

b. Test Systems, Equipment, Instruments, Reagents, Materials, and Supplies

Rationale

With the completion of the QC phase-in, laboratories performing commercial, unmodified moderate complexity testing must now meet the provisions at § 493.1252 for test systems, equipment, instruments, reagents, materials, and supplies. During the phase-in, these laboratories were required to “follow the manufacturer’s instructions for instrument or test system operation and test performance,” which would include most of the requirements listed in § 493.1252. However, now laboratories must monitor and document conditions essential for “proper storage of reagents and specimens, accurate and reliable test system operation and test result reporting.” These conditions include “water quality, temperature, humidity, and protection of equipment and instruments from electrical interruptions and fluctuations that adversely affect patient test results and test reports.”

Benefits

Monitoring and documenting environmental and other conditions necessary for proper reagent and specimen storage and test performance is essential to ensure quality test results. When conditions are outside of the prescribed acceptable range, corrective action can be taken. Without monitoring and documentation, laboratories may not be aware of conditions that may adversely affect patient test results.

Costs

The costs to implement this requirement will be minimal and will include labor to develop and maintain a monitoring and documentation system. We do not know the extent to which the specific commercial, moderate complexity procedures used in each laboratory will require monitoring of each of these conditions or the extent to which laboratories are already performing monitoring and documentation of these conditions. Therefore, we are unable to estimate a total cost for this requirement.

c. Method Verification

Rationale

Method verification is performed when a new test is brought into the laboratory and before beginning patient testing and result reporting. It consists of studies to verify that the laboratory can obtain accuracy, precision, reportable range and reference intervals with the new test system comparable to

the manufacturer’s specifications. During the QC phase-in period, laboratories could introduce testing using commercial, unmodified moderate complexity test systems approved or cleared by the FDA without verifying manufacturer’s performance specifications (accuracy, precision, and reportable range of patient test results) before testing patient’s specimens. On April 24, 2003, all laboratories must perform method verification when instituting any new moderate complexity test and before testing patient specimens, as specified in § 493.1253.

Methodology

To determine the possible impact, we did an estimate of the cost of assays to verify manufacturers’ performance claims for commercial, unmodified moderate complexity tests expected to be introduced annually among the affected laboratories. For this analysis, we assumed that existing moderate complexity test systems would be retired and replaced with a new test system approximately every 5 years according to data available for a small population of laboratories. In addition, for cost calculations, we estimated the number of verification data points needed and the costs in terms of labor, materials, and reagents to perform these studies.

The cost of method verification is typically greater for quantitative tests than qualitative tests. In most cases, fewer specimens and less labor and reagents are required to verify the performance of qualitative tests. We do not know the fraction of new tests that are qualitative, so we treated all tests as if they are quantitative to calculate the maximal impact. Also, we assumed that the laboratories that this change will affect have not been performing method verification. However, we know that some manufacturers currently offer on-site verification assistance, and we expect that practice to continue; therefore, we may be overestimating the impact.

Estimates of the Incidence of New Test Introduction

Data describing how frequently new tests or test systems are introduced into laboratories were limited. For one estimate, we used the percentages of laboratories expected to add zero, one, two, three, four, or five moderate complexity tests to their test menus from a survey of laboratories participating in the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network (LaBeau, Simon, and Steindel, 1999). Laboratories were

asked how many nonwaived new tests they added to their test menus between April 1997 and April 1999. Although these percentages are for a 2-year time period, we conservatively assumed that all tests were adopted during the last year of the period. We assumed that the incidence of test introduction is roughly the same for the affected laboratories as for the Sentinel Monitoring Network. Multiplying these percentages by the total number of laboratories (29,601), we calculated the number of laboratories that are expected to add at least one test to their test menus in a year, approximately 11,248 (38 percent) (Table 6).

Estimate of Analyzer Replacement

Because of the small sample size, we were not confident that the survey of laboratories in the Pacific Northwest Laboratory Medicine Sentinel Monitoring Network accounted for the replacement of existing multiple analyte analyzers. Replacement of an obsolete analyzer with a new model requires verification for each analyte. Therefore, the cost of replacing analyzers depends upon the existing number of analyzers, the number of years of operation before replacement, the number of tests each analyzer performs, and the labor and reagent cost per assay for method verification. We assumed laboratories replace analyzers every 5 years and, therefore, compute the number of analyzers of each type that would require replacement each year by dividing the number of analyzers by five.

NICLTS data (Steindel, *et al* 2000) gave us the percentage of Certificate of Compliance POL, Hospital, Independent and Other laboratories having chemistry, hematology, therapeutic drug, ligand, reproductive hormone, and immunology analyzers. To determine the total number of each kind of analyzer to be replaced over the next 5 years, we multiplied these percentages by the number of Certificate of Compliance and COLA laboratories of each laboratory type to obtain the number of laboratories having each kind of analyzer, and then totaled the analyzers in each laboratory type (Table 7).

Benefits

To ensure accuracy and precision, it is especially important to demonstrate acceptable performance for a new test method before testing patient specimens. Comparing results of the new method with the manufacturer’s claims and the current method, if the method is being replaced, can detect biases and problems with