BY KIM RIBBINK

Medicare Part D
A Whole New Market

Marketers, manufacturers, health plans, and other stakeholders who will play a central role in the **Medicare Modernization Act (MMA)** are gearing up for implementation. And while there is widespread support for a **change that will improve coverage to millions of seniors and disabled patients**, there also is an understanding that the road ahead will be anything but smooth.

The stage is set, and the final rules are in place for what The Centers for Medicare & Medicaid Services (CMS) has called the most significant improvement to senior healthcare in nearly 40 years. The Medicare Prescription Drug, Improvement and Modernization Act (MMA), which was signed into law by President George W. Bush Dec. 8, 2003, provides seniors and people with disabilities with enhanced drug coverage and health-plan choices.

In announcing the final regulations for the Medicare Drug Benefit and the Medicare Advantage Program, CMS Administrator Mark McClellan, M.D., Ph.D., said the act provided "unprecedented opportunities to bring more personalized, high-quality, modern healthcare to Medicare's millions of beneficiaries."

The pharmaceutical industry has expressed broad support for the MMA. Industry leaders from the Pharmaceutical Research and Manufacturers of America (PhRMA), say they, "... strongly support strict nondiscrimination against sicker beneficiaries, patients having access to the medicines they need, and affordable prescription drug coverage."

Of particular relevance from the point of view of pharmaceutical manufacturers is the Medicare Prescription Drug benefit, referred to as Part D.

"The coverage that Part D provides to seniors and disabled patients is a tremendous opportunity to be able to provide prescription drugs in a much better managed environment; patients will have pretty good coverage for drugs," says G. Lawrence Atkins, Ph.D., senior director of public policy and reimbursement at Schering-Plough Corp.

The challenges of implementing the MMA, however, are not lost on the industry.

"This is a brand new program with a lot going on all at once," Dr. Atkins says. "We're experimenting with private stand-alone drug coverage with seniors buying voluntary drug benefits. We're creating new organizations. Seniors are going to have to learn a whole lot about how to pick and choose between the different benefits. It's a challenge to make all of this work."

THE ACT IN SHORT

The MMA has two key provisions: a new prescription drug benefit and enhanced health plan choices in Medicare Advantage.

Section 101 of the MMA amended Title XVIII of the Social Security Act by establishing a new Part D: the Voluntary Prescription Drug Benefit Program. This is effective starting Jan. 1, 2006.

CMS has said the new Part D benefit constitutes perhaps the most significant change to the Medicare program since its inception in 1965.

"Part D means that access to medicine is going to be dramatically improved in this country for millions of people when the drug benefit becomes fully operational next January," says Jeff Trewhitt, spokesman for PhRMA. "This will help abate some of the industry's frustrations in recent years in terms of helping people who are having difficulty getting the medicines they need. And for us, that's the principle benefit."

According to CMS, in addition to the standard drug benefit with protection against high out-of-pocket costs, available to all beneficiaries with a 75% premium subsidy from Medicare, the MMA and the final regulations provide many approaches for beneficiaries to get even more comprehensive coverage for their prescription drug needs. Low-income seniors and people with a disability who have limited means — about one-third of all people with Medicare — will have access to comprehensive coverage, with no or limited premiums and deductibles and low or nominal cost sharing. (For more information, see box on this page.)

Coverage for the new prescription drug benefit will, in general, be provided through private prescription drug plans (PDPs) that offer drug-only coverage or through Medicare Advantage (MA), formerly known as Medicare+Choice plans, which offer integrated prescription care coverage (MA-PD plans).

"This will have a huge impact on the way seniors and disabled patients purchase prescription drugs," Dr. Atkins says. "About one-third of the beneficiaries will be covered with an almost-complete prescription coverage plan, paying no premiums with no doughnut holes and limited copayments. That's a very large population that will have fairly substantial drug coverage. Then the catastrophic cap is significant as well because no patient will experience, in any year, more than $3,600 in out-of-pocket expenses, except for small copayments after he or she reaches the $3,600 threshold. That reassurance and security for seniors and their families is pretty substantial. And, in some very involved drug regimens seniors have, in areas such as oncology, that $3,600 cap on expenses can kick in fairly quickly."

While the plans have been given flexibility in designing their benefit packages, CMS will have oversight of the program and will monitor quality. The MMA mandated that the Medicare Payment Advisory Commission (MedPAC) examine the extent to which cost-

How the MMA Works

CMS ESTIMATES THAT ALMOST 11 MILLION BENEFICIARIES WITH LIMITED MEANS WILL RECEIVE SUBSTANTIAL ADDITIONAL HELP FROM MEDICARE. IN ADDITION TO THE 75% SUBSIDY FOR THE STANDARD PART D BENEFIT PROVIDED TO ALL PART D ENROLLEES, LOW-INCOME BENEFICIARIES WILL RECEIVE ADDITIONAL PREMIUM AND COST-SHARING SUBSIDIES AVERAGING ALMOST $2,300 PER PERSON IN 2006.

- About **6.3 million** low-income beneficiaries who are full-benefit dually eligible for both Medicare and Medicaid will have no premium or deductible and copays of as little as **$1** or **$3** per prescription. For these beneficiaries, the Medicare benefit will pay, on average, **98%** of their drug costs.
- About **3 million** Medicare beneficiaries who are not full-benefit dual-eligible beneficiaries, but whose incomes are less than **135%** of the federal poverty level (in 2004, **$12,569** for an individual and **$16,862** for a couple) and with limited assets, will also pay only a few dollars per prescription. Medicare will cover **96%** of their drug costs on average.
- For about **1.6 million** beneficiaries with incomes less than **150%** of the federal poverty level and assets up to **$10,000** (or **$20,000** if married) in 2006, the Medicare benefit will provide **15%** copays with a sliding-scale premium, covering on average **85%** of their drug costs.
- The new comprehensive drug benefit also is expected to attract more than **1 million** beneficiaries with limited means who have been eligible but have not previously enrolled in Medicaid benefits (including Qualified Medicare Beneficiary and Specified Low-income Medicare Beneficiary benefits — QMB and SLMB) because of the high value of the drug benefit and Medicare's unprecedented outreach activities.

Source: Department of Health & Human Services, Centers for Medicare & Medicaid Services, Washington, D.C.
For more information, visit medicare.gov.

COMPANIES ARE ANALYZING HOW MUCH UTILIZATION WILL INCREASE VERSUS WHAT DISCOUNTS THE PDPS WILL WANT TO RECEIVE. There's a trade off to getting that extra volume from the 43 million Medicare recipients who are now covered by the benefit.

Dr. Jean Paul Gagnon
sanofi-aventis

In the future, for those private payers that choose to participate in Part D, THEY'RE SUDDENLY GOING TO BE SITTING ON MANY MORE COVERED LIVES AND A BIGGER PIECE OF BUSINESS THAN THEY WERE BEFORE, which is going to enhance their negotiating power across both market segments.

John McDermott
Covance

sharing requirements under MA plans affect access to services covered by Medicare or result in risk selection of enrollees.

"MedPAC has published a number of reports urging that quality be monitored," says Jean Paul Gagnon, Ph.D., director of public policy for sanofi-aventis. "Unlike employers, CMS will use different levers to control the program to ensure the government receives value. For example, there are performance reviews; quality measures and surveys of the beneficiaries; use of the United States Pharmacopeia (USP) model guidelines to evaluate the formularies for adverse selection; mandatory medication treatment management programs; transparency around rebates, discounts, and prices; and systematic reviews of evidence-based medicine."

THE NEED FOR A NEW MARKETING MODEL

As precarious as navigating the MMA will be for all parties, industry insiders believe it offers a huge opportunity to ensure that seniors' health needs are managed more efficiently and for the pharmaceutical companies to demonstrate value to patients and physicians.

The challenges for companies will be how best to communicate why their products should be on a plan's Part D formulary and to create awareness among the Medicare population and their physicians about the products and their benefits, industry experts say.

"This places a premium on creating and maintaining appropriate relationships with patient-advocacy and clinical groups," says William A. Sarraille, partner at Sidley, Austin, Brown & Wood LLP. "It means investing in government-relations programs and creating an awareness of the benefits of the products and the importance of the products with Congress and CMS. It may mean direct-to-consumer advertising campaigns around drugs that are most critical to a particular manufacturer to help inform patients about the importance of looking for those drugs and the standing of those drugs on a formulary when they make their Part D plan selections."

According to Dr. Atkins, this is an opportunity for companies to develop a marketing environment that's more focused on good outcomes, on good performance, and on demonstrating value with medical evidence.

"These changes will have an impact on how we approach some of our therapeutic areas," he says.

Brand managers and product directors will have to shift their strategies significantly, says Kevin Barnett, senior VP at Campbell Alliance.

"They need to have an understanding of Medicare Part D in order to focus on the specific implications for their brands because the impact on their business will vary by brand and therapeutic area," he says.

The different perspectives of the various Part D stakeholders — MCOs and PBMs, as well as the Medicare beneficiaries and their physicians — must be considered, as these different viewpoints may also have implications for a company's products.

"From the point of view of the MCO or PBM, there's a distinction between a Medicare Advantage prescription drug plan and a stand-alone prescription drug plan," Mr. Barnett notes. "They each have different perspectives and priorities. Because Medicare Advantage plans are going to be responsible for the medical and pharmacy benefit, they will be more interested in overall patient outcomes and the value that pharmaceuticals can provide."

Stand-alone prescription drug plans, on the other hand, only manage the pharmacy side and will likely be less receptive to an outcomes message or the opportunity to offset medical costs by proactively using pharmaceuticals.

"These plans are going to be more focused on managing utilization and expenditures of pharmaceutical products," he says.

Beyond the MCOs and PBMs, companies must wrap their arms around what the needs of the various beneficiaries will be and then how to target those patient populations.

"Brand managers need to do quite a bit of work to segment the Medicare population,

IT'S A MORE COMPETITIVE ENVIRONMENT THAN WE'VE BEEN IN BEFORE, and we will have to be more focused on demonstrating value with medical evidence, which in the long run is good for the industry.

Dr. Lawrence Atkins
Schering-Plough

including by low-income level, dual-eligibility status, region, or historical source of prescription drug coverage," Mr. Barnett says. "They also should know the incidence and prevalence of their product's related disease state in the Medicare population, how the disease state is managed, and how treatment might change, if at all, under Part D. They will likely require a good bit of primary and/or secondary research to truly understand the Medicare population and be able to segment the population appropriately and understand seniors' needs and priorities, as well as gaps in the marketplace."

The levers that CMS has to control the program will, Dr. Gagnon believes, encourage brand managers to place a different emphasis on how they market products.

"Marketers might concentrate more on compliance and persistence programs that are appropriate for the drug use," he says. "There will be a lot of oversight from CMS on how the drugs are being used and why they're being used. Marketers have to be careful how they market to the elderly; they need to ensure their messages are appropriate and that their drugs can withstand systematic reviews by evidence-based medicine centers and that they are truly good products."

Such an environment clearly raises the stakes for drug manufacturers, and Dr. Atkins believes that in the short run there will be big winners and losers.

"It's a more competitive environment than we've been in before," he says. "But because there is going to be more focus on demonstrating value with medical evidence, I think in the long run it is good for the pharmaceutical industry."

PROVIDING CLARITY

There is widespread agreement that one of the issues that needs to be addressed by all stakeholders is providing clarity to seniors about what Part D is and why enrollment in the program is important.

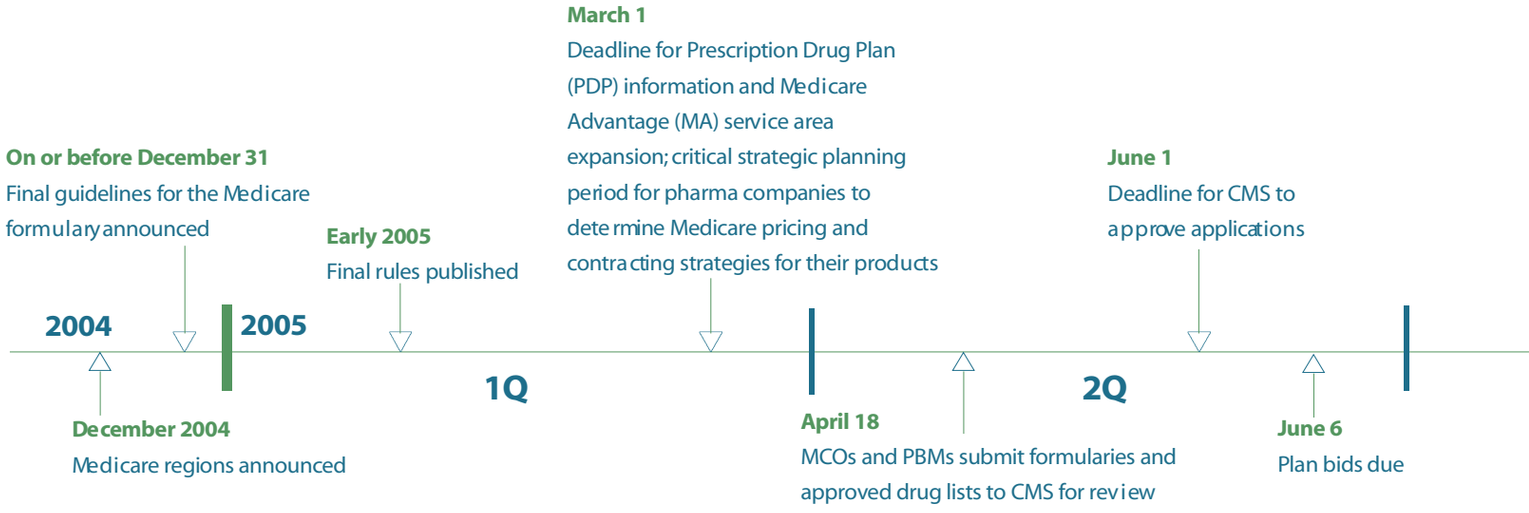
"All of the stakeholder groups that expect to be sponsors under Part D — CMS, MCOs, and PBMs, and, of course, the pharmaceutical industry — play a critical role in providing clarity around the new program and addressing any misconceptions that seniors may have about the benefit," Mr. Barnett says.

Congress has specified that prescription-drug coverage under the Medicare program is voluntary and CMS cannot, absent any legislative change, intervene with an individual's right to decline coverage.

"One hypothesis is that many seniors might not use the program because it is optional," says John McDermott, MBA, VP of Covance Health Economics and Outcomes Services Inc. "And because seniors may be unsure about the value of the benefit, companies will have to overcome the perception held by some seniors who believe that the value isn't there or that they're not going to be able to get the drugs that they need."

Medicare Modernization Act (MMA) Part D Timeline

ALTHOUGH ENACTMENT OF THE PART D DRUG BENEFIT IS NOT UNTIL 2006, NEGOTIATION FOR PRESCRIPTION DRUG PLACEMENT ON MEDICARE FORMULARIES WILL OCCUR AS EARLY AS THE FIRST QUARTER OF 2005.



Source: Campbell Alliance, Raleigh, N.C. For more information, visit campbellalliancecom.

MANAGERS OF BRAND-NAME DRUGS WITH GENERIC COMPETITION MAY WELL FIND THAT THEY WILL NEED TO DEVELOP WHOLE NEW BRAND MARKETING STRATEGIES aimed at the Medicare population who are buying drugs off-plan or out-of-pocket.

Mike Ratcliffe
Wood Mackenzie

A national Kaiser Family Foundation/Harvard School of Public Health survey found that nearly twice as many people on Medicare have an unfavorable impression of the new law that adds a drug benefit to the program, but most want Congress to fix the law rather than repeal it. The survey found that, as of July 2004, nearly twice as many people on Medicare have an unfavorable view of the law (47%) as have a favorable view (26%), and one in four (25%) say they don't know enough to offer an opinion. The survey, Views of the New Medicare Drug Law: A Survey of People On Medicare, was conducted jointly by the Kaiser Family Foundation and the Harvard School of Public Health to provide insight into the opinions of the 41 million Americans on Medicare.

Under the act, most Medicare beneficiaries will be required to pay a premium each month of about $35, and participants will have a $250 deductible each year. After the deductible, Medicare will cover 75% of drug costs, up to $2,250. Thereafter, beneficiaries pay an additional $2,850 in out-of-pocket drug costs before Medicare will continue coverage. This is called the coverage gap, also known as the doughnut hole, as AARP explains on its Website.

"Many seniors don't know what's coming, and they don't understand the doughnut hole," Dr. Gagnon says. "When they reach the doughnut hole many elderly will stretch out their drugs, for example, take one tablet every other day, thus defeating the positive outcomes associated with the benefit."

PhRMA's Mr. Trewhitt says it's going to be important for pharmaceutical companies to make sure that physicians know the choices they have for treating their patients.

THE MEDICARE POPULATION HAS BEEN A MORE PRICE-SENSITIVE AUDIENCE HISTORICALLY, and under Medicare Part D, that will likely remain the case.

Kevin Barnett
Campbell Alliance

Portfolios of U.S. Pharmaceutical Giants Heavily Exposed to Medicare Reforms

REFORMS TO MEDICARE HAVE PUT MANY LARGE PHARMACEUTICAL COMPANIES AT RISK FOR THEIR BLOCKBUSTER PRODUCTS NOT BEING INCLUDED WITHIN NEW PART D DRUG BENEFIT PLANS BEING DESIGNED FOR LAUNCH IN JANUARY 2006, ACCORDING TO MEDICARE INSIGHT, A STUDY BY WOOD MACKENZIE.

In 2004, the Medicare market accounted for almost 50% of the U.S. pharmaceutical market of $240 billion, according to Wood Mackenzie estimates, making it the second-largest drug market in the world, with revenue bigger than all of Japan. If government plans for Medicare reform succeed, Part D plans could cover up to three-quarters of the total Medicare population of 41 million.

The impact of the reforms varies significantly company-to-company. Branded drugs are already facing generic competition with blockbusters coming off patent. And the new Medicare Part D rules will introduce new competition in 20 major drug classes by forcing branded drugs to compete with both other branded drugs and generics with different mechanisms of action. In these classes, Medicare providers need only offer a minimum of two drugs per class in their plans. For example in the antidepressant class, three different types of drugs could be forced to compete with each to gain access to each plan — SSRIs such as Paxil, Zoloft, and Prozac, SNRIs such as Effexor, as well as generic tricyclics. For the first time in U.S. healthcare, this creates significant competition between branded drugs and generics that was previously managed separately.

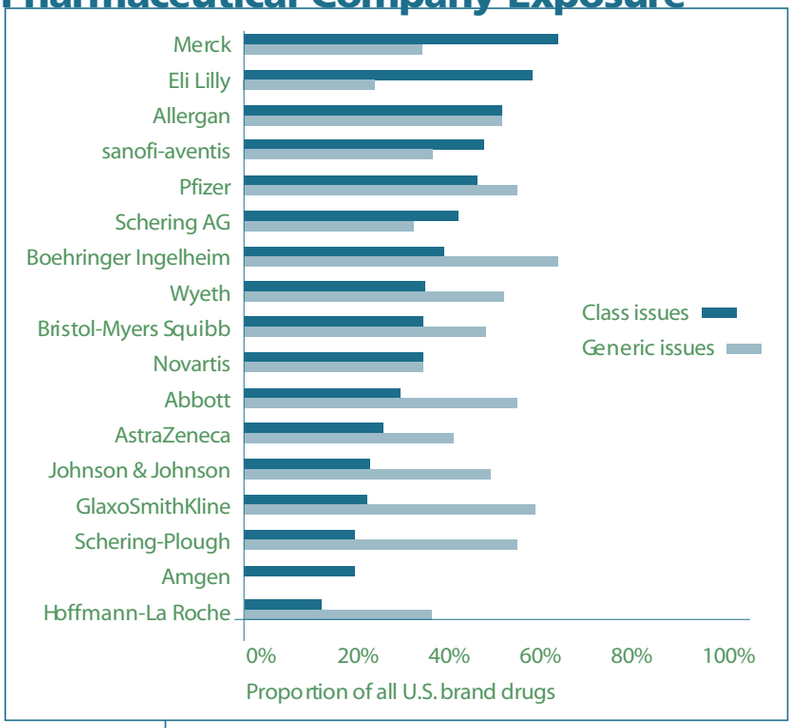
Of the 60 companies covered in Wood Mackenzie's study, six stand out as having well more than 40% of their portfolio exposed to these drug classes: Merck & Co., Eli Lilly, Allergan, sanofi-aventis, Pfizer, and Schering AG. These companies not only have higher proportions of Part D drugs in their U.S. portfolios, but also a larger number of drugs in these Medicare-specific classes that cover more than one type of drug.

Not all companies have significant exposure to these new Part D competitive forces. Companies such as Amgen and Hoffmann-La Roche have many drugs covered by the old Medicare Part B program in their portfolios and so do not have to fight to get on any drug formularies.

"Medicare is likely to have a more significant effect on the revenue of these exposed companies than most industry observers are currently predicting," says Mike Ratcliffe, director of research, U.S., at Wood Mackenzie. "Up to two-thirds of all drugs covered by these new healthcare plans could find themselves competing in a manner quite different from that of the traditional managed-care market, the market pharmaceutical companies understand. We believe manufacturers will have to rethink their strategies for many drugs as the new Part D programs unfold over the next year or two."

Source: Wood Mackenzie, Boston. For more information on the study, visit woodmac.com/medicareinsight.htm.

Pharmaceutical Company Exposure



If companies want to drive volume through the new plans, Mr. McDermott says, they will need to address their marketing approach.

"One tactic companies can employ is to promote Medicare Part D and educate seniors to let them know that this is the way to get the drugs they need," he says.

While many challenges exist with regard to reaching out to seniors and their physicians, the act significantly improves coverage for a large number of Medicare recipients. According to CMS, "one-quarter of seniors and people with a disability now in Medicare have no drug coverage, even though prescription drugs are an integral part of modern medicine to prevent diseases and their complications."

Officials from CMS say, "Medicare looks more like the rest of the American healthcare delivery system by giving beneficiaries the option of new, subsidized drug coverage, as well as new support to keep their current retiree coverage secure."

This improvement in drug coverage could well increase the number of patients who have contact with physicians. Currently, low-income patients may not go to their physician or may not fill a prescription or take a prescription less frequently than they are supposed to because of cost issues. The onus, therefore, is on pharma companies to provide clarity around the benefits and to ensure they reach the Medicare beneficiaries most in need, experts say.

At this point, however, Dr. Atkins says it's difficult to assess what impact the MMA will have on patient compliance and doctor visits.

"There probably will be some increase," he says. "Patients who have deferred treatment in the past now may be more likely to have contact with a physician for the first time, but it's hard to gauge how significant this increase will be."

Undoubtedly, the role of the physician is paramount. The physician is an important potential advocate for manufacturers, Mr. Sarraille says.

"Sales reps have links to the physicians, and one question for manufacturers is what role they may and should play in the strategy to have physicians be coverage advocates for their products," he says. "This is a set of communications that needs to be controlled and that needs to be accurate, fair, and balanced. Some manufacturers are trying to initiate communications with physicians right now to convert them into advocates for particular for-

mulary products where they see formulary fights brewing. Such communications will not be appropriate in the context of an off-label use."

On Dec. 6, 2004, CMS announced the establishment of 26 Medicare Advantage regions and 34 prescription drug plan regions as part of the move to implement the new regional MA plans and PDP programs.

"Companies will have to look at the size, structure, and alignment of their salesforces," Mr. Barnett says. "They will need to assess which physicians represent the most important targets under Part D, that is, which physicians are writing the most prescriptions for seniors and in what therapeutic categories. Salesforce incentive compensation plans will also have to be revisited as current plans will be antiquated as of Jan. 1, 2006, given the changing dynamics of Part D. Companies should start by segmenting and prioritizing the regions with the greatest potential, taking into account the number and type of beneficiaries, as well as the total prescription potential at stake."

According to industry experts, companies should start by looking at a short list of regions, such as California, Florida, New York, Illinois/Wisconsin, Texas, and Ohio, and gauge where there is the greatest concentration of Medicare beneficiaries.

Dr. Gagnon predicts that companies will begin to increase the number of representatives in heavily populated Medicare eligible areas.

"Companies are evaluating their sales territories to make sure they're calling on the physicians who will be doing the prescribing for Medicare beneficiaries," he says.

In addition, CMS has stated that one of the provisions in the final rule requires that Part D sponsors support and comply with electronic prescribing standards once final standards are in effect. The program provides for electronic transmission to prescribing physicians and the dispensing pharmacies' information on eligibility and benefits, including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization. Among the information that must be provided is the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

"When one looks at the provisions around generics and considers them in light of potential e-prescribing, it adds another layer to the price sensitivity issue," Mr. Barnett says. "Not only will the pharmacist have to counsel seniors about lower-cost generic alternatives at the point of sale, but e-prescribing will permit real-time information to be put in the hands of physicians at the point of prescribing or at the point of the treatment decision."

FORMULARY CHALLENGES

Another challenge for pharmaceutical companies will be how to best negotiate placement of their products on Part D formularies, industry experts say.

"The new Part D benefit is really the creation of a whole new marketplace," Mr. McDermott says. "There's been nothing like it before. It has some characteristics of normal managed care in that there are private entities that will be the formulary decision makers, but because of all the regulations around the formularies and the appeals processes and other details, it appears to be a much more highly regulated market than what people know as managed care today. People don't really know exactly what's going to happen here."

The Part D program goes into effect in January 2006, but already negotiations for placement on the Medicare formularies are well under way. (For more information, see chart on pages 48 and 49.)

The first step in developing the Part D program was to create model guidelines of the categories and classes that prescription drug plans can use as they design their formularies. The MMA law specifically requires the Secretary for the Department of Health and Human Services to request that USP develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes (USP Model Guidelines) that may be used by prescription drug plans in developing their formularies.

USP also is to revise such classification from time to time to reflect changes in therapeutic uses of covered drugs and additions of new covered drugs.

Sound Bites from the Field

PHARMAVOICE ASKED INDUSTRY EXPERTS TO DESCRIBE SOME OF THE MOST PRESSING CHALLENGES AS IMPLEMENTATION OF THE MMA GETS UNDER WAY.

ELIZABETH W. BOEHM is a Senior Analyst at Forrester, Cambridge, Mass., an independent technology research company that provides advice about technology's impact on business. For more information, visit forrester.com.

"At this stage, drug manufacturers' main challenge is lobbying for position on the Medicare formularies. They do this the same way they would for any health plan formulary, either by offering the best price or by successfully arguing that their drug's efficacy profile merits any differential in price. Manufacturers with preferred placement on existing non-Medicare formularies are well-positioned in this regard. Second, drug manufacturers that succeed in gaining preferred formulary placement would do well to support the efforts of plans to promote the benefit. With enrollment in discount cards languishing, consumers will need a lot of encouragement — and tutelage — to enroll in the plan that will give them the best coverage when the full benefit kicks in."

JOHN ROTHER is Director of Policy and Strategy for AARP, Washington, D.C., a nonprofit, nonpartisan membership organization that helps people older than the age of 50 have independence, choice, and control. For more information, visit aarp.org.

"The industry faces several challenges. Among the most important are: working with all parties to keep the benefit affordable to beneficiaries and taxpayers; supporting comparative effectiveness research to demonstrate value; restructuring detailing practices to move them to be more evidence-based; supporting greater transparency in both pricing and effectiveness; supporting greater postmarket surveillance to improve drug safety; assisting in efforts to enroll lower-income beneficiaries as part of broad grassroots coalitions; and supporting efforts to improve patient compliance and wise use of medications."

Pharmaceutical companies understand both the significant upside of being included in Part D formularies on a widespread basis and the significant downside that will result for many products if they are not included. COMPANIES NEED TO ORGANIZE A COMMUNICATIONS CAMPAIGN DIRECTED TO PART D PLANS AND THEIR PRODUCTS THAT IS APPROPRIATE, FAIR, AND BALANCED.

William Sarraille
Sidley, Austin, Brown & Wood

Those model guidelines, which were put together by an expert committee, were published Dec. 31, 2004. USP notes that while the model guidelines are an important tool that will help prescription drug plans and CMS in the implementation of the benefit, the formulary classification system is only the first step in a comprehensive formulary review process by CMS. The expert committee also put together a list of formulary key drug types to assist CMS in the formulary review process. The final model contains 146 unique therapeutic categories and pharmacologic classes.

The time it took to develop the guidelines has left companies with a very short timeline to provide information about their drugs to the plans, since plans must submit their formularies to CMS by no later than April 18.

"Because the USP process took as long as it did, nobody was focused on the contracting phase until late January, so all of these decisions are being made in a very short period of time," Mr. Sarraille says.

Negotiations for getting on the formulary and pricing will take place between the supply chain and the drug manufacturers, which CMS officials believe will achieve comparable or better savings than direct negotiation between the government and manufacturers, as well as coverage options that better reflect beneficiary preferences.

Mike Ratcliffe, director of research, U.S., at Wood Mackenzie, says MMA, through the U.S. Pharmacopeia and its Model Guidelines for Part D formularies, has created about 20 to 25 drug classes that have nontraditional competition between brand drugs and generics.

"Plan managers only have to include two drugs per USP class," he says. "If they do this, they could deny plan access to many major brand drugs, for example, the USP dyslipidemia class includes six subclasses that are normally separate. CMS may well recommend modifications to these guidelines in the final design of the Part D plans. As a consequence, manufacturers should be actively engaging CMS on how to modify the USP Guidelines."

For the drug manufacturers, the issues involve getting onto the formulary and at what price.

"In some ways this is raising the stakes; it becomes a situation of winner takes all, or maybe two winners take all because maybe only two drugs per class will fall into the model formulary guidelines," Mr. McDermott says. "So if a manufacturer's product isn't one of those two, it will be left out in the cold. Today, the product might be listed on additional formulary tiers, but in the future the stakes are going to be higher."

CMS has said the new drug benefit will likely give beneficiaries a drug cost savings of 15% to start and 23% after five years because of strong competitive pressures, including transparency in drug price and benefit information. Drug plans will have to negotiate discounted prices and manage drug costs to obtain the lowest costs possible while providing the drugs that beneficiaries need and to pass these savings on to beneficiaries.

"This is not going to be the standard commercial market; the plans can negotiate rebates below the Medicaid best-price thresholds, and they won't factor into the Medicaid rebate," Dr. Atkins says. "So there's a potential here — and the plans are well aware of this — to try to get larger rebates for this population."

The importance of being on the formulary is underscored by cost considerations for Medicare recipients and the fact that physicians and pharmacists will have greater access to information about drug options and costs, experts say.

According to the final rules from CMS, plans must encourage the use of generic drugs by requiring provision of information on lower-cost generic substitutions (if available) at the point of sale.

"Managers of brand-name drugs with generic competition may well find that they need to develop whole new brand marketing strategies aimed at the Medicare population who are buying drugs off-plan or out-of-pocket," Mr. Ratcliffe says.

Dr. Atkins says the legislation will create greater transparency with regard to price negotiations.

"The MMA changes the relationships between plans and manufacturers in negotiating," he says. "The act includes several provisions that will result in greater price transparency in negotiations. For example, the average selling price that the act now applies to Part B drugs as of January 2005 is the first published real-market price for drugs. It will have an effect on price concessions that are negotiated. Transparency in general will affect the strategy used to market a drug; it's a more transparent environment, and it's a more quality-focused, value-focused, and outcomes-focused environment."

According to Dr. Gagnon, pharma companies are trying to analyze how much usage a product will have in the Medicare program versus the size of discounts the plans are going to push for. Companies that produce drugs more commonly used by the elderly are in a stronger position, he contends.

"The make up of a company's products will determine what types of discounts it will offer and how incentivized it's going to be to participate," Dr. Gagnon says. "Companies that have products more likely to be used by many elderly patients are going to be incentivized to work with the PDPs to give them some discounts and to participate in the programs."

Manufacturers will likely play it safe with regard to pricing in 2006, Mr. Ratcliffe believes.

"Manufacturers are not going to give major rebates," he says. "They will wait to evaluate what happens in terms of Part D enrollment. They will wait to see which PBMs and health plans gain the largest share of Part D enrollment. Then for 2007, they will reformulate

their pricing strategy around winners and losers in the Part D channel."

The issue becomes even more complex given that the plans — the MCOs and PBMs — involved will be the same ones manufacturers negotiate with on the commercial side.

"Assuming the MCO or PBM is an approved sponsor under Part D, it could have both the managed care and commercial books of business, providing the plans with much greater leverage to negotiate prices with the manufacturer," Mr. Barnett says. "The plans are telling us that they're interested, where possible, in developing similarities between those two books of business."

"CMS is going to do a gut check to determine if what the Part D plan has done in constructing and selecting drugs as part of the Part D formulary is within the range of what is occurring commercially," Mr. Sarraille says. "And so the inclination of some Part D plans to have their Part D formulary match, or at least be based on, their commercial formulary may make some sense in that context."

In the longer run, however, Mr. Sarraille says the mirroring between the Part D and commercial formularies may yield to a more Part D specific set of formulary decisions.

"Depending on the product, the Part D and commercial markets may be fundamentally different," he says. "Part D deals with an older population, but there may also be geographic differences that result in significantly different proportions. So, while there initially may be quite a bit of mirroring between a plan's commercial formularies and its Part D formularies, I would expect that over time, Part D will increasingly deviate from its commercial standard, particularly if it does not meet its initial Part D expenditure targets."

Mr. Trewhitt says while it is going to be a competitive challenge getting onto the various formularies, this is familiar territory for pharmaceutical and biotechnology companies.

"These competitive health plans are tough, and they do hold 60% to 75% of the marketplace in the United States, and they bargain very aggressively, but because pharmaceutical companies have been dealing with and negotiating with them for the last 15 years to 20 years, they are familiar entities, so this is a familiar process," he says.

This, however, could be a double-edged sword. According to Mr. Sarraille, what might be deemed acceptable in a commercial context may create significant legal risks in a Part D context.

Though "bundled" negotiations are common in a commercial context, the Medicare program will not accept situations where concessions are made on the commercial side of a plan's business to secure access to a Part D formulary or some other benefit in the Part D context, he says.

"A few companies, though daunted by the operational limitations involved, are trying to separate the negotiation functions, commercial versus Part D, in the hope of minimizing any risk of a 'swapping' allegation," Mr. Sarraille says.

Mr. Ratcliffe says while manufacturers are accustomed to negotiating with health plans, their experience has been in an environment where they have reasonably solid figures on the number of lives covered.

"Currently no PBM or health plan has any hard figures on the Medicare lives that will be covered in 2006," he says. "The government thinks that 25 million lives will be covered under Part D in 2006; we think the figure is more realistically between 15 million and 20 million. The main point is that no one knows and there is a big difference between 15 million and 25 million, let alone which PBM or health plan will pick these lives up."

The challenge for manufacturers, Mr. Ratcliffe says, is how to set rebates for access when they have no idea how much access they are likely to get.

There could be an upside for those pharmaceutical companies that get onto a plan's Part D formulary but don't have formulary access on the commercial side for the given product.

Mr. Barnett says, in such cases, pharmaceutical companies will likely benefit from plans seeking to maintain similarities between their commercial plans and their Medicare plans. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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