*Hours:* 6,000 (For policy questions regarding this collection contact Diane Ross at 410–786–1169. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Beneficiary Customer Service Feedback Survey; *Use:* The Centers for Medicare and Medicaid Services (CMS) stresses a continuing need for setting customer service goals that include providing accurate, timely, and relevant information to its customers. With these goals in mind, the Division of Medicare Ombudsman Assistance (DMOA) needs to periodically survey its customers that correspond with CMS to ensure that the needs of Medicare beneficiaries are being met. This survey will be used to measure overall satisfaction of the customer service that the DMOA provides to Medicare beneficiaries and their representatives. The need for this previously OMB approved information collection is to further meet the customer service goals that the CMS has established and to continue to create a rapport within the Medicare community. *Form Number:* CMS–10068 (OMB#: 0938–0894); *Frequency:* Quarterly; *Affected Public:* Individuals and Households; *Number of Respondents:* 2,242 *Total Annual Responses:* 2,242; *Total Annual Hours:* 224. (For policy questions regarding this collection contact Nancy Conn at 410–786–8374. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration; *Use:* The End Stage Renal Disease (ESRD) Medical Evidence Report is completed for all ESRD patients either by the first treatment facility or by a Medicare-approved ESRD facility when it is determined by a physician that the patient's condition has reached that stage of renal impairment that a regular course of kidney dialysis or a kidney transplant is necessary to maintain life. The data reported on the CMS–2728 is used by the Federal Government, ESRD Networks, treatment facilities, researchers and others to monitor and assess the quality and type of care provided to end stage renal disease beneficiaries. The data collection captures the specific medical information required to determine the Medicare medical eligibility of End Stage Renal Disease claimants. *Form Number:* CMS–2728 (OMB#: 0938–0046); *Frequency:* Occasionally; *Affected Public:* Individuals or households; *Number of Respondents:* 100,000; *Total Annual Responses:* 100,000; *Total Annual Hours:* 75,000. (For policy questions regarding this collection contact Connie Cole at 410–786–0257. For all other issues call 410–786–1326.)

6. T*ype of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Conditions of Coverage for Organ Procurement Organizations and Supporting Regulations in 42 CFR, Sections 486.301–.348; *Use:* Section 1138(b) of the Social Security Act, as added by section 9318 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509), sets forth the statutory qualifications and requirements that OPOs must meet in order for the costs of their services in procuring organs for transplant centers to be reimbursable under the Medicare and Medicaid programs. An OPO must be certified and designated by the Secretary as an OPO and must meet performance-related standards prescribed by the Secretary. The corresponding regulations are found at 42 CFR Part 486 (Conditions for Coverage of Specialized Services Furnished by Suppliers) under subpart G (Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations).

Since each OPO has a monopoly on organ procurement within its donation service area, CMS must hold OPOs to high standards. Collection of this information is necessary for CMS to assess the effectiveness of each OPO and determine whether it should continue to be certified as an OPO and designated for a particular donation service area by the Secretary or replaced by an OPO that can more effectively procure organs within the donation service area. *Form Number:* CMS–R–13 (OMB#: 0938–0688); *Frequency:* Occasionally; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 79; *Total Annual Responses:* 79; *Total Annual Hours:* 15,178. (For policy questions regarding this collection contact Diane Corning at 410–786–8486. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *October 4, 2010.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: August 26, 2010.

**Michelle Shortt,**

*Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2010–21721 Filed 9–2–10; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[60Day–10–10GX]**

### Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, Ph.D., CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov.*

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

**Proposed Project**

Persistence of Viable Influenza Virus in Aerosols—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The National Institute for Occupational Safety and Health (NIOSH) is authorized to conduct research to advance the health and safety of workers under Section 20(a)(1) of the 1970 Occupational Safety and Health Act.

Influenza continues to be a major public health concern because of the substantial health burden from seasonal influenza and the potential for a severe pandemic. Although influenza is known to be transmitted by infectious secretions, these secretions can be transferred from person to person in many different ways, and the relative importance of the different pathways is not known. The likelihood of the transmission of influenza virus by small infectious airborne particles produced during coughing and breathing is particularly unclear. The question of airborne transmission is especially important in healthcare facilities, where influenza patients tend to congregate during influenza season, because it directly impacts the infection control and personal protective measures that should be taken by healthcare workers.

The purpose of this study is to measure the amount of viable influenza virus in airborne particles that are produced by patients when they cough, and the size and quantity of the particles carrying the virus. A better understanding of the amount of potentially infectious material released by patients and the size of the particles carrying the virus will assist in determining the possible role of airborne transmission in the spread of influenza and in devising measures to prevent it.

Volunteer participants will be recruited by a test coordinator using a flyer describing the study. Interested potential participants will be screened using a short health questionnaire to verify that they have influenza-like symptoms and that they do not have any medical conditions that would preclude their participation. Qualified participants who agree to participate in the study will be asked to read and sign an informed consent form. Based on a previous study using similar forms, we estimate that the health questionnaire will require about 5 minutes to complete, and the informed consent form will take about 20 minutes to read and sign. Once the informed consent form is signed, the participant will be asked to cough into an aerosol particle collection system, and the airborne particles produced by the participant during coughing will be collected and tested.

ESTIMATED ANNUAL BURDEN HOURS

| Type of respondent | Form | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|---|
| Initial participants | Health questionnaire | 132 | 1 | 5/60 | 11 |
| Qualified participants | Informed Consent form | 120 | 1 | 20/60 | 40 |
| Total | | | | | 51 |

Dated: August 27, 2010.

**Maryam I. Daneshvar,**

*Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2010–22053 Filed 9–2–10; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–E–0290]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; NEURX DIAPHRAGM PACING SYSTEM

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for NEURX DIAPHRAGM PACING SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

**ADDRESSES:** Submit electronic comments to *http://www.regulations.gov*. Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) 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 Patents and Trademarks 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).