document confirming the effective date of the DFR and withdrawing the companion notice of proposed rulemaking (NPRM) published elsewhere in this issue of the **Federal Register**. Such confirmation may include minor stylistic or technical changes to the DFR. For the purpose of

judicial review, the Department views the date of confirmation of the effective date of the DFR as the date of promulgation.

### III. Publication as a Direct Final Rule

In direct final rulemaking such as this, the Department is publishing a DFR which will go into effect unless the Department receives significant adverse comment within the comment period. The Department is also concurrently publishing a virtually identical NPRM. The Department plans to confirm the date that this DFR goes into effect through a separate **Federal Register** document. If the Department receives a significant adverse comment, it will withdraw this DFR and treat such comment as a response to the NPRM.

For purposes of this DFR, a significant adverse comment is one that explains: (1) Why the DFR is inappropriate, including challenges to its underlying premise or approach; or (2) why the DFR will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of this DFR, the Department will consider whether the comment raises an issue serious enough to warrant a substantive response. The Department will not consider a comment recommending an additional amendment to this regulation to be a significant adverse comment unless the comment states why the DFR would be ineffective without the addition.

In addition to publishing this DFR, the Department is publishing an NPRM in the **Federal Register**. The comment period for the NPRM runs concurrently with that of the DFR. The Department will treat comments received on the companion NPRM as comments on the DFR. Similarly, the Department will consider comments submitted to the DFR as comments to the companion NPRM. Therefore, if the Department receives a significant adverse comment on either this DFR or the NPRM, it will withdraw this DFR and proceed with the companion NPRM. In the event the Department withdraws the DFR because of significant adverse comment, the Department will consider all timely comments received in response to the DFR when it continues with the NPRM. After considering all comments to the DFR and the NPRM, the Department will decide whether to publish a new final rule or confirm the date that this DFR goes into effect through a separate **Federal Register** document.

The Department has determined that the subject of this rule is suitable for DFR because the Administrative Procedure Act authorizes an agency to issue a rule without notice and

comment when, as here, “the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. 553(b)(B). The Department for good cause finds that notice and comment rulemaking would be unnecessary because this DFR almost entirely makes conforming amendments to the SCSEP program regulations to align with changes required by the Act, which have already become effective. Accordingly, no significant adverse comments are anticipated.

### IV. Section-by-Section Discussion of Changes

The Department is making the following changes to implement the provisions of the Act. First, the Department is revising § 641.140 to define formerly incarcerated individuals as individuals who “were incarcerated at any point within the last 5 years,” or “were under supervision at any point within the last 5 years, following release from prison or jail.” The definition also specifies that the referenced 5-year period means the 5 years preceding the date of first determination of program eligibility, as described in § 641.505, for initial enrollment into the program. The current regulation does not include a definition of formerly incarcerated individuals, but the Department is defining the term in this DFR based upon language provided in the Act, which makes an individual who “has been incarcerated within the last 5 years or is under supervision following release from prison or jail within the last 5 years” eligible for priority enrollment. Public Law 116–131, sec. 401(a)(3)(B)(iii); 42 U.S.C. 3056p(b)(2)(H). The definition included in this DFR also contains an explanation of the meaning of the 5-year period specified in the Act in order to clarify the meaning of the phrase “within the last 5 years.” The Act is silent about how to calculate the 5-year period. The Department has determined that connecting this date to the individual’s possible participation in the SCSEP program aligns with the intent of the amendments and that using the “date of first determination of program eligibility” as described in § 641.505 provides a readily available date for grantees to reference when determining individuals’ eligibility for the program.

The Department is also revising § 641.140 to include “formerly incarcerated individuals” in the definition of “most-in-need.” The existing definition of most-in-need is

made up of all the categories of individuals for whom the grantees may request be made eligible for increased periods of participation (the list is at 42 U.S.C. 3056p(a)(3)(B)(ii)) and the categories of individuals who receive priority enrollment (the list in 42 U.S.C. 3056p(b)(2)). Under sec. 401(a)(3) of the Act, individuals eligible for increased periods of participation now include individuals who “have been incarcerated within the last 5 years or are under supervision following release from prison or jail within the last 5 years,” and the priority of service list now includes individuals who “ha[ve] been incarcerated within the last 5 years or [are] under supervision following release from prison or jail within the last 5 years.” Consistent with the Act’s addition of “formerly incarcerated individuals” to these two lists, the Department is adding “are formerly incarcerated as defined in this section” to the § 641.140 definition of “most-in-need.” For purposes of clarity, the Department also has restructured the definition of “most-in-need” to present the list of most-in-need individuals as a numbered list.

Similarly, based on amendments made in the Act, the Department is revising § 641.325(b) to comply with the Act’s requirement that the State Plan identify and address the relative distribution of “eligible individuals who have been incarcerated within the last 5 years or are under supervision following release from prison or jail within the last 5 years.” Public Law 116–131, sec. 401(a)(1)(C); 42 U.S.C. 3056a(a)(4)(C)(v). Currently, § 641.325(b) lists information that must be included in the State Plan, including the relative distribution of certain individuals eligible for the program. Pursuant to the Act’s requirement, see 42 U.S.C. 3056a(a)(4)(C)(v), the Department is revising § 641.325(b) to add “[e]ligible individuals who are formerly incarcerated individuals as defined in § 641.140” to the list of eligible individuals on whom the State Plan must provide information regarding relative distribution.

Additionally, the Department is revising §§ 641.420 and 641.520 to incorporate the Act’s requirement that eligible individuals who “[have] been incarcerated within the last 5 years or [are] under supervision following release from prison or jail within the last 5 years” receive priority enrollment. Public Law 116–131, sec. 401(a)(3)(B)(iii); 42 U.S.C. 3056p(b)(2)(H). Paragraphs (a)(1) through (8) of § 641.520 list the characteristics that grantees and sub-recipients must consider when

determining whether to provide eligible individuals with priority. Pursuant to the Act, see 42 U.S.C. 3056p(b)(2)(H), the Department is revising this list to include new paragraph (a)(9), which provides priority to individuals who are formerly incarcerated individuals, as defined in § 641.140. Accordingly, the Department is also making a minor technical change to § 641.420(e) to update the reference to § 641.520(a) to account for the addition of paragraph (a)(9) in § 641.520.

The Department is also revising §§ 641.570 and 641.710 to integrate the Act's requirement that the Secretary authorize a grantee to increase the period of participation for individuals who "have been incarcerated within the last 5 years or are under supervision following release from prison or jail within the last 5 years." Public Law 116–131, sec. 401(a)(3)(A)(iii); 42 U.S.C. 3056p(a)(3)(B)(ii)(VI). Existing SCSEP regulations at § 641.570(b) list the categories of individuals for whom the Department will provide increased periods of participation if requested by the grantee. Pursuant to the Act, the Department has added new paragraph (b)(6), which states that individuals who are formerly incarcerated individuals, as defined in § 641.140 are, upon a grantee's request, eligible for an extended period of individual participation. Additionally, existing SCSEP regulations at § 641.710 define core performance measures, including "service to the [m]ost-in-need" (§ 641.710(g)). Consistent with the change to the most-in-need definition at § 641.140, discussed above, the Department has added new paragraph at § 641.710(g)(14) to include individuals who "[a]re formerly incarcerated individuals as defined in § 641.140" to the list of individuals characterized as most-in-need. See Public Law 116–131, sec. 401(a)(3); 42 U.S.C. 3056p(a)(3)(B)(ii)(IV), (b)(2)(H).

Finally, sec. 401(a)(2) of the Act revises the definition of "individuals with barriers to employment" in the OAA to include "eligible individuals who have been incarcerated or are under supervision following release from prison or jail." Public Law 116–131, sec. 401(a)(2); 42 U.S.C. 3056l(e)(1). This section of the OAA requires certain national SCSEP grantees to give special consideration to selecting subgrantee organizations with demonstrated expertise in serving individuals with barriers to employment. Paragraph (d) of § 641.881(d) is the corresponding regulatory provision to implement this section of the OAA, stating that for purposes of this section, the term "individuals with barriers to

employment" includes "minority individuals, Indian individuals, individuals with greatest economic need, and most-in-need individuals." The Department notes that because the existing regulatory text in § 641.881(d) references "most-in-need individuals," the regulatory text does not require change to align with the Act. The changes explained above that add formerly incarcerated individuals to the most-in-need definition at § 641.140 and to the list of most-in-need individuals at § 641.710(g) have the effect of including formerly incarcerated individuals in the reference to most-in-need individuals in the existing definition of barriers to employment at § 641.881(d)(2).

## V. Rulemaking Analyses and Notices

### *Regulatory Flexibility Analysis, Executive Order 13272, Small Business Regulatory Enforcement Fairness Act*

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, requires the Department to evaluate the economic impact of this rule with regard to small entities. The RFA defines small entities to include small businesses, small organizations including not-for-profit organizations, and small governmental jurisdictions. The Department must determine whether the rule imposes a significant economic impact on a substantial number of such small entities.

There are 77 SCSEP grantees; 50 of these are States and are not small entities as defined by the RFA. Six grantees are governmental jurisdictions other than States (four grantees are territories, such as Guam; one grantee is Washington, DC; and another grantee is Puerto Rico). Governmental jurisdictions must have a population of less than 50,000 to qualify as a small entity for RFA purposes and the population of these 6 SCSEP grantees each exceeds 50,000. The remaining 21 grantees are non-profit organizations, which includes some large, national non-profit organizations.

The Department has determined that this DFR will impose a negligible additional burden on small entities. SCSEP grantees already review their policies on a regular basis to align with guidance and the activities related to this DFR will only add one more item to consider during these activities. SCSEP grantees also already determine eligibility on a regular basis and the additional population category is only an additional factor to consider. Whatever negligible costs that the new regulation requires of SCSEP grantees is covered by SCSEP administrative costs

and programmatic activity costs funding.

The Department certifies that this DFR does not impose a significant economic impact on a substantial number of small entities.

### *Executive Orders 12866 and 13563*

Under Executive Order (E.O.) 12866, Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs determines whether a regulatory action is significant and, therefore, subject to the requirements of the Executive order and review by OMB. 58 FR 51735 (Oct. 4, 1993).

Section 3(f) of E.O. 12866 defines a "significant regulatory action" as an action that is likely to result in a rule that: (1) Has an annual effect on the economy of \$100 million or more, or adversely affects in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as economically significant); (2) creates serious inconsistency or otherwise interferes with an action taken or planned by another agency; (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the E.O. *Id.* OMB has determined that this DFR is not a "significant regulatory action" under sec. 3(f) of E.O. 12866.

E.O. 13563 directs agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs; it is tailored to impose the least burden on society, consistent with achieving the regulatory objectives; and in choosing among alternative regulatory approaches, the agency has selected those approaches that maximize net benefits. E.O. 13563 recognizes that some benefits are difficult to quantify and provides that, where appropriate and permitted by law, agencies may consider and discuss qualitatively values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.

OMB waived review of this rulemaking because it is not a significant regulatory action.

### *Paperwork Reduction Act*

This DFR is not subject to the requirements of the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3501 *et seq.*) because it does not contain a collection of information as defined in 44 U.S.C. 3502(3). The

Department previously submitted to OMB revision requests to the three information collections affected by the statute in this DFR, which were subsequently approved by OMB. See Information Collection Request (ICR) Reference Numbers 202112–1205–003 (OMB Control Number 1205–0521), 202108–1205–007 (OMB Control Number 1205–0040), and 202103–1205–001 (OMB Control Number 1205–0448).

#### *Unfunded Mandates Reform Act*

For purposes of the Unfunded Mandates Reform Act of 1995, this rule does not include any Federal mandate that may result in increased expenditures by State, local, and tribal governments in the aggregate of more than \$100 million, or increased expenditures by the private sector of more than \$100 million.

#### *Executive Order 13132*

The Department has reviewed this rule in accordance with E.O. 13132 regarding federalism and has determined that it does not have “federalism implications.” The rule does not “have substantial direct effects on the States, on the relationship between the [N]ational [G]overnment and the States, or on the distribution of power and responsibilities among the various levels of government.” This DFR updates, defines, and implements eligibility requirements, waiver factors, and performance measures for the SCSEP. While States are SCSEP grantees, this rule merely makes minor changes to currently ongoing data collection processes. Requiring State grantees to implement these changes does not constitute a “substantial direct effect” on the States, nor will it alter the relationship or responsibilities between the Federal and State governments.

#### *Privacy Act*

The Privacy Act of 1974, 5 U.S.C. 552a, provides safeguards to individuals concerning their personal information that the Government collects. The Privacy Act requires certain actions by an agency that collects information on individuals when that information contains personally identifiable information, such as Social Security numbers (SSNs) or names. Because SCSEP participant records are maintained by SSN, the Privacy Act applies here.

A key concern is for the protection of participant SSNs. Grantees must collect the SSN in order to pay participants properly for their community service work in host agencies. When grantees send participant files to the Department for aggregation, the transmittal is

protected by secure encryption. When participant files are retrieved within the internet-based SCSEP data management system, only the last four digits of the SSN are displayed. Any information that is shared or made public is aggregated by grantee and does not reveal personal information on specific individuals.

The Department works diligently to ensure the highest level of security whenever personally identifiable information is stored or transmitted. All contractors that have access to individually identifying information are required to provide assurances that they will respect and protect the confidentiality of the data. The Department’s Office the Chief Information Officer has been an active participant in the development and approval of data security measures.

In addition to the above, the Department provides a Privacy Act Statement to grantees for distribution to all participants. The Department advised grantees of the requirement in Training and Employment Guidance Letter No. 39–11 (June 28, 2012). Participants receive this information when they meet with a caseworker or intake counselor. When the Department monitors the programs, implementation of this term is included in the reviews.

#### **Amended Regulatory Text**

##### **List of Subjects in 20 CFR Part 641**

Administrative practice and procedure, Aged, Employment, Equal employment opportunity, Government contracts, Grant programs—labor, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Department amends 20 CFR part 641 as follows:

#### **PART 641—PROVISIONS GOVERNING THE SENIOR COMMUNITY SERVICE EMPLOYMENT PROGRAM**

■ 1. The authority citation for part 641 is revised to read as follows:

**Authority:** 42 U.S.C. 3056–3056p.

##### **Subpart A—Purpose and Definitions**

■ 2. Amend § 641.140 by adding the definition of *Formerly incarcerated individuals* in alphabetical order and revising the definition of *Most-in-need* to read as follows:

##### **§ 641.140 What definitions apply to this part?**

\* \* \* \* \*

*Formerly incarcerated individuals* mean:

(1) Individuals who were incarcerated at any point within the last 5 years; or  
(2) Individuals who were under supervision at any point within the last 5 years, following release from prison or jail.

(3) The 5-year period specified in this definition refers to the 5 years preceding the date of first determination of program eligibility, as described in § 641.505, for initial enrollment into the program.

\* \* \* \* \*

*Most-in-need* means participants with one or more of the following characteristics (OAA sec. 513(b)(1)(F)):

- (1) Have a severe disability;
- (2) Are frail;
- (3) Are age 75 or older;
- (4) Are age-eligible but not receiving benefits under title II of the Social Security Act;
- (5) Reside in an area with persistent unemployment and have severely limited employment prospects;
- (6) Have limited English proficiency;
- (7) Have low literacy skills;
- (8) Have a disability;
- (9) Reside in a rural area;
- (10) Are veterans;
- (11) Have low employment prospects;
- (12) Have failed to find employment after using services provided under title I of the Workforce Innovation and Opportunity Act;
- (13) Are homeless or at risk for homelessness; or
- (14) Are “formerly incarcerated” as defined in this section.

\* \* \* \* \*

##### **Subpart C—The State Plan**

■ 3. Amend § 641.325 by revising paragraphs (b)(4) and (5) and adding paragraph (b)(6) to read as follows:

##### **§ 641.325 What information must be provided in the State Plan?**

\* \* \* \* \*

- (b) \* \* \*
  - (4) Eligible individuals who are limited English proficient;
  - (5) Eligible individuals who have the greatest social need; and
  - (6) Eligible individuals who are formerly incarcerated individuals as defined in § 641.140;

\* \* \* \* \*

##### **Subpart D—Grant Application and Responsibility Review Requirements for State and National SCSEP Grants**

■ 4. Amend § 641.420 by revising paragraph (e) to read as follows:

##### **§ 641.420 What are the eligibility criteria that each applicant must meet?**

\* \* \* \* \*

(e) An ability to move participants with multiple barriers to employment, including individuals described in § 641.570(b) or § 641.520(a)(2) through (9), into unsubsidized employment;

\* \* \* \* \*

#### Subpart E—Services to Participants

■ 5. Amend § 641.520 by revising the section heading and paragraphs (a)(7) and (8) and adding paragraph (a)(9) to read as follows:

**§ 641.520 Are there any priorities that grantees and sub-recipients must use in selecting eligible individuals for participation in the Senior Community Service Employment Program?**

(a) \* \* \*

(7) Have failed to find employment after using services provided through the one-stop delivery system;

(8) Are homeless or are at risk for homelessness; or

(9) Are formerly incarcerated individuals as defined in § 641.140. (OAA sec. 518(b).)

\* \* \* \* \*

■ 6. Amend § 641.570 by revising paragraphs (b)(4) and (5) and adding paragraph (b)(6) to read as follows:

**§ 641.570 Is there a time limit for participation in the program?**

\* \* \* \* \*

(b) \* \* \*

(4) Live in an area with persistent unemployment and are individuals with severely limited employment prospects;

(5) Have limited English proficiency or low literacy skills; or

(6) Are formerly incarcerated individuals as defined in § 641.140.

\* \* \* \* \*

#### Subpart G—Performance Accountability

■ 7. Amend § 641.710 by revising paragraphs (g)(12) and (13) and adding paragraph (g)(14) to read as follows:

**§ 641.710 How are the performance measures defined?**

\* \* \* \* \*

(g) \* \* \*

(12) Have failed to find employment after utilizing services provided under title I of the Workforce Innovation and Opportunity Act;

(13) Are homeless or at risk for homelessness; or

(14) Are formerly incarcerated individuals as defined in § 641.140.

Angela Hanks,

*Acting Assistant Secretary for Employment and Training, Labor.*

[FR Doc. 2022-02680 Filed 2-11-22; 8:45 am]

BILLING CODE 4510-FN-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 870

[Docket No. FDA-2021-N-0999]

#### Medical Devices; Cardiovascular Devices; Classification of the Adjunctive Predictive Cardiovascular Indicator

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

**ACTION:** Final amendment; final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the adjunctive predictive cardiovascular indicator 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 adjunctive predictive cardiovascular indicator'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 February 14, 2022. The classification was applicable on March 16, 2018.

**FOR FURTHER INFORMATION CONTACT:** Aneesh Deoras, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2564, Silver Spring, MD 20993-0002, 240-402-4363, [Aneesh.Deoras@fda.hhs.gov](mailto:Aneesh.Deoras@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Upon request, FDA has classified the adjunctive predictive cardiovascular indicator 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 (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.

We believe this De Novo classification will enhance patients' access to beneficial innovation. When FDA classifies a device into class I or II via the De Novo process, the device can