C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will 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.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on any Indian tribes, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it merely rescinds a FIP covering a generating station that has been decommissioned and demolished.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards. The EPA is not revising any technical standards or imposing any new technical standards in this action.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in section III above.

L. Determination Under Section 307(d)

Pursuant to CAA section 307(d)(1)(B), the EPA has determined that this action is subject to the provisions of section 307(d). Section 307(d) establishes procedural requirements specific to certain rulemaking actions under the CAA. Pursuant to CAA section 307(d)(1)(B), the rescission of the MGS FIP is subject to the requirements of CAA section 307(d), as it constitutes a revision to a FIP under CAA section 110(c). Furthermore, CAA section 307(d)(1)(V) provides that the provisions of section 307(d) apply to ''such other actions as the Administrator may determine.'' The EPA determines that the provisions of 307(d) apply to the EPA's action on the MGS FIP rescission.

M. Congressional Review Act (CRA)

This rule is exempt from the CRA because it is a rule of particular applicability. The EPA is not required to submit a rule report regarding this action under section 801 because this is a rule of particular applicability that only applies to a single, decommissioned facility.

N. Petitions for Judicial Review

Under CAA section 307(b)(1), petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 19, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Sulfur oxides.

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

Dated: October 13, 2017.

E. Scott Pruitt,

Administrator, EPA.

For the reasons set forth in the preamble, EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart DD—Nevada

§ 52.1488 [Amended]

■ 2. Section 52.1488 is amended by removing and reserving paragraph (d).

[FR Doc. 2017–22701 Filed 10–19–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS–3271–F]

RIN 0938–AS04

Clinical Laboratory Improvement Amendments of 1988 (CLIA); Fecal Occult Blood (FOB) Testing

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

ACTION: Final rule.

SUMMARY: This final rule amends the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations to clarify that the waived test categorization applies only to non-automated fecal occult blood tests.

DATES: These regulations are effective December 19, 2017.

FOR FURTHER INFORMATION CONTACT: Nancy Anderson, CDC, (404) 498–2280, or Daralyn Hassan, CMS, (410) 786–9360.

SUPPLEMENTARY INFORMATION:

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 and CMS. The Food and Drug Administration (FDA) is responsible for test categorization.

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, urine pregnancy tests—visual color comparison tests) 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 currently 97; consequently, the percentage of laboratories issued a COW has grown significantly from 20 percent to almost 72 percent of the approximate 250,000 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, as specified at § 493.15(c)(1) and (2), respectively. The regulation specifies that waived test status is applicable to ''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 test was only available as a manual or non-automated test. However, there are now 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 was therefore necessary to propose amendments to the regulations to exclude these automated tests from the list of waived tests in the CLIA regulations.

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 was our understanding that the non-automated hemoglobin by copper sulfate method at § 493.15(c)(6) was no longer in use. Therefore, we proposed to remove the hemoglobin by copper sulfate method from the list of waived tests at § 493.15(c)(6) if commenters confirmed that the method is no longer used.

II. Provisions of the Proposed Regulations

On November 7, 2014, we published a proposed rule in the **Federal Register** (79 FR 66348 through 66350) entitled, ''Clinical Laboratory Improvement Amendments (CLIA); Fecal Occult Blood (FOB) Testing.'' In that rule, we proposed to revise § 493.15(c)(2) by adding the words ''non-automated'' following ''Fecal occult blood.'' This change would exclude the more complex automated FOB analyzers from the list of waived tests in the CLIA regulations.

In addition, we proposed to remove the hemoglobin by copper sulfate method from the list of waived tests at § 493.15(c)(6) if we received public comments confirming that this method is no longer used.

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

III. Analysis of and Responses to Public Comments

In response to the November 7, 2014 proposed rule, we received 7 public comments. Interested parties that submitted comments included blood donor centers, laboratories and accreditation organizations. A summary of the comments and our responses are as follows:

Comment: One commenter supported our proposal to add the words ''non-automated'' following ''Fecal occult blood.''

Response: We appreciate the commenters' support. This change would exclude the more complex automated FOB analyzers from the list of waived tests in the CLIA regulations.

Comment: In regard to our proposal to remove the hemoglobin by copper sulfate method from the list of waived tests if comments confirmed that this method is no longer used, one commenter stated that they collect approximately 10,000 units of blood per year and currently use the hemoglobin by copper sulfate method for cost reasons. Another commenter stated that they use the hemoglobin by copper sulfate method as a qualitative method to detect hemoglobin levels of 12.5g/dl or greater.

Several commenters indicated that they use the hemoglobin by copper sulfate method to screen donors for acceptable pre-donation hemoglobin. Specifically, they perform approximately 20,000 to 30,000 tests per year.

Response: In consideration of these public comments, which indicate that the hemoglobin by copper sulfate method is still in use, we are not finalizing our proposal to remove the hemoglobin by copper sulfate method from the list of waived tests at § 493.15(c)(6).

Comment: One commenter stated that it is appropriate to require ''automated FOB tests'' to be evaluated through the CLIA waiver process instead of automatically waiving these devices. However, the commenter believed that ''waived testing'' poses risk to patients in certain settings and that any test that may result in harm should not be waived.

Response: We appreciate the commenter's support for requiring ''automated FOB tests'' to be evaluated through the CLIA waiver process instead of automatically waiving these devices. According to section 263a(d)(3) of the CLIA statute, waived tests are simple laboratory examinations and procedures that have been approved by the FDA for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that employ methodologies that are so simple and accurate that the likelihood of inaccurate result by the user is negligible, and those that the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly. Therefore, we believe that waived tests that are determined to have met the statutory criteria do not pose a significant risk of harm to patients.

IV. Provisions of the Final Regulations

We are adopting as final the provision set forth in the November 7, 2014 proposed rule (79 FR 66348 through 66350) with the following modifications:

- In consideration of public comments, we are not finalizing our proposal to remove the hemoglobin by

copper sulfate method from the list of waived tests at § 493.15(c)(6).

- Since we are not removing § 493.15(c)(6), we are not finalizing our proposal to renumber the remaining paragraphs in this section.

V. 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 (44 U.S.C. 3501 *et seq.*).

VI. 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) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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 must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

This final rule amends the CLIA regulations at § 493.15(c)(2) to provide that only non-automated FOB tests are waived by the 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 the FDA demonstrating the particular test system meets the statutory waiver criteria of being simple and having an insignificant risk of an erroneous result.

As of July 11, 2017, the FDA CLIA test categorization database includes 134 FOB test systems. Five 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*). Only two of the five automated test systems are sold in the United States. Because the current regulation governing FOB tests does not specify automated or non-automated FOB tests, it could be misconstrued that automated FOB test systems are available for use by laboratories with a COW. As amended, it will be clear that automated FOB test systems are not permitted 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 (which are categorized as moderate complexity tests) would be impacted by this rule if they are currently operating under a COW. According to the information on automated analyzers for FOB testing distributed in the United States provided by manufacturers, we estimate that no more than 26 laboratories would be impacted by this regulatory change. We developed a range of the estimated economic impact for changes that may result from this final rule. Our highest estimate totals approximately $151,000 for the first year, due to the initial costs required to change certificate types for all potentially impacted laboratories. This would decrease in years two through five, projected to be as low as approximately $3,000 per year in years two and four, when no certificate fees would be paid. Therefore, this rule does not meet the economic threshold to be considered a major rule.

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 are not preparing an analysis for the RFA because we believe that approximately 79 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 July 11, 2017 (*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 no more than 26 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 final rule because very few small entities would be subject to the provisions in this rule.

In addition, section 1102(b) of the Social Security Act (the 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 604 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 final rule to have a significant impact on a substantial number of small rural hospitals. The changes in this final 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 2017, that threshold is approximately $148 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

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 regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017 (82 FR 9339, February 3, 2017). Section 2(a) of Executive Order 13771 requires an agency, unless

prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise promulgates, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. OMB's interim guidance, issued on April 5, 2017, *https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation,* explains that for Fiscal Year 2017 the above requirements only apply to each new ''significant regulatory action that imposes costs.'' It has been determined that this final rule is not a ''significant regulatory action thus does not trigger the above requirements of Executive Order 13771.

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 amends 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.

■ 2. Section 493.15 is amended by revising paragraph (c)(2) to read as follows:

§ 493.15 Laboratories performing waived tests.

* * * * *

(c) * * *

(2) Fecal occult blood-non-automated;

* * * * *

Dated: August 24, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 5, 2017.

Anne Schuchat,

RADM, U.S. Public Health Service, Principal Deputy Director, Centers for Disease Control and Prevention.

Dated: October 12, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017–22813 Filed 10–19–17; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 20

[GN Docket No. 13–111; FCC 17–25]

Promoting Technological Solutions to Combat Contraband Wireless Devices in Correctional Facilities

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection associated with the Commission's *Report and Order,* FCC 17–25. This document is consistent with the *Report and Order,* which stated that the Commission would publish a document in the **Federal Register** announcing OMB approval of the information collection requirement and the relevant effective date of the rules.

DATES: The rule amendments to 47 CFR 1.9020(n), 1.9030(m), 1.9035(o), and 20.23(a), published at 82 FR 22742, May 18, 2017, which required OMB approval, are effective on October 20, 2017. The rule amendments to (1) 47 CFR 1.9020(d)(8), 1.9030(d)(8), 1.9035(d)(4), and 20.18(a), which did not require OMB approval; and (2) 47 CFR 20.18(r), which required OMB approval, published at 82 FR 22742, May 18, 2017, are effective on February 12, 2018.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Cathy Williams by email at *Cathy.Williams@fcc.gov* and telephone at (202) 418–2918.

SUPPLEMENTARY INFORMATION: This document announces that, on October 2, 2017, OMB approved the information collection requirement contained in the Commission's *Report and Order,* FCC 17–25, published at 82 FR 22742, May 18, 2017. The OMB Control Number is 3060–1243. The Commission publishes this document as an announcement of the effective dates of the rules. Note that the rules effective on February 12, 2018, as listed above, are effective on that date pursuant to the Report and Order, paragraph 142, the date 270 days after publication of the text or a summary thereof in the **Federal Register**. If you have any comments on the burden estimates listed below, or how the Commission can improve the collection and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street SW., Washington, DC 20554. Please include the OMB Control Number 3060–1243 in your correspondence. The Commission will also accept your comments via email at *PRA@fcc.gov.*

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received final OMB approval on October 2, 2017, for the information collection requirement contained in 47 CFR 1.9020(n), 1.9030(m), 1.9035(o), 20.18, and 20.23(a), as amended in the Commission's *Report and Order,* FCC 17–25.

Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–1243.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507. The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–1243.

OMB Approval Date: October 2, 2017.

OMB Expiration Date: October 31, 2020.

Title: Sections 1.9020(n), 1.9030(m), 1.9035(o), Community notification requirement for certain contraband