DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS-3271-P]

RIN 0938-AS04

Clinical Laboratory Improvement Amendments (CLIA); Fecal Occult Blood (FOB) Testing

AGENCY: Centers for Medicare & Medicaid Services (CMS); Centers for Disease Control and Prevention (CDC), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Clinical Laboratory Improvement Amendments (CLIA) regulations to clarify that the waived test categorization applies only to non-automated fecal occult blood tests. In addition, the proposed rule would remove the hemoglobin by copper sulfate method from the list of waived tests if commenters confirm that the method is no longer used.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: In commenting, please refer to file code CMS-3271-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to

http://www.regulations.gov. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-3271-P,

P.O. Box 8010,

Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-3271-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

7500 Security Boulevard,

Baltimore, MD 21244-1850

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the "**SUPPLEMENTARY INFORMATION**" section.

FOR FURTHER INFORMATION CONTACT:

Nancy Anderson, CDC, (404) 498-2280.

Judith Yost, CMS, (410) 786-3531.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period

are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) (section 353 of the Public Health Service Act, codified at 42 U.S.C. 263a) requires any facility performing examinations of human specimens (for example, tissue, blood, and urine) for diagnosis, prevention, or treatment purposes to be certified by the Secretary of the Department of Health and Human Services (HHS). The objective of the CLIA program is to ensure accurate and reliable laboratory testing. The Centers for Medicare & Medicaid Services (CMS) is responsible for the administration of CLIA. The Centers for Disease Control and Prevention (CDC) provides scientific and technical support/consultation to HHS/CMS. The Food and Drug Administration (FDA) is responsible for test categorization.

To enroll in the CLIA program, laboratories must first register by completing an application; pay applicable certificate fees; be surveyed, if applicable; and become certified. CLIA fees are based on the type of certificate requested by the laboratory (that is, waived,

provider-performed microscopy (PPM), accreditation, or compliance) and, for laboratories that perform moderate and high complexity testing, the annual volume and types of testing performed. Waived and PPM laboratories may apply directly for their certificates, as they are not subject to routine surveys.

To receive a certificate of waiver (COW) under CLIA, a laboratory must only perform tests listed as waived in the CLIA regulations at 42 CFR 493.15(c) (for example, blood glucose by glucose monitoring devices cleared by the FDA for home use) or tests which the FDA has determined to be waived because they are simple with an insignificant risk of error. Waived tests are exempt from most CLIA requirements, and the laboratories that perform them receive no routine surveys.

Waived laboratories must meet only the following requirements under CLIA:

- Enroll in the CLIA program;
- Pay applicable certificate fees biennially; and
- Follow manufacturers' test instructions.

Since the implementation of the CLIA program in 1992, the types of tests waived under CLIA have increased from 8 to currently119 tests; consequently, the percentage of laboratories issued a COW has grown significantly from 20 percent to almost 70 percent of the approximate 230,000 laboratories enrolled.

Dipstick or tablet reagent urinalysis (non-automated) and fecal occult blood (FOB) are two of the original 8 waived tests published in the **Federal Register** in 1992, listed at 42 CFR 493.15(c)(1) and (c)(2). The regulation specifies that waived test status is applicable to the “non-automated” dipstick or tablet reagent urinalysis, but it does not specify “non-automated” for FOB tests. At the time the regulation was adopted, the FOB was a manual or non-automated

test method. However, there are automated FOB analyzers that use complex and sophisticated technology, which do not meet the CLIA criteria for waiver and, therefore, should not be waived. It, therefore, is important to clarify these tests are not included in the list of tests waived in the CLIA regulations. As a result, we propose to revise the current regulation at §493.15(c)(2) to clarify that only non-automated FOB tests are automatically waived by regulation.

Furthermore, since the development and proliferation of the waived test for hemoglobin by single analyte instruments with self-contained or component features, as described at §493.15(c)(9), it is our understanding that the non-automated hemoglobin by copper sulfate method at §493.15(c)(6) may no longer be in use. Therefore, we are soliciting comments to determine if the waived test at §493.15(c)(6) Hemoglobin – copper sulfate – non-automated is still in use. If comments support the premise that this test is not in use, we propose to remove the test from the regulation.

II. Provisions of the Proposed Regulations

We propose to revise §493.15(c)(2) by adding the words "non-automated" following "fecal occult blood." This change would clarify the categorization of the more complex automated FOB analyzers.

In addition, we propose to remove the hemoglobin by copper sulfate method from the list of waived tests at §493.15(c)(6) if commenters confirm that the method is no longer used.

Finally, we propose to renumber the remaining paragraphs if §493.15(c)(6) is removed.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review

by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (Pub. L. 96-354, September 19, 1980), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4, March 22, 1995), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach this economic threshold and thus is not considered a major rule.

This proposed rule would amend the CLIA regulations at 42 CFR 493.15(c)(2) to clarify that only non-automated FOB tests are specifically waived by regulation. Automated test

systems that detect FOB would, therefore, be subject to test categorization by the FDA as moderate or high complexity as described in §493.17. These test systems would only be considered for waiver approval if the manufacturer submits a waiver application to FDA demonstrating the particular test system meets the statutory waiver criteria of being simple and having an insignificant risk by the user of an erroneous result.

As of April 5, 2013, the FDA CLIA test categorization database includes 111 FOB test systems. Two of these test systems are automated and are categorized by the FDA as moderate (non-waived) complexity; all others are waived non-automated methods (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm). However, because of the language in the current regulation governing FOB, it could be construed that automated FOB test systems are available for use by laboratories with a COW. If this proposed rule is finalized, these two automated test systems and any automated FOB systems that are developed in the future, will not be available for use by a laboratory with a COW under §493.15(c)(2). This means that testing sites using one or both of the two automated test systems noted above (that are categorized as moderate complexity tests) would be impacted by this rule if they are currently operating under a COW. Due to the low number of automated analyzers for FOB testing distributed in the United States, we estimate that less than 10 laboratories would be impacted by this proposed regulatory change.

Furthermore, our second proposal, the removal of the provision governing hemoglobin by the copper sulfate method at §493.15 (c)(6) is not expected to affect any laboratories, as we believe that it is no longer in use. Therefore, we believe the proposed regulatory changes outlined in this proposed rule would have little or no economic impact if they were to be finalized, and would not reach the economic threshold to be considered a major rule. We

welcome comments and supporting data regarding the potential impact of this change.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We believe approximately 73 percent of United States medical laboratories qualify as small entities based on their nonprofit status as reported in the American Hospital Association Fast Fact Sheet, updated January 3, 2013 (http://www.aha.org/research/rc/stat-studies/fast-facts.shtml). However, as previously described, due to the low number of automated analyzers distributed in the United States, we estimate that less than 10 laboratories would potentially be impacted by this regulatory change. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold would be reached by the requirements in this proposed rule because very few small entities would be subject to the provisions in this proposed rule.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We do not expect this proposed rule, if finalized, would have a significant impact on a substantial number of small rural hospitals. The changes proposed in this rule would apply only to the laboratories previously described, which do not include any small rural

hospitals at this time. Thus, an analysis under section 1102(b) of the Act is not required for this rulemaking.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. This proposed rule would not impose any mandates on state, local, or tribal governments. The impact on the private sector would be less than the threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this proposed regulation would not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

For reasons listed above, we believe this regulatory change would result in little or no economic impact. This proposed rule does not reach the economic threshold and thus is not considered a major rule. We are requesting comments and additional data to assist us in making a more thorough and accurate prediction of impact in the final rule.

List of Subjects in 42 CFR Part 493

Administrative practice and procedure, Grant programs-health, Health facilities, Laboratories, Medicaid, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR part 493 as set forth below:

PART 493 – LABORATORY REQUIREMENTS

1. The authority citation for part 493 continues to read as follows:

AUTHORITY: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)), and the Pub. L. 112-202 amendments to 42 U.S.C. 263a.

Section 493.15 is amended by--

A. Revising paragraph (c)(2).

B. Removing paragraph (c)(6).

C. Redesignating paragraphs (c)(7) through (c)(9) as paragraphs (c)(6) through (c)(8).

The revision reads as follows:

§493.15 Laboratories performing waived tests

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(c) * * *

(2) Fecal occult blood-non-automated;

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Dated: June 18, 2014.

Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: June 18, 2014.

Thomas R. Frieden,
Director, Centers for Disease Control and Prevention,

Administrator, Agency for Toxic Substances and Disease Registry.

Dated: September 18, 2014.

Sylvia M. Burwell,

Secretary,

Department of Health and Human Services.

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