■ 4. Remove and reserve § 52.679.

§ 52.679 [Remove and reserve]

[FR Doc. 05–619 Filed 1–24–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 70

RIN 0920–AA11

Establishment of Vaccination Clinics; User Fees for Investigational New Drug (IND) Influenza Vaccine Services and Vaccines

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Interim final rule and request for comments.

SUMMARY: We are amending 42 CFR part 70 to establish vaccination clinics and a user fee in connection with the administration of vaccination services and vaccine. On December 7, 2004, HHS Secretary Tommy G. Thompson announced the purchase of 1.2 million doses of GlaxoSmithKline (GSK) influenza vaccine, Fluarix, for distribution to areas most in need as determined by State public health authorities. The Fluarix vaccine has been approved in seventy-eight foreign countries, and FDA has recently reviewed extensive manufacturing and summary clinical information and conducted an inspection of the GSK manufacturing facility in Germany to determine that this vaccine, although not licensed in the United States, is suitable for use under an Investigational New Drug application (IND). The Food and Drug Administration (FDA) reviewed GSK's IND application as well as the clinical protocol and manufacturing data. CDC and CDC's Institutional Review Board approved the GSK flu vaccine response protocol including the informed consent document.

To ensure that the vaccine is properly administered to individuals identified to be most at risk and facilitate compliance with IND requirements, CDC is establishing vaccination clinics. CDC is proceeding without delay because of the unprecedented nature of this season's influenza vaccine shortage caused by contamination problems with Chiron Corporation's production facility in the United Kingdom, which effectively cut in half the expected United States supply of inactivated influenza vaccine. A user fee is being established in order to recoup the costs associated with administering the vaccine and for the vaccine itself. All individuals, other than those who are enrolled in Medicare Part B, will be required to pay the user fee.

DATES: This interim final rule is effective upon publication.

Written comments must be submitted on or before February 24, 2005. A final rule will be published after consideration of the comments.

ADDRESSES: Questions or comments concerning this interim final rule may be submitted to: Sheila Humphrey, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop D–38, Atlanta, GA 30333; telephone 404–498–4025. Comments may be emailed to: *sph5@cdc.gov.*

FOR FURTHER INFORMATION CONTACT: For information concerning program operations contact: Lisa Rotz, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mailstop C–18, Atlanta, GA 30333; telephone 404–639–0153.

SUPPLEMENTARY INFORMATION:

I. Background

Section 361 of the Public Health Service Act (42 U.S.C. 264) authorizes the Secretary of HHS to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or from one state or possession into any other state or possession. Influenza is a communicable disease caused by influenza viruses that spreads from person to person primarily through respiratory droplets of coughs and sneezes. Adults may be able to infect others 1 day before getting symptoms and up to 7 days after onset of illness. In light of the nature of the disease and the high mobility of the population, it is inevitable that influenza viruses will spread from individuals in one state to individuals of another state. The best way to prevent the transmission of influenza is for individuals to receive the influenza vaccine. Under the authority of section 361, the Secretary may establish vaccination clinics because vaccination with the influenza vaccine is the best way to prevent the transmission of influenza from one state into another.

Title V of the Independent Offices Appropriation Act of 1952 (31 U.S.C. 9701) (''IOAA'') provides general authority to Federal agencies to establish user fees through regulations. The IOAA sets parameters for any fee charged under its authority. Each charge shall be:

(1) Fair; and

(2) Based on—

(A) The costs to the Government;

(B) The value of the service or thing to the recipient;

(C) Public-policy or interest served; and

(D) Other relevant facts.

OMB Circular A–25 (''the Circular'') establishes general policy for implementing user fees, including criteria for determining amounts and exceptions, and guidelines for implementation. According to the Circular, its provisions must be applied to any fees collected pursuant to the IOAA authority.

The Circular states that ''[a] user charge * * * will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.'' The Circular gives three examples of when the special benefit is considered to accrue, including when a Government service: (a) Enables the beneficiary to obtain more immediate or substantial gains or values (which may or may not be measurable in monetary terms) than those that accrue to the general public (*e.g.,* receiving a patent, insurance, or guarantee provision, or a license to carry on a specific activity or business or various kinds of public land use); or (b) provides business stability or contributes to public confidence in the business activity of the beneficiary (*e.g.*, insuring deposits in commercial banks); or (c) is performed at the request of or for the convenience of the recipient, and is beyond the services regularly received by other members of the same industry or group or by the general public (*e.g.*, receiving a passport, visa, airman's certificate, or a Customs inspection after regular duty hours).

The Circular sets forth guidelines for determining the amount of user charges to assess. When the Government is acting in its sovereign capacity, user charges should be sufficient to cover the full cost to the Federal Government of providing the service, resource, or good.

The Circular sets forth criteria for determining full cost. ''Full cost includes all direct and indirect costs to any part of the Federal Government of providing a good, resource, or service.'' Examples of these types of costs include, but are not limited to, direct and indirect personnel costs, including salaries and fringe benefits; physical overhead, consulting, and other indirect costs, including material and supply costs, utilities, insurance, travel, and rents; management and supervisory costs; and the costs of enforcement, collection, research, establishment of standards, and regulation. Full costs are

determined based on the best available records of the agency.

Agencies are responsible for the initiation and adoption of user charge schedules consistent with the guidance listed in the Circular. In doing so, agencies should identify the services and activities covered by the Circular; determine the extent of the special benefits provided; and apply the principles set forth in the Circular in determining full cost or market cost as appropriate.

II. Introduction

Influenza, commonly known as ''the flu,'' is a contagious respiratory illness caused by a virus. In the United States, on average per year, 5% to 20% of the population gets the flu; more than 200,000 people are hospitalized from flu complications; and approximately 36,000 people die from flu. The best way to reduce the risk of getting the flu is to get a flu vaccine each fall.

On October 5, 2004, Chiron Corporation notified HHS, through the CDC, that none of its influenza vaccine would be available for distribution in the United States because of contamination problems with its facility in the United Kingdom. As a result, the expected supply of inactivated influenza vaccine (flu shot) was effectively cut in half. Increased production by MedImmune and Aventis alleviated some of the shortfall, but vaccine supplies were still cut by about 40% from expected levels. While the current influenza season has been mild so far, each influenza season is unpredictable with cases typically peaking between December and March. Therefore, the full severity of the 2004–2005 influenza season is not known.

In response to the vaccine shortage, CDC has announced priority groups that are more restricted than usual for vaccination with inactivated influenza vaccine for the 2004–2005 flu season. The priority groups, as they are called, number nearly 100 million persons and include the following persons:

- All children aged 6–23 months;
- Adults aged 65 years and older;
- Persons aged 2–64 years with underlying chronic medical conditions;
- Residents of nursing homes and long-term care facilities;
- Children aged 6 months–18 years on chronic aspirin therapy;
- All women who will be pregnant during the influenza season;
- Healthcare workers involved in direct patient care; and
- Household contacts of infants less than 6 months.

Effective January 3, 2005, in locations where state and local health authorities judge the vaccine supply to be adequate to meet the demand from groups on the restricted priority list, the priority groups for inactivated influenza vaccine may be expanded to include adults aged 50–64 years and out-of-home caregivers and household contacts of persons in high-risk groups. As demand for the vaccine evolves, CDC may further revise its recommended categories of individuals who should receive influenza vaccine, including the investigational vaccine.

On December 7, 2004, HHS Secretary Tommy G. Thompson announced the purchase of 1.2 million doses of GSK influenza vaccine, Fluarix, for distribution to areas most in need as determined by State public health authorities. Fluarix has not been licensed for use in the United States and will be administered under an IND. The Fluarix vaccine purchased by HHS has been approved in Germany and in about seventy-eight other countries worldwide, but is considered an investigational vaccine because it is not currently licensed by FDA.

Under an IND, patients who are offered the Fluarix vaccine must sign an informed consent form that provides important information on the risks and benefits, including potential adverse effects associated with the vaccine. The sponsor of this IND, GSK, is required to monitor the use of the investigational product, maintain adequate records, control the supply of the product, provide periodic reports to FDA regarding safety and other issues, and make sure informed consent is obtained from individuals before they receive the vaccine. FDA regulations in parts 312, 50, and 56 of Title 21 of the Code of Federal Regulations help ensure FDA's ability to monitor clinical investigations. These regulations specify the clinical investigators' responsibilities while administering the investigational vaccine, as well as the responsibilities of the sponsor, or a contract research organization to which the sponsor has delegated responsibilities. Those regulations also specify FDA's role and authority during and after the administration phase, such as its role in reviewing VAERS reports. To ensure that the vaccine is properly administered to individuals identified to be most at risk and facilitate compliance with IND requirements, CDC is establishing influenza vaccination clinics. A user fee is being established in order to recoup the costs associated with administering the vaccine and for the vaccine itself. Under an IND, commercialization of an investigational product in a clinical trial is not permitted without the prior written approval of FDA, and then the sponsor may only charge a price necessary to recover the costs of manufacture, research, development, and handling of the investigational drug. 21 CFR 312.7. GSK has sought and been granted a waiver of this IND provision in order to provide Fluarix on an expedited basis. 21 CFR 312.10. In addition, FDA has granted a waiver to GSK and CDC under 21 CFR 312.10 to authorize the user fee charge for costs associated with administration of the Fluarix vaccine. All persons, other than those who are enrolled in Medicare Part B, will be required to pay the user fee. Under Title 18 of the Social Security Act, the Center for Medicare and Medicaid Services will reimburse CDC's contractor for the costs associated with administration of vaccine provided to individuals enrolled in Medicare Part B. For this reason, the user fee will not be applied to such individuals.

III. Services and Activities Covered by User Fee

The user fee will cover the costs of the purchase of the Fluarix vaccine in addition to costs associated with administering the flu vaccine. The following is a list of services and activities that are covered by the user fee. Costs may be included in the user fee other than those listed here:

- Executing and administering the IND Influenza Vaccine Program according to the Protocol and Investigator's Handbook;
- Providing information to the participants about the program;
- Collecting information designated on the eligibility forms;
- Obtaining informed consent and collecting signed consent forms from eligible participants;
- Providing and administering vaccine to participants per protocol procedures;
- Tracking vaccine storage and accountability;
- Safely keeping and storing all funds collected via cash or check from IND participants;
- Ensuring the ability and capacity of the sites to correctly file and source IND documents and store them securely;
- Key punching program data at each vaccination site within two days of vaccinating participant(s) via CDC's web-accessed portal;
- Identifying any deviations from the program that might occur and documenting them accordingly;
- Providing all necessary data forms such as enrollment packets, which will also include an informed consent form and a Vaccine Adverse Event Reporting Systems (VAERS) form, to participants;

• Keeping a roster of personnel who carried out activities related to the IND including: (1) Obtained informed consent, (2) confirmed eligibility and information on eligibility form, (3) administered vaccine, and (4) were responsible for storage and maintenance of vaccine at each clinic on the days of vaccination;

• Performing all provided services in accordance with industry standards, including sterile collection, handling and processing procedures, and hazardous medical waste guidelines; and

• Recording in the medical records any adverse reactions to vaccines in accordance with the VAERS protocol and to the FDA as required by law.

IV. Special Benefit Provided

Individuals vaccinated for influenza obtain a health benefit compared to unvaccinated individuals. Influenza is a serious disease. In an average year, influenza infection is associated with 36,000 deaths (mostly among those aged 65 years or older) and more than 200,000 hospitalizations in the United States. The ''flu season'' in the United States is usually from November through April each year. During this time, flu viruses are circulating in the population. An annual flu vaccine is the best way to reduce the chances that an individual will get the flu. Individuals who get vaccinated after December can still benefit, if flu is present then or later in the community. The vaccine should continue to be offered to unvaccinated people throughout the flu season as long as vaccine is still available. Once vaccinated, the human body makes protective antibodies in about two weeks.

Individuals vaccinated with the Fluarix vaccine under CDC auspices obtain a special benefit not accruing to individuals in the general public who are not vaccinated. To assess the use of influenza vaccine this season, CDC temporarily added new questions to the Behavioral Risk Factor Surveillance System (BRFSS) beginning November 1, 2004. BRFSS is a monthly, ongoing telephone survey conducted by state health departments with assistance from CDC. Results of interviews conducted December 1–11, 2004 to assess vaccination during September 1–November 30, 2004 were published in the December 17 issue of CDC's Morbidity and Mortality Weekly Reports (MMWR).

Among adults in all vaccination priority groups, 34.8% reported receiving an influenza vaccination since September 1, 2004, compared with 4.4% of adults aged 18–64 years who were not in a priority group. Among all adults, coverage was highest among persons aged ≥65 at 51.1%, followed by 34.2% of health-care workers with patient contact, and 19.3% of high-risk adults aged 18–64 years. The percentage of persons reporting that they obtained an influenza vaccination September 1–November 30, 2004 is lower in each of these groups than the percentage who said they obtained a vaccination during the last influenza season (September 1, 2003–March 30, 2004).

Among adults in a vaccination priority group who have not received vaccine so far this season, 23.3% reported that they tried to obtain the vaccine and could not. Among persons aged 65 years and over, 32.5% reported that they tried to get the vaccine and could not. Among respondents with an unvaccinated child aged 6–23 months, 8.4% tried but could not obtain vaccination. For respondents with an unvaccinated eligible child aged 2–17 years, 14.4% reported that they tried but could not obtain vaccination. By establishing its own vaccination clinics, CDC will be able to help assure an adequate supply of the vaccine for individuals who choose to receive the Fluarix vaccine.

V. Analysis of User Fee Charge (Cost to the Government)

The cost to the Government of the user fee was determined in two parts. The first was for the cost of purchase of Fluarix by CDC at $7.00 per dose. The second part is for administration of the vaccine. CDC has entered into a contract with a Contract Research Organization to administer this vaccine. The costs associated with administration of the vaccine (see services and activities in section III above) were determined to be $18.00 per dose. The total cost to the Government and therefore the total user fee is determined to be $25.00 per dose.

VI. Emergency Action

We are proceeding without notice and comment rulemaking because we need to respond immediately to the unprecedented influenza vaccine shortage. Under the provisions of the Administrative Procedure Act at 5 U.S.C. 553(b)(3)(B) and 553(d)(3), we find good cause that prior notice and comment on this rule and a 30-day delay in effective date is impracticable and contrary to the public interest.

After November and December, many persons who should or want to receive influenza vaccine remain unvaccinated. To improve vaccine coverage, influenza vaccine should continue to be offered throughout the influenza season as long as vaccine supplies are available, including after influenza activity has been documented in the community. In the United States, seasonal influenza activity can begin to increase as early as October or November, but influenza activity has not reached peak levels in the majority of recent seasons until late December—early March, with seasons typically peaking most often in February. Therefore, although the timing of influenza activity can vary by region, vaccine administered after December on a national basis is likely to be beneficial in the majority of influenza seasons. Adults develop peak antibody protection against influenza infection 2 weeks after vaccination.

We expect influenza activity to continue and to increase over the next few to several weeks based on current surveillance data, especially the finding that only about 3.1% of respiratory specimens submitted to the World Health Organization (WHO) and the National Respiratory and Enteric Virus Surveillance System (NREVSS) for influenza testing are positive for influenza. Normally, at the peak of the influenza season over 20% of specimens submitted for influenza testing will test positive for influenza. However, we cannot predict when the season will peak or the duration of the season.

Accordingly, given the likelihood (based on historical evidence) that influenza cases may peak in February, obtaining prior notice and comment is impracticable and contrary to the public interest because it would delay implementation of this rule to the extent that the vaccine may not be administered in time for it to be effective.

VII. Regulatory Analyses

Economic Impact (Executive Order 12866)

We have examined the impacts of the interim final rule under Executive Order 12866, which directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). We have determined that the rule is consistent with the principles set forth in the Executive Order, and that while it is a significant regulatory action it is not an ''economically significant regulatory action'' within the meaning of Executive Order 12866.

Regulatory Flexibility Act

We have examined the impacts of the interim final rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). Unless we certify that the rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. The Regulatory Flexibility Analysis concludes that the rule is not expected to have a significant impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act of 1996

This regulatory action is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This interim final rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Paperwork Reduction Act

The interim final rule does not require any information collections. Therefore, we have not conducted a Paperwork Reduction Act analysis.

National Environmental Policy Act (NEPA)

The interim final rule is excluded from NEPA's environmental review requirements, pursuant to 48 FR 9374–02 (National Environmental Policy Act (NEPA), Review of Program Actions), based on the determination that it will not normally significantly affect the human environment.

Civil Justice (Executive Order 12988)

This interim final rule is in compliance with Executive Order 12988.

List of Subjects in 42 CFR Part 70

Communicable diseases, Public health, Quarantine, Reporting and recordkeeping requirements, Travel restrictions, User fees, Vaccination.

■ For the reasons set forth in the preamble, amend part 70 of title 42 of the Code of Federal Regulations as follows:

PART 70—INTERSTATE QUARANTINE

■ 1. The authority citation for part 70 is revised to read as follows:

Authority: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243); section 361–369, PHS Act, as amended (42 U.S.C. 264–272); 31 U.S.C. 9701.

■ 2. Add § 70.9 to read as follows:

§ 70.9 Vaccination clinics.

(a) The Director may establish vaccination clinics, through contract or otherwise, authorized to administer vaccines and/or other prophylaxis.

(b) A vaccination fee may be charged for individuals not enrolled in Medicare Part B to cover costs associated with administration of the vaccine and/or other prophylaxis. Such fee is to be collected at the time that the vaccine is administered. The vaccination fee, if imposed, is shown in the following table:

Vaccine	Effective dates	Amount
Fluarix	[1] 1/25/05	[2] $25.00

[1] Continuing for one year.
[2] $7.00 for the vaccine and $18.00 for administration.

Dated: January 12, 2005.

Tommy G. Thompson,

Secretary.

[FR Doc. 05–1310 Filed 1–19–05; 1:30 pm]

BILLING CODE 4160–17–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Reinstating Special Regulations for the Preble's Meadow Jumping Mouse

AGENCIES: Fish and Wildlife Service, Interior.

ACTION: Final rule; correction.

SUMMARY: On May 22, 2001, the Fish and Wildlife Service (Service) adopted special regulations governing take of the threatened Preble's meadow jumping mouse *(Zapus hudsonius preblei)*. On October 1, 2002, the Service amended those regulations to provide exemptions for certain activities related to noxious weed control and ongoing ditch maintenance activities. These regulations were set to expire on May 22, 2004. On May 20, 2004, the Service published a final rule to extend these special regulations permanently. However, in spite of this final rule, the special regulations were removed from the CFR. This removal was done in error. With this final rule, we reinstate the regulatory text at § 17.40(l) as it was set forth in the May 20, 2004, final rule.

DATES: Effective May 20, 2004.

ADDRESSES: Division of Policy and Directives Management, U.S. Fish and Wildlife Service, Mail Stop 222, Arlington Square, 4401 N. Fairfax Drive, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Sara Prigan, Federal Register Liaison, Fish and Wildlife Service, at (703) 358–2508.

SUPPLEMENTARY INFORMATION:

Background

On May 22, 2001 (66 FR 28125), the Fish and Wildlife Service (Service, or we) adopted special regulations at 50 CFR 17.40(l) governing take of the threatened Preble's meadow jumping mouse *(Zapus hudsonius preblei)*. The special regulations provided exemption from take provisions under section 9 of the Endangered Species Act for certain activities related to rodent control, ongoing agricultural activities, landscape maintenance, and existing uses of water. On October 1, 2002 (67 FR 61531), we amended these regulations to exempt certain activities related to noxious weed control and ongoing ditch maintenance activities. These regulations as amended were set to expire on May 22, 2004. On May 20, 2004 (69 FR 29101), we published a final rule to extend these special regulations permanently. We made this final rule effective on May 20, 2004, in order to avoid a gap in effectiveness. However, in spite of our efforts, by some error, the special regulations were removed from the CFR on May 22, 2004. With this correction, we reinstate the regulatory text of 17.40(l) as set forth in the May 20, 2004, final rule (69 FR 29101).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Export, Import, Reporting and recordkeeping requirements, Transportation.

Regulation Correction

PART 17—[CORRECTED]

■ For reasons set forth in the preamble, we correct 50 CFR 17.40 by reinstating paragraph (l), to read as follows:

§ 17.40 Special rules—mammals.

* * * * *

(l) Preble's meadow jumping mouse *(Zapus hudsonius preblei)*.

(1) *What is the definition of take?* To harass, harm, pursue, hunt, shoot,