



MEDICARE REPORT



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Medicare Drug Benefit, Physician Payment Top Congressional Agenda

Congressional health aides and health care experts interviewed by BNA predict 2007 will be a busy year for Medicare issues in Congress, with the Part D prescription drug benefit, physician payment, and the beginning of debate on the future of federal entitlement programs taking center stage.

Debate over Part D, physician payment, and Medicare reimbursement for managed care plans will coincide with numerous other initiatives and actions by the Centers for Medicare & Medicaid Services to implement payment changes for hospitals, home health facilities, and durable medical equipment suppliers. Finally, in the courts, 2007 will see a U.S. Supreme Court decision on the "original source" rule in the False Claims Act and hospitals will continue to follow court interpretations of rules for Medicare disproportionate share payments.

On Capitol Hill, health aides acknowledged that congressional pay-as-you go rules, requiring new spending to be taken from other programs, likely will hamper passage of sweeping new initiatives.

Aides predicted that health care issues would become one of lawmakers' top priorities, a prediction that bore out, as House Democrats submitted legislation (H.R. 4) one day after convening. The bill would authorize the federal government to negotiate with drugmakers the prices Medicare will pay for prescription drugs.

The Senate is likely to follow the House's lead on this issue, aides said, but pointed out that quick action is unlikely because the Senate will hold hearings first to craft legislation.

Providing funding for a temporary or long-term fix for Medicare's physician payment system will be a "really heavy lift[]" in 2007, Senate Finance Committee

Republican aide Mark Hayes said at a recent briefing sponsored by the Alliance for Health Reform.

It also remains unclear whether President Bush would veto any legislation and whether Congress could muster an override vote, aides said.

Bush Budget. President Bush in his fiscal 2008 budget proposal is expected to put forward Medicare spending reductions.

"I'm prepared for a very severe budget on Medicare" from the White House, Federation of American Hospitals President Charles N. Kahn III said, but health care and tax lobbyist Frederick H. Graefe, Washington, told BNA that, in a Democratic Congress, Bush's proposed Medicare cuts "will be dead on arrival."

Kahn said it could be difficult to move Medicare legislation in 2007, particularly in the Senate, where a bill

Top 10 Medicare Issues in 2007

According to a survey of *BNA's Medicare Report* Advisory Board, the top 10 Medicare issues for 2007 are:

1. Medicare Part D Benefit: Price Negotiation
2. Revision of the Physician Payment Formula
3. Medicare Advantage Funding Levels
4. Part D Benefit: Possible Program Changes
5. Stability of the Medicare Trust Fund
6. Hospital Payments: Reducing Increases
7. Home Health Care: Revision of Current PPS
8. Hospital Disproportionate Share Payments
9. MA-PD Participation Rates
10. Pay-for-Performance Programs

to increase doctors' pay, for example, could attract numerous other amendments. That problem could be solved, he said, by including the fix in a budget reconciliation bill.

Bush's fiscal 2007 budget blueprint "contained a number of significant spending cuts to the Medicare program designed to reduce Medicare expenditures by \$36 billion over five years and by \$105 billion over 10 years," Barbara B. Kennelly, president of the National Committee to Preserve Social Security and Medicare, said. "We believe the President's FY 2008 budget will contain similar cuts to the Medicare program."

In particular, Kennelly, a former Democratic congresswoman from Connecticut, said Bush may propose "automatic across-the-board cuts to all Medicare providers" and the elimination of the inflation-adjusted income thresholds for the means-tested Part B premium.

An examination of Medicare payments to managed care plans also is likely this year, Bridgett Taylor, Democratic staff aide for the House Energy and Commerce Committee, said at the Alliance briefing. Expect Democrats also to convene numerous oversight hearings on Medicare, according to staff aides and those interviewed by BNA.

"I expect 2007 to be a big year for Medicare legislation," McDermott Will & Emery LLP attorney Eric Zimmerman said. "There is incredible built up demand. It's been more than three years since Congress advanced major Medicare legislation, and there are many areas that cry out for attention."

Zimmerman, based in Washington, said "[a]nything Democrats try to do to the prescription drug benefit, Medicare Advantage program, or physician fee schedule will serve as a vehicle for a variety of other provisions."

Part D Legislation. The House began work as soon as it convened on the Medicare Part D negotiation bill. On Jan. 5, House Democrats introduced H.R. 4, the Medicare Prescription Drug Negotiation Act of 2007. A House vote on the measure is expected Jan. 12 (*see related item in the Legislative News section*).

Aides have predicted these bills will pass the House quickly.

"I think there's a good chance [Part D] negotiation legislation could pass the House," Johnson & Johnson Senior Counsel Michelle Fried told BNA.

"Many of the House members used this issue in their campaigns and it is one of [House Speaker Nancy J.] Pelosi's [(D-Calif.)] top priorities," Fried said. "That said, I think this type of legislation would not likely pass the Senate, given the very slim margin of Democrats and the fact that [Senate Finance Committee Chairman Max] Baucus [(D-Mont.)] has not previously supported it."

The content of the Medicare negotiation bill in the Senate will be determined after hearings by the Finance Committee, Kate Leone, senior health counsel to Senate Majority Leader Harry Reid (D-Nev.), said at the Alliance briefing. Since Senate Minority Leader Mitch McConnell (R-Ky.) has said he will oppose such a measure, 60 votes likely will be necessary to pass it, she said.

The Senate Finance Committee was scheduled to hold a hearing on the issue Jan. 11.

Similar legislation, offered by Sens. Olympia J. Snowe (R-Maine) and Ron Wyden (D-Ore.), passed the Senate in March 2006 with 54 votes, and in the November 2006 election, Democrats picked up some Republican seats. Leone said the committee has started canvassing lawmakers for their views on the issue.

'Tremendous Mountain.' "It goes without saying that this is a tremendous mountain for Democrats to climb," Medicare and Medicaid consultants from the Gorman Health Group, Washington, said in a Nov. 9, 2006, statement on Medicare drug pricing legislation.

"Should such a resolution be introduced in the House, it is unlikely any new legislation on this could pass the Senate," the Gorman group said. "[E]ven if such a bill could pass both chambers, it would assuredly be vetoed by the Bush White House."

Attorney Wendy Krasner, with Manatt, Phelps & Phillips LLP, Washington, said repealing the non-interference clause could have a significant effect beyond the pharmaceutical industry.

"While it may be portrayed as a simple act to allow the Secretary to negotiate drug prices, it is a very complicated and nuanced issue with major political, financial, policy, and structural issues impacting many aspects of our health care system, not just plans and pharmaceutical companies," Krasner said.

On the issue of direct price negotiations, some Democrats have argued that HHS should be allowed to negotiate for lower drug prices like those paid by the Department of Defense and Department of Veterans Affairs, despite some evidence that suggests CMS could not effectively negotiate such lower prices.

For example, John Gorman, president of Gorman Health Group, explained that DOD and the VA are unrealistic comparisons for direct government negotiations for Part D drug prices because both systems function like staff model HMOs in which physicians are employees and formularies are narrower, tiered, evidenced-based, or restricted. Furthermore, he said, physicians' prescribing patterns are monitored and are used to determine pay-for-performance bonuses.

Although Democrats have called attention to the price negotiation issue, some industry watchers called the move an attempt to gain ground for a government-run alternative to private Medicare Rx plans.

In addition to allowing Medicare to negotiate lower drug prices, Congress also is likely to examine ways to get more low-income program enrollees coverage under Part D, the Democratic aides said.

Lawmakers also could push for other incremental changes to the drug benefit, including the areas of pharmacy contracting, beneficiary open enrollment policies, and the overlap of Part B and Part D drug coverage in outpatient settings, Hayes added.

Filling the so-called doughnut hole in Part D coverage is "on the radar screen for just about every member," Leone said, but she and the other aides said filling it completely would be prohibitively expensive. Hayes said it would cost \$400 billion over 10 years to fill the doughnut hole.

Leone said lawmakers could take steps to begin to fill it, while Hayes added that allowing more low-income individuals to qualify for help by revisiting the assets test could keep more enrollees out of the doughnut hole, since low-income individuals are not subject to the doughnut hole under the Medicare drug law.

Democrats will have to tread carefully when proposing changes to the drug benefit since surveys have found the majority of seniors are happy with it, according to some interviewed by BNA.

"Democrats have a real shot at keeping the House for some time," Brent V. Miller, director of federal government relations for the Marshfield Clinic in Wisconsin, said. "They need to be cautious about what they attack. The 80 percent of seniors that are happy with the Medicare Part D will not tolerate a complete overhaul of the program."

Physician Payment. Crafting a new physician payment system under Medicare also will challenge lawmakers as they consider such issues as whether a new payment formula can be crafted that can control overutilization of services, Hayes said.

The Medicare Payment Advisory Commission is expected to issue a report on the issue early in 2007, which will contain reform recommendations lawmakers could draw from, he added.

Lawmakers in the waning hours of the 109th Congress passed legislation eliminating a scheduled 5 percent Medicare payment cut for physicians scheduled to be implemented Jan. 1, and also included a 1.5 percent bonus for physicians reporting quality data.

Hayes said lawmakers are likely to revisit the quality reporting issue when they again tackle the physician pay issue, perhaps considering expanding the provision or requiring public comparison of quality measures.

Managed Care. Medicare payments to managed care plans also will be the subject of congressional scrutiny, with hearings on the issue likely in the House Energy and Commerce Committee, Taylor said. Other observers said they do not expect business as usual for Medicare Advantage with the new Democratic Congress.

Taylor said Democrats are concerned that Medicare is paying managed care plans as much as 119 percent of fee-for-service rates. One troubling federal policy is that Medicare is giving teaching hospitals and managed care plans indirect medical education payments. "Paying the same thing to two different entities is ridiculous," she said.

Health plans lost one battle to protect their funding when Congress in December 2006 voted a significant reduction in the managed care stabilization fund con-

tained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

"It will be a stable to rocky road for [MA organizations] for the next two years due to congressional funding cuts," Ken Yale, with Matria Healthcare Inc., predicted.

Jane Galvin, director of regulatory affairs at the Blue Cross and Blue Shield Association in Washington, said there are some "who think MA plans should be funded at the traditional Medicare expense amounts even though the Congress bumped up MA payments in the rural areas to attract new plans."

She added that "now that access to MA plans is almost at the 100 percent level, some think the plans are paid more than they should—so we are back to a funding dilemma."

Vice President of Public Affairs for America's Health Insurance Plans Mohit Ghose said AHIP will be working to show members of Congress the advantages of MA plans and that cutting back could have a detrimental affect on their constituents. He said the "Coalition for Medicare Choices" (14 MCR 531, 5/16/03) will be revived to show lawmakers the value of MA plans at such venues as town hall meetings and visits to senior homes.

Vicki Gottlich, senior policy attorney for the Center for Medicare Advocacy Inc., said that, while hearings are likely, Congress would be too divided to cut MA funds this year.

Gorman also said he does not believe "Congress has the votes to enact any major legislative fix to the MMA before 2009, and even if they squeaked something through, it would be veto bait for the President, without the votes to override."

Medicare Trust Fund. Under MMA, Medicare's trustees must determine whether projected general revenue funding exceeds 45 percent of Medicare financing within the next seven years.

If the Medicare trustees make such a determination two years in a row, a Medicare funding warning will be given, mandating that the president propose legislation to respond to the warning in his next budget submission. The law then requires Congress to consider the proposal on a fast-track basis.

The trustees issued their first warning in early 2006, and are likely to issue a second one in 2007, triggering the drug law provision and likely a discussion on entitlement spending, Hayes said.

Hayes said he hoped the funding warning would "serve as a jumping off point for the public to see what's really at stake" regarding the growth in entitlement spending, but the warning likely will not spur Congress to take any immediate action.

Leone said a funding warning "generating any kind of hysteria is probably misplaced," particularly since rising health care costs are plaguing the entire health care system.

Democrats and beneficiary advocacy groups in the past have expressed concern the trigger could lead to program cuts and/or increased beneficiary co-sharing. Repealing the trigger "is not something that will come easily" given the fiscal conservatism of conservative to moderate Democrats, such as those in the Blue Dog coalition.

Part D Program Predictions

Regardless of what, if any, changes Congress makes to the Part D program, most industry observers expect beneficiaries to make few plan switches in 2007, although they also expect plans to continue experiencing some of the same systems problems as in 2006 but to a lesser degree.

HIP Health Plans Legislative Affairs Senior Vice President George Strumpf said that late December enrollments could cause problems for plans as they try to meet CMS requirements that plans send all enrollment materials to new enrollees before the effective date.

While plans have procedures in place to ensure beneficiaries are able to get prescriptions filled shortly after enrollment, Strumpf said, “the subsequent reconciliations with CMS and other Part D plans often take considerable time, effort, and administrative expense.”

The plan switches that do occur could cause some early-in-the-year administrative hiccups, particularly among low-income subsidy beneficiaries, Johnson & Johnson attorney Michelle Fried said.

Lehman Brothers Health Care Services Senior Vice President Joshua Raskin and Gorman agreed, saying plans could face greater administrative snags for dual eligibles enrolled in Part D in 2006 who were re-assigned new plans in 2007 because their previous plan did not meet the current year low-income subsidy benchmark.

Plans also begin preparing early in 2007 for the 2008 Part D plan year, and many experts predict few changes in plan premiums and do not expect formulary design changes based on cost concerns.

Strumpf said that even small premium increases in 2008 could cause beneficiaries to shop around for a new plan, so premiums are likely to be static in 2008 as part of an effort by plans to retain enrollees.

However, Strumpf also said he expected to see significant plan exits from the Part D program among insurers that did not “attract sufficient enrollment to justify continued contracting.”

Mid-year could be the first “organic growth” in membership for Part D plans—particularly MA-PDs—as some retirees begin moving out of employer group plans into Part D, Gorman said.

He said he expects the trend to begin slowly in 2007, then pick up in 2008, with public sector employers, labor unions and nonprofit/tax exempt organizations, which receive the lowest subsidy amounts, leading the way.

Managed Care Plans

The first year of the Part D drug benefit drew strong managed care organization participation into the Medicare Advantage (MA) program. The entry of MA-prescription drug plans (MA-PDs), as well as other MA plans that do not offer a drug benefit, produced a busy marketplace with particular success for certain types of plans.

“There has clearly been tremendous growth in plans and enrollment between 2005 and 2006,” Patricia Neuman, vice president of the Henry J. Kaiser Family Foundation and director of the foundation’s Medicare Policy Project, told BNA. With the strong financial incentive to join MA, in 2007 there will be even more availability.

CMS said that in 2007, there will be 3,971 Medicare Advantage plans, an increase from 3,195 in 2006. These include employer group health plans along with private health plans available to the public.

In addition, there was more market stability between 2006 and 2007 than was thought last year, as well as more loyalty to existing plans, Joel Menges, vice president of The Lewin Group, said.

Some industry watchers at the end of 2005 speculated that, with the heavy competition, a market shake-out would occur in which many plans would not survive to 2007 (17 MCR 62, 1/13/06).

Jack A. Rovner, an attorney with Neal, Gerber & Eisenberg LLP in Chicago, said he believes that so far the few departures have been tied to compliance problems.

There is a cost to exiting, Menges added. Rather than leave the MA program, if a plan finds that it is losing money in Medicare, it can increase charges to beneficiaries.

Also, the commercial market is “flat,” and managed care organizations are looking to MA for growth, according to Sharon Woda, a senior manager at Lewin.

Different Survey. Ghose said that while his industry group, AHIP, in the past surveyed members to determine how their withdrawals would affect enrollees (14 MCR 1011, 9/12/03), of late, “we haven’t had to do that.”

AHIP, instead, plans to survey enrollees in early 2007 about such matters as the types of benefits they are receiving and cost savings.

MA organizations have been assessing and, for some, reconfiguring their MA and stand-alone drug products to maintain and hopefully grow their market share in some of the more crowded areas.

Blue Cross and Blue Shield of Florida, for example, decided to consolidate two health maintenance organizations (HMOs), Lori Hallauer, a Medicare products manager, told BNA.

In the hotly competitive southern Florida marketplace, the company’s now single zero-premium HMO will allow for better benefits for enrollees and lower administrative costs for the company, according to Hallauer, director, senior market solutions product management for the not-for-profit company, headquartered in Jacksonville, Fla.

HMOs remain the company’s most popular product, with 20,000 enrollees, which is 100 times more than enrollment in its local preferred provider organization (PPO).

So, for its “BlueMedicare” PPO in 2007, BCBSF decided to halve premiums and eliminate or reduce copays for a variety of services, including durable medical equipment. Members also will receive dental benefits for the first time in 2007. Tweaks were made to their stand-alone prescription drug plans.

So far, however, their enrollees have been very loyal, allowing for a stable population. They have “grown up, knowing us” from their time in BCBS commercial products, Hallauer said.

MA Migration. Gorman said that March will be the “high-water mark for both PDPs and Medicare supplemental insurance.” After that, beneficiaries will begin migrating to the newer MA products, he said.

Two types of MA products are drawing attention for having drawn large segments of the enrollee population in 2006.

Special needs plans (SNPs) are coordinated care plans that may exclusively or disproportionately enroll individuals who are dually eligible for Medicare and Medicaid, are institutionalized, or have severe or disabling chronic conditions.

The share of beneficiaries with a SNP in their area will grow from 59 percent in 2006 to 76 percent in 2007, according to MedPAC.

Raskin, of Lehman Brothers, said "this is an attractive population because the revenues are very large and there are no lock-in restrictions. They will continue to grow."

Risk Adjustment. SNPs have thrived due to risk adjusted reimbursement, based on the health of the beneficiary, Ken Yale, with Matria Healthcare Inc., said. This "reverse cherry picking" will allow for better care to sicker patients.

Because of risk adjustment, it is very important for plans to capture the risk of their enrollees accurately and will be even more critical as payments level off, Woda, with Lewin, said.

John Baackes, chief executive officer of Senior Whole Health (SWH), agreed. His company will start serving duals as a SNP in Connecticut and New York in 2007 as an expansion of a CMS-state demonstration program for duals that he has been involved with in Massachusetts.

Beneficiary sign-ups are made at the "kitchen table," which Baackes said gives the SWH representative "huge clues to their risk status" that may not have been detected or documented. These observations have to be captured as data and transferred to CMS to get the right compensation.

Of the 602,881 SNP enrollees in December 2006, most (491,877) are duals. Gorman said that enrollment in dual SNPs will increase further as this population migrates from PDPs into the "one-stop shop" SNPs offer.

MedPAC in November 2006 said that in 2007 there will be more SNPs of the institutional and chronic illness variety.

"We'll see dramatically increased enrollments in SNPs from the chronically ill as those plans become more widely available," Gorman said. "With growing numbers of states focusing on managed long-term care in Medicaid, we suspect we'll see rapid growth in plans for the institutionalized."

Krasner observed that CMS appears to be "increasingly willing to allow for plans to target specific groups of chronically ill patients, and plans are more sophisticated now in providing effective management/coordination services for such defined populations, working out arrangements with states to coordinate Medicaid funding with Medicare funding, doing their homework on how to get the best risk adjustment factor, and making a profit."

SNP Success. Rovner said SNPs are successful because they can form their benefit packages to focus on specific needs, use disease management, and do not need large enrollments.

"There seems to be an ongoing huge interest in SNPs, despite the fact that most of the population is enrolled in a few big plans," Krasner said.

According to MedPAC, in 2007 there will be 424 SNPs, up from 276 in 2006.

Gorman said, however, that half of the SNPs have fewer than 1,000 enrollees. "That's unsustainable for long, so we suspect we will see substantial consolidation going into 2008," he said.

Gottlich said the Center for Medicare Advocacy Inc., will be watching the growth in SNPs and wants to know "what is so special about a special needs plan." She said many of the things provided are required by law. "It is not clear to us that [enrollees] are getting more benefits," she said, and the agency provides "little oversight."

Similarly, Neuman wondered what services are provided that are worth the extra cost of coverage.

SNPs cover only Medicare services, and are not required to cover Medicaid benefits, although they may contract with a state for Medicaid services.

Baackes said that, unlike most SNPs, his Cambridge-based health plan, which serves 3,000 duals in Massachusetts, has integrated Medicaid into its program. For example, if a claim is denied by Medicare, his company will file it with Medicaid.

However, Gottlich said that a big problem with many SNPs serving the duals is a lack of coordination with Medicaid. The SNP may not cover a drug or a service that is covered by Medicaid in a particular state. While SNP dual enrollees would be entitled to that, they are unaware and the SNP is not billing Medicaid for the covered service, she said.

Discussing MA overall, Gottlich said that, while there is no enrollee exodus, some have switched out of MA plans and back into fee-for-service as they have gotten sicker because of the additional or higher cost sharing for some expensive drugs, like chemotherapy.

In addition, some of the MA plans have imposed home health copays, while there are no copays in fee-for-service.

These enrollees find it less costly to be in fee-for-service Medicare with a Medigap plan, she said.

SNPs were authorized through 2008. CMS must report on their impact on enrollees by the end of 2007.

Private Fee-for-Service. The other MA product capturing attention is the private fee-for-service (PFFS) plan. These plans are actually a payment system for Medicare health care access and do not have a provider network or coordinate care. Plans may offer a drug benefit, as well as additional services and discounts on items such as hearing aids.

Rovner described them as operating like an indemnity product without a network, with low premiums, and a "little extra" benefit.

Schiffbauer said PFFS plans have proven attractive, because any provider can be used by the beneficiary. However, he said this capitated fee-for-service arrangement works only because MA payments are higher than the FFS payments.

These plans have been successful, Jane Galvin, director of regulatory affairs at the Blue Cross and Blue Shield Association in Washington, said, "as they allow access to most Medicare providers. Access to all providers who accept the plan's terms and conditions is an attractive feature to PFFS options."

CMS said that as of Dec. 1, 2006, there were 864,100 enrollees in PFFS plans

PFFS plans are “the fast growing MA option,” Strumpf told BNA. “It is relatively easy to market as it is not a managed care plan and appears to the beneficiary to have all of the same characteristics as traditional Medicare.”

However, he added that with payments higher relative to Medicare FFS, the PFFS plan option is “a target for Congress to examine with a view to reducing payment levels.”

Behind the Growth. Gorman said that PFFS plans are growing so rapidly because of two factors: wider availability and employer group retirees. PFFS plans are available to all Medicare beneficiaries, and especially in rural and secondary markets, “they are signing up in droves.”

Menges said that because Medicare pays good rates in rural areas, it is not difficult to make money on this product, while Gottlich said she expects to see more enrollees in PFFS because of the “aggressive marketing” by the plans.

However, not all enrollees understand the ramifications of enrollment and some are unhappy when they find out that their doctors or hospitals are not accessible because they do not accept the plans’ payments or do not want to get involved with the paperwork.

Gorman said the product has been “nothing less than shocking in its massive enrollment of group retirees, made possible by the ‘deemed network’ feature.”

With no network requirement, PFFS plans can serve group retirees on a national basis, which HMOs were not able to do, Gorman said. However, he added, “the wild success of PFFS notwithstanding, we think MSAs [medical savings accounts] will outpace PFFS enrollment over the next five to seven years.”

Medical Savings Accounts. The new year will bring the first crop of the MSAs-consumer-directed health care plans—to MA.

Gorman said they will be popular because they operate like a high-deductible PFFS plan but offer “the enormously attractive tax-free account funded by Medicare.”

He said “those account dollars can be used for virtually any health-related expense, even for services not covered by Medicare. That’s going to be a big draw for healthier beneficiaries who are actively involved in the management of their own care.”

Because MSAs must be offered at zero-premium, his firm suspects “they will be wildly popular among retiree groups” seeking to reduce their post-retirement health care liability.

The Indianapolis-based health benefits company, Wellpoint Inc., will offer MSAs under its Blue Cross of California and Unicare branded plans.

Under the program, Medicare places a risk-adjusted capitated payment in an account for a beneficiary to use tax-free for health care spending. After the high yearly deductible is met, the health plan would pay for Medicare-covered services. Unspent funds would be carried over for future use.

CMS has said that the beneficiaries it envisions enrolling in an MSA are those who desire more control over their health care spending, with protection from catastrophic health care expenses. This includes enrollees who had a health savings account (HSA) in the commercial market before becoming eligible for Medicare, the agency said.

MSA Enrollment. Wellpoint spokesman James Kappel said he expects those enrollees who are diligent about saving for health care will take advantage of MSAs.

However, even former CMS Administrator Mark B. McClellan said he did not expect a “drastic shift” among beneficiaries because the concept is not familiar to many current retirees.

Raskin predicted that the enrollees in MSAs at the end of 2007 will be less than 3 percent.

Kennelly said that if commercial HSAs are any indicator, then enrollment in MSAs will be low. Only about 3 million people, out of 170 million with private insurance have participated in an HSA over the past two years, she said.

However, Richard White, Wellpoint’s vice president for senior markets, pointed out that the more than 3 million enrollees in commercial HSAs in 2006 grew from 400,000 in 2004. Some of the future enrollees will come from that group, he said. These will be “innovators” who not only like to pick their own doctors but who also like to manage their own care, he told BNA.

However, Gorman said he did not expect more than 100,000 MSA enrollees by the end of the year.

Larry Goldberg, a health care consultant and senior advisor for Health Care Legislative and Regulatory Matters for Grant Thornton LLP, in Oakton, Va., predicted that beneficiaries will join if they understand the program and believe they will save over traditional Medicare.

To that end, White said that Wellpoint plans to contact each MSA enrollee in January to ensure that they understand how the new product works. The educational element will go two ways. Wellpoint marketers wants to find out the motivation behind the purchase to help with product evolution, he said.

Regional PPOs. As of Dec. 1, 2006, CMS said that 98,385 beneficiaries were enrolled in 11 regional PPOs out of 43 million beneficiaries.

PPOs clearly have not garnered the interest that was intended originally, Raskin said. “It is very difficult to offer a health insurance plan across a broad region due to the disparity of local costs,” he said. “I don’t think the regional PPO will take off in 2007, if at all.”

Galvin said “regional PPOs are a challenge as many regions are multistate, which goes against the way Blues plans are organized. We had advocated for 50 state-based PPO regions. However, the regional PPO enrollment should grow over time as more beneficiaries are aware of their features.”

Neuman speculated that the “modest” enrollment result from less aggressive marketing than with other types of plans.

Kennelly said a November 2006 *Health Affairs* article reported that regional PPOs accounted for less than 1 percent of all Part D enrollment in 2006.

When seniors compare plans, they will find that PPOs tend to have higher premiums than other private health plans, Kennelly said. “Even if these plans provide more generous benefits, seniors might be discouraged to participate because of the higher cost,” she added.

Kennelly noted that the tax and health law signed by President Bush in December 2006 will reduce the amounts available to subsidize regional PPOs in the future. Reducing amounts available for this fund is helpful, she said, although it leaves the infrastructure in place for the incentive to be funded again in the future.

Building Enrollment. Barbara H. Ryland, an attorney with Crowell and Moring in Washington, said that increases in regional PPO enrollment would be “most likely to occur in rural or smaller metropolitan areas, and, as with the HMO plans, it could take some time to build up enrollment in these areas that have been traditionally underserved by managed care plans.”

Gorman said that, depending on the point of view, the number of beneficiaries enrolled in regional plans could be “a lot or negligible. . . . It’s too early to tell, really. Another year and we should have a clearer picture. Novel products like regional PPOs take some getting used to, especially for managed care adverse beneficiaries in Medigap, which PPOs are targeted at.”

However, Gorman added, “having said that, the fundamental structure of regional PPOs is inherently problematic: the requirement to offer the same product across the entire region means that to be competitive in urban areas, the plan is often prohibitively expensive in rural areas. I’d expect no more than 250,000 beneficiaries in regional PPOs in 2007.”

According to a CMS spokesman, overall MA penetration for all products is 17 percent of beneficiaries.

Raskin predicted this will grow to 19 percent to 20 percent by the end of 2007, with a majority in HMOs, but most of the growth in PFFS plans.

Similarly, Gottlich said she expects enrollment to be 20 percent at the end of the year.

Speculating about which beneficiaries will be attracted to each type of plan, Gorman offered this thought: “We foresee an emerging micro-segmentation of Medicare Advantage, largely along income lines, with low-income and chronically ill beneficiaries moving to SNPs, leaving in HMOs and bare-bones PFFS plans the low/middle-income but relatively healthy; and more affluent beneficiaries moving from Medigap and PDPs into PPOs, MSAs, and ‘Cadillac’ PFFS plans.”

Hospital Payments

The biggest Medicare issues for hospitals in the coming year actually involve potential policy changes for 2008 and beyond, but efforts to rein in Medicare payment rate increases also may be on the horizon, according to *BNA’s Medicare Report* advisory board members.

Goldberg identified three basic questions hospitals face in 2007: whether Congress will impose controls on future payment rate increases; whether the Centers for Medicare & Medicaid Services will employ a more complex diagnosis-related group (DRG) system, like the one it set forth in an April 2006 proposed rule; and how far CMS will move toward a system that pays for care based on the type of service provided rather than the location in which the care is received.

Over the past few years, providers have received a full market basket inflation adjustment, but one way Congress could curb growth would be to use the market basket inflation measure minus some percentage point, Goldberg said.

Easy Payment Fix. Dennis M. Barry, an attorney with Vinson & Elkins LLP in Washington, agreed that the market basket “is the easiest thing to deal with.” Cutting 1 percent from a \$100 billion per year program would save \$1 billion each year, but for hospitals, that means less profitability, he said.

Given current deficits and Medicare’s growth, “it would be a surprise” if Congress did not try to act to slow the rates of increase, especially during a nonelection year, Goldberg said.

The question is whether entities like MedPAC or CMS believe the provider community can absorb the payment changes. While not “stellar,” hospitals’ financial stability is better than it was several years ago, Goldberg said, adding, “The program is expanding and profits are still somewhat healthy.”

The provider community has been fortunate the last several years, with “pretty gentle treatment” from Capitol Hill, Barry said. Medicare trust funds are continuing to dwindle, however, and Congress is refocusing on the deficit and entitlement programs. “My guess is that [the pretty gentle] treatment will not continue,” he concluded.

In August 2006, CMS issued the hospital inpatient prospective payment system (IPPS) final rule, adopting incremental changes to the diagnosis-related group (DRG) system for fiscal 2007, as well as a transition to a cost-based weighting system with new severity-based groups. What CMS did not do was adopt a major overhaul of the DRG system, Goldberg said. That will come in 2008.

Final IPPS Rules. Zimmerman offered similar comments.

“Hospitals will barely notice the shift to cost-based DRGs under the final IPPS,” he said, but cautioned that “hospitals should not take too much comfort” in CMS’s decision not to move forward with the revised and expanded DRG system as it initially proposed.

CMS “merely postponed making a final decision,” he said. “Hospitals have not seen the last of this matter.”

Aside from specific changes to the PPS system, Goldberg said, CMS also has a “clear agenda” to “level the playing field” in different types of care settings. CMS is trying to figure out a single document that will determine a patient’s course of care and follow the individual through the entire system, Goldberg said. Many provider groups like the status quo, he said, but “the changes are in CMS’s court.”

Kenneth R. Marcus, an attorney with Honigman Miller Schwartz and Cohn LLP, Detroit, added that Medicare hospital payments for the medical education of residents rotating to the so-called nonprovider setting will continue to be a challenge in 2007.

Payments for medical education is an area that “has been subject to almost annual clarifications,” Marcus said, and it likely will be the source of a good deal of appeal activity before the Provider Reimbursement Review Board. “Every time there is a clarification, it adds another element, which is a challenge for compliance.”

Price Transparency. As CMS, the American Hospital Association, and other stakeholders continue to work toward greater hospital price transparency, the average consumer still does not understand what the information means, according to Goldberg.

“CMS has made significant strides in starting to post Medicare billed charges and Medicare payments for those services,” Goldberg said, and the agency deserves credit for posting the amount of information it has to date. “The real test,” he said is “how the public and consumers use and react to such data.”

Nevertheless, in Goldberg’s view, it is an issue that needs to be brought to the public’s attention. Many fa-

cilities charge up to three times more than Medicare allows, and Goldberg said that if one facility is getting paid more than another, even after making adjustments for teaching hospitals and disproportionate share, people will want to know why.

This is an issue that will open up in time as the media and others begin to talk more about price transparency, Goldberg said.

Marcus said the push for price transparency also may correspond to the increase in the number of consumer-directed health plans and health savings accounts, which generally have higher deductibles.

A \$100 deductible is relatively negligible for a consumer, Marcus said. The cost becomes more significant, however, if the consumer has a high deductible health plan and must pay \$5,000 out of his or her own pocket. Hospitals, physicians, and other health care providers will have to become accustomed to this relatively new phenomenon, he said.

Marcus predicted that “public support for transparency will gain traction and momentum as the number of people covered by HSAs increases.”

Barry said a growing number of hospitals recognize they have a problem with billing. Realizing they are not collecting what they charge, some have reduced their billing rates. While this is not industry-wide, it is happening, he said.

At the same time, many hospitals do not have ready pricing available, Barry continued. Hospitals are starting to gather the pricing data they need, but “line item pricing” is still a ways off. He said this is an issue that will continue to evolve over the next several years.

Home Health Care

A highly significant event for home health agencies will occur in January or February, according to William A. Dombi, director of the Center for Health Care Law in Washington, as CMS likely will issue a proposed rule containing “a wholesale revision” of the Medicare home health prospective payment system in place since October 2000.

“This is the most important rule-making event that will happen for HHAs in 2007,” Dombi said. Any changes that are adopted would be implemented in 2008.

Under the current PPS, home health agencies are reimbursed a fixed rate for each beneficiary, with the amount of reimbursement determined by the type and severity of the patient’s illness. The amount of fixed payment then is modified according to each patient’s needs, using the case-mix adjustment system.

“That system is going to be pretty much reformed from top to bottom,” Dombi said. The current system distributes money in “a haphazard fashion,” but he said it will not be clear whether there will be a distribution of payments under the proposed system that levels the playing field “until we see what the system looks like and the dollar amounts attached to it.”

Kennelly of the National Committee to Preserve Social Security and Medicare discussed the new cap on renting oxygen and other durable medical equipment and its impact on the approximately one million Medicare beneficiaries who need oxygen. The new rental cap was set forth in a final rule issued Nov. 1, 2006, pursuant to provisions of the Deficit Reduction Act of 2005.

“Most beneficiaries who need oxygen rent the equipment and use it for an average of 30 months,” she said. To avoid unnecessary overpayments to providers, she said, “[t]he new provision in the Deficit Reduction Act implements a ‘rent-to-own’ rule requiring that Medicare home-care beneficiaries own their rented oxygen equipment after 13 months.”

While NCPSSM supports the goal of saving money for the Medicare program, Kennelly said, “we have heard from a number of our members who are concerned that this change would require them to pay more money out-of-pocket to maintain the oxygen equipment they depend upon. Our biggest concern is to ensure that seniors are not put in a situation where their health is adversely affected and to ensure they have the ability and financial wherewithal to properly maintain the equipment.”

Physician Payment

After legislation signed into law in December 2006 (Tax Relief and Health Care Act of 2006, PL 109-432) put off a 2007 reimbursement cut for doctors, and offered an additional 1.5 percent in payments to those who report on performance, attention will turn to the details of the bonus incentive plan.

In a Dec. 28, 2006, report, CBO estimated that the physicians, therapists, pathologists, and others included in this new quality reporting system would receive bonus payments totaling about \$300 million.

“Physicians who report those measures for services furnished from July 1-Dec. 31 will be paid an additional 1.5 percent for those services—with that payment being made in a lump sum in 2008,” CBO said (18 MCR 9, 1/5/07).

.According to the new law, the amounts will be based on the claims submitted during the reporting period.

The law has a variety of stipulations, including how the quality data are to be submitted, and the reporting of measures, which are under the Physician Voluntary Reporting Program (PVRP).

PVRP began in 2006 as a way to furnish doctors confidential feedback on their data accuracy, reporting rates, and quality of care. Physician groups, including the American Medical Association, the Medical Group Management Association, and members of the Practicing Physicians Advisory Council, initially objected to aspects, particularly because physicians were not reimbursed for the extra work involved.

Bonus Incentive Program. Shawn Martin, director of government relations for the American Osteopathic Association, told BNA that he is unaware of any members of his organization who are participating in the PVRP, which he said also has been hindered by a lack of widespread health information technology.

The new law said that other measures may be added up until April to the bonus incentive program that result from the quality measure consensus-based process that has been ongoing in the medical community.

According to language placed in the record by former Ways and Means Committee Chairman William M. Thomas (R-Calif.), the intent is “to ensure that physicians groups (such as the Physician Consortium for Performance Improvement) are actively involved in defining the quality measures and determining the quality data to be reported under the program.”

The new law requires CMS to publish in the *Federal Register* by Aug. 15 a proposed set of quality measures for 2008. After public comment, a final set will be published three months later. Another proposal is to deal with the mechanism for doctors to provide data “through an appropriate medical registry.”

The development of quality measures will continue in 2007 through the consensus-based process that involves the Physician Consortium for Performance Improvement, which had developed 151 measures as of November 2006, as well as the National Quality Forum and the Ambulatory Care Quality Alliance. AQA’s next meeting is scheduled for Jan. 22 in Washington.

Implementing Incentive Program. Patrick F. Smith Jr., senior vice president, government affairs for Medical Group Management Association in Washington, said there are “all sorts of questions” on how the incentive program will be implemented, including whether payments are to be made through the doctors’ groups or to individual practitioners, and the level of payments in 2007 since the program will run only for six months.

Physicians will need to know how much it will cost them before deciding whether to participate, he said.

John C. Lewin, chief executive officer of the American College of Cardiology, said that one of his group’s concerns is how practitioners will submit data about their performance to CMS.

He wondered whether the information would come in on paper by some physicians “because we won’t have an interoperable system that everybody can use by July.” This would delay results back to the physicians, he said.

The ACCC believes it would be feasible to utilize the cardiovascular registries that it is using in hospitals. The information in the registries would “tell Medicare whether it is getting a good return on its investment,” Lewin said.

The physician data registries in existence for inpatient care “should provide what CMS is looking for,” he added. Once an ambulatory registry for cardiologists is developed, perhaps by the end of 2007, physician performance could be tracked outside of hospitals.

Despite the upcoming activity surrounding the new law, the incoming chairman of the House Ways and Means Subcommittee on Health has called “offensive” the concept of paying doctors extra money based on quality measures.

Chairman Fortney “Pete” Stark (D-Calif.) has said that doctors should not be paid extra for reporting measures or improving the quality of care they offer but that, instead, poorly performing doctors should not be paid.

Martin said that without two key players—Thomas and former Health Subcommittee Chairman Nancy L. Johnson (R-Conn.) and their staffs—“the momentum for pay-for-performance (P4P) has subsided” on the legislative side. Thomas retired at the close of the 109th Congress; Johnson was defeated in the November 2006 elections.

Smith said he agreed that “the urgency factor” of trying to link changes in the physician payment system to quality measures may fall away.

This has been bolstered, Smith said, by a Congressional Research Service study that found little evidence that pay-for-performance (P4P) programs save money

in the long run and actually could increase health care expenditures (17 MCR 1532, 12/22/06).

Looking for Evidence. Miller said “CMS would like to pounce on any shred of evidence showing the efficacy of pay-for-performance, but the data needed to reinforce the administration’s movement toward cost efficiency and effectiveness and transparency in pricing will trickle out slowly, thwarting the administrations’ ambition to lock-on to a silver-bullet approach to save the Medicare program.”

Further enlightenment on the topic will come from a Government Accountability Office report that will examine the lessons learned from a CMS demonstration that pays physicians in group practices more for improving quality of care, Smith said.

Ten physician groups are participating in the “Physician Group Practice” demonstration, which incorporates health quality measures focusing on chronic and preventive services. Required by Congress in the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, the demonstration started in 2005 and is to run through March 2008.

Regardless of the fate of the quality measure initiatives, the saga of the sustainable growth rate formula (SGR), which bases payment updates on national service volumes and has been leading to formula-created cuts in physician reimbursements, will continue into 2007.

By passing legislation that made the physician fee schedule conversion factor the same in 2007 as in 2006, instead of a cut, Congress just “kicked the can down the road,” Smith said.

“From day one, the clock will be ticking” on solving the problem, he said.

New Payment Formula. Martin said he believes it will take more than 12 months to implement a new payment formula, with the problem probably extending into 2008.

Smith said that Congress and others will be awaiting MedPAC’s recommendations on replacing the SGR. The congressional advisory board was mandated in the Deficit Reduction Act of 2005 to report on alternatives by March and hearings may be held on those ideas.

Kennelly said it is important that physicians be paid adequately so they continue participating in the Medicare program, but beneficiaries should not be forgotten.

“[E]ach time the cuts to physician reimbursement rates are averted, seniors bear part of the costs by paying higher Part B premiums,” she told BNA. “As Congress works to ensure that physicians receive fair payment in the future, they should also ensure that seniors’ Social Security checks maintain the purchasing power necessary to cover the rising costs of other health care.”

Part B Drug Payment

Another topic that will carry over into 2007 is discussion on the level of payments for pharmaceuticals that physicians use in their offices (Part B drugs).

Congress in MMA changed the Part B drug reimbursement scheme from one known as the average wholesale price (AWP) system to one based on average sales prices (ASP). While savings since then have been reported on drug reimbursements, doctors contend they are not being reimbursed adequately.

Ted Okon, co-executive director of the Community Oncology Alliance, said he sees further cuts in in-office cancer drug reimbursement.

To compensate for reduced drug payments, oncologists, the specialty that uses these drugs most frequently, received a 27 percent boost in practice expense and a "transitional adjustment" that increased payments for specific drug administration services by an additional 32 percent for services furnished in 2004. A demonstration project in 2005 and 2006 allowed additional funding.

However, these extra funding sources have ended and along with inflation and changes in relative value units will leave some practices unable to pay their bills, Okon said.

Without further reimbursement, he said, more clinics will fail and more oncologists will leave their practices, leading to "disjointed" care for beneficiaries from hospitals.

In addition, questions surrounding the reporting of discounts under the ASP system, which relies on sales data submitted quarterly by manufacturers, remain open at the start of 2007.

MedPAC in a January report to Congress urged CMS to clarify how transaction discounts are to be reported (18 MCR 9, 1/5/07).

Treading Cautiously. However, Ryland, with Crowell & Moring, said she believes CMS will tread cautiously in adopting any regulation that could be viewed as trying to regulate how drugs are sold commercially to Part B purchasers.

The agency might offer clarification on how the ASP should be determined in the case of bundled drugs, or it could do nothing and wait for an OIG audit of the issue, and possibly even investigations of specific companies, she said. This is more consistent with how it has approached similar issues in the past.

Okon added his belief that until CMS gets a new permanent administrator, it will proceed cautiously in this area. Former administrator, Mark B. McClellan, resigned in October 2006. Since then, the agency has been led by an acting administrator.

MMA also established a competitive acquisition program (CAP) in 2006 to continue lowering the price of drugs. CAP allows physicians to purchase drugs through vendors that are able to acquire large quantities of drugs and negotiate lower prices with manufacturers.

Just one vendor, Bioscrip Corp., is participating in the program.

MedPAC staff said physicians they interviewed were unwilling to participate in CAP. MedPAC suggested in its January report that Congress consider permitting physicians to acquire some drugs through the CAP program without requiring them to order all their CAP-covered drugs through the vendor.

Okon predicted that CAP would face a "slow death" now that Chairman Thomas, a champion of the program, has retired. Using a "middleman" reduces quality and increases costs, he said.

However, Russell J. Corvese, Bioscrip's vice president of operations, told BNA that the number of physicians participating in the CAP increased from 1,380 in 2006 to a little over 2,200 in 2007. The election period for 2007 ended on Nov. 15, 2006, and sign-ups are still

being sent from carriers to the Elmsford, N.Y., pharmacy benefit manager.

The program has increased doctor office drug access for beneficiaries, he said. Before CAP, some physicians had not wanted to purchase these injectable and infused drugs from a distributor or manufacturer, then bill Medicare and wait for reimbursement. However, these doctors are willing to administer drugs in their offices if they can acquire them through CAP, Corvese said.

The program also is good for physicians who are losing money through the ASP system by purchasing drugs on their own, he continued.

Durable Medical Equipment

Congress designated 2007 as the kickoff of a nationwide competitive bidding program for suppliers of durable medical equipment (DME). However, specialists in the area told BNA that the industry is anything but ready for this dramatic change in which median winning bidding amounts will replace the DME Medicare fee schedule.

Mary Ellen Conway, president of Capital Healthcare Group, a Bethesda, Md., consulting firm, said she is "holding her breath for a big chaotic year."

The industry has faced its share of problems in the past, Jeffrey S. Baird, chairman of the health care group of Brown & Fortunato P.C., Amarillo, Texas, told BNA, but the year 2007 will be the "perfect storm."

As of Jan. 10, CMS had yet to release a final rule on the bidding program. A proposed rule, published in May 2006 (17 MCR 551, 4/28/06), said the first round of bidding would occur in 2006 and would take place in 10 of the largest metropolitan statistical areas (MSAs), excluding New York, Chicago, and Los Angeles. Other areas are to be phased in through 2010.

CMS will select the lowest bids for each product category with enough capacity to meet the expected demand in the area.

"For the initial competition, we assume that bidding will take place in fall 2006, bids will be evaluated in 2007, and prices will go into effect in October 2007," the May proposal said.

Waiting for Final Rule. However, because the final rule has not yet been published, thousands of DME suppliers do not know, at this point, in which 10 MSAs bidding will be conducted first or which products will be among the first subjects of bids.

Bidding for DME orthotics and prosthetics (DME-POS) was placed in MMA, according to the committees that wrote the legislation, because studies had found the government-determined fee schedule to be too high. The committees said that if suppliers priced their products at market value, market forces would drive down the cost for both the government and beneficiaries.

CMS in November 2006 released the names of 11 organizations that will accredit companies that want to bid to supply the first group of designated products.

If they plan to bid in 2007, they must be accredited by spring, Baird said, adding that, because of the large number of players, it will be chaotic. The major question for the accrediting organizations (AOs) is: "How quickly can they get it done?"

At a Dec. 18, 2006, meeting, CMS told the AOs that the 10 MSAs would be chosen from among these 19:

Miami; Charlotte-Gastonia-Concord, N.C.; Dallas-Ft. Worth; Riverside-San Bernardino, Calif.; Pittsburgh; Kansas City, Mo. and Kan.; Cincinnati-Middletown, Ohio; San Juan-Caguas-Guaynabo, P.R.; Cleveland-Elyria-Mentor, Ohio; San Francisco-Oakland, Calif.; Atlanta-Sandy Springs, Ga.; Houston-Baytown-Sugar Land, Texas; Detroit-Warren-Livonia, Mich.; Seattle-Tacoma-Bellevue, Wash.; Baltimore-Towson, Md.; Philadelphia-Camden-Wilmington; Phoenix-Mesa-Scottsdale, Ariz.; Boston-Cambridge-Quincy, Mass.; and Tampa-St. Petersburg-Clearwater, Fla.

Challenge for Suppliers. According to Baird, the biggest challenge facing many suppliers is their lack of understanding about their costs. To both bid and maintain a viable business, a supplier needs to know the “lowest reimbursement [it] can afford to take,” he said.

However, because many of these cottage industry companies lack sophisticated accounting systems, he said, their bids could be accepted and they still would be in the red after 18 months.

Baird said he is “keeping his fingers crossed” about the reintroduction and fate in the 110th Congress of a bill (H.R. 3559) that would have allowed any willing provider to participate in bidding as long as all requirements are met.

Once there are beneficiary deaths as a result of this, there will be hearings, he forecast. In the meantime, Baird said, “I’m confident one or more lawsuits will be filed in federal courts on constitutional grounds” after the rule comes out.

John Gallagher, of VGM Group, a 3,000-member services organization for the industry, said that his group has formed a not-for-profit organization to fight bidding.

Gallagher, vice president of government relations for the Iowa-based group, said that “Last Chance for Patient Choice” will file a federal lawsuit seeking to strike the bidding provision from law on various grounds, including that it creates a “two-tier system” in which beneficiaries in one area receive less care than in another.

New Coalition. In addition, the American Association for Homecare, a national association representing homecare providers, Dec. 20, 2006, said it has participated in the new Coalition to Ensure Beneficiary Access that will work toward repeal.

As one its principles, AAHomecare said that “the administrative process of bidding within select regions for select products will result in reduced availability of products to individuals in certain areas of the country.”

On the legislative front, Gallagher pointed out that H.R. 3559, previously sponsored by Rep. David Hobson (R-Ohio) and Rep. John Tanner (D-Tenn.), had a large number of cosponsors, 151, in the 109th Congress. “Information will be sent to every member of Congress” with emphasis on the freshmen, in the coming weeks, he said.

There is potential that more will sign on and the bill will pass, according to Conway, who works with DME companies that need to be accredited.

Gallagher said he assumes that DME suppliers who have been accredited will be grandfathered in and be able to bid without having to go through the process again.

However, he predicted, if the bidding program causes small business loans to be defaulted, and employees put out of work, there will be backlash.

Laboratory Demo Program

Another competitive bidding program required in MMA causing concern is a demonstration program for laboratories.

“The project will cover demonstration tests for all Medicare Part B beneficiaries who live in the demonstration sites, as determined by the zip code of the beneficiary’s residence,” CMS said.

The three-year demonstration excludes hospital and physician office testing, except where those labs are independent and perform tests for outside patients. It also excludes some tests.

The first of two demonstration sites is scheduled to run from April 1, 2007, to March 31, 2010. American Clinical Laboratory Association President Alan Mertz told BNA he expects CMS will name the sites and hold a bidders’ conference by the end of March.

Laboratory firms with \$100,000 or more in Part B payments will be required to bid. Those with less revenue will be considered “passive” and will not be required to bid but may do so.

Winning, Losing Bids. Labs that bid and win will be paid the competitive bidding fee schedule for tests provided to beneficiaries residing in the competitive bidding area.

Those labs that are required to bid but did not win may not receive reimbursements under Medicare for beneficiaries who reside in the demonstration sites.

“Passive” labs that do not bid will be reimbursed at the demonstration fee schedule amount up to an annual \$100,000.

Mertz said that trying to place labs into a bidding program is like trying to fit a “round peg into a square hole.” Lab tests are not equipment sold at retail but “complicated services” that require high technology and immediacy, he said.

Mertz expects that, although there may be many bidders, there will be few winners. Losers with large Medicare business could be driven out of business.

The labs chosen have to be able to perform the 1,100 tests on the fee schedule or will have to subcontract some of the work, he said.

“We are really concerned about quality of care and access for beneficiaries,” he said. Having specimens interpreted accurately and swiftly is “a matter of life and death.”

ACLA plans to step up its campaign to get Congress to repeal or delay the program in the coming weeks, he said.

False Claims Act

Health care attorneys will be anticipating a decision in a False Claims Act whistleblower case pending before the U.S. Supreme Court, *Rockwell International Corp. v. United States ex rel. Stone* (U.S., No. 05-1272, oral argument 12/5/06), which could be very significant for the health care industry, Stuart I. Silverman, an attorney with the District of Columbia Office of Inspector General’s Medicaid Fraud Control Unit, said.

Several of the amici briefs filed in the case noted that almost half of the False Claims Act qui tam actions filed between 1987 and 2005 addressed allegations of health care fraud, he said.

“[T]he federal government has decided to intervene in less than one third of those qui tam cases,” Silverman added. “Thus, there is a large number of qui tam FCA cases that are brought alleging health care fraud where the government declines intervention.”

The amici briefs challenging the U.S. Court of Appeals for the Tenth Circuit’s opinion in *Rockwell*, which included the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, and the American Health Care Association, argued that the relator had no first hand knowledge that anyone at *Rockwell* had made a specific false statement or claim to the government, he said.

The high court heard oral argument Dec. 5, 2006, in the FCA action in which petitioner *Rockwell* is challenging two determinations by the Tenth Circuit that James Stone, a former *Rockwell* employee, was an original source of information about a contractor’s concealment of environmental violations in the Department of Energy’s Rocky Flats facility, a nuclear disposal site (17 MCR 1489, 12/8/06).

Hard to Call. The case is “just too hard to call,” attorney Thomas S. Crane with Mintz, Levin, Cohen, Ferris, Glosky and Popeo PC, Boston, said. He said some judges are offended by the qui tam provisions and the qui tam relators, while others view the FCA provisions as effective fraud-fighting weapons.

“So this issue cuts across ideology,” Crane said. “Depending on the breadth of the decision, the case could chill relators. In all, it is more likely the outcome will be modest because this issue does not affect the government’s right to bring FCA cases, even if first brought to the attention of the government by a relator.”

Attorney John T. Brennan Jr., with Crowell & Moring LLP, Washington, said the addition of Chief Justice John G. Roberts Jr. and Justice Samuel A. Alito Jr. to the Supreme Court, both of whom have issued important opinions suggesting an interest in the FCA, resulted in the high court’s taking this “unusual case” in the first place. In previous opinions, Roberts and Alito have read the statute narrowly, Brennan said.

“I therefore believe the Supreme Court will narrow the [U.S. Court of Appeals for the Tenth] Circuit’s definition of original source,” Brennan predicted. “The [Ten]th Circuit says you could be an original source if you have information ‘underlying or supporting’ the allegations of fraud. Other circuits require more, e.g., ‘knowledge of the actual false statement to the government.’”

Narrowly Construed. Silverman said it is interesting that Roberts, while a judge on the U.S. Court of Appeals for the District of Columbia Circuit, wrote the opinion in *United States ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488 (D.C. Cir. 2004) in which he construed the language under the FCA very narrowly. Silverman said that could be significant for *Rockwell*.

“This may well indicate how Chief Justice Roberts will view the jurisdictional issue in the *Rockwell* International case, and overturn the decision of the Tenth Circuit as one which views the original source rule too broadly, particularly when it comes to defining the jurisdiction of the federal courts under the FCA,” Silverman said.

Brennan pointed out that the District of Columbia Circuit requires that the original source know “the facts” that made the statement false.

He suggested that, if the Supreme Court affirms the Tenth Circuit’s decision in *Rockwell*, it would open the door to more qui tam actions that could be considered parasitic; but, if the Supreme Court were to narrow the original source test, it would reduce the universe of potential whistleblowers.

Taxpayers Against Fraud staff attorney Joseph E.B. White acknowledged that it was hard to say which way the Court would go in deciding *Rockwell*.

“The good news for the government and the qui tam bar is that the plain language of the [FCA] supports affirmation of the lower court decision,” White said. “Moreover, with Senator [Charles E.] Grassley [R-Iowa] weighing in with a powerful amicus curiae brief, the Court will be reminded that the overall purpose of original source exception was to shield the Government from parasitic whistleblower suits and not to silence non-parasitic whistleblowers.”

Tightening of Standards. Nevertheless, former HHS IG Richard Kusserow said he believes there will be a tightening of standards for qualifying as a qui tam relator and reduction of the opportunity for those with unclean hands to benefit from the process.

“I believe everyone will look to this case as a signal for the future,” Kusserow, now president of Strategic Management Systems Inc., Alexandria Va., said. “The [Department of Justice] has always maintained reservations and concerns about the qui tam provision and would look to the [high] court to limit the scope of such cases.”

The issue in *Rockwell* is one that goes to the very jurisdiction of a federal court to entertain an FCA qui tam action, Silverman said. He noted that jurisdictional issues are deemed very important by courts and case law suggests that courts construe their own jurisdiction very narrowly.

“That fact may help predict how the Supreme Court in *Rockwell* will construe the original source rule under the FCA,” Silverman said. “As such, a strict construction of the text of the FCA that addresses the original source rule is likely to lead the Supreme Court to require something more than the Tenth Circuit believed was necessary for a relator to be the original source when the public disclosure bar is applicable.”

Silverman said the Tenth Circuit construed the original source language in the FCA broadly in *Rockwell*, which likely stands for the most expansive construction of that language among the courts of appeals. The Tenth Circuit ruled that the relator had “direct and independent knowledge” of the fraud, he said.

By contrast, in *United States ex rel. Mistick v. Housing Auth. of the City of Pittsburgh*, 186 F.3d 376 (3d Cir. 1999), the Third Circuit has ruled that for the original source rule to apply, the relator must have knowledge of the most critical elements of the fraud claims, a finding that is similar to the views expressed by the Eleventh Circuit, in *United States ex rel. Cooper v. Blue Cross & Blue Shield of Fla.*, 19 F.3d 562 (11th Cir. 1984), and the Ninth Circuit, in *United States ex rel. Aflatooni v. Kitsap Physicians Service*, 314 F.3d (9th Cir. 2002), Silverman said.

The D.C. Circuit, in *United States ex rel. Springfield Terminal Railway Co.*, 14 F.3d 645 (D.C. Cir. 1994), and

the Eighth Circuit, in *United States ex rel. Minnesota Association of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032 (8th Cir. 2002), however, have taken a middle ground position, Silverman said, and ruled that the relator need not have knowledge of all of the vital ingredients to a fraudulent transaction, but rather have direct and independent knowledge of an essential element underlying the fraud transaction.

Disproportionate Share Payments

The outcome of the decision in *Baystate Medical Center v. Leavitt* (D.D.C., No. 1:06-cv-01263-JDB, filed 7/14/06), a closely watched lawsuit in the U.S. District Court for the District of Columbia, will have far reaching implications for the many cases pending before the Provider Reimbursement Review Board, attorney Kenneth R. Marcus, with Honigman Miller Schwartz and Cohn, Detroit, told BNA.

Modifying a decision by the PRRB, the CMS administrator held that recalculation of a fraction used to determine the Medicare disproportionate share (DSH) payment was not available for Baystate Medical Center, a Massachusetts hospital, once the calculation was completed.

Marcus said the decision by the PRRB was based on substantial evidence that supported Baystate's position that the data used to determine the Medicare Part A Supplemental Security Income percentage was flawed.

The most noteworthy aspect of Medicare in 2007 will be the range of issues from mega-big picture policy to the micro-minutiae of implementation, Robert L. Roth, an attorney with Crowell & Moring LLP in Washington, said.

"On the micro side, the Baystate SSI case will expose agency implementation in a way rarely seen," Roth

said. "Although most of the issues in that case are quite technical, there will be 'daylighting' of some general implementation decisions by CMS that will resonate widely."

Zimmerman, an attorney with McDermott, Will & Emery, Washington, said the Baystate plaintiffs may prevail in court, but "they should be wary about congressional action that potentially undermines the value of a favorable decision in court." He said Congress "demonstrated a willingness to insulate [CMS] in the Deficit Reduction Act with respect to the Cookeville matter."

The lawsuit, *Cookeville Regional Medical Center v. Thompson* (D.D.C., No. 1:04-CV-1053), involved the applicability and validity of the Deficit Reduction Act of 2005 in determining whether 15 Tennessee hospitals were entitled to millions of dollars in Medicare payments for treating low-income patients.

Because DRA changed the law regarding the calculation of Medicare reimbursements under the DSH formula, and because that change applies retroactively, the district court determined it would grant the HHS secretary's motion to alter the judgment if the case is remanded from the United States Court of Appeals for the District of Columbia Circuit.

The D.C. Circuit did remand the case Dec. 18, 2006, although the court ordered the unpublished disposition to be withheld pending a timely petition for rehearing. There could be additional activity in 2007.

Disputes over the Medicare disproportionate share payments can involve whether the government must reimburse millions of dollars to hospitals. As Goldberg predicted, "If the monies [from a *Baystate* victory] become vast, look for Congress to step in."

By TERRY HYLAND, KENDRA CASEY PLANK, STEVE TESKE, JUDITH A. THORN, AND MINDY YOCHELSON