Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, Federal Register reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at http://www.fda.gov/cdrh. A search capability for all CDRH guidance documents is available at http:// www.fda.gov/cdrh/guidance.html. Guidance documents are also available on the Division of Dockets Management Internet site at http://www.fda.gov/ ohrms/dockets.

Dated: October 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Revisions to Nurse Practitioner and Nurse-Midwifery Education Program Guidelines

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of request for comments.

SUMMARY: The Health Resources and Services Administration (HRSA) invites comments on the proposed revised Nurse Practitioner and Nurse-Midwifery Education Program Guidelines for use in the Advanced Education Nursing Grant Program.

DATES: Comments must be postmarked by December 3, 2003.

ADDRESSES: Written comments should be submitted to the Division of Nursing, Bureau of Health Professions (BHPr), Health Resources and Services Administration (HRSA), Room 9–35, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Respondents should provide a rationale for their suggested changes or additions. All comments will be available for public inspection and copying at the Division of Nursing, BHPr, Room 9–35,

Parklawn Building at the address above weekdays between 8:30 a.m. and 5 p.m. FOR FURTHER INFORMATION CONTACT: Irene Sandvold, Division of Nursing, BHPr, HRSA, at (301) 443-6333. SUPPLEMENTARY INFORMATION: The Guidelines for Nurse Practitioner and Nurse-Midwifery Programs were initially developed in 1976 through a process that included consultation with appropriate educational and professional nursing and medical organizations, and public comment. The original final guidelines were published in the Federal Register (43 FR 43416) as regulation on November 29, 1977. On August 27, 2001 HHS issued a final rule in the Federal Register (66 FR 44981) that rescinded and removed most of the BHPr regulations, including the previous guidelines related to nurse practitioner and nurse-midwifery education programs. This action was taken by the Department in its effort to

These proposed Guidelines implement Section 811(c) of the PHS Act, which states that—

simplify government procedures.

Nurse Practitioner and nursemidwifery programs eligible for support under this section are educational programs for registered nurses (irrespective of the type of school of nursing in which the nurses received their training) that—

(1) Meet guidelines prescribed by the Secretary, and

(2) Have as their objective the education of nurses who will upon completion of their studies in such programs be qualified to effectively provide primary health care, including primary health care in homes and in ambulatory care facilities, long-term care facilities, acute care, and other health care settings.

These Guidelines are intended to promote the quality of nurse practitioner and nurse-midwifery programs funded by the Division of Nursing. Definitions in these Guidelines are those used by other Federal and State health entities. The Department invites comments on the following proposed Guidelines for the Nurse Practitioner and Nurse-Midwifery Education Program.

Federal Nurse Practitioner and Nurse-Midwifery Education Program Guidelines

Overview

Nurse practitioner education programs funded under this authority are graduate level programs that can provide evidence of accreditation from a recognized body or by a State agency, approved for such purpose by the U.S.

Department of Education. In addition, programs are expected to be consistent with the current Advanced Nursing Practice: Curriculum Guidelines & Program Standards for Nurse Practitioner Education and current Criteria for Evaluation of Nurse Practitioner Programs, A Report of the National Task Force on Quality Nurse Practitioner Education. Both documents are available from the National Organization of Nurse Practitioner Faculties, 1522 K Street, NW #702, Washington, DC 20005; telephone: (202) 289–8044. At a minimum, graduates must be prepared to meet national competencies established in Nurse Practitioner Primary Care Competencies in Specialty Areas: Adult, Family, Gerontological, Pediatric, and Women's Health. This document is available online at http://www.nonpf.com; http:// www.aacn.nche.edu/Education/ NPCompetencies.htm; and can be obtained from the HRSA Information Center (1-800-CALL-HRSA).

Nurse-Midwifery education programs must provide evidence of pre-accreditation or accreditation from the American College of Nurse-Midwives (ACNM), Division of Accreditation, recognized for this purpose by the U.S. Department of Education, prior to Notice of Grant Award. Programs must comply with the following criteria, as applicable:

(a) the current Criteria for Preaccreditation of Education Programs in Nurse-Midwifery and Midwifery with Guidelines for Elaboration and Documentation of Pre-accreditation Criteria: or

(b) The current Criteria for Accreditation of Education Programs in Nurse-Midwifery and Midwifery with Guidelines for Elaboration and Documentation of Accreditation Criteria.

At a minimum, graduates of these programs must be prepared to meet national competencies established in *The Core Competencies for Basic Midwifery Practice*. The above three documents are available from the ACNM at Suite 900, 818 Connecticut Avenue, NW., Washington, DC 20006; telephone: (202) 728–9860.

Organization and Administration

A nurse practitioner or nursemidwifery education program should actively collaborate with nurses and other health professionals who have expertise relevant to nurse practitioner or nurse-midwifery practice and primary health care, to assist in the initial and ongoing planning, implementation, and evaluation of the program.

Student Enrollment

All students enrolled in a nurse practitioner or nurse-midwifery education program should be licensed to practice nursing—

(a) At the time of enrollment, or

(b) In the case of a program leading to a graduate degree in nursing, at or prior to the time of completion of a program.

The policies for the recruitment, selection and progression of students should be consistent with the requirements of the sponsoring institution and developed in cooperation with the faculty responsible for conducting the nurse practitioner and/or nurse-midwifery program. Programs should develop, implement, and evaluate specific plans to achieve recruitment, retention, timely progression and graduation of a diverse student body.

Length of Program

A nurse practitioner or nursemidwifery education program is a formal program of study of a minimum of 1 academic year (9 months) in length and should include at least 4 months in the aggregate of full-time didactic instruction. Post-master=s programs must also meet this requirement.

Curriculum

A nurse practitioner or nursemidwifery education program should be a distinct program of study consisting of didactic instruction and supervised clinical practice designed to teach registered nurses the knowledge and competencies needed to perform the functions and scope of practice of a nurse practitioner or nurse-midwife. The faculty has the ultimate responsibility for evaluation of student clinical performance and achievement of competence. The nurse practitioner and nurse-midwifery specialty portion of the graduate curriculum should be developed and implemented cooperatively by nurse practitioner and/ or nurse-midwife educators, other graduate nursing faculty, and appropriate representatives of other health disciplines. Interdisciplinary academic and practice learning experiences are recommended to prepare graduates to serve underserved populations in complex health systems. The program content, both didactic and clinical portions, should prepare the nurse practitioner or nurse-midwife to provide primary health care within community settings. The nurse practitioner and nurse-midwife should be knowledgeable about the cultural factors that affect the health status of the populations served and how to assist

the community in making decisions about its priorities and health services.

The curriculum must include student preceptorships and/or other clinical learning experiences. Faculty should develop and assess clinical learning sites through site visits and prepare clinical faculty and preceptors for teaching, evaluating, and problem solving with nurse practitioner and nurse-midwifery students. Nurse practitioner or nurse-midwifery program faculty retain full responsibility for assuring the quality and effectiveness of each practicum site for student learning. The grant applicant should document in the application the specific criteria used for the selection of clinical learning

Faculty Qualifications

A nurse practitioner or nursemidwifery education program should have a sufficient number of qualified nursing, medical and other related health professional faculty with academic preparation and clinical expertise relevant to their areas of teaching responsibility and with demonstrated ability in the development and implementation of educational programs. The program director should be a nationally certified nurse practitioner or nurse-midwife, with appropriate academic preparation, clinical expertise and experience as an educator. Nurse practitioner and nursemidwife clinical faculty and preceptors should have national and/or State certification as appropriate for their specialty and should have at least one year of practice experience as a nurse practitioner or certified nurse-midwife. Other clinicians serving as clinical preceptors should be authorized by the State licensing entity to practice in their specific scope of practice. Faculty qualifications should be consistent with the requirements of their academic institution. The faculty should participate in maintenance of competency and clinical practice according to the National Task Force on Quality Nurse Practitioner Education guidelines and ACNM guidelines for continued competency.

Resources

A nurse practitioner or nursemidwifery education program must have available sufficient educational and clinical resources in a variety of practice settings with adequate space and equipment, number, age and type of clients needed for the number of students enrolled in the program. Where the institution or organization conducting the program does not provide the clinical practice settings itself, it should provide for such settings through written agreements with other appropriate institutions or organizations.

Definitions

The following terms are defined for purposes of the Nurse Practitioner and Nurse-Midwifery Program.

Culturally and Linguistically
Appropriate Services means health care
services that are respectful of and
responsive to cultural and linguistic
needs.

Full-time Student means a student enrolled in at least the number of credits defined as full-time by the institution.

Full-time educational program means an educational program that provides for a full-time program of study as defined by the institution. Students progressing through the program are able to enroll on a full-time basis to complete the program in a timely manner. Students in such a program may be part-time or full-time.

Nurse-Midwife means a registered nurse educated in the two disciplines of nursing and midwifery, who has successfully completed a nursemidwifery education program accredited by the American College of Nurse-Midwives (ACNM). Following national ACNM/American College of Nurse-Midwives Certification Council (ACC) certification, the nurse-midwife has abilities to provide independent management of primary health care for women, in the context of familycentered care, focusing particularly on pregnancy, childbirth, the postpartum period, care of the newborn, and the family planning and gynecological needs of women within a health care system that provides for consultation, collaborative management or referral as indicated by the health status of the client, including the abilities to:

 Assess the health status of women and infants, through health and medical history taking, physical examination, ordering and interpreting diagnostic tests and making diagnoses;

• Institute and provide continuity of primary health care to women and refer to other health care providers as appropriate;

• Prescribe pharmacological and nonpharmacological therapeutics, consistent with current standards of

 Provide instruction and counseling to individuals, families, and groups in the areas of promotion and maintenance of health and disease prevention, including involving such persons in planning for their health care; and

 Collaborate with other health care providers and agencies to provide, and where appropriate, coordinate services to individual women, children, and families.

Nurse Practitioner means a registered nurse who has successfully completed a formal program of study designed to prepare registered nurses to deliver primary health care, involving independent and interdependent decision making and direct accountability for clinical judgment, including the abilities to:

 Assess the health status of individuals and families through health and medical history taking, physical examination, ordering and interpreting diagnostic tests and making diagnoses;

• Institute and provide continuity of primary health care to individuals and families; and refer to other health care providers when appropriate;

• Prescribe treatments including pharmacological and nonpharmacological therapeutics, consistent with current standards of care:

• Provide instruction and counseling to individuals, families, and groups in the areas of promotion and maintenance of health and disease prevention, including involving such persons in planning for their health care; and

• Collaborate with other health care providers and agencies to provide, and where appropriate, coordinate services to individuals and families.

Nurse Practitioner or Nurse-Midwifery Program means a full-time educational program of study, as defined by the institution, (although students may be progressing through the program on a full-time or part-time basis), which meets the Guidelines prescribed herein. The program's objective is the education of nurses who will, upon completion of their studies in the program, be qualified to effectively provide primary health care in a variety of settings, including in homes, ambulatory care facilities, long-term care facilities, acute care, and other health care settings.

Post-Nursing Master's Certificate
Program means a formal, post-graduate
program for Registered Nurses with
master's degrees that awards a
certificate and academic credit for
completion of the program of study as
a Nurse Practitioner or Nurse-Midwife.

Preceptorship means a clinical learning experience in which the student is assigned to a faculty member or with oversight by program faculty to a designated preceptor who is a nurse practitioner or nurse-midwife or other health professional for specific aspects of the clinical learning experience. The preceptorship provides the student with practice experiences conducive to meeting the defined goals and objectives

of the particular clinical course. The preceptor is responsible for the daily teaching and assignment of individuals to be cared for, supervision, and participation in the evaluation of the nurse practitioner or nurse-midwifery student. The preceptor teaches, supervises, and evaluates the student and provides the student with an environment that permits observation, active participation, and management of primary health care. Before and during this preceptorship program faculty visits and assesses clinical learning sites and prepares clinical faculty/preceptors for teaching their students.

Primary Care means the provision of integrated, accessible health care services by clinicians, including nurse practitioners and nurse-midwives, who are accountable for addressing a large majority of personal health care needs within their scopes of practice, developing a sustained partnership with clients, and practicing in the context of family and communities. Critical elements also include accountability of clinicians and systems for quality of care, consumer satisfaction, efficient use of resources, and ethical behavior. Clients have direct access to an appropriate source of care, which continues over time for a variety of problems and includes needs for preventive services. Primary care and Primary Health Care are used interchangeably in this document. (Definition adapted from Barbara Starfield, Primary Care Concept, Evaluation, and Policy, Oxford University Press, New York, 1992 p. 4 and Institute of Medicine:

Moila S. Donaldson, Karl D. Yordy, Kathleen N., and Neal A. Vanselow, Editors, Committee on the Future of Primary Care, Division of Health Care Services, *Primary Care: America's Health in a New Era, Summary*, National Academy Press, Washington, DC, 1996, p. 23.)

Dated: October 27, 2003.

Elizabeth M. Duke,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974; New System of Records

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notification of new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Health Resources and Services Administration (HRSA) is publishing notice of a proposal to add a new system of records. The Smallpox Vaccine Injury Compensation Act of 2003 ("the Act"), amended title II of the Public Health Service Act (42 U.S.C. 202 et seq.) to provide benefits and other compensation for certain individuals with injuries resulting from the administration of smallpox countermeasures or as a result of vaccinia contracted through accidental vaccinia inoculation. The Act directs the Secretary, HHS, to establish administrative procedures to compensate certain individuals who sustained a covered injury as the direct result of the administration of smallpox vaccine, and certain individuals who sustained a covered injury as a direct result of accidental vaccinia inoculation through contact with the foregoing persons or with individuals accidently inoculated by them. This system of records is required to comply with the implementation directives of the Act, Public Law 108–20. The records will be used for the Smallpox Vaccine Injury Compensation Program's (SVICP) planning, implementation, payment, evaluation, monitoring, and document storage purposes.

DATES: HRSA invites interested parties to submit comments on the proposed New System of Records on or before December 15, 2003. As of the date of the publication of this Notice, HRSA has sent a Report of New System of Records to Congress and to the Office of Management and Budget (OMB). The New System of Records will be effective 40 days from the date submitted to OMB unless HRSA receives comments that would result in a contrary determination.

ADDRESSES: Please address comments to Health Resources and Services Administration (HRSA) Privacy Act Officer, 5600 Fishers Lane, Room 14A–20, Rockville, Maryland 20857; telephone (301) 443–3780. This is not a toll-free number. Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Director, Office of Special Programs,

Health Resources and Services Administration, 5600 Fishers Lane, Room 16C–17, Rockville, Maryland 20857; telephone (301) 443–3300. This is not a toll-free number.