ADDRESSES: You may submit comments, identified by RIN 1250–AA02, by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 693–1304 (for comments of six pages or less).
- *Mail:* Debra A. Carr, Director, Division of Policy, Planning, and Program Development, Office of Federal Contract Compliance Programs, Room C–3325, 200 Constitution Avenue NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Debra A. Carr, Director, Division of Policy, Planning and Program Development, Office of Federal Contract Compliance Programs, 200 Constitution Avenue NW., Room C–3325, Washington, DC 20210. Telephone: (202) 693–0103 (voice) or (202) 693–1337 (TTY).

SUPPLEMENTARY INFORMATION: On December 9, 2011, OFCCP published a proposed rule entitled, ''Affirmative Action and Nondiscrimination Obligations of Contractors and Subcontractors Regarding Individuals with Disabilities'' (76 FR 77056). OFCCP was to receive comments on this NPRM on or before February 7, 2012.

Various organizations and entities submitted requests to extend the comment period by an additional 90 days or more. We considered these requests and determined that it is appropriate to provide an additional 14-day period for comment on the proposed regulation. We are, therefore, extending the comment period until, Tuesday, February 21, 2012.

Extension of Comment Period: OFCCP determined that the public could use additional time to review the potential impact of the proposed requirements. Therefore, to allow the public sufficient time to review and comment on the NPRM, OFCCP is extending the comment period until February 21, 2012.

Signed at Washington, DC, this 6th day of February, 2012.

Patricia A. Shiu,

Director, Office of Federal Contract Compliance Programs.

[FR Doc. 2012–3106 Filed 2–7–12; 11:15 am]

BILLING CODE 4510–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[Docket No. CDC–2012–0002]

RIN 0920–AA47

Establishment of User Fees for Filovirus Testing of Nonhuman Primate Liver Samples

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

ACTION: Notice of Proposed Rulemaking and request for comments.

SUMMARY: Through this Notice of Proposed Rulemaking (NPRM), the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) is proposing to establish a user fee for filovirus testing of all nonhuman primates that die during the HHS/CDC-required 31-day quarantine period for any reason other than trauma. We propose to establish a filovirus testing service at HHS/CDC because testing is no longer being offered by the only private, commercial laboratory that previously performed these tests. This testing service will be funded through user fees. Elsewhere in this issue of the **Federal Register**, HHS/CDC is simultaneously publishing a companion direct final rule that proposes identical filovirus testing and user fee requirements in this **Federal Register** because it believes that these requirements are non-controversial and unlikely to generate significant adverse comment. If HHS/CDC does not receive any significant adverse comment on the direct final rule within the specified comment period, it will publish a notice in the **Federal Register** withdrawing this notice of proposed rulemaking and confirming the effective date of the direct final rule within 30 days after the end of the comment period on the direct final rule. If HHS/CDC receives any timely significant adverse comment, it will withdraw the direct final rule in part or in whole by publication of a notice in the **Federal Register** within 30 days after the comment period ends and proceed with notice and comment under this notice of proposed rulemaking. A significant adverse comment is one that explains: Why the direct final rule is inappropriate, including challenges to the rule's underlying premise or approach; or why the direct final rule will be ineffective or unacceptable without a change.

DATES: Submit written or electronic comments by April 10, 2012.

ADDRESSES: You may submit comments, identified by ''RIN 0920–AA47'': By any of the following methods:

- *Internet:* Access the Federal e-rulemaking portal at *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–03, Atlanta, Georgia 30333, ATTN: NHP NPRM.

Instructions: All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. All comments will be posted without change to *http://regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, please go to *http://www.regulations.gov.* Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Time, at 1600 Clifton Road NE., Atlanta, Georgia 30333. Please call ahead to 1–866–694–4867 and ask for a representative in the Division of Global Migration and Quarantine (DGMQ) to schedule your visit. To download an electronic version of the rule, access *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For questions concerning this notice of proposed rulemaking: Ashley A. Marrone, JD, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop E–03, Atlanta, Georgia 30333; telephone 404 498–1600. For information concerning program operations: Dr. Robert Mullan, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop E–03, Atlanta, Georgia 30333; telephone 404 498–1600.

SUPPLEMENTARY INFORMATION: This preamble is organized as follows:

I. Public Participation
II. Background
III. Rationale for Proposal
IV. User Fee
V. Services and Activities Covered by This User Fees
VI. Analysis of User Fee Charge (Cost to Government)
VII. Payment Instructions
VIII. Regulatory Analysis
IX. References

I. Public Participation

Interested persons are invited to participate in this rulemaking by submitting written views, opinions, recommendations, and data. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you do not wish to be disclosed publicly. Comments are invited on any topic directly related to this proposed rule.

II. Background

Filoviruses belong to a family of viruses known to cause severe hemorrhagic fever in humans and nonhuman primates (NHPs). So far, only two members of this virus family have been identified: Ebola virus and Marburg virus. Five species of Ebola virus have been acknowledged: Zaire, Sudan, Reston, Ivory Coast, and Bundibugyo. Most strains of Ebola virus can be highly fatal in humans, and while the Reston strain is the only strain of filovirus that has *not* been reported to cause disease in humans, it can be fatal in monkeys. (*http://www.cdc.gov/ncidod/dvrd/spb/mnpages/dispages/filoviruses.htm*).

Ebola hemorrhagic fever was first recognized in 1976, when two epidemics occurred in southern Sudan and in Zaire. Since that time, multiple outbreaks have occurred, mostly in Central Africa, and all have been associated with high (45–90%) case-fatality rates in humans (for an updated list see *http://www.cdc.gov/ncidod/dvrd/spb/mnpages/dispages/ebola/ebolatable.htm*). In these epidemics, transmission of the disease originated or occurred in a hospital (often by contaminated needles) and was followed by person-to-person transmission by individuals who were exposed to, or had close contact with blood or secretions from seriously ill patients.

The ecology, natural history, and mode of transmission of Ebola virus in nature, and of the related Marburg virus, are becoming more clearly understood with the implication of bats as reservoirs. The incubation period for Ebola disease is 5–9 days (range: 2–15 days) but can be shorter with parenteral transmission. Disease onset is abrupt and characterized by severe malaise, headache, high fever, myalgia, joint pains, and sore throat. The progression is rapid and includes pharyngitis, conjunctivitis, diarrhea, abdominal pain, and occasionally facial edema and jaundice. Severe thrombocytopenia can occur, with hemorrhagic manifestations ranging from petechiae to frank bleeding. Death occurs primarily as a result of multi-organ failures. There is no specific therapy, and patient management is usually limited to supportive measures. The disease in nonhuman primates is very similar to that in humans, with a very high mortality.

On January 19, 1990, in response to the identification of Ebola-Reston virus in NHPs imported from the Philippines, HHS/CDC published interim guidelines for handling NHPs during transit and also during quarantine (1). Importers of NHPs were informed by letter from the HHS/CDC Director on March 15, 1990, that they must comply with specific isolation and quarantine standards under 42 CFR part 71 for continued registration as an importer of NHPs (2).

On March 23, 1990, HHS/CDC held a meeting at CDC headquarters in Atlanta, Georgia, at which the public could comment on new guidelines for the importation of NHPs and the potential impact of a temporary ban on the importation of cynomolgus monkeys into the United States (3). After considering information received at this public meeting, coupled with an April 4, 1990 confirmation of asymptomatic Ebola virus infection in four NHP caretakers and serologic findings suggesting that cynomolgus, African green, and rhesus monkeys posed a risk for human filovirus infection, HHS/CDC concluded that these three species were capable of being an animal host or vector of human disease (4).

As a result, on April 20, 1990, HHS/CDC published a notice in the **Federal Register** requiring a special-permit for importing cynomolgus, African green, and rhesus monkeys (5). To be granted a special-permit, importers must submit a plan to HHS/CDC describing specific isolation, quarantine, and communicable disease control measures. The plan must detail the measures to be carried out at every step of the chain of custody, from embarkation at the country of origin, through delivery of the NHPs to the quarantine facility and the completion of the required quarantine period. Additional requirements include detailed testing procedures for all quarantined NHPs to rule out the possibility of filovirus infection. When importers demonstrate compliance with these special-permit requirements, HHS/CDC authorizes continued shipments under the same permit for a period of 180 days. Certain components of the special-permit requirement have changed slightly in response to surveillance findings and the development of improved laboratory tests. As indicated in the 1990 notice, importers were informed of these changes by letter from HHS/CDC (6). The current special-permit notice requires filovirus antigen-detection testing on liver specimens from any NHP that dies during quarantine for reasons other than trauma (7, 8). Antibody testing is also required on surviving NHPs that exhibit signs of possible filovirus infection before the cohort is released from quarantine (9).

Since October 10, 1975, HHS/CDC has prohibited the importation of NHPs except for scientific, educational, or exhibition purposes. Over time, various measures (*e.g.,* reports, letters, guidelines, notices), have been used to support implementation of these regulations. On January 5, 2011, HHS/CDC posted a Notice of Proposed Rulemaking (NPRM) to begin the process of revising these requirements. The NPRM was intended to solicit public comment and feedback on the issue of NHP importation to determine the need for further rulemaking. Please see the docket details for HHS–OS–2011–0002 on *www.Regulations.gov,* for more information. The public comment period ended on April 25, 2011. HHS/CDC is now working toward finalizing the proposed rule and is not seeking additional comment on the NPRM through this rulemaking.

Laboratory testing of suspected NHPs and early detection of infected animals within the quarantine period prevents spread of disease among NHPs and caretakers (4). Since the implementation and strengthening of the 1990 special-permit requirements for importing nonhuman primates into the United States, the morbidity and mortality of imported animals has decreased from an estimated 20% to less than 1% (10). Since 1990, these laboratory tests have been conducted by a sole commercial laboratory. Recently, a number of circumstances have arisen such that this laboratory is no longer able to perform the testing for filovirus required on liver specimens from monkeys that die during the HHS/CDC-mandated quarantine. Further, HHS/CDC notes that the reagents required for this testing are not commercially available and production of the reagents requires a biosafety level 4 laboratory (BSL–4). A BSL–4 laboratory is also required during part of the testing procedure. To our knowledge, neither commercial entities nor Federal laboratories other than those at HHS/CDC are planning to offer this service. Because HHS/CDC has the required laboratory facility, access to the reagents, and experienced personnel, it has started performing this testing when

required and in the absence of a viable alternative.

III. Rationale for Proposal

Through this NPRM, HHS/CDC is proposing to establish a user fee to reimburse HHS/CDC for the costs incurred performing the required filovirus testing and seeks public comment on this proposal. If promulgated as proposed, upon the effective date of the final rule, every NHP quarantine facility will be contacted by HHS/CDC's Division of Global Migration and Quarantine (DGMQ), and will be instructed how to transfer tissue specimens to HHS/CDC for testing. After receipt of the specimens, HHS/CDC will process the specimens in its BSL–4 laboratory and test the specimens by an antigen-detection enzyme-linked immunosorbant assay (ELISA) or other appropriate methodology. Each specimen will be held for six months. After six months, the specimen will be disposed of following established HHS/CDC protocol. Based on information supplied by the commercial laboratory, HHS/CDC estimates that between 100 and 150 specimens per year are expected to be received and tested. Results will be provided to the NHP importers. If a positive test result is found, HHS/CDC will ensure that the NHP cohort is not released from HHS/CDC required quarantine until the health status of the full cohort is determined. This testing protocol would be maintained until further notice.

HHS/CDC has chosen to establish this testing service based on the unanticipated loss of the only commercially available antigen-detection ELISA filovirus testing facility. Currently, there are no commercially available assays for filovirus antigen detection in tissue samples and this testing cannot readily be performed in the private sector because the testing requires a BSL–4 laboratory and the reagents are not commercially available. Other factors which contribute to the necessity of the testing service include the limited availability of BSL–4 laboratories, the special expertise required to perform these tests, the lack of commercially-available reagents, the need and requirement for continued and ongoing filovirus testing to protect public health, the negative effect on science, education and exhibition if imports of NHPs are disrupted, and the lack of other testing alternatives.

Nothing in this proposal is intended to prohibit a private sector facility from developing the capability and offering this same service in the future. The testing of non-human primate samples is necessary to prevent and control a potential outbreak of a filovirus infection in imported monkeys and to prevent the potential spread of filoviruses to humans.

IV. User Fees

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.

Finally, CDC has legal authority to retain collected user fees through its annual appropriations bill. In fiscal year 2012, this authority is provided through the Consolidated Appropriations Act of 2012, Public Law 112–74, 125 Stat. 1069, 1070 (2011).

V. Services and Activities Covered by This User Fee

HHS/CDC is establishing a user fee to recoup the costs associated with performing the required testing. The user fee will cover the costs of the test for filovirus for specimens submitted to HHS/CDC. The following is a list of services and activities that are covered by the user fee:

- Providing information to the participants about the service, including instructions on submission of samples and payment;
- Receiving payment and maintaining account, including distributing funds;
- Tracking the shipment to ensure a safe arrival at HHS/CDC;
- Providing reagents for and performing the antigen-detection test on submitted NHP liver samples in a BSL–4, high-containment facility;
- Performing all provided services in accordance with industry standards, including quality assurance, handling and processing procedures, and hazardous medical waste guidelines; and
- Ensuring that the importer receives the test results in a timely manner.

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

HHS/CDC's analysis of costs to the Government is based on the current methodology (ELISA) used to test NHP liver samples. This cost determines the amount of the user fee. HHS/CDC notes that the use of a different methodology or changes in the availability of ELISA reagents will affect the amount of the user fee. HHS/CDC will impose the fee by schedule and will notify importers of changes to the user fee by notice in the **Federal Register**. Importers may also contact HHS/CDC at 404–498–1600 or check its Web site (*http://www.cdc.gov/animalimportation/*) for an up-to-date fee schedule.

In its analysis of cost, HHS/CDC considered five components: (1) The cost of reagents and materials; (2) the cost of the BSL–4 laboratory in reagent production and during the assay; (3) the cost of irradiation of the sample; (4) personnel costs to perform the testing; and (5) administrative costs. The total cost to the Government is summarized in Table 1 followed by a description of each component; all monies reflected are in U.S. Dollars (USD).

TABLE 1—SUMMARY CALCULATIONS OF USER FEE CHARGE-PER-TEST

Components	Costs (USD)
1. Use of reagents and other materials	$100
2. Use of BSL–4 lab facility	112
3. Irradiation (inactivation) of sample	150
4. Personnel costs to conduct testing	145
5. Administrative costs	33
ESTIMATED TOTAL	540
User Fee	540

The first component in the estimate is the cost of the reagent materials and other materials necessary to perform the test. Two reagents are used to prepare the specific antibodies needed in the test. These reagents are not commercially available and must be made in-house by HHS/CDC scientists. Since these reagents are not commercially available, there is no commercial or observable product pricing. HHS/CDC estimates the cost for these reagents to be $70.00. This amount includes the cost of production and validation of the reagents. Material costs include plastic plates, pipettes, and other reagents. These items are available commercially and their cost is estimated at $30.00. Thus, the total estimated cost for this component totals $100.00 per test. This cost can be a bit higher or lower depending on how many tests are run at the same time. If the test requests come in one at a time, then the cost might be above $100, if there is more than one request at a time, the cost might be a bit less than $100. The test calls for the same amount of reagents for one or 3 samples to test.

The second component is the cost of the BSL–4 facility that is used to develop the reagents. We have estimated this cost on the charges made by University of Texas Medical Branch at Galveston (UTMB) of $28 per hour. The UTMB is the only BSL–4 facility in the United States that has developed commercial fees for the use of their labs. In the ELISA methodology, scientists need four hours in the BSL–4 laboratory to process the sample. The cost of this component is $112.00.

The third component in the cost estimate is the cost to inactivate the sample by irradiation in an irradiator. For this component, we estimate the cost to use an irradiator at $30 per hour. This estimate is based on a five-year cost of $300,000 to HHS/CDC to run and maintain the irradiator. Irradiators are extremely expensive to maintain for a number of reasons. Only research facilities have irradiator equipment because of the need to inactivate high-hazard pathogens. Safety restrictions on irradiators are complex and time consuming; requiring frequent, professional safety inspections and complex annual training for all personnel that work with or near the irradiator. Finally, a high level of security must be maintained because the complexities of using irradiators and the specimens being irradiated require access to be controlled and monitored. Typically it takes five hours to inactivate a sample, at a total estimated irradiation cost of $150.

The fourth component of the cost is the hourly wage and benefits of personnel who perform the laboratory tests. We assume that the scientist performing the test is a microbiologist with a masters' degree. Most of the personnel in this category are paid at a GS 11 level. For the purposes of this estimate, we have assumed a pay level of GS 11, Step 3. We set the basic wage at $25.70 per hour, and a benefit of 30% for a total hourly salary of $33.41 an hour (U.S. Office of Personnel Management 2010 General Schedule (GS) Locality Pay Tables for Atlanta; *http://www.opm.gov/oca/11tables/indexgs.asp*). In total, the tests take about 13 hours (four hours in the BSL–4; three hours of irradiation; and six hours running the test with interpretation). However, we assume that the person working on this test will be carrying on other duties simultaneously. Therefore, we assign one-third of the 13 hours of work time to the fourth part, or $145.00 ($434.33/3).

The fifth and final component is the administrative costs related to test result collection and dissemination. The individual responsible for the activities under this component is typically in a supervisory position. The supervisor examines the assay to ensure that the positive and negative tests (quality controls) are accurate, and to ensure that the test was performed according to prescribed scientific standards. The supervisor puts the results on a response form and sends the results to the importer with a copy to CDC's Division of Global Migration and Quarantine (DGMQ). To calculate this cost, we used half an hour of the salary and benefits of a GS 14 level, Senior Health Scientist (601 series). The hourly rate of a GS14, level 3 is $50 (U.S. Office of Personnel Management 2010 General Schedule (GS) Locality Pay Tables for Atlanta; *http://www.opm.gov/oca/10tables/indexgs.asp*). We added 30% of the hourly rate for benefits to total $65.00. Thirty minutes of this individual's time is $33.00.

Total cost: Adding these parts (Table 1) results in a grand total of $540. We note that our results can potentially vary from this figure for a couple of reasons. First, as mentioned already, commercial data are not available for some of the reagents so our calculation of their costs is an estimate and not based on observed market pricing. Second, the costs will vary depending on how many tests are conducted at one time. If multiple tests are run concurrently, then the costs would be a bit less. If only one test is conducted at one time, the costs will be relatively higher. Therefore, we set the cost of reimbursement per test at $540. We feel confident that this is a fair price to the importers because this amount is consistent with the sum charged by the commercial lab of $500.00 that previously performed these tests. We also note that our assumption of the effect of multiple tests is supported by past experience. HHS/CDC receives notification of about 100 to 150 requests performed per year. Although HHS/CDC cannot control the flow of tests and cannot forecast how many tests will be underway at any given point in time, HHS/CDC estimates that the total amount of fees charged will range from about $50,000 to $75,000 per year. The user fee charged for the testing will cover the costs of the test.

HHS/CDC will impose the user fee by schedule. An up-to-date fee schedule is available from the Division of Global

Migration & Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia 30333, 404–498–1600, or [insert url of Web site].

VII. Payment Instructions

HHS/CDC Importers should submit a check or money order in the amount of $540.00 (USD) made payable to Centers for Disease Control and Prevention for each test conducted at the time that specimens are submitted to the CDC for testing. The check(s) should be sent to Centers for Disease Control and Prevention, P.O. Box 15580, Atlanta, GA 30333.

VIII. Regulatory Analyses

A. Required Regulatory Analyses Under Executive Orders 12866 and 13563

We have examined the impacts of the proposed rule under Executive Orders 12866 and 13563, which direct 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). Because the purpose of this rule is to provide a framework to determine a fair fee to charge for a service that has become unavailable in private, commercial markets within the United States, we have determined that the rule will not violate the intent of either of the Executive Orders because it will in no way prevent a private entity from entering the field and providing a similar, privatized service. If any private entity expresses an interest in providing this service, we will strongly encourage them to do so.

B. Regulatory Flexibility Act

We have examined the impacts of the proposed 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. We certify that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

C. 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 proposed 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.

D. The Paperwork Reduction Act of 1995

HHS/CDC has reviewed the information collection requirements of the proposed rule and has determined that the information collection requested in the proposed rule is already approved by the Office of Management and Budget (OMB) under OMB Control No. 0920–0263, expiration date 6/30/2014. The proposed rule does not contain any new data collection or record keeping requirements.

E. National Environmental Policy Act (NEPA)

Pursuant to 48 FR 9374 (list of HHS/CDC program actions that are categorically excluded from the NEPA environmental review process), HHS/CDC has determined that this action does not qualify for a categorical exclusion. In the absence of an applicable categorical exclusion, the Director, CDC, has determined that provisions amending 42 CFR 71.53 will not have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

F. Civil Justice Reform (Executive Order 12988)

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this proposed rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

G. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' The rule does not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.''

H. Plain Language Act of 2010

Under Public Law 111–274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal Government administers or enforces. HHS has attempted to use plain language in promulgating this rule consistent with the Federal Plain Writing Act guidelines.

I. Conclusion

In accordance with the provisions of Executive Order 12866, this proposed rule was not reviewed by the Office of Management and Budget.

IX. References

1. Centers for Disease Control and Prevention. Update: Ebola-Related Filovirus Infection in Nonhuman Primates and Interim Guidelines for Handling Nonhuman Primates during Transit and Quarantine. Morbidity and Mortality Weekly Report MMWR 1990; 39(2):22–24, 29–30.
2. Roper, W.L. Dear interested party (letter). March 15, 1990. Available upon request: (404) 639–1600.
3. 55 FR 10288, March 20, 1990, ''Importation of Nonhuman Primates: Meeting.''
4. Centers for Disease Control and Prevention. Update: Filovirus Infection in Animal Handlers. Morbidity and Mortality Weekly Report MMWR 1990; 39(13):221.
5. 55 FR 15210, April 20, 1990, Requirement for a Special-permit to Import Cynomolgus, African Green, or rhesus Monkeys into the United States.
6. Roper, W.L. Dear interested party (letter). October 10, 1991. Available upon request: (404) 639–1600.
7. Ksiazek, Thomas G.; Rollin, Pierre E.; Jahrling, Peter B.; Johnson, Eugene; Dalgard, Dan W., and Peters, Clarence J. Enzyme immunosorbent assay for Ebola virus antigens in tissues of infected primates. Journal of Clinical Microbiology. 1992; (304):947–950.
8. Ksiazek, Thomas G. Laboratory diagnosis of filovirus infections in nonhuman primates. Laboratory Animal. 1991; 20(7):34–46.
9. Tipple, M.A. Dear interested party (letter). March 5, 1996. Available upon request: (404) 639–1600.
10. Demarcus, T., Tipple, M., Ostrowski, S., U.S. Policy for Disease Control among Imported Nonhuman Primates, J Infect Dis. (1999) 179 (supplement 1): S281–S282.

List of Subjects in 42 CFR Part 71

Communicable diseases, Public health, Quarantine, Reporting and recordkeeping requirements, Testing, User fees.

For the reasons set forth in the preamble, HHS proposes to amend 42 CFR part 71 as follows:

PART 71—FOREIGN QUARANTINE

1. The authority citation for part 71 continues 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.

Subpart F—Importations

2. In § 71.53, add paragraph (j) to read as follows:

§ 71.53 Nonhuman primates.

* * * * *

(j) *Filovirus Testing Fee.* (1) Non-human primate importers shall be charged a fee for filovirus testing of non-human primate liver samples submitted to the Centers for Disease Control and Prevention (CDC).

(2) The fee shall be based on the cost of reagents and other materials necessary to perform the testing; the use of the laboratory testing facility; irradiation for inactivation of the sample; personnel costs associated with performance of the laboratory tests; and administrative costs for test planning, review of assay results, and dissemination of test results.

(3) An up-to-date fee schedule is available from the Division of Global Migration & Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, Atlanta, Georgia 30333. Any changes in the fee schedule will be published in the **Federal Register**.

(4) The fee must be paid in U.S. dollars at the time that the importer submits the specimens to HHS/CDC for testing.

Dated: January 19, 2012.

Kathleen Sebelius,

Secretary.

[FR Doc. 2012–2841 Filed 2–9–12; 8:45 am]

BILLING CODE 4163–18–P