BNA's

MEDICARE REPORT

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Outlook 2011: ACO Regulations, Innovation Center, DMEPOS Bidding Top List

Health reform dominated the hospital landscape in 2010, and will continue to do so into 2011. Despite political battles that will be fought by Republicans and Democrats over whether to repeal the law, providers and health analysts say the Medicare quality and delivery reform provisions are likely to remain. The quality provisions of the Patient Protection and Affordable Care Act, like the Medicare Shared Savings Program, the Center for Medicare and Medicaid Innovation, and the Independent Payment Advisory Board, are intended to change the current Medicare payment system into a more quality-driven, low-cost payment system.

Many stakeholders have argued that the current fee-for-service system is fragmented and emphasizes quantity of care over quality of care.

Blair Childs, senior vice president of public affairs at the Premier healthcare alliance, told BNA he felt 2011 would bring no significant changes to the reform law. However, he said standard payment rules will mean hospitals will be subject to steep rate cuts during the next fiscal year.

Other representatives from Premier told BNA that since delivery system and payment reforms have bipartisan support, ''we expect these to stay in place, but as with all elements of reform, there will be intense oversight and investigations.''

Accountable Care Organizations

The looming concern among many providers is the Medicare Shared Savings Program, which calls for the formation of accountable care organizations (ACOs).

An accountable care organization is a group of medical care providers who accept responsibility for providing or arranging all care for a group of patients under a payment arrangement that allows them to profit from reducing costs and improving quality.

The cost, risk, and financial rewards would be shared among all the providers in an ACO. However, beyond an initial framework, the reform law did not give any specifics as to how the program would operate.

''The big question for 2011 will be the substance of the ACO regulations,'' Robert L. Roth, an attorney with Hooper Lundy & Bookman in Washington, told BNA.

Providers said they have been preparing for and expecting the Centers for Medicare & Medicaid Services to issue proposed regulations at any time. The Department of Health and Human Services noted in its semiannual regulatory agenda that proposed rules about ACOs would be issued in January. CMS Administrator Donald M. Berwick has said regulations would be issued by mid-January.

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Uncertain Regulations. ''ACOs require a new vision, new culture, and new practice; none of which are easy to achieve in health care,'' officials at Premier told BNA.

The law requires that CMS have the Shared Savings Program in place by Jan. 1, 2012, and CMS has received comments from numerous stakeholders on what they would like the ACO program to look like.

Most provider groups have urged flexibility in the proposed regulations, especially with regard to antitrust and anti-kickback statutes, as many of the laws are intended to prevent providers from integrating, for fear of market dominance and price fixing. Many stakeholders have also expressed a desire for CMS to test different payment models before finalizing any regulations.

For example, Jane Galvin, managing director of regulatory affairs for the Blue Cross and Blue Shield Association, told BNA ''there needs to be a balance in delivery system reforms so as not to increase provider consolidations.''

Galvin said consolidations could drive up costs. The testing of delivery system and payments models should have the goal of improving care and increasing quality with an emphasis on patient safety, she said.

Roth also spoke of the importance of how CMS and the Federal Trade Commission will apply the antitrust and fraud and abuse laws to clinical integration, which is essential to ACO adoption and expansion.

John Hellow, another attorney at Hooper Lundy & Bookman, noted that ''federal regulatory preemption'' may be called for if there is a conflict with state corporate practice of medicine (CPOM) doctrines.

States with CPOM laws prohibit an individual or entity that is not licensed to practice medicine from employing a physician and receiving fees for services rendered. It is intended to keep the decisions of physicians independent from corporate influences.

Hellow said that hospitals operating in states with CPOM could be at a disadvantage to hospitals and ACOs operating in states that do not have a CPOM doctrine. ''States with corporate practice doctrines likely may not be able to keep up, '' Hellow said, which may lead to calls for preemption.

The American Hospital Association (AHA) has said that providers are operating in silos of payment, standards, and care delivery. To transform care delivery, ''we need to bridge the silos, meaning we need to change our relationships across the silos,'' the group told CMS in a recent comment letter.

A careful balance also must be struck between the goal of care coordination to improve quality and efficiency and the desire to maintain beneficiary choice, AHA said. PPACA does not allow for restructuring the benefits or cost sharing for ACO-attributed patients.

Stakeholders and CMS have acknowledged that the ACO program is still a work in progress and will continue to be in 2011.

''CMS believes the ACO program is a tremendous opportunity,'' CMS Deputy Administrator Jonathan Blum said. He said the agency is ''not going into it having all answers,'' which is why stakeholder input has been key.

'Aggressive Schedule.' Despite all the comments CMS has received about the ACO program, they are still statutorily required to have the program in place by Jan. 1, 2012. Blum told BNA the reform law presented an ''aggressive schedule'' to develop and implement the ACO program.

He said the agency will meet the 2012 deadline while still adhering to ''all the notices and processes'' of a standard rulemaking cycle.

Still, Wendy Krasner, an attorney at Manatt, Phelps & Phillips LLP in Washington, told BNA that ''the frenzy over ACOs is not likely to abate, and indeed may overshadow or distract from other fundamental reform efforts, at least on the provider side.''

Krasner said the ''the content of the proposed rules will be critical,'' and unless CMS is able ''to thread a very fine line between providing flexibility but also providing a level framework for the many real issues of risk bearing, value, quality, transparency, antirust, fraud and abuse, beneficiary confusion, participation by specialty groups, funding and a whole litany of other issues, they could well bring these developments to a halt.''

During a December 2010 conference with stakeholders, Blum also said that providers should not focus so much on the ACO regulations that they lose sight of other delivery reforms.

Daniel Melvin, an attorney with McDermott Will & Emery's Chicago office, told BNA in October that providers should not wait for new Medicare ACO regulations to take effect before they start planning integration.

Melvin said hospitals and physicians should begin immediately to create, or convert, existing managed care integrated delivery systems. ACOs will have significant startup costs, and it would be beneficial for providers to work out the best business models for integrating before CMS comes out with its regulations, he said.

''In a perfect world, the hospital industry would know precisely what waivers/exceptions/safe harbors they will have the protection of before even forming an ACO, and so it would help to have that information before being put in a position of evaluating the proposed ACO regulations and gearing up for the Shared Savings Program in 2012,'' Melvin said.

''I doubt that CMS will be able to meet the 2012 deadline for the Shared Savings Program without forging ahead with ACO regulations and waivers/exceptions/ safe harbors on parallel tracks,'' he said.

Innovation Center

In another effort to improve quality and better coordinate care, CMS in 2011 will be testing different payment methods under the Center for Medicare and Medicaid Innovation (CMMI). The center was created under PPACA and charged with developing meaningful payment reform.

CMMI will test models that include establishing an ''open innovation community'' that serves as an information clearinghouse of best practices in health care innovation, according to CMS.

In addition, the center will work with stakeholders to create ''learning communities'' that help other providers rapidly implement these new care models. The health care law provided $5 billion in startup funds for the center and $10 billion over 10 years for new demonstration projects and pilot programs that can be implemented without congressional approval.

The CMMI will be accepting bids from stakeholders on what projects it should test. When the CMMI was officially launched in November 2010, Berwick, the CMS

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Top 10 Medicare Issues for 2011

According to a survey of the Advisory Board for *BNA's Medicare Report*, the top 10 Medicare issues for 2011 are:

1. Accountable Care Organizations: Regulations will be developed to determine shape and scope of ACOs
2. Center for Medicare and Medicaid Innovation: Regulators will test different payment methods
3. Independent Payment Advisory Board: Will propose cuts in Medicare payments that go into law unless Congress objects
4. Medicare Advantage: Includes changes in enrollment periods and a payment freeze
5. Part D Plans: Gradually reduces enrollees' share of drug costs in the coverage gap until eliminated in 2020
6. Incentive Programs: Physician quality reporting system and electronic prescribing incentive program offer extra payments for successful participation
7. E-Prescribing: Providers subjected to penalties who fail to participate successfully in the program
8. Competitive Bidding: Program requires beneficiaries who obtain competitively bid items to obtain them only from CMS-contracted suppliers that had bid successfully in 2010
9. Disproportionate Share Adjustments: Continued litigation of whether general assistance days should be included among Medicaid eligible days
10. Bad Debts: Litigation over use of collection agencies and concurrent write-offs

administrator, said it will be testing short term demonstrations, so the results can be analyzed and the programs implemented quickly, if they are successful.

''Time is of the essence,'' Berwick said at the time. ''Seven-year demonstration projects aren't going to be responsive to the pace of change that this country now needs and that the providers of care and the patients now want.''

In 2011, the CMMI will be working on, at least initially, four demonstration projects that will test the medical home and health home care concepts.

In one project, eight states were selected to participate in a demonstration to evaluate the effectiveness of doctors and other health professionals across the health care system working in a more integrated fashion and receiving payments from Medicare, Medicaid, and private health plans.

The eight states (Maine, Vermont, Rhode Island, New York, Pennsylvania, North Carolina, Michigan, and Minnesota) will participate in this demonstration, which ultimately will include up to approximately 1,200 medical homes serving up to 1 million Medicare beneficiaries, CMS said.

Another project, the Federally Qualified Health Center (FQHC) Advanced Primary Care Practice Demonstration, will test the effectiveness of doctors and other health professionals working in teams to treat low-income patients at community health centers.

CMS said the demonstration will be conducted by the CMMI in up to 500 FQHCs and provide patient-centered, coordinated care to up to 195,000 Medicare beneficiaries.

Preventable Readmissions. The Medicare program is paying too much for chronically ill beneficiaries, and while several demonstration projects by CMS have been unsuccessful, projects that will be created under the health reform law show promise to help control spending and improve quality.

For example, the Community-Based Care Transitions Program is intended to help reduce potentially preventable readmissions by covering a range of social services during the transitional period of a hospital discharge into a home or post-acute care setting.

Under the Hospital Readmissions Reduction Program, starting for discharges on Oct. 1, 2012, the secretary of health and human services must establish a hospital readmissions reduction program for potentially preventable Medicare inpatient hospital readmissions involving three high-volume and/or high-rate conditions. The number of conditions for which readmission rates are measured will be expanded by four conditions in FY 2015.

However, Premier stakeholders told BNA that the organization remains concerned that PPACA's readmissions policy would adversely impact safety net hospitals by applying payment reductions to all diagnosis-related groups (DRGs) based on readmissions within 30 days of hospitalizations for certain conditions in the prior year.

''This would have the unintended consequence of possibly increasing health disparities and unfairly disadvantaging communities that have a high proportion of vulnerable populations and higher cost burden of disease because these patients do not always have access to appropriate follow-up care in their communities, and have difficulties managing their health care needs (i.e., affording medications for chronic conditions such as diabetes and heart failure),'' Premier officials said.

Readmissions occur as a result of the totality of the health care system, and hospitals impact only part of that continuum, Premier said. Therefore, any readmissions policy must involve common incentives for physicians and post-acute care providers, recognizing that they ultimately make decisions on admission, discharge, and post-acute care for patients.

Regulatory Payment Changes. Hospitals will see their reimbursement rates for inpatient services occurring in fiscal year 2011 decrease by $440 million. CMS said the update reflects a marketbasket increase of 2.6 percent for inflation reduced by 0.25 percent, as required by PPACA.

In addition, despite the objections of hospitals, CMS kept in place a documentation and coding adjustment to recoup a portion of excess aggregate payments in FY 2008 and FY 2009 that do not reflect actual increases in patients' severity of illness.

The rule for FY 2011 set out a large proposed cut to adjust for additional payments that CMS estimated were made due to changes in documentation and coding following CMS's change to Medicare-Severity Diagnosis-Related Groups (MS-DRGs) for determining inpatient payment amounts.

CMS will implement a 2.9 percent cut ($3.7 billion) to recoup one half of the payments that the agency said were made in FY 2008 and FY 2009 due to documentation and coding changes that did not reflect increases in patients' severity of illness.

Independent consultant Larry Goldberg, Oakton, Va., told BNA that the rates of increase, coupled with the productivity adjustment and coding offsets, ''bode ill'' for hospitals.

''CMS's portrayal that next year's expected result would be to cancel itself out is quite misleading,'' Goldberg said. ''Whether you take 5.8 percent in fiscal year 2011 and zero percent in FY 2012, or 2.9 percent in each of FYs 2011 and 2012, you are reducing hospital payments by 5.8 percent.''

However, hospitals will see payments for outpatient services increase by $3.2 billion in 2011.

Hospitals also scored a victory in the outpatient rule when CMS changed the requirements for supervision of outpatient therapeutic services, including the need to establish a process for the independent consideration of the most appropriate supervision level for individual therapeutic services.

Under current policy, direct supervision is required for the duration of all outpatient therapeutic services in both hospitals and critical access hospitals (CAHs), although CMS officials have told contractors in guidance to not enforce the direct supervision requirement in CAHs for calendar year 2010.

For CY 2011, CMS is extending that decision not to enforce the requirement for direct supervision of therapeutic services provided to CAH outpatients.

However, CMS said it was concerned about establishing policies that apply only to critical access hospitals, so for the CY 2011 final rule the agency said it will be expanding the scope of the decision not to enforce the requirement for direct supervision of therapeutic services to include small rural hospitals having 100 or fewer beds.

The American Hospital Association was one of the groups that wrote to CMS, urging the agency to change the policy. AHA said it supports the development of that independent process and ''looks forward to working with CMS as it considers how the committee should be convened and operated.''

Independent Board

PPACA included a provision that created the IPAB, or Independent Payment Advisory Board. Its purpose is to cut the growth and maintain the solvency of Medicare through the recommendations of a 15-member panel. The board is required, when growth in Medicare outpaces inflation, to propose cuts to Congress, and Congress must adopt those changes, unless it votes not to.

The IPAB must include physicians, health professionals, employers, health economics researchers, and third-party payers, such as health insurance company representatives. Each member, appointed by the president, will serve a six-year term and the panel is scheduled to be appointed for duty during the next year. Funding is available starting Oct. 2011, but hospitals will be exempt from its decisions until 2020.

The IPAB has been controversial from the start, many stakeholders told BNA, but they said they were unsure if anything was going to be done about it. Premier officials said that ''the expansion of health care coverage is certainly the most threatened aspect of reform, and the movement of coverage may be slowed through state and federal resistance.''

However, the challenge, according to attorneys and stakeholders, is whether IPAB could be changed, or repealed, without finding a way to offset the savings it provides.

Medicare Advantage

The start of implementation of PPACA's Medicare Advantage (MA) provisions—including changes in enrollment periods and a payment freeze—coupled with the beginning entry into Medicare of 78 million baby boomers, should make 2011 an interesting year for Medicare Advantage plans.

MA plans were impacted by PPACA immediately in 2011 when faced for the first time with the absence of an open enrollment period.

PPACA ended the January-March timeframe in which beneficiaries were allowed to enroll in MA and replaced it with the more restrictive MA Disenrollment Period.

During the first 45 days of the year, MA enrollees are only permitted to return to fee-for-service, enroll in a stand-alone Part D prescription drug plan (PDP) or a Medicare cost plan, or buy a Medigap policy.

The change ''really takes away the opportunity for [MA] plans to continue marketing and for beneficiaries to change their mind between [MA] plans,'' according to Jennifer Kowalski, a director at Avalere Health LLC, a consulting company in Washington.

In addition, Congress moved the coordinated election period from Nov. 15-Dec. 31 to Oct 15-Dec. 7. This change will give plans more lead time for processing enrollments in preparation for the Jan. 1 beginning of the new contract year.

However, bids are still due the first Monday in June, Kowalski said in an address to a session of a recent American Bar Association Health Law Section conference.

''CMS is going to be dealing with all of these bids and all of these applications in a much more condensed timeframe'' before the start of marketing, she said. Plans will have to comply with CMS requests that flow from bid applications that much faster, she said.

Year of Preparation. Overall, however, 2011 in various respects will be a year of preparation as some of PPACA's other MA changes, such as maintaining minimum medical loss ratios, do not occur until later in the decade.

Kowalski characterized 2011 as the ''transition year'' in which Congress froze MA benchmarks at 2010 levels as part of a $200 billion 10-year cut in the program.

''The real cuts to the program are not implemented until 2012,'' Blue Cross's Galvin said. ''In 2012, for the first time we will see the beginnings of a new payment system in Medicare Advantage.''

Changes contemplated in a CMS proposal for 2012 MA program operations do not take effect until after publication of a final rule, scheduled for early spring.

Galvin told BNA the proposal, published in November 2010, with comments due Jan. 11, has several significant provisions.

''CMS has revisited the concept of sharing plan payment data publicly and asked for comments in that

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arena,'' she said. ''We will have to look at that proposal as we don't want the release to harm the competitive nature of the bid process.''

She said the proposal also contains ''a lot of new operational requirements which appear to stem from some experiences CMS had with some plans this year.'' These new requirements on plans may raise costs and will be reviewed closely, she said.

A prelude to some of the MA changes on payment and policy will occur in February, when CMS issues its advance notice and draft Call Letter.

Impact of Cuts. Faced with impending large payment reductions, Ken Yale, of ActiveHealth Management, said service area contractions are expected.

Paul Deeringer, an attorney with Hooper, Lundy & Bookman, San Francisco, told BNA that consolidation in the MA market is likely to continue ''as established players with good cost management strategies succeed and newer, less tightly-managed players exit the market.''

In addition, MA enrollment will decline or the rate of MA plan growth will slow, he said, ''as beneficiary out-of-pocket spending is projected to increase substantially.''

Deeringer predicted that, as a result of the PPACA changes, MA plans ''that combine administrative economies of scale with high quality'' will do well.

''Given the overall lower rates and the impact of quality ratings on the rebate percentage, MA plans will likely continue—and possibly accelerate—their current efforts in disease management, care coordination, and provider network management,'' he said.

Similarly, Joshua Raskin, managing director of Barclays Capital, said that ''while MA plans will be forced to reduce benefits and increase premiums, there is still ample room for efficient plans to offer attractive options to seniors in many geographies.''

Change in House. It is unclear how the new Republican majority in the House will influence CMS's enforcement efforts.

''I can't remember a [CMS or its predecessor] that has been as aggressive in its compliance oversight or its enforcement activities,'' Bruce Merlin Fried, a partner in SNR Denton, told the ABA conference.

''It's been a wake up call for the industry,'' according to Fried, an agency managed care official during the Clinton administration.

As far as oversight, he referred in particular to ''stepped up'' risk adjustment data validation (RADV) audits, in which the agency attempts to confirm the presence of risk adjustment conditions that were reported by plans for their enrollees.

In addition, he said, ''we know the industry is facing data validation audits where, for the first time, CMS is going to require all MA plans to validate 300 data elements.'' Plans will have to engage auditors to review the elements and report back to CMS. ''That's a whole new world,'' Fried said.

Scheduled to begin in the spring, the data validation reviews are intended to ensure that the data reported by the sponsoring organizations are accurate, valid, reliable, and comparable among organizations (21 MCR 432, 4/23/10.

George Strumpf, with EmblemHealth Plans, predicted that the results of the mid-term congressional elections are not likely to affect how CMS will oversee MA plans.

However, Kowalski said she believes Republicans ''will be looking at what is happening to their constituents.'' If lawmakers find their plans are exiting the market, Kowalski said, ''I would not be surprised to see more oversight of what is going on at CMS.''

As far as MA payments, Yale predicted that the change in the majority party in the House will give MA ''some breathing room.''

Similarly, Krasner said ''that with the new Congress, it can be expected that at least Medicare Advantage may not be the target of additional cuts, unlike many other providers that may be vulnerable to further reductions.''

In other words, she said, ''while it is unclear if the payment side will get any better, at least it won't get worse.''

Roth told BNA that he expects ''ongoing battles between the House and Senate where the House will send up legislation that favors MA (and the insurers) in an effort to increase the costs of reform.''

Star Ratings. Beginning in 2011, when the 2012 rates are set, CMS will offer some plans higher rates for attaining certain quality levels, Raskin said.

''This is the first time that the Medicare star rankings will be used for reimbursement and, not surprisingly, this has become a major area of focus by the health plans,'' he said.

Kowalski said the bonuses might mitigate the upheaval that could result from the payment reductions.

Under the five-star rating system, as outlined in PPACA, MA benchmarks are increased for plans that receive at least a four-star rating, with both four and five star-rated plans receiving the same bonus.

However, this methodology is on hold until the conclusion of a three-year demonstration that will expand the number of plans eligible for bonuses beginning in 2012.

Instead of just the four and five star plans receiving payments, the demonstration would add bonuses for plans rated three and 3.5 stars.

In 2012, the quality-based payments will be based on star ratings for the 2011 plan year that were posted in November 2010.

Of the 560 MA-PD contracts awarded in 2011, just three contracts received a five-star rating—Kaiser Foundation Health Plan of Colorado, the Security Health Plan of Wisconsin, and the Capital Health Plan—and 74 received four stars.

However, 42 percent of plans were ranked at three stars, and 25 percent at 3.5 stars, allowing a substantial increase in the number that qualify for bonus payments.

'Right Direction.' ''We think this three-year demonstration was a step in the right direction,'' Galvin said, by allowing more plans to access the bonus payments in 2012.

While ''PPACA came pretty close to the worst case scenario for MA plans,'' Raskin said, ''it appears that the pendulum has begun to swing back the other way.'' The demonstration project ''will end up putting a lot more money back into MA, as early as 2012,'' he said.

Based on an analysis of some plans, Raskin estimated that the new bonus system will result in an average incremental increase of 1.26 percent for 2012.

However, ''the 1.26 percent does not translate directly into revenue increases,'' he said. ''There are factors included in the overall calculations that mitigate the impact of the bonus payments, and we expect plans to pass the bonus payments on to customers through lower premiums, and in turn grow membership.''

Both MA plans and CMS will use 2011 to focus on aspects of the star ratings on which the quality bonus program is based.

Ratings Focus. Liz Goldstein, director of CMS's Division of Consumer Assessment and Plan Performance, told the ABA conference that CMS wants to make the rating system more ''robust.'' Over the next few years, she said, the ratings will change as CMS incorporates findings from its research.

CMS bases its ratings on such sources as its own administrative data, enrollee surveys like the Consumer Assessment of Healthcare Providers and Systems and the Medicare Health Outcome Survey, and from the Healthcare Effectiveness Data and Information Set, Plan Finder Pricing Files, and its contractors.

However, CMS has had difficulties coming up with enough data to rate plans that are too new or too small.

''We're going to do more work in the coming year to try to come up with measurements for these contracts,'' Goldstein said.

In 2011, the agency also will look at developing ''improvement'' measures aimed at low performers, she said, and at ways to compare the quality of care of MA plans with that received under fee-for-service Medicare in the same geographic area.

CMS also wants to have a way of ''weighing measures'' so that not all are rated equally. For example, CMS could give a lower weight to telephone customer service and a higher weight to outcomes of care.

CMS would also like to see ''case mix'' taken into consideration for ''harder to treat'' enrollees, as well as ''geographic adjustment issues'' that come into play in professional shortage areas, Goldstein said.

Part D Plans

Although Part D plans are rated on different domains than MA plans, like MA plans, the bulk of Part D plans were rated at three or 3.5 stars in 2010 and 2011.

However, four contracts in 2011 received five stars—Simply Prescriptions, Medco Medicare Prescription Drug Plan, MedicareBlue Rx, and EmblemHealth Medicare PDP, Goldstein said.

As for policy, the Part D drug benefit ''has not seen the scope of significant legislative change'' that was made under Part C, Fried said.

But those items that were addressed within Part D ''were significant nonetheless,'' he said. These include the Medicare Coverage Gap Discount Program.

Beginning Jan. 1, enrollees' share of drug costs in the coverage gap (doughnut hole) was reduced gradually over 10 years, until 2020.

''We will have to see how the new Part D discount program, established by PPACA, works in 2011,'' Galvin said, including ''how many access that program and at what costs to the program overall.''

In 2011, for the first time, those who fall into the coverage gap—which begins when total drug costs reach $2,840—will receive a 50 percent discount on brand drugs and a seven percent discount on generics and compounded medications.

Those in the gap who purchase brands will get through the gap faster because the out-of-pocket costs count the full cost—not the 50 percent cost—of the drug.

Discount Workings. Drug plan sponsors receive monthly prospective payments from CMS, which provides cash flow to Part D sponsors for advancing the gap discounts at the point of sale.

On a quarterly basis, CMS invoices manufacturers for discounts provided by Part D sponsors, and the manufacturers remit payments for invoiced amounts directly to Part D sponsors.

The prospective payments made to Part D sponsors will be reduced by the discount amounts invoiced to manufacturers. These offsets will ensure that Part D sponsors do not receive duplicate payments for discounts made available to their enrollees.

However, concerned that manufacturers will raise prices in response to the discount program, Barbara Kennelly, president and CEO of the National Committee to Preserve Social Security and Medicare, told BNA that it is important that CMS ensure effective oversight.

''It is possible that manufacturers will 'game' their prices or that drug plans may encounter difficulty ensuring that the discounts apply at the point of sale,'' she said.

On another issue, Krasner said that CMS wants to establish rules to reduce the cycle for dispensing prescription drugs in long term care (LTC) facilities.

Academy of Managed Care Pharmacy Executive Director Judith Cahill called the dispensing change one of ''the most significant provisions'' in the November 2010 proposed rule.

Specifically, Krasner said, CMS proposed to require all pharmacies, closed-door exclusively LTC pharmacies, retail pharmacies, mail order pharmacies, and others servicing LTC facilities to dispense brand-name medications to Part D beneficiaries in no greater than seven-day increments.

''There are a large number of issues raised—such as impact on dispensing fees, billing, prescribers, and return of drugs for credit and reuse,'' she said. ''At a minimum, it can be expected to lead to a large number of administrative and reporting requirements for Part D sponsors, let alone the LTC stakeholders.''

Physician Payments

As Part B providers look to the next 12 months of CMS regulatory policies, enthusiasm for a 10 percent bonus payment that begins in 2011 by associations that count primary care physicians among their members is tempered by wariness of other upcoming policy changes.

PPACA offered extra payments to primary care practitioners for primary care services equal to 10 percent of their allowed charges. Groups representing generalists had told Congress that such a bonus was needed because of a shortage of primary care doctors and a differential in payments between primary care and specialties.

Robert Doherty, senior vice president of governmental affairs and public policy at the American College of Physicians, said that while the payments are ''not a

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magic bullet'' for physician payment problems, doctors could collect $60,000 over the five years of the dedicated funding stream.

CMS is determining a practitioner's eligibility using claims data and the provider's specialty designation from 2009.

Anders M. Gilberg, vice president, public and private economic affairs, Medical Group Management Association, said he was ''cautiously optimistic'' that those entitled will receive the payments without bureaucratic snafus.

Among the Part B regulatory issues, intended to stop fraud and/or improve quality of care, that will affect day-to-day operations in 2011 are those dealing with enrollment, incentive/penalty quality programs, purchasing of durable medical equipment, and doctor signature requirements.

Medicare Enrollment. In the latest in a series of delays, CMS said in November 2010 that it would put off for at least another six months a Jan. 3 deadline for denying claims for Part B items and services when the ordering or referring providers are not in its Provider Enrollment, Chain and Ownership System (PECOS,) an agency repository of enrolled Medicare providers.

Providers who enrolled in Medicare prior to 2003 and have not updated their records are required to do so before PECOS takes effect.

A ''placeholder'' effective date of July 5 was issued to give CMS ''flexibility to determine the appropriate date'' to institute rejection edits for claims received and processed on or after Oct. 5, 2009, that lack a PECOS-enrolled provider.

To prevent fraudulent billing, CMS has said that if an ordering/referring physician is not in PECOS and is not in the claims system, claims submitted by pharmacies, durable medical equipment, and other suppliers are subject to automatic rejection.

If CMS upholds the July 5 date, at that point ''warning messages'' from CMS on claims without the needed provider information will end and the claims will start to be rejected.

CMS said its staff ''is working diligently to resolve backlog'' of enrollment forms and other systems issues that led to the postponements and ''will provide ample advance notice to the provider and beneficiary communities before we begin any automatic nonpayment actions.''

Gilberg told BNA that CMS appears to be putting more resources toward reducing the backlog, and he predicts the edits that will deny claims will be implemented in mid-to-late 2011.

Lab Signature Requirement. Another January deadline that CMS postponed following complaints by industry is the laboratory physician signature requirement. CMS said it would put off the requirement until April (21 MCR 1504, 12/24/10).

Currently, physicians are not required to sign requisitions for diagnostic tests and, instead, have nonphysician staff take care of this paperwork, which is provided to a laboratory and identifies the tests to be performed.

Similar to the situation with PECOS—while the responsibility for the task is on physicians, it is the supplier of services, such as laboratories, that will get turned down for Medicare reimbursement, not the physician, if there is no physician signature.

''In fact, laboratories' experience with other comparable Medicare requirements—including those related to diagnosis codes and physician enrollment in PECOS—is that physicians are simply too busy treating patients and with their own practices to be concerned about what information the laboratory needs for it to be paid,'' the American Clinical Laboratory Association said.

The group asked that implementation be delayed for at least a year.

Shawn Martin, director of government relations for the American Osteopathic Association, told BNA that he found it inconsistent that CMS is moving quickly toward electronic prescribing requirements and yet is now requiring more paperwork in this area.

Instead, Martin suggested the use of a ''digital signature'' as the more appropriate route.

Doherty said that many physicians are unaware of the requirement and more outreach is needed.

Incentive Programs. ''In the physician payment rule, we watch the quality and performance measures and the direction of the agency on those two important areas,'' Galvin told BNA.

Primary among these are CMS's intertwined incentive programs—the physician quality reporting system (PQRS) and the electronic prescribing (eRx) incentive program—that offer extra payments for successful participation.

Gilberg praised CMS's decision to reduce the PQRS reporting sample requirements for claims-based reporting of individual measures from 80 percent of eligible cases seen during the reporting period to 50 percent. This will hopefully help some providers who did not qualify in the past, Gilberg said.

Martin said he expects a ''greater take up rate'' on PQRS in 2011, particularly with the ability to submit measures through approved registries, which are considered by some to be less cumbersome and more effective than claims reporting.

While Gilberg praised the relaxed reporting threshold, he said that it is difficult for providers when CMS does not post the list of eligible registries prior to the beginning of the reporting year.

Physician groups have said that they would prefer that CMS publish notices of registries that are designated as eligible to submit quality data prior to the start of the year to help physicians assess their reporting options.

Finally, in preparation for 2012, CMS will host a meeting in February seeking input on individual quality measures being considered for possible inclusion in the program.

E-Prescribing. In the area of e-prescribing, the first six months of 2011 will be critical for providers with authority to prescribe, as they will be subject to penalties based on their electronic prescribing success rate from January to June.

Under the program, eligible professionals who are not successful electronic prescribers are subject to losing 1 percent of their reimbursements on their fee schedule-covered services in 2012, whether or not they agreed to participate in the incentive program.

The American Medical Association and other groups asked the Department of Health and Human Services in December 2010 to revise the dates on which the 2012 penalty is based.

The letter, which is under review, said ''[i]n these hard economic times, it is inconceivable to force physicians to purchase and use a stand-alone e-prescribing program during the initial months of 2011 to avoid penalties that by law are not even required to be imposed until 2012'' (21 MCR 1482, 12/17/10).

Nonetheless, doctor groups questioned see higher participation levels in 2011.

Gilberg said that a larger percentage of his members are purchasing the technology needed for e-prescribing.

Doherty said that practice business managers are realizing it makes more sense to invest in electronic health record systems now, rather than waiting to maximize incentives.

DME Bidding

While physician groups do not appear focused on the issue, the DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies) Competitive Bidding Program will get the attention of Medicare suppliers.

The program, which was stopped by Congress after two problematic weeks in 2008, took effect Jan. 1 in nine areas of the country.

A congressionally-mandated effort to combat fraud and save money, the program in 2011 requires beneficiaries who obtain competitively bid items in nine competitive bidding areas (CBAs) to obtain these items only from CMS-contracted suppliers that had bid successfully in 2010.

''There continue to be significant concerns that are not being acknowledged, let alone addressed by CMS,'' Eric Zimmerman, an attorney with McDermott Will & Emery LLP, Washington, told BNA.

''The agency is betting on successful implementation to quiet the program's critics,'' Zimmerman said. ''If they're wrong, and problems with beneficiary access arise, Congress may have no choice but to step in to address concerns.''

Walter Gorski, vice president of government relations, American Association for Homecare, told BNA that he expects a repeat of the problems that occurred in 2008.

At that time, the group, which has led the opposition to bidding, said patients had to stay longer in hospitals because discharge personnel were unable to find hospital beds, power wheelchairs, home oxygen therapy, and other equipment and services needed for home use.

CMS has said that it has instituted improvements in the program and will monitor the outcome.

Activity in CBAs. On the local level, the Drake Center, a medical and rehabilitative hospital in Cincinnati, developed a form letter for constituents to send to CMS and Congress to stop the program.

''The program would require all Medicare patients in affected areas to use a limited number of suppliers for necessary medical equipment, such as wheelchairs, hospital beds, walkers, oxygen,'' Drake said in a November 2010 statement. ''For complex patients like ours, who often require several types of medical equipment, this will be a real hindrance.''

In another example, the MED Group, a purchasing/ referral network for home care providers, said in December 2010 that as many as 85 percent of medical equipment companies will be excluded from providing equipment in the Dallas-Fort Worth area.

''CMS has tried to educate referral sources and Medicare beneficiaries but with this large a change, it is nearly impossible to reach such a large segment of the population,'' according to the Lubbock, Texas.-based group, which created a website to help those in need of supplies.

Gorski said his group spent months collecting examples of how the program will impede beneficiaries' access to care.

He cited communications to CMS and Congress from 167 economists urging that, because of design flaws, the program be stopped ''to prevent harm to Medicare beneficiaries.''

Gorski said he expected problems to crop up first in the area of diabetic testing supplies, where pricing is low and beneficiaries may be forced to switch equipment.

''We are asking providers, patients, family members, and referral sources to report problems to the association related to the bidding program'' on http://www.biddingfeedback.com, AAHomecare said.

The bidding process in another 91 areas is scheduled to start later in the year.

Medicare Cases to Watch

Health care attorneys told BNA they are following several legal cases regarding Medicare reimbursement that may be decided in 2011.

Outlier Payments. When the cost of providing health care services exceeds Medicare's specified threshold, the Medicare program makes additional ''outlier'' payments to hospitals. Roth told BNA that the courts will begin addressing litigation concerning outlier payment shortfalls in 2011.

''[A] case to be filed shortly will challenge as arbitrary and capricious the establishment of the 2004 through 2006 outlier thresholds,'' Roth said. ''In each of those years, while the target set for aggregate outlier payments was 5.1 [percent] of [diagnosis-related group (DRG)] payments (and such payments were reduced by that amount), actual payments fell significantly below that level.''

The industry explained, in comments to the proposed threshold, the errors in the secretary of health and human services' methodology, Roth said. ''If those comments had been properly addressed by CMS, outlier payments would have more closely approached the 5.1 [percent] target,'' he added.

Disproportionate Share Adjustments. Medicare disproportionate share hospital (DSH) adjustment issues will continue to be litigated, including whether general assistance days should be included among Medicaid eligible days, Kenneth R. Marcus, an attorney with Honigman Miller Schwartz and Cohn, in Detroit, told BNA.

''Also subject to litigation are the three DSH adjustment components coming within the scope of CMS Ruling 1498-R: the [Supplemental Security Income percent], labor and delivery room days and exhausted dual eligible days,'' Marcus said. ''The validity of CMS Ruling 1498-R itself is also being challenged, with several cases pending before the United States District Court for the District of Columbia.''

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The cases Marcus referred to include *Alegent Health-Bergan Mercy Health System v. Sebelius*, D.D.C., No. 1:10-cv-01354-ESH, which was stayed until 45 days after the D.C. Circuit issues its decision in *Northeast Hospital Corp. v. Sebelius*; *Salt Lake Regional Medical Center LP v. Sebelius*, D.D.C., No. 11:10-cv-01447-ESH (*notice of voluntary dismissal by Salt Lake granted* 10/15/10); *Adcare Hospital of Worcester Inc. v. Sebelius*, D.D.C., No. 1:10-cv-02009-ESH; and *Trinity Health v. Sebelius*, D.D.C., No. 1:10-cv-02070-PLF; and one case pending before the U.S. District Court for the District of Hawaii, *The Queens Medical Center v. Sebelius*, Haw., No. 1:10-cv-00434-DAE-LEK.

The issue relating to whether Part C days should be included in the DSH adjustment is pending before the U.S. Court of Appeals for the District of Columbia in *Northeast Hospital Corp. v. Sebelius*, D.C. Cir., No. 10-5185 Marcus said (*see related item in the Legal News section*).

Bad Debts. Both Marcus and Roth told BNA that the courts will be looking at more bad debt cases in 2011. The bad debt cases will be focused on the use of collection agencies and concurrent write-offs, Roth said.

According to Marcus, two issues continue to be controversial. First is the validity of the so called ''must bill'' policy regarding persons dually eligible for Medicare and Medicaid. Under this policy, a hospital must first file a claim with the state Medicaid program, which in many instances pays little or nothing as the secondary payer, Marcus said.

Although the U.S. Court of Appeals for the Ninth Circuit upheld this policy in *Community Hospital of the Monterey Peninsula v. Thompson*, 323 F.3d 782 (2003) (14 MCR 338, 3/28/03), the issue continues to be litigated before the Provider Reimbursement Review Board, Marcus said.

Marcus also pointed out that under the policy regarding use of an outside collection agency, Medicare bad debt that has been referred to a collection agency cannot be included in a hospital's bad debt claim until the year in which the collection agency ceases collection activity and returns the claim to the hospital.

The Sixth Circuit upheld this policy in *Battle Creek Health System v. Leavitt*, 498 F.3d 401(2007) (18 MCR 961, 8/17/07), Marcus told BNA. The U.S. District Court for the District of Columbia, however, held that the policy violated the Bad Debt Moratorium in *Foothill Hospital-Morris L. Johnston Memorial v. Leavitt* (D.D.C., No. 1:07-cv-00701-ESH, 5/30/08) (19 MCR 629, 6/6/08), he added.

Medical Education. Marcus said that two cases are pending before the courts regarding payment for residents training in the nonprovider setting, *Covenant Medical Center Inc. v. Sebelius*, 6th Cir., No. 09-2443 and *MedCenter One Health Systems v. Sebelius*, 8th Cir., No. 10-1377, regarding the specific issues of whether a ''written agreement'' requirement was satisfied and whether two or more hospitals may support a single medical education entity.

''There are at least six cases pending before the federal district court in the District of Columbia regarding whether patient days relating to persons covered by a Medicare managed care plan may be counted for medical education purposes where the hospital did not satisfy a UB-92 report filing requirement,'' Marcus said.

He added that the lead case, *Loma Linda University Medical v. Sebelius*, (D.C. Cir., No. 10-5116, 12/2/10) recently received a favorable decision from the D.C. Circuit.

Hospice Cap Rule. More than 20 federal cases involving the hospice cap rule are pending nationwide, including certain group cases in the District of Columbia, attorney Brian M. Daucher, with Sheppard Mullin Richter & Hampton LLP, in Costa Mesa, Calif., told BNA.

To date, more than a dozen federal district courts have held the cap unlawful, as contrary to the statute, and no court has upheld the regulation, he said.

The Medicare hospice cap is a retrospective cap on total annual reimbursement from Medicare to hospices. If payments to a provider exceed allowances in any year, then the Centers for Medicare & Medicaid Services demands repayment of the difference, Daucher said.

In an October 2010 decision, the U.S. District Court for the Eastern District of North Carolina ruled that the regulation used by the Department of Health and Human Services to calculate the reimbursement cap for the hospice care provided by Native Angels Home Care Agency is contrary to law and invalid.

Despite the statutory language in 42 U.S.C. § 1395f(i)(2)(C), which directs a hospice's number of beneficiaries in a fiscal year be reduced to reflect the proportion of hospice care provided to each individual in a prior or subsequent accounting year, the court found the rule at 42 C.F.R. § 418.309(b)(1) assigns the entire amount of a beneficiary's allocation to a single year based solely on the date of admission (21 MCR 1278, 11/5/10).

Daucher told BNA that the hospice cap affects about 300 hospices per year with resulting repayment demands against the hospices of approximately $300 million.

In 2007, hospices began filing lawsuits to challenge the Medicare regulation, asserting that the allocation method used by Medicare is inconsistent with the proportional allocation method required under the statute.

A nationwide injunction against further use of the regulation was issued by a court in the Central District of California but was stayed pending appeal to the U.S. Court of Appeals for the Ninth Circuit (*Haven Hospice Inc. v. Sebelius*, 9th Cir., No. 09-56391, *argued* 10/6/10), Daucher said.

However, Daucher told BNA, until Medicare ceases use of the regulation (voluntarily or by court order), each hospice must take steps to preserve its appeal rights by filing appeals with the Provider Reimbursement Review Board.

In 2011, the Fifth, Ninth, Tenth, and D.C. Circuit Courts of Appeal are expected to hear and decide pending hospice cap cases. Daucher, who is counsel for many of these hospices, told BNA that decisions in these cases, if in agreement with the district courts as to invalidity of the regulation, may result in suspension of use of the regulation by the end of 2011, he said.

By Judith A. Thorn, Nathaniel Weixel, and Mindy Yochelson