G2 INTELLIGENCE

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## Supreme Court Takes Up Challenge to Medicaid Pay Rates

*For clinical laboratories and pathologists, the case is significant because it affects whether they and other providers have the right to sue in federal court to stop cash-strapped states from slashing their Medicaid reimbursement.*

The U.S. Supreme Court opened its new term Oct. 3 by hearing oral arguments in a case that has major implications for all Medicaid beneficiaries and health care providers in the federal-state funded program for low-income individuals and families.

At issue is the broad question of whether courts can stop states from cutting Medicaid payments that allegedly violate federal law, which requires that Medicaid rates be set high enough to get health care providers to participate and serve low-income patients. Before a state can cut the rates, it must study the potential consequences and get federal approval.

In the case before the high court, doctors, hospitals, and pharmacists in the California Medicaid program, known as Medi-Cal, sued to stop reimbursement cuts of up to 10 percent imposed by the state legislature in 2008 and 2009 to help solve the state's budget crisis but without approval from federal authorities.

The plaintiffs argued that if the cutbacks took effect, the state would not provide the level of care required under Medicaid. They won an

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## House Panel Gets an Earful on Extending Pathology 'Grandfather' Protection

A host of health care provider groups registered strong support for continuance of the pathology "grandfather" protection in testimony and comments presented to the House Ways and Means health subcommittee at its Sept. 21 hearing on expiring Medicare provider payment policies.

The protection expires Dec. 31 and the Centers for Medicare and Medicaid Services (CMS) has announced plans to eliminate it (*NIR 11, 13/July 14, p. 1*).

The grandfather provision allows certain independent clinical laboratories to bill Medicare separately for the technical component (TC) of pathology services to hospital inpatients and outpatients. It applies to hospital-lab arrangements in effect since July 22, 1999, the date when CMS first proposed to end this billing practice. The agency has since repeatedly sought to end the protection, contending that the TC is reimbursed via the hospital's prospective payment and the lab should seek payment from the hospital, not Part B. But since 2001, Congress has stepped in repeatedly to block the change with a series of extensions.

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**House Panel Gets an Earful,** *from p. 1*

At the House hearing, top officials of the American Hospital Association (AHA) and the American Medical Association endorsed extension of the grandfather provision. In its comments, the College of American Pathologists (CAP) said it "strongly supports a permanent extension of the 'grandfather' provision contained in bipartisan legislation, H.R. 2461, the Physician Pathology Services Continuity Act of 2011, introduced by Reps. Geoff Davis (R-Ky.) and Mike Ross (D-Ark.). Unless Congress acts this year, the 'grandfather' will expire, adversely impacting hospitals, independent laboratories, and the patients they serve."

*The grandfather protection applies to the hospital, not the lab, CMS has ruled. Hospitals may switch labs without forfeiting the protection; however, independent labs cannot switch hospitals and still be protected. The technical component of pathology services includes anatomic services, cytopathology, and surgical pathology.*

If the protection expires at the end of this year, CAP warned, this will pose a hardship for both independent labs and hospitals, requiring them to install new complex billing systems and administrative operations. The burden will fall heaviest on small and rural hospitals, noted AHA President and CEO Richard Umbdenstock in his testimony. These hospitals don't typically have the volume to support in-house pathology testing services, necessitating reliance on independent laboratories. "The hospitals would also have to pay the independent laboratories directly for their services, despite the fact that Medicare DRG payments do not include these costs," he added.

In its comments, the American Clinical Laboratory Association (ACLA) backed the pending legislation to make the protection permanent. "Since the beginning of the Medicare program, independent labs have been allowed to bill Medicare directly for both the TC and the professional component (PC) of physician pathology services provided to hospital inpatients and outpatients. These services are vital to a successful surgical service in a hospital and include pathological examination of tissue removed during surgery, such as tumors, inflammatory tissue, and biopsies, to determine whether and what disease is present."

Many hospitals have outsourced the pathology work over the years for various reasons, ACLA noted. "Some hospitals lack the surgical volume that would support an in-house pathology practice. Other hospitals choose to send specimens out because the independent lab, by taking in referrals from multiple sites, can provide more sophisticated diagnostic techniques for a wider range of cases than a single hospital can afford for its patients alone.

"A permanent solution, however, is necessary to ensure uninterrupted access for Medicare beneficiaries to these critical health care services," ACLA said in urging passage of H.R. 2461.

The protection is part of an extenders package with an estimated total cost of $2 billion annually, and Congress must scrutinize all of the spending, said subcommittee chairman Wally Herger (R-Calif.). "History shows that Congress has continued to blindly extend these policies year in and year out, which raises the question: Given that these additional payments do not appear to be 'temporary,' isn't the true cost of the extenders package actually $25 billion, when measured over Congress' standard 10-year budget window?"

CMS estimates that the savings achieved by ending the protection would be approximately $80 million for 2012. G2

  

# Joint Committee Urged to Purge Pathology From Stark Physician Self-Referral Exceptions

The Alliance for Integrity in Medicare (AIM) has asked the congressional Joint Select Committee on Deficit Reduction to tighten the Stark physician self-referral exceptions for in-office ancillary services and physician services.

AIM submitted draft legislative language that would exclude anatomic pathology, radiation therapy and supplies, advanced diagnostic imaging, and physical therapy from these exceptions.

**Signatories to AIM Letter on Stark In-Office Service Exception**

American Clinical Laboratory Association
American College of Radiology
American Physical Therapy Association
American Society for Clinical Pathology
American Society for Radiation Oncology
Association for Quality Imaging
College of American Pathologists
Radiology Business Management Association

In a Sept. 20 letter to joint committee co-chairs Sen. Patty Murray (D-Wash.) and Rep. Jeb Hensarling (R-Texas), AIM said "misapplication of the exceptions results in increased spending, unnecessary overutilization of services, and could lead to compromised patient choice and care.

"Closing the self-referral loophole for the services noted above . . . will create savings for the Medicare program through a reduction in inappropriate utilization of diagnostic tests, and in some cases, follow-up treatments." However, the letter did not specify the amount of savings anticipated.

In other provisions, AIM's draft legislative language would:

- ❏ Create a new exception to permit multispecialty group practices, as defined in the law, to bill and be paid for excluded services without violating the self-referral law.
- ❏ Change regulations governing the technical component (TC) of physician pathology services. They are currently exempt from physician supervision requirements. AIM said this "virtually exempts them from Medicare's anti-markup requirements." The proposed change would make "TC services subject to the same supervision requirements as the professional component of these services."

AIM earlier this year argued for removal of anatomic pathology, advanced diagnostic imaging, physical therapy, and radiation therapy from the in-office ancillary services exception in a letter to leaders of the House Ways and Means Committee in advance of the May 12 hearing on alternatives to the current sustainable growth rate (SGR) system for physician fee updates (*NIR 11, 10/May 26, p. 3*). AIM said this could help offset the costs of repealing the SGR.

### Arguments for and Against

Medical specialty practices have defended their use of the in-office ancillary services exception, saying it enables them to make rapid diagnoses and initiate treatment during a patient's office visit, improves care coordination, and encourages patients to comply with diagnostic and treatment recommendations.

But AIM argues that these arrangements flout the congressional rationale for establishing the in-office exception, namely, "to allow physicians to offer services integral to a single visit to the physician office." A common feature of anatomic pathology, advanced diagnostic imaging, physical therapy, and radiation therapy is "that each requires time to complete outside of an office visit, specialized training, and independent professional judgment to perform."

  

# Obama Backs Stronger Independent Payment Advisory Board

Despite strong and widespread opposition to its very existence, President Obama wants to not only keep the Independent Payment Advisory Board (IPAB) alive but also strengthen its mandate to help curb Medicare spending growth.

The wider role for the board is part of a $3.2 trillion, 10-year package of savings proposals (including $248 billion from Medicare) that the White House has submitted to the Joint Select Committee on Deficit Reduction, which is to deliver its plan for up to $1.5 trillion in federal budget savings by Nov. 23.

Under terms of the health care reform law, beginning in 2014, in any year in which the Medicare per capita growth rate exceeds a target growth rate, the board must recommend program spending reductions that would become law unless Congress passes an alternative.

## The Board at a Glance

**Composition:** Fifteen members appointed by the president, subject to Senate confirmation. Nonvoting ex officio members: the secretary of Health and Human Services, the administrator of the Centers for Medicare and Medicaid Services, and the administrator of the Health Resources and Services Administration.

**Terms of Office:** First members appointed will be divided into three staggered classes in order to ensure that their terms do not expire simultaneously. A member may not serve more than two full consecutive terms.

**Function:** Recommend proposals to Congress to curb Medicare spending growth, including reductions when a target growth rate is exceeded that would become law unless lawmakers come up with an alternative.

**Limits:** By law, "proposals shall not include any recommendation to ration health care, raise revenues or Medicare beneficiary premiums, increase beneficiary cost sharing (including deductibles, coinsurance, and copayments), or otherwise restrict benefits or modify eligibility criteria."

**Deadlines:** The board is to be established in 2014, file its first report by July 2014, and implement its recommendations in 2015.

But the law also sets boundaries for the board. It cannot make recommendations that would ration care, increase Medicare beneficiary cost sharing, or otherwise restrict benefits or modify eligibility criteria.

The latest White House proposal for the IPAB would reduce the target growth rate from the gross domestic product per capita plus 1 percent to the GDP plus 0.5 percent and give the board "additional tools, including the ability to consider value-based benefit design and enforcement mechanisms."

Hundreds of business and provider groups, including pathology and clinical lab organizations, have called for repeal of the IPAB. Their chief criticism is that the board gives unelected officials too much power over Medicare payment rates and short-circuits the time frame for an open legislative airing of important health care policies. Also, much of Medicare spending is exempt from the board's purview until 2020 (hospital spending, for example), so the groups most affected by any cuts that have to be made are physicians, clinical laboratories, drug companies, medical device makers, Medicare Advantage plans, Part D prescription drug plans, and beneficiaries.

Earlier this year, the president's budget request for fiscal 2012 made a pitch for the IPAB, saying that in addition to its responsibilities, it would provide a "backstop" for other Medicare reforms by ensuring that the program's spending growth does not outstrip the ability to pay for it over the long run. The board also would concentrate on keeping control of the growth in beneficiary premiums.

Business and provider groups in the Coalition for Affordable Health Coverage have long expressed concerns about the board, arguing that it shifts responsibility for Medicare coverage and payment decisions historically made by Congress to an unelected body in the executive branch.

Legislation has been introduced in the House and the Senate to repeal the IPAB. In a letter earlier this year to the sponsor of the House measure, Rep. David P. Roe, M.D.,

  

(R-Tenn.), the coalition said, "While Congress must find ways to reduce Medicare costs, giving unelected and unaccountable officials the authority to unilaterally reduce Medicare reimbursement rates, without strengthening the ability of private payers to resist cost-shifting, risks doing more harm than good."

Critics of the IPAB say it has limited tools to engineer a Medicare makeover and fear the board is likely to focus on reducing provider payment rates rather than tackling new methods of payment. They also argue that the statutory time frame for debating the IPAB recommendations is too short to allow for a full congressional debate.

The controversy has drawn in more than 100 health policy experts who urged Congress not to scuttle the board, saying it will offer independent professional expertise to help lawmakers evaluate payment options. They said Congress still retains authority to approve or disapprove IPAB recommendations or enact its own version and forces lawmakers to make difficult choices they have not yet addressed.

## It's 'No Go' for Rehearing on Myriad Gene Patent Case

The U.S. Court of Appeals for the Federal Circuit has turned down petitions by both sides to again air arguments in the legal challenge to gene patents held by Myriad Genetics (Salt Lake City).

In a 2-1 decision released July 29, the court upheld patents granted to Myriad Genetics and the University of Utah Research Foundation for the BRCA1 and BRCA2 genes associated with hereditary breast and ovarian cancer (*NIR 11, 15, August, pp. 1, 4-5*). That decision overturned a lower court's ruling that the gene patents were invalid because the genes are products of nature.

*As the patent holder, Myriad has the exclusive right to perform testing on the BRCA genes, license the testing to other users, and threaten litigation against any unlicensed use. Plaintiffs say this monopoly stifles research and curtails women's access to a lifesaving test.*

The plaintiffs' request for a panel rehearing, filed by the American Civil Liberties Union (ACLU), alleged factual and legal errors in the decision on standing and patient-eligibility issues, primarily in its interpretation of "isolated DNA."

The appellate court ruled that Myriad's patents are valid because they involve DNA isolates that are "markedly different" in molecular composition than the DNA that exists in chromosomes in the body.

Myriad's petition for a rehearing sought to make the entire matter moot on the issue of whether any of the plaintiffs in the case had the standing needed to continue.

The petition from ACLU was denied on Sept. 13, that from Myriad on Sept. 16. Each side has 90 days from the denial date to petition the Supreme Court.

The plaintiffs plan to file such a petition with the high court, according to the ACLU. This could be a long shot, court watchers say, since the court's calendar is quite limited; however, the court has shown an interest in patent cases in recent months and could opt to take on the challenge to Myriad.

The biotech firm hailed its victory before the appellate court, saying the DNA isolates in dispute are "new chemical matter with important clinical utilities which can exist only as a product of human ingenuity."

The appellate decision also benefits the biotechnology, agricultural, and pharmaceuticals industries that rely on strong patent protection to develop products to better people's lives. Nearly 20 percent of human genes are patented, including genes associated with Alzheimer's disease, muscular dystrophy, colon cancer, asthma, and many other illnesses.

  

**Supreme Court Takes Up Challenge,** *from p. 1*
injunction against the cuts from two lower federal courts, prompting the state to appeal to the Supreme Court.

The case involves more than $1 billion in contested reimbursement, but the lawsuits against the state of California seek only to affirm the right of providers in the state to sue in federal court. In agreeing to hear the case, the Supreme Court said it would consider whether there is such a right of private action but not whether the state acted illegally in enacting the rate cuts.

California is joined in its appeal by the Obama administration and 31 states, while supporters of the plaintiffs include a host of hospital, physician, and other provider groups, the U.S. Chamber of Commerce, Democratic lawmakers, and former officials of the U.S. Department of Health and Human Services (HHS).

In arguments presented to the high court Oct. 3, California state officials contended that under the Medicaid Act, Congress did not give private parties the right to sue and that federal oversight of state Medicaid plans and the required approval process is sufficient to ensure state compliance with the act.

The plaintiffs' advocate countered that judicial review is needed to stop funding cuts that threaten equal access to Medicaid services, urging the high court to recognize the longstanding practice of federal courts to hear and resolve lawsuits by parties seeking to enforce federal law requirements through the supremacy clause of the U.S. Constitution. Relying solely on HHS administrative review to ensure compliance with Medicaid law is not enough, plaintiffs and supporters contend, noting that in this case California ignored the department's rejection of the rate cuts. Further, HHS review is limited to consideration of information provided by the state.

Chief Justice John G. Roberts Jr. said he agreed with the state's position that Congress did not give private parties the right to sue under the Medicaid Act. Justices Ruth Bader Ginsburg and Elena Kagan weighed in for the plaintiffs, noting that California officials sought to slash Medi-Cal reimbursement even before the move had been cleared by federal Medicaid officials. But several justices appeared to lean to the position that judges could stop proposed state cuts until federal Medicaid officials could view them.

Meantime, in a bid to protect Medi-Cal from budget cuts, the Alliance for Patient Care, a coalition of patient and provider groups, including the California Clinical Laboratory Association (CCLA), has met with top officials of the Centers for Medicare and Medicaid Services (CMS) and congressional staff. CMS administrator Donald Berwick, M.D., said the agency will do a complete view of California's request for payment reductions, patient copayments, and patient visit caps. But he noted that CMS is under pressure from California and other states on the need to find savings in Medicaid.

Before acting on the state's request, CMS has asked for additional information from the state. The state is pushing for an early response so it can implement cuts as soon as possible, noted CCLA. "The statute calling for the 10 percent payment reduction allows the state to make that cut retroactive to June 1. The Department of Health Care Services has flexibility in how it will implement the cuts, if approval from CMS is granted. CMS has authority to approve the request, deny it, or approve it with conditions." Labs would be hard hit if the cuts go through, CCLA said. Medi-Cal payments are capped at 80 percent of the Medicare lab fee schedule rates but can be lower.

  

# Time Running Out to Switch to Version 5010, Prevent Disruption to Your Cash Flow

There are fewer than 90 days to go before all Medicare fee-for-service providers must use Version 5010 for electronic transmission of claims. "If you are not ready, your claims will not be paid," says the Centers for Medicare and Medicaid Services (CMS). "It is essential to begin the transition now to prevent a disruption to your claims processing and cash flow."

*For the latest CMS guidance and resources for completing the switch to Version 5010, go to* http://www.CMS.gov/Versions5010andD0. *Note too that CMS offers free billing software that is Version 5010 compliant. Contact your contractor to obtain it.*

Full implementation of the Version 5010 standard under the Health Insurance Portability and Accountability Act (HIPAA) is set for Sunday, Jan. 1, 2012. In a series of alerts, CMS has urged providers and suppliers to contact their local Medicare Administrative Contractor (MAC) and test now to avoid possible delays in payment due to the end-of-year rush in 5010 testing. Testing now will allow time for any needed corrections prior to Jan. 1, the date when only 5010 transactions will be accepted.

The transition to 5010 affects more than just Medicare or Medicaid payments. The new standards regulate and standardize the electronic transmission of specific health care transactions such as eligibility, claims, referrals, and remittances for all health plans, clearinghouses and billing services, and providers covered by HIPAA, CMS noted.

Version 5010 accommodates the ICD-10 diagnosis code sets, which Medicare will require starting in 2013. Currently, ICD-9 diagnosis codes are required on Medicare claims in order for them to be processed and paid. Version 5010 expands the number of diagnosis codes that can be reported from eight to 12.

CMS says that its second national Version 5010 testing event showed promising results. During that week in August, 1,252 Medicare fee-for-service trading partners conducted testing with the MACs. They submitted a total of 67,782 test files and no significant error scenarios were reported. Additionally, 74 trading partners responded to a follow-up survey that found, among other things, that 54 percent were exchanging test files with payers other than Medicare.

# Annual Adjustment to Dollar Amounts in Medicare Appeals

The Centers for Medicare and Medicaid Services has published the calendar-year 2012 amount in controversy (AIC) thresholds for a hearing before an administrative law judge (ALJ) and judicial review under the Medicare appeals process.

*When the annual adjustment required by the MMA was first applied in 2005, the AIC threshold for an ALJ hearing was $100, while that for judicial review was $1,050.*

The thresholds below are effective for requests for the above on or after Jan. 1, 2012, the agency said in a notice in the Sept. 23 *Federal Register*:

- ❑ $130 for an ALJ hearing (no change from the amount in effect since 2010); and
- ❑ $1,350 for judicial review (up from $1,300 in 2011 and $1,260 in 2010).

The updated amounts are based on the 34.51 percent increase in the medical care component of the consumer price index from July 2003 to July 2011.

For 2012, this increase changes the ALJ hearing amount to $134.51, but in accord with the Medicare Modernization Act (MMA), this is rounded to the nearest multiple of $10, or $130. For judicial review, the updated amount is $1,345.11, rounded to the nearest multiple of $10, or $1,350.

  

# Medicare Goes All Electronic on Claims Payment

Existing regulations require that at the time of enrollment, enrollment change request, or revalidation, providers and suppliers that expect to receive payment from Medicare for covered services must also agree to receive Medicare payments through electronic funds transfer (EFT).

Now, the law (Section 1104 of the Patient Protection and Affordable Care Act of 2010) mandates federal payments to providers and suppliers *only by electronic means*.

As part of enrollment revalidation efforts, the Centers for Medicare and Medicaid Services said all suppliers and providers who are not currently receiving EFT payments will be identified and required to submit the CMS 588 EFT form with the Provider Enrollment Revalidation application. CMS has staggered the time frame for revalidations of clinical laboratories, pathologists, and others who enrolled in the program prior to March 25, 2011, and are subject to new risk-screening criteria. The agency has advised affected providers to wait until they hear from their Medicare Administrative Contractor (MAC). "Do not submit your revalidation until notified to do so," said CMS. "You will receive a notice to revalidate between now and March 2013."







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