

individuals who participate as subjects in the research project specified in the Certificate while the Certificate is in effect. The authorization applies to all persons who, in the performance of their duties in connection with the research project, have access to information which would identify the subjects of the research. Persons so authorized may not, at any time, be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify the research subjects encompassed by the Certificate, except in those circumstances specified in paragraph (b) of this section.

(b) A Confidentiality Certificate granted under this part does not authorize any person to refuse to reveal the name or other identifying characteristics of any research subject in the following circumstances:

(1) The subject (or, if he or she is legally incompetent, his or her guardian) consents, in writing, to the disclosure of such information,

(2) Authorized personnel of DHHS request such information for audit or program evaluation of a research project funded by DHHS or for investigation of DHHS grantees or contractors and their employees or agents carrying out such a project. (See 45 CFR 5.71 for confidentiality standards imposed on such DHHS personnel), or

(3) Release of such information is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) or the regulations promulgated thereunder (title 21, Code of Federal Regulations).

(c) Neither a Confidentiality Certificate nor the regulations of this part govern the voluntary disclosure of identifying characteristics of research subjects.

§ 2a.8 Termination.

(a) A Confidentiality Certificate is in effect from the date of its issuance until the effective date of its termination. The effective date of termination shall be the earlier of:

(1) The expiration date set forth in the Confidentiality Certificate; or

(2) Ten days from the date of mailing a Notice of Cancellation to the applicant, pursuant to a determination by the Secretary that the research project

has been completed or discontinued or that retention of the Confidentiality Certificate is otherwise no longer necessary or desirable.

(b) A Notice of Cancellation shall include: an identification of the Confidentiality Certificate to which it applies; the effective date of its termination; and the grounds for cancellation. Upon receipt of a Notice of Cancellation the applicant shall return the Confidentiality Certificate to the Secretary.

(c) Any termination of a Confidentiality Certificate pursuant to this section is operative only with respect to the names and other identifying characteristics of individuals who begin their participation as research subjects after the effective date of such termination. (See § 2a.4(k) requiring researchers to notify subjects who enter the project after the termination of the Confidentiality Certificate of termination of the Certificate). The protection afforded by a Confidentiality Certificate is permanent with respect to subjects who participated in research during any time the authorization was in effect.

PART 3 [RESERVED]

PART 4—NATIONAL LIBRARY OF MEDICINE

Sec.

4.1 Programs to which these regulations apply.

4.2 Definitions.

4.3 Purpose of the Library.

4.4 Use of Library facilities.

4.5 Use of materials from the collections.

4.6 Reference, bibliographic, reproduction, and consultation services.

4.7 Fees.

4.8 Publication of the Library and information about the Library.

AUTHORITY: 42 U.S.C. 216, 286.

SOURCE: 56 FR 29188, June 26, 1991, unless otherwise noted.

§ 4.1 Programs to which these regulations apply.

(a) The regulations of this part govern access to the National Library of Medicine's facilities and library collections and the availability of its bibliographic, reproduction, reference, and

§ 4.2

related services. These functions are performed by the Library directly for the benefit of the general public and health-sciences professionals as required by sections 465(b) (3)–(6) of the Act (42 U.S.C. 286(b) (3)–(6)).

(b) The regulations of this part do not apply to:

(1) The Library's internal functions relating to the acquisition and preservation of materials and the organization of these materials as required by sections 465(b) (1) and (2) of the Act (42 U.S.C. 286(b) (1) and (2)).

(2) The availability of "records" under the Freedom of Information Act or the Privacy Act of 1974 (5 U.S.C. 552, 552a). These matters are covered in 45 CFR parts 5 and 5b.

(3) Federal assistance for medical libraries and other purposes which are authorized by sections 469–477 of the Act (42 U.S.C. 286b to 286b–8). (See parts 59a, 61 and 64 of this chapter.)

(4) The availability of facilities, collections, and related services of Regional Medical Libraries established or maintained under the authority in section 475 of the Act (42 U.S.C. 286b–6). (See part 59a, subpart B of this chapter.)

§ 4.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Collections means all books, periodicals, prints, audiovisual materials, films, videotapes, recordings, manuscripts, and other resource materials of the library. It does not include data processing tapes or programs used solely for internal processing activities to generate reference materials, nor does it include "records" of the Library as defined in 45 CFR 5.5. Records of the Library are available in accordance with the regulations under the Freedom of Information Act and Privacy Act of 1974. (See 45 CFR parts 5 and 5b.)

Director means the Director of the National Library of Medicine or the Director's delegate.

Health-sciences professional means any person engaged in: (1) The administration of health activities; (2) the provision of health services; or (3) research, teaching, or education concerned with the advancement of medicine or other

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sciences related to health or improvement of the public health.

Historical collection means: (1) Materials in the collections published or printed prior to 1914; (2) manuscripts and prints; (3) the archival film collection; and (4) other materials of the collections which, because of age, or unique or unusual value, require special handling, storage, or protection for their preservation, as determined by the Director.

Library means the National Library of Medicine, established by section 465 of the Act (42 U.S.C. 286).

Regional Medical Library means a medical library established or maintained as a regional medical library under section 475 of the Act (42 U.S.C. 286b–6).

§ 4.3 Purpose of the Library.

The purpose of the Library is to assist the advancement of medical and related sciences and aid the dissemination and exchange of scientific and other information important to the progress of medicine and the public health. The Library acquires and maintains library materials pertinent to medicine, including audiovisual materials; compiles, publishes, and disseminates catalogs, indices, and bibliographies of these materials, as appropriate; makes available materials, through loan or otherwise; provides reference and other assistance to research; and engages in other activities in furtherance of this purpose.

§ 4.4 Use of Library facilities.

(a) *General*. The Library facilities are available to any person seeking to make use of the collections. The Director may prescribe reasonable rules to assure the most effective use of facilities by health-sciences professionals and to protect the collections from misuse or damage. These rules must be consistent with the regulations in this part and applicable Department regulations and policies on nondiscrimination.

(b) *Reading rooms*. Public reading rooms are available for obtaining and reading materials from the collections. The Director may prescribe reasonable rules designed to provide adequate

reading space and orderly conditions and procedures.

(c) *Study rooms.* Upon request a limited number of study rooms may be made available to individuals requiring extensive use of Library materials. Requests for study rooms shall be addressed in writing to the Director. The Director shall give priority, in the following order, for study room use to:

- (1) Persons engaged in "special scientific projects" under section 473 of the Act (42 U.S.C. 286b-4),
- (2) Health-sciences professionals, and
- (3) The general public.

§ 4.5 Use of materials from the collections.

(a) *Unrestricted materials.* Except as otherwise provided in this section, materials from the collections are generally available to any interested person only in facilities provided by the Library for this purpose. The Director may prescribe additional reasonable rules to assure the most effective use of the Library's resources by health-sciences professionals and to protect the collections from misuse or damage. The rules must be consistent with the regulations in this part and applicable Department regulations and policies on nondiscrimination. Materials in the collections are available upon each request which assures, to the Director's satisfaction, that the materials will be safeguarded from misuse, damage, loss, or misappropriation, and will be returned promptly after use or upon request of the Library.

(b) *Restricted materials*—(1) *Historical collection.* Materials from the historical collection are available only as the Director may permit to assure their maximum preservation and protection. Copies of these materials may be made available in the form of microfilm and other copies, for which reasonable fees may be charged.

(2) *Gifts.* Materials in the collections are available only in accordance with any limitations imposed as a condition of the acquisition of those materials, whether the acquisition was by gift or purchase.

(c) *Loans*—(1) *General.* Requests for loans of materials must assure the Library that (i) the materials will be safeguarded from misuse, damage, loss,

or misappropriation and (ii) the materials will be returned promptly after use or upon request of the Library. The Library may provide copies in lieu of original materials, which need not be returned unless otherwise stated at the time of the loan.

(2) *Loans of audiovisual materials.* Audiovisual materials are available for loan under the same general terms as printed materials.

(3) *Loans to other libraries.* Upon request materials or copies are available for use through libraries of public or private agencies or institutions. The requesting library must assure that it has first exhausted its own collection resources, those of other local libraries in the geographic area, and those of the Regional Medical Library network (including Regional and Resource Libraries) before making a request for a loan.

(4) *Loans to health-sciences professionals.* The Director may make loans of materials directly to health-sciences professionals. An individual wishing a loan of library materials must assure to the satisfaction of the Director that the individual is geographically isolated, in terms of distance or available transportation, from medical literature resources likely to contain the desired material.

(Approved by the Office of Management and Budget under control number 0925-0276)

§ 4.6 Reference, bibliographic, reproduction, and consultation services.

(a) *General.* To the extent resources permit, the Library will make available, upon request, reference, bibliographic, reproduction, and consultation services. Priority will be given to requests from health-sciences professionals for services not reasonably available through local or regional libraries.

(b) *Specialized bibliographic services.* The Director may provide bibliographies on individually selected medical or scientific topics upon request where it is consistent with the Library's purpose. The Director may publish and make available for general distribution by the Library, bibliographic searches determined to be of general interest. The Library may also produce

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and distribute a limited number of bibliographies on topics of general interest to public or nonprofit health-related professional societies, research organizations, and other group users. These bibliographies may be produced on a regularly recurring or intermittent basis under contract between the Library and public or nonprofit agencies, when determined in each case by the Director to be necessary to assure more effective distribution of the bibliographic information.

(c) *Information retrieval system computer tapes.* To the extent Library resources permit and in order to further the Library's purpose, the Director may make available upon request by agencies, organizations, and institutions copies of all or part of the Library's magnetic tapes.

§ 4.7 Fees.

The Director may charge reasonable fees for any service provided by the Library under this part, in accordance with a schedule available at the Library upon request, which are designed to recover all or a portion of the cost to the Library of providing the service.

§ 4.8 Publication of the Library and information about the Library.

Lists of bibliographies, Library publications sold by the Government Printing Office, necessary application forms, and other information concerning the organization, operation, functions, and services of the Library, are available from the National Library of Medicine, Bethesda, Maryland 20894.

PART 5—DESIGNATION OF HEALTH PROFESSIONAL(S) SHORTAGE AREAS

Sec.

- 5.1 Purpose.
- 5.2 Definitions.
- 5.3 Procedures for designation of health professional(s) shortage areas.
- 5.4 Notification and publication of designations and withdrawals.

APPENDIX A TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PRIMARY MEDICAL CARE PROFESSIONAL(S)

APPENDIX B TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF DENTAL PROFESSIONAL(S)

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APPENDIX C TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF MENTAL HEALTH PROFESSIONALS

APPENDIX D TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VISION CARE PROFESSIONAL(S)

APPENDIX E TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PODIATRIC PROFESSIONAL(S)

APPENDIX F TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF PHARMACY PROFESSIONAL(S)

APPENDIX G TO PART 5—CRITERIA FOR DESIGNATION OF AREAS HAVING SHORTAGES OF VETERINARY PROFESSIONAL(S)

AUTHORITY: Sec. 215 of the Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); sec. 332 of the Public Health Service Act, 90 Stat. 2270–2272 (42 U.S.C. 254e).

SOURCE: 45 FR 76000, Nov. 17, 1980, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 5 appear at 57 FR 2480, Jan. 22, 1992.

§ 5.1 Purpose.

These regulations establish criteria and procedures for the designation of geographic areas, population groups, medical facilities, and other public facilities, in the States, as health professional(s) shortage areas.

§ 5.2 Definitions.

Act means the Public Health Service Act, as amended.

Health professional(s) shortage area means any of the following which the Secretary determines has a shortage of health professional(s): (1) An urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services); (2) a population group; or (3) a public or nonprofit private medical facility.

Health service area means a health service area whose boundaries have been designated by the Secretary, under section 1511 of the Act, for purposes of health planning activities.

Health systems agency or *HSA* means the health systems agency designated, under section 1515 of the Act, to carry out health planning activities for a specific health service area.

Medical facility means a facility for the delivery of health services and includes: (1) A community health center,