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CMS PROPOSES IMPROVEMENTS TO CERVICAL CANCER PROFICIENCY TESTING PROGRAM

The Centers for Medicare & Medicaid Services (CMS) today announced proposals to further improve the regulations that are in place to assure the competency of those conducting the most common screening test for cervical cancer, the Papanicolaou (Pap) test.

The proposed rule would update the current regulatory provisions that were promulgated under certain provisions of the Public Health Service Act. These provisions require certain physicians (pathologists) and cytotechnologists (laboratory technologists with special training in the formation, structure, and function of cells) who screen Pap tests to demonstrate their proficiency in reading and interpreting Pap test specimens.

"Soon after Pap screening became available, the number of women dying from cervical cancer dropped nearly 75 percent, and today, with improved testing and treatment procedures, a woman who is diagnosed in the early stages of the disease has a 92 percent chance of being alive five years later," said CMS Acting Administrator Kerry Weems. "The Pap test's impact was so dramatic that it was one of the first screening procedures to be granted coverage under the Medicare law."

Today, far from being a leading cause of death for women in the United States, fewer than 4,000 die each year from cervical cancer. While deaths from cervical cancer have been greatly reduced through the use of Pap testing, further improvement is needed as the death rate for minority women is twice that of white women.

Over the years, Congress has repeatedly recognized the importance of Pap testing. Concerns about erroneous Pap test results were one of the major impetuses behind the enactment of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the first major overhaul

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of federal regulation of clinical laboratories since enactment of the original Clinical Laboratory Improvement Act of 1967. The new law extended Federal regulation beyond laboratories that sent and received specimens through interstate commerce to all laboratories in which clinical testing occurs for the purposes of diagnosis or treatment of a medical condition. It established minimum quality standards for nearly all clinical laboratory testing in the United States from simple tests performed in a doctor's office to the most complex testing performed in large independent laboratories and academic medical centers.

Two years later, to improve access to screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990, which led to the creation of the National Breast and Cervical Cancer Early Detection Program in 2000 within the Centers for Disease Control and Prevention (CDC). In 2000, Congress passed the Breast and Cervical Cancer Prevention and Treatment Act, giving states the option to cover screening for these cancers under their Medicaid programs.

The U.S. Preventive Services Task Force, an independent task force administered by the Agency for Healthcare Research and Quality (AHRQ), gives its highest rating (A) to its recommendation for routine Pap testing as a measure to prevent cancer deaths. While Medicare paid approximately $34.2 million for over a million screening Pap tests in 2007, the test may be even more important to public and private programs that serve women of child-bearing age, who are at greater risk of cervical cancer.

The proposed rule would enhance and clarify CLIA's proficiency testing requirements for Pap testing. While CLIA provides for proficiency testing of laboratories in other specialties, it requires that proficiency testing for cytology laboratory personnel (those reading Pap tests) be scored for each individual. This is because this kind of screening requires intense concentration by the cytotechnologist/pathologist as they examine the cells in the Pap test under a microscope, and poor skills in reading the test (which is generally only read by one individual unless an abnormality is noted) can have a direct and significant impact on patient outcomes.

Due to the difficulty of developing an appropriate proficiency testing program for Pap tests, the cytology proficiency testing requirement was not implemented on a nationwide basis until 2005. The proficiency testing results from the first three years of this nationwide testing have demonstrated the importance of the program in ensuring quality and improving proficiency. For example, failure rates on the initial test of each annual testing cycle dropped from 33 percent in 2005 to 11 percent in 2007 for pathologists reading slides without the assistance of a cytotechnologist. Nonetheless, given the consequences of false Pap test results, the current level of failure is still of great concern to CMS. During the same period, the failure rates dropped from 10 percent to 3 percent for pathologists reading slides with the assistance of a cytotechnologist, and from 7 percent to 3 percent for cytotechnologists reading slides alone under the supervision of a pathologist.

Each individual who undergoes cytology proficiency testing is given four opportunities (an initial test and up to three retests) within each testing cycle to pass the test. To improve the statistical validity of the proficiency test the proposed rule would increase the number of slides or other approved test media ("challenges") from 10 to 20 for the initial test and first retest. This is the number of challenges currently required for second and third retests. While the proposal would increase the number of challenges in the initial test and the first retest, it would reduce the overall burden on those conducting Pap testing by decreasing the testing frequency from annually to biennially.

The proposed rule would modify requirements regarding the design and scoring scheme of the Pap test proficiency testing, in part to account for the greater number of slides to be read in the initial test and first retest. The proposed rule would also improve the appeal process and impose new requirements on CMS-approved providers of Pap test proficiency testing to improve the testing process. In addition, CMS is requesting additional information from cytology PT providers and others to analyze trends in PT failures over time.

The proposed changes are largely the result of recommendations from the Clinical Laboratory Improvement Advisory Committee (CLIAC), an advisory committee established by the Department of Health and Human Services (HHS) to promote ongoing improvement in clinical laboratory oversight. The CLIAC is comprised of experts from the laboratory community and other stakeholders, as well as representatives from CMS, CDC, and the Food and Drug Administration (the three agencies within HHS that share responsibility for implementing the CLIA program). CMS has also sought input from the wider laboratory community affected by this testing and has worked in collaboration with the CDC in developing this proposed rule. We are soliciting comments from the public in the areas where changes are proposed.

“Even with the most highly skilled testing personnel and the best diagnostic and treatment tools, it will not be possible to prevent all cervical cancer deaths,” said Weems, “but no woman should die because someone failed to read a screening test correctly. We believe the proposed changes to the cytology proficiency testing requirements will continue to protect women’s health while reducing the regulatory burden on the pathologists and cytotechnologists who screen Pap tests.”

Comments on the proposed rule will be accepted until March 17, 2009. After carefully considering the comments it receives, CMS, in collaboration with the CDC, plans to issue a final rule.

More information on CLIA and a copy of the proposed rule are available on the CMS website at: www.cms.hhs.gov/center/clinical.asp.

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