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Lab Groups Upset About CMS Proposal To Require Signature on Test Requisitions

Groups representing clinical laboratories are expressing concern over a proposal by the Centers for Medicare and Medicaid Services (CMS) to require the signature of a physician or nonphysician practitioner (NPP) on all requisitions for tests paid under the Part B lab fee schedule. The proposal would reverse longstanding Medicare policy.

The proposal, announced in a July 13 proposed rule for the 2011 Medicare physician fee schedule, drew swift opposition from the Clinical Laboratory Coalition, which includes 10 major lab associations. CMS invited comments by Aug. 24 and said it will address them in the final physician fee schedule that it expects to publish in November.

Currently, under a rule finalized in 2001 resulting from a congressionally mandated lab-negotiated rulemaking and reiterated by CMS in subsequent manual issuances, a physician's signature is one way to document that the treating doctor ordered the service,

Continued on page 2

EHR 'Meaningful Use' Rules Ease Access

The final rule on "meaningful use" of electronic health records is loose and flexible enough to make provider adoption easier, say experts.

The final rule, issued by the Centers for Medicare and Medicaid Services (CMS) July 13, loosens the core requirements that a provider needs to qualify as a "meaningful user" of health information technology (HIT). Under the "all or nothing" approach in the proposed rule, hospitals would need to meet all 25 objectives to qualify for reimbursement. Under the final rule, "eligible professionals" (EP) must meet 15 objectives, and eligible hospitals need to meet 14. Providers also can choose five optional objectives to defer in 2011 or 2012.

A qualifying EP can receive EHR incentive payments for up to five years with payments beginning as early as 2011. In general, the maximum amount of total incentive payments that an EP can receive under the Medicare program is \$44,000.

Continued on page 9

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Inside this issue

- Lab groups upset about CMS proposal to require signatures on lab test requisitions 1
- EHR 'meaningful use' rules ease access 1
- What's next for lab-developed tests?..... 3
- Lab Institute to include discussion on LDTs, DTC tests 4
- OCR proposes to extend HIPAA obligations to subcontractors on business associates, implement HITECH provisions: see *Perspectives* 5
- Fraud crackdown nets \$251 million in false claims 10
- AAB wins key court decision against N.Y. health department 10
- CAP urges consistency in federal oversight of array-based cytogenetic testing 11
- News in brief 12

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For The Last Word In Healthcare Compliance

Lab Groups Upset, from page 1

but it is not the only permissible way and should not be required as long as such documentation exists in an alternate form. For example, the physician may document the ordering of specific services and their medical necessity in the patient's medical record.

CMS says the approach it is proposing would address concerns raised about the present policy, resulting in a less confusing process and providing a straightforward directive for laboratories to meet. Requiring the signature of a physician or NPP for all requisitions and orders would eliminate "uncertainty over whether the documentation is a requisition or an order, whether the type of test being ordered requires a signature, or which payment system does or does not require a physician or NPP signature."

Nor would it increase the burden on physicians, CMS says. "It is our understanding that, in most instances, physicians are annotating the patient's medical record with either a signature or an initial (the order), as well as a signature on the paperwork that is provided to the clinical diagnostic laboratory that identifies the test or tests to be performed for a patient (the requisition).

"Further, this policy would make it easier for reference laboratory technicians to know whether a test is appropriately requested, and potential compliance problems would be minimized during the course of a subsequent Medicare audit because a signature would be consistently required."

"Labs will have the unenviable task of getting physicians to comply with this requirement. It will also leave labs in an untenable position when a test sample arrives with an unsigned requisition. If they don't perform the test until they receive a physician signature, the lab specimen may be compromised and the physician may not receive the timely test result that he or she requires to diagnose or treat the patient. But if they do perform the test and aren't able to obtain a signature, then they are at risk of not being paid."

— Rober Mazer, Ober/Kaler

Problems Posed for Labs

Robert Mazer, an attorney with Ober/Kaler in Baltimore, explains that while CMS says this policy will result in less confusion, it appears to have created the confusion it attempts to minimize in recognizing a distinction between "orders" and "requisitions" for clinical lab tests.

"Complying with this new requirement, if finalized, will be a huge problem for many labs. They won't know what the requirements will be until sometime in November and will then have to have new procedures in place on Jan. 1," notes Mazer. "This may require them to print new requisitions, if existing ones

don't accommodate a physician's signature. It will also require them to educate physicians about this new requirement. It's also unclear how this will impact electronic ordering arrangements. Will an electronic signature be required? If so, will there be specific rules as to what is considered acceptable? Many existing electronic ordering systems cannot accommodate an electronic signature."

Mazer says he suspects that labs and physicians will strongly disagree with CMS that this requirement would not increase the burden on physicians. While physicians may initial or sign the medical record entry, it is unlikely they can sign the requisition at the same time. The requisition requires significant patient demographic information and may not be completed until much later—possibly after the physician has left the office to go on hospital rounds.

“Labs will have the unenviable task of getting physicians to comply with this requirement,” says Mazer. “It will also leave labs in an untenable position when a test sample arrives with an unsigned requisition. If they don’t perform the test until they receive a physician signature, the lab specimen may be compromised and the physician may not receive the timely test result that he or she requires to diagnose or treat the patient. But if they do perform the test and aren’t able to obtain a signature, then they are at risk of not being paid.”

In its recent alert to members, the Clinical Laboratory Management Association said the reversal of Medicare policy “places a burdensome and unnecessary requirement on both labs and physicians, creating a literal blizzard of paperwork, expense and resource commitment for no good reason. If there is no signature on the requisition the lab receives, the tests on the requisition would not be considered medically necessary so the lab would not be able to file a claim for the tests. Correcting this requires that the requisition be faxed, mailed, or delivered by courier back to the physician’s office for the signature, a simple phone call would not be sufficient.” 🏠

What’s Next for Lab-Developed Tests?

As the events of the last couple of months have made clear, the Food and Drug Administration (FDA) has decided to step up regulation of laboratory-developed tests (LDTs). What’s not so clear is just what approach the agency will take in its oversight.

The FDA recently announced its intention to move to a risk-based application of LDT oversight. How that goal will be accomplished remains to be seen, but the agency heard a variety of suggestions, concerns, and frustrations at a two-day public meeting it convened in July.

LDTs and diagnostic test kits are subject to different standards and uneven enforcement, the FDA has acknowledged. Courtney Harper, Ph.D., of the FDA’s Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), described the current regulatory strategy as bifurcated, with commercially distributed tests and LDTs taking divergent paths to market. The proportion of tests taking the LDT route, which does not require FDA submission, has climbed in the past 10 to 15 years, she said, and the volume and variety of LDTs has grown exponentially. The self-determined nature of LDT status is also problematic, noted Harper. “An LDT is not always lab-developed.”

Commercially offering LDTs through a CLIA-certified laboratory created specifically for that purpose is now frequently used as a mechanism for market entry, allowing novel tests to reach the national market without going through the FDA. “We see LDTs being used more and more as a loophole,” said Elizabeth Mansfield, Ph.D., director for personalized medicine at FDA OIVD. “Preliminary medical data is being packaged as medical information.”

Risk vs. Benefit

The FDA’s move to actively regulate this class of in vitro diagnostics (IVDs), which are manufactured and offered within a single clinical laboratory, is a response to public health risks created by LDTs that may not provide a reasonable assurance of safety and effectiveness. “The goal of regulation is to maximize value and minimize risk,” said Principal Deputy FDA Commissioner Joshua M. Sharfstein, M.D. “We really do want to foster innovation in testing while ensuring high quality.”

The assembled stakeholders at the FDA meeting were also focused on risks, including those of stifling innovation among test developers, depriving patients and clinicians of critical diagnostic information, burdening the small clinical laboratories for whom the LDT designation was originally designed, and over-taxing the limited resources of the FDA.

Presenters at the meeting urged FDA to undertake in-depth research on many fronts before proceeding with draft guidance. Industry consultant Mary Pendergast was one of many attendees who suggested that the agency thoroughly examine how clinicians and patients are using LDTs and how they understand the results. Pendergast agreed that a risk-based approach to regulation was needed but argued that the FDA was in danger of regulating “on opinion and anecdote,” not facts.

Lab Institute to Include Discussion on LDTs, DTC Tests

The discussion about the federal government’s evolving role in regulating lab-developed tests and direct-to-consumer tests continues at G-2 Reports’ 28th Annual Lab Institute, which will be held Oct. 13-15, 2010, in Arlington, Va.

You won’t want to miss this lively discussion with Alberto Gutierrez, director of the Office of In Vitro Diagnostics at the Food and Drug Administration; Sharon Terry, president and CEO of the Genetic Alliance; and Ronald Weiss, M.D., professor of pathology at ARUP Laboratories/University of Utah.

More details about Lab Institute are available at www.labinstitute.com. Please note that early-bird registration rates expire Sept. 3.

Bridging Worlds

FDA representatives conceded that they have no clear idea of the scope of the LDT market they are seeking to regulate and suggested that efforts to learn who is offering what tests would be coordinated with the National Institutes of Health, which recently announced its plan to develop a genetic testing registry. “There are thousands of LDTs out there. Most have been offered safely and efficaciously for many years,” said Gail Vance, M.D., representing the College of American Pathologists (CAP). “If I were the FDA, I would start by gathering data. Get to know the universe—CAP, CLIA. It’s going to take a considerable amount of effort to bridge the CLIA and FDA worlds.”

Possible roles for third-party organizations in LDT regulation figured prominently in the two-day discussion,

with presenters and panelists referring to regulatory schemes proposed by groups including CAP and AdvaMed. In highlighting CAP’s 2009 proposal to clarify oversight of LDTs, Vance emphasized the potential value of a risk-based approach that would be realized through “a partnership between [the Centers for Medicare and Medicaid Services], FDA, and third-party accreditors.”

A collaborative solution was also favored by Judy Yost, director of laboratory services at CMS and head of the CLIA program. “A public-private partnership is probably a good way to go,” she said. “We clearly offer the resources of CMS and CLIA to assist in this process.” FDA’s Mansfield said that the agency was considering using CLIA inspectors for the LDT inspection process.

The FDA has said that it will review comments from the meeting, as well as those submitted to the docket by Aug. 15, and develop a draft oversight framework for public comment. Such a framework would likely be phased in over time based on the level of risk of the test. 

COMPLIANCE PERSPECTIVES



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OCR Proposes to Extend HIPAA Obligations to Subcontractors of Business Associates, Implement HITECH Provisions

On July 14, 2010, the Office for Civil Rights of the Department of Health and Human Services (OCR) published its notice of proposed rulemaking to implement various provisions of the Health Information Technology for Economic and Clinical Health Act (the HITECH Act) by revising the privacy, security, and enforcement rules that were previously issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The proposed rule would extend HIPAA obligations and potential penalties not only to business associates but also to direct or indirect subcontractors who perform activities for a business associate involving the use or disclosure of protected health information (PHI). The HITECH Act required the extension of these obligations only to business associates, so the proposed rule would expand the reach of the statute. This article focuses on these proposed revisions and several other business associate changes, as well as OCR's proposal to allow additional time to comply with these and various other changes arising out of the HITECH Act.

The HITECH Act expanded the definition of business associate to include health information exchanges, regional health information organizations, e-prescribing gateways, and other organizations that provide data transmission of PHI to a covered entity, as well as vendors that provide personal health record systems for covered entities.

Business Associate Relationships

The privacy and security rules allow covered entities to disclose PHI to business associates, and business associates to create or receive PHI on behalf of the covered entity. In general, the current HIPAA regulations define a "business associate" as a person (other than a member of the covered entity's workforce) or entity who, on behalf of a covered entity, performs a function or activity involving the use or disclosure of PHI, such as the performance of financial, legal, actuarial, accounting, consulting, data aggregation, management, administrative, or accreditation services to or for a covered entity.

The HITECH Act expanded the definition of business associate to include health information exchanges, regional health information organizations, e-prescribing gateways, and other organizations that provide data transmission of PHI to a covered entity, as well as vendors that provide personal health record systems for covered entities.

As a condition for allowing a business associate to create, receive, maintain, or transmit PHI (and, in the case of the security rule, ePHI) on behalf of a covered entity, the privacy and security rules require the covered entity to obtain written assurances, in the form of a business associate agreement, that the business associate will safeguard the information.

Background: HITECH Act

On Feb. 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act of 2009, which includes the HITECH Act. Prior to the HITECH Act, business associates had contractual obligations under their business associate agreements to maintain the privacy and security of PHI but were not subject to sanctions for failure to comply with the HIPAA rules. The HITECH Act expanded the HIPAA obligations and exposure of business associates by applying most of the security standards and some of the privacy standards directly to business associates, requiring business associates to comply with the security breach notification requirements, and subjecting business associates to civil and criminal penalties for HIPAA violations. Furthermore, the HITECH Act strengthened HIPAA penalties and enforcement mechanisms, and required the secretary of Health and Human Services to perform periodic audits to ensure that covered entities and business associates comply with HIPAA's privacy and security rules.

Under the proposed rule, a business associate that engages a subcontractor to perform PHI-related functions or provides a subcontractor with access to PHI will be required to enter into a business associate agreement with the subcontractor.

Many of the HITECH Act security and privacy changes became effective in February 2010, although some (such as security breach notification requirements and increased penalties for HIPAA violations) previously took effect, and some others will take effect later.

Extension of BA Obligations to Downstream Subcontractors

OCR proposes to revise the definition of "business associate" to include subcontractors that create, receive, maintain, or transmit PHI on behalf of a business associate, and to define "subcontractor" to mean a person who acts on behalf of a business associate, other than in the capacity of a member of the business associate's workforce. With respect to business associates, the definition of "workforce" is proposed to include employees and other persons whose conduct is under the direct control of the business associate.

Under the proposed rule, a business associate that engages a subcontractor to perform PHI-related functions or provides a subcontractor with access to PHI will be required to enter into a business associate agreement with the subcontractor. If a business associate's subcontractor engages another party to perform any of its PHI functions then the direct subcontractor would be required to enter into a business associate agreement with its subcontractor. The covered entity would not be required to enter into a business associate agreement with any of the subcontractors, as this burden falls on the business associate or subcontractor engaging subcontractors. All downstream subcontractors would be regarded as business associates, and therefore subject to HIPAA obligations and penalties for noncompliance, even in the absence of a business associate agreement.

OCR described the extension of business contractor obligations to subcontractors as necessary to avoid the lapse of privacy and security protections when a function is performed by a subcontractor rather than by a business associate with a direct relationship with the covered entity. OCR has asked for comments on the subcontractor provisions.

The extension of HIPAA obligations would create potentially burdensome HIPAA obligations and exposure for many subcontractors who may perform functions relating to PHI but have no direct relationship with the covered entity and may not even be familiar with the covered entity or the underlying business associate

relationship. These obligations include security rule requirements to implement administrative, physical, and technical safeguards that many business associates and subcontractors will find difficult and expensive to satisfy, as well as obligations to report security breaches and to comply with the nuances of the privacy rule and a proposed obligation to enter into business associate agreements with their subcontractors. Subcontractors would also be subject to civil and criminal penalties for noncompliance.

Removal of Obligation to Snitch

OCR's proposed regulation to implement Section 13404(b) of the HITECH Act, a provision that had been construed to potentially require a business to report problems to the secretary of Health and Human Services, will come as a relief for many covered entities and business associates. Under the proposed rule, a business associate that becomes aware of noncompliance by its subcontractor would be required to respond by curing the breach or terminating its business associate agreement with its subcontractor.

The proposed rule would provide further relief from the "snitch" obligation by removing the requirement that the covered entity report problems to the HHS secretary if termination of the business associate agreement is not feasible.

Other Business Associate Provisions

The proposed rule would implement the HITECH Act's extension of many other HIPAA obligations, as well as exposure to potential civil and criminal penalties, to business associates. In particular:

- ❖ Most provisions of the security rule would be extended to business associates;
- ❖ Business associates would be permitted to use or disclose PHI only as permitted or required by the business associate agreement;
- ❖ Business associates would generally not be allowed to use or disclose PHI in a manner that would violate the privacy rule if done by the covered entity;
- ❖ When using, disclosing, or requesting PHI a business associate (like a covered entity) would generally be required to make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose, although this requirement would not apply to disclosures to a health care provider for treatment;
- ❖ The standards for business associate agreements would be revised so that the security and privacy rule requirements would be more consistent with each other and to incorporate HITECH and subcontractor provisions;
- ❖ A covered entity would be subject to civil monetary penalties based on the acts and omissions of its business associates who are deemed to be agents of the entity, even if a compliant business associate agreement is in place; and
- ❖ A business associate would be subject to civil monetary penalties based on the acts and omissions of its workforce members and its subcontractors who are deemed to be its agents.

Proposal for Additional Time to Comply With New Regulations

Although many of the provisions under the HITECH Act took effect in February 2010, OCR recognized that covered entities and business associates will need some time after the effective date of the final rule to comply with the final rule.

The proposed rule is available at <http://edocket.access.gpo.gov/2010/pdf/2010-16718.pdf> and is subject to a comment period ending on Sept. 13, 2010.

OCR therefore stated its intention to allow 180 days after the effective date of the final rule to come into compliance with the new or modified standards and implementation specifications.

It is important to keep in mind, however, that OCR is not the only agency with authority to enforce the HITECH Act requirements. For example, the HITECH Act allows state attorneys general to enforce the HIPAA rules. It is possible that other potential enforcers might not respect this delay.

OCR proposes allowing additional time (on top of the 180-day compliance period) to revise business associate agreements to bring them into compliance with the HITECH requirements. Proposed transition provisions would allow covered entities and business associates to continue to operate under existing business associate agreements for up to one year beyond the compliance date (i.e., nearly 18 months after the effective date of the final rule) if the written business associate agreement is in place as of the publication of the final rule and complies with the security and privacy rules as in effect immediately prior to the publication date and, in addition, the agreement is not modified or renewed.

This additional time for grandfathered business associate agreements applies only to the written documentation requirement, so covered entities, business associates, and downstream contractors would be required to comply with all other HIPAA requirements beginning on the compliance date.

Other Proposed Changes

This article highlights just a few of the proposed revisions set forth in the notice of proposed rulemaking. Some other provisions of note would:

- ❖ Revise the definition of PHI to exclude information regarding a person who has been deceased for more than 50 years, so that the privacy and security rules would not apply to such information;
- ❖ Require that covered entities include additional information in their notices of privacy practices;
- ❖ Implement the HITECH Act provision requiring a covered entity to agree to an individual's request to restrict disclosure of PHI about the individual to a health plan when the individual pays for the item or service in full;
- ❖ Implement the HITECH Act prohibition on the sale of PHI without authorization from the individual and add a requirement of authorization in order for a covered entity to receive remuneration for disclosing PHI;
- ❖ Implement the HITECH Act requirement of authorization for marketing if the covered entity receives financial remuneration for the communication;
- ❖ Implement the HITECH Act provision allowing individuals to obtain a copy of PHI in an electronic format if the covered entity uses an electronic health record; and
- ❖ Revise standards for determining the levels of civil monetary penalties.

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EHR 'Meaningful Use' Rules Ease Access, from page 1

A companion rule, issued July 13 by the National Coordinator for Health Information Technology, identifies the standards and certification criteria for EHR technology so that eligible professionals and hospitals may be assured that the systems they adopt are capable of performing the required functions.

The two final rules also complement recently issued rules for a temporary certification program and expanded privacy, security, and enforcement protections under the Health Insurance Portability and Accountability Act (HIPAA). All four rules are "key components" of the regulatory structure needed to facilitate the EHR incentive program, CMS said in a statement.

Alan Mertz, president of the American Clinical Laboratory Association (ACLA), notes the changes have lowered the bar to permit more physicians and hospitals the ability to leverage money made available through the Health Information Technology for Economic and Clinical Health Act (HITECH Act). "ACLA's members have been providing health IT solutions to providers for decades and are poised to help them meet the criteria set forth in the meaningful use rule."

Flexibility for Providers

In addition to reducing the number of required objectives, the final rule also makes a number of other changes to the original proposal, including:

- ❖ Adding objectives requiring patient-specific educational resources for both eligible professionals and hospitals and recording advance directives;
- ❖ Defining "hospital-based providers" as providers who perform substantially all of their services in an inpatient hospital setting or emergency room only; and
- ❖ Including critical-access hospitals in the definition of acute-care hospitals so they are eligible for the incentive funding.

The final rule also relaxes the threshold requirement for meeting Stage 1 meaningful use criteria. For example, the proposed rule required that 75 percent of all prescriptions be transmitted electronically; however, the final rule requires that only 40 percent of the prescriptions be sent electronically. In addition, the quality reporting measure requirements in the final rule have been reduced to 44 (from 90 in the proposed rule).

Standards, Certification Criteria

According to the Office of the National Coordinator for Health Information Technology (ONC), the final rule for standards and certification is "very similar" to the interim final rule released Dec. 30 and published in the Jan. 13 *Federal Register*. The final rule clarifies or revises certain standards and certification criteria, for the most part to align with changes to the final rule on meaningful use, according to an ONC document.

The interim final rule described standard formats for clinical summaries and prescriptions; standard terms to describe clinical problems, procedures, laboratory tests, medications, and allergies; and standards for the secure transportation of this information using the Internet.

ONC does not anticipate that the final rule is an economically significant rule, because it has estimated that the costs to prepare complete EHRs and EHR modules to be tested and certified will be less than \$100 million per year. 🏛️

Fraud Crackdown Nets \$251 Million in False Claims

The latest nationwide crackdown on health care fraud has led to more than 90 people being charged in connection with alleged billing schemes involving more than \$251 million in false Medicare claims.

The announcement by Attorney General Eric Holder and Department of Health and Human Services Secretary Kathleen Sebelius came during a “summit” of federal, state, and local officials; providers; and others gathered in Miami in July to discuss new methods to eliminate fraud within the U.S. health care system. The meeting was the first in a planned series of regional health care fraud prevention summits.

Holder and Sebelius said the arrests in Miami; Baton Rouge, La.; Brooklyn, N.Y.; Detroit; and Houston were the latest in a continuing operation of the Medicare Fraud Strike Force—a multiagency team of federal, state, and local investigators designed to combat Medicare fraud through the use of Medicare data-analysis techniques and an increased focus on community policing.

In unsealed charges, 94 individuals were accused of various Medicare offenses. The charges are based on a variety of fraud schemes, including physical therapy and occupational therapy schemes, home health care schemes, HIV infusion fraud schemes, and durable medical equipment (DME) schemes.

The strike force operation was part of the Health Care Fraud Prevention and Enforcement Action Team (HEAT), a joint initiative announced in May 2009 between HHS and the Department of Justice. The HEAT program was an expansion of targeted anti-fraud activity that HHS and DOJ began in 2007 in South Florida.

The defendants allegedly participated in schemes to submit claims to Medicare for treatments that were medically unnecessary and often not provided. 🏠

AAB Wins Key Court Decision Against N.Y. Health Department

For more than 11 years, the American Association of Bioanalysts (AAB) has fought a court battle against the New York State Department of Health, claiming that it was intentionally overcharging clinical laboratories so that it could subsidize its many other research programs that had no relation to covering the necessary costs of regulating clinical labs and blood banks.

“The department abused a program properly established by the legislature, used it as a slush fund, and then tried every maneuver imaginable to hide what it did.”

— Jeffrey Sherrin, AAB

According to AAB’s complaint, “Lab levies have increased sevenfold on an industry-wide basis from \$2.4 million per year in 1984 to more than \$17 million per year today.”

AAB scored a key victory July 22 when the state’s Appellate Division, Third Department, rejected an appeal from the health department and unaniously upheld a lower court’s decision, agreeing that the fees charged to labs were “arbitrary and capricious” and that the department’s “bald estimates” of the actual costs of lab regulation could not support the fees charged when the department failed to keep accurate, up-to-date financial records or even disclose those documents in support of the cost estimates.

Writing for the court, Justice Robert S. Rose noted, "The department's intention to shift as many costs as possible onto clinical labs was further revealed in testimony that the director had once boasted he had been able to transfer 17 percent of the Wadsworth Center's budget to the clinical labs."

AAB commenced the lawsuit when it learned that expenditures were being made from lab fees for salaries of persons whose jobs had nothing to do with the regulation of New York-licensed clinical labs, and in some cases who did not even work for the department. Monies were also used to pay for trips to California and Europe and cars for the New York health commissioner.

AAB's general counsel Jeffrey Sherrin, who both tried the case and successfully argued the appeal, said, "The department abused a program properly established by the legislature, used it as a slush fund, and then tried every maneuver imaginable to hide what it did."

The case now goes back to the department to recalculate the fees that should have been charged to AAB member labs. This should enable labs to recover 75 percent of the money they paid between 1998 and 2006. But noted AAB administrator Mark S. Birenbaum, Ph.D., "All labs will benefit from the fight we have waged," since the department will have to conform its future billings to the court decision. The department has 30 days from the court's ruling to appeal to the state's highest court, which typically limits its caseload to those where legal findings are in sharp dispute. 🏛️

CAP Urges Consistency in Federal Oversight of Array-Based Cytogenetic Testing

The College of American Pathologists (CAP) recently submitted comments to the Food and Drug Administration (FDA) on regulating array-based cytogenetic tests, noting that this emerging technology should be no different from other laboratory tests introduced into medical practice.

The college emphasized that pathologists and other laboratory professionals use their professional expertise and knowledge of the literature and available resources to interpret the results of array-based cytogenetics. In addition, CAP urged the agency to avoid burdensome regulations that might restrict access to these tests.

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"Array-based cytogenetics constitutes an important and expanding aspect of the medical practice of laboratory professionals for decades to come," stated the college. "The college therefore has a keen interest in ensuring that our ability to interpret tests based on professional expertise in order to provide high quality diagnostic services to patients and other physicians we serve is not unduly restricted. Patient care is compromised when diagnostic testing services are less readily and affordably available because of burdensome regulation."

The FDA convened a June 30 meeting to gather stakeholder input on challenges related to evaluating performance, determining clinical significance, reporting results, and interpreting these tests. Some examples of this type of testing include microarray-based comparative genomic hybridization (aCGH) arrays and single-nucleotide polymorphism (SNP) arrays. 🏛️

HHS TO DESTROY LAB COMPETITIVE BIDDING DATA: The Department of Health and Human Services (HHS) has agreed to destroy the bid data that San Diego-area laboratories submitted to the Centers for Medicare and Medicaid Services (CMS) as part of CMS's competitive bidding demonstration project. In a statement released by the American Association of Bioanalysts (AAB) and the National Independent Laboratory Association (NILA), administrator Mark Birenbaum, Ph.D., said that HHS has until Aug. 20 to destroy all the documents. After successfully defeating the competitive bidding project in 2008, AAB and other laboratory groups demanded the return of the data submitted by laboratories in response to the bid proposal. When HHS refused, the labs pursued litigation further, culminating in the signing of a settlement agreement and dismissal of the case Aug. 3, 2010. 🏛️

GEORGETOWN SHUTS DOWN MOLECULAR DIAGNOSTIC LAB: Georgetown University Hospital in Washington, D.C., has shut down its molecular diagnostics laboratory amid allegations of inaccurate testing and a pending investigation by the federal government and the College of American Pathologists (CAP). According to an Aug. 6 article in the *Washington Post*, the lab received failing results from a quality-control assessment of its HER2 testing in January 2010. An employee asked supervisors to notify patients of potential problems and recommend retesting, but in an April complaint to hospital administrators, she alleged that nothing had happened. Soon after, the lab began retesting hundreds of samples it received since May 2009. The retesting process ultimately identified two women who had been falsely told they did not have a particular aggressive form of breast cancer known as HER2 positive, according to the *Post* article. In July the employee and her lawyer made a formal complaint to the Centers for Medicare and Medicaid Services and CAP, expressing concern that the lab was taking too long to do the retesting and was not yet sharing the problem with patients. Federal regulators and inspectors from CAP visited the lab the week of July 19. About that time, Georgetown began alerting physicians of patients whose tests came back positive for HER1 breast cancer. After two rounds of outside retesting, six patients were found positive. 🏛️

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