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Physician Payment: House Panel Ponders Life After the SGR

Under the sustainable growth rate (SGR) formula, Medicare physician fees are scheduled for a cut of 29.5 percent in 2012. The SGR has triggered negative updates since 2002 though Congress has repeatedly blocked the cuts. Critics say it's time for a complete overhaul.

Kicking off this year's congressional debate over fundamental reform of the Medicare physician payment system, the House Energy and Commerce health subcommittee opened the floor May 5 to air ideas on legislation to achieve that goal.

In welcoming remarks, chairman Joseph Pitts (R-Pa.) said, "The current payment system is fundamentally flawed and keeping it or making minor adjustments is no longer a viable option." The need now, he said, is "to move to a system that reduces the growth in health care spending, preserves access to care for Medicare beneficiaries, and pays providers fairly, based on the value, not the volume of their services."

The hearing follows a bipartisan letter from Energy and Commerce health leaders to 51 physician organizations inviting proposals for a "permanent, sustainable" Medicare physician fee fix (*NIR 11, 7/April 8, p. 3*).

The consensus that emerged among those who submitted comments and those testifying at the hearing was that a permanent fix requires a number of steps:

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Exceptions Likely in FDA Guidance on Lab-Developed Tests

The Food and Drug Administration's (FDA) long-awaited guidance on lab-developed tests—currently under review—is likely to contain exceptions for certain types of tests, according to Alberto Gutierrez, Ph.D., director of FDA's Office of In Vitro Diagnostic Device Evaluation and Safety.

These types would include tests for rare diseases, biothreats, and emerging infectious diseases, as well as "traditional, low-risk" tests.

Gutierrez, who spoke at the annual meeting of the American Clinical Laboratory Association (ACLA) April 20, could not say when the FDA's guidance on lab-developed tests (LDTs) would be released but was hopeful it could be issued within the next six months.

The guidance is expected to set up a regulatory framework for LDTs based on risk and to contain requirements for registration of LDTs and a mechanism for classifying them, he explained.

Tests ranked as Class III medical devices, such as those for human papilloma virus (HPV), would probably be required to go

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through the FDA's 510(k) approval process while those classified as Class I devices probably would not, he said.

LDTs are in vitro diagnostics manufactured by and offered in the same CLIA-certified laboratory. The tests number in the thousands and include genetic tests and others used to prevent, diagnose, and treat patients with a wide range of cancers, cardiovascular and neurological disease, Alzheimer's, and many other serious health conditions.

Gutierrez also indicated that the agency's guidance on companion diagnostics should be out soon and that clinical trial guidance for both therapeutics and diagnostics should be released by July 31.

While the FDA is working on a regulatory framework for LDTs, ACLA is planning to pursue an alternate strategy for regulation of such tests, according to Alan Mertz, association president. ACLA would prefer to see LDTs regulated under the Clinical Laboratory Improvement Amendments (CLIA) and is planning to seek a statutory change that would specify such oversight, he told G2 Intelligence.

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 on how it should proceed. Currently, the agency has limited its enforcement discretion to analyte-specific reagents and in vitro diagnostic multivariate index assays (IVDMIAs) using a proprietary algorithm to produce patient-specific results.

Independent Payment Board Under Renewed Assault

The president's proposal in his fiscal 2012 budget to strengthen the Independent Payment Advisory Board (IPAB) has fired up its foes in Congress and among health care provider and business groups that want it repealed.

Opponents' chief criticism is that the provision, enacted in the health care reform law, gives unelected officials, appointed by the executive branch, too much power over Medicare reimbursement rates. The IPAB is to set spending growth targets that, if exceeded, would require cuts unless Congress comes up with an alternative that meets the targets.

The president's budget says that in addition to the board's responsibilities under the law, 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.

Republican chairmen of the House committees on Ways and Means and Energy and Commerce recently sent a letter to the president, requesting more information on the IPAB's functions. Ways and Means head Dave Camp (Mich.) and Energy and Commerce chief Fred Upton (Mich.) asked:

- ❏ "Do you recommend making all providers subject to the board in 2014?" Hospitals, for example, are exempt until 2020.
- ❏ "To what degree do you expect your IPAB ideas will reduce Medicare spending by 2021, 2023, and the subsequent decade? What is the source of those estimates?"

- "What specifically do you mean by 'giving the IPAB additional tools to improve the quality of care while reducing costs, including allowing it to promote value-based benefit designs?' Would this require a statutory change given that the board is not currently allowed to consider changes to the Medicare benefit package?"

The Board's Role

The Patient Protection and Affordable Care Act created a 15-member Independent Payment Advisory Board with significant authority over Medicare payment rates.

Beginning in 2014, in any year in which the Medicare per capita growth rate exceeded a target growth rate, the board would be required to recommend Medicare spending reductions. The recommendations would become law unless Congress passed an alternative that achieved the same level of budgetary savings.

Subject to some limitations—hospitals, for example, are exempt until 2020—the IPAB could recommend spending reductions affecting Medicare providers and suppliers, as well as Medicare Advantage and prescription drug plans.

In years in which the IPAB would not be required to make recommendations, it would have to submit an advisory report. Every two years, the board would make recommendations on slowing the growth of private health expenditures.

The American Medical Association, the College of American Pathologists, and a host of other groups have long expressed concerns about the creation of 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. The groups say the current process provides an open and transparent legislative airing of important policies on health care services.

Business and provider groups in the Coalition for Affordable Health Coverage are concerned that much of Medicare spending is exempt from the board's recommendations until 2020 and that if reimbursement rates become inadequate, costs will shift to private payers and consumers.

In an April 25 letter to Rep. David P. Roe, M.D., (R-Tenn.), sponsor of H.R. 452 that would repeal the IPAB, 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."

Since hospitals are exempt from IPAB purview until 2020, the groups most affected by any cuts that have to be made are physicians, clinical laboratories, drug companies, and medical device makers.

Under current law, the board is to be established in 2014, file its first report by July 2014, and implement its recommendations in 2015.

Since Roe introduced the House bill, 81 co-sponsors have joined him, including a handful of Democrats. Sen. John Cornyn (R-Texas) introduced a similar measure (S. 668) that 17 Republicans senators have joined as co-sponsors.

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 discussion.

focus on: Emerging Public Health Threats

Lab Alert: Responding to the Spread of Carbapenem-Resistant 'Superbug'

Clinical laboratories should be on the lookout for a dangerous multidrug-resistant pathogen, thought to be confined to health care-associated facilities and communities on the East Coast, which has now emerged in Southern California.

That alert was sounded by researchers from the Los Angeles County public health department at the annual scientific meeting of the Society for Healthcare Epidemiology of America (SHEA) last month in Dallas.

The pathogen is carbapenem-resistant *Klebsiella pneumoniae* (CRKP), a relative of *E. coli* and resistant to most antibiotics except colistin, a drug so powerful it can cause kidney damage.

CRKP has been found in Los Angeles County at unexpectedly high rates in patients in long-term acute care hospitals compared to general acute care hospitals, the researchers reported.

"The emergence and spread of CRKP and other types of carbapenem-resistant Enterobacteriaceae *is another in a series of worrisome public health developments regarding anti-microbial resistance among gram-negative bacteria and underscores the immediate need for aggressive detection and control strategies." Centers for Disease Control and Prevention, which has been tracking CRKP across 35 states since 2009. The infection was first described in North Carolina in 1999.*

Outbreak in Los Angeles County

In the wake of reports of CRKP at local hospitals in the spring of 2010, the county public health department added CRKP to the list of reportable diseases, effective June 1, 2010, and required clinical laboratories to report all cases of it (confirmed cases within 10 working days).

Department researchers analyzed reports from June 1 through Dec. 31, 2010, filed by 52 hospitals and a regional lab. Results released in March 2011 found a total of 356 cases. Many of them, 42 percent, occurred in patients in long-term acute care facilities. Six percent of cases occurred in patients in skilled nursing facilities. The bacterium tends to strike elderly patients who often have extended stays and those on ventilators or who take long courses of antibiotics.

The study did not address why high rates were found. Researchers said they do not know if this resulted from improper care or had more to do with the population served. The study did not look at follow-up on the patients, so it could not discern whether they brought the pathogen with them from a nursing home to a hospital or got infected while in the hospital.

"The survey establishes a baseline for the overall frequency of CRKP infections in the county," said department director Jonathan E. Fielding, M.D., M.P.H., in a statement. "It is important to note that 356 cases represent a very low percentage

of health care-associated infections, and CRKP is only one of a growing number of multiple-drug-resistant organisms."

The department will continue CRKP surveillance in Los Angeles County, he said, and has notified physicians about the survey and is providing continuing education about multidrug-resistant bacteria and the role of appropriate antibiotic use in combating resistance development.

"Patients can help prevent the spread of antibiotic-resistant bacteria," Fielding said, "by fully completing the course of treatment for any prescribed antibiotics and not insisting on antibiotic therapy for a health problem if not recommended by their physician. Finally, both health care staff and patients can reduce the spread of CRKP and other pathogens through frequent hand washing or use of a waterless alcohol-based hand rub."

Targeting the Pathogen

Klebsiella is a type of gram-negative bacteria that can cause infections in health care settings, including pneumonia, bloodstream infections, wound or surgical site infections, and meningitis. Studies in the United States and Israel have shown that about 40 percent of infected patients die, according to the Centers for Disease Control and Prevention (CDC).

"Increasingly, *Klebsiella* bacteria have developed antibiotic resistance, most recently to the class known as carbapenems," CDC has noted. "When bacteria such as *Klebsiella pneumoniae* produce an enzyme known as a carbapenemase, they are referred to as KPC producing organisms or carbapenem-resistant *Klebsiella pneumoniae* (CRKP). This is considered a threat to patient safety because carbapenem antibiotics often are the last line of defense against gram-negative infections that are resistant to other antibiotics."

To get a *Klebsiella* infection, a person must be exposed to the bacteria. For example, it must enter the respiratory tract to cause *pneumoniae* or the blood to cause a bloodstream infection. In health care settings, *Klebsiella* bacteria can be spread through person-to-person contact (for example, from patient to patient via the contaminated hands of health care personnel or other persons) or, less commonly, by contamination of the environment. The bacteria are not spread through the air.

CRKP is compared to other "superbugs," such as methicillin-resistant *Staphylococcus aureus*, or MRSA, against which most antibiotics are useless. But CRKP is more difficult to treat. The current treatment, a drug called colistin, is an older antibiotic with toxic side effects, and industry trackers do not see newer, more effective treatments any time soon.

CDC Guidance on Infection Control Strategies

- ❏ All acute care facilities should implement contact precautions for patients colonized or infected with carbapenem-resistant or carbapenemase-producing *Enterobacteriaceae.*

- ❏ Clinical laboratories should follow the guidelines of Clinical and Laboratory Standards Institute for susceptibility testing and establish a protocol to detect carbapenemase enzymes, including performance of the modified Hodge test to confirm carbapenemase activity.

- ❏ Labs should promptly notify infection prevention staff of all nonsusceptible *Enterobacteriaceae* isolates, or *Klebsiella spp* or *Escherichia coli* isolates, that test positive for a carbapenemase.
- ❏ Acute care facilities should review clinical culture results for the preceding six to 12 months to see if previously unrecognized carbapenem-resistant *Enterobacteriaceae* have been present.
- ❏ If such organisms are found, perform a single round of active surveillance cultures in high-risk units, including intensive care, wards where previous cases have been identified, and units where many patients are exposed to broad-spectrum anti-microbials.
- ❏ If resistant or carbapenemase-producing pathogens are detected or if the point prevalence survey reveals unrecognized colonization, the facility should investigate for possible transmission. This should include active surveillance testing of patients with epidemiologic links to an infected patient and should continue until no new cases suggesting transmission are identified.

Thwarting superbug outbreaks is a multidisciplinary team effort, say medical experts: the lab running the susceptibilities, the pharmacists who understand the pharmacology of the antibiotics, the physician who orders the drug, and the infection control officer for the facility. Make appropriate use of the drugs we have, CDC advises, concentrating on improving patient safety and treatment outcomes while slowing the growth of resistance. Individual-level data can be used to inform both the basic science and the implementation of anti-microbial stewardship programs, says the agency, which is fielding numerous initiatives against health care-associated infections.

Troubling Trends in Use of 'Last Resort' Antibiotics

The spread of CRKP and other multi-drug-resistant superbugs has also raised concerns about the increasing use of antibiotics. At the SHEA meeting, researchers from the Veterans Affairs department reported on a large-scale study that found a dramatic rise in carbapenem use in VA facilities over the last five years. The results are similar to what has been described in non-VA facilities, they said.

The increasing use is "alarming because carbapenem-resistant bacteria are becoming more common," the researchers said. "Overuse of these drugs could weaken their efficacy, threatening their effectiveness against these and other emerging infections."

Using barcode medication administration data for antibiotics administered in 110 VA acute care health facilities from 2005 through 2009, researchers noted a gradual increase in overall antibiotic use but striking increases in the use of carbapenems (up 102 percent), intravenous vancomycin (up 79 percent), and combinations of penicillin with beta-lactamase-inhibitors (up 41 percent). Fluoroquinolones were the most frequently used drugs across facilities, accounting for 20 percent of all antibiotic use.

CDC recently awarded $10 million for new research to five academic centers as part of its Prevention Epicenter grant program aimed at reducing infections in health care settings. Reducing these infections also is on the agenda of the new Center for Medicare and Medicaid Innovation. CDC estimates that 1 out of 20 hospitalized patients will acquire an infection while receiving treatment for other conditions.

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- ❏ Repeal the sustainable growth rate (SGR) formula used to calculate annual physician fee updates. The cost: an estimated $300 billion over 10 years.
- ❏ Replace the current "one size fits all" fee-for-service system with an assortment of reimbursement options tailored to the medical specialty, its capabilities, and the patient population served.
- ❏ Provide stable fee increases over a five-year period to ensure a smooth transition to a new payment system beginning in 2017.

The start of what appears to be a serious effort to reform Medicare physician payments is a cue for clinical laboratories to reexamine and possibly think about restructuring their business arrangements with referring physicians and hospitals.

In briefing the panel, physician groups and health policy experts advised lawmakers to consider an array of payment models, some of which are being tested in the private sector and in Medicare or will be tested in Medicare under provisions of the health care reform law, including accountable care organizations in the new shared savings program (*NIR 11, 7/April 8, p. 1*). The American Medical Association cautioned, however, that in many cases major investments are required to retrieve and analyze data, spot inappropriate utilization, and coordinate patient care. "With the vast majority of medical practices qualifying as small businesses, it is important to put in place transitional models that will help small and solo practices develop these capabilities."

Selected Payment Options

Bundled Payments: These provide payment for a complete product or service with a warranty to follow up on problems at no extra charge. One approach is to pay physicians and hospitals a single amount per episode of care; another is to make a global payment that covers all of the health care services patients need for their health conditions during a specific period of time (e.g., a year). The amount of payment is adjusted based on the health of patients, how many conditions they have, and other factors affecting the level of services needed.

Patient-Centered Medical Home: This team-based primary care model is advocated by the American Academy of Family Physicians. It is designed to coordinate care and to use a broad range of patient encounters, like telephone, e-mail, group visits, health coaching, community services, and interoperable coordination of a wide range of health providers for patients with multiple chronic conditions.

Private Contracting: Patients and physicians could freely contract, without penalty to either party, on fees for services (except for emergency or urgent care). Beneficiaries could use their Medicare benefits and physicians could bill the patient for all amounts not covered by Medicare. Physicians could exercise this option on a per-patient basis, could maintain Medicare participating or nonparticipating status for other beneficiaries they treat, and would not have to opt out of Medicare for two years for all patients, as is required under existing law. This option is embodied in legislation, H.R. 1700, introduced May 3 by Rep. Tom Price (R-Ga.). It has drawn support from the AMA and the Coalition of State Medical and National Specialty Societies. AARP opposes it, saying relaxing rules on balance billing only shifts costs to beneficiaries.

Transition to a New Payment System

To prepare for the switch to a reformed payment system, physician organizations call for a five-year period of statutorily mandated fee increases. The AMA says the update should be in line with the growth in medical practice costs. The American College of Surgeons proposes separate service category growth rates (SCGR) for like services with increased payments for primary care.

Washington Enacts Pathology Direct Billing Law

Washington is the latest state to enact direct billing legislation for anatomic pathology (AP) services. The legislation, signed into law April 20 by Gov. Chris Gregoire (D) and effective July 1, 2011, ensures that patients are billed for AP services only by the physician who performs or supervises the service. Similar legislation is pending in Indiana, and if approved, Indiana would become the 18th state with a direct billing law.

The College of American Pathologists has long supported direct billing of pathology services and opposed the practice of client billing, in which a treating physician realizes a profit by charging a patient full price for a laboratory service the physician received at a discount. In some cases, a physician marks up the price of the service to widen the profit margin. Client billing gives providers an incentive to choose a laboratory test based on price, rather than quality, critics say. It also creates an incentive to order more tests than necessary, as each service ordered results in an incremental increase in profit.

At present, more than 75 percent of the U.S. population is billed for certain pathology services under a direct billing, anti-markup, or disclosure law at either the federal or state level, notes the American Medical Association.

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