and is designed to establish a fixed but reasonable time for implementing this policy change. This phase-in period will provide agencies with time to comply with their obligations under the Federal Service Labor-Management Relations Act, as amended, 5 U.S.C. Ch. 71, Labor-Management Relations, in those circumstances where there is an exclusive union representative for the employees.

b. The only exceptions to the general policy against smoking as described in EO 13058 and this bulletin are:

(1) Residential accommodations for persons voluntarily or involuntarily residing, on a temporary or long-term basis, in a building owned, leased or rented by the Federal Government;

(2) Portions of federally owned buildings leased, rented or otherwise provided in their entirety to non-federal parties; and

(3) Places of employment in the private sector or in other non-Federal Governmental units that serve as the permanent or intermittent duty station of one or more federal employees.

c. The exception in the Federal Management Regulation (FMR) for designated smoking areas, 41 CFR 102–74.320(a), is being eliminated. Accordingly, all designated interior smoking areas will be closed [insert date 6 months after publication of FMR amendment on smoking, FMR Case 2008–102–3]. This date provides a six-month phase-in period and is designed to establish a fixed but reasonable time for implementing this policy change. This phase-in period will provide agencies with time to comply with their obligations under the Federal Service Labor-Management Relations Act, as amended, 5 U.S.C. Ch. 71, Labor-Management Relations, in those circumstances where there is an exclusive union representative for the employees.

d. Executive agency heads may establish limited and narrow exceptions that are necessary to accomplish agency missions. Such exceptions must be in writing, approved by the agency head and, to the fullest extent possible, provide protection of non-smokers from exposure to environmental tobacco smoke. Authority to establish such exceptions may not be delegated.

e. The heads of executive agencies are encouraged to use existing authority to establish programs designed to help employees stop smoking. Cessation program materials for agencies interested in establishing a smoking cessation program for their employees are available from the Department of Health and Human Services, Centers for Disease Control and Prevention, Web site at *http://www.cdc.gov/tobacco/quit_smoking/index.htm.* This Web site also identifies several How to Quit resources for individuals interested in smoking cessation.

f. The heads of executive agencies are responsible for ensuring compliance with the requirements of this bulletin.

[FR Doc. E8–30377 Filed 12–19–08; 8:45 am]

**BILLING CODE 6820–RH–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0990–0260]**

### Agency Information Collection Request; 30-Day Public Comment Request

**AGENCY:** Office of the Secretary.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services (HHS), is publishing the following summary of a proposed information collection request for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *Sherette.funncoleman@hhs.gov*, or call the Reports Clearance Office on (202) 690–5683. Written comments and recommendations for the proposed information collections must be directed to the OS Paperwork Clearance Officer at the above e-mail address within 30 days.

*Proposed Project:* Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation—OMB No. 0990–0260—Office for Human Research Protections.

*Abstract:* Section 491(a) of Public Law 99–158 states that the Secretary of HHS shall by regulation require that each entity applying for HHS support (e.g., a grant, contract, or cooperative agreement) to conduct research involving human subjects submit to HHS assurances satisfactory to the Secretary that it has established an institutional review board (IRB) to review the research in order to ensure protection of the rights and welfare of the human research subjects. IRBs are boards, committees, or groups formally designated by an entity to review, approve, and have continuing oversight of research involving human subjects.

Pursuant to the requirement of the Public Law 99–158, HHS promulgated regulations at 45 CFR part 46, subpart A, the basic HHS Policy for the Protection of Human Subjects. The June 18, 1991 adoption of the common Federal Policy (56 FR 28003) by 15 departments and agencies implements a recommendation of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research which was established on November 9, 1974, by Pub. L. 95–622. The Common Rule is based on HHS regulations at 45 CFR part 46, subpart A, the basic HHS Policy for the Protection of Human Subjects.

The respondents for this collection are institutions engaged in such research. Institutional adherence to the Common Rules also is required by other federal departments and agencies that have codified or follow the Common Rule which is identical to 45 CFR part 46, subpart A. The information being requested related to the Common Rule should be readily available to the institution or organization that registers the IRB.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

| Title | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|
| .103(b)(4), .109(d) IRB Actions, .116 and .117 Informed Consent ..... | 6,000 | 39.33 | 1 | 235,980 |

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

| Title | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|
| .115(a) IRB Recordkeeping | 6,000 | 15 | 10 | 900,000 |
| .103(b)(5) Incident Reporting, .113 Suspension or Termination Reporting .. | 6,000 | 0.5 | 45/60 | 2,250 |
| Total | ..... | ..... | ..... | 1,138,230 |

**Seleda Perryman,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. E8–30274 Filed 12–19–08; 8:45 am]

**BILLING CODE 4150–36–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Declaration Under the Public Readiness and Emergency Preparedness Act

**AGENCY:** Office of the Secretary (OS), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** Declaration pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to provide targeted liability protections for pandemic influenza diagnostics, personal respiratory protection devices, and respiratory support devices based on a credible risk that an avian influenza virus spreads and evolves into a strain capable of causing a pandemic of human influenza.

**DATES:** This notice and the attached declaration are effective as of the date of signature of the declaration.

**FOR FURTHER INFORMATION CONTACT:** RADM W.C. Vanderwagen, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** Highly pathogenic avian influenza A H5N1 viruses have been spread by infected migratory birds and exports of poultry or poultry products from Asia through Europe and Africa since 2003, and could spread into North America in 2008 or later, and have caused disease in humans, with over 60% of infected people dying from H5N1. In addition to H5N1, other animal influenza A viruses have also caused disease in humans, including H2N2, H7N7, H7N2, and H9N2 influenza A viruses, and also pose a pandemic threat. Section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d), which was enacted by the Public Readiness and Emergency Preparedness Act, is intended to alleviate certain liability concerns associated with pandemic countermeasures, and, therefore, ensure that the countermeasures are available and can be administered in the event an avian influenza virus spreads and evolves into a strain capable of causing a pandemic of human influenza.

### HHS Secretary's Declaration for the Use of the Public Readiness and Emergency Preparedness Act for Pandemic Influenza Diagnostics, Personal Respiratory Protection Devices, and Respiratory Support Devices

*Whereas* highly pathogenic avian H5N1 influenza A viruses have spread, through various mechanisms, from Asia through Europe and Africa since 2003 and have caused disease in humans with an associated high case fatality. The real possibility that these viruses could be spread into North America exists as well as the possibility that these H5N1 viruses could participate directly or indirectly in development of a human pandemic strain;

*Whereas* other animal influenza viruses such as H2N2, H7N2, H7N7 and H9N2 viruses have also caused illness among humans and pose a pandemic threat;

*Whereas* avian H5N1 or other influenza A viruses might evolve into strains capable of causing a pandemic of human influenza;

*Whereas* there are countermeasures to identify, reduce exposure to, or support patients infected by highly pathogenic avian H5N1 influenza A viruses, other animal influenza viruses that pose a pandemic threat, or pandemic influenza in humans;

*Whereas* such countermeasures that currently exist or may be the subject of research and development include diagnostics to identify avian or other animal influenza A viruses that pose a pandemic threat, or to otherwise aid in the diagnosis of pandemic influenza; personal respiratory protection devices to reduce exposure to avian or other animal influenza A viruses; and respiratory support devices to support patients infected by avian or other animal influenza A viruses;

*Whereas* such countermeasures may be used and administered in accordance with Federal contracts, cooperative agreements, grants, interagency agreements, and memoranda of understanding, and may also be used and administered at the Regional, State, and local level in accordance with the public health and medical response of the Authority Having Jurisdiction;

*Whereas,* the possibility of governmental program planners obtaining stockpiles from private sector entities except through voluntary means such as commercial sale, donation, or deployment would undermine national preparedness efforts and should be discouraged as provided for in section 319F–3(b)(2)(E) of the Public Health Service Act (42 U.S.C. 247d-6d(b)) (''the Act'');

*Whereas,* immunity under section 319F–3(a) of the Act should be available to governmental program planners for distributions of Covered Countermeasures obtained voluntarily, such as by (1) Donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles;

*Whereas,* the extent of immunity under section 319F–3(a) of the Act afforded to a governmental program planner that obtains Covered Countermeasures except through voluntary means is not intended to affect the extent of immunity afforded other covered persons with respect to such Covered Countermeasures;

*Whereas,* in accordance with section 319F–3(b)(6) of the Act, I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacturing, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration,