Health Business Outlook 2011

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This report is a compilation of stories that appeared in AIS’s health business newsletters in December 2010 and January 2011.
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Outlook for Health Plans

If You Thought 2010 Was a Challenging Year for Insurers…You Ain’t Seen Nothin’ Yet

With new medical loss ratio (MLR) rules in effect, a new Republican majority in the House already looking to dismantle the health reform law, pressure from state and federal regulators to keep rate hikes in check and a flurry of new regulations yet to be finalized and released, 2011 will make 2010 look like a walk in the park for health insurers. But issues tied to the reform law are far from the only ones health plan executives will struggle with in 2011. In this issue of AIS, we ask some of our top industry sources to identify the most significant challenges for health insurers in 2011.

11 Challenges Insurers Will Face in ’11

From ensuring profitability to improving collaborations with providers, health insurers have their work cut out for them in 2011. Here’s a look at some of the top challenges they will face:

(1) Staying in the black: Medical cost inflation, unprecedented premium controls and underfunded Medicare Advantage (MA) programs will place enormous pressure on health plans, cause profit margins to shrivel and could cause “one or two familiar insurers to crumble by the end of the year,” says Carlton Doty, vice president and practice leader at Cambridge, Mass.-based Forrester Research. Over the past few years, he notes, for-profit health plans have been effective at managing their top and bottom lines. They’ve been so good, in fact, that some quarterly earnings have prompted negative press “that portrays them as greedy profit mongers,” he asserts, adding that a profit margin of 3% to 5% is hardly greedy. But even justified rate hikes are likely to be rejected if state or federal regulators deem them as “unfair and unreasonable,” he predicts.

(2) Interpreting and implementing reform law provisions: The most significant challenge insurers will face is interpreting — and implementing — the myriad new compliance requirements of the health reform law (e.g., medical loss ratio levels, insurance coverage mandates, limits on underwriting and rate increases), says John Hickman, an employee benefits attorney with the law firm Alston & Bird. “All of the interim final regulations (IFRs) are set to be finalized in early 2011 and insurer attention will turn from interpretation of the IFRs to implementation of the newly refined mandates,” he says. Paul Fronstin, a senior research associate with the Employee Benefit Research Institute, agrees and says juggling implementation of the reform law with cost controls — in a political environment where the future of health reform is uncertain — will be the year’s biggest challenge.

(3) Countering continued vilification: As the White House and HHS use the health reform law to cast health insurers in a negative light, “I think the greatest challenge for insurers will be one of public relations,” says Mark Stember, a partner at the law firm Kilpatrick Townsend & Stockton, LLP in Washington, D.C. Requests to increase premiums will be used to illustrate that health insurers are not complying with the new law and/or are over-charging consumers, he predicts. While providers, pharmaceutical companies and medical device manufacturers appear
to be accelerating price increases, “as a society we lack the political and social will to address it,” adds Peter Kongstvedt, M.D., principal of Virginia-based consulting firm P. R. Kongstvedt Co. “As the run-up to the [reform law] demonstrated, it is far more satisfying to beat on the payers, so they’ll probably get cuffed around some more [in 2011],” he says.

(4) Improving collaboration with providers: To control the overall cost of care and coverage, providers and health insurers need to develop a more holistic approach, says Henry Loubet, vice president and chief strategy officer at Keenan, a California-based consulting and insurance brokerage firm. “There needs to be more collaboration between health insurers and providers because increased government regulation isn’t going to get us to where we need to be.” While CEO of UnitedHealth Group’s western region in the mid to late 1990s, Loubet says he emphasized the need to build relationships with providers while recognizing the tensions that existed because of the contractual negotiations. Over the past several years, however, provider/payer relationships have grown much more adversarial, he tells AIS. “I have seen a deterioration of relationships that exist between health insurers and providers. It always will be challenging, but I think there can be improvements.”

(5) Dealing with new lawsuits: While it might be good news for attorneys and legal consultants, health insurers could see more class-action lawsuits and individual legal challenges from “disaffected plan members who feel insurers are not complying” with the reform law, says industry consultant and actuary Ronald Bachman, a senior fellow at the Center for Health Transformation. Moreover, he says, health insurers will need to sink more money into lobbying efforts to ensure they receive waivers or exemptions to provisions that might be difficult to comply with.

(6) Coping with new MLR regulations: The medical loss ratio floors, which went into effect Jan. 1, 2011, require a minimum MLR of 80% for small-group and individual products and an 85% MLR on the large-group side. Plans unable to meet those requirements will be required to refund a portion of premium dollars to members. “Coping with the MLR limitations will present a significant challenge since it sharply limits the upside but places no limits on the downside,” says Kongstvedt. A recent PriceWaterhouseCoopers report says health plans already are considering outsourcing some services or looking at ways to reclassify some administrative costs. For example, some insurers might consider contracting with provider-run accountable care organizations to manage costs through capitated payments, according to the report.

(7) Educating the public: Health insurers will need to improve transparency and explain to members the impact the reform law will have on their coverage and rates, according to several industry observers. With regulatory unknowns related to many reform law provisions — and the likelihood of last-minute state and federal regulatory guidance — health plans must be ready “to rapidly deploy timely, relevant and personalized member communications to educate their members on their coverage and rates,” says Fred Karutz, general manager of health plan solutions at Silverlink Communications. “We expect that plans will use scalable and pervasive communications, such as text [messaging] and HIPAA-secure voice, to ensure that members ‘get the message.’” Prior to joining Silverlink, Karutz spent 10 years as a corporate vice president at Health Care Service Corp., which operates Blues plans in four states.

(8) More self-insured employers: Rising premiums and innovations in stop-loss insurance will prompt more small employers to self-insure their health benefits, predicts Mac McCarthy, president of Virginia-based McCarthy Actuarial Consulting, LLC. A growing number of employers are already considering a shift toward self-insured benefits, according to a report released...
in December 2010 by the ratings firm Standard & Poor’s. A migration away from commercially insured group products would likely result in lower revenue and cash-flow generation levels. Third-party administrators and health plans, he adds, will partner with stop-loss carriers to avoid the MLR rule, state mandates and premium taxes as well as anticipated federal insurance company fees, he tells AIS. Brokers and agents will support and promote this trend “as commissions on traditional lines dry up,” he adds.

(9) More demanding employers: Work-site wellness programs will continue to proliferate, but employers will become “much more assertive” with vendors and will insist that they deliver on promised ROI or face penalties. Independent measurement of results and aggressive performance guarantees are increasingly being used to hold wellness and disease management vendors’ feet to the fire, says McCarthy.

(10) Ensuring affordability and sustainability: Health plans will be asked to demonstrate their value in leveraging new ways of engaging consumers, patients, providers and markets, says Michael Parkinson, M.D., principal at P3 Health LLC, a consulting firm that promotes personal and organization prevention, performance and productivity improvements. “Closer alignments with delivery systems, access to better clinical information, new broker/consultant relationships and serious consumer engagement in health and health care should all be part of the post-reform strategy,” he says. “But unless these elements are executed with a sense of urgency and true patient-centeredness to deliver more effective and safer care for the consumer, then plans will have a hard time justifying their role and perhaps existence going forward.” Parkinson previously was chief health and medical officer at Lumenos, a seller of account-based health plans that WellPoint, Inc. acquired in 2006. He also is a former president of the American College of Preventive Medicine.

(11) Maintaining or growing enrollment: One final but significant challenge for health plan operators will be a continued reduction in the overall number of covered lives as well as increased cost sharing, says Kongstvedt. That, he explains, will result in “lower actual premium dollars for insured business and more effort required to administer self-insured business. This is compounded by the continuing rapid increase in cost in combination with stubbornly high unemployment.” One market segment likely to grow or at least be immune to significant enrollment declines is Medicare Advantage, he adds. “However, it will require ever-increasing efforts to produce an acceptable margin.”

Predictions for AIS’s Health Plan Week’s Five Most Surprising Headlines of 2011

AIS’s Health Plan Week asked several industry observers to offer their thoughts on the most unexpected headline the health insurance industry is likely to see in the year ahead. Here’s a look at their predictions:

♦ HHS Sec. Sebelius Steps Down
— Carlton Doty, Forrester Research

♦ U.S. Uninsured Population Tops 50 Million (as employers and individuals drop coverage in anticipation of federal subsidies in 2014)
— Ronald Bachman, Center for Health Transformation

♦ White House Endorses Repeal of Individual Mandate (bowing to mounting public pressure and court challenges)
— Mac McCarthy, McCarthy Actuarial Consulting, LLC

♦ Employers Partner Directly With Select Providers to Create New Insurance Option
— Michael Parkinson, M.D., P3 Health, LLC

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Aetna, CDPHP, CIGNA and Geisinger CEOs Weigh in On ’11 Challenges

AIS’s Health Plan Week queried top executives from Aetna Inc., CIGNA Corp., CDPHP and Geisinger Health System and asked them to describe some of their new product and technology innovations for the year ahead. We also asked them to weigh in on what they see as the biggest hurdles the industry faces under the reform law. Here’s a look at their responses:

(1) What plan-design tweaks or added features do you anticipate for your commercial products (small and large group) in 2011?

John Bennett, M.D., president and CEO of CDPHP: For our large groups, we have introduced CDPHP Shared Health. This product gives employers the security of a fully insured plan with the financial flexibility and control of a unique funding mechanism and is available to groups with 50 or more enrollees in CDPHP EPO [exclusive provider organization], PPO plans and high-deductible plans. Employers can manage their upfront health care dollars by funding a portion of the claims paid. We also expanded our Life Points incentives program — which rewards members for healthy activities — to be offered upon group renewal with most CDPHP benefit packages. The program provides members ages 19 and older the opportunity to earn up to $365 in points annually per contract for a variety of healthy activities. For our small groups, we have teamed up with a regional health care system in one of our service areas to offer a targeted EPO product to provide affordable access to comprehensive, high-quality, value-based health care. This product is designed to provide employers additional choice and value for health care options in this region.

David Cordani, president and CEO of CIGNA Corp.: Our clients are focused on improving their employees’ health and productivity. To help them achieve this goal, we are launching two new programs for our middle market clients, a fast-growing market for us with employers who have 500 to 2,500 employees. The first, our Chronic Care Support program, takes an integrated medical and lifestyle approach that enables our health coaches to access an individual’s full health history to understand the whole person and evaluate his or her health risks and conditions. The coach will help individuals develop a personal health plan specific to their complete health needs. The coaches have the ability and resources to assist those who have lifestyle habits that are hindering their ability to manage their chronic conditions. The second initiative, “Better Health Guaranteed,” is designed to help individuals at risk for diabetes, stroke, cancer and other illnesses. These risk factors will comprise potentially 85% of a company’s health care costs in the next few years. CIGNA believes so strongly in the power of our health programs that we will provide a guarantee: If an employer implements our programs, and we do not improve the health of the employer’s at-risk employees in 14 months, CIGNA will invest more than $1,000 in health services for each participating employee who is at risk.

Mark Bertolini, president and CEO of Aetna Inc.: We will continue to engage and empower our members by delivering better resources such as our member payment estimator, which allows members to research the cost of a service before they go to the doctor’s office. We will also look for new ways to deliver useful information such as mobile applications that help members check on the status of a claim while they do their grocery shopping. These types of resources will help people get the most out of their health plan by giving them the tools they need to be smarter health care consumers.
Jean Haynes, president and CEO of Geisinger Health Plan: We are encouraging employers who are interested in improved employee health and wellness to implement value-based incentives. This approach helps motivate employees through an enhanced cost-sharing structure. These features are part of new products that we currently are selling. In addition, employers expect a health plan that proactively engages and educates employees in wellness and consumer awareness, and offers networks that offer higher quality and greater value. Employers are also looking to insurers for guidance regarding health care reform.

(2) What will you do to streamline your administrative costs to help ensure compliance with the medical loss ratio rules?

Bertolini: We will continue to look for ways to be more efficient by simplifying the way we operate. For example, over the past several years we have reduced the number of IT systems we use to administer our products and services, lowering costs associated with supporting multiple systems and enabling us to adapt more quickly to changes in the marketplace.

Bennett: In New York, the MLR is set at 82% for certain products, so adhering to these requirements is familiar to us. However, the federal MLR requirements, and in particular the recognition of quality improvement activities, bolster our company goals of finding ways to improve quality, reduce costs, and improve efficiency. This includes research and investment into IT resources and initiatives; supporting the use of [electronic medical records] and information exchanges; working with our provider community to create different payment methodologies to recognize quality, including enhancing our medical home initiatives; and developing products/programs that will accommodate our members’ individual needs. Our focus has always been on quality of care, and the MLR requirements make this a perpetual goal.

Cordani: We are making better use of technology to improve customer engagement and reduce costs while improving our service delivery and investing in programs key to our future effectiveness. As we look ahead, we see further opportunities for efficiency gains in five categories of spending: vendor management, or purchased services; targeted outsourcing; real estate consolidation; leveraging technology; and employment-related costs. The second critical part of this strategy revolves around improving our medical cost position by, for example, implementing specific contracting programs with health care professional and driving incentive-based programs in which we work effectively with customers, clients and physicians to remove costs from the system. We are already reducing costs while improving the quality of care.

Haynes: We will continue to lower overhead by investing in new technologies that automate manual processes, as well as standardize plan designs and consolidate benefit options where it makes sense.

(3) For health insurers overall — and your company specifically — what do you see as the most challenging provision of the reform law?

Bertolini: Reform provides new ways for insurers to deliver value to the health care system, such as becoming an integral part of the health information exchange (HIE) backbone of the country. Our recent acquisition of Medicity is one example of how we can use technology based solutions to help improve the quality and efficiency of patient care. You will also continue to see Aetna innovate in the area of product design and consumer tools that enable smarter health care decisions. All of this work will help address the issues that the health care reform bill left largely unanswered: affordability and quality.
Bennett: The most challenging provision of the reform law is [that] it’s multifaceted: First, overlapping regulation with many new aspects of federal regulation of the commercial insurance market overlays our operations in an already heavily regulated state. Second — because of the significant amount of regulatory discretion given to the HHS secretary — is the timeliness and clarity of HHS guidance and requirements in implementing the bill. Third, the new definitions of allowable medical expenses for the purposes of computing MLR will require new methods of “bucketing” expenses for reporting purposes, yet it’s not clear if auditing standards have caught up, or will catch up soon, with the NAIC recommendations and looming HHS regulations on the issue. Lastly, with all the new requirements on health insurer pricing and reporting, not enough was accomplished in the bill to address the true drivers of medical costs.

Haynes: Additional taxes on health plans and strict MLR requirements may hinder the ability of health plans, especially regional health plans such as Geisinger Health Plan, to reinvest in innovations that improve the health and wellbeing of our members and all Americans. It is important to ensure that quality performing regional plans like us have representation at the table when the health care reform rules and regulations are being developed. We will continue to reach out to federal and state legislators and policy makers to share our experiences and successes. Finally, we will continue to develop payment models that financially reward providers for quality outcomes, not units of work. ☄
Outlook for Blues Plans

Reform Law Leads Blues to Tweak Employee Benefit Plans

Employees of Blue Cross and Blue Shield plans will see changes to their benefits in 2011, as plans of all shapes and sizes continue their aggressive efforts to keep costs down and steer enrollees to tools and tactics designed to keep them healthier. Also driving employee benefit design changes: the emerging mandates of health reform. Indeed, plan activity in many regions is focused on beefing up their employee benefits’ coverage without, in some cases, raising premiums.

Blue Cross Blue Shield of Louisiana is an example. Calling it “probably the most exciting highlight for our employee benefit plan in 2011,” John Maginnis, the insurer’s vice president of corporate communications, notes that the insurer projects no premium increase for employees for its medical, dental or vision plans.

“The company has experienced reduced expenses since implementing a comprehensive wellness program in 2006,” he reports. “And we’ve been able to keep premium increases down even with the increased coverages required by the PPACA [i.e., the Patient Protection and Affordable Care Act].” For example, the insurer has eliminated all annual and lifetime limits.

For 2011, the Louisiana Blues plan also is adding a personalized weight management offering to the employee wellness program and continuing company-paid health savings accounts contributions for participants in the high-deductible health plan at $1,000 for single coverage and $2,000 for dependent or family coverage.

BCBSRI Adds Wellness Incentives

Similarly, “the associate health plan premium contribution structure will not change” at Blue Cross & Blue Shield of Rhode Island, reports spokesperson Kimberly Reingold. But enrollees must meet wellness requirements, including completing a personal health assessment and seeing a primary care physician and dentist for an annual well visit. “If the member and his or her spouse or domestic partner do not complete the wellness requirements,” Reingold adds, “the member will be subject to a 5% premium increase for the 2012 plan year.”

For everyone, however, the new plan does raise the deductible and some copayments. “And we’ll include a vision benefit. The plan also will cover dependent children through age 26,” Rein-gold says.

Those are familiar themes. Blue Cross and Blue Shield of Florida says it’s “improving the cost structure of its benefits plans to make them more affordable,” according to spokesperson Mark Wright, “and promoting financial and personal wellness through a variety of programs that emphasize education, preparation and personal responsibility.”

In the Volunteer State, BlueCross BlueShield of Tennessee “took a market-based approach to adjusting the health plan design for its employees,” says spokesperson Mary Thompson-Daniel-son. “Premiums increased as a result of the increasing costs of medical care, and our seed contributions to health savings accounts decreased slightly.”
To help encourage employees to take a more active role in managing their health, she adds, the plan is “providing an incentive for those who keep a current biometric screening on file.” At the same time, she notes, the plan revamped its wellness incentive program to make it “more accessible to more employees.” A new points-based system “offers a variety of ways to participate and earn incentive dollars,” she says, “from tracking steps with pedometers to engaging with a health or disease management coach.”

Out West, Blue Shield of California reports that the majority of the medical plan design changes taking place in 2011 are in response to health reform legislation, including coverage for dependents up to age 26, removal of lifetime plan maximums and no reimbursement for non-prescribed drugs under plans that are compatible with flexible spending arrangements and health savings accounts.

Blue Shield of California is also making changes in the area of wellness through Wellvolution, its wellness initiative. In 2011, employee participants will be eligible to earn a premium discount for meeting specified health goals. Previously, “participation” goals were the only way to earn rewards. In addition, the plan says, “recognizing the power social cohesion has on making and maintaining lifestyle changes, Wellvolution will be rolling out a number of social networking tools and initiatives for employees and their family members.”

Premera Blue Cross is also beefing up its wellness tools. “Examples of additional support for wellness and prevention for our associates include annual onsite biometric measurement, onsite flu shots and mammograms, healthy dining options in our campus cafés and onsite cooking classes to promote healthier eating choices at home,” says spokesperson Eric Earling.

K.C. Blues Blends Buy-Up Options

And right in the center of the country, Blue Cross and Blue Shield of Kansas City has “taken several innovative steps for 2011 with its own employee health plan to ensure that it can continue to control costs and keeps employees healthy,” says spokesperson Sue Johnson. “Our company contribution will remain consistent, with an average contribution by the company of 89%. However, we are blending our base and buy-up plan options to allow for changes in copays and deductibles with minimal impact on overall rates.”

The only change to its HMO — which is the plan selected by the majority of eligibles — is an increase in emergency department copays, Johnson notes. “The blending of our plans also sets the stage for implementing value-based incentive programs for health conditions relating to diabetes and coronary artery disease,” she says. Also, the Kansas City Blues plan will provide benefits for office visits for nutritional or diet counseling for obesity and morbid obesity when received at a facility or from a physician.

In addition, BCBSKC says it’s “asking its employees to engage more fully in their own health by taking an electronic health risk appraisal and calling a health coach,” Johnson points out. “If our employees are identified as having three or more risks, we are asking that they engage in programs in 2011 designed to reduce risk,” she explains. “If they choose not to take the HRA [i.e., health risk assessment], call the health coach or participate in programs, they will incur an additional health premium in the amount of 20% of the equivalent of the total cost of the employee-only coverage.” The Kansas City Blues plan is also asking employees to make a “declaration of non-tobacco use. If they chose not to, they’ll pay an additional health premium.” ÷
Blues Launch New Small-Group Products With Focus On Wellness, Cost Controls

Expect to see a fairly robust crop of new small-group and individual products from Blue Cross and Blue Shield plans in 2011. The focus in most cases, as in the design of the plans’ traditional products, will be on keeping members healthy and keeping costs down.

In April 2011, for example, Blue Cross & Blue Shield of Rhode Island will launch a new product for small employers, a PPO design that provides access to the same national provider network as the carrier’s premier product Healthmate Coast-to-Coast. The new product “is designed to encourage members to live healthier lives by providing incentives for healthy behaviors such as a reward when they fill out a personal health assessment and reduction or waiver of copayments for preventative services and medications to treat certain chronic conditions,” reports spokesperson Kimberly Reingold.

And on the cost side, Blue Cross and Blue Shield of Kansas City will provide a two-year rate cap after the first year for small-group customers that buy plans with an effective date after Jan. 1, 2011, says spokesperson Sue Johnson. “At first renewal, those groups will receive a 7.9% rate increase, and at their second-year renewal they’ll receive a 9.9% increase,” she says, “generally far less than the increases those types of companies typically would experience.”

Blue Cross and Blue Shield of Florida, similarly, says it’s introducing new individual and small group products into the market in 2011 and that it “continues to add benefit designs focused on wellness, alternate locations of service, pharmacy formulary choice and indemnity-type coverage for certain types of services.”

And Highmark Inc. will launch a value-based benefit design product for group customers in 2011, says spokesperson Michael Weinstein. “Value-based benefit designs target chronic diseases, which make up more than 75% of health care costs,” he says. “The logic behind value-based benefit design is that if employees have to pay less — or nothing — for the screenings, tests, prescriptions and medical visits to treat their chronic conditions, they are more likely to follow the recommended treatment and stay healthier, ultimately saving the employer long-term costs.”

Blue Shield of California plans to launch new plans in 2011 with “a focus on delivering a wide range of benefit levels and price points,” a spokesperson says, “but they will be easier to understand and use. We want consumers to be able to select a plan that fits their needs and their budgets.” All plans will comply with federal health reform benefit and eligibility requirements, the spokesperson adds.

BlueCross BlueShield of Tennessee, meanwhile, won’t unveil any new individual products 2011 — because it just launched Personal Blue in 2010. That product line includes a richer wellness benefit and additional higher-deductible options to provide more affordable plans, says spokesperson Mary Thompson-Danielson.

There are a number of new small-group products and programs on tap, however, for in 2011 and next, says Thompson-Danielson, based “on where we know we are going with health care reform as well as on our existing group market.” Some specific plan aspects slated for fleshing-out, she adds, include higher deductibles for some of the carrier’s PPOs and high-deductible health plans; packaged value-based benefit designs to allow for different drivers and incentives; and packaged programs with disease management participation, mandatory wellness, limited prescription drug programs and a focus on preventive services. ♦
Competing IT Demands Force Blues Plans to Triage Resources

Nobody’s particularly excited, of course, about balancing the competing information technology resource needs of the switch to ICD-10 coding and the electronic medical records and other mandates of the health reform law. But Blue Cross and Blue Shield plans, for the most part, say they have long experience in balancing competing IT demands. The head-to-head projects may be bigger than usual, but most plans are using tried-and-true tactics to stay on top of all of them.

“Like most companies, we constantly have competing needs on all fronts,” comments Kimberly Reingold, spokesperson at Blue Cross & Blue Shield of Rhode Island. “Whether our technology demands are a result of the reform mandates or projects that are required to conduct day-to-day business more efficiently, we have cross-functional teams responsible for understanding the needs and resources across all projects, as well as prioritizing and coordinating those technology efforts.”

Preparing for the 10th revision to the International Statistical Classification of Diseases and Related Health Problems involves preparing IT systems to accept the greatly expanded list of ICD-10 diagnostic codes, among other fixes. Meanwhile, the health reform law, through provisions such as the medical loss ratio minimum and rebate requirements, requires insurers to operate more efficiently.

The law also encourages insurers to “work collaboratively with providers to expand the quality improvement and medical management programs to help ensure that members receive the right care in the right health care setting,” explains Highmark Inc. spokesperson Michael Weinstein. At the same time, “we must lower our administrative costs so that we can be more competitive in the marketplace and continue to grow our business. That’s a marketplace imperative.”

Blues Add Staff for IT Fixes

One of the biggest challenges facing the Rhode Island Blues plan, says Reingold, is “having enough individuals to complete all the work that needs to be done, which makes the cross-functional teams’ jobs extremely important.”

Blue Cross and Blue Shield of Louisiana is facing the same issue, reports spokesperson John Maginnis. “We are outsourcing more work and hiring more programmers,” he says.

Blue Cross Blue Shield of Delaware also “will increase its capital spending significantly in 2011 to address the requirements of HIPAA 5010, ICD-10 and health care reform,” a spokesperson says. The insurer has been planning for 5010 and ICD-10, along with their required components, for the last couple of years. “Through a structured internal prioritization process and comprehensive resource oversight,” the spokesperson adds, “we have been able to meet all health care reform timelines and requirements thus far.”

Regence BlueShield, for its part, is relying on the response teams it established in 2010 with representatives from operations, health care services, IT, legal, policy and customer service. “Those individuals meet regularly and often to learn about the latest developments in reform legislation as well as clarifying responses,” says Rachelle Cunningham, spokesperson for the
plan. “They have been very active within the corporation to inform the appropriate teams when action is necessary.”

Further, she says, the company’s long-term strategy for reform and its impact on technology operations there is to “build on its current process of business and IT sitting together to identify the best, most prudent and successful solutions to meet the needs of health care reform — as well as our customers’ expectations of service.”

Regence is also active within several Blue Cross Blue Shield Association committees, Cunningham adds, working with other Blues technology leaders to “create shared technology solutions to help serve the needs of the many Americans who are currently Blue Cross Blue Shield members as well as the many who will be with the enactment of reform.”

Teams are already on alert at Blue Shield of California, too. “Legal mandates are the first priority in the company,” a spokesperson says. “We have established dedicated teams with senior-level leadership for each of the [IT] projects,” coupled with consultants and vendors.

There’s a bit of silver lining, adds Mary Thompson-Danielson, spokesperson at BlueCross BlueShield of Tennessee, and it actually relates to the timing of the competing IT projects. “Fortunately, most of the 9/23/2010 provisions and near-term requirements [of health reform] did not involve any of the systems or resources related to ICD-10 implementation,” she notes. And going forward, there will be some overlap with administrative simplification provisions. “Another fortunate aspect of the administrative simplification changes is that most of them will be accomplished with the January 2012 implementation of HIPAA II,” she says, “and well ahead of the ICD-10 implementation.”
Outlook for Reform

GOP Will Go After Reform Funds in 2011; One Expert Calls for Bipartisan Compromise

Assaulting the health reform law’s administrative funds may be as far as the Republicans get in dismantling its power in 2011, although one health care industry observer says that President Obama should try to adopt a middle-of-the-road approach with the GOP to avoid an even bigger political battle on repeal in 2012.

Dan Mendelson, CEO of consulting firm Avalere Health LLC and a former health budget official during the Clinton administration, offers two scenarios of what could happen on the reform front in 2011. “One is to fight and to defend the construct, which puts you on the defensive. The second is to come with some moderate package of compromises so that the president appears willing at that point to be more moderate in his outlook,” Mendelson tells AIS.

Republicans since regaining control of the House have made no secret of their plans to wage full-scale war against the law. Rep. Fred Upton (R-Mich.), the new chairman of the House Energy and Commerce Committee, indicated in news reports and in op-ed articles in late December 2010/early January 2011 that the House would take immediate steps to dismantle the sweeping reform law, either in its entirety or piece by piece. Pundits expected the House to vote to repeal the law on Jan. 12, 2011.

House Republicans seem confident they’ll have enough votes to override a presidential veto there, but the repeal bill first faces an obvious hurdle in the Senate, where Democrats still hold the majority. According to news reports, Senate Democratic leaders have already warned new House Speaker John Boehner (R-Ohio) that they’ll block any effort to repeal the law. Outgoing chairs of key health care committees in the House also pushed back in a Jan. 4, 2011, letter to the Republican counterparts taking over their positions. “Repealing the health care law will increase the deficit, kill jobs, increase taxes, and deny care to women, children, and seniors,” says the letter signed by Reps. Henry Waxman (D-Calif.), Sander Levin (D-Mich.) and George Miller (D-Calif.).

Robert Moffit, Ph.D., senior fellow with the Heritage Foundation’s Center for Policy Innovation, a conservative think tank in Washington, predicts the real debate will begin once a full-scale repeal vote takes place in the House and then is ultimately held up in the Senate. Following that will be votes to defund portions of the law, with the mandates on employers, the states and Medicaid, and the individual mandate “as legitimate up-front targets. I think the reason why the state issues are so important is because the states are going to be the institutional centers of resistance over the next two years. You’ve got 29 GOP governors…many of whom were elected because they opposed the federal law.”

Outside of Congress, state challenges to the law have been hot and heavy in the courts, with a federal district court judge in Virginia taking the biggest swing to date on Dec. 13 by striking down the individual mandate. The latest action against the mandate took place Jan. 3, 2011, when new Wisconsin Gov. Scott Walker (R) authorized Attorney General J.B. Van Hollen to proceed with a legal challenge to the same provision.
Republicans can spew rhetoric about killing the individual mandate, or repealing the entire law, but to be successful, they’ll need key three ingredients: enough support from Democrats in the Senate to pass the repeal, an alternative that fully offsets the savings in the law, and sufficient political pressure to bring the president to the table, Mendelson says.

He suggests that Obama could take a centrist approach similar to 2010’s tax compromise, and work with the Republicans to craft a moderate package of fixes. “He could come to the Congress and say: ‘Let’s work together to make sure some of your ideas are incorporated into this bill.’ If he could actually get them to play on that, he could take away one of their most potent electoral issues.”

A compromise of this sort might include efforts to eliminate unpopular provisions such as the IRS Form 1099 filing requirement for small businesses’ payments to vendors, the Independent Payment Advisory Board (IPAB), the requirement that higher-income Medicare eligibles pay more in premiums, and new restrictions on health savings accounts, he says. “No one really wanted to tighten down on health savings accounts. But it was done as a way to generate budgets so they could cover more people,” Mendelson says.

Some See Small Odds for Big Compromise

Alexander Vachon, Ph.D., a health care consultant with Hamilton PPB, contends that such a compromise is a long shot. The tax bill included other Democratic priorities, and there was room for old-fashioned horse trading, he explains. “In the scheme of things, letting the rich have two more years of tax relief seemed to be an acceptable price. But what can Obama trade with Republicans [on health reform]? Sure, the GOP might be willing to deep six the IPAB and the 1099 provision, but I don’t see them backing off because [Obama] agreed to go along with some of these minor changes.”

The core controversies of health reform are the individual mandate, subsidies for the individual purchase of insurance and the expansion of Medicaid. “On those three issues, I don’t know where there’s a compromise for the president,” Vachon tells AIS.

There’s also the appropriations piece to this equation, sources noted. Congress has yet to finish fiscal 2011 appropriations; a continuing resolution to fund the government expires March 31, 2011. The CR contained no new spending on health reform. This sets up a big fight on reform spending for the first quarter, as House appropriators work to either complete action on the remaining appropriations bills or draft another CR for part of or the entire year. If GOP appropriators wanted to use a scalpel, they could put a rider in whatever spending bills they craft “to shut down HHS’s authority to do any administrative work on health care reform…that no funds could be used for Jay Angoff’s salary,” Vachon says. Angoff heads HHS’s Office of Consumer Information and Insurance Oversight (OCIIO), which is charged with implementing many provisions of the reform law that address private health insurance.

Turning to the budget for fiscal year 2012, which begins Oct. 1, 2011, “this will be a budget serving up more fiscal austerity. There’s a broad consensus resounding coming out of the election that people want to see Washington more attentive to more fiscal discipline. As a result, I think there will be more health care offsets or payment reductions loaded into the budget,” Mendelson said.

In seeking to defund specific health reform activities, Mendelson says the main target will be administrative funding for key departments and agencies charged with the implementation of
the law, including OCIIO and CMS, plus the IRS, which is responsible for collections relating to
the reform law. “This will be a high-stakes budget game that may well result in threats to shut
down the federal government if accommodations can’t be reached...clearly a source of leverage

HHS Sec. Kathleen Sebelius told reporters in a Jan. 4, 2011, conference call that “this is go-
ing to be a tough budget time not just for implementation of health reform but across the federal
government.”

The president has made it clear that he intends to work with federal agencies to reduce the
deficit and control federal spending, “and so we’ve been in the process of scrubbing our budgets
and agencies to eliminate redundant programs, to figure out ways to maximize the efforts that
we have,” Sebelius said. On whether the Republicans could successfully underfund reform, she
noted that some implementation money was immediately available to implement the law when
it was enacted. In addition, “there are some features like the new exchanges that are sort of self-
funded, so unless they are repealed, they actually have a funding stream that is available.”

The Congressional Budget Office on Jan. 6 estimated the cost of repeal would be $230 billion.
“Those that argue to reduce spending” need to produce answers on where they could fill that
gap in the event reform is repealed, Sebelius asserted. ♦
Outlook for Pharmacy

Experts Predict: Reform Fallout, Limited Networks, Specialty Rx Glut, Consolidation

’Tis the season to ponder what the coming year may bring. AIS consults an array of experts on what to expect for pharmacy management in 2011. From the intended and unintended consequences of health reform to the increased leveraging of limited pharmacy networks to the burgeoning cost and influx of specialty drugs, our Magic 8 Ball of insiders forecast the shape of things to come in the drug benefit world.

◆ Jon Andrews, director of product and sales strategies, HealthTrans, LLC:

Managing clinical costs: As rising medical and pharmacy costs continue, look for clinical programs to truly start driving medical cost offset. More specifically, disease management and advanced clinical programs will truly need to come into their own in 2011 as pharmacy vendors deliver programs and services designed to support MCOs in hitting their MLR numbers.

Continued consolidation of PBMs: Following the trends in 2009 and 2010, we can expect to see a lot of consolidation activity in 2011. PBMs with less than 10 million lives will find it increasingly more difficult to compete against larger players who dominate the landscape through market share-driven discounts. To combat this trend, smaller players will need to deliver innovative solutions that truly separate them from the larger competitors and focus on faster, more efficient approaches to typical pharmacy benefit issues. One key area in this will need to be claims processing flexibility and speed to adjust benefit design in a matter of days versus weeks.

Raising the GUR bar: For 2011, generics will continue as the new key savings ground. Generic utilization rates should trend from high 70%s to low 80%s for carefully managed plans. In light of this, benefit designs that reinforce and further support generic utilization will be key. We can also expect to see greater use of “generic only” formularies as another cost control tool.

◆ Steve Miller, M.D., chief medical officer, Express Scripts, Inc.:

Impact of specialty drugs: A prominent trend in 2011 will be increased attention on specialty drug spend — specifically on that part of the spend occurring in the medical benefit. On average, more than 55% of total specialty drug spend occurs in the medical benefit. To be competitive over the next decade, PBMs must meet plan sponsors’ demand for a new generation of tools designed to curb the unsustainable increases in drug spend across both pharmacy and medical. Going forward, plan sponsors will look for a comprehensive specialty benefits organization that can manage specialty spend as a whole.

Until now, most PBMs have been able to manage pharmacy drug spend only, and plan sponsors have had to rely on a health plan or turn to non-PBM vendors to manage their medical drug spend. Leading consultants are projecting that as soon as the next 12 to 15 months, plan sponsors will select a PBM based on who can most effectively control specialty drug spend and enhance patient care in both the pharmacy and medical benefit.
Wide Range of Services

Meeting demands of plan sponsors: Specifically, plan sponsors will expect a wide range of medical benefit management services, helping them to ensure the safe and appropriate use of drugs billed through the medical benefit; direct patients and drugs through the most cost-effective and clinically appropriate channel; verify the accuracy and efficiency of their reimbursement and billing practices; and control spend across many complex disease states, such as cancer and pulmonary arterial hypertension.

◆ Tim Watson, Pharm.D., executive director, Pharmacy Benefit Management Institute, LP:

Shift to outcomes-based contracting: Discounted fee-for-service arrangements have been the prevailing contracting model for health care services, including prescription drug programs. While optimal provider reimbursement strategies play an important role in controlling health care costs, it isn’t the only, or most, important factor. As the market begins its transformation into accountable care organizations, we believe the pharmacy benefit program will begin its own shift to outcomes-based contracting. Agreements with pharmaceutical firms will focus less on unit price of the product, and more on achievement of value as determined by payers. In addition, pharmacy service providers will be held accountable for not only delivering products at a reasonable price, but for demonstrating meaningful improvement in health status for participants served by those firms.

Direct-contracting movement: A growing list of payers may embrace a direct-contracting strategy for their pharmacy benefit programs. Some major employers (e.g., Caterpillar, Delta) have already led the charge to direct contracting with providers of pharmacy services. As the results of early mover strategies become publicized, a broader segment of employers may look for strategies to follow in their footsteps. In 2011, we may see the direct-contracting approach evolve further to include participants from a broad segment of the employer market.

Erosion of traditional formulary management: The patent cliff facing brand products across the therapeutic spectrum has been well documented. With many plans exceeding 80% of all prescriptions being dispensed as generics, the remaining patent-protected small molecules will be subject to very aggressive management approaches. The state of the environment has led many in the pharmaceutical community to shift the entire focus of their R&D programs towards niche markets that are underserved.

In many cases, these niche markets include rare conditions with limited or no competition. As formulary management strategies rely on competition between therapeutic participants in major classes to achieve preferred pricing arrangements (e.g. cholesterol), this strategy becomes less effective as the availability of competitor products decreases.

It will take a while for the wholesale changes in the pharmaceutical R&D model to alter the approved product landscape, but we believe a steady erosion of traditional formulary management processes has begun. The next generation of appropriate use determinations/price negotiations needs to be developed. It will be centered more on discussions of the overall value provided by the product, with outcomes based contracting pillars included into future payer/pharmaceutical agreements.

◆ Ed Pezalla, M.D., national medical director for pharmacy policy and strategy, Aetna Inc.:

Continued health reform fallout: Health care reform will continue to be a major issue as payers try to modify payment systems and benefit designs while regulations are still being written. The fate of some provisions is in doubt adding a great deal of uncertainty, which will cause
payers to be cautious. Impact on pharmaceuticals for the commercial sector will be limited in 2011 but greater in subsequent years as exchanges go into place and minimum coverage rules are solidified.

Impact of specialty drugs: Specialty pharmaceuticals will continue to be an area of discussion. Their high cost makes them a target for utilization management, but the promise of better outcomes will increase the need to cover these medications. Cost sharing for members will be more widespread stimulating the debate over the price of these medications and over benefit design issues. States will examine cost-sharing by members but in writing new legislation and regulations will be cautious that they do not impose mandates that will increase the cost of state and municipal programs for employees and retirees.

◆ Dan Mendelson, president, Avalere Health, LLC:
Continued health reform fallout: Areas of focus may include pharmacy and therapeutics committee operations, whether some products oriented to prevention should have preferential tiering, and how benefit designs, patient cost sharing and drug availability should be regulated. Federal intervention has increased as PBMs will need to report medical costs as part of the medical loss ratio rule, increasing the transparency of their operations.

Streamlined Medicare Advantage and Medicare Prescription Drug Plans: At the same time, CMS is becoming a more proactive regulator for Medicare Advantage and the Medicare Prescription Drug Plans. CMS is limiting the number of choices plans can offer and cracking down on plan premium increases and benefit design, increasing the pressure on plans to manage costs to avoid premium increases. At the state level, budget pressures and the expanding Medicaid program requirements are forcing a reconsideration of Medicaid pharmacy benefit structure and coverage. States may move more aggressively for supplemental rebates given the new expansion population and may look for ways to leverage the new exchange population to get better rebates. In MA-PD, the use of quality scores will also have plans focused on how to increase their payments, and some of the present measures are directly related to pharmacy.

Innovation Rules

Adapt early, adapt often: Innovation will also continue in private markets. Present trends that will intensify include aggressive tiering, management of specialty benefits, leverage of generics in light of major patent expiries and rapid deployment of maximum allowable cost pricing. As pharmacy markets become more competitive, we expect to see more use of preferred relationships along the lines of Humana-Walmart Preferred Rx Plan, [a low premium, low copayment plan utilizing Walmarts’s pharmacy network] that will challenge independent pharmacy.

◆ Adam Fein, Ph.D., president, Pembroke Consulting, Inc.; author, DrugChannels.net blog:
Impact of specialty drugs: Specialty trend will continue to grow by 15% to 20% yearly. The complex channels for specialty drugs still make it hard for payers to get full visibility on spending or manage utilization. In 2011, we’ll see new types of competition emerge as everyone jumps at this opportunity. PBMs will move into the buy-and-bill business. GPOs will enter the specialty pharmacy business. Retail pharmacies will expand specialty services, especially for Medicare Part D populations. Distributors will try to consolidate their influence with community oncology practices. It will be a free-for-all.

Continued consolidation among PBMs: Scale matters in the PBM industry, especially in these last few years of major generic launches. PBMs will be big winners from health care reform since
they are the likely administrators of expanded prescription drug coverage in plans sold through health insurance exchanges. This brand-new market will appear in 2014, which is conveniently right after the big wave of generics crests.

Proliferation of preferred pharmacy networks: The trend toward preferred pharmacy networks will accelerate in 2011. Preferred networks use consumer incentives to shift prescription volume into the pharmacies that provide lower costs for the payer. Consumers retain the ability to choose their pharmacy, while the consumer is partially exposed to the costs of this choice.

Cost-plus pharmacy reimbursement: Reimbursement approaches based on pharmacy acquisition cost (rather than list prices) will gain momentum. Two state Medicaid programs began to implement these programs, and a number of new direct-to-payer, cost-plus agreements were announced by large pharmacies. These models will accelerate consolidation in the pharmacy industry, but payers will need to evaluate the potential negative impact on generic dispensing incentives.

Mark Merrit, president and CEO, Pharmaceutical Care Management Association:

Curbing Medicaid spending: Modernizing Medicaid pharmacy is more of a possibility now that health reform has eliminated incentives for states to carve pharmacy benefits out of managed Medicaid programs in order to collect rebates from drug manufacturers. The problem is that most Medicaid programs have state officials determine how much to pay drugstores for each prescription filled (dispensing fees) and ingredient costs (the reimbursement for the cost of the actual drug). Unlike Medicaid fee-for-service (FFS) programs, most health plans use third parties to improve generic utilization and to negotiate pharmacy payments directly with chain drugstores and the drug wholesalers that represent independent pharmacies.

Modernizing Medicaid

The result is that Medicaid FFS pharmacy programs use fewer generic drugs and pay pharmacies higher dispensing fees and ingredient costs than other programs. Modernizing Medicaid pharmacy can reduce costs without cutting benefits, limiting eligibility, demanding deeper manufacturer rebates, or paying drugstores ever-higher dispensing fees in hopes that it will increase generic dispensing.

George Van Antwerp, general manager, pharmacy solutions, Silverlink Communications:

The things that I’m monitoring and think will affect the industry include mobile health, behavioral science application, preference-based marketing, risk based contracting, and integration with home monitoring devices. Rising costs will push several things such as increased management of the specialty benefit, more focus on adherence, and an increased understanding of how consumers impact health outcomes and how to best engage them. In 2011, innovations and changes in benefit design could include limited networks, more and more utilization management especially step therapy and 90-day retail or mail.

The biggest area of discussion in Medicare Part D right now is the Star Ratings. There are questions for PBMs about how they support the MA metrics and there are now specific PDP metrics. Understanding what those are, how to track them, how to influence them, and how to improve them will be a major focus in 2011.

This coming year and beyond, PBMs will begin to look more like disease management companies with their retail relationships being key in driving outcomes.
Kemp Dolliver, managing director, Avondale Partners, LLC:

Continued health reform fallout: The Patient Protection and Affordable Care Act has triggered a consolidation and outsourcing wave among health plans and PBMs in a drive for increased scale, bargaining power and efficiency. …This environment will create turmoil in the PBMs’ health plan client base. Health plan mergers will lead to changes in vendors (usually in favor of the acquiring plan’s PBM.) In addition, some health plans may simply exit the market and cede their business to a different carrier (witness Principal Financial ceding its business to United Healthcare). In addition, we expect consolidation involving smaller PBMs. Walgreen’s PBM business reportedly is for sale, and CIGNA continually evaluates options for its PBM. CVS Caremark’s agreement to purchase Universal American’s Medicare Part D business [see story p. 1] is only the latest example of consolidation in this market segment.

Separately, the PPACA eliminates the tax deduction for employers who receive Medicare Part D retiree drug subsidy payments in 2013. This provision has led many employers to consider dropping retiree drug coverage in favor of letting them enroll in Medicare Advantage or PDPs. 3M, for example, has announced plans to drop retiree coverage, and other employers could follow suit.
Outlook for Specialty Pharmacy

New Oral Specialty Drugs Will Complicate Management of Many Therapeutic Classes

Although the FDA approved only about 20 drugs in 2010, there were many notable specialty therapies that came onto the U.S. marketplace. The 2011 pharma pipeline similarly looks stuffed with potential entrants to multiple specialty classes, some of which will fill gaps in care that are sorely needed and others that will add to already-crowded classes. Plans would be wise to keep abreast of these developments, as the costs for these medications show no signs of decreasing.

Laurie Amirpoor, Pharm.D., staff vice president of clinical program policy at WellPoint, Inc., points out that “30% to 40% of the [pharma] pipeline is related to specialty,” with almost half of those drugs oncolytic therapies. “Newer drugs, although they will be very helpful to members, will be expensive.”

Ed Pezalla, M.D., national medical director for pharmaceutical policy and strategy at Aetna Inc., agrees, noting that “we have seen double-digit increases as far as some of the drugs [hitting the market] over the last few years.”

One drug that could absolutely impact drug trend is the lupus therapy Benlysta (belimumab), says Debbie Stern, vice president of managed care consulting firm Rxperts, Inc. Human Genome Sciences, Inc. and GlaxoSmithKline plc are co-developing the drug — which had its FDA action date extended from Dec. 9, 2010, to March 10, 2011 — for the treatment of systemic lupus erythematosus (SLE), the form of lupus that can affect internal organs. The autoimmune disorder affects about 1.5 million in the U.S., and Benlysta “would be the first new drug to treat SLE approved in decades,” Stern notes.

According to Atheer Kaddis, Pharm.D., vice president of managed markets for Diplomat Specialty Pharmacy, SLE “really does not have good treatment options today.”

Benlysta’s approval would be “significant” because it fills “an unmet need,” contends Alan Lotvin, M.D., president of ICORE Healthcare.

In the category of hepatitis C treatments, protease inhibitors boceprevir from Merck and telaprevir from Vertex Pharmaceuticals are expected to receive FDA approval midway through the year, says Steve Burman, CEO of Burman’s Specialty Pharmacy. “Right now there are approximately 25,000 patients being treated for hepatitis C,” he tells AIS, and “an estimated 600,000 patients that are waiting for treatment.”

Among the patients waiting for new drugs, Burman says, “50%...have already failed conventional therapy,” perhaps due to the severe flu-like side effects of the drugs, as well as the fact that they just aren’t effective in all hepatitis C patients. “The other 50% of the patients are naïve” and have never been treated for hepatitis C, he explains. “Naïve patients should see their chance of clearing the virus increase from 50% to 75%.” After the two drugs are approved, “the patients on hepatitis C therapy are likely to increase substantially.”

Stern tells AIS that this new class of drug to treat hepatitis C has the “potential to add on to current interferon therapy.” While the 2009 Drug Trend Report from PBM Express Scripts, Inc.
says the average cost per prescription for hepatitis C is $1,201.42, it also contends that per-member per-year costs for hepatitis C are expected to rise 155.2% over the next three years.

Joseph Morse, Therigy president and chief operating officer, tells AIS that the treatment plan for the new hepatitis C therapies “will be considerably complex, and the need for patient management by specialty pharmacies, as well as comprehensive policies by payers, is going to be critical. The service model and tools from manufacturers will need considerable improvements to ensure patients’ start of therapy and ongoing support are optimized.”

**RA May See New Entrants**

Payers should keep an eye out for new oral biotech treatments for rheumatologic conditions, says Helen Sherman, Pharm.D., chief pharmacy officer for The Regence Group’s RegenceRx, a not-for-profit PBM. “This is already a complex area which spans across medical and pharmacy benefits.” Potential 2011 entrants to the U.S. market, she says, include Pfizer Inc.’s tasocitinib for rheumatoid arthritis (RA) and psoriasis and Celgene Corp.’s apremilast — whose approval may slide to 2012 — for psoriasis and psoriatic arthritis.

Kaddis adds that “there is also a self-injectable version of Orencia (for rheumatoid arthritis) in development.”

In September 2010, the FDA approved Novartis’s Gilenya (fingolimod), the first oral multiple sclerosis (MS) medication. Sherman says additional oral options could hit the marketplace in 2011, including Merck Serono’s Movectro (cladribine) for relapsing forms of MS and two more for relapsing remitting MS: sanofi-aventis SA’s teriflumonide and Biogen Idec’s dimethyl fumarate, also known as BG-12.

New oral and IV MS therapies would “introduce more choice into that area and hopefully provide more care…to patients” who have been unresponsive to currently available therapies, Pezalla tells AIS. He also points to an ongoing trend within the class of neurological conditions, including MS, of newly approved medications that “improve quality of life…even though the drugs do not” specifically impact the disease. For example, the FDA approved Ampyra (dalfampridine), an oral agent that improves walking in people with MS, early in 2010. Such drugs are not “trying to modify the disease process, but are add-on therapies to improve” various functions, he says.

RA and MS are two of the top therapeutic conditions driving drug trend, and both classes have seen huge price increases among the available therapies.

According to Red Book, in January 2003, wholesale costs per year for the MS drugs Avonex (interferon beta-1a), Copaxone (glatiramer acetate), Rebif (interferon beta-1a) and Betaseron (interferon beta-1b) were in the $10,000 to $20,000 range. By January 2010, though, their wholesale costs per year had increased to about $40,000. And Gilenya came onto the market with a price tag of almost $50,000 per year.

Moreover, Express Scripts lists the average cost per prescription as $1,744.19 for drugs to treat inflammatory conditions. Per-member per-year costs for these therapies are expected to increase 62.9% over the next three years, says the PBM.

“As in the past, there will be drugs for select rare disease conditions” — such as Uplyso (taliglucerase alfa) for Gaucher disease from Protalix BioTherapeutics, Inc. — hitting the U.S. marketplace, says F. Randy Vogenberg, Ph.D., a principal with the Institute for Integrated Healthcare and strategic pharmacy advisor to the Business Group Pharmacy Collaborative. “But
from a national viewpoint, there is not much impact on coverage issues or insurance product planning. As health reform unfolds, how underwriting is achieved at the state level will be most important to watch,” he tells AIS.

Sherman maintains that these “additional options for rare conditions” provide “an opportunity for differentiating products based on formulary designs and/or utilization management approaches.”

These coming alternatives for very expensive therapies are “fascinating,” says Lotvin. Uplyso and Shire plc’s Vpriv (velaglucerase alfa), which was approved in 2010, offer alternatives to Genzyme Corp.’s Cerezyme (imiglucerase) for Gaucher patients. He says that potential competitors to GlaxoSmithKline’s pulmonary arterial hypertension therapy Flolan (epoprostenol sodium) may offer options to patients as well.

According to Craig Kephart, president and CEO of Centric Health Resources, Inc., a handful of drugs to treat muscular dystrophy could come to market within the next 12 to 14 months.

In addition, “there is a lot of interest in Huntington’s, a devastating disease,” he says, noting that he’s hearing “a lot of buzz” on the condition.

One interesting drug to watch in 2011 is Egrifta (tesamorelin), which is a synthetic analogue of growth hormone-releasing factor, says Sherman. The FDA approved the drug Nov. 11, 2010, to treat HIV patients with lipodystrophy, which causes excess fat in the liver, stomach and other abdominal organs and is a side effect of many of the antiretroviral treatments for HIV.

“The dilemma for payers is to determine whether treatment of lipodystrophy is a medically necessary covered benefit — in other words, whether treatment of lipodystrophy improves health outcomes or is a treatment that changes body appearance,” she tells AIS. “RegenceRx is in the process of working through this issue, as well as evaluating potential safety issues.”

More Oncology Immunotherapies Expected

Kephart points out that “40% of the specialty pipeline is oncology,” and many of these will be “at the forefront of companion diagnostics….Oncology is a place to keep an eye on.”

“We’ve seen a flurry of activity around prostate cancer,” notes Pezalla. Plans should “expect to see more therapies geared toward more common cancers, such as breast, melanoma, non-small cell lung and prostate.”

2010 saw the FDA approve Dendreon Corp.’s prostate cancer therapeutic vaccine — or immunotherapy — Provenge (sipuleucel-T), the first of its kind to receive approval. Sherman points to other immunotherapies in the oncology pipeline, noting that “these are treatments often reserved for severe or resistant cases. Traditional chemotherapy weakens the immune system while it destroys cancer cells. Cancer ‘vaccines’ boost the immune response as the mechanism to treat cancer.”

Similar drugs to watch for in 2011 include the subcutaneous BiovaxID, from Biovest International, Inc., for the treatment of non-Hodgkin’s lymphoma, and Merck’s oral ridaforolimus for soft-tissue and bone sarcomas, says Sherman.

Other oncology trends, says Stern, include more oral agents and targeted therapies.

Kaddis tells AIS that “the exciting oral oncology in development are for melanoma and acute myelogenous leukemia. Both of these diseases are treated with infused chemotherapy agents currently.”
However, Elan Rubinstein, Pharm.D., founder and principal of consulting firm EB Rubinstein Associates, contends that “in oncology, one of the big problems is there are more and more oral agents. Doctors and nurses can’t see how patients are doing week to week and whether they’re having side effects. There’s a need for a new approach for orals.”

**Specialty Pharmacy’s Investor Interest Should Continue Into ’11**

Following dismal merger and acquisition (M&A) activity in specialty pharmacy in 2009, the sector rebounded in a big way in 2010, more than doubling the prior year’s deals. And that performance, experts say, will continue into 2011 due to multiple factors.

In 2009, six specialty pharmacy deals were completed, a sharp drop from the 12 to 17 deals done over the previous few years. “There was a big fall-off in 2009, likely due to fears about the economy,” says Dexter Braff, president of The Braff Group, an investment banking firm specializing in home health sectors.

But through the end of the third quarter of 2010 — the most recent data available — The Braff Group has identified 12 specialty pharmacy deals, Braff tells AIS. “Over the same period [in 2010], there were four” specialty deals, he says. “That’s a very big difference.”

He adds that there was another notable aspect to the 2010 specialty pharmacy M&A climate: the number of platform deals, which are when private-equity companies make an initial acquisition in a segment upon which they’ll base a business strategy. Platform deals are usually trailed by follow-on transactions to grow the business. Previously, 2007 saw the largest number of platform deals within the specialty pharmacy sector, with three, Braff says. But through the end of the 2010 third quarter, there were five such deals, and his company has identified at least two more from the fourth quarter.

“We know we’ll wind up the year with at least seven of these deals,” he notes. In specialty pharmacy, 2010 has “seen more investment in private-equity platform acquisitions than any other year by far.”

And those seven deals “portend extremely well for a surge in follow-on transactions,” Braff asserts. “The rebound in activity seen in 2010 is going to have greater legs than other periods where we saw a surge,” he adds, pointing to the “geometric” pattern of platform transactions prompting follow-on transactions.

Because of the “unique expertise” required for specialty pharmacy, “the easiest way to grow is to acquire companies,” he says. “There is a great synergistic economic incentive to do follow-on transactions. Specialty really can boost economies of scale.” Once a firm has a base company, it can “layer on another revenue stream” fairly easily, he explains.

“Looking into 2011, we expect to see continued consolidation and investment throughout the specialty pharmacy sector,” says Michael Patton, managing director at Provident Healthcare Partners. “Similar to 2008 when we saw Omnicare, a traditional institutional pharmacy, expand into the specialty market with their acquisition of Advanced Care Scripts, we continue to see outside-the-box buyers looking for opportunities to expand outside their typical service lines and bring in-house a specialty platform.”
Patton also points to “a considerable amount of interest” in specialty pharmacy within the private-equity community and cites examples such as Enhanced Equity Fund’s deal for Specialty Therapeutic Care and H.I.G. Capital LLC’s purchase of Allion Healthcare, Inc.

“The main differentiator between the two buyer pools has less to do with up-front cash valuations, but the longer term play,” Patton tells AIS. “With a strategic acquirer, they will be looking into synergies which can be leveraged for cross-sell potential and structure multiyear earnouts to continue to reward shareholders with the increased profits.

“For private-equity groups, the hook is to remain a stand-alone platform with a strong and experienced capital backing and to experience a second liquidity event years down the road; however, most growth achieved will be through organic or acquisition methods. While both groups look to structure their transactions in differing fashions, each is aggressive in valuation multiples and very interested in working to get deals done.”

Interest in the specialty pharmacy sector can be attributed to “basic things and comparative things,” says Braff. “Essentially, when health care reform passed, there was a general lift in the notion of the greater use of pharmaceuticals. The expectation is that we’ll see increased utilization.” And with this boost in utilization “will be the increased need to keep costs down. Specialty pharmacy is a cost-saving model,” he contends. “Specialty pharmacy is considered not only an area that will grow,” he explains, but there will also be “gravitation toward it because of cost-effectiveness” concerns.

According to Braff, “although margins may not be as high” among specialty pharmacies compared with other health care services, “they generally have high revenues with extremely high growth rates. They’re attractive [to potential buyers] because of their high profile, high revenues and high growth.”

### Annual Breakdown of Health Care Services Merger & Acquisition Activity

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<th>Sector</th>
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SOURCE: The Braff Group, December 2010
NOTE: The gray areas highlight private-equity activity within each sector.
In addition, because the specialty pharmacy sector “benefits from not being in the bull’s-eye” of margin pressure, in which other areas such as Medicare home health are finding themselves, this has boosted interest in companies within the industry, says Braff. The Medicare home health sector has been averaging four or five platform deals per year since 2006, he points out, but had only one through the third quarter of 2010.

“People are getting skittish about Medicare,” so there has been a refocusing of attention from Medicare-reimbursed services to non-Medicare-reimbursed services, he maintains.

**Lenders Are Funding Larger Deals**

Another plus for M&A activity is the “lending environment is favoring larger deals,” Braff points out. Unlike home infusion transactions, which tend to involve companies with annual revenues around $10 million, “specialty pharmacy deals tend to be large — it’s not uncommon” for these companies’ revenues to be in the $100 million to $200 million range, he says. While the “lack of access to debt capital and borrowing” has hampered some activity, more recently the “greatest expansion in the availability of credit...has been with larger-size credit needs....This is a contributing factor in getting deals done,” says Braff. Companies “couldn’t get the debt before but can get it now.”

So what specialty pharmacies are potential acquisition targets? “Any specialty pharmacy doing more than $50 million annually and has multiple therapies will be an attractive acquisition candidate,” he maintains. “Whether they want to sell or not, they will be called on.”

Also stoking specialty pharmacy investment interest is the fact that many of these firms have matured in terms of industry experience and have become the focus of acquisition attempts.

“What often happens in a market when there are not a lot of players” is that “people get drawn into the industry, responding to interest from the investment community and buyers” — which is exactly what happened in the early 2000s, when specialty pharmacy began to capture attention, Braff says. These new companies, though, need time to mature — which is just what the market entrants from the pre-2005 period have done, he contends.

**Wholesalers May Play Interesting Role**

One industry consultant points to both recent and potential future M&A activity among drug wholesalers as something to keep an eye on.

2010 saw major activity in the oncology services space by two of the three major drug wholesalers. In June, Cardinal Health, Inc. unveiled a deal to purchase Healthcare Solutions Holding, LLC, which has subsidiaries that offer various services across the specialty industry with a large focus on oncology, most notably P4 Healthcare. That was followed by McKesson Corp.’s purchase of US Oncology, a deal that closed Dec. 30, 2010.

“McKesson/US Oncology and Cardinal/P4 may decide to do something different in the marketplace with regard to specialty pharmacy, infusion suites and/or home infusion,” says Elan Rubinstein, Pharm.D., founder and principal of consulting firm EB Rubinstein Associates.

He also points out that the third of the big distributors, AmerisourceBergen Corp., “hasn’t made a move, but is unlikely to sit on its hands given that McKesson and Cardinal just made major oncology-centered acquisitions....I’m waiting to see what AmerisourceBergen does and what they all do to gain competitive advantage.”
A spokesperson for AmerisourceBergen tells AIS that “in 2011, AmerisourceBergen will continue to lead the community oncology and specialty pharmacy markets by delivering innovative programs and services to providers.

“Our national specialty pharmacy, US Bioservices, will continue to provide continuity-of-care services that help patients receive their medications faster and remain on appropriate therapy longer. And our network of community oncology practices, ION Solutions, will continue to implement practical technologies that help physicians manage inventory more efficiently, receive correct reimbursement and work more collaboratively with payers.”

Home Infusion 2011 Deals Should Continue Consistency Theme

Although recent merger and acquisition (M&A) activity in the home infusion sector has not been as robust as the action during recent years, it was consistent from 2009 to 2010, and 2011 looks to shape up in a similar fashion.

The home infusion sector, however, has “less going on” than does the specialty pharmacy industry, which boasted renewed interest among buyers through the third quarter of 2010, says Dexter Braff, president of The Braff Group, an investment banking firm specializing in home health sectors. His company has identified eight deals through third-quarter 2010 — the same number as in the comparable 2009 period.

These past two years have been down transaction-wise from the 27 and 20 home infusion deals in 2007 and 2008, respectively. 2009 ended with 13 home infusion deals, and 2010 will have probably about 10 to 12 transactions, estimates Braff. In addition, the surge of activity occurring a few years ago among private-equity-sponsored companies within the home infusion sector died down in 2009 and 2010.

“The theme [in home infusion M&A] is fairly consistent,” Braff says. “It’s a continuation of what we saw [in 2010]….A lot of buyers have consolidated, so there are fewer buyers out there. At the same time, there are fewer sellers.”

Looking to the year ahead, says Braff, “there just aren’t a lot of pure-play IV therapy companies out there.” For that reason, he says, “if you have a pure-play infusion company that’s doing between $5 million and $10 million” in revenues for core therapies, “it’ll be sold. There are buyers who want this, and buyers will be all over it.”

“The home infusion space is expected to be very attractive in 2011 for a variety of reasons,” contends Greg Wappett, senior analyst at Provident Healthcare Partners. He tells AIS that “the sector as a whole is very fragmented and primed for consolidation. We know of multiple private-equity groups scouring the industry for platforms which they can build up through acquisitions similar to AxelaCare Health Solutions, CarePoint Partners and HomeSolutions, and the Walgreens and Aprias of the industry will always be looking for acquisitions to tuck into their current service offerings.”

Still, although Braff says his company “love[s] this space,” he explains that it’s “difficult to build critical mass through consolidation. The pool of prospects is not as wide and deep as we otherwise would have hoped.”
A continuing trend among home infusion providers is creating a specialty-focused offshoot of the company, says Laurie Amirpoor, Pharm.D., staff vice president of clinical program policy at WellPoint, Inc. She also tells AIS that the home infusion industry is “moving toward more ambulatory infusion suites.” Physicians, she says, see these as new revenue models with administrative savings and are installing them within their offices.

Alana HealthCare, which provides infusion and durable medical equipment services, is one company looking to grow “through both acquisitions and organic expansion of our infusion therapy centers,” CEO Steven A. Schneider tells AIS. “The economy has brought pressure on business valuations, and we have seen opportunities that in the past may not have been on our radar screen.” In addition to buying a handful of companies, Alana has “added two infusion centers in central and west Tennessee, with a third in Knoxville scheduled to open in the second quarter of 2011. We see infusion therapy centers, situated close to our hospital-based and physician-owned clinics, as an engine of growth for the company.”

Diversified Offering of Specialty Therapies Attracts Buyers

The evolving theme for 2011 in specialty pharmacy acquisitions is that “buyers are strongly drawn to companies that have developed [expertise in] multiple therapies — not just one or two — and have developed strong contracts,” says Dexter Braff, president of The Braff Group, an investment banking firm specializing in home health sectors — essentially, factors that “help mediate margin compression.”

That said, there are some specific specialty therapies drawing more interest than others:

1. **IVIG:** There has been “an explosion of interest” in intravenous immune globulin, says Braff. Although IVIG has been available for some time, there is “greater interest now,” he asserts, “perhaps due in some part to elder clinical modalities.” The therapy is being studied in Alzheimer’s patients, which has “caught people’s attention.”

2. **New drugs** for hepatitis C.

3. **Hemophilia therapies:** Braff tells AIS that he’s seen “some spiking in hemophilia” interest, most recently in private-equity firm Enhanced Equity Fund’s deal for Specialty Therapeutic Care, a transaction handled by The Braff Group. The margins in hemophilia “can be stable,” but the business model “has been one that a lot of buyers have to get comfortable with,” he adds. “This is definitely the most patient-centric model we’re aware of.”

Because hemophilia is a lifetime disease, the potential revenues “are huge,” with some patients racking up annual claims exceeding $1 million. “This is a stable population, with high revenues per patient and high customer service,” he says.

One glitch, though, could be reimbursement, as these patients often are covered by Medicaid, and “some states are better than others” in their payments.
Outlook for Medicare Advantage and Part D

MA Enrollment, Profit Margins Will Flatten In Transition Year Before Payment Cuts

Look for 2011 to be a transition year for Medicare Advantage from the bounteous growth of the past few years to the much tougher climate that will begin in 2012. Consensus forecasts compiled by AIS from seven industry executives and consultants call for flat to minimal enrollment growth and flat to lower profit margins in 2011 compared with 2010 levels. And not a single one of the seven envisioned Congress taking any actions in 2011 that would soften the payment cuts slated to begin for MA plans in 2012.

On the regulatory side, there are several key issues on which major developments are likely in 2011. Topping everybody’s fear list is extrapolation of risk adjustment data validation (RADV) audit findings, on which a big concern is that CMS won’t distinguish between unintentional errors and efforts to defraud. There also seems to be a consensus that CMS will add substantially to the measures determining “star ratings” for MA plans, with many of the new measures focusing on care for chronic illnesses.

Moreover, the development of Medicare Accountable Care Organizations (ACOs) will affect how providers view MA plans, says Frank Ingari, CEO of multistate MA plan operator Essence Healthcare, which has close relationships with providers. There are many similarities between how ACOs will operate and how good MA plans operate, he suggests, and ACOs could have a big impact on MA plans depending on the specifics in the regulations governing ACOs that are due out in the first quarter of 2011.

Prospects for ACOs, though, are uncertain, and Ingari does foresee some greater certainties in the MA 2011 outlook. Enrollment industrywide, for instance, he tells AIS, will be “flat to a small increase” compared with 2010 levels. Numerous MA private-fee-for-service plans shut down at the end of 2010 in light of the end of PFFS network “deeming” in most counties, and many affected enrollees did not sign up for MA HMOs (which is all that Essence operates), although those plans — including Essence’s — will show gains, he says.

On the profit-margin side, Ingari envisions a “pretty good year” despite flat expected revenues. MA plan profitability will get worse in 2012 and 2013 as payment cuts under the reform law take hold, he says, but for 2011 there will be a plus from “some diminution in the cost trend” since consumers remain under financial pressure.

He foresees only “modest” requested service-area and product expansions in the MA applications due in February for 2012. They will be mainly in the form of “prudent” expansions by large plan operators, which also stand to be the principal buyers in the increased acquisition activity Ingari foresees in 2011. Getting bigger can reduce the risks of new-customer acquisitions and lower per-unit compliance costs.
Regulatory Issues Seen Having Large Impact

Consultant John Gorman, CEO of Gorman Health Group, LLC, sees regulatory issues having a big impact on MA in 2011. He envisions CMS using its expanded bid-denial authority perhaps even to deny service-area expansions requested for 2012. And he tells AIS that the “safe money” in betting circles would be on “a lot more measures” related to chronic care being added in 2011 for the next round of star-rating evaluations by CMS.

Requirements for MA plans to begin submitting encounter data in 2011 will prove to be a “substantial” issue for MA plans and take a lot of work, he says. It is another sign, he adds, that “this will really be the year to see accountability of risk-adjustment data.” Coupled with the steps it is taking on RADV audits, CMS is making clear that it wants risk-adjustment data to be based on chart reviews or direct patient assessments, according to Gorman.

Profit margins “will decline slightly” in 2011 for many MA plans, Gorman forecasts, attributing this to factors such as the second consecutive year of no rise in plan payments plus continued medical cost increases. Plans in some cases have traded profit margins for membership gains, he asserts. But he also says that many plans have cut administrative costs and improved risk-adjustment scores in ways that will help preserve margins.

Overall, MA profit margins will be lower in 2011, says actuary Brian Weible, president of Wakely Consulting Group, partly as a result of plans getting “more aggressive” in maintaining benefit levels “even at the expense of margins.” A potentially heavier flu season — more like 2009 than the weak one in 2010 — also could hurt margins, he adds.

Weible forecasts “relatively small” enrollment growth in 2011 compared with 2010, with the potential to get members from other plans hampered by both the shorter enrollment period in 2011 and the minimal benefit changes not creating big incentives for plan switches during the just-completed AEP. He also envisions only “pretty sparse” service-area expansions for 2012, with the big decline in payment levels in many counties in 2012 being one deterrent.

There is some reason for hope that the bidding process in 2011 will go smoother than it did in 2010, Weible tells AIS, since CMS in an actuarial user group call in December 2010 said that it will make available its model for calculating the “meaningful differences” that MA plans must have among their products. Some plans in 2010 thought they had met requirements such as at least a $20 per month premium variation among products only to find out CMS had calculated it in a different way, he recalls, and it looks as though that situation “will be avoided” this time.

The new encounter-data requirements, however, will be a problem because of the diversity of arrangements between MA plans and providers, and some MA plans are “not even at the starting line” in doing the “lot of work” needed to gather data that will be required, he contends.

Consultant Stephen Wood, senior vice president of Ingenix Consulting, doesn’t fault CMS for asking for encounter data, which is “something that is needed,” but wonders about the timing, coming when the agency is figuring out how to deal with bundled payments for ACOs. It is a “completely mixed message,” he tells AIS.

Looking at the bid-evaluation process in 2011 for 2012, Wood predicts it will be similar to 2010, with a lot of plan-CMS negotiations “on the back end” after bids are submitted.

On the financial side, Wood says, “the years of plenty are gone, but I don’t think the years of lean are here yet.” That means “modest” enrollment growth targets of MA plans are being met, including a “strong showing” for some plans, so “enrollment won’t be down.” This won’t be the
case for profit margins, he suggests, but 2011 still can benefit from better care management and won’t be the big negative year 2012 may be.

Consultant Russ Mohawk, vice president for health plan services at Visante, Inc., envisions “probably a decrease” in MA enrollment in 2011, partly a result of PFFS and other MA plan pullouts plus an “uptick in Medigap.” Profit margins, though, he forecasts, may remain at 2010 levels since payment cuts haven’t started yet and since utilization will fall from 2010 levels.

“It’s going to be a very difficult year to keep margins at levels they were at,” Gary Jacobs, senior vice president for corporate development at Universal American Corp., tells AIS, speaking of the MA industry as a whole.

Jacobs predicts that 2011 “will really separate efficient low-cost [plan] providers” from companies that aren’t as efficient. Factors that will drive such efficiencies, he says, are scale, especially since large plans can better control administrative costs, and medical management.

MA industry enrollment for the next year will wind up on the “lower side,” according to Jacobs. He attributes that forecast partly to high levels of rhetoric and confusion, which, coupled with the new lack of an MA Open Enrollment Period, will create a situation in which seniors who like their plans are more likely to stick with them than in the past. Where there is movement of beneficiaries from plan to plan, he says, it will be based on price.

One bright side to this reduced enrollment activity is that there are fewer “transactions” needing to comply with the increased and tougher operational requirements on MA plans, notes Gary Donner, a principal with MMC 20/20, a consulting firm that works with MA sponsors on operational issues. While nobody knows yet what the new Open Disenrollment Plan, which enables MA enrollees to drop their plans and move to fee-for-service Medicare from Jan. 1 through Feb. 14, “will look like, it doesn’t look like much” activity, Donner says.

Part D Plans Need to Work With PBMs for Success in 2011

As Part D sponsors enter contract year 2011, there are some important compliance and operational areas, including transition drug coverage and star ratings, they should focus on. According to health care consultant Steve Arbaugh, principal of ATTAC Consulting Group, LLC, these “hot button” issues that involve working closely with pharmacy benefit managers are critical to the success of the organization’s plan.

As part of CMS’s switch to risk-based auditing, the agency will not be randomly auditing Part D plans. Instead it will be monitoring plans to see if they run afoul of the Medicare requirements, particularly where that failure will impact beneficiaries in a negative way. Then CMS will come calling on those plans to conduct audits.

Arbaugh recommends that sponsors watch for “transition coverage issues.” Many plans, including Health Net, Inc., which was just subjected to intermediate sanctions, have been audited by CMS for problems with nonformulary or step-therapy edit claim denials in the transition period, “and a number of plans have been found to have significant issues here,” he tells AIS. Typically, says Arbaugh, “this is due to faulty PBM edit logic.” But he warns plans to “closely monitor the number of denials for nonformulary drugs and step therapy for new enrollees in
2011.” If plans have time, he suggests they order reports on denials from 2010 to make sure the PBM edits are appropriate and that they monitor this closely for 2011.

**Know When to Hold ‘Em**

Another area to focus on is data validation audits (DVAs), says Arbaugh. Some PBMs, he contends, are “holding closely” the systems information and data related to delegated administrative services that they provide to plans and consequently DVA contractors.

PBMs consider this information in some cases “proprietary” and require on-site examination only, he maintains. This is similar to what PBMs do for rebate audits, explains Arbaugh. Providing this information on-site only “raises the cost of performing the DVA and diminishes the plan’s ability to conduct oversight on a routine basis,” he says. In general, notes Arbaugh, plans need this information to monitor how their contractors are performing. He suggests plans address this “contractually.” When revising their contracts with PBMs, plans should clarify exactly what information the PBMs must provide, when to provide it and how.

Plans also should start “asking their PBMs what they have designed” with regard to edits and algorithms for star ratings in 2011, he adds. “Much of the clinical components” for these ratings in 2011 “will require close work with…the PBMs to set up appropriate edits,” Arbaugh says, such as the “level of dispensing drugs with a high level of side effects.” PBMs should be “developing edits and algorithms to identify users and incorporate point-of-sale messaging” if there are questions as to whether a particular drug was prescribed.

**Compliance Plan Effectiveness Audits Pick up Speed In 2011**

Part D and Medicare Advantage sponsors that did not experience compliance plan effectiveness audits in 2010 can breathe a sigh of relief. This is “good news,” said Elizabeth Lippincott, principal of Lippincott Law Firm PLLC. Although it is likely these plans will be audited in 2011, they still have time to prepare, she maintained.

CMS is now placing a much greater emphasis on sponsors’ compliance plans as a direct result of criticism the agency has received from its oversight agencies, Lippincott told listeners during a Nov. 18, 2010, AIS-sponsored webinar on compliance plan effectiveness audits. It is a “top priority” for CMS, the HHS Office of Inspector General and the Government Accountability Office.

While some compliance plan effectiveness audits did take place in 2010, these audits “will really begin in earnest in first-quarter 2011,” said Dorothy DeAngelis, senior managing director at FTI Consulting, who also spoke at the webinar.

Neither DeAngelis nor Lippincott is sure whether every sponsor will be subject to a compliance plan effectiveness audit. According to Lippincott, “early on CMS may have said” all plans would be subject to them, but “there seems to be some backing away from that.” DeAngelis advised thinking of it in terms of eligibility. “All plans are eligible, but whether CMS can logistically get it done or might rely on a contractor” remains to be seen.
Should We? We Must.

As revised by final regulations in the spring and effective Jan. 1, 2011, CMS has made the seven elements of a compliance plan regulatory requirements, not best practices or recommendations, she noted. “‘Shoulds’ have become ‘Musts.’”

According to Lippincott, one firm “pushed back” at CMS, telling the agency that what it saw as a requirement was actually a recommendation in Chapter 9 of the Prescription Drug Benefit Manual. CMS told that plan, she said, that the recommendation will become a requirement in the next version of Chapter 9.

In particular, said Lippincott, CMS revised regulatory language to state that plans must “adopt and implement effective compliance programs.” It is no longer enough just to have a compliance program on the books, she said. In some enforcement letters received by plans in 2010, Lippincott explained that CMS indicated the “worst thing [a plan] can do is have something on the books and not actually be doing it.”

For example, one plan had its marketing and enrollment frozen because it had a compliance program that stated the plan would have a compliance committee. However, the plan couldn’t produce any minutes or agendas showing that the committee actually functioned.

As more evidence of CMS’s increased focus on compliance programs, the agency included a provision for compliance officer training in its recently released proposed regulation. Beginning in 2013, all compliance officers will be required to complete annual MA and Part D training.

Lippincott called it a “minor requirement,” but she maintained that it reveals a lot about what the agency is thinking. She pointed to the preamble as seeming to say that CMS is not convinced compliance officers understand how different the Part D and MA products are from commercial lines of business. The agency seems to be saying that it “will not tolerate a reactive approach,” she contended.

DeAngelis added that CMS may feel that compliance officers don’t know as much as they should about the operational side of the business. Compliance plan effectiveness audits “inextricably intertwine” compliance and operational performance, she said.

Lippincott acknowledged that there is tension between compliance and operations. Compliance officers should be at a sufficiently high level that they have the authority and clout they need to get the resources to operate a robust compliance program, she said.

They also need to feel comfortable calling the chairman of the organization if there is an issue that needs to be addressed. Unfortunately, she said, the in-depth knowledge required of a compliance officer “usually is present at a lower level” in the organization.

A Look Back at 2010

As plans prepare for 2011 compliance plan effectiveness audits, it is valuable to look at the audits conducted in 2010. Informally, said Lippincott, the 2010 series of audits are complete and plans are starting to receive results. Based on these results, “we are waiting to hear what changes will be made to the audit approach for 2011,” she said.

2010 saw “intensive on-site performance and compliance audits,” noted Lippincott. Some plans received just compliance plan effectiveness audits, and some plans received both compliance plan effectiveness audits and operation performance audits, she explained.
This goes along with what Brenda Tranchida, director of CMS’s Program Compliance and Oversight Group, told attendees at the 2010 Medicare Advantage and Prescription Drug Plan Fall Conference in Baltimore in September 2010.

She said the agency will perform compliance plan effectiveness audits when auditing a sponsor for any reason. The “key to getting a handle on any issue [a sponsor] has” is a compliance plan effectiveness audit, she explained.

The 2010 audits had a “very aggressive time table,” said Lippincott. Plans had less than one week to produce extensive documentation, she asserted.

Types of documentation CMS required included:

- All reports made to the compliance officer;
- A list of all employees;
- The compliance program budget;
- All reports by the compliance officer to senior management and the board; and
- Risk assessment methodology and results.

For plans that had both compliance plan effectiveness audits and operational performance audits, CMS asked for universes that included:

- Enrollment requests and denials;
- Part D claim rejections;
- All grievances and appeals requests;
- All coverage determination and exception requests;
- Involuntary disenrollments due to premium nonpayment; and
- Comparison of formularies on plans’ websites with CMS-approved utilization management.

**Audits Are On Site**

Within one week of receipt of documentation, between 10 and 30 auditors showed up on site, including representatives from CMS regional and central offices and contracted auditors.

Along with a detailed questionnaire, the on-site auditors had in-person interviews with board members, senior executives, compliance personnel and other employees at all levels.

Lippincott described how one sponsor with multiple locations was being audited at one location. CMS made senior management fly out to the location of the audit for interviews on one day’s notice.

Although CMS has not released the questionnaire it is using during the audits, some examples of questions, according to Lippincott, include:

- **Are all employees sufficiently informed** about MA and Part D requirements?
- **Are core processes documented** in a way that facilitates change?
- **Are all policies and procedures up to date?**

Lippincott also described facility tours during some audits where auditors would try to enter through side doors to see if employees would let them in or tell them they had to go to the main entrance.
Outlook for Medicare Compliance

Providers Will Find 2011 Is ‘Big Year’ for Regulations, Recoupment, Whistleblowers

In compliance and enforcement, 2011 will be the year that proves past is prologue.

“To predict the future, you have to look at the past,” says former Department of Justice prosecutor John Kelly, now with Fulbright & Jaworski in Washington, D.C. The previous two years have brought a slew of new laws and regulations, including health reform, piles of money for program integrity and fraud enforcement, and growing urgency to cut government spending. “It forecasts a buildup to 2011, which I would imagine will be a big year in terms of regulations, prosecutions and recoupment,” he says.

Welcome to 2011, the year that Medicare and Medicaid program-integrity contractors spread to every corner of the country, executives are held responsible for their organizations’ folly, health reform hits home and enforcement agencies deploy their new weapons, according to predictions from various experts. As the year unfolds, the industry will move closer to mandatory compliance programs, ICD-10 diagnosis and procedure coding, and interoperable electronic health records. It will be a record year for recoveries from whistleblower-initiated false claims lawsuits, and more frustrated compliance officers will morph into whistleblowers, says Jeb White, former president of Taxpayers Against Fraud, a watchdog group in Washington, D.C. “There is a lot of pressure in this administration to get settlements. Fraud-fighting is the political gold ring.”

2011 will be a turning point for compliance programs and Medicare and Medicaid exclusions in different and unexpected ways. The nexus between them will be whistleblowers, who will capitalize on providers’ failures to identify and self-report overpayments — including overpayments stemming from excluded providers.

Sec. 6402 of the health reform law requires providers and suppliers to disclose and return Medicare and Medicaid overpayments within 60 days of identification, with an explanation of their cause. Providers may submit overpayments to HHS, the state, an intermediary, a carrier or a contractor.

“Sec. 6402 is huge,” says New York state Medicaid Inspector General Jim Sheehan, a former longtime associate U.S. attorney. But complying with the repayment mandate is another story. The New York state Office of Medicaid Inspector General (OMIG) has a self-disclosure process for Medicaid errors, and “in our experience, [providers] can’t quantify an overpayment within 60 days,” he says.

Extensions May Be Inevitable

Suppose a home health agency (HHA) realizes that one of its home health nurses is billing for services provided to an inpatient. The HHA puts a stop to it, but must then determine whether the nurse has pulled this stunt with other patients. After reviewing the medical records, the
HHA tries to interview the nurse, but he refuses to answer questions and quits. That sets back any attempt to quickly calculate the overpayments.

“We are working our way through this,” Sheehan says. If providers send the state a letter explaining the progress and asking for two additional weeks or months, New York is inclined to grant it. And CMS might do the same, especially because it hasn’t issued guidance to help providers navigate the process or ask for extensions in the event an overpayment opens a can of worms that proves far too complex to be quantified in 60 days.

The worst thing providers can do is stick their heads in the sand. “My expectation is we will see a fair amount of whistleblower activity. Providers will identify an overpayment and not report it,” he says. “We are already hearing about it from relators and relators’ counsel.”

At the same time, activity on the exclusion front will intensify. “Organizations not checking the exclusion list are toast,” Sheehan says. Any whistleblower or relators’ counsel can run an organization’s employee roster through the OIG exclusion database. If there are hits, and they are paired with the Sec. 6402 Medicare repayment obligation, “you got your whistleblower case,” he says, because reimbursement stemming from excluded employees is an overpayment. “It’s no longer just the government” enforcing the exclusion rules. “Anyone can check” exclusion and debarment databases, he says.

OIG might soon shed more light on provider screening for Medicare and Medicaid exclusions. In November 2010, OIG asked the industry for ideas on updating the 1999 Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs, and comments were due by Jan. 5, 2011. San Francisco attorney Judy Waltz, with Foley & Lardner LLP, thinks it’s likely OIG will provide guidance on how often providers and suppliers should perform checks for excluded provider status. (CMS has recommended to the states that Medicaid require checks every month.)

Waltz also thinks that OIG may explain its views on how repayments should be calculated when an excluded provider contributes to the service that is billed without directly related billing — for example, a nurse who cares for a patient during a hospital stay but whose services are not billed separately.

Another exclusion trend is “increased use by OIG of its exclusion authority, particularly as it relates to corporate executives,” says former OIG senior attorney Howard Young, who is now with Morgan Lewis and Bockius in Washington, D.C. Several exclusion actions against executives are pending, although they’re not public yet, he says. OIG set the stage for this crackdown in October 2010 when it issued guidance describing the factors it will weigh when considering permissive exclusions against owners, officers and managing employees if their entity is excluded or convicted of certain offenses.

**First Compliance Guidance Is Due in 2011**

Former IG Richard Kusserow calls this the “accountable executive doctrine of OIG,” and notes the government is starting to hold executives and board members accountable for fraud that occurs on their watch. The pressure on health care executives will intensify once CMS issues its compliance-program mandate because executives will be required to certify, in writing, that they have an effective compliance program, says Kusserow, president of Strategic Management Systems, Inc. in Alexandria, Va. They won’t feel comfortable making that attestation without
metrics, so compliance officers should expect increasing demands for proof of effectiveness, he says.

It’s a good time for executives and board members to pay attention, because “compliance officers are probably the largest contingency of whistleblowers in the hospital setting,” says White, now an attorney with the law firm Nolan & Auerbach. “It makes sense. Compliance officers raise issues to their bosses, who [sometimes] say ‘stop looking.’ Compliance officers are alienated, isolated, terminated — and then they call me.” Lately, hospital compliance officers have been calling him because the incipient Medicaid recovery audit contractor (RAC) program has prompted internal scrutiny of claims, and compliance officers have identified pervasive problems, such as missing admission orders and physicians signing off on care that wasn’t provided, White says.

Speaking of compliance programs, the first CMS regulation to come from the health reform law will appear by year’s end. The health reform law has two general mandates in this area: (1) compliance and ethics programs for skilled nursing facilities that must be effective at preventing and detecting criminal, civil and administrative violations and promoting quality of care, and (2) compliance programs that will be a condition of Medicare and Medicaid enrollment for other providers and suppliers.

CMS specified only a deadline for the nursing facility compliance program, and it’s staggered. By Dec. 31, 2011, HHS must implement a quality assurance and performance improvement program for nursing facilities that will address best practices, says Kim Brandt, CMS’s former director of program integrity. Within a year, nursing facilities have to submit a plan to HHS that describes how they will fulfill the best practices. By March 23, 2012, CMS is required to issue compliance-program guidance for nursing facilities.

There’s no deadline for compliance-program regulations for other providers and suppliers, but CMS asked the industry for input in the proposed anti-fraud provider screening regulation issued Sept. 23, 2010. However, CMS made it clear that it would not finalize the compliance-program requirements until some later point in time. When it happens, says Brandt, the guidance is expected to be issued on a “rolling” basis.

More Audits to Come

Brandt predicts an increase in the amount of Medicare and Medicaid auditing. On the Medicare side, CMS will complete the transition from 15 program safeguard contractors (PSCs) to seven zone program integrity contractors (ZPICs), which investigate fraud and abuse across Parts A, B, C and D, says Brandt, the new chief investigative counsel for health care issues for Sen. Orrin Hatch (R-Utah), ranking minority member of the Senate Finance Committee.

ZPICs are a force to be reckoned with because each ZPIC is assigned to one region of the country and is not restricted by Medicare claim type. It’s much easier for ZPICs to detect, for example, when a retail pharmacy bills Medicare Part D for medication for a beneficiary who is in intensive care, an obvious error or perhaps fraud.

Brandt says in the physician practice arena, ZPICs will focus on the following:

- **Home health and hospice** length of stay;
- **Freestanding labs and independent diagnostic testing facilities** with respect to frequency of testing and number of tests performed; and
- **Durable medical equipment orders**, with an emphasis on orthotics (a shift away from oxygen, diabetic supplies and wheelchairs).
The reason for the scrutiny, she says, is that earlier in 2011, Medicare published a regulation that bans payments for these services unless ordering and referring providers (e.g., physicians or nonphysician practitioners) are enrolled in Medicare. Though CMS has delayed this crackdown (see change requests 6417 and 6412), Brandt expects it to take effect in 2011.

Watch out for ZPICs during the appeals process in particular. Until recently, only providers attended appeals of claims denials before administrative law judges (ALJs), Brandt says. But the tide is starting to turn, with ZPICs showing up to support their paperwork arguments, says Brandt. “They are starting to aggressively fight back because ALJs are finding in favor of providers,” she says. “It is almost adversarial.”

**Billing Agents Must Enroll in Medicaid**

Hospitals face scrutiny from Medicare administrative contractors (MACs) on the prepayment side and RACs on the postpayment side. In 2011, they will increase their coordination to improve overpayment recovery. Medical necessity seems to be the watchword for 2011, as Medicare auditors hammer away at site-of-service errors, CMS’s “PEPPER” reports add at least 24 more admission necessity targets, and Department of Justice medical-necessity investigations of kyphoplasty and implantable cardioverter defibrillators march on.

On the Medicaid side, CMS’s Medicaid integrity contractors (MICs) are showing up in more states — Ohio is a recent addition — and RACs will begin work in April 2011. “Compliance officers should be looking at Medicaid risk areas, especially because there are more people coming on the Medicaid rolls as a result of reform,” Brandt says.

2011 will also usher in a new category of Medicaid enrollees. Billing agents and clearing-houses that submit claims on behalf of providers are required to enroll in Medicaid, according to Sec. 6503 of the health reform law.

This is a big deal, Sheehan says, because claims preparation, submission, review and payment are now virtually all electronic. “Almost no one in the provider side of the system has an end-to-end understanding of the process, and errors or fraud once introduced into the system can proliferate (e.g., default diagnosis codes or billing for services incorrectly numbered on a chargemaster or superbill).

“Third-party billing companies and service bureaus market themselves as experts in coding, billing, payment and revenue cycle management and promise significant increases in ‘recoveries’ by using their services, and most get paid a percentage of their recoveries. Thus, they have significant incentives to be aggressive in coding and billing,” he says. “Regulation of this business activity is required because the current contracts between these companies and their customers push back all responsibility on the providers, and the providers tell us that they relied upon the billing companies’ expertise.”

Across the board, expect to hear more about Medicare and Medicaid recoupment. Executive departments and agencies of the federal government were required to report Jan. 14, 2011, to the Office of Management and Budget on their plans to cut erroneous payments through “recapture audits,” also known as “recovery audits.” President Obama got this ball rolling in a 2009 executive order (13520), when he announced plans to reduce improper payments by identifying duplicate payments, payments for services not rendered, overpayments and fictitious vendors.

Meanwhile, CMS will start flexing its new Medicare payment suspension muscle in 2011, Brandt predicts. In addition to its existing payment suspension authority, Sec. 6402(h) of the
Health reform law allows CMS to suspend Medicare payments to providers when there is a “credible allegation of fraud,” unless there is “good cause not to suspend payments.” A suspension of payments would mean shutting down some or all of a provider’s cash flow pending resolution of the investigation.

“Medicare contractors said they really want to start using this more,” Brandt says.

**ICD-10 Implementation Is One Year Closer**

Hospitals face all sorts of billing and coding challenges. For one thing, “ICD-10 takes on another level of importance in organizations. We are one year closer to implementation,” says Kathy DeVault, manager of professional practice resources for the American Health Information Management Assn. ICD-10 is a sea change in coding diagnoses and procedures, allowing far greater detail and requiring more documentation specificity. Unless hospitals have gotten the ICD-10 ball rolling, “they are potentially behind.” CMS pushed the go-live date to Oct. 1, 2013, to avoid overwhelming hospitals, which need to train, budget and reconfigure software. “It looms a little bigger every year.”

On a related note, as of Jan. 1, 2011, hospitals also can start using the new 5010 version of the HIPAA transaction standards to electronically report and inquire about certain health care transactions. The “second level” 5010 standard is a prerequisite for ICD-10, but more immediately, it allows hospitals to report 25 diagnosis codes and 25 procedure codes per claim — far more than they can report now, DeVault says. The claim “wasn’t telling the full story of what happened to the patient,” she says.

The new 5010 also allows for automated present-on-admission (POA) indicator reporting, which lets Medicare know whether a condition was hospital-acquired and may affect reimbursement.

But compliance officers will still focus on core issues in 2011, says Beth Hickman, compliance officer for Mercy Health Partners in Toledo, Ohio. One example is physician signatures. Medicare contractors are cracking down because of pervasive noncompliance with Medicare rules. Physician documentation must be dated, signed and timed; verbal orders must be signed within 48 hours; hospitals must have admission orders that unambiguously state the physician’s intent; and now lab requisitions must be signed as of Jan. 1, 2011, though CMS delayed enforcement of the lab signature rate until the second quarter. “This is a fundamental part of the business,” she says. It’s easier for an auditor to deny a claim because the physician didn’t sign than it is for an auditor to challenge the medical necessity of a pacemaker implantation.

On the enforcement side, providers are more likely to feel the “HEAT.” The DOJ-HHS’s joint enforcement initiative — the Health Care Fraud Prevention and Enforcement Action Team — and its Medicare Fraud Strike Force have investigated and prosecuted hundreds of providers and recovered millions of dollars. Although HEAT has been focused on more egregious fraud, Jay Darden, former assistant chief of the DOJ criminal division’s fraud section and a leader of HEAT, says “potentially HEAT information will be used to go after more mainstream providers.”

Investigators and auditors are turning the electronic age into the enforcement age. The DOJ fraud section, for example, has two employees dedicated solely to analyzing data for the Medicare strike force. “We will continue to see the government using data as a way to focus limited investigative and prosecutorial resources,” says Darden, with Patton Boggs in Washington, D.C. Health care organizations should be mimicking the government’s data analytics in some form or fashion. “It is one of the few instances where facilities have the same information the govern-
ment has and can analyze that information on a regular basis and [use] it to clean house, rather than wait for the government to do it,” Darden says.

**More U.S. Attorneys Will Hop On Fraud Bandwagon**

Prosecutors also are expected to start deploying the new enforcement tools from the health reform law. There are 32 sections on program integrity and health fraud in the law, making it easier to nail providers for fraud, waste and abuse, including improper hospital-physician relationships. The law also created a CMS self-disclosure process for Stark-only violations, which providers hope is a quid pro quo for reduced penalties.

Whistleblower cases will continue to mount, though the big-dollar cases against pharmaceutical manufacturers have probably run their course, Sheehan says. “I think we will see an increase in the number of provider *qui tam* cases, especially in U.S. attorneys’ offices that historically were not known for their health fraud prosecutions,” Young says. With all the money being poured into enforcement, “U.S. attorneys around the country understand the importance of being a leader and being proactive in this area.” Move over, Boston and Philadelphia. Less-well known fraud-enforcement hubs may get in the game, spurred on by whistleblower lawyers who are tired of waiting for prosecutors to slog through a backlog of cases.

Companies facing enforcement actions will start to benefit from compliance programs in more concrete ways in coming years. “DOJ and other enforcement agencies are going to start acknowledging companies that are given leniency in the settlements because of their compliance programs,” says Roy Snell, president of the Health Care Compliance Assn. “That is big news because they haven’t done it much.” Snell says this development is important because compliance officers can help boards grasp the cost-benefit ratio of compliance programs.

Compliance officers could use the help. “The stress level for compliance professionals will go off the charts” in 2011, Snell says. With the number of challenges they face, from keeping up with the changes in the health reform law to coping with RACs, ZPICs, MICs and MACs, compliance officers must find ways to manage the flow of information and ensure they remain independent voices in their organizations. ✩
Outlook for Managed Medicaid

Despite State Budget Crunches, Medicaid Plans See Strong Year

Despite a host of uncertainties now surrounding the Medicaid expansion in the health reform law, Medicaid managed care firms expect a strong 2011, including new or expanded business in several states. Their worsening financial conditions and needs to deal with chronic illness in their populations, in fact, seem to be pushing the states toward more managed care in Medicaid, albeit with rate increases likely to trail even 2010’s modest levels.

While chances have increased in the wake of November 2010’s election results that the huge Medicaid expansion beginning in 2014 under the reform law may be modified, the bigger players in Medicaid managed care still express confidence about their prospects. And no entity reflects that confidence more than UnitedHealthcare Community & State, the newly named entity that runs UnitedHealth Group’s 24-state (plus the District of Columbia) Medicaid business—the nation’s largest, with 3.3 million enrollees.

The Medicaid managed care outlook for 2011 is “quite strong and positive,” Jack Larsen, the entity’s CEO, tells AIS in an exclusive interview. He notes that some industry financial analysts have said there will be $30 billion to $40 billion in new business up for grabs in the next few years, and “I wouldn’t quibble with that.”

Much of that new and expanded business could come in 2011. It includes contracts in:

- **Texas,** which is preparing to receive bids in March 2011 for renewing existing Medicaid contracts and may expand managed care to southern regions along the Rio Grande Valley. Securities analyst Carl McDonald of Citi Investment Research & Analysis estimates that the new contracts could add 750,000 eligible beneficiaries, an increase of 22%.

- **Georgia,** which is rebidding its current 1.8-million-beneficiary program and expanding Medicaid managed care to the aged, blind and disabled population. “I’d certainly be excited about participating” in that procurement, says Larsen. The ABD expansion, according to McDonald, could add 100,000 enrollees and $1 billion in new spending. The request for proposals is expected to be out this quarter, with an award likely in fall 2011, he says.

- **Florida,** where the legislature, when it convenes in March 2011, will consider expansion of Medicaid managed care. United already has a presence in that state, including via Florida’s Healthy Kids program, notes John Kaelin, senior vice president of UnitedHealthcare Community & State. And it would like to participate in any Medicaid managed care expansion in the state, Larsen says.

- **California,** where more managed care in the huge Medi-Cal program is likely. “We admire from afar” in that state, quips Larsen, who points out that the company formerly participated in the state’s program but withdrew. “We would like to find a way to work constructively with them [i.e., California] in the future.”

Despite those opportunities and potential new business in Arizona and South Carolina, dire state finances raise questions about the adequacy of payment rates Medicaid plans can expect in
2011. United has always found a way “to earn an adequate return” while aiding states with their financial woes, says Larsen. But he adds that the many new incoming state administrations are facing unprecedented financial problems, especially since Medicaid is their top or second-largest budget item.

In 2010, he says, Medicaid managed care plans got rate hikes averaging about 2.5% industry-wide. He projects the figure in 2011 will be “less” than that and perhaps only 1.5%.

One factor in how that will transfer to profit-margin impact for Medicaid plans is what the states will do in response to the climate. Larsen predicts that the “more savvy” states will trim some Medicaid benefits that they’re allowed to cut (e.g., prescriptions, dental and vision), particularly since the states are “getting toward the end of what they can do” in terms of reducing payments to providers. Managed Medicaid plans themselves are doing “internal streamlining,” and in light of that and states’ benefit cuts, Larsen doesn’t envision “cataclysmic” profit problems in 2011.

However, states are looking for more help, and this is where things could get dicey for the Medicaid plans. On Jan. 7, 2011, for instance, 33 Republican governors and governors-elect sent a letter to President Obama and congressional leaders asking them to remove the “maintenance of effort” provisions in the reform law that prevent states from dropping Medicaid enrollees unless they are willing to stop getting federal money that accounts for the bulk of Medicaid funding.

Several states, including Texas, have considered even opting out of Medicaid when the reform law-mandated expansion begins in 2014. This would be an “extraordinary” thing for a state to contemplate, asserts Larsen, but since the United unit’s purpose is to help states in whatever they need, it would aid even those opting out. He is quick to add, however, that to the extent states can reduce nonessential benefits, they are likely to stay in Medicaid “up to a point.”

**Planning for Expansion but OK Without It**

For UnitedHealthcare Community & State itself, “We’re acting as if it’s [i.e., the reform expansion] going to happen,” he says. If it doesn’t, though, he contends, “I’m not sure as an industry we’re any worse off” since “the care for these kinds of people is not going away.”

Like other industry observers, Larsen foresees more consolidation in the Medicaid managed care industry in the years leading up to 2014 because of the growing costs and complexity of operations and the need to slash operating costs. Will United make Medicaid acquisitions in 2011? Larsen replies, “We are always interested in looking for opportunities to increase our footprint.”

So are other big managed Medicaid firms. Centene Corp., for instance, is at risk for lost business since about $1.4 billion or 27% of its existing revenue is up for bid in 2011, notes McDonald. But it could benefit from the expansions in Georgia and Texas, which it already serves. Centene estimated in December 2010 that the Georgia expansion is worth $1 billion in revenues, while the Texas growth could add $4 billion for the winning bidders.

And AMERIGROUP Corp., the largest stand-alone managed Medicaid company with about 2 million covered lives, told the J.P. Morgan health care conference in San Francisco Jan. 11 that it foresees revenue growth in the “high single digit” range and a medical loss ratio of 83.7% to 84.7% in 2011. ♦
Outlook for Medicaid Compliance

MIG Gives Peek at Pending Projects, Addresses Common Provider Gripes

CMS held an open-door forum in November on the Medicaid Integrity Group to highlight some upcoming projects it has planned for 2011 such as new algorithms for data mining and a website for information on audits, plus its accomplishments in the past year. MIG officials also addressed concerns from providers about ongoing reviews by Medicaid Integrity Contractors (MICs) at the forum, for which CMS released a transcript and recording in late December.

In the data mining arena, the group’s Division of Fraud Research and Detection during 2010 worked with review MICs to develop 328 state-specific algorithms, DFRD Director Mark Anderson said. “These…algorithm implementations are in support of 69 state-independent concepts within four broad areas of focus, those areas being pharmacy, inpatient, professional services and long-term care,” Anderson said.

“Our algorithms and efforts come in different analytical areas,” he explained. “The first is basically a rule-based algorithm where we apply logic to calculate a potential overpayment. The second is a metric where we derive metrics and values for comparison of utilization and trends. Finally, models where we look at a number of indicators and produce a composite ranking based upon…the combination of those indicators.”

DFRD also is working with the education MICs to develop a website for the MIG’s educational material, including links to information on training, Anderson said. “The website will also house at some point sanitized results of analysis to show utilization and prescribing trends that can be viewed,” Anderson said. “The plan is that the website will be open to all states and the provider community.”

The MIG continues to work with MICs to improve the audit processes, said Robb Miller, director of the Division of Field Operations. When the MIG sees the contractor’s draft report, Miller’s department makes sure that “we … have not misinterpreted any of the issues. I’m sure you can imagine, even though Medicaid is a national program, there are 50 variations of it across the country and we have to be very careful to make sure we’re not overlooking some state-specific issue.”

On Sept. 29, 2010, CMS released a bulletin announcing a standardized look-back period of five years for MIC audits, and an increase in the length of time providers have to produce and submit requested records to 30 days (up from 10), Miller pointed out.

Medicaid has been a major target of Executive Order 13520, “Reducing Improper Payments and Eliminating Waste in Federal Programs,” signed by President Obama in November 2009.

The MIG’s work to comply with that order could impact providers, said Monica Harris, director of the Division of Audits and Accountability. For example, “we launched the first national supplemental measurement project in October [2010]” with a cluster of states focusing on over-prescribing. “The intervention that’s being put in place is provider education tailored to mitigate the identified vulnerabilities in each of the states,” she said.
Twelve states are participating in the project, and Harris’s division is conducting the baseline measurements. The participating states will decide how to measure themselves once the project is implemented. Then provider education will take six months, and officials will do a second measurement to evaluate the project.

“If it [isn’t] successful, we can share those lessons learned,” Harris said. “And if states express more interest in this project and they develop common themes, we’ll work with them as well to launch additional clusters both targeting the national focus areas…and state-specific areas.” Results will be published on paymentaccuracy.gov.

**MICs Go AWOL**

Provider participants in the forum brought up common complaints about MICs. “We received our audit requests and the identifiers listed are inadequate for us to locate the patients…. Is there any work being done on the data and the accuracy of the data from CMS’s standpoint?” one asked.

Anderson said there is: “We have identified that there is a need for some additional data particularly in this specific area. We’ll be working with the states closely to have the states supply that additional information so that when we go out to the providers, things like the Rx number are supplied, and we can identify both the beneficiary and whatever needs we have for that provider information to be supplied.”

A particularly sticky area is in audits of pediatric services, another listener pointed out. “Sometimes the identification cannot be obtained through Social Security numbers because often that’s obtained with parent information.”

“The only thing we would have is whatever identification number comes in as part of the claim, and that is the Social Security number as well as the Medicaid ID,” Anderson responded. “And until we start to capture the parent’s name as part of what is submitted to us in that claim, I don’t know how we could solve that issue.”

Another participant asked about MICs that make requests, then go AWOL. “How long does the audit MIC have to respond to the provider? [We sent] the requested medical records to our audit MIC and it’s been over six months since we’ve got a response. Our contact…said there is a data problem and our request is still pending.”

“The audit MICs are responsible for reviewing it in a timely manner,” said Crystal High, deputy director of the Division of Medicaid Integrity Contracting. “Where the slowdown comes in is during communication between the MIC, the state and the feds, she said. “We don’t know how that back-and-forth is going to be and if the extensions are being requested or not.” The provider should contact CMS so “we can look into that in further detail,” she said. 

**N.Y. OMIG to Focus on Compliance Programs, Governance in 2011**

The New York State Office of Medicaid Inspector General (OMIG) released its long-awaited work plan for 2011, which is modeled after the HHS Office of Inspector General’s annual work plan. As Medicaid program integrity grows in importance at the federal and state levels, more and more states may start publishing similar roadmaps. Some highlights of the OMIG plan are:
State-mandated compliance programs: On Oct. 1, 2009, OMIG became the first program integrity agency in the U.S. to require every major health care provider receiving more than $500,000 annually in Medicaid reimbursement to have an effective compliance program. Covered providers were required to certify to OMIG by Dec. 31, 2009, that they adopted and implemented effective compliance programs. Several hundred providers subject to the requirement failed to file the certification as of July 1, 2010 (six months after the deadline). During 2011, OMIG staff will visit and talk with providers to identify and communicate best practices, assess implementation and identify impediments to successful compliance programs.

Governance: OMIG has found governance weaknesses during its reviews of organizations, which it says “contribute directly to compliance failures.” OMIG will conduct investigations of significant compliance failures to identify the potential governance weaknesses and determine the appropriate action, including the possible censure and exclusion of board members. OMIG will also evaluate board responses to identified compliance failures, in order to determine what systems the boards had in place to inform themselves of compliance issues and provide reasonable assurances of compliance.

Reporting, refunding, and explaining overpayments: Providers who show up in other OMIG and Department of Health audits, but have never reported an overpayment through the state’s disclosure protocol or identified and reversed a payment through the state’s void process, will be identified and reviewed. OMIG is undertaking efforts to identify them and assess and improve their performance. The duty of reporting identified overpayments is not limited to those overpayments identified by OMIG. Every provider has a legal responsibility under the health reform law to report, refund and explain overpayments identified within the organization, or identified through the efforts of other persons, within 60 calendar days of identification.

Hospitals:

(1) Duplicate clinic claims audits: Through data mining, OMIG has identified Medicaid clinic rate code billing combinations billed by hospital outpatient clinics and diagnostic and treatment centers that constitute duplicate payments. The services were billed on the same date of service for the same recipient.

(2) Outpatient department services: OMIG will review Medicaid payments for selected hospital outpatient services to provide preventive, diagnostic, therapeutic, rehabilitative or palliative items or services furnished by or under the direction of a physician. OMIG will select a sample of services and review the underlying documentation such as physician orders and test results to ascertain compliance with Medicaid regulations.

(3) Readmissions: When a patient returns to the hospital for an illness for which they were hospitalized in the past 31 days, hospitals at certain times were required to combine the billing charges of the two admissions when submitting the claim to Medicaid. OMIG will audit claims data, looking at inpatient readmissions within 30 days of the original discharge.