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Outlook 2015: Legal Challenges to Subsidies, Enrollment Among Top Issues

egal challenges to health insurance premium tax credits for coverage through the Affordable Care Act federally facilitated marketplace (FFM) top the list of issues for 2015 noted by BNA's Health Insurance Report advisory board members in our annual Outlook survey.

Other top issues will be the success of re-enrolling consumers from 2014; compliance with subsidy tax laws; requirements that employers offer coverage; uncertainty about what the new Republican Congress will do with regard to the ACA; and regulatory issues such as self-sufficiency of the state-based marketplaces, the adequacy of provider networks in exchange plans and updated regulations to define essential health benefits that individual and small group plans must cover.

The second ACA open enrollment period runs from Nov. 15, 2014, through Feb. 15.

On the Medicare front, Medicare Advantage health plans should expect increased enforcement for noncompliance issues and network adequacy but at the same time may face a more generous reception from a Republican Congress. The CMS will address the need to hold private plans with large numbers of dual-eligible members to different quality standards.

The Medicare-Medicaid financial alignment demonstration will continue, but problems faced by plans and states are not likely to disappear. And the CMS's proposed Call Letter to Medicare Advantage and Part D plans in February could reveal the agency's latest posture on a variety of topics including preferred pharmacies.

Legal Challenge to Federal Exchange Subsidies

The ACA states that moderate- and low-income individuals are eligible to receive subsidies to help pay premiums "through an Exchange established by the State." The U.S. Supreme Court is scheduled to hear oral arguments in one of the lawsuits challenging an Internal Revenue Service rule allowing the subsidies to be issued through the FFM, *King v. Burwell*, on March 4, with a ruling expected in late June.

Top 10 Issues for Health Insurers in 2015

A survey of Bloomberg BNA's *Health Insurance Report* Advisory Board members determined that the top 10 health insurance issues for 2015 are:

- 1. Will Affordable Care Act subsidies remain the law once the U.S. Supreme Court rules in *King v. Burwell*?
- 2. Enrollment for 2015. Will additional new uninsured patients enroll in the private plans offered in the exchanges or are we just seeing insured people move from employer-based to exchange-based coverage?
- 3. Exchange plan networks. Will regulators issue more restrictive regulations on issuers?
- 4. What will the new Republican Congress do with regard to the ACA?
- 5. 2016 benefit and payment parameters final rules for qualified health plans, stand-alone dental plans and exchanges.
- 6. Medicare Advantage and Prescription Drug Plan 2015 and 2016 contract changes.
- 7. Impact of rising drug costs, especially specialty drugs, on patients' out-of-pocket costs and on insurers.
- 8. Impact of the employer mandate on employer coverage and on businesses.
- 9. Functioning of the ACA's risk adjustment programs and opposition to the risk corridors program.
- 10. Fixing and paying for the Medicare sustainable growth rate formula and the impact on private Medigap policies.

"If the court upholds the subsidy, then ACA will be 'here to stay,' just like Social Security or Medicare," Howard Wizig, president and chief executive officer of health insurance technology company Vivius of Overland Park, Kan., told Bloomberg BNA. "I think the era of trying to repeal ACA via a challenge in the courts

would come to an end, and the opponents' strategy would shift to a legislative repeal after the 2016 elections ... which will be a much more difficult 'take away' since ACA will have been in place for three full years."

If the court doesn't uphold the IRS rule, "it is not just the subsidies but the non-group market that is at stake. Providers will take a big hit as well."

—Timothy Jost, Washington and Lee School of Law

Timothy Jost, a professor at Washington and Lee School of Law in Lexington, Va., and a consumer representative to the National Association of Insurance Commissioners, argued that "Once the Supreme Court focuses on the language of the statute they should uphold the rule." However, if the court doesn't uphold it, "it is not just the subsidies but the non-group market that is at stake," he said. "Providers will take a big hit as well."

But Joshua Raskin, a managing director and senior analyst in the equity research department at Barclays PLC in New York, said that if the court were to side with the plaintiffs against the IRS, "In terms of impact, there will be very little. We estimate that less than 1 percent of revenues for health insurance companies come from individuals enrolled in exchanges that are run by the federal government. Profits are even lower since most companies are actually losing money on exchanges."

For hospitals, Barclays estimates that less than 1 percent of total earnings are related to individuals enrolled in the federal exchanges, Raskin said. Further, "we would expect work-arounds at the state level to mitigate the potential impact."

Need for Legislative Fix. William Schiffbauer, a health-care attorney in private practice in Washington, predicted that Justices Antonin Scalia, Clarence Thomas and Samuel Alito will argue for a strict textual analysis of the case, while Chief Justice John Roberts and Justice Anthony Kennedy "will argue the need for a legislative fix of defective language and not another 'court made' fix," such as the 2012 ruling allowing the ACA to stand. That would amount to a ruling favoring the plaintiffs.

"The Obama administration will have to seriously 'bargain' with [the] Republican Congress for ACA 'fixes' to allow subsidies in federal exchanges or expand state-run exchanges," Schiffbauer said. "Alternately, the ACA will dangle through the remainder of 2015 and into 2016 to become a major issue for the 2016 election."

George Strumpf of EmblemHealth Inc. of New York predicted "another 5-to-4 decision will uphold the law," as happened in the landmark 2012 Supreme Court deci-

sion upholding most of the ACA. But, "If the court finds against the act, the [approximately] 80 percent of current enrollees who are now receiving some amount of subsidy would probably disenroll as soon as possible."

State Actions to Receive Subsidies. If the high court overturns the IRS rule, the question would turn to whether states using the FFM would take action to be designated a state-based marketplace (SBM) in order for their residents to continue receiving the subsidies, HIR advisory board members said.

Close to 5 million people received subsidies through the federally facilitated marketplace in 2014. In 2015, 37 states will use the FFM, up from 36 states in 2014.

A Department of Health and Human Services report released Dec. 30 said that about 87 percent of people who selected plans through the HealthCare.gov enrollment website for the federal marketplace for coverage beginning Jan. 1, 2015, were determined to be eligible for financial assistance to lower their monthly premiums. More than 3.4 million people selected a plan in the 37 states that are using the HealthCare.gov platform for 2015, it said.

"Some states may act in a way to continue qualifying for subsidies" using a path set by the HHS, "but some others will not," Arthur Lerner, a partner with law firm Crowell & Moring LLP, Washington, said.

States with Republican governors and state legislatures that aren't offering exchanges won't "rush to implement one," Wizig said.

Enrollment

ACA enrollment will clearly be smoother for 2015 than it was for 2014, board members said. But it won't be glitch-free, said Lynn Shapiro Snyder, an attorney in the Washington office of Epstein Becker & Green PC. More will enroll but not in the numbers expected, she said.

"Nobody even remembers that last year at this time, we were talking about the entire ACA failing because the federal website wasn't functioning," said Barclays' Raskin. "It sure seems like exchanges worked in 2014 at this point."

Raskin expects "modest" enrollment of about 8.5 million people on public exchanges in 2015, "but the process is working." The HHS has forecast that between 9 million and 9.9 million people will enroll in coverage through the exchanges for 2015.

The second ACA open enrollment is going "reasonably well for individual enrollment, sluggish for small group" enrollment, Lerner said.

"Lessons were learned from last year's enrollment," Wizig said. "There will always be challenges to such a system but I believe they won't be as noticeable to the consumer."

Renewals. Raskin said he expected a "reasonably high" amount of retention for the exchanges, "though this will always be a more transient population than the

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employer group market. A large majority of individuals selected the cheapest options in 2014 and those are the plans that are requesting some of the largest rate increases. This will cause many enrollees to shop again for new plans."

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Jost also was optimistic that most 2014 enrollees would renew coverage. "Those who are going to drop have dropped and most will renew," he said.

"A half million returned in the first week to shop and many more will," Jost said. "The remaining uninsured are being reached, but those who remain to be reached at this point are the hardest to reach."

"Most people choose health insurance through inertia, so I think that most who have insurance will renew with their current plan," Wizig said. But getting people to review their choices is another matter, he said. "They tend to stay with what they have, even if an alternative would be better for them. It is a very complex decision for most people and they find comfort in staying with the plan they know (i.e., their current plan)."

As for reducing the numbers of those remaining uninsured, "I don't expect much of a change," Wizig said. "People who do not have financial assets worth protecting are not going to be quick to buy health insurance." Over the coming year, when penalties get larger, "it could trigger some uninsured to buy insurance," he said.

Subsidy Compliance for 2014 Enrollees. Enrollees from 2014 will renew, "but they may not be in compliance since they may not have updated their information to determine continuing eligibility for the subsidies," Shapiro Snyder said.

Exchange customers "continue to be confounded by the combination of lower premiums in exchange for higher cost-sharing and narrower networks."

—ATTORNEY WILLIAM SCHIFFBAUER

Strumpf of EmblemHealth went so far as to say "the major issue in Year Two will probably be the failure of many Year One enrollees to update their financial data in order to continue receiving a subsidy" due to a lack of understanding about the ACA's eligibility requirements.

ACA premium tax credit subsidies are available to people in households with incomes between 100 percent and 400 percent of the federal poverty level. The

subsidies are paid on an "advance" basis directly to insurers as monthly premiums are due, and overpayments or underpayments to beneficiaries are to be reconciled when tax returns are filed the following spring.

Exchange customers "continue to be confounded by the combination of lower premiums in exchange for higher cost-sharing and narrower networks," Schiffbauer said. "This will continue to be problematic for the expectations of customers and the reality of the marketplace even with subsidies."

To help consumers, hospitals and the drug industry may offer cost-sharing assistance in view of the administration's "ambiguous and divergent positions on what are 'federal health programs' " subject to anti-kickback laws and concerns about adverse selection, Schiffbauer said. In 2013 the HHS sent a letter to Rep. Jim McDermott (D-Wash.) saying that qualified health plans purchased through ACA exchanges aren't "federal health care programs" for the purposes of the anti-kickback law. Sen. Charles Grassley (R-Iowa) expressed concern that the agency's position could hamper its ability to fight fraud in exchange plans.

Open enrollment "seems to be functioning fine, except for issues in a few states," Jost said. However, "The back end is still not [fully] operational and needs to get there." The HHS has concentrated on getting HealthCare.gov operating well for consumers, but functions involving premium tax credits to insurers still aren't being done automatically.

"The administration is asking the industry to 'be patient'" and not be publicly critical of the HHS or the ACA, Strumpf said.

Employer Mandate

On Jan. 1, the employer mandate went into effect after a one-year delay for companies with at least 100 employees. Under the ACA, employers with at least 50 employees are required to provide affordable coverage of at least a minimum value or make large "shared responsibility" payments. The mandate was delayed until 2016 for companies with between 50 and 99 employees.

Companies that previously haven't offered coverage are likely to have major problems, Shapiro Snyder said. These "large" employers that don't provide affordable coverage of minimum value to full-time employees face large "shared responsibility" payments under the law.

Changing the full-time work definition as well as "large" employer mandate rules are on the agenda in Congress, Schiffbauer said. The ACA defines full-time work as 30 hours per week, and small businesses are pushing to move the definition to 40 hours per week.

But Raskin said he thinks large employers are prepared for 2015. "There has been some movement to part-time workers, but most of these groups have insurance," he said. But, he added, "I expect to see more employer dumping in 2016 as employers haven't been able to see what the options are for more than one year."

"There will be a lot of complaining but compliance should be manageable with few disruptions," Jost predicted. "The stories of layoffs or moving to part-time work are likely anecdotal and overblown," says Arthur Lerner of Crowell and Moring LLP, who predicts the government "will be light on enforcement" of the employer mandate.

"The stories of layoffs or moving to part-time work are likely anecdotal and overblown," Lerner said. He also said he thinks the government "will be light on enforcement. There has been little enforcement so far."

Wizig said he sees the employer mandate resulting in employers hiring fewer workers, or a shift to part-time workers who wouldn't qualify for health insurance.

There is growing interest among employers to use the private exchange market outside of the public exchanges, Schiffbauer said. "It will be interesting to see how the 'retail' use and enrollment of employees into the private exchange market compares to enrollment in the federal and state exchange markets."

Aside from the employer mandate, Strumpf said low enrollment in the Small Business Health Options Program (SHOP) exchanges will be a problem. The federally facilitated marketplace as well as some of the state-based marketplaces are just beginning to get SHOP exchanges online in 2015 after focusing on getting their individual consumer websites operating in 2014.

Congress

Republicans will take control of the Senate in 2015 and their majority in the House will be bolstered. But while the Republican-controlled House has voted numerous times to repeal the ACA, it is unlikely it will be able to do so without enough votes to overturn a certain veto from President Barack Obama, advisory board members agreed. Action will center on finding enough bipartisan support to make changes to the law, they said.

Republicans "had a great opportunity right after the elections," Raskin said. "They could have proposed legislation to make sensible fixes to the ACA and forced the president to make a decision. Instead they went with symbolic ACA-repeal legislation, which obviously won't get signed by Obama. I don't think anything gets done until the 2016 elections are settled."

But there could be a bipartisan consensus in Congress to change the ACA's definition of full-time workers from 30 hours a week to 40 hours, Shapiro Snyder, Jost and Strumpf said. Congress wouldn't have to find much revenue to cover the cost of the action, and it has business and labor support, Strumpf said.

Jost and Strumpf also listed repealing the medical device tax as a likely target. However, doing so would result in large revenue losses, Strumpf said.

ACA Repeal Unlikely. Board members agreed ACA repeal was unlikely, but Republicans may offer repeal bills that won't be enacted.

After an unsuccessful attempt at a "blanket repeal" of the ACA, "They then may try to repeal individual pieces, such as the risk sharing, the medical device tax, the individual mandate, and other elements," Lerner said. "If they delay implementation of some of those, then the president might not have to veto." The law's risk corridors program, which helps protects insurers from losses through 2016, has been a congressional target as a "bailout" for insurers.

There could be bipartisan consensus in Congress to change the ACA's definition of full-time workers from 30 hours a week to 40 hours, several board members say.

There will be a debate "on how 'real' the individual mandate is, or whether the subsidies really drive coverage," Schiffbauer said. "The staged theater will be the Republican Congress sending these reform measures to the president's desk only to have them vetoed and unable to be overridden in the Senate. Vetoes will be welcomed in order to make the case for a Republican president and to elect more Republican senators in 2016."

Edith Rosato, chief executive officer of the Academy of Managed Care Pharmacy, which represents managed pharmacy benefit providers, sees some bipartisan support to pursue bills "that make modest, practical changes to the ACA that President Obama will either support or can't afford politically to veto, such as 'keep your doctor' or 'keep your plan' amendments."

Regulatory Issues

An ACA requirement that state-based marketplaces find ways to become self-supporting in 2015 will be among the major regulatory issues in 2015, along with enforcement of the employer mandate and the Centers for Medicare & Medicaid Services' updating regulations to define essential health benefits that must be covered by all individual and small group plans that took effect since the ACA was enacted in 2010, Shapiro Snyder said.

The adequacy of provider networks in exchange plans, including the accuracy and availability of provider directories, will receive regulatory attention in 2015, Jost said. "Balance billing," when out-of-network providers bill patients for fees not covered by insurers, also will be a topic for regulators, he said.

"A major regulatory issue will be the cost that individuals must incur in out-of-pocket spending in the health insurance marketplaces under the essential health benefits" requirement of the ACA, Rosato said. The HHS and states will continue seeking ways to reduce drug prices, particularly in areas of high-cost medications, she said.

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—Edith Rosato, Academy of Managed Care Pharmacy

Nondiscrimination requirements in benefits could be a big issue in 2015, particularly as they pertain to specialty drugs, Lerner said. In May 2014, the AIDS Institute and the National Health Law Program filed an administrative complaint with the HHS Office for Civil Rights alleging that four Florida health insurers violated the ACA and federal civil rights laws by structuring their prescription drug policies in a way that discourages people with HIV/AIDS from selecting their plans.

Humana, Cigna and Coventry Health Care, a part of Aetna, have all reached agreements recently with the Florida Office of Insurance Regulation to reduce patients' out-of-pocket expenses for HIV/AIDS prescription drugs.

Final Rule for Qualified Health Plans. Schiffbauer is looking for a final rule for the 2016 benefit and payment parameters governing qualified health plans, standalone dental plans and exchanges, as well as proposed rules for individual nondiscrimination as major regulatory developments in 2015.

Other regulatory problems include "the federal bureaucracy's continued use of sub-regulatory guidance to make 'law' as an end-run around the [Administrative Procedure Act's] notice-and-comment requirements; and (2) the wrong-headed treatment by the regulated community of this sub-regulatory guidance as having the legal effect and force of law when in fact it does not," Schiffbauer said.

"Regardless of what regulations are proposed or imposed the Republicans will declare them to be either over-reaching, job killers, unconstitutional or a combination of immoral, illegal or fattening," Strumpf said. "However, I don't expect the congressional leadership to make the ACA their major focus until later in the year and after the Supreme Court acts. Their initial focus will be the economy/job creation, not health care as that is old news and the public's mind is already firm on Obamacare."

The HHS needs to issue guidance related to the enforcement of the Mental Health Parity and Addiction Equity Act in Medicaid, Pamela Greenberg, president and chief executive officer of the Association for Behavioral Health and Wellness, said. Guidance and potentially a notice of proposed rulemaking should come out in early 2015, she said.

ICD-10

The debate over whether the implementation date for the ICD-10 code set will again be delayed is expected to continue in 2015.

A number of hospital groups, including the American Hospital Association and Premier Inc., urged Congress in a Dec. 11 letter not to delay the Oct. 1, 2015, implementation date for the transition from ICD-9 (International Classification of Diseases, Ninth Revision) to ICD-10.

The groups said the previous delays have been "disruptive and costly for hospitals and health systems."

But Jim Oakes, a principal with Baltimore-based Health Care Information Consultants, told Bloomberg BNA there is still pressure from industry groups to again delay the transition. He said there are "a surprising number of organizations that are still not anywhere near prepared for the transition."

Vivius Inc.'s Wizig called it a "toss up" whether ICD-10 implementation is delayed again in 2015. Implementation has been twice delayed already; once in 2013 and again in 2014.

"I expected the current delay, but don't know if there will be an additional delay," Wizig said. "I believe that a delay, if any, will be due to political considerations such as the administration trying to avoid another embarrassment."

ICD-10 updates health-care diagnoses and procedure codes from the currently used 13,000 codes in ICD-9 to 68,000, and upon implementation, will be required for all Health Insurance Portability and Accountability Act entities.

Medicare Advantage

Despite the conclusion of the CMS's quality bonus demonstration, which gave extra funds to mid-ranking Medicare Advantage plans, and another year of phased-in ACA payment reductions, the 2015 MA contract year is anticipated to be generally positive for marketplace stability and enrollment.

A total of 309 new plans will enter markets in 2015, according to the Kaiser Family Foundation, a nonprofit organization focusing on national health issues. The overall number of MA plans will be similar to that in 2014, declining by 3 percent from 2,014 to 1,945 in 2015, according to the KFF.

In terms of stability, 84 percent of 2015 plans were also available in 2014. While some have terminated their contracts with Medicare, most have decided to continue operating, and others are launching new plans across the country in 2015, according to the KFF.

The 2015 Landscape. For the 2015 contract year, plans debuted and MA organizations expanded throughout the nation.

As a sampling: Highmark started an MA health maintenance organization in western Pennsylvania and Aetna introduced one in northern New Jersey. In the Midwest, UnitedHealthcare launched its first MA plan in DuPage County, Ill. Blue Cross Blue Shield of Michigan expanded its service areas to additional counties. Humana expanded offerings in North Carolina.

"Medicare Advantage overall remains an attractive program for many retirees, and enrollment is projected to remain strong on both the plan and beneficiary side."

—Martin A. Corry and Keith J. Fontenot, Hooper Lundy & Bookman

The launch of special needs plans (SNPs) that focus on service to beneficiaries eligible for Medicare and Medicaid included those by Anthem Blue Cross and Blue Shield in Wisconsin, Ohio and Missouri and by Amerigroup in Tennessee.

Funding Changes. The 2015 MA county rates reflect the continued phase-in of the ACA funding cuts that will reduce MA funding by more than \$200 billion in years 2010-2019.

The ACA also tied MA plan quality to reimbursement through the CMS's one-to-five-star rating system.

The CMS's three-year quality bonus demonstration, which allowed for extra payments to MA contracts with three and 3.5 stars, ended Dec. 31. The program reverted to the ACA requirement that only those contracts achieving an overall rating of at least four stars may receive a boost in county rates.

With the CMS's reporting that 60 percent of MA plan contracts will have less than four stars and Avalere's conclusion that the average enrollment-weighted star rating for MA plans that offer the prescription drug benefit (MA-PDs) was 3.92 for 2015, there are predictions of shifting marketplace dynamics.

Relative Impact. Barclays' Raskin said that the conclusion of the CMS's quality bonus demonstration will have a large impact on MA plans but on a relative basis. A four-star plan has a major advantage over a three-star plan because of the increased reimbursement, he said. Five-star plans have an even bigger advantage because they aren't restricted to enrolling beneficiaries during the open enrollment season, he said. The CMS allows beneficiaries to switch to a five-star MA plan or Part D plan in their area anytime during the year.

These benefits "could make it more challenging for plans with fewer stars to compete with higher-rated plans that receive higher rebates and, for some, continuous enrollment," the KFF said.

But Martin A. Corry, chair of the Government Relations & Public Policy Department of Hooper, Lundy & Bookman, and Keith J. Fontenot, managing director of the department, said in a joint e-mail that the pressure is "not just those below four stars, as the benchmark caps are squeezing quality incentive payments to plans above four stars."

However, they added: "Medicare Advantage overall remains an attractive program for many retirees, and enrollment is projected to remain strong on both the plan and beneficiary side."

Enrollment Growth. Enrollment predictions are for more growth despite previous speculation to the contrary.

"Some questioned whether the Medicare Advantage market would shrink in response to the reductions in payments to Medicare Advantage plans included in the ACA," the KFF said.

Instead, "companies may have adjusted their business strategies and tightened their belts in response to the changes in the ACA and the sequestration of Medicare spending put in place under the Budget Control Act of 2011," it said.

Raskin predicted more MA growth despite the continued reimbursement pressure. "As we look at 2015, I believe that growth could be very similar to the 10 percent growth seen in 2013 and 2014," he told Bloomberg BNA.

The two biggest MA companies, Humana and United-Healthcare, said they expect their MA membership in 2015 to grow 8 percent.

Problems on the Horizon? However, Michael Lutz, director, health reform, at Avalere Health, said that shrinking reimbursements could affect "plans' ability to enhance benefits or remain viable in some markets."

The purchase of physician groups by hospitals is driving up MA premiums and making contractual negotiations more difficult.

—George Strumpf, EmblemHealth

He told Bloomberg BNA that he expects to see consolidation in the number of benefit plans that MA organizations offer in each marketplace.

Another encroaching issue for MA, according to EmblemHealth's Strumpf, is "provider consolidation in large urban areas where the majority of MA members are now enrolled."

The purchase of physician groups by hospitals is driving up MA premiums and making contractual negotiations more difficult, Strumpf said.

"Restoration of any of the MA payment reductions is unlikely and the combination of provider consolidation, payment cuts and the health insurance tax will reduce margins and gradually cause exits from the program," he predicted.

Change in the Senate. However, the new bicameral Republican majority on Congress led Corry and Fontenot to comment that "Republicans in general have been more favorable to MA, seeing it as a better alternative than the traditional fee for service system."

Xavier Baker, a counsel in Crowell & Moring's Health Care Group, pointed out that after some congressional pressure, the CMS raised 2015 rates from a proposed 1.9 percent decline in February 2014 to a 0.4 percent increase in its final Call Letter in April 2014.

Several Republican senators, including then-Minority Leader Mitch McConnell (R-Ky.) and then-Minority Whip John Cornyn (R-Texas), gave speeches on the Senate floor denouncing the 1.9 percent cut, saying it would "increase premiums, reduce choices, and cause America's seniors to lose access" to benefits.

Stepped-Up Enforcement. Epstein Becker & Green's Shapiro Snyder predicted that in addition to increased consolidation of players, "there will increased enforcement for noncompliance."

Similarly, Christine M. Clements, a partner at Crowell & Moring, said that another challenge for plans is the CMS's compliance oversight and enforcement activities. The agency views the MA and Part D prescription drug plan program as "mature" and has become increasingly impatient with plan missteps, she said.

In 2015, the CMS is expected to exercise sharper scrutiny of MA provider network terminations.

"As MA plans attempt to narrow their networks, similar to the trends in exchange and group plans, they will need to make sure they do so in accordance with the network requirements established for the program," Lutz said.

Audit Tool. A CMS spokesman told Bloomberg BNA that the agency is "developing an audit model to test plan sponsors' network adequacy."

Following complaints about UnitedHealthcare and other MA organizations dropping doctors from their contracted networks, the CMS in its 2015 Call Letter required plans to provide the agency with 90 days' notice of any significant network changes.

In addition, starting in 2015, the CMS will allow enrollees to switch plans when MA organizations initiate midyear provider terminations.

This special enrollment period is available on a caseby-case basis when the CMS determines that changes to a network that occur outside of the routine contracting are significant.

In addition to increased consolidation of players, "there will be increased enforcement for noncompliance."

—Lynn Shapiro Snyder, Epstein Becker & Green

Congressional Activity. Legislation introduced by Sen. Sherrod Brown (D-Ohio) and Rep. Rosa DeLauro (D-Conn.) in the 113th Congress would place more restrictions on MA organizations that want to eliminate doctors from their provider networks.

Both members plan to reintroduce their bills in the 114th Congress.

Lauren Kulik, a spokeswoman for Brown, told Bloomberg BNA that the legislation might be revised. "We also plan to ask CMS to do some of these things via regulation, since not all of these protections require legislative action," she said.

The industry, however, is expected to push back, contending that it's important for MA plans to have the flexibility to design high-value provider networks—particularly in light of MA funding cuts.

Different Ratings for Some Plans. In a memo sent to plans in November, the CMS said that MA organizations should expect more information in February about what, if anything, should be done about plans that enroll a disproportionate share of dual eligible or low-income subsidy beneficiaries and then experience particular difficulty achieving high star quality ratings.

After complaints by some plans, the CMS in September asked the public about the feasibility of achieving high-quality performance when a large proportion of enrollees are low income.

Also on the topic of different ratings for plans with large numbers of low-income members, the CMS's November memo to plans said that more information will be provided during the first quarter of 2015 about the development of an integrated star rating system for Medicare-Medicaid Plans (MMPs).

The MMPs are health plans participating in the CMS capitated financial alignment demonstration for beneficiaries dually eligible for Medicare and Medicaid. The idea behind a separate rating system for the MMPs, according to the November memo, is to acknowledge the additional needs of Medicare-Medicaid enrollees and measure the performance of the MMPs in integrating Medicare and Medicaid benefits.

State Participation. Five of the states that are involved with the demo—Virginia, Massachusetts, Illinois, Ohio and California—have contracts with MMPs.

In 2015, five more models using MMPs are expected to become active in Michigan, Texas, New York, South Carolina and Washington.

The CMS's Medicare-Medicaid Coordination Office has been undertaking various tasks to prepare for the 2015 additions, such as putting out model marketing materials for Michigan MMPs, translating member handbooks into Spanish for the South Carolina MMPs and updating ombudsman contact information in New York.

Demo Problems. However, problems such as provider opposition; difficulty integrating data, particularly enrollment files; and trouble tracking down potential enrollees are among those that plagued participating states in 2014. Also, the program no longer has a leader, with the Dec. 30 departure of Melanie Bella, director of the Medicare-Medicaid Coordination Office at the CMS.

In addition, Clements of Crowell & Moring said, this is a difficult time because of financial pressure on states and the federal government.

Michael Monson, Centene Corp.'s vice president for long-term care and dual eligibles, said providers are encouraging their patients to drop out. "Some just don't understand the program," he said.

Rosato of the Academy of Managed Care Pharmacy told Bloomberg BNA that, "at some point, the percentage of dropouts could reach such a level that CMS will have to decide whether to continue demonstrations."

Raskin said the opt-out rate is running higher than expected because of "less than scrupulous behavior" by certain providers.

"This is a complex set of individuals that will take time to manage," he told Bloomberg BNA. "That said," he added, "it is too important to fail."

Both the federal government and the states "cannot afford to allow these individuals to remain unmanaged," he continued. "We could see over 500,000 duals in managed care plans in 2015 and that is a solid start."

Part D Drug Benefit

The potential benefit of preferred pharmacies, locking in certain beneficiaries to one or two pharmacies and new requirements for pharmaceutical prescribing

are among the policy issues involving the Medicare Part D drug benefit as it enters its ninth year.

The number of PDPs shrunk between 2014 and 2015. In 2015, a total of 1,001 prescription drug plans will be offered nationwide, down by 14 percent from the 1,169 PDPs offered in 2014 and the lowest number of PDPs in program history, the KFF said.

The reduction in PDPs is largely driven by consolidation of offerings by a number of top plan sponsors, including Aetna, Cigna, CVS and UnitedHealth, Avalere Health says.

The lower number of plans reflects the impact of mergers and CMS policies that encourage plan sponsors to eliminate low-enrollment plans and ensure there are meaningful differences among plan offerings, the KFF said.

According to Avalere Health, the reduction is largely driven by consolidation of offerings by a number of top plan sponsors, including Aetna, Cigna, CVS and United-Health.

Despite those activities, the average number of PDPs by region will be 29 in 2015, according to the KFF.

Preferred Pharmacies. The debate over Part D preferred pharmacies—in which enrollees must fill their prescriptions from a subset of network pharmacies to receive lower cost sharing—won't stop in 2015.

The share of PDPs with this type of pharmacy network grew from 7 percent in 2011 to 72 percent in 2014, the KFF said, and a CMS study released at the end of 2014 put the issue back in the spotlight.

The study showed that some Medicare Part D plans' use of preferred pharmacies may not allow for consistent access to these lower-cost pharmacies for all plan enrollees, particularly in urban areas, according to CMS staff.

Yet the Pharmaceutical Care Management Association, a strong proponent of preferred pharmacies, said its own study showed that in urban and suburban areas, the average Medicare beneficiary need only travel about one extra mile to use a preferred retail pharmacy to save \$20-\$40 on monthly cost sharing.

CMS's Position. CMS's latest study findings were in line with the agency's general stance that preferred cost sharing may not be beneficial to all of a plan's enrollees.

In its 2015 Call Letter, the CMS said that, instead of passing on lower costs available through economies of scale, some plans with preferred cost sharing charge higher negotiated prices.

When the latest study was released, CMS staff said that a next step could be indicated in the proposed 2016 Call Letter, to be released in February.

The issue also may be pushed forward by Congress. A bill (H.R. 4577) in the 113th Congress, introduced by Rep. Morgan Griffith (R-Va.), would have required PDPs in medically underserved areas to extend to any pharmacy "the option to be an in-network pharmacy."

The National Community Pharmacists Association, a supporter of the legislation, said the bill, which had 80 co-sponsors, will be reintroduced in the 114th Congress.

The NCPA's position is that independent community pharmacies are often excluded by PDPs from such arrangements, causing some enrollees to change pharmacies or pay higher copays.

The NCPA's "any willing provider" stance is that discounted copays should be offered at any pharmacy that is willing to accept the insurance plan's terms and conditions.

Pharmacy Lock-In. In another area that will be continuing in 2015, legislation is expected to be reintroduced that would give beneficiaries determined to be at risk for prescription drug abuse access to a limited number of pharmacies.

In December, the bipartisan leadership of the House Ways and Means Health Subcommittee introduced a bill (H.R. 5780) that would place limits on at-risk beneficiaries regarding the purchase of certain opioids and similar drugs.

These enrollees would be allowed a choice of a pharmacy and provider to fill their prescriptions for the problem drugs.

The provision is one section of a wide-ranging fraud bill that garnered 21 co-sponsors in the waning days of the 113th Congress. It would also give states the authority to share information in an effort to prevent prescription drug abuse across state borders.

Committee Attention. In the Senate, the concept, known as pharmacy lock-in, has caught the attention of the Homeland Security and Governmental Affairs Committee.

A spokeswoman told Bloomberg BNA that Chairman Tom Carper (D-Del.) plans to work with colleagues in the 114th Congress on efforts to reduce Medicare waste, fraud and abuse, including measures that would curb so-called doctor and pharmacy shopping.

The drug abuse topic was also discussed by the Medicare Payment Advisory Commission last October and may be so again in the spring when Congress's Medicare advisers look at other aspects of Part D medication use, such as contraindicated drug combinations and polypharmacy, or the use of multiple or excessive prescriptions, according to commission staff.

As of June 2014, the CMS said that, of the 40 million Part D enrollees, 22,000 have been identified as potentially overusing opioids.

In the first half of 2014, 233 Part D plan contracts submitted 4,299 overuse issues to the CMS's Medicare Part D Overutilization Monitoring System.

Updated Regulation? Speculation abounds on the status of provisions of a CMS regulation proposed a year ago.

In January 2014, the CMS proposed a wide-ranging update rule for Medicare Parts C and D that contained a variety of controversial changes to the MA and Part D programs, including those to criteria for protected drug classes, preferred pharmacies, noninterference and the medication therapy management programs.

After protest from Congress, beneficiaries, providers and various trade groups, CMS Administrator Marilyn Tavenner said that, due to the complexities of the issues

and stakeholder input, the agency wouldn't finalize most of the proposals at that time.

When the rule was finalized in May 2014 (RIN 0938-AR37, CMS-4159-F), it contained a list of more than 40 provisions that wouldn't be made final then, but could be addressed later.

Others were withdrawn, including the provision on classes of clinical concern. "We are not finalizing any new criteria and will maintain the existing six protected classes," the final rule said.

Among the provisions that the CMS put on hold were:

- a two-year limitation on submitting a new bid in an area where an MA organization has been required to terminate a low-enrollment plan;
- termination of contracts of MA organizations offering the drug benefit for failing for three consecutive years to achieve three stars on the Part C and Part D summary star ratings in the same contract year;
- expansion of quality improvement program regulations;
- strategies for the medication therapy management program; and
- agent and broker training and testing requirements.

Profound Impact. A "question is whether CMS will repropose the provisions," Rosato told Bloomberg BNA. Some of the provisions, such as changes to preferred networks and a medication therapy management expansion, "could have a profound impact on plans and beneficiaries if implemented," she added.

Testifying under oath in September 2014 during a hearing of the House Committee on Oversight and Government Reform, Tavenner was asked to confirm that she wouldn't put forth a "rule that is similar in nature" to the gutted regulation.

"I'm not interested in bringing back the pieces that we pulled," she responded.

Rosato told Bloomberg BNA that a recent federal regulatory agenda, however, suggests that CMS might reconsider at least some of the provisions.

The HHS's fall 2014 regulatory agenda listed several Medicare rules including "the remaining policies not finalized" for 2015 under the MA and Part D programs.

"If CMS proposes and finalizes provisions for 2016, plans will have a short time-frame to prepare," Rosato said.

Prescriber Enrollment. Although the CMS didn't finalize controversial issues in its proposed rule, one of the provisions that stayed still resulted in some controversy.

The section required physicians and other eligible professionals who write prescriptions for Part D drugs or supplies to be enrolled in Medicare, or have a valid opt-out affidavit on file for their prescriptions to be covered under Part D, effective June 1, 2015.

However, following an outcry by providers who said that beneficiaries could be put in jeopardy if they are unable to fill a subscription, the CMS extended the effective date to Dec. 1, 2015, "to allow adequate time to address outstanding issues associated with the new provision."

As of that date, claims are to be denied if the prescriber lacks an active and valid national provider identifier (NPI) to be contained on the claims and isn't enrolled in or opted-out of Medicare.

Despite the rollback of the effective date, the CMS wants clinicians who haven't enrolled in Medicare to submit their enrollment applications or opt-out affidavits to their Medicare Administrative Contractors by June 1

Lerner called the requirement "a compliance headache for Part D stand-alone plans."

Rosato said that "for many years, the Medicare Part D program has sought effective ways to ensure that prescribers enroll in the system, but has had limited success." She said that "plans are concerned about the implementation process to ensure that beneficiaries continue to receive their medications in a timely manner."

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