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Physician Payment Reform: House Panel Looks to the States

Congress is again under pressure to come up with a permanent Medicare physician fee fix. Under the current formula, fees are to be cut 29.5 percent on Jan. 1, 2012, unless lawmakers cancel it.

The House Ways and Means health subcommittee opened its consideration of Medicare physician payment reform at a May 12 hearing with a look at reimbursement models at the state level, including capitation, the patient-centered medical home, and all-inclusive care contracts.

Witnesses from health care organizations in California, Vermont, and Massachusetts briefed the panel on payment approaches they said have improved the care of patients while cutting costs.

Chairman Wally Herger (R-Calif.) said their experience could help Congress evaluate options for replacing the current sustainable growth rate (SGR) system used to update physician payments.

"The program should move away from a fee-for-service system to one in which incentives are aligned with better patient care," he noted. "It is my hope, that by starting early, we will arrive at a payment system overhaul that can pass the House."

State Approaches

Testifying for the California Association of Physician Groups (CAPG), Keith Wilson, M.D., discussed capitated arrangements. Wilson, chair

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FDA Issues New Warnings on Direct-to-Consumer Genetic Tests

In the latest crackdown on genetic test kits marketed to consumers, the Food and Drug Administration has sent warning letters to three companies stating that their products "appear to be medical devices" requiring premarket approval by the agency.

The companies and test kits cited are:

- ❏ Precision Quality DNA (Fallon, Nev.): Precision Quality DNA, targeting genes such as BRCA1 and BRCA2 to determine risk factors or likely response to a particular drug.
- ❏ Lumigenix Inc. (Palo Alto, Calif.): Comprehensive Kit, for genetic predisposition for 79 disease conditions such as breast cancer and intended to help individuals take steps to maximize their health.
- ❏ American International Biotechnology Services (Richmond, Va.): Sports X Factor Test Kit, also referred to as Sports X Factor Genetic Athletic Assessment Test, aimed at athletes and parents of young sports competitors to provide information about potential health conditions, including undiagnosed heart conditions.

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Physician Payment Reform: House Panel, *from p. 1*

of the CAPG governing board and executive committee, noted that the association includes more than 150 multispecialty medical groups and independent practice associations serving over 15 million or one-half of the state's insured population.

Under capitated arrangements, provider groups are paid up front a fixed amount for each enrolled patient for services over a span of time, most commonly per member, per month, regardless of the amount of care the patient consumes.

This has allowed groups to establish programs that have reduced unnecessary hospital admissions and emergency department visits and helped patients with chronic illnesses, said Wilson, who is regional medical director of HealthCare Partners.

Vermont's Blueprint for Health, enacted in 2006, is based on the Advanced Primary Care Practice (APCP) model, said Lisa Dulsky Watkins, M.D., associate director of the program. The aim of the blueprint is "to temper costs of caring for the chronically ill by requiring practices to develop a medical home that meets certain criteria."

Under this approach, she told the panel, all insurers pay each recognized APCP an enhanced provider payment above the existing fee-for-service payments—calculated on a per-patient, per-month basis and based on the quality of the health care they provide, she said. Insurers also must pay for services furnished by a community health team.

"Early trends are pointing towards decreases in utilization of expensive services, such as emergency room visits and inpatient admissions in the initial pilot sites," said Watkins, who works in the Department of Vermont Health Access.

Dana Gelb Safran, Sc.D, briefed the panel on the Alternative Quality Contract (AQC) developed by Blue Cross Blue Shield of Massachusetts. "To our knowledge" this is a unique "payer-led initiative that has stimulated the formation of multiple accountable care organizations within a single market," said Safran, senior vice president for the Blues.

Under this model, a provider organization that agrees to a five-year AQC must be accountable for the full continuum of patients' care, regardless of where it is provided. The Blues determine a global budget for AQC provider organizations to cover services and costs of inpatient, outpatient, pharmacy, behavioral health, and other costs and services associated with each of their insured patients. The model also provides for incentive payments for performance on nationally accepted measures of quality, outcomes, and patient care experiences.

Sentiment Strong to Scrap the SGR

There is broad acknowledgement of the shortcomings of the current Medicare physician payment system and the growing importance of moving to payment models that incentivize patient-centered, high-quality, and outcomes-oriented care, said Rep. Wally Herger (R-Calif.), chairman of the House Ways and Means health subcommittee, at the opening of the May 12 hearing.

"The Medicare fee-for-service (FFS) payment system provides an inherent financial incentive for physicians to increase the number of services they provide. The sustainable growth rate (SGR) formula has failed to constrain FFS expenditure growth, primarily because of increased utilization but also because Congress has repeatedly passed legislation to override the cuts called for by the SGR. In addition, Medicare payments to physicians are currently made without taking into account the quality of the services provided."

The SGR limits the growth in Medicare physician service spending to the rate of growth in the overall economy. The formula is cumulative in that the tally of actual and target expenditures is maintained on an ongoing basis. If expenditures are lower than the target, physician payments are increased. If expenditures are higher, payments are decreased.

As the rate of growth in expenditures on physician services has consistently exceeded the rate of growth in the economy in recent years, the SGR system has called for a cut in physician payments in each of the past 10 years. Congress has intervened to avert the cuts each year since 2003. As a result of this intervention and the cumulative nature of the SGR, the magnitude of the projected cuts to physician reimbursements and the cost to override future cuts have grown. The nonpartisan Congressional Budget Office estimates that freezing payment rates at their 2011 levels for the next 10 years would increase Medicare spending by $298 billion.

In the first year, all AQC groups met their budgets and achieved a surplus, Safran said.

Word of Caution

"If we want to move most physicians and providers to accept new payment models," Stuart Guterman, a vice president of the Commonwealth Fund, told the panel, the rewards for doing so must be "large enough both to offset any perceived loss of revenue involved in moving away from fee-for-service and the potentially substantial costs involved in reorganizing the delivery system."

The Ways and Means hearing follows on the heels of a May 5 hearing held by its Energy and Commerce counterpart where witnesses called for replacing the SGR with an array of reimbursement options, such as payments bundled per episode of care or per comprehensive care and private contracting (*NIR 11, 9/May 12, p. 1*).

New Push to Purge Pathology From Stark Exception

In reforming the Medicare physician payment system, Congress should remove anatomic pathology, advanced diagnostic imaging, physical therapy, and radiation therapy from the in-office ancillary services exception allowed under the Stark physician self-referral law.

The Alliance for Integrity in Medicare (AIM), a coalition representing providers of these services, made this recommendation 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 (*related story, p. 1*).

The "expansive use" of the in-office service exception by physicians subverts "the purpose of the self-referral law," the coalition said, potentially resulting in "overutilization of services and substantial increased costs to Medicare and its beneficiaries."

Closing this loophole could potentially yield savings that Congress could tap to help offset part of the costs of repealing the SGR before moving to a reformed Medicare physician payment system, the coalition noted.

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

Point Counterpoint

The Stark law prohibits Medicare and Medicaid referrals of beneficiaries for designated health services to entities with which they have a financial relationship (either by ownership interest or compensation arrangements or both) unless it fits within an exception.

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."

focus on: ICD-10 Coding Transition

Switch to ICD-10: Get Ready Sooner, Not Later, CMS Says

Oct. 1, 2013, may seem like a long way off, but a major coding change is required as of that date for Medicare, Medicaid, and all other entities covered under the Health Insurance Portability and Accountability Act (HIPAA).

The change involves a switch from diagnosis and procedure codes in the Internal Classification of Diseases, Version 9 (ICD-9) to ICD, Version 10:

- ICD-10-CM (diagnoses) will apply to claims from all providers in all settings.
- ICD-10-PCS (procedures) will apply to claims for inpatient hospital services only (but not on physician claims even for inpatient visits).

No ICD-10 code sets will be accepted prior to the above compliance date; however, after that date, claims and other transactions will be rejected without ICD-10 code sets, warns the Centers for Medicare and Medicaid Services (CMS), and you will have to resubmit them with the required codes. To avoid delays and disruptions to cash flow, the agency says it is important to start now to prepare for the changeover.

CMS held a May 18 national provider teleconference to discuss the ICD-10 conversion process taking place within the agency, including a case study from the coverage and analysis group on the transition to ICD-10 diagnosis codes for the laboratory national coverage determinations (NCDs).

Lab NCD Analysis

The lab NCDs cover 23 of the most commonly ordered clinical laboratory tests and provide for uniform claims processing and payment by contractors nationwide (*see box*). Developed by a negotiated rulemaking and in place since 2003, the NCDs specify which diagnoses Medicare will accept for each of the tests.

For each lab NCD, there were two key challenges, explained Jeffrey Roche, M.D., M.P.H. First, translate the ICD-9 diagnosis codes and descriptors to their ICD-10 equivalents and update the translations to account for both ICD-9 and ICD-10 changes prior to Oct. 1, 2013. Second, prepare a preliminary version of ICD-10 translations that CMS and its contractors could use to test shared system functions well ahead of the 2013 deadline.

The ICD-10 codes differ from ICD-9 versions in that they provide greater detail, there are more of them, and they use more alpha characters. To accomplish the translations, Roche said, the coverage and analysis group used the general equivalent mappings (GEMs) developed by CMS and the Centers for Disease Control and Prevention. These are tools that function essentially as a crosswalk between ICD-9 and ICD-10 diagnosis codes.

The main task was to be sure that the mappings were numerically accurate and that the translations were consistent with the disease conditions described in ICD-9,

Lab National Coverage Determinations: Transition to ICD-10 Diagnosis Codes

- ❒ Culture, Bacterial, Urine
- ❒ HIV Testing (Prognosis including monitoring)
- ❒ HIV Testing (Diagnosis)
- ❒ Blood Counts
- ❒ Partial Thromboplastin Time
- ❒ Prothrombin Time
- ❒ Serum Iron Studies
- ❒ Collagen Crosslinks
- ❒ Blood Glucose Testing
- ❒ Glycated Hemoglobin/Glycated Protein
- ❒ Thyroid Testing
- ❒ Lipids
- ❒ Digoxin Therapeutic Drug Assay
- ❒ Alpha-fetoprotein
- ❒ Carcinoembryonic Antigen (CEA)
- ❒ Human Chorionic Gonadotropin (hCG)
- ❒ Tumor Antigen by Immunoassay CA 125
- ❒ Tumor Antigen by Immunoassay CA 15-3/CA 27.29
- ❒ Tumor Antigen by Immunoassay CA 19-9
- ❒ Prostate-Specific Antigen (PSA)
- ❒ Gamma Glutamyl Transferase (GGT)
- ❒ Hepatitis Panel
- ❒ Fecal Occult Blood

The 23 NCDs follow the same basic format:

- *Title*: Each has an official title; generic or colloquial terms for the tests covered are also given.
- *Description:* Tests addressed by the NCD.
- *HCPCS codes*: CPT and other *HCPCS* codes covered by the NCD.
- *Limitations:* Any frequency limits, as well as other limits, on Medicare coverage of the test addressed in the NCD.
- *ICD-9 codes covered:* In all but one of the 23 NCDs (Blood Counts), this section lists covered *ICD-9* codes, *i.e.*, those presumed to demonstrate medical necessity. The NCD for Blood Counts lists only the diagnoses that are not covered. Thus, any code not listed is covered.

Roche said. "Merge, de-dup, and check descriptors for consistency."

There are several GEM mapping relationships involved:

- ❑ One-to-one: One of the covered ICD-9 codes for the NCD for Alpha-fetoprotein (CPT 82105) is 121.3, Fascioliasis. This would be mapped to ICD-10 code B66.3, Fascioliasis.
- ❑ Many-to-one: There are 21 ICD-9 codes for tuberculosis of the lung in various stages, such as 011.20, TB with cavitation, unspecified. These codes are linked to one ICD-10 code, A15.0, TB of the lung.
- ❑ One-to-many: For ICD-9 code 017.30, tuberculosis of the eye, there are six linked ICD-10 codes providing greater disease specificity: A18.50, A18.51, A18.52, A18.53, A18.54, and A18.59.

Picking the appropriate matches from multiple alternative ICD-10 codes suggested by a GEM translation may sometimes require a review of the descriptors to determine the most appropriate ones for a given lab NCD, Roche said.

Code proliferation is not uncommon when moving from ICD-9 codes to ICD-10 codes, he noted. "You could start with nine codes and end up with 16 codes for the

diagnoses. While trying to avoid 'code explosion,' we have tended to include all potential ICD-10 codes suggested by the GEM translation if clinically appropriate."

The approach taken by the coverage and analysis group is presented only for illustrative purposes, Roche emphasized. It is only one part of the ICD-10 conversion process within CMS and should not be considered as finalized.

Questions and Answers on ICD-10 Conversion

In answers to questions posed during the teleconference, CMS officials said:

- ❏ The ICD-10 transition does not affect CPT and HCPCS codes.
- ❏ The ICD-10 diagnosis codes for the 23 lab NCDs will be publicly available in advance of the 2013 deadline after being tested in shared systems files with local Medicare contractors to ensure a "seamless" transition for claims for NCD tests.
- ❏ CMS is implementing a partial code freeze in response to provider objections that continuous updates and changes to the current code sets make the transition difficult. Starting Oct. 1, 2012, there will be only limited updates to the ICD-9 and ICD-10 code sets to capture new technology and new diseases. On Oct. 1, 2014, regular updates to the ICD-10 code sets will begin.
- ❏ The agency is working toward full ICD-10 conversion as of Oct. 1, 2013, and has no reason to believe this deadline will change. CMS is aware of congressional concerns about the timeline, but lawmakers "seem content" with the agency's response to those issues.

Another Key Transition Deadline

Jan. 1, 2012, is the compliance date for all HIPAA-covered entities to switch to the Version 5010 standard for submitting electronic claims and related transactions. The new standard replaces the current Version 4010 standard. Unlike the 4010, the 5010 has room for ICD-10 code sets (mandatory as of Oct. 1, 2013).

CMS has posted on its Web site a series of frequently asked questions regarding the implementation of the 5010 standard, including testing issues that organizations will face as they move to 5010 and any potential requirements they might have to show to demonstrate their readiness to transmit claims and relations transactions using 5010.

Providers will be required to test their ability to submit information using 5010 prior to a full-scale transition but will not have to provide certification or other documentation that they are 5010-compliant. Additionally, CMS said, organizations most likely will have to upgrade their practice-management software to become compliant with 5010. The 5010 FAQs are at *http://tinyurl.com/3za4bpj.*

CMS has declared June 15 as National Version 5010 Testing Day. This is a special effort to encourage Medicare fee-for-service trading partners—providers, clearinghouses, and vendors—to contact their Medicare Administrative Contractors (MACs) and facilitate testing to gain a better understanding of MAC testing protocols and the transition to 5010. On that date, trading partners can benefit from real-time help desk support and immediate access to MACs.

However, CMS's National 5010 Testing Day does not preclude trading partners from testing transactions immediately with their MAC. Don't wait, the agency says, begin now to ensure timely compliance. For more information on HIPAA Version 5010, visit *http://www.CMS.gov/Versions5010andD0.*

FDA Issues New Warnings, *from p. 1*

In the May 11 letter, the FDA requested a response within 15 days as to why the companies believe their services can be legally marketed without premarket clearance.

Tougher oversight of direct-to-consumer testing is expected to be part of the FDA guidance, currently under review, on new regulation of laboratory-developed tests (LDTs), agency officials have stated at numerous public forums in recent months.

The FDA announced in July 2010 that it planned to expand its regulatory reach to include LDTs based on their level of risk and solicited comments from stakeholders. LDTs are in vitro diagnostics manufactured by and offered in the same CLIA-certified laboratory. Currently, the FDA has limited its enforcement discretion to analyte-specific reagents and in vitro diagnostic multivariate index assays (IVD-MIAs) using a proprietary algorithm to produce patient-specific results.

Quest to Settle California Medicaid Lawsuit

Quest Diagnostics has agreed to pay $241 million to settle allegations that it illegally overcharged California's Medicaid program (Medi-Cal) for covered clinical laboratory tests over a 15-year period.

The company also agreed to price reporting obligations for a limited time and, in lieu of such obligations for a transitional period, to provide Medi-Cal with a discount until the end of July 2012. In reaching a settlement, the company admitted no wrongdoing but sought to avoid the risk, time, and expense of lengthy litigation.

The qui tam (whistleblower) lawsuit against Quest, LabCorp, and five other labs was filed under seal in 2005 by a competitor, Hunter Laboratories and its CEO Chris Riedel.

In 2009, the California attorney general's office joined the case, noting that under state law, "no provider shall charge [Medi-Cal] for any service . . . more than would have been charged for the same service . . . to other purchasers of comparable services . . . under comparable circumstances" (*NIR 09, 6/March 30, p. 1*).

The attorney general's office blasted what it called a pattern of abuse whereby the labs in the case charged Medi-Cal up to six times more for tests than it charged other customers, such as independent practice associations, physician offices, and hospitals.

The settlement with Quest is the largest recovery under the state's False Claims Act, said the attorney general's office. Riedel stands to gain 15 percent to 25 percent of the recovery, in addition to reimbursement for legal expenses.

Meanwhile, LabCorp reported that California is seeking $97.5 million for its alleged overcharges, including interest, from November 1995 through November 2009. The company is trying to reach a settlement. It is currently scheduled to go to trial in January 2012.

Others in the original lawsuit have either settled or been dropped from settlement discussions.

The broader issue raised by the case is whether it will motivate Medicaid officials in states with similar laws to seek similar settlements. Other states reportedly scrutinizing lab billings include Florida, Massachusetts, Michigan, New York, and Virginia.

New at CMS

Photo credit, Cincinnati Children's Hospital

Patrick Conway

Patrick Conway, M.D., director of hospital medicine and an associate professor at Cincinnati Children's Hospital, became the new chief medical officer at the Centers for Medicare and Medicaid Services and director of the agency's Office of Clinical Standards and Quality on May 9. He succeeds Dr. Barry Straube, who retired in March.

While at Cincinnati Children's Hospital, Conway led faculty and staff in efforts to improve health outcomes across a $1.5 billion health care system that included more than 1 million outpatient visits and 30,000 hospital admissions. He was responsible for all divisions and institutes, as well as the electronic health record measurement system, provider performance measurements, and external reporting of quality measures.

From 2009 to 2010, Conway served as chief medical officer at the Department of Health and Human Services (HHS) in the Office of the Assistant Secretary for Planning and Evaluation. From 2007 to 2008, he was a White House fellow assigned to the office of the secretary at HHS and to the director of the Agency for Healthcare Research and Quality.

G2 Conference Calendar

Upcoming Conferences

June 15-17
Laboratory Outreach: Repositioning Your Program for the New Normal
Caesars Palace
Las Vegas

Sept. 22
Molecular Diagnostics-Fall 2011
W San Francisco
San Francisco

Oct. 19
Lab Leaders Summit 2011
Come for the summit and stay for Lab Institute
Ritz-Carlton Pentagon City
Arlington, Va.

Oct. 19-21
Lab Institute 2011
Crystal Gateway Marriott
Arlington, Va.

Dec. 12-14
LabCompete: Laboratory Sales & Marketing
Sheraton Wild Horse Pass Resort
Chandler, Ariz.

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