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President Signs Genetic Information Non-Discrimination Act

The new law removes key barriers to use of genetic testing in personalized medicine, advocates say. It encourages individuals to get tested without fear of reprisal, thus enabling physicians to customize prevention, treatment, and therapy to the patient's unique genetic profile.

At a signing ceremony on May 21, President Bush signed into law the Genetic Information Non-Discrimination Act (GINA, H.R. 493) that prohibits employers and health insurers from discriminating against individuals based on their genetic information and test results. The signing is the culmination of a 13-year effort to get such a law on the books.

In signing the bill, Mr. Bush paid homage to the members of Congress supporting it and singled out Sen. Ted Kennedy, just diagnosed with a malignant brain tumor, praising him for "working for over a decade to get this piece of legislation to the president's desk."

The American Clinical Laboratory Association called GINA "a vote for the future." President Alan Mertz said in a statement, "Genetic testing is already making great strides in cancer, HIV, heart disease, and other areas—and this is just a start. GINA protects that future by giving patients the confidence of knowing that their personal information will not be used against them."

The Coalition for Genetic Fairness hailed GINA as "the first civil rights legislation of the new millennium." The new law gives individuals confidentiality and privacy protections, noted coalition president Sharon Terry, CEO of Genetic Alliance, *Continued on p. 2*

CMS Awards Another MAC Contract in Switch To New Medicare Claims Processing System

The Centers for Medicare & Medicaid Services has announced the seventh contract award to be made in the rollout of the Medicare Administrative Contractor (MAC) program that combines Part A/B claims processing with one entity and replaces the current system that splits the work between fiscal intermediaries and carriers.

National Heritage Insurance Corporation has been selected as the MAC for Jurisdiction 2, which includes Alaska, Idaho, Oregon, and Washington, CMS said May 8. NHIC, a subsidiary of EDS, is headquartered in Hingham, Mass. The company is expected to take full responsibility for the Part A/B workload by no later than Dec. 31 of this year.

CMS plans to award a total of 15 A/B MACs covering every state and U.S. jurisdiction by 2009, two years ahead of the transition schedule set by the Medicare Modernization Act of 2003. *Continued on p. 6*

INSIDE *NIR*

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Non-Discrimination Act, *from p. 1*

and "with this assurance, the promise of genetic testing and disease management and prevention can be realized more fully."

Main Provisions of Non-Discrimination Act

The new law governs use of the genetic information of an individual as well as family members in the following areas:

- ❑ Employers are barred from using such information in decisions on hiring, firing, job placement, or promotion.
- ❑ Group health plans and other health insurers in both the group and the individual market are barred from using genetic information to deny coverage or set premium rates and from requiring individuals to undergo genetic testing.
- ❑ The prohibitions apply to employment agencies, labor unions, and Medicare supplemental policy plans as well.
- ❑ Purchasing of genetic information is prohibited for underwriting purposes or for any individual prior to enrollment, but employers may purchase it for certain purposes, including when it is required to comply with certification rules under family and medical leave laws, when it is used for genetic monitoring of persons exposed to the risk of toxic substances in the workplace, and when the employer conducts forensic DNA analysis for law enforcement.
- ❑ Any reference to the genetic information of an individual or family member includes a fetus and an embryo legally held by an individual or family member utilizing an assisted reproductive technology.

A majority of states have laws to protect the public from genetic discrimination, and they vary widely in approach, application, and level of protection. While GINA establishes uniform national safeguards, it does not preempt state requirements.

CMS Gets 30-Day Extension in Lab Bidding Demo Case

With the Medicare lab competitive bidding demonstration stopped in its tracks for now, the government has until June 9 to decide how to proceed. The deadline was set when the Centers for Medicare & Medicaid Services requested and was granted a 30-day extension to respond to the preliminary injunction issued by a federal district court in San Diego.

CMS is still reviewing its options, the agency's press office told *NIR*. Industry sources speculate that CMS could seek a reconsideration, file an appeal, or even retool the demo to meet the court's objections and follow public notice and comment procedures in developing the demo's design.

The Medicare demo, required by Congress in the Medicare Modernization Act of 2003, is designed to see if competitive bidding can be used to pay for independent lab services at rates below the current Part B lab fee schedule.

Regardless of how the government responds, the San Diego labs that filed suit to stop the demo intend to continue their court fight. When asked about this, their lead attorney, Patric Hooper, with Hooper, Lundy & Bookman in Los Angeles, exclaimed, "I should think so!"

The preliminary injunction, granted April 8 by the U.S. District Court for the Southern District of California (San Diego), prevented CMS from moving ahead with the bidding demo until further notice. The court gave the government 30 days to respond or 60 days to appeal. Ruling for the

plaintiffs—Sharp Healthcare, Scripps Clinic, and Internist Laboratory—the court enjoined CMS from:

- ❑ Announcing winners in the bidding process. CMS had planned to disclose the winning labs on April 11 and begin the demo on July 1. Labs that lost would not be able to bill Medicare for demo tests for fee-for-service beneficiaries during the three-year run of the project.
- ❑ Otherwise implementing or carrying out the project in the demo area.
- ❑ Disclosing any information in the bid applications submitted.

Previous *NIR* coverage of the demo has reported on the lab industry's support for the plaintiffs in the San Diego lawsuit, including national organizations and companies that have contributed to the legal fund to help defray court costs. We should also note that the College of American Pathologists supported the lawsuit by filing an amicus brief with the court.

Competitive Bidding Alive and Well for Durable Medical Equipment

Meantime, unfazed by industry and congressional critics, CMS is set to implement, as of July 1, the first stage of the shift to nationwide Medicare competitive bidding for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The national program was enacted in the Medicare Modernization Act of 2003, following reports of significant savings in two bidding pilot sites.

Winners in the first stage, CMS announced May 19, include 325 suppliers in 10 communities across the country. Based on bids submitted by these suppliers, prices will be on average 26 percent lower than Medicare currently pays for DMEPOS items/services. The bidding program is expected to save Medicare $1 billion a year when fully implemented in 2010. Beneficiaries also would benefit from the lower prices, CMS noted, since they are liable for 20 percent coinsurance for DMEPOS items/services.

CMS said it received bids from 1,005 suppliers and close to 6,200 bids for one or more product categories in the competitive bidding sites. CMS offered contracts to 23 percent of suppliers that submitted bids.

Acting CMS administrator Kerry N. Weems said May 19 that the agency does not anticipate postponing implementation and is working on further rollout of the program, despite concerns about its impact on small businesses and local competition. Six members of the Senate Finance Committee cautioned HHS secretary Michael Leavitt, in a May 16 letter, that savings should not come "at the expense of beneficiary access to high-quality products and services" and asked him to consider at least a six-to 12-month delay in launching the second phase.

Hopes for Lab Bidding Demo Repeal Riding on Medicare Bill

The clinical laboratory industry is united in efforts to get Congress to kill the demo by repealing its statutory authority. Bipartisan legislation to do that is pending in the Senate (S. 2099) and in the House (H.R. 3453).

The best vehicle to get it enacted, lab lobbyists told *NIR*, is to attach it to the Medicare bill that the Senate is to take up in early June to address the physician fee cut of 10.6 percent looming on July 1.

"The Clinical Laboratory Coalition is in communications on demo repeal with members of Congress and their staff," Mark Birenbaum, administrator of the American Association of Bioanalysts and the National Independent Laboratory Association, told *NIR*.

The House bill, introduced by Nydia Velazquez (D-N.Y.), has drawn more co-sponsors recently, bringing the total to 44. Signing on this month were Reps. Peter King (R-N.Y.), Zoe Lofgren (D-Calif.), and Carolyn Maloney (D-N.Y.). The Senate bill, introduced by Ken Salazar (D-Colo.) has eight co-sponsors and is backed by four members of the Finance Committee.

OIG Again Warns Labs Against Offering 'Freebies'

In an advisory opinion (No. 08-06) posted May 9, the OIG said the arrangement could generate remuneration prohibited under federal anti-kickback law and thus the government could impose administrative sanctions on the lab.

The HHS Office of Inspector General has given the thumbs-down sign to a clinical laboratory's proposal to provide free labeling of test tubes and specimen collection containers to dialysis facilities.

The lab requesting the opinion provides testing services to dialysis patients under service contracts with dialysis facilities. Services include tests payable under Medicare's composite rate and tests that are separately billable to Part B (noncomposite rate tests).

The lab proposed to provide the free labeling services to selected dialysis facilities, with preference for those whose business the lab wants to obtain or retain. It would not charge for the services that are currently performed internally by the dialysis facility's own personnel. The lab says its competitors are offering the same type of free services it would offer.

According to CMS payment rules, the OIG noted, lab test preparation services are included in composite rate payments, regardless of whether the services are for a composite or noncomposite rate test. Medicare does not make separate payment for administrative tasks associated with lab tests, such as labeling test tubes and specimen collection containers.

No Safe Harbor

The anti-kickback safe harbor for personal services and management contracts would not apply, the OIG concluded, because the selected dialysis facilities would not pay anything to the lab for the labeling services, despite the fact that these services have value to the facilities, given that lab specimen processing costs (including those associated with labeling) are included in the composite rate payments that the facilities receive from Medicare.

The absence of safe harbor protection is "not fatal," the OIG said, but faulted the arrangement for providing free or below-market goods or services to actual or potential referral sources. The OIG noted that it has long held that free or below-market arrangements are suspect and may violate anti-kickback law, depending on the circumstances.

Improper Swapping of Business

The OIG further said the proposed arrangement smacks of improper "swapping" arrangements. In its 1994 special fraud alert on lab arrangements, the OIG warned labs against offering discounts to a dialysis facility for composite rate tests payable out of the facility's pocket, in exchange for referrals of all or most of the facility's noncomposite rate tests that the lab can bill directly to Medicare or other federal health care programs.

Based on the facts presented by the requesting party, the OIG concluded that the lab would appear to be offering nonmonetary discounts to the selected dialysis facilities for their composite rate business with the intent to induce referrals for the more lucrative noncomposite rate business.

An OIG advisory opinion is issued only to the requesting party and is limited in scope to the specific arrangement described. It has no application to, and cannot be relied on by, any other individual or entity. It is legally binding only on the U.S. Department of Health & Human Services and the party requesting it.

CMS to Clarify Physician Signature Policy for Lab Claims

The Centers for Medicare & Medicaid Services will correct problems that have recently occurred in the medical review by the Comprehensive Error Rate Testing (CERT) contractor of clinical laboratory test claims over requirements for the signature of the ordering physician.

CMS was alerted to the problem by the American Clinical Laboratory Association (ACLA), which said many of its member labs had received documentation requests from the CERT contractor—AdvanceMed, a wholly owned subsidiary of Computer Sciences Corporation—for the physician's signature on both paper and electronic claims. Without it, the contractor would recommend that the claim be rejected.

In a March 14 letter to CMS, ACLA noted that labs routinely respond to CERT requests for medical records to determine whether claims were correctly paid. "However, in the past month, several ACLA member labs have reported that after the records are submitted, the CERT contractor has said they are inadequate because they do not include an original signed requisition slip. When the lab reports that no such document exists—nor is it required—the lab is told the testing is inappropriate. This [has happened] not only when the testing is ordered on paper (where there is no signature requirement), but even when the test is ordered electronically, where, of course, no physician signature would be expected to exist."

Unless the situation is corrected, ACLA said, "virtually every lab in the country is at risk for millions in recoupment," going back as much as five years, "even though they have fully complied with Medicare requirements."

In a May 1 response to ACLA, CMS officials agreed that there is no requirement for a physician signature on a test requisition. According to policy established via the congressionally mandated lab negotiated rulemaking, while a signed requisition would be proof of the treating physician's order, there are other permissible ways to document the order.

CMS told ACLA it has instructed CERT "to accept documentation of the treating physician's order in any format that clearly conveys the physician's intent that the test be performed." CERT also is to list the documentation requested as "physician orders," not as "signed physician orders" as has occurred in some cases, CMS said.

CMS has agreed to issue a Change Request to update the Medicare Benefit Policy Manual, making it clear that physician signatures are not required on requisitions for lab tests. This will correct instructions issued earlier this year by the Center for Medicare Management (Change Request 5743, Jan. 11) that omitted language stating that requisitions need not be signed.

Finally, the agency said, it found that the CERT contractor had not been requesting documentation of the order from the physician if it was not included in the documentation submitted by the billing provider. CMS has instructed AdvanceMed to revise its procedures to request the documentation in these instances.

The CMS response to ACLA was signed by Timothy Hill, director of the office of financial management, and Jeffrey Rich, M.D., director of the Center for Medicare Management.

CMS Awards Another MAC Contract, *from p. 1*

The NHIC contract has a total estimated value of approximately $148 million over five years. Most of the MAC operations will be performed in Marysville, Calif., with approximately 200 employees, CMS noted.

NHIC is subcontracting with National Government Services to handle most of the claims processing, provider customer service, appeals, medical review, and reimbursement services. NGS, headquartered in Indianapolis, got the MAC contract for Connecticut and New York (Jurisdiction 13) earlier this year, with a target completion date of November 2008. That contract has an estimated value of $323 million over five years (*NIR, 29, 11/Mar 31 '08, p. 7*).

Of special note to clinical labs: Under the A/B MAC system, they will continue to be paid in accord with existing program instructions, CMS officials confirmed to* NIR. *Labs will be paid via their local Part B lab fee schedule, while local medical review policies will be made consistent across all the states within a MAC's jurisdiction.

In the jurisdiction that NHIC will serve, there were approximately 1.6 million Medicare beneficiaries and 233 Medicare hospitals as of March 31, 2007, and approximately 54,876 physicians and other medical professionals provided services in the area. An estimated 2.9 percent of the national Medicare claims workload comes from the four states in the jurisdiction.

Status of the MAC Transition

In response to a *NIR* inquiry, CMS officials said that, by June 1, four MACs for durable medical equipment and two MACs for institutional and practitioner claims will be fully implemented. The latter two MACs cover 10 states in all:

- Jurisdiction 3: Arizona, Montana, North Dakota, South Dakota, Utah, and Wyoming. The contractor is Noridian Administrative Services LLC (Fargo, N.D.).
- Jurisdiction 5: Iowa, Kansas, Missouri, and Nebraska. The contractor is Wisconsin Physicians Health Insurance Corp. (Madison, Wis.).

Other MAC contracts in various stages of implementation include, in addition to Jurisdictions 2 and 13 above:

- Jurisdiction 12: Delaware, Maryland, New Jersey, and Pennsylvania, as well as the District of Columbia. The contractor is Highmark Medicare Services Inc. (Camp Hill, Pa.).
- Jurisdiction 1: California, Hawaii, Nevada, American Samoa, Guam, and the Northern Mariana Islands. The contractor is Palmetto GBA (Columbia, S.C.).
- Jurisdiction 4: Colorado, New Mexico, Oklahoma, and Texas. The contractor is TrailBlazer Health Enterprises (Richardson, Tex.).

Histocompatibility labs providing services in tissue typing for possible organ recipients and donors will have their claims handled by a specialty MAC yet to be selected. These labs operate on a cost reimbursement basis and bill transplant centers for their services.

MAC awards are determined by open competition under federal procurement rules and must be open for bidding every five years. Contractors that meet or exceed service standards set by CMS may earn award fees, based on their performance. For beneficiaries and providers, the new MAC system is intended to provide a single point of contact with the Medicare program. For more information, go to *www.cms.hhs.gov/MedicareContractingReform/*

FDA Approves ParagonDx's Warfarin Genotyping Test

The FDA has previously cleared warfarin sensitivity tests manufactured by Nanosphere (Northbrook, Ill.) and AutoGenomics (Carlsbad, Calif.).

The Food and Drug Administration has approved a third genotyping test to help physicians identify patients at greater risk for sensitivity to warfarin, a blood thinner used to prevent and treat blood clots, also known as Coumadin.

The assay is the first cleared test that can easily be done within a one-hour turnaround time, enabling patients to have their treatment customized quickly, said the test's manufacturer, ParagonDx, based in Research Triangle Park, N.C.

The FDA gave marketing clearance to ParagonDx's Rapid Genotyping Assay, used to detect variations in the genes CYP2C9 and VKORC1 and approved for use on Cepheid's SmartCycler Dx platform.

Warfarin is currently used regularly by more than 30 million patients in this country. Two million of those are new patients just beginning warfarin treatment. In August 2007, the FDA relabeled warfarin to recommend that genetic testing be performed before initiating warfarin therapy. The ParagonDx test can be used to help prevent some of the most serious adverse events for warfarin patients, including excessive bleeding, which occurs in 10 percent to 16 percent of all patients, the company said.

♦ Medicare Billing *Advisory*

CMS Clarifies Payment Policy for Blood, Blood Products

Citing inconsistencies in billing and claims processing requirements, the Centers for Medicare & Medicaid Services has clarified the payment rules for providers who bill Parts A and B for covered blood and blood products and how the beneficiary's deductible should be assigned.

The agency noted the following key points:

- ❑ Medicare does not pay for the first three units of whole blood or packed red cells that are furnished under Parts A or B in a calendar year.
- ❑ The Part B blood deductible is reduced to the extent that it has been met under Part A, and vice versa.
- ❑ The blood deductible does not apply to the costs of processing, storing, and administering blood.
- ❑ To meet the blood deductible, beneficiaries have the option of paying for the hospital's charges for the blood or packed red cells or arranging for it to be replaced.
- ❑ Beneficiaries are not responsible for the blood deductible if the provider obtained the whole blood or packed red cells at no charge other than the processing charge.

CMS also clarified the revenue code standards set by the National Uniform Billing Committee:

- ❑ Hospitals shall report charges for red blood cells using revenue code 381. For charges for whole blood, use revenue code 382. Failure to report the correct code will cause the claim to be returned.
- ❑ Revenue code 380 is not valid for Medicare.

CMS announced the above in Change Request 5876, issued May 2 to fiscal intermediaries and Medicare Administrative Contractors and effective Oct. 1 of this year.

Action on Medicare Physician Fee Fix Likely in Early June

A fee fix bill is the target vehicle for getting other key lab and pathology priorities enacted, including repeal of lab competitive bidding, extension of the TC "grandfather" protection for independent labs, and overhaul of the CLIA cytology PT program.

Senate Finance Committee chairman Max Baucus (D-Mont.) said May 21 that he aims to get a Medicare bill to the floor most likely by the second week of June. The measure would include an 18-month payment increase for physicians, averting a cut of 10.6 percent slated for July 1. Congress spared Part B physician fees from a 10.1 percent cut that had been scheduled to take effect on the first of this year and granted a 0.5 percent increase through June 30.

Baucus said his bill would cut spending to Medicare managed care plans, despite White House opposition, and add protections for beneficiaries, especially to help more low-income individuals qualify for aid under the drug benefit. His legislative package would cost an estimated $18.2 billion over five years versus the Republican alternative costing $14.9 billion. The GOP plan has been rejected, a Baucus aide said, in part because it does not do enough to reduce overpayments to Medicare managed care.

While Baucus and his Democratic colleagues plan to move ahead on their own at this point, they do not rule out a bipartisan bill later since GOP support will be needed if a Medicare bill is to clear the Senate.

G-2 Conference Calendar

June 18-20:
Laboratory Outreach 2008, Winning With the Right Numbers
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26th Annual Lab Institute
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