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Supreme Court Tempers Stance on Lab Test Testimony

The high court has previously ruled that forensic analysts who perform testing used as evidence in a criminal trial must be available for cross-examination. Prosecutors could not rely solely on test reports or surrogate testimony.

In a 5-4 decision issued June 18, the U.S. Supreme Court upheld a rape conviction despite the defendant's objection that his constitutional right to confront prosecution witnesses was violated because he could not cross-examine the lab test analyst who produced his DNA profile.

In the case, *Williams v. Illinois*, his profile was produced by Cellmark, a Maryland lab, from a semen sample taken from the victim. Later it was computer-matched to a DNA profile produced by the Illinois State Police lab from a blood sample taken from the defendant after his arrest on other charges.

At Williams's bench trial, where he was convicted and sentenced to life in prison, a forensic expert from the state lab testified as to how the match was made, though the expert took no part in the testing done by Cellmark and its work was not introduced as evidence.

The court majority was split into two factions, with four of the justices—Samuel Alito, Anthony Kennedy, Stephen Breyer, and Chief Justice John Roberts—giving prosecutors more leeway in using lab test reports without having to produce the testing analysts for cross-examination.

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Claims Alert: Version 5010 Mandatory on Medicare Claims as of July 1

In an alert to providers, the Centers for Medicare and Medicaid Services (CMS) reiterated that effective July 1, 2012, Medicare fee-for-service (FFS) will accept only electronic claims in ASC X12 Version 5010 (Version 5010) or NCPDP Telecom D.0 (NCPDP D.0).

This ends the grace period which CMS, using its enforcement discretion, granted to enable providers covered by the Health Insurance Portability and Accountability Act to make the transition. Use of Version 5010 was effective Jan. 1, 2012.

This change, CMS said, affects providers that are still conducting one or more of the Version 4010 transactions electronically, such as submitting a claim or checking claim status, or that rely on a software vendor, billing service, or clearinghouse to do this on their behalf.

Claims (837 I and P): All claims received after normal close of business cutoff times on June 29, 2012, must be sent as ASC X12 version 5010 or NCPDP D.0. Any Medicare FFS claims received in Version 4010 format after that time will be rejected back to the submitter.

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Supreme Court Tempers Stance on Lab Test Testimony, *from p. 1*

They held that the expert testimony as to the DNA match was sufficient. "This form of testimony does not violate the Sixth Amendment's confrontation clause because that provision has no application to out-of-court statements that are not offered to prove the truth of the matter asserted. When an expert testifies for the prosecution in a criminal case, the defendant has the opportunity to cross-examine the expert about any statements that are offered for their truth."

They further noted that the defense could have subpoenaed the Cellmark test analysts to testify if the reliability of their work was in doubt.

Concurring with the above justices but writing for himself, Justice Clarence Thomas said the expert's explanation of the DNA match was not hearsay that is barred by the confrontation clause. The Cellmark report "could not be considered testimonial and so does not fall under the cross-examination requirement. It lacks the solemnity of an affidavit or deposition, for it is neither a sworn nor a certified declaration of fact."

In two previous 5-4 decisions, one involving testing for cocaine (*Melendez-Diaz v. Massachusetts*) and the other involving blood alcohol testing (*Bullcoming v. New Mexico*), a majority of the high court held that the lab test analyst who performed the testing introduced as evidence must be available for cross-examination by the defendant under the confrontation clause.

Dissenting Views

The four dissenting justices in *Williams v. Illinois* said, "Under our confrontation clause precedents, this is an open-and-shut case." It was the state lab expert, rather than any Cellmark employee, "who informed the trier of fact that the testing of the victim's vaginal swabs had produced a male DNA profile implicating Williams." The expert thus "became just like the surrogate witness in *Bullcoming*—a person knowing nothing about 'the particular test and testing process,' but vouching for them regardless."

"The court now has left significant confusion" over when lab analysts must testify, the dissenters noted, concluding "Until a majority of this court reverses or confines those decisions (Melendez-Diaz and Bullcoming), [we] would understand them as continuing to govern, in every particular, the admission of forensic evidence."

New Physician Fee Fix Proposal Floated in Congress

A draft legislative proposal for a transition to a new Medicare physician payment system has been prepared by two members of the 21-member House GOP Doctors Caucus and is being circulated for consideration and feedback.

The proposal advocates annual increases to providers based on the Medicare Economic Index over five years while Congress works to reform the physician payment system, now based on the sustainable growth rate (SGR) formula which has triggered ever-deeper physician fee cuts that Congress has repeatedly blocked over the last decade. The pay cut looming for 2013 is as high as an estimated 30.9 percent, according to preliminary projections by the Centers for Medicare and Medicaid Services.

Fixing a 'Broken' System

In a Dear Colleague letter, Republican Reps. Tom Price (Ga.) and Charles W. Boustany Jr. (La.) said, "The current Medicare physician payment formula produces unrealistic savings on paper, requires Congress' consistent short-term intervention, and creates needless delays and hassles for seniors."

Their proposal would:

- ❑ Institute a five-year period of stability for Medicare providers with annual increases tied to the Medicare Economic Index to keep up with the rising cost of medical practice;
- ❑ Create a timeline for legislation to reform the physician payment model and require its consideration in the House and Senate;
- ❑ Limit malpractice lawsuits against physicians following best practice guidelines established by the Department of Health and Human Services.
- ❑ Allow Medicare beneficiaries to contract with providers without penalty; and
- ❑ Establish safe harbors to allow nonsalaried physicians to receive payments for helping to reduce costs and improve quality within acute-care hospitals.

No Cost Offset

The proposal does not specify offsets to the cost of replacing the current system, currently estimated at $300 billion over 10 years. "While budget experts have identified a wide variety of offsets to fund reform, we have chosen not to include one for the purposes of this draft," the congressmen note. The cost, however, has been a major obstacle to permanent Medicare physician payment reform, leading Congress to opt for short-term SGR fixes instead.

"It is our intention that this proposal serves as an invitation for Congress and industry stakeholders to work together to enact true reform of the Medicare physician payment system," the Dear Colleague letter said.

Also Up for Consideration

The Price-Boustany draft is the second proposal being floated in the House in the past month. A bipartisan bill (H.R. 5707), introduced in the House May 9 by Reps. Allyson Y. Schwartz (D-Pa.) and Joseph J. Heck (R-Nev.), would repeal the SGR system (*NIR 12, 10/May 24, p. 2*).

In 2013, the bill would keep physician fees at their 2012 levels. Beginning in 2014, fees would get an annual 0.5 percent update for four years (2.5 percent for primary care).

Beginning in 2018, physicians in CMS-approved models would receive stable reimbursements (according to their primary care/nonprimary care payment system), with an opportunity to earn more for quality and cost savings.

In 2019, annual updates (to both primary and nonprimary care services) would be -2 percent, -3 percent in 2020, -4 percent in 2021, and -5 percent in 2022.

But H.R. 5707 would pay for SGR repeal by using unspent funds from the wars in Afghanistan and Iraq, an idea that has gained little traction inside Congress.

Policy Change Imminent for Pathology Grandfather Protection: *A Quick Guide to Its Impact on Hospital-Lab Arrangements*

As of July 1, certain independent clinical laboratories will lose the Medicare fee-for-service billing and payment protection they have enjoyed for more than a decade.

This protection is the grandfather provision that allows these labs to bill and be paid by Medicare for the technical component (TC) of pathology services to hospital inpatients and outpatients. It applies to hospital-lab arrangements in effect as of July 22, 1999, the date when the Medicare program first sought to end such billings. The hospital is covered and can switch labs but not vice versa.

The loss of the grandfather protection will have an impact far wider than previously thought on hospital-lab arrangements, say industry sources, affecting not just hundreds of small and rural hospitals that outsource pathology work but also large hospital and health systems.

It will require labs and hospitals with these arrangements to institute new billing and payment systems and other administrative changes to achieve compliance with the federal anti-kickback law and the federal Stark physician self-referral law and their respective regulations.

Major Policy Shift

As of July 1, the labs previously protected will have to seek reimbursement from the hospital for TC services for inpatients and outpatients. The Centers for Medicare and Medicaid Services (CMS) has long sought this policy change, arguing that the TC is already reimbursed under the hospital's prospective payment systems and Part B should not duplicate this payment. Pathology and lab organizations have long sought to preserve the protection, persuading Congress to block CMS repeatedly.

But this year CMS prevailed. Congress first extended the protection (which expired Dec. 31, 2011) through February, then granted a four-month transition before terminating the protection at the end of June (Middle Class Tax Relief and Jobs Creation Act of 2012, signed Feb. 22). Bills introduced in the House to extend the protection (H.R. 2461 and H.R. 3859) have languished in committee.

In letting the protection lapse, Congress agreed that it allowed duplicate payment and noted that CMS did not even know how many grandfathered hospitals there are.

How will previously protected labs get paid for the pathology TC?

For dates of service on and after July 1, 2012, the labs must bill the hospital for the TC furnished to inpatients and outpatients. They will have to negotiate with the hospital for payment for pathology TC services and typically this will be below what Medicare would have paid them directly. Key points for labs to keep in mind:

- For inpatient services, the hospital will get no additional payment because the TC is considered part of the inpatient prospective payment system based on diagnosis-related groups (DRGs).
- Under the hospital's outpatient prospective payment system, the hospital will bill for the TC and be paid based on ambulatory payment classifications (APCs). APCs are adjusted by the hospital wage index and other factors and are subject

to a 20 percent copayment. The APC rate varies by state and region, but in general it is estimated that hospitals receive 55 percent to 60 percent of the Medicare physician fee schedule amount for outpatient services.

Must the lab bill the hospital for the TC?

Yes. If it does not, the hospital is getting something of value at no charge, and this would likely be considered "remuneration" under the Medicare anti-kickback law, that is, giving a service to a referrer for no cost or below market value. It could also create a compensation arrangement under the Stark physician self-referral law.

The rules for clinical laboratory services remain unchanged. The lab must bill the hospital for Medicare inpatient work but can bill Medicare directly for outpatient services covered under the Part B lab fee schedule. Labs taking part in Medicare's demonstration project for highly complex tests can bill Part B directly for those tests.

Because critical-access hospitals (CAHs) are paid not on a DRG basis but on a cost basis, the requirement to bill the hospital does not apply. However, legal experts recommend that labs negotiate TC payment with CAHs and let the hospitals collect directly from Medicare. This will help labs avoid having to prove in case of scrutiny by a Medicare Recovery Audit Contractor (RAC) that they were allowed to bill Medicare directly, especially since the grandfather protection language in the statute does not mention CAHs specifically.

Must the hospital pay the lab for the TC?

Yes, otherwise both parties risk violation of the Medicare anti-kickback statute as well as state fraud and abuse laws.

How does the policy change interact with the 14-day rule?

This rule requires that for biopsy specimens collected in the hospital, the date of service (DOS) depends on when the test is ordered. If ordered 14 days or more after the patient is discharged, the DOS is the date the test is performed. Since the patient is not a hospital patient on that DOS, hospital bundling rules do not apply and the service can be billed to Medicare. If the test is ordered 13 days or less after the patient is discharged, the DOS is the date the specimen is collected. Since the patient is a hospital patient on that DOS, hospital bundling rules do apply and the service must be billed to the hospital.

How should the pathology TC payment be determined?

There are several ways to set the payment, ranging from a fixed monthly payment (allowing for periodic adjustments for fluctuations in volume and case mix) to cost-plus pricing to a fixed fee schedule payment based on current procedural terminology code. The bottom-line standard is that payment in the lab-hospital arrangement should set a reasonable amount that reflects fair market value.

But in determining the payment, TC services should never be priced below cost, regardless of whether the lab is factoring in its marginal or fully loaded costs. Doing so is generally considered an inducement or an illegal kickback implicating both the lab offering it and the hospital receiving it.

The College of American Pathologists (CAP) notes that labs, when determining the cost of providing the TC, may want to consider not only the operational costs but also overhead and capital requirements. The purpose, CAP says, is to enable the lab to see at what point it needs to walk away from negotiations and avoid compliance risks for both parties. "A practice that knows its cost will know where it can be flexible and where it must be rigid in the negotiation process."

Why should labs seek an attestation statement from each hospital they serve?

The grandfather exception applies to "covered" hospitals and there is no master

registry of which hospitals are covered and which are not. Thus, labs are advised to get an attestation statement from each hospital that the hospital was, in fact, covered by the grandfather protection prior to the June 30, 2012, expiration. The statement is important if a lab were to undergo a RAC audit since the lab may be required to prove that the direct billings to Medicare prior to July 1, 2012, were appropriate.

How will the change in federal policy affect pathology TC payment in state Medicaid programs and among private payers?

The grandfather protection was only available to beneficiaries covered by traditional fee-for-service Medicare. Medicare managed care plans, state Medicaid programs, and private payers were never required to recognize it, though some did. State Medicaid programs must be checked on a case-by-case basis because each sets its own rules. Private payers have handled the issue in different ways with great variation by region.

Since Medicare policy generally leads the way and others follow suit, some industry sources think it likely that state Medicaid programs and private payers will align their policies on the issue with Medicare's new position.

Snapshot of National Health Care Spending

Health care spending in the United States is expected to grow at an annual rate of 5.7 percent from 2011 to 2021, 0.9 percentage points faster than the projected growth in the gross domestic product (GDP), according to a recent report from the Office of the Actuary at the Centers for Medicare and Medicaid Services.

Health care spending as a share of GDP is expected to go from 17.9 percent in 2010, or $2.7 trillion, to 19.6 percent in 2021, or $4.8 trillion, accounting for roughly one-fifth of the economy.

The growth rate of national health care spending over the 2011-2021 period is projected to be "fairly similar with or without the health care reform law, the Patient Protection and Affordable Care Act of 2010 (PPACA)," according to the report. Expenditures without PPACA changes are estimated at $4.72 trillion over the 2011-2021 period versus $4.78 trillion with PPACA changes.

Trends Within the Broad Picture

Overall growth rate: All health care spending grew 3.9 percent in 2011, a historic low, reflecting the recession and slow economic recovery. The slow pace is expected to continue until 2014 when it will jump to 7.4 percent as PPACA reforms are implemented (without the law the increase would be 5.3 percent). From 2015 to 2021 the spending growth rate will average 6.2 percent annually.

Government's share: The share of health care spending by all levels of government is projected to be nearly 50 percent by 2021, up from 46 percent in 2011, with federal spending accounting for about two-thirds of the total share. "Rising government spending in this area is expected to be driven by faster growth in Medicare enrollment, expanded Medicaid coverage, and the introduction of premium and cost-sharing subsidies," the report noted.

Spending on physician and clinical services: This is estimated to have grown slightly faster in 2011, at a rate of 2.7 percent (totaling $529.2 billion), compared to historically slow growth of 2.5 percent in 2010. Overall, however, the growth rate in this sector remains relatively slow due to the economic downturn as consumers and employers cut back on services they use and offer. In 2012 it is projected at 3.8

percent, slowing to only 0.9 percent in 2013 under current law, primarily because of the 30.9 percent reduction in physician payment rates under Medicare's sustainable growth rate (SGR) update formula. Under an alternative Medicare projection scenario in which physician payments are assumed to grow 1 percent, physician and clinical spending growth is projected to be 5 percent in 2013.

After a spike in 2014, when major coverage provisions of PPACA take effect (up 8.5 percent versus 5.2 percent without the changes), spending in this sector is projected to grow 6.2 percent per year on average over the 2015-2021 period, the report said, "as a result of increased demand from the aging population, obesity-related health conditions, and expanded insurance coverage under reform. As more baby boomers enter Medicare, accelerations in the program's spending growth are expected to contribute to this trend."

Medicare spending: Following a projected increase of 5.9 percent in 2012, Medicare spending growth under current law is estimated to slow to 1.3 percent in 2013, mainly as a result of two factors. The first is the sequestration requirement in the Budget Control Act that Medicare payments across all types of service be reduced by 2 percent from Feb. 1, 2013, through Jan. 31, 2022. The second factor is an estimated 30.9 percent SGR cut in physician payment rates required under current law. Under an alternative scenario in which physician payment rates do not follow current law but instead receive a 1 percent increase, Medicare spending is projected to grow 5 percent in 2013.

After growing 6.1 percent in 2014, Medicare spending is expected to average growth of 6.8 percent per year from 2015 through 2021. This rate is the net result of fast enrollment growth as more baby boomers become eligible for Medicare, provisions of PPACA that call for slower growth in fee-for-service provider payment updates, lower payments to private plans, and the 2 percent sequestration reduction.

Medicaid and private insurance spending: Beginning in 2014 an estimated 30 million uninsured Americans are expected to gain coverage from PPACA expansions of Medicaid and creation of new health insurance exchanges. Spending growth in 2014 for both Medicaid and private insurance will grow 18 percent and 7.9 percent, respectively, largely because of higher enrollment leading to increased use of services. Spending growth will accelerate more substantially in some health care sectors than in others. The newly insured are expected to be younger and healthier and to devote a higher share of their medical spending to physician services and prescription drugs.

Premium hikes: Consumers will pay more for coverage as rising costs outpace economic growth. Between 2014 and 2021, household spending on insurance premiums is expected to increase 6.8 percent on average each year.

Caveats

The actuary's report comes with these cautionary notes: "These projections remain subject to substantial uncertainty, given the variable nature of future economic trends and a lack of historical experience with many forthcoming health system reforms. The pending Supreme Court decisions regarding the health care reform law contribute an additional amount of uncertainty. The supply-side effects of the law, such as changes in providers' behavior in reaction to an influx of newly insured patients, also remain highly speculative and are not included in these estimates."

The report, *National Health Expenditure Projections: Modest Annual Growth Until Coverage Expands And Economic Growth Accelerates*, is scheduled to appear in the July issue of *Health Affairs.*

Claims Alert: Version 5010 Mandatory, *from p. 1*

The message you receive if a claim is rejected will depend on your Medicare contractor. A detailed list of 4010 rejection error messages may be found on the Medicare Fee-For-Service 5010 and D.0 Technical Documentation page.

Claim Status (276/277): The last claim status inquiry will be accepted in Version 4010 at the end of the business day on June 29, 2012. Following that date, all claim status activity will be in ASC X12 Version 5010.

Remittance Advice (835): Citing issues in this area, CMS said it will be allowing an additional 30 days to complete the 835 transition. Information will be forthcoming concerning the final cutoff and cycle timing for the Remittance Advice.

As of July 1, 2012, all complaints that CMS receives regarding noncompliance with the electronic transaction standard will be subject to enforcement action, the agency warns.

Coordination of Benefits (837): CMS has directed all its contractors to begin sending all claims to the Coordination of Benefits Contractor in Version 5010 as of June 29, 2012.

For more information on ASC X12 Version 5010 and NCPDP D.0, visit *www.cms.gov.*

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Chicago
www.mdxconference.com

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Crystal Gateway Marriott
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Nov. 14

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