Type of form	Number of respondents	Responses per respondent	Average burden per response
Borrower	42	1	0.08 hours.
Physician	42	1	2.75 hours.
Loan Holder.	35	1.2	0.17 hours.

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 27, 1995.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 95–19054 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–15–P

Public Health Service

[0905–ZA93]

Notice of Redesignation of Contract Health Service Delivery Area

AGENCY: Indian Health Service, HHS.

ACTION: Notice with request for comments.

SUMMARY: This notice advises the public that the Indian Health Service (IHS) proposes to redesignate the geographic boundaries of the Contract Health Service Delivery Area (CHSDA) for the Jamestown S'Klallam Tribe (''The Tribe''). The Jamestown S'Klallam CHSDA currently is comprised of Clallam County in the State of Washington. This county was designated as the Tribe's CHSDA when the IHS published its updated list of CHSDA's in the **Federal Register** of January 10, 1984 (49 FR 1291). It is proposed that the redesignated CHSDA be comprised of Clallam County and Jefferson County in the State of Washington. This notice is issued under authority of 43 FR 34654, August 4, 1978.

DATES: Comments must be received on or before September 5, 1995.

ADDRESSES: Comments may be mailed to Betty J. Penn, Regulations Officer, Indian Health Service, Room 450, 12300 Twinbrook Parkway, Rockville, Maryland 20852. Comments will be made available for public inspection at this address from 8:30 a.m. to 5:00 p.m., Monday-Friday, beginning approximately 2 weeks after publication of this notice.

FOR FURTHER INFORMATION CONTACT: Leslie M. Morris, Deputy Director, Division of Legislation and Regulations, Office of Planning, Evaluation and Legislation, Indian Health Service, Room 450, 12300 Twinbrook Parkway, Rockville, MD 20852, telephone 301–443–1116. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Secretary of the Interior acknowledged the Tribe as an Indian tribe, effective February 10, 1981 (45 FR 81890). The Tribe has entered into a self-governance compact with the IHS under Title III of the Indian Self-Determination Act (Pub. L. 93–638, as amended) to provide direct services at a clinic facility and also to provide, for eligible Indians, services purchased from private sector health care providers. Such purchased services are called ''contract health services.''

On August 4, 1978, the IHS published regulations establishing eligibility criteria for receipt of contract health services and for the designation of CHSDA's (43 FR 34654, codified at 42 CFR 36.22, last published in the 1986 version of the Code of Federal Regulations). On September 16, 1987, the IHS published new regulations governing eligibility for IHS services. Congress has repeatedly delayed implementation of the new regulations by imposing annual moratoriums. Section 719(a) of the Indian Health Care Amendments of 1988, Pub. L. 100–713, explicitly provides that during the period of the moratorium placed on implementation of the eligibility regulations, the IHS will provide services pursuant to the criteria in effect on September 15, 1987. Thus, the IHS contract health services program continues to be governed by the regulations contained in the 1986 edition of the Code of Federal Regulations in effect on September 15, 1987. See 42 CFR 36.21 *et seq.* (1986).

As applicable to the Tribe, these regulations provide that, unless otherwise designated, a CHSDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation (42 CFR 36.22(a)(6) (1986)). The regulations also provide that after consultation with the tribal governing body or bodies of those reservations included in the CHSDA, the Secretary may, from time to time, redesignate areas within the United States for inclusion in or exclusion from a CHSDA. The regulations require that certain criteria must be considered before any redesignation is made. The criteria are as follows:

(1) The number of Indians residing in the area proposed to be so included or excluded;

(2) Whether the tribal governing body has determined that Indians residing in the area near the reservation are socially and economically affiliated with the tribe;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and

(4) The level of funding which would be available for the provision of contract health services.

Additionally, the regulations require that any redesignation of a CHSDA must be made in accordance with the procedures of the Administrative Procedure Act (5 U.S.C. 553). In compliance with this requirement, we are publishing this proposal and requesting public comment.

Since approximately 1984, the Tribe has been providing contract health services to 20 of its tribal members residing in Jefferson County, Washington. Under existing regulations, the CHSDA for the Tribe consists of only Clallam County. On December 21, 1992, the Tribe most recently requested the Secretary to redesignate its CHSDA as Clallam County and Jefferson County in the State of Washington. The Tribe based its request on the fact that S'Klallam tribal members are indigenous to Jefferson County, Washington, yet are still ineligible to receive contract health services because they do not reside within the Tribe's existing CHSDA. In addition, the Tribe has developed a land consolidation plan, which has been approved by the Department of the Interior, through the Bureau of Indian Affairs, and which includes tribal trust land in Jefferson County. However, the Jefferson County tribal trust land has not yet been added to the reservation by proclamation of the Secretary of the Interior.

In applying the aforementioned CHSDA redesignation criteria required by operative regulations (43 FR 35654), the following findings are made:

(1) There are 112 Indians residing in Jefferson County, of which 59 are members of the Tribe or have close socioeconomic ties to the Tribe. Of these 59, 20 are already receiving services due to a previous administrative decision. The remaining 53 individuals are not covered by this request as they do not have close social and economic ties to the Tribe and are therefore, not eligible for contract health services under existing law.

(2) The Tribe has determined that contract health services would be available to all of its members and to all federally recognized Indians in Jefferson

County having social and economic affiliation with the Tribe.

(3) Although the Tribe's reservation is in Clallam County, the Tribe has trust land in Jefferson County that is included in an approved land consolidation plan and is pending proclamation to add it to the Tribe's reservation. This tribal trust land is contiguous to the existing reservation and extends into Jefferson County.

(4) It is estimated that the current eligible contract health service population will be increased by 39 individuals, changing the active patient population from 192 to 231, assuming 100 percent utilization for Jefferson County eligibles. Based upon data from the fiscal year 1994 application of the health services priority system and the modified resource requirements methodology, the total clinical work units (CWU's) generated by the user population of 192 was 998.4, or 5.2 per individual. Assuming the same utilization, the 39 new users will generate an additional 202.8 CWU's. The calculated cost per CWU in the inpatient and ambulatory contract health care category was $139.22 for the Tribe. Therefore, potential added costs for contract health services resulting from new users is approximated at $139.22 X 202.8 CWU's = $28,233.82. Total resources available to the program in fiscal year 1994 were $139,000. The addition of new usage would not be expected to result in an increase in funding for the Tribe. The impact on existing contract health services will not be substantial. The current funding level will allow sufficient flexibility to assure that there will be no significant reduction in the level of contract health services to current CHSDA residents, so the designation of the two-county CHSDA is within available resources.

Accordingly, after considering the Tribe's request in light of the criteria specified in the regulations, I am proposing to redesignate the CHSDA of the Tribe to consist of Clallam and Jefferson Counties of the State of Washington.

This notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of Management and Budget under the Paperwork Reduction Act of 1930.

Dated: May 23, 1995.

Michel E. Lincoln,

Acting Director.

[FR Doc. 95–19095 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–16–M

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility

AGENCY: Public Health Service, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted section 340B of the Public Health Service Act (PHS Act), ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed that amount determined under a statutory formula.

The purpose of this notice is to inform interested parties of decisions regarding certain issues of program implementation. The notice will discuss the determination of covered entity status (i.e., PHS entity and disproportionate share hospital eligibility) and the administrative program requirements for ''covered entity'' status. Further, PHS is proposing a definition of eligible covered entity ''patient'' in section III for public comment.

DATES: The public is invited to submit comments on the proposed definition of ''patient'' in section III by September 5, 1995. After consideration of the comments submitted, the Secretary will issue the final guidelines.

FOR FURTHER INFORMATION CONTACT: Marsha Alvarez, R. Ph., Attn: Drug Pricing Program, Bureau of Primary Health Care, 4350 East West Highway, 10th Floor, Bethesda, MD 20814, Phone (301) 594–4353.

SUPPLEMENTARY INFORMATION: The Office of Drug Pricing has developed the following guidelines to facilitate program implementation and is proposing a definition of ''patient'' in section III for public comment.

I. Covered Entity Status

PHS Entities

Section 340B(a)(4) of the PHS Act lists the various categories of PHS programs eligible to receive section 340B outpatient drug discount pricing. For each category, there is a Federal program office which oversees the grant program. The respective Federal program offices determine which individual facilities receive the grant funds specified by section 340B or are eligible under other criteria and compile a list of such entities. The Federal program office then submits this list to the Office of Drug Pricing (ODP) for inclusion on the master list of eligible facilities (''covered entities'').

Each program office is responsible for maintaining a current data file of eligible entities and submitting all updated information to the ODP. This information may either be submitted on a quarterly or yearly basis, depending upon the number of entity status changes in a given period. Each program office determines how often updates are necessary to maintain current entity information on the ODP master list of covered entities and notifies the ODP of their respective update time periods. The update file data is submitted to ODP in either a dbf or ASCI file, the formats of which are available from the ODP. Program offices submit their updates to the ODP on the following dates: (a) December 1 for the January 1 update, (b) March 1 for the April 1 update, (c) June 1 for the July 1 update, and (d) September 1 for the October 1 update.

The ODP will update the master covered entity file on a quarterly basis. The name of an entity will not be added or deleted at any other time. For example, if an entity becomes an eligible PHS grantee, its name will not appear on the ODP master list until the program office submits the name in its update package and the ODP subsequently updates the ODP master list during the next quarterly cycle. ODP will not directly add to or delete an entity name from the ODP master list. An entity name to be added or deleted must be submitted by the program office during a scheduled update period.

The following is a list of the Federal program offices which oversee the 340B eligible programs and contact persons (except as otherwise indicated, references are to sections of the Public Health Service Act):

1. Federally-qualified health center, as defined in section 1905(1)(2)(B) of the Social Security Act (42 U.S.C. § 1396d(1)(2)(B)), means an entity that:

(a) receives a grant under section 329 (migrant health center), section 330 (community health center), section 340 (health services for the homeless), and section 340A (health services for residents of public housing); or

(b) (i) receives funding from such a grant under a contract with the recipient of the grant, and (ii) meets the requirements to receive a grant under section 329, 330, 340 and 340A; or

(c) based on the recommendation of the Health Resources and Services Administration (HRSA) within the Public Health Service, is determined by the Secretary to meet requirements for