

Public Health Service, HHS

§ 24.2

§ 23.12 Who will supervise and control the assigned personnel?

Assigned National Health Service Corps personnel will at all times remain under the direct supervision and control of the Secretary. Observance of institutional rules and regulations by the assigned personnel is a mere incident of the performance of their Federal functions and does not alter their direct professional and administrative responsibility to the Secretary.

§ 23.13 What nondiscrimination requirements apply to National Health Service Corps sites?

National Health Service Corps sites are advised that in addition to complying with the terms and conditions of this regulation, the following laws and regulations are applicable—

(a) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) and its implementing regulations, 45 CFR part 80 (prohibiting discrimination in federally assisted programs on the grounds of race, color, or national origin); and

(b) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and its implementing regulations, 45 CFR part 84 (prohibiting discrimination in federally assisted programs on the basis of handicap).

(c) The Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*) and its implementing regulations, 45 CFR part 91 (prohibiting nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance).

[45 FR 12790, Feb. 27, 1980, as amended at 49 FR 38109, Sept. 27, 1984]

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.

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§ 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:

Public Health Service, HHS

§ 24.7

(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

42 CFR Ch. I (10–1–25 Edition)

§ 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.