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CMS Proposes New Rules for Accountable Care Organizations

The aim is to provide seamless care versus the fragmented care that is common today, CMS said, and to align Medicare payment with improved care outcomes and efficiencies.

The Centers for Medicare and Medicaid Services (CMS) March 31 released proposed rules governing accountable care organizations (ACOs) that voluntarily participate in Medicare's new shared savings program, set to begin Jan. 1, 2012. The rules will be published in the April 7 *Federal Register*, with a comment deadline of June 6.

The new program, authorized by the health care reform law, is intended to help doctors, hospitals, and other health care providers better coordinate care for Medicare patients with incentives to work together to treat individual patients across care settings, including doctor's offices, hospitals, and long-term care facilities.

At the core of the ACO concept are primary care and related services by a patient-centered team, including pathologists and clinical laboratory professionals.

Concurrent with the release of the proposed rules, other federal agencies weighed in on ACO issues subject to their purview, including anti-kickback law, the physician self-referral ban, antitrust law, civil money penalties, and tax policy.

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INSIDE *NIR*

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It's Official: Contractors Not to Enforce Signature Policy for Lab Test Requisitions

The Centers for Medicare and Medicaid Services (CMS) has instructed its local contractors not to enforce the policy requiring the signature of a physician or nonphysician practitioner (NPP) on paper requisitions for Medicare-covered clinical laboratory tests.

This is good news for labs, said Alan Mertz, president of the American Clinical Laboratory Association, and should allay concerns that without an official directive from CMS their contractor could start denying claims without the requisite signatures.

Until now, the only indication that the agency was pulling back on the requirement came from calls by CMS officials to lab groups in February.

The signature requirement was finalized in the 2011 Medicare physician fee schedule rule, released Nov. 29, 2010. It was to take effect Jan. 1, 2011, for services payable under the Part B lab fee schedule.

However, on Dec. 20, 2010, CMS told contractors that because some physicians, NPPs, and clinical labs were not aware of, or did not

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Physician Signature Policy Not in Force, *from p. 1*
understand, the new policy, enforcement would be delayed for the first quarter of 2011. The agency said it would use this time to conduct an education campaign to dispel confusion.

Then, on Feb. 11, in calls to clinical lab groups, which had argued against the requirement, CMS officials said the agency was withdrawing it altogether and an official announcement would be forthcoming (*NIR 11, 4/Feb. 24, p. 1*).

Along with the March 31 memo declaring the enforcement moratorium, CMS said on its listserv that it "has decided to focus for the remainder of 2011 on changing the requirement because of concerns that physicians, NPPs, and clinical diagnostic laboratories are having difficulty complying with this policy." The notice did not specify changes that might be made or a timeline for when a revision might be released.

CMS officials have given no sign at this point that they are considering anything other than rescinding the controversial requirement. The logical place to do this, industry sources said, is the 2012 physician fee schedule, to be proposed in a few months.

Meantime, pending at the Office of Management and Budget (OMB) is an interim final rule entitled "Changes to the Signature Requirement on Clinical Laboratory Services Requisition" that CMS sent on March 21 for review. At press time, however, OMB has not disclosed the details.

AAB Labs Get New York State Refunds

A second lawsuit challenging the state's permit and inspection fees from 2007 to the present is still pending, AAB said. Over 100 laboratories are plaintiffs in that lawsuit.

Over $5 million is being refunded by the New York State Department of Health (NYSDOH) to 35 laboratories resulting from a lawsuit brought by the American Association of Bioanalysts (AAB) alleging that the department massively overcharged these labs for state inspection and reference fees between 1998 and 2006.

On Feb. 17, 2011, after 12 years of litigation, the department lost its last appeal of lower court rulings favoring AAB assertions that labs were substantially overcharged to subsidize activities unrelated to regulating labs and blood banks (*NIR 11, 3/Feb. 24, p. 3*).

Lower courts stated that inspection and reference fees charged by NYSDOH were "arbitrary and capricious" and its "bald estimates" of the actual costs of the state's regulation program could not support the fees charged, absent reliable documentation and disclosure.

The court rulings directed NYSDOH to recalculate the inspection and reference fees for the eight-year period covered by the lawsuit, AAB noted in an April 5 statement. The department subsequently determined that 78 percent of the fees should be refunded, an amount equal to $5,041,377 for the 35 laboratories. The refund checks were dated March 28 and March 30, 2011.

AAB filed the lawsuit after learning that the lab fees were being used to pay 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 state health department. The money was also used to pay for trips to California and Europe and cars for the New York health commissioner.

Medicare Physician Fee Fix: House Panel Asks Doctors for Ideas

Comments are requested by the end of April. The request was made by Reps. Fred Upton (R-Mich.) and Henry A. Waxman (D-Calif.), chairman and ranking member of Energy and Commerce, respectively. The committee's chairmen emeritus and leaders of the health subcommittee also signed on.

In advance of a hearing planned for early May, the bipartisan leadership of the House Energy and Commerce Committee and its health subcommittee has asked 51 medical organizations for their ideas on how to devise a permanent fix to the Medicare formula used to set physician payment rates.

Under the sustainable growth rate (SGR) formula used to calculate annual updates to the Part B physician fee schedule, payments are slated for a cut of 29.5 percent in 2012.

In the March 28 letter to the medical groups the committee said it "is determined to achieve a permanent, sustainable solution to the SGR problem this year. Toward that end, [we] welcome specific ideas on how to move toward a system that reduces spending, pays providers fairly, and pays for services according to their value to the beneficiary." The ideas should be in a form that can be translated into legislative proposals, the letter advised.

Calling the current payment system "a major threat to the integrity of Medicare and to seniors' access to care," the health leaders said they want to avoid any further short-term fixes as has happened over the past 10 years but note that abandoning the SGR will cost $300 billion.

"The problems preventing reform are twofold: a budgetary hole of $300 billion and a lack of consensus among experts and stakeholders about what kind of payment system should replace the Medicare physician fee schedule. It is the latter question on which we invite your comment."

Arguments Aired in BRCA Gene Patent Lawsuit

Oral arguments were presented April 4 in Myriad Genetics' appeal against a district court ruling that some of the company's patents on BRCA1 and BRCA2 genes are invalid. The case was heard by a panel of three judges of the U.S. District Court of Appeals for the District of Columbia Circuit in Washington, D.C.

In question is whether a human gene or its isolate can be patented. The judges' answer will have great import for the health care industry because thousands of gene patents are currently held by biotechnology companies. A decision is expected in the coming months.

The patents at issue in the appeal were granted to Myriad Genetics and the University of Utah Research Foundation, both based in Salt Lake City. Various mutations in these genes are associated with hereditary breast and ovarian cancer. The patent holders claim the exclusive right to perform diagnostic testing on these genes, license the testing to other users, and threaten litigation for patent infringement against any unlicensed use.

But a lower court ruled in 2010 that the isolated DNA at issue is a "product of nature" not significantly different, either in function or in the information it contains, from DNA that exists in the body, and thus is not eligible for a patent (*NIR 10, 7/April 8, pp. 3-5*).

Attorneys for the patent holders argued in a brief asking the appellate court to dismiss the case that the patent exclusivity has benefited patients and providers

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CMS Proposes New Rules for Accountable Care Organizations, *from p. 1*

Integrated delivery systems are among those well poised to make a transition to ACO operations and tap into additional payments from Medicare offered by the shared savings program. But for all entrants, the risk is that benchmarks won't be met, leaving them liable to pay Medicare back for the losses.

The potential for the ACO program to target beneficiaries with serious health problems and at the same time lower spending was cited in a CMS fact sheet. "Today, more than half of Medicare beneficiaries have five or more chronic conditions such as diabetes, arthritis, hypertension, and kidney disease.

"They often receive care from multiple physicians. A failure to coordinate care can often lead to patients not getting the care they need, receiving duplicative care, and being at an increased risk of suffering medical errors. On average, each year, one in seven Medicare patients admitted to a hospital has been subject to a harmful medical mistake in the course of their care. And nearly one in five Medicare patients discharged from the hospital is readmitted within 30 days—an outcome that many could have avoided if their care outside the hospital had been aggressive and better coordinated."

Key Features of ACOs

Under provisions of the Patient Protection and Affordable Care Act, an ACO may include the following types of groups of providers and suppliers of Medicare-covered services:

- ❏ ACO professionals (physicians and hospitals meeting the statutory definition) in group practice arrangements;
- ❏ Networks of individual practices of ACO professionals;
- ❏ Partnerships or joint venture arrangements between hospitals and ACO profesionals;
- ❏ Hospitals employing ACO professionals; or
- ❏ Other Medicare providers and suppliers as determined by the Health and Human Services secretary.

In the proposed rules, the Health and Human Services secretary has used her discretion to add certain critical-access hospitals as eligible for the shared savings program.

The statute requires each ACO to establish a governing body representing ACO providers and suppliers of services and Medicare beneficiaries. Each ACO would be responsible for routine self-assessment, monitoring, and reporting of the care it delivers.

Under the proposed rules, ACOs would target patients with traditional Medicare (that is, who are not in Medicare Advantage private health plans). To share in savings, ACOs would have to meet quality standards in five key areas:

- ❏ Patient/caregiver care experiences;
- ❏ Care coordination;
- ❏ Patient safety;
- ❏ Preventive health; and
- ❏ At-risk population/frail elderly health.

ACOs also must have in place procedures and processes to promote evidence-based medicine and beneficiary engagement in their care.

Providers and suppliers would continue to receive Medicare fee-for-service payments under Parts A and B and be eligible for additional payments based on meeting specified quality and savings requirements.

Existing ACOs will not be automatically accepted into the shared savings program. If accepted by CMS, an ACO must serve at least 5,000 Medicare beneficiaries and participate for three years. Beneficiaries do not enroll in an ACO, but they must be told that their providers are. A beneficiary's choice of providers may not be limited to the ACO. They can still choose to see doctors outside the ACO. Patients choosing to receive care from providers in ACOs will have access to information about how well their doctors, hospitals, or other caregivers are meeting quality standards.

Other Federal Guidance on Accountable Care Organizations

At the same time that CMS released the proposed ACO rules, the Department of Justice (DOJ) and the Federal Trade Commission (FTC) issued a joint proposed statement of enforcement policy that would establish different levels of antitrust scrutiny depending on the specific ACO arrangement.

For example, they would give "rule of reason" treatment to an ACO if it uses the same governance and leadership structure and the same clinical and administrative processes in the commercial market as it uses to qualify for and participate in the shared savings program. For details, go to *www.ftc.gov/opp/aco*.

Also, CMS and the Health and Human Services Office of Inspector General (OIG) jointly issued a notice with comment period outlining proposals for waivers of the physician self-referral law (known as the Stark law), the anti-kickback statute, and certain provisions of the civil monetary penalty law in connection with the shared savings program (posted at *oig.hhs.gov*).

And the Internal Revenue Service issued a notice (2011-20) inviting comments on how ACOs and the shared savings program would apply to hospitals and other health care organizations that enjoy tax-exempt status (*www.irs.gov*).

Choice of Risk Models

In order to provide an entry point for organizations with varied levels of experience with and willingness to assume risk, CMS proposes a choice of two models when participating in the shared savings program:

- ❏ A one-sided risk model (share savings only for the first two years and share savings and losses in the third year); or
- ❏ A two-sided risk model (share sav ings and losses for all three years).

Though ACOs that participate in the two-sided model would be able to obtain greater savings, CMS also proposes to establish a minimum savings rate. ACOs in the one-sided risk program that have smaller populations (and more variation in expenditures) would have a larger savings rate, and ACOs with larger populations (and less variation in expenditures) would have a smaller rate. Under the two-sided approach, CMS proposed a flat 2 percent minimum rate.

CMS is to develop a benchmark for savings to be achieved by each ACO or losses for which it can be held liable. Additionally, an ACO would be accountable for meeting or exceeding the quality performance standards to be eligible to receive any shared savings.

The proposed rules outline a monitoring plan that includes analyzing claims and specific financial and quality data as well as quarterly and annual aggregated reports, performing site visits, and performing beneficiary surveys.

In a number of circumstances CMS may terminate the agreement with an ACO, including avoidance of at-risk beneficiaries and failure to meet the quality performance standards.

CMS has launched a dedicated Web page at *www.cms.gov/sharedsavingsprogram* that will continue to add information on the program.

Arguments Aired in Gene Patent Lawsuit, *from p. 3*
alike by creating an incentive to devise cutting-edge technologies for the human genome. "But for [this] Myriad Genetics would not have been established and funded by investors."

Lawyers for the plaintiffs in the case, *Association of Molecular Pathology et al.*, say the exclusivity prevents women from getting a second opinion on their test results and impedes cancer research in other health care institutions. The plaintiffs question whether isolating a part of DNA from other genetic material makes it a "new invention" that can be patented or does it remain a "product of nature."

The lawsuit was filed in 2009 by the American Civil Liberties Union and the Public Patent Foundation on behalf of a host of plaintiffs, including cancer patients and medical groups. Pathology and clinical lab interests are among the many who joined the lawsuit, arguing that gene patenting harms patients and limits advances in both research and the field of medicine.

Regardless of how the appellate judges rule, many observers expect that in the end the case will be pursued all the way to the U.S. Supreme Court.

Medicare Imposes New Enrollment Fee

The fee requirement does not apply to physicians, nonphysician practitioners, physician group practices, and nonphysician practitioner groups. However, when they enroll as a supplier of durable medical equipment, prosthetics, orthotics, and supplies via the CMS-855S application, they must pay the fee.

As of March 25, an application fee of $505 must be paid by institutional providers that are enrolling in Medicare for the first time, revalidating their enrollment, or adding a new practice location, the Centers for Medicare and Medicaid Services (CMS) has announced.

CMS has defined "institutional provider" to mean "any provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-855B (excluding physicians and nonphysician practitioner organizations), or CMS-855S form, or using the Internet-based Provider Enrollment, Chain, and Ownership System (PECOS) enrollment application." The term also includes enrolling and revalidating Medicaid and Children's Health Insurance Program providers.

The $505 fee is for this calendar year, CMS announced March 23. It will be updated in future years for inflation. The 2012 fee is to be published in the *Federal Register.*

The fee application requirements as well as provisions for obtaining a hardship exception or waiver were included by CMS in a Feb. 2 final rule that tightened up on the screening of program providers, including independent labs. The tighter oversight was required by Section 6401(a) of the Patient Protection and Affordable Care Act or PPACA (*NIR 11, 3/Feb. 10, p. 1*). Fees collected are to be used to cover the costs of CMS's fraud and abuse efforts, including the beefed-up screening procedures.

According to the final rule's regulatory impact statement, costs in 2011 for Medicare providers and suppliers (a total of 91,406 entities) are projected to be $46 million, while costs for Medicaid providers (18,851 entities) are pegged at $9.5 million.

How Affected Providers Must Pay

Payment of the enrollment application fee must be made electronically via *Pay.gov* by electronic check, credit card, or debit card. *Pay.gov* is operated by the Treasury Department. Paper checks will not be accepted. Payment cannot be made by mail or telephone, CMS emphasized.

"Users need not worry about submitting the incorrect amount; CMS has pre-populated the field for the correct payment amount for the specific calendar year. Users may not make multiple payments in one transaction and must make separate payments for each application."

Once on *Pay.gov*, type "CMS" in the search box under "Find Public Forms" and click the "GO" button. Click on the "CMS Medicare Application Fee" link. Providers are "strongly encouraged," CMS noted, to submit their receipt of payment with their enrollment application.

Medicare *Claims Advisory*

CMS Announces New Waived Tests, Billing Codes

Contractors are not required to search their files to either retract payment or retroactively pay claims; however, they should adjust claims if they are brought to their attention, CMS said.

The April 1, 2011, update to the list of tests waived under the Clinical Laboratory Improvement Amendments (CLIA) includes 16 more devices, the latest approved by the Food and Drug Administration (FDA) for this category. New waived tests are approved on a flow basis and are valid as soon as approved.

In announcing the update, the Centers for Medicare and Medicaid Services (CMS) cautioned that when billing for the tests below, you must use the QW modifier so your local Medicare contractor can recognize the code as waived under CLIA. Prior to approval for payment, your claims are checked to see whether you are certified for waived testing.

CPT CODE	EFFECTIVE DATE	DESCRIPTION
87880QW	Oct. 4, 2010	BTNX Inc. Strep A Rapid Test
86308QW	Oct. 4, 2010	Consult Diagnostics Mononucleosis Cassette {Whole Blood}
82274QW, G0328QW	Oct. 4, 2010	BTNX Inc. Rapid Response Fecal Immunochemical Test (FIT)
82274QW, G0328QW	Oct. 4, 2010	American IVD Biotechnology Services Inc. FOB/CRC Advanced+
G0434QW	Jan. 1, 2011	Amedica Biotech AmediCheck Instant Test Cup
G0434QW	Jan. 1, 2011	Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
G0434QW	Jan. 1, 2011	Insight Medical Multi-Drug of Abuse Urine Test
G0434QW	Jan. 1, 2011	Jant Pharmacal Corp. Accutest Drug Test Cup
G0434QW	Jan. 1, 2011	Micro Distributing II, Ltd Multi-Drug of Abuse Urine Test
G0434QW	Jan. 1, 2011	Millenium Laboratories Multi-Drug of Abuse Urine Test
G0434QW	Jan. 1, 2011	NexScreen LLC, NexScreen Cup
G0434QW	Jan. 1, 2011	On the Spot Drug Testing Multi-Drug of Abuse Urine Test
G0434QW	Jan. 1, 2011	Physicians' Test Multi-Drug of Abuse Urine Test
G0434QW	Jan. 1, 2011	Total Diagnostic Solutions Multi-Drug of Abuse Urine Test
G0434QW	Jan. 1, 2011	UCP Biosciences Inc. Drug Screening Test Cards
G0434QW	Jan. 1, 2011	UCP Biosciences Inc. Multiple Drug Screen Cups

For 2011, the code G0430 has been deleted and G0434 is its replacement. Therefore, the code G0434QW replaces G0430QW in the list of CLIA-waived devices for drug screening. In addition, the descriptor for code G0431 was changed to apply to screening for multiple drug classes by high-complexity test method, per patient encounter. As a result, 18 waived test systems have their code changed from G0431QW to G0434QW (see those affected, plus the current complete list of CLIA waived devices at *www.cms.gov/Transmittals/downloads/R2155CP.pdf*).

National Medical Laboratory Professionals Week

Laboratory Professionals Get Results

April 24-30, 2011

This marks the 36th annual salute to the individuals who practice clinical laboratory science in the United States. Today, there are more than 300,000 practitioners. The week-long celebration is held each year to raise local and national awareness of the vital role they play in disease diagnosis and prevention and in ensuring quality care and patient safety.

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American Society for Clinical Pathology	American Society for Microbiology
American Association for Clinical Chemistry	Association of Public Health Laboratories
American Association of Blood Banks	Clinical Laboratory Management Association
American Medical Technologists	College of American Pathologists
American Society of Cytopathology	National Society for Histotechnology
American Society for Cytotechnology	

Activity guides, posters, and promotional materials are available at *www.ascls.org*.
Also, check the Web pages of the sponsoring organizations for additional information.

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