

generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device ZEPHYR ENDOBRONCHIAL VALVE IMPLANT. ZEPHYR ENDOBRONCHIAL VALVE IMPLANT is indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. Subsequent to this approval, the USPTO received patent term restoration applications for ZEPHYR ENDOBRONCHIAL VALVE IMPLANT (U.S. Patent Nos. 6,527,761 and 7,798,147) from Pulmonx Corp., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated October 29, 2019, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of ZEPHYR ENDOBRONCHIAL VALVE IMPLANT represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

## II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ZEPHYR ENDOBRONCHIAL VALVE IMPLANT is 5,744 days. Of this time, 5,565 days occurred during the testing

phase of the regulatory review period, while 179 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* October 9, 2002. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on March 11, 2005. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on October 9, 2002, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* January 2, 2018. The applicant claims December 29, 2017, as the date the premarket approval application (PMA) for ZEPHYR ENDOBRONCHIAL VALVE IMPLANT (PMA 180002) was initially submitted. However, FDA records indicate that PMA 180002 was submitted on January 2, 2018.

3. *The date the application was approved:* June 29, 2018. FDA has verified the applicant's claim that PMA 180002 was approved on June 29, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 5 years or 1,510 days of patent term extension.

## III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.)

Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 25, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## 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 (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** This notice informs the public of the availability of the complete lists of all geographic areas, population groups, and facilities designated as primary medical care, dental health, and mental health professional shortage areas (HPSAs) as of April 30, 2021. The lists are available on the shortage area topic page on HRSA's [data.hrsa.gov](https://data.hrsa.gov) website.

**ADDRESSES:** Complete lists of HPSAs designated as of April 30, 2021, are available on the website at <https://data.hrsa.gov/topics/health-workforce/shortage-areas>. Frequently updated information on HPSAs is available at <https://data.hrsa.gov/tools/shortage-area>. Information on shortage designations is available at <https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation>.

**FOR FURTHER INFORMATION CONTACT:** For further information on the HPSA designations listed on the website or to request additional designation, withdrawal, or reapplication for designation, please contact Janelle D. McCutchen, DHEd, MPH, CHES, Chief, Shortage Designation Branch, Division of Policy and Shortage Designation, Bureau of Health Workforce (BHW), HRSA, 5600 Fishers Lane, Room 11W14, Rockville, Maryland 20857, [sdb@hrsa.gov](mailto:sdb@hrsa.gov).

**SUPPLEMENTARY INFORMATION:**

## Background

Section 332 of the Public Health Service (PHS) Act, 42 U.S.C. 254e, provides that the Secretary 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 lists of the designated geographic areas, population groups, and facilities. The lists of HPSAs are to be reviewed at least annually and revised as necessary.

Final regulations (42 CFR part 5) were published in 1980 that include the criteria for designating HPSAs. Criteria were defined for 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.

HPSA designation offers access to potential federal assistance. Public or private nonprofit entities are eligible to apply for assignment of National Health Service Corps (NHSC) personnel to provide primary medical care, mental health, or dental health services in or to these HPSAs. NHSC health professionals enter into service agreements to serve 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 HRSA's BHW. Other federal programs also utilize HPSA designations. For example, under authorities administered by the Centers for Medicare and Medicaid Services, certain qualified providers in geographic area HPSAs are eligible for increased levels of Medicare reimbursement.

## Content and Format of Lists

The three lists of designated HPSAs are available on the HRSA Data Warehouse shortage area topic web page and include a snapshot of all geographic areas, population groups, and facilities that were designated HPSAs as of April 30, 2021. This notice incorporates the most recent annual reviews of designated HPSAs and supersedes the HPSA lists published in the **Federal**

**Register** on June 15, 2020 (**Federal Register**/Vol. 85, No. 115/Monday, June 15, 2020/Notices 36219).

In addition, all Indian Tribes that meet the definition of such Tribes in the Indian Health Care Improvement Act of 1976, 25 U.S.C. 1603, are automatically designated as population groups with primary medical care and dental health professional shortages. Further, the Health Care Safety Net Amendments of 2002 provides eligibility for automatic facility HPSA designations for all federally qualified health centers (FQHCs) and rural health clinics that offer services regardless of ability to pay. Specifically, 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. Absence from this list does not exclude them from HPSA designation; facilities eligible for automatic designation are included in the database when they are identified.

Each list of designated HPSAs 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, a county is part of a larger designated service area, or a population group residing in a 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. A county that has a whole county geographic or population group HPSA is indicated by the phrase "County" following the county name.

## Development of the Designation and Withdrawal Lists

Requests for designation or withdrawal of a particular geographic area, population group, or facility as a HPSA are received continuously by BHW. Under a Cooperative Agreement between HRSA and the 54 state and territorial Primary Care Offices (PCOs), PCOs conduct needs assessments and submit applications to HRSA to designate areas as HPSAs. BHW refers requests that come from other sources to PCOs for review. In addition, interested parties, including Governors, State Primary Care Associations, and state professional associations, are notified of requests so that they may submit their comments and recommendations.

BHW reviews each recommendation for possible addition, continuation, revision, or withdrawal. Following review, BHW notifies the appropriate

agency, individuals, and interested organizations of each designation of a HPSA, rejection of recommendation 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 from BHW and are updated daily on the HRSA Data Warehouse Find Shortage Area website. The effective date of a withdrawal will be the next publication of a notice regarding the list of designated HPSAs in the **Federal Register**.

**Diana Espinosa,**

*Acting Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

**Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Performance Report, OMB No. 0906-0016, Revision**

**AGENCY:** Health Resources and Service's Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than September 7, 2021.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, 14N136B, 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 Lisa Wright-Solomon, the HRSA