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CMS Proposes Changes to Cytology Proficiency Testing

The College of American Pathologists says the PT rule, enforced nationwide since 2005, is fatally flawed and the new proposals do not go far enough to correct the flaws. CAP favors replacing the CLIA program with a continuing medical education alternative.

The Centers for Medicare and Medicaid Services on Jan. 16 released its long-awaited proposal to revise regulatory requirements for screening and interpreting Pap smears.

In a rule published in the Jan. 16 *Federal Register*, CMS invites comments on a series of changes to the proficiency testing (PT) program for gynecologic cytology under CLIA (the Clinical Laboratory Improvement Amendments of 1988).

They include lengthening the testing interval, increasing the minimum number of slides (challenges) per testing event, requiring validation of cytology challenges before use in testing, and allowing for new technologies—for example, digital images—as they become available.

But CMS is adamant that the CLIA statute requires PT testing of individuals and thus is not included in the rulemaking. Critics contend that this is too narrow a reading of the law and that testing the lab as a whole, as is the case with noncytology PT, is a better way to assure Pap smear quality results. For more on the new proposals, see the *Focus*, pp. 4-6.

Obama Halts Pending Federal Rulemaking

The Obama administration has asked federal departments and agencies to halt work on pending regulations. At press time, it was unclear how this would apply to rules published this month that affect clinical laboratories and pathologists, including CLIA cytology proficiency testing proposals (*see story above*) and final rules on the transition to ICD-10 code sets (*related story, p. 3*).

A CMS media spokesperson could not comment on these specific rules but told *NIR* that "HHS is currently reviewing the collection of regulations in various stages of completion to determine which fall under the parameters laid out by Mr. Emanuel's memo of Jan. 20. Until that review is complete, it is not possible to determine which ones are affected."

In that memo, Rahm Emanuel, the president's chief of staff, said the halt will allow the president's appointees and designees "to review and approve any new or pending regulations." A government-wide freeze is not unusual in a change of administrations, and this one is expected to target relaxed environmental rules the Bush administration pushed in its waning days. Sources told *NIR* they doubted that the cytology PT or ICD-10 rules would be derailed but could at most be delayed.

INSIDE *NIR*

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Congressional Democrats Moving on the Health Care Front

Democratic leaders have been quick to put their health care reform plans on the legislative table during this first month of the 111th Congress, and the Obama administration is expected to offer specifics on the president's approach in his budget due for release soon.

At press time, there has been a flurry of activity on major health care issues on Capitol Hill, including:

Electronic health records: Economic stimulus legislation advancing in the House would provide Medicare and Medicaid funding for providers, as well as grants to states, to help them adopt health information technology (HIT). Up to $20 billion is authorized. "Physicians will be eligible for $40,000 to $65,000 for showing they are meaningfully using HIT, such as through the reporting of quality measures," said the Ways and Means Committee. "Hospitals will be eligible for several million dollars in Medicaid and Medicare to similarly use HIT." Other providers will be eligible as well. Incentive payments would be phased out over time, and Medicare payments would be reduced for physicians and hospitals that do not use certified electronic health records that allow them to electronically communicate with others. Obama's economic stimulus plan also backs investment in HIT as a way to lower costs and improve quality.

SCHIP reauthorization and expansion: The House has passed a 4.5-year reauthorization (H.R. 2) of the State Children's Health Insurance Program (SCHIP), preserving coverage for seven million children and expanding it to 4.1 million more in families whose income disqualifies them for public programs. The Senate is expected to follow suit soon, and the president is expected to sign the final bill. H.R. 2 would expand the program by $32.3 billion above baseline spending and would be funded primarily by a 61-cent increase in the federal tobacco tax, to $1 per pack. SCHIP expires March 31 of this year, and the Bush administration used the veto several times to block expansion of the program despite broad bipartisan support for it.

Medicare legislation: Regardless of whether action on health care reform is comprehensive or incremental, Congress will have to take up a Medicare bill to deal with the physician fee update issue and avoid another round of deep cuts in payments under the current update formula. Democratic leaders have signaled a willingness to rebase the update, including separate targets for groups of specialties. Also in the Medicare hopper is a provision in the health care reform plan advocated by Senate Finance Committee chairman Max Baucus (D-Mont.) that would allow persons ages 55 to 64 to buy into the program.

Stark reform bills: Rep. Pete Stark, chairman of the House Ways and Means health subcommittee, has introduced two bills, modeled on the Medicare program, for "universal health coverage," including a measure to enroll children automatically at birth. The AmeriCare bill (H.R. 193) would ensure "comprehensive, affordable, and reliable health insurance for everyone," Stark said. "People would be covered under AmeriCare or continue to obtain health coverage through their employers." The bill includes a public plan option and maintains employer-sponsored coverage. The MediKids bill (H.R. 194) would create universal coverage for children. They would be enrolled at birth and maintain that eligibility through age 23, but parents could opt for private plans, Medicaid, or SCHIP.

HHS Grants More Time for Switch to ICD-10 Code Sets

HHS had proposed a much shorter transition period in previous rules (NIR, 29, 21/Sep 15 '08, p. 1). It now is delaying implementation dates between the proposed and final rules by 21 months for the X12 Version 5010 standard and 24 months for the ICD-10 code sets.

Heeding concerns widespread in the nation's health care industry, the U.S. Department of Health and Human Services has agreed to give providers, payers, and clearinghouses up to two more years to complete the transition to ICD-10 code sets and an updated electronic transaction standard needed to accommodate the code sets.

But HHS did not heed industry recommendations that the switch to the updated transaction standard and the code sets should not overlap, since this involves a vastly expanded number of codes and nomenclatures and poses major administrative and educational complexities. Leading provider and payer groups had recommended that they be allowed to achieve compliance with the updated transaction standard before moving to implement the ICD-10 system.

In a final rule published in the Jan. 16 *Federal Register*, HHS extended the compliance deadline for adoption of the ICD-10 coding system to Oct. 1, 2013 versus the proposed deadline of Oct. 1, 2011. The new system will replace the current International Classification of Diseases (ICD-9) diagnosis and procedure coding system used in transactions subject to HIPAA (the Health Insurance Portability and Accountability Act).

In moving the deadline, HHS said it recognized that more time is required to complete the investment, training, and testing, especially with trading partners, needed for the changeover, which involves moving from 17,000 codes in the ICD-9-CM to more than 155,000 codes in the ICD-10 code sets.

In a separate final rule published the same day, HHS extended the compliance deadline for adoption of the updated X12 standard, Version 5010, for health care transactions, the Prescription Drug Programs standard, Version D.0, for pharmacy transactions, and the NCPDP Version 3.0 for the Medicaid pharmacy subrogation standard to Jan. 1, 2012 versus the proposed deadline of April 1, 2010. Small health plans have until 2013 to comply.

The final rules affect all HIPAA-covered entities, public and private, that transmit any electronic health information in a transaction for which HHS has adopted a standard. HHS says use of the ICD-10 will improve disease tracking and speed the shift to an electronic health care environment. The ICD-9 system is outdated, the agency notes, and cannot handle new diagnoses and procedures. "The greatly expanded ICD-10 code sets will enable us to fully support quality reporting, pay-for-performance, biosurveillance, and other critical activities," noted HHS secretary Michael Leavitt, including comparing U.S. data with international data to track diseases and outcomes.

Under the final rule for ICD-10 code sets, HHS will concurrently adopt the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) for inpatient hospital procedure coding. The new codes will replace the ICD-9-CM, Volumes 1 and 2, and the ICD-9-CM, Volume 3, for diagnosis and procedure codes, respectively.

The ICD-10-CM is maintained by the National Center for Health Statistics at the Centers for Disease Control and Prevention. The ICD-10-PCS is maintained by the Centers for Medicare and Medicaid Services.

focus on: CLIA Regulatory Policy

CMS Rewrites CLIA Cytology Proficiency Testing Rules

After years in development, the Centers for Medicare and Medicaid Services this month released its proposals to modify requirements for Pap smear proficiency testing (PT) under CLIA (the Clinical Laboratory Improvement Amendments of 1988). The changes, if finalized, would impact 2,142 cytology laboratories and 12,831 individuals who screen or interpret 65 million gynecologic cytology preparations in the United States each year, CMS noted.

CLIA requirements for cytology PT, written in 1992, have been highly controversial since 2005 when CMS began enforcing them nationwide through a program offered by the Midwest Institute for Medical Education (the program was later bought by the American Society for Clinical Pathology). The College of American Pathologists and other industry voices assailed the 1992 rules as outdated and urged CMS to update them to account for advances in science and clinical practice. In response to industry pressure and to congressional inquiries, CMS took up the task in earnest to rewrite the rules, assigning a large role to the Clinical Laboratory Improvement Advisory Committee (CLIAC).

CMS says the proposed changes, published in the Jan. 16 *Federal Register*, reflect in large part the recommendations that CLIAC endorsed in 2006 and in follow-up meetings as well as input from industry sources and federal agencies, including the Centers for Disease Control and Prevention and the Food and Drug Administration, which share jurisdiction with CMS over the CLIA program. Comments on the proposals are due by March 17.

No Budging on Required Testing of Individuals

CMS gave no ground on this issue, saying the CLIA statute allows no alternative to the PT testing of individuals. The agency reiterated that its reading of the statute requires such testing and thus the matter is not subject to this rulemaking. And government officials took pains to keep any legislative fix off the table, telling the CLIAC workgroup that this was not to be considered and the panel should stick to overhauling the 1992 rules.

CAP said it had a fundamental objection to CMS's interpretation. The college said it reads the statute broadly, that proficiency should be measured at the lab level since under normal working conditions, the screening is performed by a team of pathologists and trained medical staff.

Highlights of the New Proposals

The rule changes unveiled by CMS reflect most, but not all, of the revisions recommended by CLIAC, based on a study by its workgroup assigned to evaluate the cytology PT requirements and advise on updates needed (*NIR, 27, 17 /Jun 29 '06, p. 1*).

CMS said its proposals would improve the efficiency and effectiveness of cytology PT and reduce the regulatory burden on clinical laboratories that perform this

screening by decreasing the PT testing frequency to once every two years. Currently, it is required once a year. CLIAC recommended once every three years.

And while CMS did not agree to drop different scoring grids for pathologists and cytotechnologists in favor of the same scheme for both, as recommended by CLIAC, it does invite further comment on this issue.

CMS also proposes to double the number of slides or other approved media (challenges) in the first test and first retest from 10 to 20, and the time for completing the test from two hours to four hours. The passing score would remain at 90 percent, CMS says, but by doubling the number of challenges, each error would have only half as much impact on the total score. Missing two high-grade lesions or cancers would result in automatic failure.

In other areas, the proposed rule would:

- ❑ Retain the diagnosis categories used to develop the PT challenges, consistent with those listed in the 2001 Bethesda Conference report:
  - — Unsatisfactory samples: scant cellularity, air drying, and obscuring material (blood, inflammatory cells, or lubricant).
  - — Normal or benign changes: normal, negative, or otherwise within normal limits, infections other than human papilloma virus (HPV) (e.g., *Trichomonas vaginalis*, changes or morphology consistent with *Candida* spp., *Actinomyces* spp., or *Herpes simplex* virus).
  - — Low-grade squamous intraepithelial lesions (LSIL): includes cellular changes associated with HPV, Mild Dysplasia/CIN-1.
  - — High-grade squamous intraepithelial lesion and carcinoma (HSIL): includes moderate dysplasia/CIN-2 and severe dysplasia/carcimona in-situ/CIN-3, Squamous Cell Carcinoma, Adenocarcinoma and other malignant neoplasms.
- ❑ Eliminate the requirement for tissue biopsy confirmation of response Category C (LSIL) cytology challenges.
- ❑ Make the laboratory director responsible for ensuring proper test administration (meeting CMS requirements) when PT is held on-site in the laboratory and for reporting identifying information for all individuals to CMS and PT programs.
- ❑ Allow appropriately trained proctors to administer the testing event on-site in the laboratory.
- ❑ Require continuous field validation of cytology challenges throughout their use in testing.
- ❑ Provide for approval of potential media other than glass slides for cytology PT, such as computer-based virtual slides or alternative testing formats.

CMS Cytology PT Proposals at a Glance

CURRENT RULE	PROPOSED RULE
10 slides/test	20 slides/test
2 hours/test	4 hours/test
Annual test	Biennial testing
Test Composition:	*Test Composition:*
• 1 unsatisfactory challenge	1 unsatisfactory challenge
• 1 normal challenge	1 normal challenge
• 1 low grade (LSIL) challenge	1 low grade (LSIL) challenge
• 1 high grade (HSIL) or cancer (CA) challenge	2 high grade (HSIL) or cancer (CA) challenges
1 missed HSIL/CA = automatic failure	2 missed HSIL/CA = automatic failure
Glass slide test	Glass slide test and opportunity for new technologies
Field validation of slides not required	Continuous field validation of slide required
Appeals process not required	Appeals process required
Different scoring grids for pathologists, cytotechnologists	Same

Source: CMS.

- Require providers of cytology PT to explain their appeals process in writing before administering a test and to meet more stringent obligations to maintain high-quality testing sets. CMS also wants to request additional information from these providers and others to analyze trends in PT failures over time.

Reaction From CAP

The College of American Pathologists (CAP) took a dim view of the proposed revisions, noting in a statement that they "come almost four years after the college and other pathology societies first appealed to CMS to initiate changes to a program that was clearly scientifically flawed and out-of-date. The lengthy passage of time to propose these changes demonstrates the need for a different approach that makes it easier for proficiency testing programs to be modified to keep pace with changing medical science. The college believes the regulation is fatally flawed, and the proposed changes do not go far enough to correct these flaws."

CAP said that it will analyze the CMS proposals with its 60-plus partners in the Cytology Improvement Coalition and will comment within the allowed deadline.

But CAP also signaled its preference for a legislative solution with a continuing medical education approach, noting there was "significant bipartisan support in the last Congress for an alternative that would have corrected the self-evident shortcomings of the current regulatory schema. This legislation laid the foundation for an appropriate and preferred pathway to correcting the current program and was widely viewed as a workable solution, evidenced by its passage in the House and the support of 43 Senate co-sponsors before the session closed."

PT Testing a Success, CMS Says

In publishing the PT proposals, CMS underscored the importance of the program in ensuring quality and improving proficiency, based on PT results from the first three years of nationwide testing. "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."

In 2009, cytology PT testing continues under the current CLIA program. The College of American Pathologists and the American Society for Clinical Pathology are the two nationally approved PT providers. The Maryland health department runs an approved program for testing the specimens of state residents.

CMS acting administrator Kerry Weems observed that "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, a woman diagnosed in the early stage has a 92 percent chance of being alive five years later. While deaths from cervical cancer have been greatly reduced through Pap testing, further improvement is needed as the death rate for minority women is twice that of white women."

CMS earlier last year reported to CLIAC that the CLIA PT program registered major gains in the passing scores of pathologists and cytotechnologists since nationwide enforcement began in 2005, with the pass rate rising from 91 percent in 2005 to 96 percent in 2007 (*NIR, 29, 12/Apr 14 '08, p. 2*).

CMS Awards Final Five MAC Contracts

The five contracts impact clinical laboratories, pathologists, and other providers in 14 states, mostly in the South and the Midwest. The contracts account for 36 percent of national annual Medicare claims volume, have an approximate value of $1.4 billion over five years, and must be reopened for bidding thereafter.

The Centers for Medicare and Medicaid Services this month announced the winning bidders for the final five of 15 awards in the transition to the Medicare Administrative Contractor (MAC) system combining claims processing under Medicare Part A (hospital insurance) and Part B (medical insurance). The MACs replace the system of fiscal intermediaries and carriers that has handled these claims since the start of Medicare in 1965.

The final five MACs listed below will assume full responsibility for Medicare A/B claims processing in their respective jurisdictions no later than March 2010:

—***Jurisdiction 6:*** Illinois, Minnesota, and Wisconsin. Noridian Administrative Services, LLC, headquartered in Fargo, N.D.
Total number of fee-for-service beneficiaries: 3,323,986 (as of July 1, 2007).
Total beneficiaries (including managed care plans): 3,865,786 (as of July 1, 2007).
Total number of physicians, other practitioners: 97,408 (as of July 31, 2007).
Total number of Medicare hospitals: 501 (as of Dec. 31, 2007).

—***Jurisdiction 8:*** Indiana and Michigan. National Government Services, headquartered in Indianapolis.
Total number of fee-for-service beneficiaries: 2,479, 017 (as of July 1, 2007).
Total beneficiaries (including managed care plans): 2,805,761 (as of July 1, 2007).
Total number of physicians, other practitioners: 66,022 (as of July 31, 2007).
Total number of Medicare hospitals: 337 (as of Dec. 31, 2007).

—***Jurisdiction 10:*** Alabama, Georgia, and Tennessee. Cahaba Government Benefit Administrators, headquartered in Birmingham, Ala.
Total number of fee-for-service beneficiaries: 2,864,309 (as of July 1, 2007).
Total beneficiaries (including managed care plans): 3,287,910 (as of July 1, 2007).
Total number of physicians, other practitioners: 73,824 (as of July 31, 2007).
Total number of Medicare hospitals: 458 (as of Dec. 31, 2007).

—***Jurisdiction 11:*** North Carolina, South Carolina, Virginia, and West Virginia. Palmetto Government Benefits Administrators, with operational headquarters in Columbia, S.C., and some operations in Columbus, Ohio.
Total number of fee-for-service beneficiaries: 3,451,137 (as of July 1, 2007).
Total beneficiaries (including managed care plans): 3,883,805 (as of July 1, 2007).
Total number of physicians, other practitioners: 88,721 (as of July 31, 2007).
Total number of Medicare hospitals: 392 (as of Dec. 31, 2007).

—***Jurisdiction 15:*** Kentucky and Ohio. Highmark Medicare Services, headquartered in Camp Hill, Pa.
Total number of fee-for-service beneficiaries: 2,512,529 (as of July 1, 2007).
Total beneficiaries (including managed care plans): 2,908,777 (as of July 1, 2007).
Total number of physicians, other practitioners: 66,027 (as of July 31, 2007).
Total number of Medicare hospitals: 339 (as of Dec. 31, 2007).

The switch to MACs was authorized under contracting reform provisions in the Medicare Modernization Act of 2003 (Pub. L. No. 108-173). CMS awarded the first Medicare A/B MAC contracts in July 2006. A complete list of contractors and the states they cover, along with other information, can be found at *www.cms.hhs.gov/MedicareContractingReform*.

Ohio Law Requires Direct Billing for Anatomic Pathology

Enactment of the markup prohibition was a key priority of the Ohio Society of Pathologists, in partnership with the College of American Pathologists.

Legislation banning the markup of certain anatomic pathology services by an ordering physician who does not perform or supervise the service became law this month in Ohio. This prevents a treating physician from profiting by charging a patient the full price for a service the physician received at a discount.

Gov. Ted Strickland on Jan. 6 signed the measure that requires the billing to be sent directly from the laboratory or physician performing or supervising the service to the patient or insurer.

The law includes an exception that permits a physician to bill for anatomic pathology services performed on a dermatology specimen if the billing physician discloses the name of the laboratory used and the amount that the lab charged for the service.

Ohio is the 15th state to enact a direct billing law for certain anatomic pathology services, notes the College of American Pathologists. The others include Arizona, California, Iowa, Kansas, Louisiana, Maryland, Massachusetts, Montana, Nevada, New Jersey, New York, Rhode Island, South Carolina, and Tennessee.

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