



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 24

RIN 0991-AC12

Silvio O. Conte Senior Biomedical Research and Biomedical Product

Assessment Service

AGENCY: Public Health Service, Assistant Secretary for Administration, Office of the Secretary, HHS

ACTION: Final rule.

SUMMARY: The U.S. Department of Health and Human Services (HHS) is issuing this final rule to amend regulations for the Senior Biomedical Research Service, a component of the Public Health Service. These amendments are necessary to ensure consistency with amendments made to the 21st Century Cures Act to improve scientific expertise and outreach within the Service

DATES: The rule is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Policy and Accountability Division, Office of Human Resources, Assistant Secretary for Administration, Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue S.W., Suite 801, Washington D.C. 20201.

SUPPLEMENTARY INFORMATION: The U.S. Department of Health and Human Services (HHS) is issuing this final rule to amend regulations under 42 CFR Part 24 for the Senior Biomedical Research Service, a component of the Public Health Service.

These amendments are necessary to ensure consistency with amendments made to section 228 of the Public Health Service Act (codified at 42 USC Sec. 237) by section 3071 of the 21st Century Cures Act to improve scientific expertise and outreach within the Service. HHS is publishing this final rule without previously publishing a proposed rule because HHS has determined that the rule qualifies for exemption from notice-and-comment rulemaking under section 4 of the Administrative Procedure Act, 5 U.S.C. 553 (Pub. L. 79-404, enacted June 11, 1946) (APA), both because it is a “matter relating to agency management” under section 553(a)(2)¹ and a “rule of agency organization, procedure or practice” under section 553(b)(3)(A).

The Senior Biomedical Research Service (Service) was originally established in the Public Health Service by Section 304 of Public Law 101-509, adding section 228 to the Public Health Service Act (PHS Act). HHS promulgated regulations at 42 CFR Part 24 to implement section 228 of the PHS Act.

The purpose of the Service is to help recruit and retain individuals outstanding in the fields of biomedical research, clinical research evaluation, and biomedical product assessment without regard to the provisions of Title 5 of the U.S. Code concerning appointments. Section 228 of the PHS Act originally limited appointments to the Service to up to 500 members who are actively engaged in peer-reviewed original biomedical research and clinical research evaluation. Section 3071 of the 21st Century Cures Act, Public Law 114-255 amended section 228 of

¹ Although HHS's predecessor agency, the U.S. Department of Health, Education, and Welfare (HEW), waived the APA's exemption to the requirement for notice and comment rulemaking for “public property, loans, grants, benefits, or contracts” in section 553(a)(2), see “Public Participation in Rule Making,” 36 FR 2532 (Feb. 5, 1971), HEW did not waive the exemption in section 553(a)(2) for “matter[s] relating to agency management or personnel.”

the PHS Act, 42 U.S.C. Sec. 237, to revise the requirements of the Service. The purpose of those statutory amendments was to further enhance the Department's capacity to recruit and retain outstanding and qualified scientific and technical experts for the Service. Specific statutory changes affect matters such as: (1) renaming of the Service to be called the Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS); (2) increasing the number of members to up to 2,000; (3) extending eligibility requirements for appointments to include the field of biomedical product assessment, in addition to clinical research evaluation, and biomedical product assessment and expanding academic qualifications to include a doctoral or master's level degree in engineering, bioinformatics, or related or emerging fields, in addition to a doctoral-level degree in biomedicine or a related field; (4) increasing the maximum pay of members not to exceed the amount of annual compensation (excluding expenses) specified in 3 U.S.C. 102 and removing the requirement for presidential approval of certain pay rates; and (5) terminating the Secretary's discretion to make contributions to a retirement system of an institution of higher education on a member's behalf. This final rule updates the implementing regulations at 42 CFR part 24 to incorporate these statutory amendments along with other minor technical changes to clarify language of the existing regulations. The regulations may be supplemented by HHS personnel instructions.

Collection of Information Requirements

This final rule does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements.

Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*).

Regulatory Impact Analysis

HHS has examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (Public Law 96-354, enacted September 19, 1980) (RFA), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4, enacted March 22, 1995), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any one year).

This final rule is not “economically significant” within the meaning of section 3(f)(1) of Executive Order 12866 because it is unlikely to have an annual effect of \$100 million in any single year. In addition, for the reasons noted in this final rule, HHS does not believe that this final rule is a major rule under the Congressional Review Act.

The RFA requires agencies to analyze options for regulatory relief of small businesses. This rule would not have a significant impact on small businesses.

In addition, section 1102(b) of the Social Security Act requires HHS to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This rule would not have a significant impact on small rural hospitals because the amendments contained in this final rule do not pertain to hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by state, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately \$150 million. HHS anticipates this rule would not impact state governments or the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. HHS does not anticipate this rule would impose direct requirement costs on state or local governments, preempt state law, or otherwise have federalism implications.

Executive Order 13771 establishes certain requirements that an agency must meet when it promulgates new regulations. Pursuant to the Executive Order these implementing regulations are designated as “exempt.” They are specifically exempt under the terms of the Executive Order because they are administrative in nature,

namely because they relate to agency organization, management, or personnel issues. In this case the regulations implement statutory changes made to the authority to hire into the Senior Biomedical Research and Biomedical Product Assessment Service.

List of Subjects in 42 CFR part 24

Administrative practice and procedure, Employment, Public health, Scientists, Research

For the reasons set forth in the preamble, the Public Health Service is revising part 24 of title 42 of the Code of Federal Regulations to read as follows.

PART 24-SENIOR BIOMEDICAL RESEARCH AND BIOMEDICAL PRODUCT ASSESSMENT SERVICE

Sec.

24.1 Establishment, number of members, and purpose.

24.2 Allocation.

24.3 Policy board.

24.4 Eligibility.

24.5 Pay and compensation.

24.6 Performance appraisal system.

24.7 Inapplicability of provisions regarding appointments.

24.8 Removal from the Service.

24.9 Reporting.

Authority: 42 U.S.C. 237; Pub. L. 114-255, div. A, title III, sec. 3071, Dec. 19, 2016, 130 Stat. 1133; Section 228 of the Public Health Service Act; 5 U.S.C.

301.

§ 24.1 Establishment, number of members, and purpose.

(a) There is established in the Public Health Service the Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS or Service) consisting of members the maximum number of which is prescribed by law. The purpose of the Service is to recruit and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment.

(b) The Secretary may not use the authority in paragraph (a) of this section to reduce the number of employees serving in any other employment system to offset the number of members within the Service.

§ 24.2 Allocation.

(a) The Secretary shall determine the number of SBRBPAS slots to be allocated to each participating operating division, taking into account the need for such expertise within the operating division.

(b) The SBRBPAS Policy Board may advise the Secretary regarding adjustments to the allocation of slots at any time.

(c) SBRBPAS appointments shall be made judiciously in supporting the recruitment and retention of outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment.

(d) The Secretary will ensure that SBRBPAS assignments are used primarily in support of high priority programs authorized by Congress and which directly support the goals and priorities of the Department in the areas of biomedical research, clinical

research evaluation or biomedical product assessment.

§ 24.3 Policy Board.

The Secretary, or designee, may establish an SBRBPAS Policy Board to serve in an advisory capacity, recommending allocation of SBRBPAS slots among the participating operating divisions; assessing the administration of the SBRBPAS and ensuring consistent application of regulations, policies, and procedural guidelines; and recommending to the Secretary, or designee, changes to the Service as warranted. Membership will include representatives from the Office of the Assistant Secretary for Administration and representatives from the operating divisions which use the Service. The Secretary, or designee, shall determine the number of Board members; select the individual members, including the chairperson; and decide the length of service of each Board position.

§ 24.4 Eligibility.

(a) No individual may be appointed to the SBRBPAS unless such individual:

(1) Has earned a doctoral level degree in biomedicine or a related field, or a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field; and

(2) Meets the qualification standards prescribed by the Office of Personnel Management for appointment to a position at GS-15 of the General Schedule.

(b) Individuals eligible under paragraph (a) of this section shall be experts outstanding in the field of biomedical research, clinical research evaluation, or biomedical product assessment. The criteria in paragraphs (c) through (e) of this section are indicators that the individual is considered an expert outstanding in their

respective field.

(c) An individual will be considered an expert outstanding in biomedical research when the individual is actively engaged in original biomedical research, including behavioral research, and whose work in this area is considered by recognized experts or peers to be outstanding. One or more of the following achievements will indicate the individual has been recognized by experts or peers as outstanding:

(1) Conducted original research that has been published in peer-reviewed journals of high stature;

(2) Received major prizes and awards (such as visiting professorships and named lectureships) in recognition of original contributions to research;

(3) Received invitations to speak at or to chair major national or international meetings or symposia;

(4) Been elected to membership in professional societies of high stature; or

(5) Meet other criteria demonstrating sufficient rigor or accomplishment in a field that is relevant and necessary to the accomplishment of the agency's mission.

(d) An individual will be considered an expert outstanding in Clinical Research Evaluation when the individual is actively engaged in clinical research evaluation and is considered by recognized experts or peers to be outstanding. One or more of the following achievements will indicate the individual has been recognized by experts or peers as outstanding:

(1) Significant experience dealing with complex, precedent-setting evaluation issues, including those arising during product development, that involved significant scientific controversy, had far reaching implications for clinical research or resulted in

a widespread economic effect in the health-care delivery system;

(2) Taken an active role in the development of significant scientific or regulatory guidelines for clinical research evaluation;

(3) Been the recipient of invitations to speak at or to chair major national or international meetings and symposia; or

(4) Meet other criteria demonstrating sufficient rigor or accomplishment in a field that is relevant and necessary to the accomplishment of the agency's mission.

(e) An individual will be considered an expert outstanding in biomedical product assessment when an individual is actively engaged in the development or assessment of biomedical products and whose work in this area is considered by recognized experts or peers to be outstanding. One or more of the following achievements will indicate the individual has been recognized by experts or peers as outstanding.

(1) Significant experience dealing with complex, precedent-setting evaluation, scientific policies or development issues (e.g., those associated with novel biomedical products, novel approaches to biomedical product- manufacturing, or use of novel evaluation methods);

(2) Demonstrated cutting-edge expertise in a scientific or technical discipline critical to design, development, manufacturing, clinical performance assessment, or other technical aspects of effective oversight of biomedical products;

(3) Played a leadership role in planning and conducting public meetings to seek public input and communicate regulatory scientific policies;

(4) Been the recipient of invitations to speak at or to chair major national or international meetings and symposia; or

(5) Meet other criteria demonstrating sufficient rigor or accomplishment in an activity or field that is relevant and necessary to the accomplishment of the agency's mission.

§ 24.5 Pay and compensation.

The Service is an ungraded system, with a single flexible pay range to include all members.

(a) Pay of SBRBPAS members is determined by the Secretary. A member's pay shall not be less than the minimum rate payable for GS-15 of the General Schedule and shall not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3 of the U.S. Code. Although the full pay range will be implemented, pay at the higher end of the range will be used only as needed to recognize individual scientific value and expertise as is necessary to recruit and retain exceptionally well-qualified scientists and technical experts.

(b) The following factors will be used in setting pay for individual members:

- (1) Impact of the individual on the field of biomedical research, clinical research evaluation, or biomedical product assessment;
- (2) Recognition of the individual by his or her peers in the respective field;
- (3) Originality of the individual's ideas or work products;
- (4) Specific clinical or highly technical skills of the individuals which are of benefit to the agency and which are in addition to requirements of the basic scientific assignment;
- (5) The individual's earnings and monetary benefits; and
- (6) Other relevant factors.

(c) Annual adjustments to pay rates may be made effective on the first day of the first pay period on or after January 1 of each calendar year. The rate of such adjustments will be at the discretion of the Secretary, or designee, except that the minimum rate payable in the SBRBPAS will be increased to the amount of the minimum rate of the GS-15 of the General Schedule.

(d) Other pay adjustments may be made by the Secretary or designee on an individual basis.

(e) New appointees to the SBRBPAS, who are not covered by the Civil Service Retirement System, will be covered by the Federal Employees Retirement System.

§ 24.6 Performance appraisal system.

The members of the Service shall be subject to a performance appraisal system that is designed to encourage excellence in performance and shall provide for periodic and systematic assessment of the performance of members.

§ 24.7 Inapplicability of provisions regarding appointments.

(a) Appointments to the Service shall be made without regard to the provisions of title 5 of the U.S. Code regarding appointments.

(b) Members of the Service shall not be covered by the following provisions of title 5 of the U.S. Code:

(1) Subchapter I of chapter 35 (relating to retention preference in the event of reduction in force);

(2) Chapter 43 (relating to performance appraisal and performance-based actions);

- (3) Chapter 51 (relating to classification);
- (4) Subchapter III of chapter 53 (relating to General Schedule pay rates); and
- (5) Chapter 75 (relating to adverse actions).

§ 24. 8 Removal from the Service.

(a) A member of the Service may be subject to disciplinary action, including removal from the Service, for substandard performance of duty as a member of the service, for misconduct, for reasons of national security or for other reasons as determined by the Secretary.

(b) A member for whom disciplinary action is proposed is entitled to:

(1) Written notice of the proposed action and the basis therefor;

(2) A reasonable opportunity to answer the notice of proposed action both orally and in writing;

(3) The right to be represented by an attorney or other representative in making such answer; and

(4) A written decision on the proposal.

(c) The decision may be made by an official with delegated authority to take such action, but in no case may the official be at a level below the head of the Operating Division where the member is assigned.

(d) A member who is separated from the Service involuntarily and without cause and who, immediately prior to his appointment to the Service, was a career appointee in the civil service or the Senior Executive Service, may be appointed to a position in the competitive civil service at grade GS-15 of the General Schedule. Such an appointment

may be made by the Secretary or his/her designee without regard to the provisions of title 5, U.S. Code regarding appointments in the civil service.

(e) A member who is separated from the Service involuntarily and without cause and who, immediately prior to appointment to the Service, was not a career appointee in the civil service or the Senior Executive Service may be appointed to a position in the excepted civil service at grade GS-15 of the General Schedule for a period not to exceed two years.

(f) There shall be no right to further review of the final decision on a disciplinary action. At his/her discretion, the Secretary may review an action taken under this section and may reduce, suspend, or overrule the action taken.

(g) A member of the Service may be removed from the Service for such other reasons as may be prescribed by the Secretary.

§ 24.9 Reporting.

(a) No later than May 1, 2020, and annually thereafter, each participating operating division shall submit to the Secretary a report of its implementation of the SBRBPAS authority in accordance with the Agency's policy requirements.

(b) At his or her discretion, the Secretary may use the information provided in the report under paragraph (a) of this section to inform the work of the Policy Board, including allocation of SBRBPAS slots.

Scott W. Rowell,
Assistant Secretary for Administration.

Approved: April 2, 2020.

Alex M. Azar II,
Secretary,

Department of Health and Human Services.

[FR Doc. 2020-07367 Filed: 4/17/2020 8:45 am; Publication Date: 4/20/2020]