

phase-in provision and have served or are serving as directors of laboratories performing high complexity testing and have at least 2 years of training or experience, or both, and 2 years of experience directing or supervising high complexity testing to continue to serve as directors.

#### Miscellaneous Changes

There are a number of minor, miscellaneous changes. Some, like the change in the consensus requirements for PT grading from 90 percent to 80 percent, are the result of comments made to the former regulation. For the most part, these changes are considered to have no significant positive or negative impact. We consider many of them to be clarifications of implied requirements, or standard laboratory practices already in place, such as the requirement for laboratories to verify accuracy of analytes, subspecialties and specialties assigned a PT score that does not reflect the laboratories' actual test performance. In many cases, we have moved specific sections to make the regulation fit within the new regulatory framework (movement of the specimen through the laboratory) and to make the requirements easier to read and comprehend. While we expect positive benefits from these clarifications, it would be impossible to quantify these benefits.

#### C. Methodology and Approach

##### Basis for Estimates and Reliability of Projections

These projections are based upon some necessary assumptions concerning the current and future status of laboratory practices, technological advances, and the marketplace, making some degree of inaccuracy unavoidable. As each change is considered, the assumptions are stated. Due to the limitations in our data and information, we used a range of reasonable alternatives to estimate future events and reflect our degree of uncertainty. For much of this analysis, we use well-defined data from CMS Online Survey and Certification Reporting System (OSCAR) (2001) concerning laboratory demographics and test volume. When using less defined data, we made projections on the more costly side to provide an estimation of maximal impact.

We estimate the impact of these regulatory changes for those entities that these changes may affect, and we project the impact over the next 5 years. The completion of the QC phase-in period affects a portion of laboratories performing unmodified moderate

complexity testing cleared by the FDA. Other changes in specialty and subspecialty QC requirements affect laboratories performing both moderate and high complexity testing. The changes in the high complexity laboratory director requirements primarily affect laboratories performing high complexity testing that need to hire a director on or after February 24, 2003. As appropriate for each specific change, in addition to the impacts on laboratories, we considered the potential impacts on manufacturers of laboratory test systems, controls, and calibration materials, and possible impacts on patients.

For this analysis, CDC used the services of Research Triangle Institute (RTI) to assist with data collection and cost-benefit analyses. RTI used data concerning current testing practices to estimate both immediate consequences and the impact over the next 5 years. A 7 percent discount rate was applied for projections after the first year, consistent with OMB recommendations (Economic Analysis of Federal Regulations under Executive Order 12866). Both RTI and HHS have sought data from a number of sources, including scientific articles, Government reports, CMS data, CDC studies, including data from CDC cooperative agreements, industry reports, reports by marketing consultants, interviews with manufacturers and laboratorians, and studies by professional groups, like the American Medical Association.

For each specific regulatory change, we outline the parties these changes will affect, methodological approach, necessary assumptions and limitations in the reliability of the conclusions, and possible alternatives.

#### D. Impacts

This discussion of regulatory impacts is organized as follows:

- Section 1 contains the demographics of the laboratories that the completion of the QC phase-in will impact.
- Section 2 has specific provisions not required during the phase-in period that certain laboratories will now need to meet.
- Section 3 has changes in specialty and subspecialty QC, including changes in microbiology, immunology, syphilis serology, and hematology.
- Section 4 has the completion of the phase-in requirements for laboratory directors.
- Section 5 contains miscellaneous changes, including the change from 90 percent to 80 percent consensus requirements for PT results grading.

In this final rule impact analysis, for each regulatory change, as appropriate, our discussion is organized under the following topics:

- Rationale.
- Methodology.
- Benefits.
- Costs.
- Alternative approaches.

#### 1. Laboratories Affected by Completion of the QC Phase-in Characteristics of Affected Laboratories Laboratory Demographics

The total number of certified and exempt laboratories in the United States (U.S.) is 174,856 (Table 5). This number includes a total of 168,688 CLIA-certified laboratories (96 percent), consisting of 91,540 laboratories with Certificates of Waiver (52 percent), 38,304 with Certificates for Provider-Performed Microscopy (PPM, 22 percent), 22,720 with Certificates of Compliance (13 percent), and 16,124 with Certificates of Accreditation (9 percent) (OSCAR, April 2001). In addition, there are 6,168 laboratories in the CLIA-exempt States of New York and Washington (4 percent).

This final rule will not affect the 74 percent of clinical laboratories holding Certificates of Waiver and PPM (129,844 laboratories). Laboratories with a Certificate of Waiver are only subject to limited CLIA requirements, they must only perform waived tests and tests cleared by the FDA for home use, follow manufacturer's instructions for testing, and maintain their waived certificates. Laboratories with a Certificate for PPM procedures must meet applicable requirements in subparts J and K of this final rule (formerly subparts J, K, and P). PPM procedures were not under the QC phase-in; therefore, PPM procedures were subject to the more stringent requirements in subpart K of the February 28, 1992 final rule with comment period. However, there are no QC materials for most PPM procedures.

For this analysis, we assume that all Certificate of Compliance laboratories perform some moderate complexity testing and that these laboratories have been meeting only the minimum QC requirements for FDA-cleared, unmodified moderate complexity test systems under the requirements of the QC phase-in period. In addition, we assume the completion of the QC phase-in would affect all of these laboratories (22,720 laboratories or 13 percent).

Similarly, we assume that the completion of the QC phase-in will affect the COLA-accredited laboratories because COLA's requirements are equivalent to the CLIA QC phase-in requirements. Therefore, these changes