

affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);

- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on Tribal governments or preempt Tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: June 26, 2009.

Jane Diamond,

Acting Regional Administrator, Region IX.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

Possession, Use, and Transfer of Select Agents and Toxins; Proposed Addition of SARS-Associated Coronavirus (SARS-CoV)

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The biological agents and toxins listed in § 73.3 of Title 42 of the

Code of Federal Regulations have been determined by the Secretary of the U.S. Department of Health and Human Services (HHS Secretary) to have the potential to pose a severe threat to public health and safety. We are now proposing to add SARS-associated coronavirus (SARS-CoV) to the list of HHS select agents and toxins. We are proposing this action because (1) SARS-CoV can cause significant mortality, especially in the elderly; (2) the virus has the capability of easily being transmitted from human to human; (3) there is currently no vaccine or antiviral approved for the prevention or treatment of infections caused by the SARS-CoV virus; and (4) it has been documented that the virus may persist in the environment.

DATES: Written comments must be received on or before September 11, 2009. Comments received after September 11, 2009 will be considered to the extent practicable.

ADDRESSES: Comments on the proposed addition of SARS-CoV to the list of select agents and toxins should be marked “SARS-CoV” and mailed to: Centers for Disease Control and Prevention, Division of Select Agents and Toxins, 1600 Clifton Road, MS A-46, Atlanta, GA 30333. Comments may be e-mailed to: SAPcomments@cdc.gov.

FOR FURTHER INFORMATION CONTACT: Robbin Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road, MS A-46, Atlanta, GA 30333. Telephone: (404) 718-2000.

SUPPLEMENTARY INFORMATION: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107-188 (42 U.S.C. 262a) (the Bioterrorism Act), requires the HHS Secretary to establish by regulation a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety. In determining whether to include an agent or toxin on the list, the HHS Secretary considers the effect on human health of exposure to an agent or toxin; the degree of contagiousness of an agent and the methods by which an agent or toxin is transferred to humans; the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent illnesses resulting from an agent or toxin; the potential for an agent or toxin to be used as a biological weapon; and the needs of children and other vulnerable populations.

SARS-associated coronavirus (SARS-CoV) causes a viral respiratory illness, severe acute respiratory syndrome (SARS), which was first reported in Asia

in February 2003. According to the World Health Organization (WHO), a total of 8,098 people worldwide became sick with SARS during the 2003 outbreak, resulting in 774 deaths. SARS-CoV is thought to be transmitted most readily by respiratory droplets (droplet spread) produced when an infected person coughs or sneezes. The virus also can spread when a person touches a surface or object contaminated with infectious droplets and then touches his or her mouth, nose, or eye(s). In addition, it is possible that SARS-CoV might be spread more broadly through the air (airborne spread) or by other ways that are not now known. There is currently no known SARS transmission anywhere in the world. The last known human cases of SARS-CoV infection as reported by the World Health Organization occurred in China in April 2004 in an outbreak resulting from laboratory-acquired infections.

After consulting with subject matter experts from the CDC, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the United States Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/CVB (Center for Veterinary Biologics), and the Department of Defense (DOD)/United States Army Medical Research Institute for Infectious Diseases (USAMRIID) and conducting a review of relevant published studies, we are proposing that SARS-CoV should be added to the list of HHS select agents and toxins because:

- The virus causes significant mortality, especially in the elderly.^{i, iii}
- The virus has the capability of easily being transmitted from human-to-human.^{iv}
- There is currently no method to treat infections caused by the virus.^v
- It has been demonstrated that the virus may persist in the environment.

We will consider comments that are received within 60 days of publication of this notice in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any changes to the list of HHS select agents and toxins.

Compliance Dates

We recognize that there may be some individuals and/or entities that are not currently registered under either the HHS or USDA Select Agent Programs, but that do possess SARS-CoV and would therefore be required to register

with HHS should this proposed amendment be finalized.

Accordingly, as a result of this rule, an individual or entity that currently possesses SARS-CoV, if they are not already a registered entity, would have to either transfer the SARS-CoV to an individual or entity that was registered to possess SARS-CoV or become a registered individual or entity themselves. We recognize that an individual or entity that chooses to become registered for possession of SARS-CoV will need time to come into full compliance with the requirements of the regulations, including the granting of individual access through the security risk assessment process. To minimize the disruption of research, educational projects (e.g., teaching demonstrations), or other important activities involving SARS-CoV that might be underway as of the effective date of these proposed regulations, we are also proposing to provide that any unregistered individual or entity possessing SARS-CoV as of the effective date (current unregistered possessors) will be afforded time to reach full compliance with the select agent regulations (42 CFR part 73). Therefore, we are proposing that any current possessor of SARS-CoV must be fully registered and in full compliance with all provisions of the Select Agent Regulations not later than 180 days after the effective date of a final rule.

The Responsible Official for currently registered individuals or entities that possess SARS-CoV would be required to provide notice in the form of an amendment to their registration to HHS or USDA regarding their possession of SARS-CoV not later than 15 days after the effective date of this proposed amendment.

Regulatory Analyses

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Executive Order 12866 and Regulatory Flexibility Act

This rule will add SARS-CoV to the HHS select agent list. The purpose of the regulation of select agents and toxins is to reduce the potential for these agents and toxins to pose a severe threat to public health and safety by establishing Federal requirements for biosafety, security, training, and personnel surety. Should any select agent or toxin be intentionally or accidentally introduced into the

population of the United States, the consequences could be significant. The individuals and entities most likely to be affected by this proposed rule are those individuals at laboratories and other institutions conducting research and related activities that involve the use of SARS-CoV.

Based on CDC data, there are 138 entities that currently possess SARS-CoV. Of those 138 entities, 73 entities are registered with the select agent program of either HHS or USDA. The majority of the non-registered entities are commercial entities.

Costs. Our estimate of the long-term cost of implementing the select agent regulations is based on the actual costs incurred by registering entities implementing the interim final rule that became fully applicable on November 12, 2003. Additionally, before the interim final rule was issued in December 2002, CDC contacted a number of entities to assess existing practices. Because many of the laboratories that will register under this proposal are already substantially in compliance with the required practices, the costs of the rule should be limited.

Benefits. The benefits to public health and safety from implementation of the rule are clear, although difficult to quantify. The benefits of the final rule will be the decreased risk of accidental or intentional release of a select agent derived from the establishment of Federal requirements for biosafety, security, training, and personnel surety. The cost of such an event in human life could be very high. The release of a select agent or toxin could result in a public health emergency requiring an extensive and expensive response. This effort could include extensive public health measures, such as quarantine, preventative treatment and health testing for large numbers of potentially exposed persons, and extensive decontamination. Substantial costs could be incurred by hospitals and other medical facilities and institutions of government at all levels. A release, or widespread fear of one, also would create significant secondary effects. It could disrupt business, transportation, and many other aspects of normal behavior, on both a short-term and potentially a long-term basis.

The impacts resulting from the October 2001 anthrax attacks provide an example of the costs that a release could incur. The anthrax attacks caused five fatalities and 17 illnesses, disrupted business and government activities, and caused widespread apprehension and changes in behavior. Costs included more than \$23 million to decontaminate one Senate office building;

approximately \$2 billion in revenues lost to the postal service, and as much as \$3 billion in additional costs to the postal service for cleanup of contamination and procurement of mail sanitizing equipment.¹ Substantial costs due to lost productivity throughout the economy and from ongoing costs of the investigations into the incident are additional impacts.

Implementation of this rule will continue to provide a means for the registration of those who possess select agents; ensure that their transfer, storage, and use can be tracked; provide for the screening of personnel with access to such agents; and require that entities in possession of such agents develop and implement effective means of biosafety and physical security. The benefit of these provisions is a reduced likelihood of either an accidental or intentional release of select agents or the consequent avoidance of costs associated with such a release.

Impacts resulting from the costs of the rule should not be significant. The annualized cost on small entities would not exceed one percent of sales or revenue stream and the initial cost would not exceed three percent of sales or revenue stream, according to the economic analysis, "Regulatory Impact Analysis, 42 CFR part 73, Possession, Use, and Transfer of Select Biological Agents and Toxins Final Rule." To request a copy of this report, send an e-mail to SAPcomments@cdc.gov. The HHS Secretary hereby certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Insert on Small Entity Impact

The Regulatory Flexibility Act (RFA) of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires agencies to prepare an initial regulatory flexibility analysis for any rule subject to notice and comment rulemaking unless the agency is able to certify that the rule will not have a significant economic impact on a substantial number of small entities.

HHS guidance on the treatment of small entities suggests that a "substantial number" should be considered to mean 5 percent or more of the affected small entities within an identified industry. The U.S. Small Business Administration (SBA) has established size standards for all for-profit industries based on either the

¹ Regulatory Impact Analysis for 42 CFR Part 73: Possession, Use, and Transfer of Select Biological Agents and Toxins Final Rule. Centers for Disease Control and Prevention, Department of Health and Human Services. February 3, 2005.

number of employees or annual revenue, depending on the North American Industry Classification System (NAICS) classification. Most affected entities would be considered part of NAICS code 5417102 Research and Development in Life Sciences. Per the SBA's *Table of Small Business Size Standards*, the Research and Development entities in NAICS code 5417102 are considered small if they have fewer than 500 employees.² According to the Economic Census, there are 4,674 life sciences research and development establishments that are categorized as "small" using this standard.³ Based on CDC data, there are 138 entities that are known to currently possess SARS-Co-V, and even if all 138 entities were considered small, less than 3 percent of the small facilities in NAICS code 5417102 would be affected by the rule.

Furthermore, the HHS guidance defines a "significant economic impact" as an average annual impact of 3 to 5 percent or more of total costs or revenues. The 65 entities that are not registered with the select agent program must comply with the select agent regulations, including becoming registered and ensuring adequate biosafety and containment measures, physical security, training, and recordkeeping. The average cost for a facility to register with CDC and otherwise comply with 42 CFR part 73 is estimated to range from \$15,300 to \$170,000 (70 FR 13315, March 18, 2005). The 73 entities that are already registered because they possess other listed select agents or toxins would need to amend their registrations, but they are likely to already have adequate physical security, training programs, and recordkeeping systems to enable them to safely and securely possess and use SARS-CoV. The average revenue for the small establishments in NAICS code 5417102 is about \$3,493,000, so the average annual impact for facilities to comply with the rule would range from less than 1 percent to less than 5 percent.

Therefore, the HHS Secretary has certified that the final rule will not have a significant economic impact on a substantial number of small entities.

² U.S. Small Business Administration. Table of Small Business Size Standards Matched to North American Industry Classification System Codes. August 22, 2008. Available at: http://www.sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf.

³ http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=8-fds_name=EC0200A1&-skip=800&-ds_name=EC0254SSSZ5&-lang=en.

Executive Order 12988

This Notice of Proposed Rulemaking has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Would preempt all State and local laws and regulations that are inconsistent with this rule; (2) would have no retroactive effect; and (3) would not require administrative proceedings before parties may file suit in court challenging this rule.

List of Subjects in 42 CFR Part 73

Biologics, Incorporation by reference, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Transportation.

Dated: June 9, 2009.

Kathleen Sebelius,
Secretary.

For the reasons stated in the preamble, we are proposing to amend 42 CFR part 73 as follows:

PART 73—SELECT AGENTS AND TOXINS

1. The authority citation for part 73 continues to read as follows:

Authority: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188, 116 Stat. 637 (42 U.S.C. 262a).

2. Amend paragraph (b) of § 73.3 by adding the following entry in alphabetical order to read as follows:

§ 73.3 HHS select agents and toxins.

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(b) * * *

SARS-associated coronavirus (SARS-CoV)

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[FR Doc. E9–16536 Filed 7–10–09; 8:45 am]

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ⁱ World Health Organization, *SARS: How a global epidemic was stopped*. 2006.

ⁱⁱ Poutanen SM, Low DE, Henry B, *et al.* Identification of severe acute respiratory syndrome in Canada. *N Engl J Med* 2003; 348:1995–2005.

ⁱⁱⁱ Lee N, Hui D, Wu A, *et al.* A major outbreak of severe acute respiratory syndrome in Hong Kong. *N Engl J Med* 2003; 348:1986–1994.

^{iv} Ksiazek TG, Erdman D, Goldsmith CS, *et al.* A novel coronavirus associated with severe acute respiratory syndrome. *N Engl J Med* 2003; 348:1953–1966.

^v Holmes KV. SARS coronavirus: a new challenge for prevention and therapy. *J Clin Invest* 2003; 111:1605–9.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 411, 414, 415, and 485

[CMS–1413–CN]

RIN 0938–AP40

Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction of proposed rule.

SUMMARY: This document corrects a technical error in the proposed rule entitled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010" which appears elsewhere in this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Diane Milstead, (410) 786–3355.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. E9–15835 of July 13, 2009, there was a technical error that is identified and corrected in the Correction of Errors section below.

II. Summary of Errors

In section V., Regulatory Impact Analysis, of the preamble of the proposed rule entitled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010" that is published elsewhere in this **Federal Register**, we inadvertently omitted language regarding the impact of the proposed Physician Fee Schedule Update for CY 2010.

III. Correction of Errors

In FR Doc. E9–15835 of July 13, 2009, to make a correction to section V. of the preamble, the Regulatory Impact Analysis, prior to the section labeled "U. Alternatives Considered," the following language should be inserted: "L. Physician Fee Schedule Update for CY 2010 In section II.P. of the proposed rule, we describe our proposal to remove physician-administered drugs from the definition of physicians' services for purposes of calculating allowed and actual expenditures for all years since the 1996/1997 base year, and for purposes of calculating the SGR for 2010 and all subsequent years. While this proposal would not change the