



MEDICARE REPORT



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Health Reform Changes, Payment Reforms, Quality Focus Top 2010 Agenda

Congress appears on the brink of sending landmark health care reform legislation to President Obama that will contain sweeping Medicare changes, but negotiations on the House measure (H.R. 3962) and Senate measure (H.R. 3590) by Democratic leaders must take place before a final bill is sent to Obama for his signature.

The two bills contain numerous similar Medicare provisions that likely will survive discussions between the two chambers. For example, the measures would improve Medicare coverage for prescription drugs and preventive services and implement major Medicare delivery system and payment reforms. And the bills The bills also implement several reforms to enhance quality and value for Medicare beneficiaries.

Whatever the outcome of reform legislation, Medicare regulatory changes and legal cases will proceed. Although the Centers for Medicare & Medicaid Services lacks a permanent administrator, changes to hospital payments, quality initiatives, physician payment changes, home health payment cuts, regulation of Medicare Advantage and Part D plans, and court cases involving Medicare reimbursement will continue in 2010.

Congressional Activity

Numerous sticking points on Medicare provisions in reform legislation will have to be negotiated between House and Senate Democrats. For example, the Senate bill would establish a new entity to set Medicare payment policy, a provision supported by Obama. Supporters say it would save \$28 billion over five years.

The House bill does not include such a provision, as lawmakers decided to mandate Institute of Medicine

Studies on Medicare geographic payment disparities around the country.

There are also several key differences between the bills on Medicare Advantage (MA) payment policy. The House bill eliminates MA overpayments by phasing them down over three years—putting them on par with fee-for-service provider payments. This policy would save \$154 billion over 10 years. Along with MA coding adjustments, the House bill would cut MA payments by \$170 billion.

The Senate bill does not eliminate overpayments, but, instead, establishes a new competitive bidding approach to set MA payments. That policy would save \$118 billion savings. Along with coding adjustments, the Senate bill would reduce MA spending \$120 billion.

The House bill also would phase out the so-called doughnut hole in the Medicare Part D benefit by 2019. Payments would be financed with industry drug rebates for those eligible for Medicare and Medicaid and with money from an agreement reached this summer by the industry, the White House, and the Senate Finance Committee.

In that agreement, the industry said it would contribute \$80 billion to help seniors pay for the cost of medications when they are in the doughnut hole.

The Senate bill includes the industry contribution and also would implement a one-time, \$500 reduction in the doughnut hole in 2010 only.

Hospital Reimbursement Provisions

Health reform dominated the hospital landscape in 2009 and will continue to do so in 2010.

In July 2009, hospitals reached an agreement with the Senate Finance Committee and assented to \$155 billion in Medicare spending reductions over 10 years to help pay for the reform bill.

In return, they were promised a permanent ban on new specialty hospitals; a budget-neutral, value-based purchasing program; and a hospital readmissions policy that would be limited to conditions where there is sound medical science and achievable health care outcomes. The reimbursement cuts also were linked to increased insurance coverage.

In terms of coverage, the Senate's Patient Protection and Affordable Care Act (H.R. 3590) expands insurance to 31 million more people in 2019, compared with current law, or 94 percent of all legal, nonelderly residents, according to the Congressional Budget Office.

Tom Nichols, senior vice president for federal relations at the American Hospital Association, told BNA in early December 2009 that the coverage numbers are not enough to justify the spending reductions.

The coverage numbers "have to go up or our cuts have to go down," Nichols said.

Nichols said the hospital group liked the coverage numbers in the House bill, which, according to CBO, would cover 36 million Americans in 2019 at a net cost of \$894 billion over 10 years. Nichols said the group hopes to work with lawmakers to ensure that when the bills are merged, the final numbers align more closely with those from the House than from the Senate.

Rick Pollack, AHA's executive vice president, told BNA Jan. 4 that Senate Majority Leader Harry Reid's (D-Nev.) manager's amendment (S. Amdt. 3276), which was incorporated into the final bill, did not do anything to improve the provisions AHA had problems with. However, he was realistic about policy changes as House and Senate Democrats merge the two bills.

"We want the bill to improve, but we want the process to move forward," Pollack said. "It's a mix and match" of different favorable provisions.

Other health care experts watching the reform effort have said that, although the Senate and House bills contain other provisions to improve quality and reform the delivery system, they have not received much attention

and should not be considered serious stumbling blocks to passage.

Payment Reform. Hospital payment is a continuing issue. On the reform side, independent consultant Larry Goldberg, Oakton, Va., said one of the more significant payment provisions in the Senate bill would substantially reduce the growth of Medicare's payment rates for most services, relative to the growth rates projected under current law.

The bill revises annual updates for inpatient hospital, long-term care hospitals, home health, skilled nursing facility, home health providers, and other providers, and incorporates adjustments to reflect productivity gains.

Under the House bill, the marketbasket payment update for inpatient hospitals, outpatient hospitals, skilled nursing facilities, long-term care hospitals, and other providers could not be less than 0 percent.

The Senate bill changed that provision, Goldberg said, and the result for hospitals could be negative payment rates-of-increase and a reduction in payment from the previous fiscal year, which "is a cause for concern."

Independent Board Concerns. The idea of creating an independent commission responsible for setting Medicare provider rates has been viewed by its supporters—most notably Sen. John D. Rockefeller IV (D-W.Va.)—as a viable approach for containing health care spending, but AHA's Pollack told BNA that the hospital group remains concerned over the proposed Independent Payment Advisory Board.

Although the provision appears only in the Senate bill, Pollack said hospitals are wary about having their reimbursement rates cut even further if it passes.

"We prepaid," Pollack said. "The \$155 billion [in cuts] is enough," Pollack said. Setting Medicare rates "is something Congress should do."

Hospitals and other providers would be exempt from any recommendations prior to 2019, something that Rockefeller, and Sens. Joseph I. Lieberman (I-Conn.) and Sheldon Whitehouse (D-R.I.) are attempting to change with an amendment.

Rockefeller has expressed concern with the provider exemptions, which are the result of an agreement reached last summer with the White House and the Senate Finance Committee, in which hospitals assented to \$155 billion in Medicare spending reductions to help pay for the reform bill (20 MCR 763, 7/10/09).

Under HR. 3590, the board would make binding recommendations for reducing Medicare spending, while maintaining quality and access, if Medicare per capita growth rates exceed targets, beginning in January 2014. The Board's proposals would be implemented automatically unless Congress enacts alternative proposals that achieve the same level of savings.

Hospitals and some other providers would be exempt from any recommendations prior to 2019. Since there is no provision regarding an independent payment board in the House's Affordable Health Care for America Act, Pollack said he hopes that the merged bill would eliminate the board altogether. Failing that, AHA would hope to keep the hospital exemption into 2019 and beyond.

One pharmaceutical industry expert told BNA the provision has the potential of dramatically changing how policy is developed in the Medicare program, since a group of un-elected individuals would be making de-

Top 10 Medicare Issues for 2010

According to a survey of the Advisory Board for *BNA's Medicare Report*, the top 10 Medicare issues for 2010 are:

1. Hospital Reimbursement: hospitals agreed to \$155 billion in Medicare payment cuts in exchange for support to require individual mandates for insurance coverage

2. Part D Drug Benefit: reimbursement gap (doughnut hole) could be phased out by 2019 in House bill, and secretary of health and human services could be required to negotiate prescription drug costs

3. Physician Payment: physicians supported health care reform measures to ensure congressional support for repealing the sustainable growth rate formula

4. Medicare Advantage: heightened regulatory environment with stricter rules, audits, and data collection requirements

5. Value-Based Purchasing: Hospital reimbursement levels will be governed by satisfactory compliance with selected quality markers

6. Accountable Care Organizations: establishment of ACOs, integrated delivery systems with legal structures allowing the organization to receive and distribute bonuses

7. Medicare Secondary Payer: mandatory reporting of MSP information by liability, no-fault, and workers' compensation insurance plans

8. Health Information Technology: CMS issues a notice of proposed rulemaking for "meaningful use" criteria for electronic health records

9. Independent Commission: Senate bill would establish a nonelected board of experts to set Medicare provider rates to bypass Congress's traditional role

10. Lack of CMS Administrator: Obama administration's failure to name permanent leader in first year leaves career management officials in charge of two massive health care programs

decisions behind closed doors that would not be subject to administrative or judicial review.

Quality Focus. The Senate bill attempts to build on the recent quality movement. It contains a number of hospital quality measures, and attempts to move providers toward a system of pay-for-performance that would tie hospitals' Medicare payments to quality measures, including the number of readmissions and hospital-acquired conditions.

It also would implement a budget-neutral value-based purchasing (VBP) program for hospitals. Blair Childs, senior vice president of public affairs at Premier Healthcare Alliance, a hospital group purchasing organization, said members of the group strongly support the VBP program as a way to reward high performing hospitals and to achieve best practices.

The House bill does not explicitly establish a hospital value-based purchasing program, but, according to the bill's text, it instead requires the Institute of Medicine (IOM) to consider the adoption of a value index based on a composite of quality and cost measures that would adjust Medicare provider payments on a regional or provider-level basis.

Yet Bruce Merlin Fried, an attorney at Sonnenschein Nath & Rosenthal in Washington, said it is a misconception to think that the House bill does not have a VBP provision.

Giving the IOM authority over hospitals "is a real different way to do health policy and would give a lot of people pause," but it is still VBP, Fried told BNA.

"The community writ large would be anxious to have anyone other than Congress driving" policy, so it makes sense that the Senate provisions would be popular with those in the hospital industry, Fried said.

He said it would be very likely that a final bill would have VBP provisions closer aligned with the Senate's version than what is in the House version. Still, he said, "the differences are reconcilable. Both [bills] are looking for incentives to achieve high performance. It will just be worked out."

Patient Readmissions. Childs said Premier did not agree with the fact that the Senate bill has multiple provisions that could cut hospital payments because of hospital-acquired conditions (HACs).

The bill includes a certain level of HACs as a measure hospitals must meet in determining VBP payments. Hospitals will see reduced payment if they are in the top 25 percent nationwide of HAC occurrences. Childs said hospitals are hit multiple times "for the same thing. We like that HACs are included in VBP, but an additional penalty for the top 25 is unnecessary. It's antithetical" to the reform effort, he said.

In terms of hospital readmissions, Childs said the Senate bill calls for a reduction in payment starting in 2013 if a patient is readmitted within 30 days. He said Premier would rather have seen a reduction policy based on a seven-day to 15-day readmission. Beyond that point, Childs said, the patient's condition is largely beyond the hospital's control.

Prior to the bill's passage, Nichols of AHA also disagreed with the approach taken to readmissions. Nichols said the group expected the Senate to adopt the narrower policy that was in the Finance Committee bill, but, instead, it adopted a much broader one that mirrored the House. The House bill would begin penalizing hospitals starting 2012, and would hold all hospital and post-acute providers accountable, including critical access hospitals.

Both bills reduce hospital payments for hospital discharges to account for "excess readmissions" for a limited number of conditions. Payment reductions would apply to all "preventable" admissions (whereas the Senate Finance bill limited reductions to discharges relating to excess readmissions).

Home Health Regulation. While Congress is focusing on passing reform, the Centers for Medicare & Medicaid Services will still set payments for hospitals, home health agencies, skilled nursing facilities, and other Part A providers through case-mix adjustments, prospective payment system (PPS) rules, and other regulatory means.

Home health agencies especially face cuts in 2010 and beyond due to a combination of reform and regulation. William A. Dombi, lead counsel for the National Association for Home Care and Hospice, told BNA the reductions in the reform bills “would seriously jeopardize the future of home health care and hospice.”

Dombi noted, however, that regulatory rate cuts “can far exceed any imposed through legislative action.”

The home health prospective payment system, which took effect Jan. 1, instituted a 2 percent marketbasket update and capped home health outlier payments at 10 percent per home health agency (HHA) for 2010.

Total aggregate outlier payments will be targeted at 2.5 percent of all home health prospective payments. The 2009 target for aggregate outlier payments is 5 percent, and the 2.5 percent drop in 2010 will increase home health base rates by 2.5 percent.

When the final rule was announced, Goldberg said the 2 percent marketbasket increase, coupled with a 2.75 percent case-mix reduction, “negates much of this year’s marketbasket affect.”

In fact, Goldberg said, CMS estimated that the net impact of the final rule, including the 2.75 percent reduction to the national standardized 60-day episode payment rates and the non routine medical supply (NRS) conversion factor, is approximately \$140 million in CY 2010 savings. That is, overall payments to home health agencies will decrease \$140 million in CY 2010 compared to CY 2009.

Hospital Regulatory Changes. On the regulation side, most hospital outpatient departments (HOPDs) will receive an inflation update in 2010.

According to CMS, total payments for services furnished to Medicare beneficiaries in HOPDs during calendar year 2010 will be \$32.2 billion, a \$1.9 billion increase over projected payments in CY 2009. The total projected CY 2010 payments under the ASC payment system will be approximately \$3.4 billion, CMS said.

Quality is a major concern in CMS regulations. The agency is establishing procedures to make quality measure data reporting publicly available as early as June 2010.

As required by law, CMS said it will reduce the CY 2010 annual inflation update factor by 2 percentage points for most services furnished by hospitals that failed to meet the CY 2009 reporting requirements of the Hospital Outpatient Department Quality Data Reporting Program (HOP QDRP).

CMS will continue to require hospitals subject to quality reporting requirements to provide quality data for the current seven chart-abstracted emergency department and surgical care measures and four claims-based imaging efficiency measures for CY 2011 payment determinations.

Secondary Payer. Robert L. Roth, an attorney with Crowell & Moring LLP, Washington, said the top item he is working on that is unlikely to be affected by the reform legislation is the mandatory reporting of Medicare secondary payer information by liability, no-fault, and workers’ compensation insurance plans, which started Jan. 1.

The requirement, he said, was mandated by the Medicare, Medicaid, and SCHIP Extension Act of 2007 (codified at 42 U.S.C. § 1395y(b)(8)). CMS expects the law will require more than 20,000 entities to report in-

formation to it. He said these entities historically have had no direct ties to CMS.

“Once CMS has this information, it will be better able to determine whether it is being reimbursed for ‘conditional’ payments made by Medicare for injury-related care to the extent required by the MSP provisions,” Roth said.

ASC Regulation. Since 2008, ambulatory surgical centers have been paid under a revised payment system that both aligns payment in ASCs and hospital outpatient settings by basing ASC payment rates on the ambulatory payment classification relative weights for similar services and extends payment to more surgical services in ASCs than under the prior payment system.

To minimize the impact of the revised payment system, the ASC payment rates calculated under the new rate-setting methodology are being phased in over four years. CY 2010 is the third year of the transition, CMS said.

CMS in 2010 will add 26 surgical procedures to the list of procedures for which Medicare would pay when performed in an ASC. CMS also is designating six procedures as office-based procedures (subject to payment at the lesser of the national office practice expense payment to the physician or the national ASC rate), and will update the list of device-intensive procedures and covered ancillary services and their rates.

CMS Administrator

The Obama administration entered 2010 without a permanent administrator at CMS. Health care experts were divided on the potential impact on reform, yet all seem to think one will be appointed in time to implement reform.

There has not been a permanent administrator in place since Mark McClellan left the agency in October 2006.

Eric Zimmerman, an attorney at McDermott, Will & Emery in Washington, told BNA he can understand the political thinking that likely went into the decision to not name an administrator. However, he said the decision has significant practical consequences.

“The administration is going to have a lot at stake with the implementation, which will be almost as important politically as enacting reform in the first place,” Zimmerman said.

“It is in the administration’s interests that the implementation go smoothly, that deadlines be met, and that Congress be satisfied. That will be a tall order without a good administrator,” he said. “It puts the agency at a disadvantage to not have a principal who was there at the creation.”

Fried, of Sonnenschein, said CMS “has suffered significantly” from the lack of an administrator. Fried was director of the Center for Health Plans and Providers at CMS’s predecessor organization during the Clinton administration.

“Too many decisions which should be made at the agency level are being made elsewhere in the administration,” Fried told BNA.

“Assuming the passage of a health care reform bill, CMS must hit the ground running to implement the major new programs” and without an administrator “who is settled and ready, that will not be possible,” Fried said.

Pollack of AHA said there will be an administrator appointed in time to implement reform. He said the question is not whether there will be someone in charge at CMS, but whether the agency has the resources necessary for such a massive undertaking.

“Implementing VBP, a center for Medicare innovation . . . these are all sophisticated things to do,” Pollack said. The agency is being given a lot of new authority, he said, and needs to be able to handle it correctly.

Roth said “one wonders whether the president might want someone intimately familiar with the health reform bills to oversee the implementation of whatever passes (assuming something does).”

Attorney Kenneth R. Marcus, with Honigman Miller Schwartz and Cohn, Detroit, said “when the administration of CMS is left to the career managers, one cannot expect innovation.”

Thomas A. Scully, an attorney at Alston & Bird in Washington and the CMS administrator from 2001-2003, said during a December 2009 conference that he was not concerned about the current lack of a permanent leader at CMS, and said he expects one to be appointed in the coming months.

Scully said the difference between a political appointee, which he was during the administration of President George W. Bush, and a career agency staff head, like interim administrator Charlene Frizzera, is that a political appointee can push innovative ideas.

Normally, innovative ideas are important, but with health reform, Scully said they are not necessary. Scully worked with Congress to pass the Medicare Part D drug benefit.

“When it’s just a matter of pushing what Congress does, you don’t need a political appointee,” Scully said. “The innovation is coming from Congress, not CMS.”

Physician Reimbursement

Like other providers, physicians began 2010 facing unfinished Medicare business as the House and Senate attempt to construct a compromise health care bill.

Spotlighted for Part B providers is the extension through Feb. 28 of the 2009 Medicare conversion factor that avoids a 21 percent pay cut that doctors were facing Jan. 1, created by the sustainable growth rate (SGR) formula. The two-month delay was part of a defense spending bill (H.R. 3326) that President Obama signed into law in December 2009.

In addition, the House in November 2009 passed a \$210 billion bill that would replace the SGR formula (H.R. 3961) and increase doctors’ pay by 1.2 percent in 2010.

Although the Senate has taken no action on the bill, Majority Leader Harry Reid (D-Nev.) said that work would begin on a permanent change to the reimbursement-lowering SGR formula in 2010.

However, skepticism among observers abounds about the outcome.

Matthew Farber, director, provider economics and public policy for the Association of Community Cancer Centers (ACCC), told BNA that “all indications are pointing to another short term fix for 2010 and possibly 2011.”

Farber expressed the belief that, particularly in an election year, Congress will not “have the stomach to spend another \$200 billion to \$300 billion to fix the SGR

formula, since they will have just passed a nearly \$1 trillion bill in the early part of the year.”

Instead, his group foresees Congress “giving a small update for 2010 and possibly 2011,” but not making SGR reform part of the health care legislation.

Report Due. Jason A. Scull, program officer for clinical affairs, Infectious Diseases Society of America (IDSA), told BNA that he believes Congress will postpone finalizing a long-term solution to physician reimbursement woes until after legislators receive a report on value-based purchasing (VBP), due in May.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA; Pub. L. No. 110-275) required CMS to develop a plan to transition to VBP payments for Part B providers with recommendations for legislative and administrative action.

Congress will refrain from finalizing “creative solutions” for a “physician fix” until after the CMS workgroup finishes the value-based purchasing plan, known as “PVBP,” Scull predicted.

However, another observer, Brian Whitman, associate director of regulatory affairs, American College of Cardiology, put less emphasis on the importance of the report, particularly with the departure from CMS in 2009 of the team leader, former medical officer and senior advisor Thomas B. Valuck. Whitman said that there has not been much discussion of it lately.

Despite the 60-day postponement of the 2010 physician reimbursement update, other Part B provisions, which provider groups had counted on as passing in health care legislation before 2010, went into effect on Jan. 1.

Those left behind include continuation of the “exception process” for the caps on outpatient physical therapy and speech pathology and on outpatient occupational therapy. This means that the \$1,860 caps took effect at the start of the year. CMS and its contractors reminded beneficiaries who exceed the caps and want to avoid paying out of pocket to obtain services in the outpatient department of a hospital.

Pending Exemptions. The House’s American’s Affordable Health Choices Act (H.R. 3962) extends the exemption until the end of 2011 and the Senate’s Patient Protection and Affordable Care Act (H.R. 3590) extends it to the end of 2010.

CMS said in December 2009 that providers may choose not to submit their claims until it becomes clearer whether new legislation will be enacted.

At the same time, CMS reminded pharmacies that their temporary exemption from the durable medical equipment (DME) accreditation requirement, which went into effect Sept. 30, 2009, for other suppliers, expired Jan. 1.

“We encourage all pharmacies going through the accreditation process to resolve any outstanding issues on your accreditation report,” CMS said.

H.R. 3590 would postpone the requirement and exempt pharmacies with less than 5 percent of revenues from Medicare DME billings. H.R. 3962 would exempt pharmacies that sell diabetic testing supplies, canes, crutches.

Regulatory Changes. Regardless of the ultimate disposition of health care legislative discussions, a number of regulatory changes for Part B providers go on as planned.

CMS, as part of the physician fee schedule published in November 2009, undertook a “pretty significant redistribution of payments of relative value units” following a new survey performed by the AMA and other medical groups, Whitman said.

Use of the data from the Physician Practice Information Survey (PPIS), which will be phased in over four years, hurt some specialists, such as cardiologists, more than others, he said.

In reaction, the ACC filed a complaint in federal court alleging that CMS unlawfully adopted the payment rates for cardiology services by using the PPIS in a manner that threatens access to care for patients and increases medical care costs (21 MCR 14, 1/1/10).

The ACC wants CMS to conduct a different survey to determine a new 2010 fee schedule for cardiology services.

Another change that went into effect on Jan. 1 involved an increase in the equipment utilization assumption—the amount of time that imaging equipment operates during the hours a physician office is open for business—for equipment valued over \$1 million.

The new year starts the four-year transition for non-therapeutic equipment from 50 percent of the time to 90 percent of the time in 2014.

If advanced imaging equipment is used more frequently, providers’ reimbursements per service are lower because the fixed cost of the machine is spread across more units of service.

The imaging changes and PPIS cuts combined will lead to some cardiologists selling their practices to hospitals, Whitman predicted.

Farber said he was thankful that the imaging cuts will not all take effect in 2010, as proposed. “CMS decided, after numerous comments against the cuts from groups like ACCC, to phase in the reductions over four years, giving both medical and radiation oncology a roughly 1 percent reduction for 2010,” he said.

MIPPA also required that Medicare payment be made only for the technical component of advanced diagnostic imaging services to a supplier that has been accredited.

CMS-designated accrediting organizations (AOs) would apply standards for medical personnel who furnish the technical component in mobile units, physicians’ offices, and independent diagnostic testing facilities.

The agency in November 2009 invited organizations to apply to become AOs and a panel will now evaluate the applications.

Consultation Codes. A big change for doctors in 2010 is the elimination of their ability to bill for consultations, referred to as “cognitive” work, requiring them to substitute codes for office and facility visits.

The American Medical Association predicted in early December 2009 that the new policy will result in “panic and confusion” among those who are aware of it, but that “of even greater concern, however, are the hundreds of thousands of Medicare participating providers who have no idea the change in policy is occurring.”

Without a delay in implementation, the AMA said that 2010 will be a time of payment denials, re-submissions, and appeals that could create claims backlogs, and cash flow problems that could lead some physicians to avoid treating Medicare beneficiaries.

The change mostly affects those who mainly do cognitive work rather than procedures.

The American Association of Clinical Endocrinologists said in December 2009 that the coding change “threatens to marginalize the critical role clinical endocrinologists play as consultants—at a time when our nation is facing a diabetes epidemic and we are striving to coordinate complex medical care for an increasing number of our patients.”

A membership survey indicated that most plan to reduce the number of Medicare patients seen in their practices, the group said in a statement.

Scull of IDSA also said that access for beneficiaries to infectious disease doctors could be reduced because consults are their “bread and butter.” Although Medicare bumped up the reimbursement level for evaluation and management services, these specialists “can’t cover their costs” based on code substitution, he said.

As an example, he said, one of the higher level consultation codes in 2009 paid \$203, compared to the closest substitution in 2010 for a hospital admissions that pays \$186.

Although CMS in December 2009 issued written guidance on the new coding process, Whitman forecast that it will take the year to iron out the issues.

In addition, it remains to be seen whether other payers adopt the Medicare change. Over the long term, many do follow Medicare, Scull said.

At least one major company—United Healthcare—said that while there will be no change to its commercial plans on consultation billing, it will follow CMS for reimbursing its Medicare Advantage plans by denying consults and increasing the values for evaluation and management services.

Incentive Programs. Incentive programs will play an increasing role in Part B and CMS and the AMA are hoping for fuller participation in the new year.

With reimbursement cuts to some specialists, such as oncologists, “many members are saying that they are trying to maximize every bonus payment possible, Farber said, including the Physician Quality Reporting Initiative and the electronic prescribing incentive program, “but that they are still coming up short with some Medicare patients.”

For claims-based reporting of individuals measures, providers must report at least three measures and report each measure for at least 80 percent of the fee-for-service patients during the reporting period.

The AMA lamented that while participation was on the rise, in 2008, “a mere 56 percent [or 85,000 of eligible professionals] were successful and received an incentive payment.”

For 2010, in addition to the current claims-based reporting mechanism, providers will be allowed to report the e-prescribing measure through qualified registries or through a qualified electronic health records product. Only registries and EHR products that qualify for the 2010 PQRI and have the capability to report the e-prescribing measure will be qualified for submitting data on the e-prescribing measure for 2010.

CMS also is expected to post a list of qualified registries for the e-prescribing incentive for which the registry is qualified and intends to report.

As required by MIPPA, the names of those who satisfactorily report in 2010 will, for the first time, be made public.

Quality Initiatives. Doctors also will be under scrutiny in CMS's resource use measurement and reporting program in which upwards of 3,000 reports to both individuals and groups will be distributed under Phase II of the program.

Emphasis on quality in Medicare provider services is also a theme in pending health reform legislation but would start over the next few years.

As examples, H.R. 3590 as amended would require a Physician Compare Website in 2013; require that beginning in 2014, physicians who do not submit measures to PQRI will have their Medicare payments reduced; and mandate adjustments to physician payments based on the quality and cost of the care they deliver, beginning in 2015.

Providers have until April 5 to enroll in CMS's Provider Enrollment, Chain and Ownership System (PECOS) if they want their claims to continue to be paid. Medicare will not pay claims for services unless the referring and ordering physician/health care practitioner is in PECOS or in the Medicare contractor's master provider file.

Although the deadline had been rolled forward from January, the AMA said it continues to believe that "more time is needed to re-enroll all physicians who refer or order services."

While CMS has said that claims will be paid if a provider who is not in PECOS is in the contractor's data base, "since this requires a data matching process, however, these claims could still be denied," the AMA forecast in December 2009.

The group was referring to the transition in 2008 to the National Provider Identifier in which data matching processes were used and "countless physicians saw their claims denied and experienced massive wait times for enrollment application processing."

The AMA wants CMS to suspend the plan indefinitely to deny these claims and wait until all physicians can be revalidated, re-enrolled, or enrolled for the first time in PECOS.

Enrollment requirements also apply to DME suppliers.

Competitive Bidding. Another program that applies to DME suppliers is the competitive bidding program.

After the close of the 60-day bidding window in December 2009, CMS began the bid evaluation process, a spokesman said.

In time for the start of the program on Jan. 1, 2011, in nine geographic areas, CMS expects in June to announce single payment amounts and begin the contracting process.

In September, the agency will announce the contracted suppliers and educational campaigns aimed at suppliers, referral agents, and beneficiaries.

CMS said it has implemented process changes to address some of the concerns raised in the first round of bidding, which was terminated in July 2008.

These include improvements to the on-line bidding system and enactment of the covered document review process in which suppliers were notified of missing required financial documents.

Also, as part of the bid evaluation process, CMS will be paying particular attention to suppliers that are new to an area or to a product category.

All suppliers, regardless of whether they bid, were required to be accredited by Sept. 30, 2009, to continue to

serve beneficiaries. Those that did not do so, were advised to formally disenroll from Medicare.

CMS said there were about 105,000 suppliers, including pharmacies, in October 2009. By Dec. 15, 2009, about 3,400 voluntarily terminated their supplier numbers and another 1,200 deactivated their numbers. About 11,000 numbers were revoked, but a CMS spokesman told BNA "that number may change because there are some in the accreditation queue and others in appeal."

Despite CMS's actions to improve bidding, the main suppliers' group on this topic expects difficulties to arise.

Michael Reinemer, vice president, communications and policy, American Association for Homecare, said that his group believes that the outcome of the rebidding in 2010 will be largely the same as the first round that was terminated because of problems in 2008.

"CMS will not allow most of the DME providers to continue serving beneficiaries—even if they agree to new, lower reimbursement rates—which means most of these providers will go out of business," Reinemer said.

"The result," he said, "will be fewer home care choices for seniors, less access to care, and ultimately a less competitive market since most of the competitors will have gone out of business."

Medicare Advantage

Regardless of the fate of numerous pertinent provisions pending in health care legislation, organizations that sell private health plans to Medicare beneficiaries will have to deal with a heightened regulatory environment complete with stricter rules, audits, and data collection requirements, and for Medicare Advantage plans—lower rates.

Even if health reform legislation were to "crash and burn," John K. Gorman, chief executive officer of the consulting company Gorman Health Group, said, major administrative changes are coming to Medicare and especially to Medicare Advantage.

MA plans "had an eight-year party under the Bush administration," he said. "The hangover is here."

Also, not only is MA a funding source for health insurance reform, Gorman said during a December 2009 teleconference, but if reform fails, MA monies could be used to eliminate a 21 percent cut for physicians and other Part B providers.

Regulatory Requirements. Following the first year of a Democratic administration, Medicare plans face mounting requirements.

The industry is "extensively regulated," Wendy Krasner, an attorney with Manatt, Phelps & Phillips LLP, Washington, said, with one of the latest goals being to improve beneficiary comprehension of their choices.

In addition to formal regulations, Krasner commented on the "astounding" amount of "subregulatory" guidance that emerges from CMS through memoranda and meeting materials. At the same time, she said, CMS "lacks tolerance for errors."

Early in 2010, CMS will have to finalize its proposed regulation, "Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2011 and Subsequent Contract Years," published on Oct. 22, 2009.

The proposal pertains to 2011 bids. CMS released the MA applications on Jan. 5, which starts the contracting process.

As part of the steps in the contracting process, applications for 2011 are due Feb. 25 and bids are due June 7.

In addition, the 2011 Call Letter, with its policy expectations and clarifications, is expected out early in the year. In 2009, a draft Call Letter for MA and Part D drug plans initially was posted in January, although it was retracted and revised in February.

Granular Requirements. Gorman pointed out that one type of MA plan in particular—special needs plans (SNPs) that serve beneficiaries who are dually eligible for Medicare and Medicaid, institutionalized, or have chronic illness—is subject to “super prescriptive granular requirements,” such as for models of care.

Moreover, he forecast that SNPs are like “the canary in the coal mine” in that other MA plans might soon have similar requirements.

Although the various requirements lead to higher operating costs for plans, he said Medicare payment rates for MA plans are down about 4.5 percent from 2009. Gorman said 2010 marks the first time that the Medicare risk program has been cut, with the previous low being a 2 percent increase.

Discussing what she described as a cyclical “love-hate” relationship the government has with Medicare health plans, Krasner said that, although the relationship is on the downside, she is not a doomsayer and believes that, at some point, private plans will again be in a hospitable environment. However, she added, in the meantime, it is important for plans to show they can offer a value proposition.

Data Collection, Validation. Reporting and validating data will be a big theme for MA plans in 2010. In response to what was determined to be a lack of “robust data,” CMS officials have told plans that one of the agency’s priorities is to increase performance levels through the use of data collection.

Data are used for CMS’s “five-star” ratings that allow beneficiaries to compare plans’ quality and performance on the Medicare.gov web site. The system also is being eyed by Congress as the basis for a new pay-for-performance program.

Draft standards and procedures for validating the data are expected to be released early in the year in advance of data validation audits to be conducted by external auditors in 2011.

These procedures are being developed by a contractor, and will be subject to public comment, after which they will be pilot tested, CMS said. The specifications will be utilized by auditors hired by the plans to conduct the data validation, the results of which will be forwarded to the agency.

Also in 2010, CMS said it plans to expand use of its Medicare Drug Integrity Contractor (MEDIC) and a “surveillance console” as a way of transmitting to plans problems it observes during marketing and enrollment activities.

Market Trends. Market consolidation is already here, Gorman said, particularly for MA and prescription drug plans (PDPs) with low membership.

He foresees 30 percent fewer plans contracting with Medicare by 2014. Of 750 companies, 500 will remain

by 2014 “as a result of the new environment,” he forecast.

As for specific types of MA plans, the preferred provider organization’s (PPO) “space is getting very crowded as the curtain begins to fall” on private fee-for-service (PFFS) plans in 2011, he said.

Beginning in 2011, non-employer PFFS plans in areas having at least two network-based plans must develop networks; all employer PFFS plans must be network-based.

As of Dec. 1, 2009, CMS had 69 contracts with PFFS plans, compared to 77 the year before.

Gorman said that by 2014, the 2.4 million Medicare beneficiaries enrolled in PFFS plans will be down to 600,000, mostly in rural areas. He forecast that not many PFFS enrollees will return to traditional Medicare and instead will opt to enroll in a PPO. This is particularly true for more affluent baby boomers who enter the program in 2011. Others will see that a PPO is better value than a stand-alone PDP, he said.

He characterized SNPs, authorized to the end of 2010, as “on standby” until the outcome of health care reform is known. The House bill extends authorization for dual eligible SNPs to the end of 2015 and for other types to the end of 2012. The Senate bill extends the program through the end of 2013. Both bills place other restrictions on SNPs.

Payment Proposals. The House and Senate bills make a large number of other changes to MA plans, including the payment method.

“Although the House and Senate bills take somewhat different approaches to changing the MA program, they both attempt to achieve the same goal of eliminating the extra payments,” Brian Biles, a professor in the Department of Health Policy in the School of Public Health and Health Services at The George Washington University, said in a brief issued Dec. 21, 2009, by the Commonwealth Fund.

“These bills’ common strategy is to encourage MA plans to provide coordinated care for their enrollees more efficiently and effectively than could be provided under the traditional Medicare program,” he said.

The House’s H.R. 3962 would phase in a three-year reduction of MA county payment rates to 100 percent of traditional Medicare by 2013.

The Senate’s H.R. 3590 would phase in a competitive bidding system based on the average of bids received from plans in each market. Payments would be weighted by the numbers of MA plans’ enrollees in a state’s metropolitan areas and individual rural counties.

Although the Senate bill is largely thought of as the one that will emerge from conference committee negotiations, Gorman said he believes that on MA payments, the House will prevail and that bidding will not be in a final bill.

The various ramifications of a new system could be “very messy,” he said, including the use of anti-competitive strategies by plans to initially drive out competition in certain markets.

Larger plans could “dip into reserves to under-bid in key markets and drive out smaller competition,” he said. Bidding below parity with traditional Medicare would lead to rates well below the level of traditional Medicare, he said.

Moreover, a new bidding system could be plagued by design issues, he said. For instance, he questioned how SNPs would bid in the same market as PPOs.

Krasner said that if competitive bidding does pass, it would be so complicated that it will take years to implement. It could also lead to bid protests, she said.

Both bills have increased penalties for marketing violations and additional compliance measures.

An MA pay-for-performance bonuses based on CMS's five-star system would cover part of the cuts for certain plans.

The House bill creates an incentive system to increase payments to high quality plans in low-cost areas in 2011-2013. The Senate would create bonuses based on a plan's level of care coordination and care management and achievement on quality rankings.

"The role of private plans in Medicare is at risk if this industry doesn't deliver" higher quality care and lower costs, Gorman said. The plans that will survive in this "toxic" environment will be the ones that are able to demonstrate improved outcomes in the care of chronically ill enrollees.

Part D Coverage Gap. Compared to MA, the reform legislation enhances the Part D prescription drug plan (PDPs) program.

Currently, PDP enrollees are required to pay 100 percent of drug costs after spending exceeds the initial coverage limit and before reaching catastrophic coverage limit. A study by the Kaiser Family Foundation in November 2009 found that for 2010, 80 percent of PDPs and 48 percent of MA-PDs do not offer gap coverage.

The House measure would eliminate the Part D coverage "doughnut hole," beginning in 2010 by increasing the initial coverage limit by \$500 and completing the phaseout by 2019.

In other words, the bill would increase the dollar level at which the doughnut hole starts and lower the level at which it ends each year until the gap is closed in 2019.

The Senate bill only includes a one-time, one-year \$500 reduction of gap coverage in 2010.

Both bills include the PhRMA agreement to cover 50 percent of the cost of brand name drugs in the coverage gap, starting in 2010.

In addition, the House bill requires HHS to negotiate Part D drug prices, while the Senate bill lacks a similar provision.

Medicare Cases to Watch

Attorneys told BNA they are following several legal cases regarding Medicare reimbursement that may be decided in 2010.

Public Disclosure of Physician Claims. In 2010, the U.S. Supreme Court will decide whether to review an appeals court's decision in *Consumers' Checkbook Center for the Study of Services v. HHS*, U.S., No. 09-538, petition filed 10/30/09, which denied the release of Medicare claims by physicians under the Freedom of Information Act (FOIA) to a Washington consumer group.

The petition, submitted by Consumers' Checkbook Center for the Study of Services (CSS), argued that the U.S. Court of Appeals for the District of Columbia Circuit erred in holding that the statutory obligations of the Department of Health and Human Services in overseeing the Medicare program and promoting quality in

Medicare services do not create a "cognizable public interest" in monitoring how well HHS is fulfilling its statutory duty to promote quality.

When the Centers for Medicare & Medicaid Services refused to provide data in Medicare reimbursement claims forms submitted by physicians in specified states for medical services provided during 2004 as requested, CSS brought the action in district court, which found the asserted privacy interest to be "minimal."

However, on appeal by HHS, the D.C. Circuit reversed the district court's decision to allow CSS to see documents disclosing records for Medicare claims by physicians after finding that the disclosure of the information would constitute a clearly unwarranted invasion of the physicians' personal privacy.

CSS also argued in its petition to the Supreme Court that the appeals court's decision undermined FOIA's objective of exposing the workings of government to the public. CSS contended that the requested data would allow the public to monitor HHS's compliance with its general statutory obligation to promote quality in health care and would allow the public to evaluate the extent to which CMS is issuing reimbursements for fraudulent claims or unnecessary procedures (20 MCR 1424, 11/20/09).

Resident Training. In a case that may be decided in 2010 by in the U.S. Court of Appeals for the Sixth Circuit, *Covenant Medical Center Inc. v. Sebelius*, 6th Cir., No. 09-2443, docketed 11/10/09, a hospital is appealing a district court's decision that Covenant Medical Center Inc., based in Saginaw, Mich., failed to comply with a regulation requiring hospitals seeking Medicare reimbursement for training of residents in nonhospital settings to have a written agreement in place with each nonhospital site.

The district court held that a written agreement requirement is a reasonable way for the health and human services secretary to verify that a hospital is actually incurring the costs for which it seeks reimbursement. The regulation was ultimately rescinded, but the court found that had no bearing on its validity while it was in effect (20 MCR 1126, 9/18/09).

Attorney Kenneth R. Marcus, whose law firm Honigman, Miller Schwartz and Cohn, Detroit, represents Covenant, told BNA a decision on *Covenant* will be the first court of appeals decision regarding Medicare payment for residents rotating to the nonprovider setting.

"The core issue relates to the "written agreement" requirement between the hospital and the 'nonprovider' setting for purposes of claiming Medicare direct and indirect medical education for resident rotations to the nonprovider setting," Marcus said.

Marcus also referred to a similar case (*Kingston Hospital v. Sebelius*, N.D.N.Y., No. 1:09-cv-01303-GLS-RFT, filed 11/20/09) that is pending in the U.S. District Court for the Northern District of New York. Kingston Hospital, a teaching hospital in Kingston, N.Y., is appealing a decision by the Provider Reimbursement Review Board, which upheld the fiscal intermediary's adjustment to the direct graduate medical education and indirect medical education full-time equivalent counts after finding the hospital was not in compliance with the regulation's requirements for a written agreement (20 MCR 1323, 11/6/09).

Hospital-Based Nursing Facilities. Marcus is following another case that just held oral argument on Jan. 5 (*Montefiore Medical Center v. Sebelius*, D.C. Cir., No. 08-5489, oral argument 1/5/10) in which the HHS secretary appealed a district court's determination that a hospital-based skilled nursing facility of Montefiore Medical Center, Bronx, N.Y., was entitled to \$2.4 million in reasonable costs for treating Medicare patients.

The core Medicare payment issue is the validity of *Medicare Provider Reimbursement Manual Section 2534.5*, Marcus told BNA.

"This provision relates to a hospital-based skilled nursing facility's exception request regarding its Medicare cost limit," Marcus said. "Additionally, the case presents a significant Administrative Procedure Act issue because, arguably, PRM § 2534.5 did not comply with APA notice and comment rulemaking."

The district court held that the government violated the APA by relying on an interpretation that substantially reduced the reimbursement amount from previous years. The HHS secretary asked the appeals court to reverse the district court's decision, arguing that PRM § 2534.5 is an interpretive rule that is exempt from the notice and comment requirement of the APA (19 MCR 1117, 10/3/08).

Disproportionate Share Adjustment. An ongoing case to watch this year is *Baystate Medical Center v. Leavitt* (D.D.C., No. 1:06-cv-0263-JDB, 3/31/08), in which a federal district court directed the HHS secretary to correct disproportionate share hospital (DSH) payments after finding Medicare arbitrarily and capriciously failed to use readily available data in calculating the original adjustments.

A briefing set for Jan. 15 on two counts remaining in a ground-breaking decision may not take place if Baystate Medical Center, in Springfield, Mass., is not satisfied with the data supplied by the Centers for Medicare & Medicaid Services under orders of the U.S. District Court for the District of Columbia and thinks the data is inadequate or incorrect, John R. Jacob, an attorney with Akin Gump Strauss Hauer & Feld LLP, Washington, told BNA.

Under the landmark decision that could involve millions of dollars, the court directed the HHS secretary to correct disproportionate share hospital (DSH) payments after the court found Medicare arbitrarily and capriciously failed to use readily available data in calculating the original adjustments for fiscal 1993 to 1996. The court, however, granted deferment of an alternative argument by Baystate that the secretary turn over certain Supplemental Security Income (SSI) entitlement records from the Social Security Administration that would allegedly affect the amount of the adjustments (19 MCR 355, 4/4/08).

The decision by the court ordering the secretary to revise the calculations for the DSH payments related to count one, in which the court agreed with Baystate's argument that the secretary computed the SSI, which is the Medicare fraction used in calculating DSH payments, in an arbitrary and capricious fashion, Jacob said. Counts two and three relate to getting access to data that CMS used to recalculate the SSI fractions.

"For as long as the DSH adjustment has been available, the SSI has been an unknown—the ultimate 'black box,' and no one knew how it was calculated," Jacob

said. "Now for the first time, the court ruled that CMS's calculation was arbitrary and capricious."

When revising the Medicare fractions, CMS issued a revised notice of program reimbursement, which fixed the Medicare fraction and provided additional reimbursement to the hospitals, Jacob told BNA. However, CMS did not release additional information to explain what was done to fix the SSI fractions, although the court decision enumerated a number of serious errors, which was disturbing, given the instructions by Judge John D. Bates, Jacob said.

Although Baystate repeatedly requested the information, the government was very slow in providing the data. In November 2009, Baystate finally received information that purports to tie to the numbers used in the revised SSI fractions, Jacob said.

"We will shortly see whether Baystate is happy with the data and all of its questions were answered," Jacob said. "But, if Baystate has determined the data is inadequate or incorrect, I suspect they will push for further litigation on counts two and three."

Jacob told BNA that CMS has always been very reluctant to turn over data it uses to calculate the SSI fractions.

"For the first time a court has said this was done improperly," Jacob said. "This is good news for a lot of hospitals that have appeals before the [Provider Reimbursement Review Board]."

Jacob said that the interesting unknown is how big the reimbursement impact is. He added that litigation will probably continue on the issue.

Stark Law Case. Thomas S. Crane, with Mintz, Levin, Cohn, Ferris, Glovsky and Popeo PC, in Boston and Washington, told BNA that the case, *Council for Urological Interests v. Johnson*, D.D.C., No. 1:09-cv-00546-HHK, is a very important case to watch in 2010.

According to Crane, the U.S. District Court for the District of Columbia will have the opportunity to reconsider the "ill-considered decision" in *Colorado Heart Institute v. Leavitt*, D.D.C., No. 1:08-cv-01626), which denied jurisdiction to cardiologists seeking to challenge the inpatient prospective payment system 2009 Stark II law change to the definition of the designated health services (DHS) entity. Crane, who was lead counsel for the plaintiffs, said the implication of the *Colorado Heart Institute* decision is that physicians can virtually never bring a pre-enforcement challenge to a Stark law regulation.

"Not only will the [*Council for Urological Interests*] court revisit this jurisdictional issue, but if it finds jurisdiction, it will substantively rule on the DHS entity definition as well as the per-click restrictions made at the same time," Crane said. "Both these changes became effective on October 1, 2009."

The Stark law prohibits the referral of Medicare and Medicaid designated health services to an entity in which the referring physician has a financial interest, regardless of the setting in which such services were provided or the payment category under which they were billed. When a hospital or physician group leases large medical equipment, payments are contracted on a unit of service, or "per-click," basis, which means that every time a hospital or physician group uses the leased piece of equipment, it must pay the lessor.

In *Colorado Heart Institute*, the district court dismissed a challenge to a recent change to the Medicare

physician self-referral rules that, they claimed, would destroy their businesses.

The court said it did not have jurisdiction over the action because the plaintiffs, a group of cardiologists and the cardiac catheterization laboratories they own and operate, could get their claims heard administratively, even though they could not directly bring an administrative challenge to a change in the regulation interpreting the Stark law (20 MCR 454, 4/24/09).

Other Legal Issues to Watch. Another case to watch in 2010 is *Cape Cod Hospital v. Sebelius* (D.C. Cir., No. 09-5447, appeal docketed 12/29/09), in which five hospitals asked the U.S. Court of Appeals for the District of Columbia Circuit to review a trial court decision that found they could not pursue their claims because an alleged flaw in a final rule that determined the 2007 rates under the Medicare prospective payment system was reversed in a 2008 final rule and had no further impact on PPS rates (*see related item in the legal section*).

In an action scheduled for trial in 2010 in the U.S. District Court for the Southern District of Florida, the United States alleged that Christi Sulzbach, a former general counsel and corporate integrity program director at Tenet Healthcare Corp., violated the False Claims Act by submitting false certifications to Medicare (*United States v. Sulzbach*, S.D. Fla., No. 07-61329, order setting trial 1/5/10). Judge Kenneth A. Marra sched-

uled the bench trial for April 5, 2010, and set a calendar call for April 2, 2010.

According to attorneys familiar with the litigation, the case is important because it raises a question about the advisability of appointing a general counsel to the position of compliance officer and essentially focuses on whether the general counsel can conduct his, or her, duties as a compliance officer with the requisite level of independence.

On the administrative front, Eric Zimmerman, an attorney with McDermott, Will & Emery, Washington, told BNA that he is watching closely budget neutrality adjustment appeals currently pending before the Provider Reimbursement Review Board. These cases affect several hundred hospitals with sole community hospital (SCH) and Medicare-dependant hospital (MDH) status, and are claiming more than \$100 million in lost reimbursement, he said.

Finally, a proposed class action filed by Medicare beneficiaries challenging the collection practices used to recover Medicare reimbursement claims under the Medicare Secondary Payer program will continue in 2010 after the U.S. District Court for the District of Arizona denied a motion by the health and human services secretary to dismiss the action. The court scheduled a conference for Jan. 21, 2010 (20 MCR 1463, 12/4/09).

By BY STEVE TESKE, JUDITH A. THORN, NATHANIEL WEIXEL, AND MINDY YOCHELSON