burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Incorporation by reference will not impose any new burdens on small entities. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Order 13132 (64 FR 43255, August 10, 1999), does not apply to this rule because it will not have federalism implications (i.e., substantial direct effects on the States, on the relationship between national government and the states, or on the distribution of power and responsibilities among the various levels of government). This action also does not have Tribal implications within the meaning of Executive Order 13175 (65 FR 67249, November 6, 2000).

This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. This action is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply Distribution or Use'' (66 FR 28344, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

EPA approves state programs as long as they meet criteria required by RCRA, so it would be inconsistent with applicable law for EPA, in its review of a state program, to require the use of any particular voluntary consensus standard in place of another standard that meets requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply to this rule.

As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. The final rule does not include environmental justice issues that require consideration under Executive Order 12898 (59 FR 7629, February 16, 1994). EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order.

The Congressional Review Act (5 U.S.C. 801 *et seq*), generally provides that, before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This action will be effective September 20, 2013.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This notice is issued under the authority of Sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: June 27, 2013.

Mark Hague,

Acting Regional Administrator, Region 7.

[FR Doc. 2013–17566 Filed 7–19–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 7

[Docket No. CDC–2013–0013]

RIN 0920–AA53

Distribution of Reference Biological Standards and Biological Preparations

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

ACTION: Direct final rule and request for comments.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) proposes to update four sections of its regulations titled ''Distribution of Reference Biological Standards and Biological Preparations'' to update the authority citation and reflect the agency's current name, address, and contact information for fees schedules and terms of payment. These updates will not affect current practices.

DATES: The direct final rule (DFR) is effective on September 20, 2013 unless significant adverse comment is received by August 21, 2013. If we receive no significant adverse comments within the specified comment period, we intend to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days of the conclusion of the comment period. If we receive any timely significant adverse comment, we will withdraw this DFR in part or in whole by publishing a notice in the **Federal Register** within 30 days of the conclusion of the comment period.

ADDRESSES: You may submit comments, identified by ''RIN 0920–AA52'': 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 Scientific Resources, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS C–17, Atlanta, Georgia 30333, ATTN: Part 7 DFR.

Instructions: All submissions received must include the agency name and docket number or Regulation Identifier Number (RIN) for this rulemaking. All relevant 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 404–639–3466 and ask for a representative in the Division of Scientific Resources (DSR) 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 direct final rule: Dr. Carolyn M. Black, Director, Division of Scientific Resources, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop C–17, Atlanta, Georgia 30333; telephone 404–639–3466.

SUPPLEMENTARY INFORMATION: The preamble is organized as follows:

I. Public Participation

HHS/CDC is publishing a DFR because it does not expect to receive any significant adverse comments and believes that these updates add clarity to the regulation and are non-controversial. However, interested persons may 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. You may submit comments on any topic related to this DFR.

II. Authority for These Regulations

The legal authority for this rulemaking is primarily based on Title V of the Independent Offices Appropriation Act of 1952 (31 U.S.C. 9701) which provides general authority to Federal agencies to establish user fees through regulations. HHS/CDC has legal authority to retain collected user fees through its annual appropriations bill. In fiscal year 2013, this authority is provided through the Continuing Appropriations Resolution, 2013, P.L. 112–175, 126 Stat. 1313 (2012). Additionally, HHS/CDC has legal authority under section 352 of the Public Health Service Act (42 U.S.C. 263). This section states that HHS/CDC may prepare any biological product described under section 351 of the Public Health Service Act (42 U.S.C. 262) for use by other Federal departments or agencies, and public or private agencies and individuals engaged in work in the field of medicine when such a product is not available from establishments licensed by HHS. HHS/CDC is also revising the legal authority section of the regulations to cite additional legal authority found in section 301(a) of the Public Health Service Act (42 U.S.C. 241(a)). This section states that the HHS Secretary may make substances and living organisms available to individuals and entities for biomedical and behavioral research under such terms and conditions (including payment) as the Secretary determines appropriate.

III. Why are we doing this rulemaking?

Under Executive Order 13563 (Improving Regulation and Regulatory Review), Federal agencies are required to periodically review existing regulation and consider how best to modify rules that may be outmoded, ineffective, insufficient, or excessively burdensome. As part of its periodic review of its regulations, HHS/CDC has identified this regulation as one that requires updating.

The regulations at 42 CFR 7 ''Distribution of Reference Biological Standards and Biological Preparations'' were promulgated in 1987 and have not been revised since then. In 1992, the U.S. Congress, as part of the Preventive Health Amendments of 1992, recognized CDC's leadership role in prevention by formally changing its name to the Centers for Disease Control and Prevention. The mailing address for HHS/CDC's Financial Management Office changed in the mid-1990s when the office moved from the Buckhead location. This update removes that address. Finally, this update will now include current contact information to obtain information concerning the availability of reference biological standards, the fee schedule, and payment instructions.

Thus, through this Direct Final Rule (DFR), HHS/CDC is simply updating the regulation to clarify the rule for the public. This DFR does not create any additional requirements or burden, nor does it affect the current practices of HHS/CDC. This rulemaking does not change the method by which fees are calculated.

HHS/CDC is publishing a DFR because it does not expect to receive any significant adverse comments and believes that these updates add clarity to the regulation and are non-controversial. If HHS/CDC does not receive any significant adverse comments on this DFR within the specified comment period, we will publish a document in the **Federal Register** confirming the effective date of this final rule within 30 days after the comment period on the DFR ends. If HHS/CDC receives any timely significant adverse comment, we will withdraw the DFR in part or in whole by publishing a notice in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is one that explains: (1) Why the DFR is inappropriate, including challenges to the rule's underlying premise or approach; or (2) why the DFR will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of the DFR, HHS/CDC will consider whether it warrants a substantive response in a notice and comment rulemaking process. If we receive significant adverse comment on this DFR, we will publish a timely withdrawal in the **Federal Register** informing the public that the amendment in this rule will not take effect. If this DFR is withdrawn, we will carefully consider all public comments before proceeding with any further rulemaking.

IV. Updates to Part 7

The regulations found at 42 CFR 7 describe how private entities may obtain reference biological standards and biological preparations from HHS/CDC and how charges for such standards and preparations are determined. In this DFR, HHS/CDC is updating the Authority citation, Section 7.1 (Applicability), Section 7.4 (Schedule of Charges), and Section 7.5 (Payment Procedures).

Updates to Authority

The authority citation will be amended to add section 301(a) of the Public Health Service Act (42 U.S.C. 241(a)).

Updates to Section 7.1 Applicability

Section 7.1 will be amended to change the agency's name from ''Centers for Disease Control'' to its current name, ''Centers for Disease Control and Prevention''.

Updates to Section 7.4 Schedule of Charges

Section 7.4 directs private entities to contact a particular unit within HHS/CDC by mail to obtain a current schedule of charges. This section will be amended to remove the reference to an organizational unit that no longer exists and replace it with current contact information to obtain information concerning the availability of reference biological standards and a current schedule of charges. Due to the changing inventory of the unique biological standards or biological preparations available to the public, some of which are prepared only upon request, a phone number in addition to a mailing address will be provided for

the public to request a current inventory and fee schedule. This rulemaking does not change the method by which fees are calculated.

Updates to Section 7.5 Payment Procedures

Section 7.5 instructs the public on how to obtain information on terms of payment and the current fee schedule. This section will be amended to provide current contact information for the public.

V. Alternatives Considered

Under Executive Order 13563 agencies are asked to consider all feasible alternatives to current practice and the rule as proposed. HHS/CDC notes that the main impact of this proposed rule is to update current definitions and clarify language in the current regulation to reflect modern terminology and plain language commonly used by global private sector industry and public health partners. The intent of this update is to clarify the name of the agency and the mailing address in the existing regulation to help the regulated community comply with current regulation. HHS/CDC believes that this rulemaking complies with the spirit of the Executive Order; updating the agency name and address provides good alternatives to the current regulation.

VI. Required Regulatory Analyses

A. Required Regulatory Analyses Under Executive Orders 12866 and 13563

Under Executive Order 12866 (EO 12866), Regulatory Planning and Review (58 FR 51735, October 4, 1993) HHS/CDC is required to determine whether this regulatory action would be ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Orders. This order defines ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may:

- Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients; or,
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in EO 12866.

Executive Order 13563 (EO 13563), Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011), updates some of the provisions of EO 12866 in order to promote more streamlined regulatory actions. This EO charges, in part, that, while protecting ''public health, welfare, safety, and our environment'' that regulations must also ''promote predictability and reduce uncertainty'' in order to promote economic growth. Further, regulations must be written in common language and be easy to understand. In the spirit of EO 13563, this DFR clarifies the regulation by updating the agency name and mailing address.

HHS/CDC has determined that this DFR is simply an update and clarification of the authority citation, agency name, and mailing address used in the current regulation. As such, the DFR complies with the spirit of EO 13563. Further, HHS/CDC has determined that this DFR is not a significant regulatory action as defined in EO 12866 because the DFR is administrative and does not change the baseline costs for any of the primary stakeholders. The Office of Management and Budget (OMB) has not reviewed this rulemaking.

B. Regulatory Flexibility Act

We have examined the impacts of the 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 (RFA), 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 DFR is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This 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 already determined that the Paperwork Reduction Act applies to the data collection requirements of 42 CFR Part 7 and has obtained approval by OMB to collect information under OMB Control No. 0920–0591, expiration 07/31/2014. The changes in this rule do not impact the data collection and do not require revision to the approval from OMB.

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, HHS/CDC has determined that provisions amending 42 CFR Part 7 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 rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this 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)

HHS/CDC 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/CDC has attempted to use plain language in

promulgating this rule consistent with the Federal Plain Writing Act and requests public comment on this effort.

List of Subjects in 42 CFR 7

Public health, CDC, Reference biological standards, Biological preparations, Schedule of charges

Amended Text

For the reasons discussed in the preamble, the Department of Health and Human Services amends 42 CFR Part 7 as follows:

PART 7—DISTRIBUTION OF REFERENCE BIOLOGICAL STANDARDS AND BIOLOGICAL PREPARATIONS

■ 1. The authority citation for part 7 is revised to read as follows:

Authority: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); title V of the Independent Offices Appropriations Act of 1952 (31 U.S.C. 9701); and secs. 301(a) and 352 of the Public Health Service Act, as amended (42 U.S.C. 241(a) and 263).

* * * * *

■ 2. Revise § 7.1 to read as follows:

§ 7.1 Applicability.

The provisions of this part are applicable to private entities requesting from the Centers for Disease Control and Prevention (CDC) reference biological Standards and Biological preparations for use in their laboratories.

■ 3. Revise § 7.4 to read as follows:

§ 7.4 Schedule of charges.

The charges imposed in § 7.2 are based on the amount published in CDC's price list of available products. These changes will reflect direct costs (such as salaries and equipment), indirect costs (such as rent, telephone service, and a proportionate share of management and administrative costs), and the cost of particular ingredients. Charges may vary over time and between different biological standards or biological preparations, depending upon the cost of ingredients and the complexity of production. An up-to-date schedule of charges is available from the Division of Scientific Resources, Centers for Disease Control, 1600 Clifton Road NE., MS C–17, Atlanta, Georgia, 30333 or 404–639–3466.

■ 4. Revise § 7.5 to read as follows:

§ 7.5 Payment procedures.

An up-to-date fee schedule and instructions for terms of payment are available from the Division of Scientific Resources, Centers for Disease Control and Prevention, 1600 Clifton Road, MS C–17, Atlanta, Georgia 30333 or 404–639–3466. Any changes in the fee schedule will be published in the **Federal Register**. The fee must be paid in U.S. dollars at the time that the requester requests the biological reference standard or biological preparation.

Dated: July 12, 2013.

Kathleen Sebelius,

Secretary.

[FR Doc. 2013–17543 Filed 7–19–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4173–CN]

RIN 0938–AR69

Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Correction

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

ACTION: Final rule; correction.

SUMMARY: This document corrects technical, typographical, and cross-referencing errors in the final rule that appeared in the May 23, 2013 **Federal Register** titled ''Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs.''

DATES: This correction document is effective on July 22, 2013.

FOR FURTHER INFORMATION CONTACT: Ilina Chaudhuri, 410–786–8628 or *Ilina.Chaudhuri@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2013–12156 of May 23, 2013 (78 FR 31284), there were a number of technical, typographical, and cross-referencing errors that are identified and corrected in the Correction of Errors section of this correcting document. The provisions in this correction document are effective as if they had been included in the document published May 23, 2013. Accordingly, the corrections are effective July 22, 2013.

II. Summary of Errors

• On page 31307, in § 422.2401-Definitions, Non-claims costs, paragraphs (3) and (4) of the regulations text, we made errors in the parenthetical cross-references for the definition of non-claims cost.

• On page 31308, in § 422.2420(c) Determining the MLR denominator, we made an error in the parenthetical cross-references for the regulatory requirement for the total revenue.

• On page 31310, in the table of contents for part 423 Subpart X—Requirements for a Minimum Medical Loss Ratio, we made a typographical error in a section number.

• On page 31311, in § 423.2410-General requirements, and in § 423.2420-Calculation of medical loss ratio, of the regulations text, we made several technical errors in the regulatory requirements as well as typographical errors in several references.

• On page 31312, in § 423.2420(c)(4) and (c)(5) of the regulations text, we incorrectly stated the section number for two parenthetical references. We also made a typographical error in the discussion of total revenue.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive this notice and comment procedure if the Secretary finds, for good cause, that the notice and comment process is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons therefore in the notice.

In our view, this correcting document does not constitute a rulemaking that would be subject to the APA notice and comment or delayed effective date requirements. This correcting document corrects technical, typographical, and cross-referencing errors in the Medicare Program; Medical Loss Ratio Requirements for the Medicare Advantage and the Medicare Prescription Drug Benefit Programs final rule and does not make substantive changes to the policies or payment methodologies that were adopted in the final rule. As a result, this correcting document is intended to ensure that the regulations text of the final rule accurately reflects the policies adopted.

In addition, even if this were a rulemaking to which the notice and comment applied, we find that there is good cause to waive such requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the final rule would be contrary to the