

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.<sup>2</sup> According to the Economic Census, there are 4,674 life sciences research and development establishments that are categorized as "small" using this standard.<sup>3</sup> 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.

<sup>2</sup> 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](http://www.sba.gov/idc/groups/public/documents/sba_homepage/serv_sstd_tablepdf.pdf).

<sup>3</sup> [http://factfinder.census.gov/servlet/IBQTable?\\_bm=y&-geo\\_id=&-fds\\_name=EC0200A1&-skip=800&-ds\\_name=EC0254SSSZ5&-lang=en](http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-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.

\* \* \* \* \*

(b) \* \* \*

SARS-associated coronavirus (SARS-CoV)

\* \* \* \* \*

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

**BILLING CODE 4163–18–P**

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

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

<sup>iii</sup> 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.

<sup>iv</sup> 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.

<sup>v</sup> 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

projected – 21.5 percent physician payment rate update for services furnished on or after January 1, 2010, this change would reduce the discrepancy between actual and target expenditures. Based on the President’s budget, we estimate this proposal would cost \$45.4 billion from 2010 to 2014.

Projected updates would increase over this same period from between – 6.3 and – 5.4 percent to between – 3.1 and +1.4 percent respectively.”

**Authority:** Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774,

Medicare—Supplementary Medical Insurance Program.

Dated: July 8, 2009.

**Ashley Files Flory,**

*Acting Executive Secretary to the Department.*

[FR Doc. E9–16507 Filed 7–8–09; 4:15 pm]

**BILLING CODE 4120–01–P**