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Congress Soliciting Comments on How to Approach SGR

Lawmakers are hoping to have legislation that permanently fixes the Medicare physician payment system on the House floor this summer.

The sustainable growth rate (SGR) formula might be considered health policy's equivalent of the man-made sinkhole.

Though cuts mandated by the SGR are always threatening, actual cuts rarely appear. When SGR cuts were implemented the only time in 2002, the effects were relatively moderate: a 4.8 percent cut to the rates Medicare pays physicians and other health care providers, based on a variety of cost and economic formulas.

Nevertheless, the entire provider community fears the worst should SGR cuts ever be allowed to go into effect again. Under the current formula, physician payments under Medicare Part B would be slashed 24.4 percent if the SGR cuts were implemented in January 2014. However, Congress almost certainly will not allow that to happen.

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CMS to Consider More Participants for Bundled Payment Initiative

The Centers for Medicare and Medicaid Services (CMS) May 16 announced an open period for additional organizations to be considered for participation in the first model of a new payment initiative under the Affordable Care Act.

In a *Federal Register* notice published May 17 (*78 Fed. Reg. 29, 139*), CMS said organizations interested in participating in Model 1 of the Bundled Payments for Care Improvement Initiative must submit an intake form for CMS screening by July 31.

The Bundled Payments for Care Improvement initiative will test how bundling Medicare payments for episodes of care can result in more coordinated care for beneficiaries and lower costs.

The initiative is based around four broadly defined models of care, three of which will involve a retrospective bundled payment arrangement, with a target price (target payment amount) for a defined episode of care. Providers have flexibility to determine which episodes of care and which services will be bundled together.

The initiative is administered under the Center for Medicare and Medicaid Innovation. Its goal is to align payments for services delivered across an episode of care, such as heart bypass or hip replacement,

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"The sustainable growth rate threatens a massive cut to physician payments that could mean many seniors lose access to their doctors," said Sen. Max Baucus, a Montana Democrat and chair of the Senate Finance Committee, in a recent statement. "It is time to repeal this broken system once and for all."

The problems with the SGR are due in part to how the formula has been managed, its effects having been compounded by a decade of Congress routinely voting to shelve what should be an annual recalculation of Medicare payments. Those years of putting it off means the cumulative cuts to Medicare payments ballooned to 26.5 percent had they been enacted at the start of 2013—a terrifying prospect for pathologists and other physicians.

With virtually everyone agreeing that the massive backlog of never-enacted reimbursement cuts has rendered the SGR untenable, Baucus's Senate Finance Committee and the House Energy and Commerce Committee have begun soliciting input from the provider community as to what they would like to see in its place.

Among the proposals that have been floated is one from the Medicare Payment Advisory Commission (MedPAC) that would include three consecutive annual 5.9 percent reductions in payments, followed by seven years of frozen payments. MedPAC introduced that plan in 2011 and still stands by that proposal, although it has since admitted there might be some wiggle room because of recent dips in health care cost inflation.

According to MedPAC Executive Director Mark Miller's recent testimony before the Senate Finance Committee, the three years of consecutive payment cuts could be reduced to as little as 3 percent annually.

Providers Seek Repeal

By contrast, representatives of the provider community have floated a proposal to repeal the SGR but keep payments at the present rate. Future payments would be based on the medical practice costs. Critics have noted such a formula would all but guarantee automatic payment increases to doctors indefinitely.

Repeal of the SGR has been debated almost as soon as it was passed into law in 1997, itself a replacement for the Medicare volume performance standard formula, which had only been enacted five years prior. However, given Congress's willingness to vote each year to shelve the formula in lieu of giving providers modest pay increases instead, there has been little momentum to actually repeal the law. There have been 15 such "doc-fixes" over the past decade, costing about $150 billion in total, according to Baucus's office.

But the fact two congressional committees have been soliciting input from the provider community suggests changes may be coming. What changes are proposed have yet to emerge, however.

Debbee Hancock, the press secretary for the House Committee on Energy and Commerce, said the comments gathered have not been made public. She did not respond to other queries. A spokesperson for the Senate Finance Committee did not respond to written and telephonic requests for comment.

There is no timetable for introducing SGR legislation though sources believe it could happen as early as this summer.

New Guidelines on HIV Testing Could Be Boon for Labs

Emerging recommendations from federal regulators on HIV testing could prove a miniboon to the laboratory sector.

Draft guidelines released by the U.S. Preventive Services Task Force (USPSTF) recommend every person in the United States between the ages of 15 and 65 be tested for the HIV virus at least once in their lifetime and that pregnant women unaware of their HIV status be tested even if they are in labor.

More regular testing should also be undertaken by those at a higher risk of contracting the disease, regardless of their age, including gay and bisexual males, intravenous drug users, and those who live in poverty for prolonged periods of time, according to the guidelines.

Officials with the USPSTF have indicated that automatic coverage for AIDS testing will likely be part of the Patient Protection and Affordable Care Act, the bulk of which will be implemented in 2014.

The sweeping parameters of the HIV testing are likely to boost the bottom lines of companies that specialize in HIV testing, such as OraSure Technologies Inc. in Bethlehem, Pa.

The guidelines come in the wake of the continued spread of HIV. As many as 50,000 new cases are diagnosed each year in the United States, according to the Centers for Disease Control and Prevention. Another 1.2 million Americans already have HIV, and up to a quarter do not know they have it, increasing the risk they will spread the virus.

By contrast, transmission of HIV is reduced by 96 percent when those individuals who have the virus are aware of it, according to the USPSTF.

Contracting HIV was an almost guaranteed death sentence until the mid-1990s, when anti-retroviral therapies were shown to effectively control the disease, rendering it the equivalent of a controllable chronic illness.

The American Clinical Laboratory Association (ACLA) supports the new guidelines.

"We applaud the USPSTF in encouraging greater testing to help identify afflicted patients," said ACLA President Alan Mertz. "It is critically important for patients to receive the proper screening tests for HIV. The dramatic decline in HIV-related deaths over the past few decades could not have occurred without laboratory testing. With early detection, drug treatments, and careful monitoring through tests including viral load and HIV resistance testing, HIV has been transformed from a death sentence into a manageable chronic condition."

The sweeping parameters of the HIV testing are likely to boost the bottom lines of companies that specialize in HIV testing, such as OraSure Technologies Inc. in Bethlehem, Pa.

OraSure's OraQuick In-Home HIV Test, approved by the Food and Drug Administration in 2012, is an over-the-counter version of OraQuick ADVANCE, an oral swab rapid test with more than 25 million units sold in the professional market. OraQuick's over-the-counter version retails for about $40. For the first quarter of 2013, OraSure had $1.5 million in gross sale of the OraQuick test.

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rather than paying for services separately. Bundled payments will give doctors and hospitals new incentives to coordinate care, improve care quality, and save money for Medicare, the agency has said.

On Jan. 31, CMS announced the selection of 32 awardees in Model 1, which began testing bundled payments for acute-care hospital stays in April. CMS has been reviewing applications for the first model since the October 2011 submission deadline.

Under Model 1, the episode of care is defined as the inpatient stay in the acute-care hospital. Medicare will pay the hospital a discounted amount based on the payment rates established under the Part A diagnosis-related groups. Medicare will continue to pay physicians separately for their services under the Part B fee schedule. Under certain circumstances, hospitals and physicians will be permitted to share gains arising from the providers' care redesign efforts.

Acute-care hospitals paid under the inpatient prospective payment system and organizations that wish to convene acute-care hospitals in a facilitator convener role are eligible to be considered for participation in Model 1, CMS said.

Additional information about Model 1 is available at *http://innovation.cms.gov/initiatives/BPCI-Model-1/index.html*.

CAP Seeks Exception for Meaningful Use Requirements

The College of American Pathologists (CAP) is urging the Centers for Medicare and Medicaid Services (CMS) to grant pathologists a full five-year exception from meeting meaningful use requirements of electronic health records (EHRs).

The Medicare meaningful use (MU) program was created to help all physicians adopt interoperable EHR systems. However, the focus on primary-care and office-based physicians has frustrated a number of medical specialists, including pathologists, whose scope of practice and the information systems they use prevent them from qualifying for the program's incentives but provide no protection from penalties, which would come in the form of pay cuts—up to 2 percent per year, starting in 2015 based on 2013 reporting.

CMS has granted pathologists a hardship exception from penalties in 2015, but the exception is only for one year at a time, up to five years. Legislation (H.R. 1309) is pending in Congress that would exempt pathologists from participating in the program and protect them from penalties for failing to meet federal requirements for meaningful use of EHRs.

In a letter send to Marilyn Tavenner, CMS administrator, the chair of CAP's Council on Government and Professional Affairs and co-chair of its HIT Policy Working Group urged the agency to work with the college and Congress to extend the exception for pathologists.

"It continues to be the case that the vast majority of pathologists practice using laboratory information systems (LISs), not certified EHRs," wrote Richard Friedberg, M.D., Ph.D. "LISs are highly specialized systems that are required and engineered specifically to support laboratory operations in pursuit of patient testing."

Friedberg notes a recent CMS "Specialist Tipsheet" appears to provide a pathway for a small number of pathologists who practice at integrated settings to meet MU at least in Stage 1.

"Indeed, according to a CMS April 2, 2013, publicly available data file, only 324 pathologists, representing approximately 1.8 percent of all practicing pathologists, have attested to Stage 1 MU," he writes. "Most pathologists practicing in community hospitals and independent laboratories, outside of large integrated and often academic medical centers, will still be unable to meet either Stage 1 or Stage 2 MU."

While a small minority of pathologists in large integrated practices may be able to "ride the data" of other eligible providers, particularly in Stage 1 to meet MU, it is unlikely that doing so is practical in Stage 2, Friedberg says.

"Most pathologists also do not control what electronic systems they have access to or use or what data is entered by other eligible providers so their ability to meet MU even through the data riding path—which is the only route currently available to them—is completely outside their control," he writes.

EHRs Can Help With Improperly Ordered Lab Tests: AHRQ

Electronic health record (EHR) systems can be used to identify and correct diagnostic errors by clinicians, including improperly ordered laboratory tests, according to a study sponsored by the Agency for Healthcare Research and Quality (AHRQ).

The majority of misdiagnoses identified in the study were attributed to clinical process breakdowns in patient encounters, typically related to failures to properly record patient health histories, said AHRQ.

Researchers for the study, titled "Types and Origins of Diagnostic Errors in Primary Care Settings," used EHRs to examine medical records at an unidentified large urban Veterans Affairs health facility and a large integrated private health care system between Oct. 1, 2006, and Sept. 30, 2007. In the 190 clinical encounters studied, researchers identified 68 cases of diagnostic errors.

Errors stemming from process breakdowns were most frequently related to patient-practitioner clinical encounters, the study said. Nearly 80 percent of the errors identified were related to patient-practitioner encounter issues, with referrals the second-most common cause of errors at 19.5 percent of all cases.

The most common problems linked to clinical encounters were failures to properly record patient history (56.3 percent), examination (47.4 percent), and improperly ordered laboratory tests (57.4 percent), the study said. Most errors were associated with the potential for moderate to severe harm to the patient.

Better methods are needed to help clinicians gather and synthesize clinical information, AHRQ said. Preventive interventions should target the data-gathering process.

The study was published in *JAMA Internal Medicine*, a journal published by the American Medical Association.

CMS to Fund Innovative Health Care Initiatives

The Centers for Medicare and Medicaid Services (CMS) May 15 announced a funding opportunity that will award up to $1 billion in grants to test new payment and service delivery models that will deliver better care and lower costs for Medicare, Medicaid, and Children's Health Insurance Program (CHIP) enrollees.

The second round of the Health Care Innovation Awards will be administered by the Center for Medicare and Medicaid Innovation (CMMI) to support public and private organizations in four defined areas that have a high likelihood of driving health care system transformation, the agency said.

Funds will go to those applicants that demonstrate that they can improve quality of care and deliver sustainable net savings to CMS within three years. The grant program was included in the Affordable Care Act.

CMS in 2012 awarded 107 first-round Health Care Innovation Awards, out of nearly 3,000 applications, to organizations that are currently testing innovative solutions to improve outcomes and reduce costs. The 107 projects will save Medicare, Medicaid, and CHIP $1.9 billion over the three-year length of the agreements. Grantees include collaborations of hospitals, doctors, nurses, pharmacists, technology innovators, community-based organizations, and patient advocacy groups in urban and rural areas.

CMMI announced the first round of awards in May 2012 with the second and final batch of awards under round one announced a month later.

More Specific Proposals

Although the projects CMMI funded in the first round were broadly targeted to improve health outcomes, the second round is more specific, CMMI Director Richard Gilfillan said during a May 15 briefing.

Specifically, in the second round, CMS is seeking proposals for models that:

- ❑ Are designed to rapidly reduce Medicare, Medicaid, and/or CHIP costs in outpatient and/or post-acute settings;
- ❑ Improve care for populations with specialized needs;
- ❑ Test approaches for specific types of providers to transform their financial and clinical models; and
- ❑ Improve the health of populations.

CMS also said it is specifically seeking new payment models to support the service delivery models funded by the initiative. All applicants must submit, as part of their application, the design of a payment model that is consistent with the new service delivery model that they propose. Eligible applicants include, but are not limited to, provider groups, health systems, payers and other private-sector organizations, faith-based organizations, states, local governments, public-private partnerships, and for-profit organizations, CMS said.

CMS said it will accept letters of intent from June 1 until June 28. Applications will be accepted from June 14 until Aug. 15, CMS said.

Lawsuit Against Carolinas Pathology Group Dismissed

A pathologist whose employment was terminated following critical remarks he made about a hospital at a staff meeting could not succeed on a claim that he was discharged in retaliation for exercising his First Amendment rights, a federal appeals court affirmed May 13 (*Shenoy v. Charlotte-Mecklenburg Hospital Authority*, 4th Cir., No. 12-1786).

In an unpublished opinion, the U.S. Court of Appeals for the Fourth Circuit found that B. Vittal Shenoy, M.D., was not speaking as a private citizen when he criticized the administration of a Carolinas Healthcare System (CHS) hospital for what he viewed as systemic failures that led to a large number of sentinel events. The court also affirmed summary judgment for CHS and Carolinas Pathology Group (CPG) on Shenoy's claims for tortious interference with contract and False Claims Act (FCA) retaliation.

Shenoy, a pathologist, was employed by CPG and was the medical director of the pathology laboratory at Carolinas Medical Center-Pineville (CMC-Pineville). He voluntarily took on a leading role on CMC-Pineville's peer review committee, the medical staff quality improvement committee, and the sentinel events committee.

In March 2005, Shenoy spoke up at a medical staff quality improvement committee meeting, criticizing CMC-Pineville's administration for the hospital's high number of sentinel events. He said the administration placed too much blame for incidents on the doctors.

After the meeting, CMC-Pineville's director, Curtis Copenhaver, asked CPG to remove Shenoy from the hospital. CPG subsequently terminated Shenoy's employment.

Lawsuit Filed

Shenoy filed this lawsuit against CHS, CPG, and others, alleging he was terminated in retaliation for exercising his free speech rights, intentional interference with contractual relations, and FCA retaliation. The last claim was based on Shenoy's 2003 filing of a qui tam complaint against CPG.

The court treated Shenoy as a public employee for purposes of the First Amendment claim. For a public employee to succeed on such a claim, it said, he had to show, as a threshold matter, that he was speaking as a citizen on a matter of public concern.

In this case, the court said, the district court concluded that Shenoy's remarks at the committee meeting were made pursuant to his duties as committee chair and were "precisely the sorts of comments made . . . pursuant to official duties." The appeals court found no error in this conclusion.

Even though Shenoy volunteered for the committee, and his remarks were "not explicitly required" as part of his official day-to-day job, Shenoy's speech still fell within his official duties, it said.

Once Shenoy accepted his committee roles, the court added, his service became part of his duties at the hospital, and he did not have an unfettered right to criticize its administration.

The court also affirmed summary judgment for the defendants on Shenoy's interference with contract claim. CHS, it said, had an absolute right under its contract with CPG, to inform CPG that Shenoy's services were no longer satisfactory and to ask CPG to take necessary action, including removing Shenoy from CMC-Pineville. CHS's decision to exercise this legal right did not constitute tortious conduct, the court said.

Tavenner Confirmed as CMS Administrator

The Senate on May 15 confirmed Marilyn Tavenner as administrator of the Centers for Medicare and Medicaid Services (CMS), making her the first Senate-confirmed administrator since 2006. Tavenner has served for more than a year as acting CMS administrator.

Provider and advocacy groups praised the confirmation, with the American Hospital Association saying she "has demonstrated her willingness to listen to, learn from, and work in partnership with the nation's health care providers."

Senate Finance Committee Chairman Max Baucus (D-Mont.) described Tavenner as an excellent choice to lead CMS. Tavenner's nomination was held up briefly when Sen. Tom Harkin (D-Iowa), chairman of the Health, Education, Labor, and Pensions Committee, placed a hold on it April 24. The hold was in response to the Obama administration's taking some $332 million from the Prevention and Public Health Fund, which Harkin championed and pushed to be included in the Affordable Care Act. The administration said it needed the money to help pay for consumer education and outreach efforts on new health insurance marketplaces, which begin enrollment in October. Harkin released the hold May 7.

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Jim Curren, Editor; Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, President and Publisher.

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