

forms) may add to the anxiety level associated with PT participation and adversely affect PT performance. Decreasing the time frame in which individuals must complete the PT examination may increase the overall costs of cytology PT due to an increase in the failure rate of individuals who would be forced to examine PT slides at a rate greater than their normal workload rate (for individuals who examine slides at a workload rate that is less than the maximum). In the case of pathologists, who do not routinely screen slides and therefore are not subject to a workload limit, a higher failure rate might also be expected.

Costs associated with taking the second test and rescreening slides for the 20 work days between tests would increase in proportion to the increased failure rate. In addition, if a greater number of individuals must take the third retest off-site, we assume one day of work per examinee would be lost.

The costs of this proposed rule would be confined to the difference in lost wages because of an expected increase in rates of failure for both cytotechnologists and cytopathologists and an increase in costs needed because of rescreening more slides and retraining an increased number of examinees.

*Estimated Costs*

The data we are using in this proposed rule are the data we used to determine the impact of the February 1992 rule. The regulatory impact analysis in that rule projected national costs from data pertaining to 1990 that we received from the Maryland State Cytology Testing Program. We have no more recent data from which to project national figures at this time, and there is no other HCFA-approved testing program to validate or invalidate the Maryland State experience.

The base population that we are using for this impact analysis consists of 7,950 cytotechnologists and 8,690 pathologists. We are assuming a range of wages for cytotechnologists of \$14 to \$20 per hour and for pathologists a range of \$75 to \$110 per hour. We are assuming that conducting an on-site test that lasts 45 minutes will consume 2 hours per examinee, instead of the 5 hours we currently allot for each examinee to take a 2-hour test.

Based on these assumptions, we project the following: The first round of tests will cost from \$2.0 to \$2.9 million. This represents savings of \$3.0 to \$4.3 million from our estimate of what it would cost to test under current requirements.

In order to measure the possible costs of retesting, we estimated that under the new time constraints 25 percent of the examinees would fail the first test. We project that costs associated with taking the second test, assumed to be conducted off-site, will be \$3.1 to \$4.5 million.

We estimate that 25 percent of the persons taking the second test will fail that examination and that it would cost \$1.7 to \$2.4 million for the rescreening required and from \$0.4 to \$0.7 million in time lost to conduct the third test. Again, we assume one day of work per examinee will be lost due to off-site testing. If an on-site testing option is offered and selected, costs may be significantly lower.

We estimate that 25 percent of those failing the second test would fail the third test (260 persons) and that it would cost from \$0.6 to \$0.8 million in lost time to retrain cytotechnologists and from \$3.3 to \$6.5 million to retrain pathologists. The costs of retraining include the cost of 40 days of time lost; this includes 5 days for training and 35 days waiting for the next examination to be given, assuming the examinations are not offered more than once a month. We have no data or information on which to base an estimate of the cost of the training itself.

The total costs attributable to the proposed PT requirements would range from \$10.9 to \$17.8 million in the first year of testing in a nationwide cytology PT program. This represents an increase of \$0.5 to \$1.6 million over our original projected costs of \$10.4 to \$16.1 million (excluding the cytology slide test costs which would remain unchanged in this proposed rule) for our current PT requirements. This difference reflects the impact of the assumed increase in the test failure rate on the associated costs of retesting and retraining an increased number of examinees and rescreening more slides. It is possible that costs would go down somewhat in subsequent years: the Maryland State Cytology Testing Program showed a decrease in the percentage of examinees failing the testing after the first year.

PROJECTED ANNUAL COSTS OF CYTOLOGY PROFICIENCY TESTING

	Low	High
Conduct of first testing .....	\$2,025,000	\$2,895,000
Conduct of second testing .....	3,058,000	4,467,000
Cost to rescreen for 20 workdays .....	1,667,000	2,383,000
Conduct of third testing .....	384,000	733,000

PROJECTED ANNUAL COSTS OF CYTOLOGY PROFICIENCY TESTING—Continued

	Low	High
Loss of 40 days Cytotechnologist ..	561,000	802,000
Loss of 40 days Cytopathologist ....	3,246,000	6,493,000
Costs through hired testing ..	10,941,000	17,773,000

The effect of the proposed change on the only HCFA-approved cytology PT program, Maryland State Cytology Testing Program, is difficult to predict, until we are notified whether the program intends to make revisions to its requirements for examination of PT slides complying with these proposed revisions (if finalized). However, if Maryland maintains an approved program, we predict that it would have comparable increases in costs after the first test because of the greater number of persons failing.

If Maryland chooses not to make the revisions, the program would fail to meet the criteria for CLIA-approval as a cytology PT program. HCFA would notify the program of the nonapproval, and the program would then have to notify all laboratories enrolled in the program of the nonapproval and the reasons for nonapproval within 30 days of the HCFA notification. If this occurs, until other State programs are approved or a nationwide cytology PT program is available, none of the cytotechnologists and pathologists in this country who examine gynecologic cytology preparations would be participating in an approved cytology PT program.

We are not preparing an analysis for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed 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.

Also, we considered the economic aspects of whether or not the proposed change would reduce or increase health care costs by leading to the correct earlier diagnosis of pap smears that would otherwise be misread as false positive or false negative under the existing regulations. Because the potential economic effects of this proposal are so speculative pertaining to any impact on health care costs, we are unable to factor such costs into this analysis. Similarly, we considered the economic impact on individuals due to