

burden is three individuals \times 0.6 hrs./yr. = 1.8 hrs./laboratory/yr.

There are 264 laboratories performing histocompatibility testing; therefore, the estimated burden for this requirement in this final rule is 264 histocompatibility laboratories \times 1.8 hrs./yr. = 475 hrs./yr.

Change in Burden

Since this burden is not required in this final rule, we estimate the decrease in burden to be 475 hrs./yr.

Section 493.1291 Test Report

The following information collection requirements under paragraph (c) are new: The test report must indicate (1) either the patient's name and identification number or a unique patient identifier and identification number; (2) the test report date; and (3) the specimen source, when appropriate.

While this information collection requirement is subject to the PRA, we believe the burden with it is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services,

Office of Strategic Operations and Regulatory Affairs, ORDI, DRD-B, Attn: Julie Brown, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

VII. Regulatory Impact Analysis

Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs 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 regulation has no budget implications that impact Medicare benefit payments. We have, however, performed a complete regulatory impact analysis, although the specified thresholds to require a full analysis may not have been met.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$11.5 million or less in any 1 year. For purposes of the RFA, all laboratories are considered to be small entities.

Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of 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 and has fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This final rule does not mandate any requirements for State, local, or tribal governments, or by the private sector. Therefore, we certify that this rule would not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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. We have determined that this final rule does not significantly affect States' rights, roles, and responsibilities.

A. Executive Summary

This final rule includes changes that will impact many laboratories and indirectly impact manufacturers of test systems and controls. Most laboratories that perform nonwaived testing will be

affected. This includes laboratories performing unmodified moderate complexity testing approved or cleared by the FDA, and laboratories testing in microbiology, syphilis serology, immunology, and hematology. Although we had insufficient data and information to calculate some of the costs and savings that may result from these changes, we estimate the overall impact will result in a savings of approximately \$23 to \$38 million the first year and \$101 to \$166 million over the next 5 years (Tables 1 and 2). The term "savings" as used in this RIA is defined as reduced compliance costs for laboratories subject to the CLIA regulations.

The most significant change in this final rule is related to the delayed effective dates (phase-in period) that allowed laboratories performing unmodified moderate complexity testing approved or cleared by the FDA to meet certain general QC requirements. Laboratories performing this type of testing did not have to verify methods before their introduction for patient testing or to periodically verify calibration. As shown in Table 1, we expect this change to immediately impact 29,601 Certificate of Compliance and COLA-accredited laboratories. We estimate the cost of completing the QC phase-in period to be between \$28.3 million and \$37.1 million the first year and between \$124.1 and \$162.5 million over the next 5 years.

Additional changes in this final rule will impact laboratories performing various specialties and subspecialties. The impact of these changes will vary depending on the volume and frequency of testing being done in each specialty or subspecialty.

Overall, the changes in microbiology will result in significant savings of approximately \$55.9 million the first year and \$245.2 million over the next 5 years. The changes in bacteriology and mycology are based on data demonstrating that for several reagents, QC is not required as frequently as required under the previous regulation. We assume the changes in bacteriology will affect 27,443 laboratories and result in immediate savings of \$62.4 million and aggregate savings of \$273.7 million over the next 5 years. In addition, we expect changes in mycology to affect 9,059 laboratories with immediate annual savings of \$1.4 million and approximately \$6.1 million savings over the next 5 years. For mycobacteriology, we are requiring more frequent QC testing and expecting this change to affect 3,185 laboratories with an estimated increase in costs of \$7.9