1993—Subsec. (a). Pub. L. 103–43, §1701(1), inserted '', acting through the Director of NIH,'' after ''Secretary shall'' and struck out '', except for the purposes of the Ethics in Government Act and the Technology Transfer Act,'' after ''shall not''.

Subsec. (b). Pub. L. 103–43, §1701(3), added subsec. (b) and struck out heading and text of former subsec. (b). Text related to duties of Foundation.

Subsec. (c). Pub. L. 103–43, §1701(3), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 103–43, §1701(2), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (f).

Subsec. (d)(1). Pub. L. 103–43, §1701(4)(A), substituted ''appointed members of the Board'' for ''members of the Foundation'' in subpar. (A), ''Board'' for ''Council'' in subpar. (B), and ''appoint to the Board'' for ''appoint to the Council'' in subpar. (C), and added subpars. (D) to (G).

Subsec. (d)(2). Pub. L. 103–43, §1701(4)(B), designated existing provisions as subpar. (A), substituted ''an individual to serve as the initial Chair'' for ''an appointed member of the Board to serve as the Chair'', and added subpar. (B).

Subsec. (d)(3)(A). Pub. L. 103–43, §1701(4)(C), substituted ''(1)(C)'' for ''(2)(C)''.

Subsec. (d)(5), (6). Pub. L. 103–43, §1701(4)(D), added pars. (5) and (6).

Subsec. (e). Pub. L. 103–43, §1701(2), redesignated subsec. (e) as (g).

Subsecs. (f) to (h). Pub. L. 103–43, §1701(2), redesignated subsecs. (d) to (f) as (f) to (h), respectively. Former subsecs. (g) and (h) redesignated (i) and (j), respectively.

Subsec. (i). Pub. L. 103–43, §1701(2), redesignated subsec. (g) as (i). Former subsec. (i) redesignated (m).

Subsec. (i)(4). Pub. L. 103–43, §1701(5)(A), inserted before period at end '', and define the duties of the officers and employees''.

Subsec. (i)(5), (6). Pub. L. 103–43, §1701(5)(B), (C), redesignated par. (6) as (5) and struck out former par. (5) which read as follows: ''prescribe by its Board its bylaws, that shall be consistent with law, and that shall provide for the manner in which—

''(A) its officers, employees, and agents are selected;

''(B) its property is acquired, held, and transferred;

''(C) its general operations are to be conducted; and

''(D) the privileges granted by law are exercised and enjoyed;''.

Subsec. (i)(7). Pub. L. 103–43, §1701(5)(C), (D), redesignated par. (8) as (7) and substituted ''part'' for ''subtitle''. Former par. (7) redesignated (6).

Subsec. (i)(8). Pub. L. 103–43, §1701(5)(C), (E), redesignated par. (9) as (8) and substituted ''establish a process for the selection of candidates for positions under subsection (c)'' for ''establish a mechanism for the selection of candidates, subject to the approval of the Director of the National Institutes of Health, for the endowed scientific positions within the organizational structure of the intramural research programs of the National Institutes of Health and candidates for participation in the National Institutes of Health Scholars program''.

Subsec. (i)(9), (10). Pub. L. 103–43, §1701(5)(C), redesignated pars. (10) and (11) as (9) and (10), respectively. Former par. (9) redesignated (8).

Subsec. (i)(11). Pub. L. 103–43, §1701(5)(C), (F), redesignated par. (12) as (11) and inserted ''solicit'' before ''accept''. Former par. (11) redesignated (10).

Subsec. (i)(12), (13). Pub. L. 103–43, §1701(5)(C), redesignated pars. (13) and (14) as (12) and (13), respectively. Former par. (12) redesignated (11).

Subsec. (i)(14). Pub. L. 103–43, §1701(5)(G), (H), added par. (14). Former par. (14) redesignated (13).

Subsec. (i)(15). Pub. L. 103–43, §1701(5)(I), substituted ''part'' for ''subtitle''.

Subsec. (j). Pub. L. 103–43, §1701(2), redesignated subsec. (h) as (j).

Subsecs. (k), (*l*). Pub. L. 103–43, §1701(6), added subsecs. (k) and (*l*).

Subsec. (m). Pub. L. 103–43, §1701(7), amended heading and text of subsec. (m) generally. Prior to amendment, text read as follows:

''(1) AUTHORIZATION OF APPROPRIATIONS.—Subject to paragraph (2), for the purpose of carrying out this part, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1995.

''(2) LIMITATIONS.—

''(A) Amounts appropriated under paragraph (1) or made available under subparagraph (C) may not be provided to the fund established under subsection (b)(1)(A) of this section.

''(B) For the first fiscal year for which amounts are appropriated under paragraph (1), $200,000 is authorized to be appropriated.

''(C) With respect to the first fiscal year for which amounts are appropriated under paragraph (1), the Secretary may, from amounts appropriated for such fiscal year for the programs of the Department of Health and Human Services, make available not more than $200,000 for carrying out this part, subject to subparagraph (A).''

Pub. L. 103–43, §1701(2), redesignated subsec. (i) as (m).

Subsec. (n). Pub. L. 103–43, §1701(8), added subsec. (n).

1992—Subsec. (g)(9). Pub. L. 102–321 struck out ''or the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration'' after ''Director of the National Institutes of Health'' and ''and the Alcohol, Drug Abuse, and Mental Health Administration'' after ''research programs of the National Institutes of Health''.

1991—Subsec. (c)(1)(C). Pub. L. 102–170, §216(1), substituted ''11'' for ''9''.

Subsec. (c)(1)(C)(iii). Pub. L. 102–170, §216(2), substituted ''5'' for ''3''.

Statutory Notes and Related Subsidiaries

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

PART J—ADVANCED RESEARCH PROJECTS AGENCY–HEALTH

§ 290c. Advanced Research Projects Agency–Health

(a) Establishment

(1) In general

There is established within the National Institutes of Health the Advanced Research

Projects Agency–Health (referred to in this section as ''ARPA–H''). Not later than 180 days after December 29, 2022, the Secretary shall transfer all functions, personnel, missions, activities, authorities, and funds of the Advanced Research Projects Agency for Health as in existence on December 29, 2022, to ARPA–H established by the preceding sentence.

(2) Organization

(A) In general

There shall be within ARPA–H—

(i) an Office of the Director;

(ii) not more than 8 program offices; and

(iii) such special project offices as the Director may establish.

(B) Requirement

Not fewer than two-thirds of the program offices of ARPA–H shall be exclusively dedicated to supporting research and development activities, consistent with the goals and functions described in subsection (b).

(C) Notification

The Director shall submit a notification to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives if the Director determines that additional program offices are required to carry out this section.

(3) Exemption from certain policies of NIH

(A) In general

Except as otherwise provided for in this section, and subject to subparagraph (B), in establishing ARPA–H pursuant to paragraph (1), the Secretary may exempt ARPA–H from policies and requirements of the National Institutes of Health that are in effect on the day before December 29, 2022, as necessary and appropriate to ensure ARPA–H can most effectively achieve the goals described in subsection (b)(1).

(B) Notice

Not later than 90 days after December 29, 2022, the Secretary shall publish a notice in the Federal Register describing the specific policies and requirements of the National Institutes of Health from which the Secretary intends to exempt ARPA–H, including a rationale for such exemptions.

(b) Goals and functions

(1) Goals

The goals of ARPA–H shall be to—

(A) foster the development of novel, breakthrough, and broadly applicable capabilities and technologies to accelerate transformative innovation in biomedical science and medicine in a manner that cannot be readily accomplished through traditional Federal biomedical research and development programs or commercial activity;

(B) revolutionize the detection, diagnosis, mitigation, prevention, treatment, and cure of diseases and health conditions by overcoming long-term and significant technological and scientific barriers to developing transformative health technologies;

(C) promote high-risk, high-reward innovation to enable the advancement of transformative health technologies; and

(D) contribute to ensuring the United States—

(i) pursues initiatives that aim to maintain global leadership in science and innovation; and

(ii) improves the health and wellbeing of its citizens by supporting the advancement of biomedical science and innovation.

(2) Functions

ARPA–H shall achieve the goals specified in paragraph (1) by addressing specific scientific or technical questions by involving high-impact transformative, translational, applied, and advanced research in relevant areas of science, by supporting—

(A) discovery, identification, and promotion of revolutionary advancements in science;

(B) translation of scientific discoveries into transformative health technologies with potential application for biomedical science and medicine;

(C) creation of platform capabilities that draw on multiple disciplines;

(D) delivery of proofs of concept that demonstrate meaningful advances with potential clinical application;

(E) development of new capabilities and methods to identify potential targets and technological strategies for early disease detection and intervention, such as advanced computational tools and predictive models; and

(F) acceleration of transformational health technological advances in areas with limited technical certainty.

(c) Director

(1) In general

The President shall appoint a director of ARPA–H (in this section referred to as the ''Director'').

(2) Qualifications

The Director shall be an individual who, by reason of professional background and experience—

(A) is especially qualified to advise the Secretary on, and manage—

(i) research and development programs; and

(ii) large-scale, high-risk initiatives with respect to health research and technology development across multiple sectors, including identifying and supporting potentially transformative health technologies; and

(B) has a demonstrated ability to identify and develop partnerships to address strategic needs in meeting the goals described in subsection (b)(1).

(3) Reporting

The Director shall report to the Secretary of Health and Human Services.

(4) Duties

The duties of the Director shall include the following:

(A) Establish strategic goals, objectives, and priorities for ARPA–H to advance the goals described in subsection (b)(1).

(B) Approve the projects and programs of ARPA–H and restructure, expand, or terminate any project or program within ARPA–H that is not achieving its goals.

(C) Develop funding criteria and assess the success of programs through the establishment of technical milestones.

(D) Request that applications for funding disclose current and previous research and development efforts related to such applications, as appropriate, and identify any challenges associated with such efforts, including any scientific or technical barriers encountered in the course of such efforts or challenges in securing sources of funding, as applicable.

(E) Coordinate with the heads of relevant Federal departments and agencies to facilitate sharing of data and information, as applicable and appropriate, and ensure that research supported by ARPA–H is informed by and supplements, not supplants, the activities of such departments and agencies and is free of unnecessary duplication of effort.

(F) Ensure ARPA–H does not provide funding for a project unless the program manager determines that the project aligns with the goals described in subsection (b)(1).

(G) Prioritize investments based on considerations such as—

(i) scientific opportunity and potential impact, especially in areas that fit within the strategies and operating practices of ARPA–H and require public-private partnerships to effectively advance research and development activities; and

(ii) the potential applications that an innovation may have to address areas of currently unmet need in medicine and health, including health disparities and the potential to prevent progression to serious disease.

(H) Encourage strategic collaboration and partnerships with a broad range of entities, which may include institutions of higher education, minority-serving institutions (defined, for the purposes of this section, as institutions and programs described in section 1063b(e)(1) of title 20 and institutions described in section 1067q(a) of title 20), industry, nonprofit organizations, Federally funded research and development centers, or consortia of such entities.

(5) Term

Notwithstanding section 284(a)(2) of this title, the Director—

(A) shall be appointed for a 4-year term; and

(B) may be reappointed for 1 consecutive 4-year term.

(6) Autonomy of Agency regarding recommendations and testimony

No office or agency of the United States shall have authority to require the Director to submit legislative recommendations, or testimony or comments on legislation, to any officer or agency of the United States for approval, comments, or review prior to the submission of such recommendations, testimony or comments to Congress, if such recommendations, testimony, or comments to Congress include a statement indicating that the views expressed therein are those of the Director and do not necessarily reflect the views of the President or another Federal department, agency, or office.

(7) Deputy Director

The Director shall appoint a Deputy Director to serve as the principal assistant to the Director.

(8) Nonapplication of certain provision

The restrictions contained in section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note) related to consultants and individual scientists appointed for limited periods of time shall not apply to the Director appointed under this subsection.

(d) Application of certain flexibilities

The flexibilities provided to the National Institutes of Health under section 241(g) of this title shall apply to ARPA–H with respect to the functions described in subsection (b)(2).

(e) Protection of information

(1) No authorization for disclosure

Nothing in this section shall be construed as authorizing the Director to disclose any information that is a trade secret or other privileged or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(2) Reporting

If there have been requests under section 522[1] of title 5 or the Secretary has used such authority to withhold information within the preceding year, not later than 1 year after December 29, 2022, and annually thereafter, the Director shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on—

(A) the number of instances in which the Secretary has used the authority under this subsection to withhold information from disclosure; and

(B) the nature of any request under section 552 of title 5 or section 1905 of title 18 that was denied using such authority.

(3) Clarification

The protections for trade secrets or other privileged or confidential information described in paragraph (1) shall not be construed to limit the availability or disclosure of information necessary to inform and facilitate the evaluation required under subsection (k)(2). Any such information made available to members of the National Academies of Sciences,

[1] So in original. Probably should be ''section 552''.

Engineering, and Medicine (referred to in this section as the ''National Academies'') for such evaluation shall be kept confidential by such members and shall not be used for any purposes other than informing and facilitating the evaluation required under subsection (k)(2).

(f) Cooperation with the Food and Drug Administration

(1) In general

In order to facilitate the enhanced collaboration and communication with respect to the most current priorities of ARPA–H, the Food and Drug Administration may meet with ARPA–H and any other Federal partners at appropriate intervals to discuss the development status, and actions that may be taken to facilitate the development, of medical products and projects that are the highest priorities to ARPA–H.

(2) Reimbursement

Utilizing interagency agreements or other appropriate resource allocation mechanisms available, the Director shall reimburse, using funds made available to ARPA–H, the Food and Drug Administration, as appropriate, for activities identified by the Commissioner of Food and Drugs and the Director as being conducted by the Food and Drug Administration under the authority of this subsection.

(g) Awards

(1) In general

In carrying out this section, the Director may—

(A) award grants and cooperative agreements, which shall include requirements to publicly report indirect facilities and administrative costs, broken out by fixed capital costs, administrative overhead, and labor costs;

(B) award contracts, which may include multi-year contracts subject to section 3903 of title 41;

(C) award cash prizes, utilizing the authorities and processes established under section 3719 of title 15; and

(D) enter into other transactions, as defined by section 247d–7e(a)(3) of this title, subject to paragraph (2).

(2) Limitations on entering into other transactions

(A) Use of competitive procedures

To the maximum extent practicable, competitive procedures shall be used when entering into other transactions under this section.

(B) Written determination required

The authority of paragraph (1)(D) may be exercised for a project if the program manager—

(i) submits a request to the Director for each individual use of such authority before conducting or supporting a program, including an explanation of why the use of such authority is essential to promoting the success of the project;

(ii) receives approval for the use of such authority from the Director; and

(iii) for each year in which the program manager has used such authority in accordance with this paragraph, submits a report to the Director on the activities of the program related to such project.

(3) Exemptions from certain requirements

Research funded by ARPA–H shall not be subject to the requirements of section 284a(a)(3)(A)(ii) of this title or section 289a of this title.

(h) Facilities authority

(1) In general

The Director is authorized, for administrative purposes, to—

(A) acquire (by purchase, lease, condemnation or otherwise), construct, improve, repair, operate, and maintain such real and personal property as are necessary to carry out this section; and

(B) lease an interest in property for not more than 20 years, notwithstanding section 1341(a)(1) of title 31.

(2) Locations

(A) In general

ARPA–H, including its headquarters, shall not be located on any part of the existing National Institutes of Health campuses.

(B) Number of locations

ARPA–H shall have offices or facilities in not less than 3 geographic areas.

(C) Considerations

In determining the location of each office or facility, the Director shall make a fair and open consideration of—

(i) the characteristics of the intended location; and

(ii) the extent to which such location will facilitate advancement of the goals and functions specified in subsection (b).

(i) Personnel

(1) In general

The Director may—

(A) appoint and remove scientific, engineering, medical, and professional personnel, which may include temporary or term-limited appointments as determined by the Director to fulfill the mission of ARPA–H, without regard to any provision in title 5 governing appointments and removals under the civil service laws;

(B) notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, fix the base pay compensation of such personnel at a rate to be determined by the Director, up to the amount of annual compensation (excluding expenses) specified in section 102 of title 3; and

(C) contract with private recruiting firms for assistance in identifying highly qualified candidates for technical positions needed to carry out this section.

(2) Support staff

The Director may use authorities in existence on December 29, 2022, that are provided to

the Secretary to hire administrative, financial, clerical, and other staff necessary to carry out functions that support the goals and functions described in subsection (b).

(3) Number of personnel

The Director may appoint not more than 210 personnel under this section. The Director shall submit a notification to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives if the Director determines that additional personnel are required to carry out this section.

(4) Clarification on previous positions

(A) In general

Except as provided in subparagraph (B), the Director shall ensure that the personnel who are appointed to staff or support ARPA–H are individuals who, at the time of appointment and for 3 years prior to such appointment, were not employed by the National Institutes of Health. The Director may grant an exemption only for individuals who are uniquely qualified, by way of professional background and expertise, to advance the goals and functions specified in subsection (b).

(B) Nonapplication of provision

The restriction provided under subparagraph (A) shall not apply to any individuals who are employed by ARPA–H on December 29, 2022.

(5) Additional considerations

In appointing personnel under this subsection, the Director—

(A) may contract with private entities for the purposes of recruitment services;

(B) shall make efforts to recruit a diverse workforce, including individuals underrepresented in science, engineering, and medicine, including racial and ethnic minorities, provided such efforts do not conflict with applicable Federal civil rights law, and individuals with a variety of professional experiences or backgrounds; and

(C) shall recruit program managers with demonstrated expertise in a wide range of scientific disciplines and management skills.

(6) Use of Intergovernmental Personnel Act

To the extent needed to carry out the authorities under paragraph (1) and the goals and functions specified in subsection (b), the Director may utilize hiring authorities under sections 3371 through 3376 of title 5.

(7) Authority to accept Federal detailees

The Director may accept officers or employees of the United States or members of the uniformed service on a detail from an element of the Federal Government, on a reimbursable or a nonreimbursable basis, as jointly agreed to by the heads of the receiving and detailing elements, for a period not to exceed 3 years.

(j) Program managers

(1) In general

The Director shall appoint program managers for 3-year terms (and may reappoint such program managers for 1 additional consecutive 3-year term) for the programs carried out by ARPA–H.

(2) Duties

A program manager shall—

(A) establish, in consultation with the Director, research and development goals for programs, including timelines and milestones, and make such goals available to the public;

(B) manage applications and proposals, through the appropriate officials, for making awards as described in subsection (g) for activities consistent with the goals and functions described in subsection (b);

(C) issue funding opportunity announcements, using uniform administrative processes, as appropriate;

(D) select, on the basis of merit, each of the projects to be supported under a program carried out by ARPA–H, and taking into consideration—

(i) the scientific, technical merit, and novelty of the proposed project;

(ii) the ability of the applicant to successfully carry out the proposed project;

(iii) the potential future commercial applications of the project proposed by the applicant, including whether such applications may have the potential to address areas of currently unmet need within biomedicine and improve health outcomes;

(iv) the degree to which the proposed project has the potential to transform biomedicine and addresses a scientific or technical question pursuant to subsection (b);

(v) the potential for the project to take an interdisciplinary approach; and

(vi) such other criteria as established by the Director;

(E) provide project oversight and management of strategic initiatives to advance the program, including by conducting project reviews not later than 18 months after the date of funding awards to identify and monitor progress of milestones with respect to each project and prior to disbursement of additional funds;

(F) provide recommendations to the Director with respect to advancing the goals and functions specified in subsection (b);

(G) encourage research collaborations and cultivate opportunities for the application or utilization of successful projects, including through identifying and supporting applicable public-private partnerships or partnerships between or among award recipients;

(H) provide recommendations to the Director to establish, expand, restructure, or terminate partnerships or projects; and

(I) communicate and collaborate with leaders and experts within the health care and biomedical research and development fields, including from both the public and private sectors and, as necessary, through the convening of workshops and meetings, to identify research and development gaps and opportunities and solicit stakeholder input on programs and goals.

(k) Reports and evaluation

(1) Annual report

(A) In general

Beginning not later than 1 year after December 29, 2022, as part of the annual budget request submitted for each fiscal year, the Director shall submit a report on the actions undertaken, and the results generated, by ARPA–H, including—

(i) a description of projects supported by ARPA–H in the previous fiscal year and whether such projects are meeting the goals developed by the Director pursuant to subsection (c)(4)(A);

(ii) a description of projects terminated in the previous fiscal year, and the reason for such termination;

(iii) a description of planned programs starting in the next fiscal year, pending the availability of funding;

(iv) activities conducted in coordination with other Federal departments and agencies;

(v) a description of any successes with, or barriers to, coordinating with other Federal departments and agencies to achieve the goals and functions under subsection (b);

(vi) aggregated demographic information, if available, of direct recipients and performers in funded projects and of the ARPA–H workforce (consistent with the reporting requirements under paragraph (3)); and

(vii) a summary of award recipient compliance with section 242v of this title.

(B) Submission to Congress

The report under subparagraph (A) shall be submitted to—

(i) the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives; and

(ii) the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate.

(2) Evaluation

(A) In general

Not later than 5 years after December 29, 2022, the Director shall seek to enter into an agreement with the National Academies under which the National Academies conducts an evaluation of whether ARPA–H is meeting the goals and functions specified in subsection (b).

(B) Submission of results

The agreement entered into under subparagraph (A) shall require the National Academies to submit the evaluation conducted under such agreement to the Director, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, and make the report publicly available.

(3) Reporting related to ARPA–H personnel

(A) In general

The Director shall establish and maintain records regarding the use of the authority under subsection (i)(1)(A), including—

(i) the number of positions filled through such authority;

(ii) the types of appointments of such positions;

(iii) the titles, occupational series, and grades of such positions;

(iv) the number of positions publicly noticed to be filled under such authority;

(v) the number of qualified applicants who apply for such positions;

(vi) the qualification criteria for such positions; and

(vii) the demographic information of individuals appointed to such positions.

(B) Reports to Congress

Not later than 2 years after December 29, 2022, and annually thereafter for each fiscal year in which such authority is used, the Director shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing the total number of appointments filled under subsection (i) within the fiscal year and how the positions relate to the goals and functions of ARPA–H.

(C) GAO report

Not later than 2 years after December 29, 2022, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the use of the authority provided under subsection (i)(1)(A). Such report shall, in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum, include information on—

(i) the number of positions publicly noticed and filled under the authority under subsection (i);

(ii) the occupational series, grades, and types of appointments of such positions;

(iii) how such positions related to advancing the goals and functions of ARPA–H;

(iv) how the Director made appointment decisions under subsection (i);

(v) a summary of sources used to identify candidates for filling such positions, as applicable;

(vi) the number of individuals appointed;

(vii) aggregated demographic information related to individuals appointed; and

(viii) any challenges, limitations, or gaps related to the use of the authority under subsection (i) and any related recommendations to address such challenges, limitations, or gaps.

***(l)* Strategic plan**

Not later than 1 year after December 29, 2022, and every 3 years thereafter, the Director shall provide to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a strategic plan describing how ARPA–H will

carry out investments each fiscal year in the following 3-year period. The requirements regarding individual institute and center strategic plans under section 282(m) of this title, including paragraph (3) of such subsection, shall not apply to ARPA–H.

(m) Independent review

Not later than 1 year after December 29, 2022, and every 4 years thereafter, the Comptroller General of the United States shall conduct, and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, an independent review of the biomedical research and development portfolio of the Department of Health and Human Services, including ARPA–H, the National Institutes of Health, the Food and Drug Administration, and the Biomedical Advanced Research and Development Authority—

(1) to assess the degree of any potential duplication of existing Federal programs and projects; and

(2) to make any recommendations regarding any potential reorganization, consolidation, or termination of such programs and projects.

(n) Prioritization

(1) In general

The Director shall—

(A) prioritize awarding grants, cooperative agreements, contracts, prizes, and other transaction awards to entities that will conduct funded work in the United States;

(B) as appropriate and practicable, encourage nondomestic recipients of any grants, cooperative agreements, contracts, prizes, and other transactions under this section to collaborate with a domestic entity;

(C) not make awards under this section to nondomestic entities organized under the laws of a covered foreign country (as defined in section 3059 of title 50); and

(D) in accordance with the requirements of chapter 33 of title 41 and the Federal Acquisition Regulation, not make awards under this section to entities that have more than 3 ongoing concurrent awards under this section.

(2) Clarification

In making an award under this section, the Director may waive the requirements of subparagraphs (A), (B), and (D) of paragraph (1) if such requirements cannot reasonably be met, and the proposed project has the potential to advance the goals described in subsection (b)(1). The Director shall provide notice to Congress not later than 30 days after waiving such requirements.

(*o*) Additional consultation

In carrying out this section, the Director may consult with—

(1) the President's Council of Advisors on Science and Technology;

(2) representatives of professional or scientific organizations, including academia and industry, with expertise in specific technologies under consideration or development by ARPA–H;

(3) an existing advisory committee providing advice to the Secretary or the head of any operating or staff division of the Department;

(4) the advisory committee established under subsection (p); and

(5) any other entity the Director may deem appropriate.

(p) Advisory Committee

(1) In general

There is established an ARPA–H Interagency Advisory Committee (referred to in this subsection as the ''Advisory Committee'') to coordinate efforts and provide advice and assistance on specific program or project tasks and the overall direction of ARPA–H.

(2) Members

The Advisory Committee established under paragraph (1) shall consist of the heads of the following agencies or their designees:

(A) The National Institutes of Health.

(B) The Centers for Disease Control and Prevention.

(C) The Food and Drug Administration.

(D) The Office of the Assistant Secretary for Preparedness and Response.

(E) The Office of the Assistant Secretary of Health.

(F) The Defense Advanced Research Projects Agency.

(G) The Office of Science of the Department of Energy.

(H) The National Science Foundation.

(I) Any other agency or office with subject matter expertise that the Director of ARPA–H determines appropriate to advance programs or projects under this section.

(3) Nonapplicability of FACA

The Federal Advisory Committee Act (5 U.S.C. App.)[2] shall not apply to the Advisory Committee.

(4) Advisory nature

The functions of the Advisory Committee shall be advisory in nature, and nothing in this subsection shall be construed as granting such Committee authority over the activities authorized under this section.

(5) Performance measures framework

(A) In general

The Director, in consultation with the Advisory Committee, shall develop a performance measures framework for programs or projects supported by ARPA–H in order to inform and facilitate the evaluation required under subsection (k)(2), including identification of any data needed to perform such evaluation,

(B) Availability of performance measures

The Director shall provide to the National Academies such performance measures and data necessary to perform the evaluation required under subsection (k)(2).

(q) Rule of construction

The authorities under this section, with respect to the Director, are additional authorities

[2] See References in Text note below.

that do not supersede or modify any existing authorities.

(r) Transformative health technology defined

In this section, the term ''transformative health technology'' means a novel, broadly applicable capability or technology—

(1) that has potential to revolutionize the detection, diagnosis, mitigation, prevention, cure, or treatment of a disease or health condition that can cause severe health outcomes and which is an area of currently unmet need; and

(2) for which—

(A) significant scientific or technical challenges exist; or

(B) incentives in the commercial market are unlikely to result in the adequate or timely development of such capability or technology.

(s) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $500,000,000 for each of the fiscal years 2024 through 2028, to remain available until expended.

(t) Additional budget clarification

Any budget request for ARPA–H shall propose a separate appropriation from the other accounts of the National Institutes of Health.

(July 1, 1944, ch. 373, title IV, § 499A, as added Pub. L. 117–328, div. FF, title II, § 2331(a), Dec. 29, 2022, 136 Stat. 5770.)

Editorial Notes

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (p)(3), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which was set out in the Appendix to Title 5, Government Organization and Employees, and was substantially repealed and restated in chapter 10 (§ 1001 et seq.) of Title 5 by Pub. L. 117–286, §§ 3(a), 7, Dec. 27, 2022, 136 Stat. 4197, 4361. For disposition of sections of the Act into chapter 10 of Title 5, see Disposition Table preceding section 101 of Title 5.

PRIOR PROVISIONS

A prior section 499A of act July 1, 1944, was renumbered section 499 by Pub. L. 103–43 and is classified to section 290b of this title.

SUBCHAPTER III–A—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

PART A—ORGANIZATION AND GENERAL AUTHORITIES

§ 290aa. Substance Abuse and Mental Health Services Administration

(a) Establishment

The Substance Abuse and Mental Health Services Administration (hereafter referred to in this subchapter as the ''Administration'') is an agency of the Service.

(b) Centers

The following Centers are agencies of the Administration:

(1) The Center for Substance Abuse Treatment.

(2) The Center for Substance Abuse Prevention.

(3) The Center for Mental Health Services.

(c) Assistant Secretary and Deputy Assistant Secretary

(1) Assistant Secretary

The Administration shall be headed by an official to be known as the Assistant Secretary for Mental Health and Substance Use (hereinafter in this subchapter referred to as the ''Assistant Secretary'') who shall be appointed by the President, by and with the advice and consent of the Senate.

(2) Deputy Assistant Secretary

The Assistant Secretary, with the approval of the Secretary, may appoint a Deputy Assistant Secretary and may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the activities to be carried out through the Administration.

(d) Authorities

The Secretary, acting through the Assistant Secretary, shall—

(1) supervise the functions of the Centers of the Administration in order to assure that the programs carried out through each such Center receive appropriate and equitable support and that there is cooperation among the Centers in the implementation of such programs;

(2) establish and implement, through the respective Centers, a comprehensive program to improve the provision of treatment and related services to individuals with respect to substance use disorders and mental illness and to improve prevention services, promote mental health and protect the legal rights of individuals with mental illnesses and individuals with substance use disorders;

(3) carry out the administrative and financial management, policy development and planning, evaluation, knowledge dissemination, and public information functions that are required for the implementation of this subchapter;

(4) assure that the Administration conduct and coordinate demonstration projects, evaluations, and service system assessments and other activities necessary to improve the availability and quality of treatment, prevention and related services;

(5) support activities that will improve the provision of treatment, prevention and related services, including the development of national mental health and substance use disorder goals and model programs;

(6) in cooperation with the National Institutes of Health, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration, develop educational materials and intervention strategies to reduce the risks of HIV, hepatitis, tuberculosis, and other communicable diseases among individuals with mental or substance use disorders, and to develop appropriate mental health services for individuals with such diseases or disorders;

(7) coordinate Federal policy with respect to the provision of treatment services for sub-