

The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: June 27, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Lists of Designated Primary Medical Care, Mental Health, and Dental Health Professional Shortage Areas

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice advises the public of the published lists of all geographic areas, population groups, and facilities designated as primary medical care, mental health, and dental health professional shortage areas (HPSAs) as of May 13, 2016, available on the Health Resources and Services Administration (HRSA) Web site at <http://www.hrsa.gov/shortage/>. HPSAs are designated or withdrawn by the Secretary of Health and Human Services (HHS) under the authority of section 332 of the Public Health Service (PHS) Act and 42 CFR part 5.

**FOR FURTHER INFORMATION CONTACT:**

Requests for further information on the HPSA designations listed on the HRSA Web site below should be submitted to Kae Brickerd, Ph.D., Director, Shortage

Designation Branch, Division of Policy and Shortage Designation, Bureau of Health Workforce (BHW), HRSA, Mail Stop 11SWH03, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 594–5168 or [KBrickerd@hrsa.gov](mailto:KBrickerd@hrsa.gov).

**SUPPLEMENTARY INFORMATION:**

### Background

Section 332 of the PHS Act, 42 U.S.C. 254e, provides that the Secretary of HHS shall designate HPSAs based on criteria established by regulation. HPSAs are defined in section 332 to include (1) urban and rural geographic areas with shortages of health professionals, (2) population groups with such shortages, and (3) facilities with such shortages. Section 332 further requires that the Secretary annually publish a list of the designated geographic areas, population groups, and facilities. HPSAs are to be reviewed at least annually and revised as necessary. HRSA's BHW has the responsibility for designating and updating HPSAs.

Public or private nonprofit entities are eligible to apply for assignment of National Health Service Corps (NHSC) personnel to provide primary care, mental, or dental health services in or to these HPSAs. NHSC health professionals with a service obligation may enter into service agreements to serve only in federally designated HPSAs. Entities with clinical training sites located in HPSAs are eligible to receive priority for certain residency training program grants administered by BHW. Many other federal programs also utilize HPSA designations. For example, under authorities administered by the Centers for Medicare & Medicaid Services, certain qualified providers in geographic area HPSAs are eligible for increased levels of Medicare reimbursement.

### Development of the Designation and Withdrawal Lists

Criteria for designating HPSAs were published as final regulations (42 CFR part 5) in 1980. Criteria then were defined for each of seven health professional types (primary medical care, dental, psychiatric, vision care, podiatric, pharmacy, and veterinary care). The criteria for correctional facility HPSAs were revised and published on March 2, 1989 (54 FR 8735). The criteria for psychiatric HPSAs were expanded to mental health HPSAs on January 22, 1992 (57 FR 2473). Currently funded PHS Act programs use only the primary medical care, mental health, or dental HPSA designations.

Individual requests for designation or withdrawal of a particular geographic

area, population group, or a facility as a HPSA are received and reviewed continuously by BHW. The majority of the requests come from the Primary Care Offices (PCO) in the State Health Departments, who have access to the on-line application and review system. Requests that come from other sources are referred to the PCOs for their review and concurrence. In addition, interested parties, including the Governor, the State Primary Care Association and state professional associations are notified of each request submitted for their comments and recommendations.

Recommendations for possible additions, continuations, revisions, or withdrawals from a HPSA list are reviewed by BHW, and the review findings are provided by letter to the agency or individual requesting action or providing data, with copies to other interested organizations and individuals. These letters constitute the official notice of designation as a HPSA, rejection of recommendations for HPSA designation, revision of a HPSA designation, and/or advance notice of pending withdrawals from the HPSA list. Designations (or revisions of designations) are effective as of the date on the notification letter from BHW. Proposed withdrawals become effective only after interested parties in the area affected have been afforded the opportunity to submit additional information to BHW in support of its continued or revised designation. If no new data are submitted, or if BHW review confirms the proposed withdrawal, the withdrawal becomes effective upon publication of the lists of designated HPSAs in the **Federal Register**. In addition, lists of HPSAs are updated daily on the HRSA Web site, <http://www.hrsa.gov/shortage/>, so that interested parties can access the most accurate and timely information.

### Publication and Format of Lists

Due to the large volume of designations, a printed version of the list is no longer distributed. This notice serves to inform the public of the availability of the complete listings of designated HPSAs on the HRSA Web site. The three lists (primary medical care, mental health, and dental) of designated HPSAs are available at a link on the HRSA Web site at <http://www.hrsa.gov/shortage/> and include a snapshot of all geographic areas, population groups, and facilities that were designated HPSAs as of May 13, 2016. This notice incorporates the most recent annual reviews of designated HPSAs and supersedes the HPSA lists published in the **Federal Register** on July 1, 2015 (**Federal Register**/Vol. 80,

No. 126/Wednesday, July 1, 2015/ Notices 37637). The lists also include automatic facility HPSAs, designated as a result of the Health Care Safety Net Amendments of 2002 (Pub. L. 107–251), not subject to update requirements. Each list of designated HPSAs (primary medical care, mental health, and dental) is arranged by state. Within each state, the list is presented by county. If only a portion (or portions) of a county is (are) designated, or if the county is part of a larger designated service area, or if a population group residing in the county or a facility located in the county has been designated, the name of the service area, population group, or facility involved is listed under the county name. Counties that have a whole county geographic HPSA are indicated by the “Entire county HPSA” notation following the county name. Further details on the snapshot of HPSAs listed can be found on the HRSA Web site: <http://www.hrsa.gov/shortage/>.

In addition to the specific listings included in this notice, all Indian Tribes that meet the definition of such Tribes in the Indian Health Care Improvement Act of 1976, 25 U.S.C. 1603(d), are automatically designated as population groups with primary medical care and dental health professional shortages. The Health Care Safety Net Amendments of 2002 also made the following entities eligible for automatic facility HPSA designations: All federally qualified health centers (FQHCs) and rural health clinics that offer services regardless of ability to pay. These entities include: FQHCs funded under section 330 of the PHS Act, FQHC Look-Alikes, and Tribal and urban Indian clinics operating under the Indian Self-Determination and Education Act of 1975 (25 U.S.C. 450) or the Indian Health Care Improvement Act. Many, but not all, of these entities are included on this listing. Exclusion from this list does not exclude them from HPSA designation; any facilities eligible for automatic designation will be included in the HRSA Data Warehouse list of HPSAs as they are identified.

#### Future Updates of Lists of Designated HPSAs

The lists of HPSAs at <http://www.hrsa.gov/shortage/> consist of all those that were designated as of May 13, 2016. It should be noted that HPSAs are currently updated on an ongoing basis based on the identification of new areas, population groups, facilities, and sites that meet the eligibility criteria or that no longer meet eligibility criteria and/or are being replaced by another type of designation. As such, additional HPSAs

may have been designated by letter since that date. The appropriate agencies and individuals have been or will be notified of these actions by letter. These newly designated HPSAs will be included in the next publication of the HPSA list and are currently included in the daily updates posted on the HRSA Web site at <http://www.hrsa.gov/shortage/find.html>.

Any designated HPSA listed on the HRSA Web site is subject to withdrawal from designation if new information received and confirmed by HRSA indicates that the relevant data for the area involved have significantly changed since its designation. The effective date of such a withdrawal will be the next publication of a notice regarding this list in the **Federal Register**.

All requests for new designations, updates, or withdrawals should be based on the relevant criteria in regulations published at 42 CFR part 5.

#### Electronic Access Address

The complete list of HPSAs designated as of May 13, 2016, are available on the HRSA Web site at <http://www.hrsa.gov/shortage/>. Frequently updated information on HPSAs is also available at <http://datawarehouse.hrsa.gov>.

Dated: June 24, 2016.

**James Macrae,**

*Acting Administrator.*

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**BILLING CODE 4165–15–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Comment Request

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or

to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

**DATES:** Comments on this ICR should be received no later than August 30, 2016.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or by mail to the HRSA Reports Clearance Officer, 14N39, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Countermeasures Injury Compensation Program.

OMB No. 0915–0334—Extension.

**Abstract:** This is an extension request for OMB approval of the information collection requirements for the Countermeasures Injury Compensation Program (CICP or Program). CICP, within the Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau, HRSA, administers the compensation program specified by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act). CICP provides compensation to eligible individuals who suffer serious injuries directly caused by a covered countermeasure administered or used pursuant to a PREP Act Declaration, or to their estates and/or to certain survivors. A declaration is issued by the Secretary of the Department of Health and Human Services (Secretary). The purpose of a declaration is to identify a disease, health condition, or a threat to health that is currently, or may in the future constitute, a public health emergency. In addition, the Secretary, through a declaration, may recommend and encourage the development, manufacturing, distribution, dispensing, and administration or use of one or more covered countermeasures to treat, prevent, or diagnose the disease, condition, or threat specified in the declaration.

To determine whether a requester is eligible for Program benefits (compensation) for the injury, CICP must review the Request for Benefits Package, which includes the Request for Benefits Form and Authorization for