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Red Cross Fined For Releasing Unsuitable Blood Components

This is the third and largest fine the Red Cross has agreed to pay under its consent decree with the FDA, bringing the overall total to more than $4 million. The two previous fines, each in the half-million-dollar range, involved internal quality assurance and program management

The Food & Drug Administration has fined the American National Red Cross $3.4 million for distributing 1,443 unsuitable blood components over a one-year period from April 15, 2003 through April 15, 2004.

In imposing the penalty, the FDA relied on a provision in its amended consent decree with the Red Cross, signed April 15, 2003, which permits the agency to fine the non-profit organization for each unit of unsuitable blood or blood component whose release could have been prevented.

The FDA identified 136 events in which the Red Cross reported to the agency that it had retrieved unsuitable blood components distributed over the one-year period. Though close to 10,000 such units were released, the penalty was based on 1,443 because nine events involved more than 100 unsuitable products and, for penalty purposes, were limited to 100 units per event. ➥ *p. 2*

Heads Roll Over Pap Test Failures

Jacobi Medical Center in New York City has undergone a big shakeup following disclosure that 307 women may not have been notified of abnormal results from Pap smear tests performed at the hospital over the past 16 months. The women were since contacted, Jacobi's executive director was fired, the deputy director of nursing for women's health services was axed, and the clinical director of gynecologic services was demoted.

Jacobi said the "vast majority" of 19,650 women tested over the 16-month period had normal Pap results; of the rest, most were notified and got follow-up treatment. The hospital said the problem stemmed from a change in notification practices when a single clerk was made responsible for notifying all women of their Pap results and scheduling follow-up appointments as needed. The lapses surfaced when a patient realized she had not gotten her test results and made a formal complaint.

"We're implementing systems to ensure this never happens again," said Alan Aviles, acting president of parent company New York City Health & Hospitals Corp. He also ordered a review of patient files at the health system's other facilities, which concluded they have been notifying patients promptly about abnormal Pap results.

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In a May 16 adverse determination letter, the FDA gave the Red Cross 20 days to submit a compliance plan or put in writing why it should not have to comply. The agency also warned it may fine the Red Cross for additional violations over the one-year period, depending on further review. In an attachment to the letter, the FDA listed the number and type of recalls, the reasons for them, and the associated penalties. Some of the more common problems:

- ❑ Suspect donor suitability due to travel in malarial risk areas.
- ❑ Failure to defer donors for risk of cancer, hepatitis, or Creutzfeldt-Jakob disease.
- ❑ Failure to quarantine after receiving post-donation information.
- ❑ Inadequate arm scrub and other collection failures, such as failure to follow manufacturer's instructions.
- ❑ Low platelet yield.
- ❑ Discovery of clots in red blood cells.

The original FDA-Red Cross consent decree was signed in 1993. Then in 2001, in order to compel the Red Cross to make changes it wanted, the FDA sought to put more teeth into the accord with the threat of financial penalties. Despite strong resistance, the Red Cross finally agreed in the 2003 amended consent decree to pay fines for failure to meet deadlines for improvements and to address blood safety violations (*National Intelligence Report, 24, 13/Apr 21 '03, p. 1*).

Medicare To Consider Upping Flow Cytometry Fees

Medicare officials have agreed to at least consider increasing flow cytometry reimbursement in 2006, based on data the American Clinical Laboratory Association has submitted.

A battle over flow cytometry payment has been brewing in recent years as the volume of these services has shot up, with labs adding more and more markers to flow cytometry panels. Last year, the Centers for Medicare & Medicaid Services tried to convince the American Medical Association's CPT editorial panel to switch from per-marker to per-panel coding. In the end, the CPT 2005 update took a hybrid approach, deleting the per-marker code 88180 and establishing five new codes—two for the technical component (88184-85) and three for the physician's interpretation (88187-89)—but not until after CMS had issued its proposed rule for the 2005 Part B physician fee schedule.

Rise In Medicare Outlays For Flow Cytometry

Year	Rank*	Allowed Services	Allowed Charges	Avg Allowed Charge
2001	46	1.3M	$41.1M	$31.29
2002	32	1.9M	$57.0M	$29.85

Note: Based on Medicare data for CPT 88180.

*Where CPT 88180 ranked in the top 100 lab/pathology procedures by allowed services. Source: Washington G-2 Reports, *Medicare Reimbursement Manual*, 2003 and 2004 editions.

Pathology interests were dismayed by Medicare's subsequent pricing of the new codes in the interim final fee schedule rule, which they said would result in cuts of 50% or more for flow cytometry services—a prediction that pathologists tell *NIR* has come true (*NIR, 26, 5/Dec 16 '04, p. 8*). However, they have been unable to convince CMS to revise 2005 pricing retroactively to January 1 (*NIR, 26, 7/Jan 24 '05, p. 7*). Now they're hoping to see some relief in the 2006 physician fee schedule, which CMS is expected to propose in July.

"We're working with the College of American Pathologists on getting some of those cuts restored," said ACLA president Alan Mertz. "We've given CMS the data. I'm cautiously optimistic we will get some restoration of the technical component."

In re-pricing flow cytometry services for 2005, CMS had assumed that laboratory technicians could handle all the staff work involved. In its comments on the interim final rule, ACLA said a cytotechnologist would be more appropriate. In a recent meeting, CMS asked ACLA if there were any tasks that did not require the skills of a cytotech. ACLA replied in an April 15 letter that a lab tech could handle the pre- and post-clinical staff activities, while services such as preparing stains, examining specimens, calibrating equipment, running procedures, and reviewing histograms with pathologists would require a cytotech.

Further, ACLA said in the letter, based on input from CAP, this type of testing requires the use of certain additional equipment beyond what CMS had assumed.

Most importantly, ACLA noted, its member organizations say flow cytometry requires the use of many more markers, or antibody reagents, than are actually reported. For example, while they would typically report 26 markers for a myeloid/lymphoid panel, they would actually perform 48 or more, including controls. Based on these findings and cost data from Becton Dickinson, ACLA recommended a cost per marker of $8.50 for new codes 88184 and 88185, for technical component services for initial and subsequent markers.

Legislators Aim To Avert Another Medicare Physician Fee Cut

The last time Congress intervened to stop Medicare cuts in physician fees was in 2003, when lawmakers approved a 1.5% increase in each of years 2004 and 2005

With Medicare Part B payments for pathology and other physician services estimated to drop 4.3% in 2006 under the current fee update formula, members of Congress on both sides of the aisle are lining up to mandate an increase instead.

Bipartisan bills recently unveiled in the House and in the Senate would mandate a minimum increase of 2.7%, starting January 1. The Senate bill, S. 1081, was introduced by Jon Kyl (R-AZ) and Debbie Stabenow (D-MI); the House bill, H.R. 2356, by E. Clay Shaw, Jr. (R-FL) and Benjamin Cardin (D-MD).

A major difference between the two bills is that, for 2007 and beyond, the House measure would replace the sustainable growth rate (SGR) factor used to adjust physician fees up or down annually with a new update formula based on medical cost inflation minus productivity gains. The Senate measure would use a similar update formula for 2007, but allow a reversion to the SGR in 2008 and beyond.

The College of American Pathologists, the American Medical Association, and other physician specialty groups have lobbied long and hard to repeal the SGR or at least stave off its impact from year to year. Congress imposed the SGR in 1998 in an attempt to constrain the growth in Medicare expenditures for physicians' services by tying it to the growth rate in the general economy. Physician groups say the SGR does not account for legitimate inflationary factors in the medical sector and penalizes doctors for volume increases they cannot control.

Unless Congress steps in, the Medicare Trustees project that Medicare payments for physicians' services will be cut about 26% from 2006 to 2011. This in turn, warns AMA, would lead many physicians to reduce the number of Medicare patients they see and defer the purchase of information technology. Meantime, key health leaders on the House Ways & Means and Energy & Commerce Committees have said they want to find a long-term fix to the physician fee update problem. The Congressional Budget Office recently estimated that eliminating the SGR and substituting automatic updates based on the Medical Economic Index would cost $154.5 billion over 10 years.

AARP has also urged Congress to "hold beneficiaries harmless" from any physician fee increases. "Medicare providers should be paid fairly, but each time reimbursement is increased, beneficiaries shoulder 25% of the cost through their monthly premiums," noted AARP's CEO William Novelli. The Part B premium this year is 17% higher than the previous year's level, and is expected to jump another 14% in 2006.

Proposal For Genetic Test Task Force Draws Broad Support

The recommendations of the HHS Secretary's genetics panel "are but the first step to address the sweeping policy changes needed to allow genetic testing to fulfill its full promise of improved healthcare," said the College of American Pathologists

The genetic testing and services industry has rallied around a federal advisory committee's call for the Health & Human Services Secretary to establish a group of experts to set forth principles for coverage of genetic tests.

The Secretary's Advisory Committee on Genetics, Health & Society (SACGHS) called for the task force in its report, "Coverage of Reimbursement of Genetic Tests and Services," drafted in April, with comments due last month. The committee will consider the comments at its next meeting, scheduled for June 15-16.

The American Society for Microbiology suggested modeling the task force after the negotiated rulemaking panel that developed 23 Medicare national coverage decisions for clinical laboratory tests through a consensus-based process.

The College of American Pathologists expressed hope that the task force would lead to more efficient, productive interactions with private insurers, which, CAP said, typically don't publicize their genetic test and service coverage policies.

When Is Genetic Screening Reasonable & Necessary?

SACGHS suggested that Medicare should cover tests for genetic predispositions and other preventive services that meet evidence standards and that the HHS Secretary should add a benefit category for such preventive services. Further, a patient's family history should play a role in determining whether a genetic test is "reasonable and necessary." The draft report said the Secretary should disseminate coverage-related evidence to state agencies for use in establishing their policies for Medicaid coverage of genetic testing.

ASM said there should be a way for Medicare to cover some genetic tests that are currently denied as screening tests, but that have great cost-saving potential. A good example, the Society noted, is the combination of a Pap test and a molecular diagnostic test for HPV (human papillomavirus), which does a far better job than a Pap test alone in pinpointing women at risk for cervical cancer.

Is It Reasonable To Price Tests Below Cost?

SACGHS recommended that the HHS Secretary address the problem of Medicare paying less for many genetic tests than it costs to perform them by directing the

Centers for Medicare & Medicaid Services to use its "inherent reasonableness" authority to increase payment. The Association for Molecular Pathology emphasized its concerns about this problem, saying, "We strongly support the SACGHS recommendation for CMS to review and revise reimbursement for molecular CPT codes."

AMP suggested that CPT's new genetic testing modifiers "are raising more questions than they answer" (*NIR, 26, 2/Oct 25 '04, p. 1; 26, 4/Nov 22 '04, p. 3*). For example, a modifier can show if a genetic test is done for cystic fibrosis, but cannot show if that test was for one possible mutation (as when there is a family history of that particular mutation) or as many as 80 mutations in a CF panel.

Changing The Medicare Coverage Decision Process

Lab groups generally agreed with language in the draft report favoring swift implementation by CMS of a provision in Section 731 of the Medicare Modernization Act of 2003 for evaluating local coverage determinations for national adoption.

CAP noted that the new Section 731 comment process is open, unlike the existing CMS national coverage decision process. CAP agreed with SACGHS about the potential negative impact that genetic test licensing agreements and royalty fees could have on the availability of genetic testing services.

ASM agreed with SACGHS' recommendation on Section 731, adding that one major Medicare contractor, TrailBlazer Health Enterprises, last year developed a molecular infectious disease local coverage decision with input from ASM and other professional societies (*NIR, 25, 20/Aug 16 '04, p. 11*). Coverage decisions such as this, ASM said, could benefit from the streamlined process for national adoption envisioned under Section 731.

Clarifying Who Can Bill For Genetic Services

SACGHS favored having the HHS Secretary give genetic counseling a boost by several means, including letting providers bill directly for genetic counseling services, allowing non-physician genetic counselors to have National Provider Identifiers, and, for those who now bill "incident to" services, using the full range of evaluation and management codes available for genetic counseling.

CAP disagreed with giving NPIs to non-physicians and suggested a different approach to enable genetic counselors to bill more for evaluation and management services. ASM, on the other hand, liked the idea of giving genetic counselors NPIs so they could bill directly and favors expanding this approach to encompass non-physician clinical lab scientists with PhDs.

Scope Of Genetic Tests

CAP urged SACGHS to narrow its definition of genetic tests to those with predictive value, leaving out those that don't warrant genetic education and counseling. AMP said it may not be appropriate to include pharmacogenetic testing in the definition.

ASM called for clarification of the relationship between the FDA clearance process and coverage eligibility for in vitro diagnostics designated for research or investigational use only. The Society also called for criteria for validating home-brew genetic assays.

Tissue Donor Testing Rule Takes Effect, With Revisions

Through a series of three rulemakings, the FDA has put in place a comprehensive risk-based system to regulate donated human cells and tissues: registration of tissue establishments, donor eligibility, and good tissue practices (inspection and enforcement)

The Food & Drug Administration recently completed a rulemaking process that establishes screening and testing requirements to help prevent the transmission and spread of communicable diseases by donated human cells and tissues, as well as cellular and tissue-based products. The requirements, published last year in a donor-eligibility rule, took effect May 25, 2005 (*NIR, 25, 16/Jun 7 '04, p. 1).*

Also on May 25, the FDA issued an interim final rule, effective that same day, to amend certain requirements in order to facilitate compliance by reproductive tissue establishments. (Comments on the interim final rule are due Aug. 23. Submit them at *www.regulations.gov*, referring to Docket No. 1997N-0484T.)

Under last year's donor-eligibility rule, the FDA allowed specimen collection for donor tissue testing up to seven days before or after tissue recovery. Under the interim final rule, this requirement is revised with regard to testing of tissues from cadaveric donors. The agency said either pre-mortem specimens obtained within seven days before death or post-mortem specimens are appropriate. However, the pre-mortem specimens may be preferable. The problem with post-mortem specimens is twofold, the FDA said: they may be more hemolyzed, which can interfere with test results, or their plasma could be diluted by fluid infusions the donor may have received prior to death, which could also affect test results.

Last year's rule included an exception for peripheral blood stem progenitor cells. The FDA allowed testing of samples collected up to 30 days prior to recovery, so that testing could precede the decision to prepare the patient for treatment with chemotherapy and irradiation. The interim final rule expanded this provision on sample collection timing to cover bone marrow and oocyte donors, who also must undergo conditioning regimens beginning more than seven days prior to recovery.

The FDA added an exemption from screening and testing for cryopreserved embryos. In the original rule, there was an exception when the donor and the recipient were sexually intimate partners. However, such partners often later donate cryopreserved embryos after completion of their fertility treatments. In such cases, the new provision recommends appropriate screening and testing of the semen and oocyte donors before transfer of the embryo, when possible. The recipients would have to be told if screening and testing did not occur until after cryopreservation, or if it did not occur at all—but in either case, embryo transfer would not be prohibited.

JCAHO Adds To Patient Safety Goals For Labs

The Joint Commission on Accreditation of Healthcare Organizations on May 31 said that in 2006 it will expand the National Patient Safety Goals for the clinical laboratories it accredits. This fourth annual set of goals for labs includes a new requirement for standardizing the hand-off of patients from one caregiver to another in order to improve communications between caregivers. There also is a new goal to encourage the active involvement of patients and their families in the patient's care. And there is a specific requirement under this goal for the laboratory to define and communicate the means for patients and their families to report concerns about safety and encourage them to do so. The requirements associated with the patient safety goals are posted online at *www.jcaho.org/accredited+organizations/patient+safety/npsg.htm*.

Battle Brewing Over Specialty Hospital Ban

Getting Congress to approve a permanent ban on new physician-owned specialty hospitals, as proposed by Senate Finance leaders, could prove daunting, given opposition from House Energy & Commerce chairman Joe Barton, who has vowed not to let any similar bill out of his committee or have it attached as a rider to an appropriations measure

The statutory 18-month moratorium on physician referrals of Medicare and Medicaid patients to certain specialty hospitals owned by the physicians expires June 8, and the battle between supporters and foes of the ban is heating up. Supporters say these hospitals furnish quality, efficient care. Foes say they put community hospitals at a competitive disadvantage, siphoning off profitable business and leaving community hospitals to provide a full range of care including emergency room treatment, burns and trauma care, even at a loss.

The moratorium was imposed by the Medicare Modernization Act of 2003 and affects only those hospitals specializing in cardiac care, surgery, or orthopedics that were not in operation or under development as of November 18, 2003 (*NIR, 25, 12/ Apr 5 '04, p. 7*).

The Medicare Payment Advisory Commission has recommended continuing the moratorium to 2007 so that further study can be made of the quality and efficiency of care these hospitals furnish. The Centers for Medicare & Medicaid Services opposes any extension, though administrative actions it plans to take will, in effect, continue the hold placed on new facilities for another six months, said CMS head Mark McClellan in testimony before the House Energy & Commerce Committee. This was good news to the panel's chairman, Joe Barton (R-TX), and other Republicans on the committee who have long opposed the ban.

Senate Finance Committee leaders take the opposite side. Legislation (S. 1002), introduced by committee chairman Charles Grassley (R-IA) and the ranking Democrat, Max Baucus (MT), would extend the moratorium permanently and, while allowing existing facilities to continue, would restrict the type of care they provide and freeze physician investment at current levels. The bill basically would exclude new specialty hospitals from the "whole hospital" exemption under the Stark physician self-referral law. This exemption allows Medicare and Medicaid referrals by doctors who have a financial interest in an entire hospital, as opposed to a unit or department of a hospital.

♦CODING A·D·V·I·S·O·R·Y

On July 18 the Centers for Medicare & Medicaid Services will hold a public meeting at its Baltimore headquarters to get input on fees to be established for new CPT codes to be added to the Part B lab fee schedule for 2006. The new lab codes will be listed on or after June 20 at *cms.hhs.gov/suppliers/clinlab*.

CMS invites recommendations on whether payment for the new codes should be determined by either the cross-walk or the gap-fill method. Under the cross-walk method, a new test code is matched to an existing code on the fee schedule and is assigned the related local fee schedule amount and the national payment limitation. The gap-fill method is used when no comparable existing test code is available. In this instance, payment is set based on the prevailing pricing patterns of local carriers.

Registration for the July 18 meeting begins June 20 and may be completed online at *cms.hhs.gov/suppliers/clinlab* or by calling Anita Greenberg at 410-786-4601.

Regulatory Calendar

The HHS semi-annual regulatory agenda which appeared in the May 16 *Federal Register* laid out a timetable for finalizing the Medicare rules highlighted below:

December 2006

- ❑ A final rule for HIPAA-compliant electronic claims submissions to Medicare. Though HIPAA-compliant claims were required as of October 16, 2003, Medicare has allowed HIPAA-covered entities to file non-compliant claims as long as these entities are working toward compliance (*NIR, 25, 1/Oct 10 '03, p. 2*).
- ❑ A final rule on how "inherent reasonableness" will apply to payments for all Medicare Part B services (except physicians' services). An interim final rule has been in effect since February 2003 (*NIR, 24, 9/Feb 24 '03, p. 3*).

June 2007

A final Stark II rule on physician referrals to healthcare entities with which they have a financial relationship. An interim final Stark II rule took effect July 26, 2004 (*NIR, 25, 12/Apr 5 '04, p. 1; 25, 18/Jul 5 '04, p. 4*).

G-2 SPECIAL AUDIO CONFERENCE

Are You Ready For A Surprise Survey?

You can't afford not to be, given the current quality and enforcement environment. JCAHO and the College of American Pathologists, which together accredit more than 8,600 hospital and independent labs, already plan to switch to unannounced surveys.

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The audio conference will run from 2:00-3:30 p.m. (Eastern). Registration fee: G-2 subscribers, $227 (regular rate, $277). Your single paid registration entitles you to as many listeners per site as you like. Three easy ways to register:

- ❑ Online: *www.g2reports.com*
- ❑ Call 1-800-401-5937, ext. 2
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March 2008

A final rule revising hospital Conditions of Participation under Medicare and Medicaid, including requirements for completion of history and physical exams, authentication of verbal orders, security of medications, and completion of post-anesthesia evaluations (*NIR, 26, 12/Apr 11 '05, p. 6*).

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