WASHINGTON G–2 REPORTS

NATIONAL INTELLIGENCE REPORT®

Covering Government Policy For Diagnostic Testing & Related Medical Services

Celebrating Our 31st Year of Publication

Vol. 10, Iss. 13, July 12, 2010

Obama Installs Donald Berwick in Top Slot at CMS

Donald M. Berwick, M.D.

With the Senate away on summer break, President Obama announced July 7 that he is installing Donald M. Berwick, M.D., as administrator of the Centers for Medicare and Medicaid Services (CMS), a post without a permanent occupant since 2006. He will serve in the position through 2011.

The president moved him into the top CMS slot via a recess appointment, bypassing the Senate confirmation process and thwarting opposition from Republicans who have opposed Berwick since his nomination in April, claiming that his past statements indicate he favors government rationing of health care.

In announcing the appointment, the president said, "It's unfortunate that at a time when our nation is facing enormous challenges, many in Congress have decided to delay critical nominations for political purposes." More than 180 of his nominees are still pending before the Senate.

Despite strong Republican objections to the president's pick and outrage over the recess appointment, Berwick has widespread

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CMS Delays July Start of Claims Rejection

In welcome news for clinical laboratories and pathologists, the Centers for Medicare and Medicaid Services (CMS) is not automatically rejecting claims based on orders or referrals from providers that do not have a current Medicare enrollment record.

The agency had planned to start the new policy as of July 6, the deadline set in its May 5 interim final rule implementing changes made by the Patient Protection and Affordable Care Act (PPACA) to Medicare and Medicaid enrollment and reimbursement requirements (*NIR 10, 12/June 25, p. 3*).

The new policy requires denial of payment for claims when the ordering or referring physician is not enrolled in Medicare's Provider Enrollment, Chain, and Ownership System (PECOS) or has a valid opt-out record, and when the physician is not identified on the claim by his or her legal name and National Provider Identifier (NPI).

The law specifies that this applies to claims for durable medical equipment, prosthetics, orthotics, and supplies and for home health. In the interim rule, CMS added claims for laboratory testing, specialist

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New Concern Raised About Pathology's Place in Stark In-Office Ancillary Service Exception

Should anatomic pathology be removed from the in-office ancillary service (IOAS) exception to the Stark ban on physician self-referrals?

This has been long advocated by leading pathology and clinical laboratory groups that say physicians are abusing the exception to increase their Medicare revenue from referrals for services that they order.

Opponents argue that the exception enables physicians to make rapid diagnoses and initiate treatment during a patient's office visit, improves care coordination, and encourages patients to comply with their physicians' diagnostic and treatment recommendations.

The Stark law prohibits Medicare and Medicaid referrals of beneficiaries for designated health services to entities with which the physicians have a financial relationship unless the relationship fits within an exception.

Latest to Chime In

The influential Medicare Payment Advisory Commission (MedPAC) is the latest to add to the controversy in its June 2010 report to Congress, *Aligning Incentives in Medicare*. In testimony before the House Energy and Commerce health subcommittee, MedPAC chairman Glenn Hackbarth, J.D., noted that over the last several years, many physicians have restructured their practices to utilize the Stark in-office exception, and the trend has been toward volume growth and increased Part B spending.

There is mounting evidence, he said, "that physician investment in ancillary services leads to higher volume through greater overall capacity and financial incentives for physicians to order additional services. In addition, there are concerns that physician ownership could skew clinical decisions—incenting physicians to provide certain tests or treatments that their clinical judgment would not otherwise lead them to order if they did not have a financial stake in the equipment."

In analyzing the frequency with which services covered by the IOAS exception are provided on the same day as an office visit, MedPAC looked at Medicare claims data. The commission found that physical and occupational therapy is rarely provided on the same day as the visit. Also, half or fewer than half of imaging, clinical laboratory, and pathology services are performed on the same day as the visit. "This raises questions about one of the key rationales for the exception—that it enables physicians to provide ancillary services during a patient's visit," Hackbarth said.

While MedPAC has not yet made recommendations, it has been exploring the pros and cons of several options, he noted, including excluding diagnostic tests, such as anatomic pathology services, that are not usually provided during an office visit. Other options include:

- ❑ Excluding therapeutic services such as physical therapy and radiation therapy.
- ❑ Limiting the exception to physician practices that are clinically integrated.
- ❑ Reducing payment rates for diagnostic tests performed under the exception.

- ❑ Improving payment accuracy and creating bundled payments.
- ❑ Adopting a carefully targeted prior authorization program for imaging services.

Hackbarth noted that these are suggested interim steps toward a shift away from current Medicare fee-for-service payment systems, which reward higher volume and create incentives to provide more ancillary services. Under a different model, in which providers received a fixed payment amount for a group of beneficiaries (capitation) or an episode of care (bundling), physicians could still self-refer, he pointed out, but would not be able to generate additional revenue by ordering more services.

The IOAS coalition—which includes the College of American Pathologists, the American Society for Clinical Pathology, the American Clinical Laboratory Association, and several independent labs—welcomed the MedPAC analysis. Members have been meeting with CMS senior officials recently to persuade the agency to yank anatomic pathology from the Stark exception. They note that pathology services, primarily biopsies, cannot be completed in time to allow a diagnosis while the patient is physically present in the physician's office.

Myriad Genetics Appeals BRCA Gene Patent Ruling

As expected, Myriad Genetics has filed an appeal against a district court ruling that some of the company's patents on BRCA1 and BRCA2 genes are invalid. The case now goes to the Federal Court of Appeals in Washington, D.C. Oral arguments are set for the fall, and the case could go all the way to the U.S. Supreme Court.

The case is closely watched by the health care industry because the outcome could have a substantial impact on thousands of gene patents currently held by biotechnology companies. Pathology and clinical lab groups are among the many who joined the lawsuit against Myriad, arguing that gene patenting harms patients and limits advances in both research and the field of medicine.

The company is challenging a March 29 lower court ruling by Judge Robert W. Sweet that invalidated some of the BRCA patents granted to Myriad and the University of Utah Research Foundation, both based in Salt Lake City. Various mutations in these genes are associated with hereditary breast and ovarian cancer. The patent holders claim the exclusive right to perform diagnostic testing on these genes, license the testing to other users, and threaten litigation for patent infringement against any unlicensed use. Sweet ruled that the isolated DNA at issue is not significantly different, either in function or in the information it contains, from DNA that exists in the body, and thus is not patentable (*NIR 10, 7/April 8, pp. 3-5*).

Meanwhile, a highly anticipated Supreme Court ruling in the *Bilski* case was seen by many, including those involved in the Myriad litigation, as a potential bellwether for patent law. But the decision, handed down June 28, does little, observers agreed, to address questions about the patentability of complex technologies and the information they generate, including sequencing technology used to identify human genes.

In *Bilski*, the majority found that a method of predicting business or economic cycles was ineligible for a patent. The court found that patenting the concept of hedging risk and applying it to energy markets amounts to "attempts to patent abstract ideas," which the statute does not allow. Further, the majority said the court "need not define further what constitutes a patentable process," beyond pointing to the statutory definition and looking to guiding precedents.

focuson: *Physician Payment Policy*

Medicare Fix Only a Short-Term Compromise; What's Next When It Expires Nov. 30?

Since the start of this year, Congress has kept the Medicare physician fee schedule update at zero, freezing fees at their 2009 levels via three separate extensions. The latest lapsed May 31, and with no congressional intervention, a 21.3 percent fee cut took effect under the Sustainable Growth Rate (SGR) formula used to calculate the annual update.

Time is short to decide how to proceed on physician payments, and the legislative calendar is crowded with a host of big initiatives that both parties are jockeying over to gain advantage leading up to the volatile midterm elections in November. Some speculate the physician fee issue may have to be handled in a lame-duck session following the elections.

After the Centers for Medicare and Medicaid Services (CMS) June 18 began processing claims for services on and after June 1 with the cut, Congress approved H.R. 3962, replacing the cut with a 2.2 percent increase retroactive to June 1 through Nov. 30, 2010. President Obama signed it into law June 25. CMS this month began processing claims at the new rates. The increase results in a conversion factor of $36.8729, used to translate a service's relative value units (work, practice, and malpractice expense) into a dollar amount.

Unless Congress again steps in, physician payment rates are set to be cut 23.5 percent Dec. 1. Next year a cut of 6.1 percent is projected to kick in, according to CMS's June 26 proposed rule for the 2011 physician fee schedule. The combined cuts would result in a net drop of approximately 30 percent.

Indecision 2010

Lawmakers, divided over how to reform the SGR system, have punted on the issue, turning to temporary fixes, where the major sticking points are how long a fix, its cost, and how to pay for it without adding to the federal budget deficit.

The House late last year repealed the SGR and replaced it with updates tied to growth in the gross domestic product at a net cost of $210 billion over 10 years, but the change was not fully paid for, a point that caused a similar bid for SGR repeal in the Senate to fail this year. Since then, proposals have flown back and forth between the houses for a short-term fix, and its timeframe and cost have been steadily trimmed, from $65 billion for a fix through 2014, to $23 billion for a 19-month fix, to the final $6.4 billion for the 2.2 percent increase approved for the rest of this year.

The SGR Question

Repeal of the SGR is a top priority of medical groups, including pathology and clinical labs, as well as the AARP senior lobby, all of which have urged Congress to use the six-month reprieve to devise a different system that provides reasonable and predictable updates to Medicare physician fees.

The SGR formula was adopted in the Balanced Budget Act of 1997 as a way to restrain aggregate spending by Medicare under the physician fee schedule. If spend-

ing over a period is less than the cumulative spending target for that period, the update is increased. If the spending exceeds the target, future updates are reduced to bring it back in line with the target. In the first few years of the SGR, spending did not breach the targets and updates were granted. But the formula has required across-the-board reductions in physician payments every year beginning with 2002. Every year thereafter, the cuts have been averted by legislative action.

"Delaying the problem further is not a solution," AMA said in response to the latest fix. "It doesn't solve the Medicare mess Congress has created with a long series of short-term Medicare patches over the last decade. Congress is playing a dangerous game of Russian roulette with seniors' health care." AARP agreed, saying that while the latest patch "offers some hope, it is far from the permanent solution older Americans deserve. The short-term band-aid gives little reassurance to the 46 million Americans in Medicare who need reliable access to their doctors."

CMS also has weighed in on the controversy. "We are very concerned about the impact the continuing uncertainty about payment rates and cash flow disruptions may have on physician practices and on beneficiary access to physicians' services," said senior CMS official Jonathan Blum in a statement on the proposed 2011 rule.

"Although over 97 percent of physicians have chosen to participate in Medicare for 2010 and have agreed to accept Medicare's payment as payment in full for the services they provide to beneficiaries, we are hearing more stories of physicians limiting the number of beneficiaries they will see."

Options For a Fix

Congress has several options to think about before the current fix expires Nov. 30, according to a June 25 online article by the Robert Wood Johnson Foundation and the journal *Health Affairs*.

- ❑ Continue SGR targets but with modifications. For example, forgive past overspending and base future targets on actual current spending levels.
- ❑ End the SGR system and freeze future rates or let them rise with inflation. The cost of freezing fees at 2009 levels for 10 years: $276 billion.
- ❑ Set separate spending targets for different services, different geographic areas, or specific providers or groups of providers. "For example, Congress could allow more spending growth in primary and preventive care, while clamping down on such fast-growing areas as x-rays and other imaging services."
- ❑ Establish separate targets for areas with lower and higher average per capita spending, thereby constraining spending in high-cost areas.
- ❑ Set targets for specific providers who order an unusually high number of services, with reduced fee updates for those who fail to change behavior. This would be controversial because it would require consensus to distinguish inefficient providers from those who are treating difficult cases.

OIG Reassures Providers

The HHS inspector general will not impose sanctions for waiving retroactive beneficiary liability for Medicare cost-sharing due to the 2.2 percent payment rate increase retroactive to June 1 and applied to claims on that date of service and thereafter.

When a retroactive payment increase is applied, beneficiaries are liable for the difference between the original Medicare cost-sharing amount at the lower payment rate and the new, higher rate.

To avoid sanctions, providers and suppliers must apply the waiver to all affected beneficiaries and not offer it as part of an advertisement.

New Rules for Expanded Medicare Preventive Services

Starting Jan. 1 next year, the Medicare program will make major changes to benefits covered under its preventive services package that will affect payments under the physician fee schedule. The program will cover an annual wellness visit, following up on the currently covered one-time only "Welcome to Medicare" baseline physical exam. And it will pick up 100 percent of the tab for most of the other preventive benefits.

Cost Sharing Dropped for Most Medicare Preventive Services*

Deductible, Copay Waived	Yes	No
"Welcome to Medicare" initial preventive physical exam	X	
Optional electrocardigram as part of the physical		X
Annual wellness visit with personalized prevention plan services	X	
Abdominal aortic aneurysm	X	
Breast cancer: mammograms, Pap smears	X	
Cervical or vaginal cancer: pelvic exam, plus clinical breast exam	X	
Cardiovascular disease (lipids)	X	
Colorectal cancer	X	
Diabetes screening	X	
Diabetes self-management training		X
HIV screening	X	
Prostate cancer: PSA test	X	
Prostate cancer: Digital rectal exam		X
Glaucoma		X
Osteoporosis: bone mass measurements	X	
Medical nutrition therapy	X	
Vaccinations: influenza, pneumococcal, hepatitis B	X	

** Effective Jan. 1, 2011. CMS proposed rule for the 2011 Medicare physician fee schedule.*

Requirements for the expansion of benefits are set forth by the Centers for Medicare and Medicaid Services (CMS) in a June 26 proposed rule for the 2011 physician fee schedule. They implement provisions in the Patient Protection and Affordable Care Act (PPACA).

The rule also would implement incentive payments for primary care and promote access to health services in rural areas, CMS said. The agency will accept comments until Aug. 24 and will respond in a final rule to be issued on or about Nov. 1, 2010.

Elimination of Cost Sharing

Under PPACA, out-of-pocket costs for beneficiaries—the annual deductible and 20 percent copay—will be scrapped for most preventive services, including the new annual wellness visit, starting in 2011, at a cost of $110 million on a fiscal-year cash basis, CMS said.

The law waives the deductible and coinsurance for the initial preventive physical exam (IPPE) and the annual wellness visit and for Medicare-covered preventive services that have been recommended with a grade of A ("strongly recommends") or B ("recommends") by the U.S. Preventive Services Task Force (*NIR 10, 9/May 5, p. 5*). Also waived: the Part B deductible for tests that begin as colorectal cancer screening but, based on findings during the test, become diagnostic or therapeutic services. Clinical laboratory tests in the preventive services package are not affected. They are paid under the Medicare lab fee schedule, and beneficiary cost sharing is not required.

New Annual Wellness Visit

The annual wellness visit is "an opportunity for the physician and patient to develop a more comprehensive approach to maintaining or improving the patient's health and reducing risks of chronic disease," CMS said.

The law requires the annual wellness visit to include at least the following six elements:

- ❑ Establishes or updates the individual's medical and family history.
- ❑ Lists the individual's current medical providers and suppliers and all prescribed medications.
- ❑ Records measurements of height, weight, body mass index, blood pressure, and other routine measurements.
- ❑ Detects any cognitive impairment.
- ❑ Establishes a screening schedule for the next five to 10 years, including screenings appropriate for the general population and any additional screenings related to the individual patient's risk factors.
- ❑ Furnishes personal health advice and coordinates appropriate referrals and health education.

CMS is proposing to develop separate Level II HCPCS codes for the first annual wellness visit, to be paid at the rate of a level 4 office visit for a new patient (similar to the IPPE), and for the subsequent annual visits, to be paid at the rate of a level 4 office visit for an established patient.

CMS Delays July Start, *from p. 1*

services, and imaging to the list, using its discretionary authority under the law.

In announcing the delay, CMS said, "While the regulation will be effective July 6, we will, for the time being, not implement automatic rejections of claims submitted by providers that have attempted to enroll in the Medicare database. Until the automatic rejections are operational, providers should not see any change in the processing of submitted claims. They will continue to be reviewed and paid as they have been historically."

Without the reprieve, pathologists and clinical labs who provide services to Medicare patients referred to them by physicians who are not enrolled or re-enrolled in Medicare would take a serious financial hit.

The delay is needed, CMS said, to allow more time to streamline the PECOS process and sign up more providers and suppliers. "While more than 800,000 physicians and other health professionals have approved applications, some providers have encountered problems. We are continuing to update the process, and more providers have been enrolled in the past few days."

The PECOS-NPI match is intended to weed out fraudulent entities from legitimate health care providers and suppliers, making it harder for the former to bill federal health care programs.

CMS is vague on when it will fully implement the required match. Pathology and other medical specialties, clinical labs, and pharmacy groups have urged the agency to wait until Jan. 3, 2011, as CMS had planned earlier this year. Initially, CMS would have rejected claims as of Jan. 5, 2010, but delayed action until April 5, then again to Jan. 3 of next year, after running into enrollment and outreach glitches.

But CMS cautioned that though it is taking "a more deliberative approach to using the PECOS system, the agency will employ a contingency plan to meet the PPACA requirement that written orders, certifications, and referrals are only issued by eligible providers and suppliers, effective July 1, 2010." (*NIR 10, 10/May 25, p. 2*).

Berwick takes the helm at CMS as the agency grapples with implementing changes mandated by the health care reform law, including expansion of Medicaid, cuts in Medicare to slow spending growth, and a shift in Medicare from fee-for-service to alternative ways to pay for covered services.

Obama Installs Berwick, *from p. 1*

respect and support among leading hospital groups and others in the health care industry, as well as three former CMS heads who served in GOP administrations.

Berwick, a pediatrician, is founder and president of the Institute for Healthcare Improvement in Cambridge, Mass., and a professor at Harvard Medical School and the Harvard School of Public Health. He is widely known for advising and working with hospitals and clinics nationwide to reduce medical errors, improve information sharing, and deliver quality care while reducing its cost.

He has had extensive experience with government, chairing the National Advisory Council of the Agency for Healthcare Research and Quality and as an elected member of the Institute of Medicine, serving on its governing council from 2002 to 2007. He also has served as vice chair of the U.S. Preventive Services Task Force. In 1997 and 1998, he was appointed by President Clinton to the Advisory Commission on Consumer Protection and Quality in the Healthcare Industry.

NATIONAL INTELLIGENCE REPORT (ISSN 0270-6768) is published twice monthly (except August and December, which are one-issue months) by Washington G-2 Reports, 1 Phoenix Mill Lane, Fl. 3, Peterborough, NH 03458-1467 USA. Telephone: (973) 718-4700. Fax: (973) 718-0595. Web site: www.g2reports.com.

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