

## **Conversation On Medicare**

### **The Prescription Drug Benefit: Preparing For What Lies Ahead**

*"The Pink Sheet" editors met with reimbursement experts Grant Bagley, a partner with Arnold & Porter, LLP in Washington, D.C., and Rosemary Maxwell, Arnold & Porter counsel, in January to discuss how the drug industry can prepare for and will be affected by the major changes stemming from the Medicare Modernization Act of 2003.*

#### **Medicare Part B, Part D Offer Risk And Opportunities**

**"The Pink Sheet":** *It's been more than one year since the MMA was signed into law. Since that time, drug companies have been struggling to both understand the complex legislation and start planning for the Jan. 1, 2006 implementation date. What insights can you provide to manufacturers regarding the greatest potential risks and rewards that lay ahead?*

**Bagley:** Some of the risks have become pretty evident, and they have to do with price reporting and with how the market is going to shape up in terms of dealing with different purchasers. It is clear that drug plans are going to be the purchasers, rather than patients and providers who act as surrogate purchasers for patients. Those both offer some pretty clear challenges.

On the other hand, the opportunities remain to be seen. This is going to be a new industry that is going to operate in a new and very different way. It may be too early to fully predict what the opportunities are going to be, although I think that the people in industry who guess right are going to be the winners.

**Maxwell:** On the Part D side, obviously the greatest opportunity – for manufacturers, patients, health care providers, everybody, really – is for the Part D benefit to work well and to be successful. One of the risks that I see there is the complexity of the statute – not any particular provision – but just the complexity of the benefit and the opportunity for beneficiary confusion.

What worries me a little bit is the Section 641 demonstration project. This is a sort of a precursor to Part D and a program that was expected to be oversubscribed, with enrollment having to be allocated by lottery. It has the same benefit structure as Part D but it has had a slow uptake.

People are reporting that part of the problem is that beneficiaries have been confused by the program. CMS [Centers for Medicare and Medicaid Services] initially did not ensure that beneficiaries understood that patient assistance foundations can help with co-pays on some of the expenses. There has just not been a sufficient beneficiary education effort to help people with this program. In one sense the demonstration project has been a good experience, because we've seen this response and we can identify some of the problems and make sure they do not emerge under Part D. CMS and a lot of other groups need to work together to make things as simple as possible for beneficiaries and educate them.

In a totally different area, one of the opportunities on the Part B side – and I think this could be a sleeper – is the competitive acquisition program that is supposed to start in 2006. In 2005 we are moving to payments for most Part B drugs that are based on 106% of average sales price. We're going to find out in 2005 whether that new system is creating a significant access problem for patients, either in general or perhaps for particular categories of drugs. Under the competitive acquisition program there is not a requirement that CMS pay contractors at or below 106% of ASP. There could be higher prices. It is conceivable that if [the competitive acquisition program] works well and doctors feel comfortable with it, it could in some sense function as a safety valve in the event that certain drugs have access problems at the 106% of ASP reimbursement rate.

**Bagley:** That's a good point. One of the very big unknowns is the competitive bidding program, which could well offer opportunities for manufacturers. But, as Rosemary mentioned, it may well be that it is not a savings over the 106% of ASP but rather it may even be a way that drugs are available at a higher cost. However, certain drugs might otherwise be unavailable if physicians suffer losses with the 106% of ASP payment. So, we don't know how that program is going to be implemented – it's still very early. We

***Part B competitive acquisition program may be "sleeper" opportunity.***

haven't heard from CMS yet and I think they are still trying to get their thinking around how to make competitive bidding happen. But it may well be one of the biggest potential opportunities for some manufacturers as well as a safety valve for access problems.

### Price Controls: Gone But Not Forgotten?

**"The Pink Sheet":** *The MMA explicitly prohibits government price controls, but members of Congress have expressed interest in legislation that would allow HHS to negotiate prices, and a recent Kaiser survey indicated that 80% of the public favors repealing the "interference prohibition." In light of these developments, what are the chances of a change in this area?*

**Maxwell:** As far as repeal of the noninterference clause, I don't expect that. It's not inconceivable – proposals have been introduced to repeal that MMA provision almost since the day after the legislation was passed. But perhaps the greater threat on that front is slow erosion of that clause.

**Bagley:** There is a great deal of confusion and misunderstanding over assertions that drug prices are too high because they are lower in other countries and in the [Department of Defense/Department of Veterans Affairs] programs. It is not a realistic comparison. The implication is that if only the government could get in there and bargain, they could get the same prices that are charged in Canadian pharmacies and in the DOD/VA system across the board.

Most people in industry realize that's just not realistic, that those represent different markets and that they have different prices for a variety of reasons, including price controls. To expect that those kinds of prices would be present if the government was negotiating for the Medicare program just doesn't make sense. But the popular perception from the media is that that is what would happen, and I think that's why the poll turns out that way.

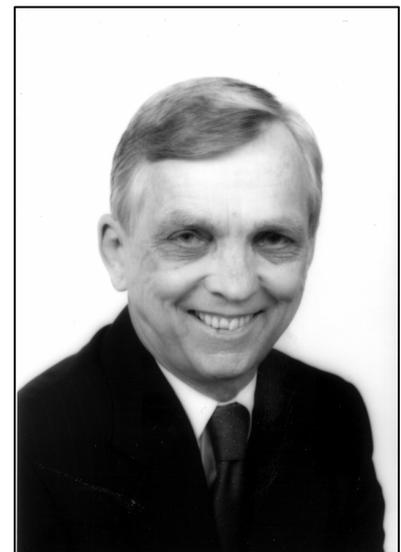
**Maxwell:** As a logical matter, the only way that the government could conceivably negotiate lower prices than the PDPs [prescription drug plans] that will be providing Part D benefits would be if the government collectively said, "We are going to use our clout to exclude a drug from all of Medicare because we are not happy with the price negotiated."

If people understood that if the government could conceivably get any savings at all, it would be at the cost of having the government make decisions about what drugs are available to all of the Part D beneficiaries, I think the perception of that whole issue would be different. As it is, it makes an overly simplistic sound byte: "Oh, let's just let the government negotiate." It sounds like common sense, but it would have real costs to patients. It would reduce choice if we really had CMS out there doing it.

**"The Pink Sheet":** *Conversely, in the absence of price controls, do you think we'll see the federal government getting involved in PDP/drug company negotiations in subtle ways?*

**Bagley:** It's generally understood that in putting together a prescription drug plan, that the majority opinion was that we should create a plan in which the administration would be done in the private marketplace, that it would be somewhat driven by market forces, that there would be beneficiary participation in payment so that there would be some cost sensitivity on the part of the patient, and that it be organized into regions, so that there is some responsiveness and accountability and connection with the locality, which again, is beneficiary friendly. Those are all characteristics of the new plan, and the government was told to keep out of the plan, to not negotiate prices.

It's interesting to look back 40 years, and look at Medicare as it was originally designed. Tensions existed then about whether or not we should have a federally-administered plan, or whether we should simply provide payment assistance and let people make local decisions, let the private market handle it and leave administration up to the private entities. And in fact that was part of



**Grant Bagley**  
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the compromise in 1965 – Medicare is not administered in Baltimore, but administered by private contractors that are organized in a regional way, in which many of the decisions are made by contractors with local input from carrier advisory committees.

There were certain protections built into the statute, such as the provision that CMS would not interfere with the practice of medicine. Now, this sounds suspiciously like many of the protections and the structures that were put in place for Part D.

Today, it would be hard to say that Medicare is locally administered by contractors with very little input from CMS. CMS is increasingly making decisions at a national level. Whether that’s a good thing or a bad thing – and I think there are times when it’s both – the reality is that CMS is an agency that is more and more involved in giving direction and mandates. It would be unrealistic to think they might suddenly develop a “hands off” attitude for Part D.

**Maxwell:** Vigilance is called for in maintaining the vision of the statute in which Part D is a privately delivered benefit without the government determining what’s going to be on formularies and what the prices are going to be for drugs. Looking back at the very first provision in the Medicare statute prohibiting federal interference over the practice of medicine, it was clear that people were fearful of the degree of federal interference that could result from a large national health care program. And today it would be difficult to identify specific constraints imposed by that provision.

### 2005 Implementation Steps

**“The Pink Sheet”:** *There is no question that the Part D prescription drug benefit will create an increasingly competitive market for pharmaceutical companies. With the coverage landscape changing, where should drug makers focus their energies during the next six to 12 months?*

**Maxwell:** It’s so critical for the whole Part D process to work smoothly and for beneficiaries to understand the benefit, which has to operate as easily as possible for them. To make this happen, manufacturers really need to pay attention to all the guidance that CMS is putting out. They need to identify problems and work with CMS to make things simpler and less confusing for Medicare beneficiaries. And to the extent possible, I think companies should do whatever they can to help CMS with those educational and outreach efforts.

**Bagley:** There are a number of ways industry can help in terms of a transition into the Part D program. It’s a complicated program and it’s hard to explain, but nevertheless, the individual Medicare beneficiary and the Medicare providers – the physicians and the institutions – haven’t yet come to grips with Part D. So, I think manufacturers must and have begun to play a critical role in that area: explaining the program, what it does and what it doesn’t do. They can provide a valuable service in this way.

**“The Pink Sheet”:** *To clarify, do you mean educating consumers?*

**Bagley:** Yes, consumers in terms of Medicare beneficiaries, and maybe more importantly, providers. Physicians, as the drug prescribers, are being asked to operate in a much different way and respond to patients who are having their drugs paid for in a new way. Physicians need to understand the program and what its implications are. The drug industry has always had a major role in helping to educate providers. It’s been an important role and it’s one they need to continue from a policy point of view.

The other thing manufacturers are dealing with is how to help patients adjust to the payment system in Part D. There may be some real problems in Part D in terms of co-payment and the “donut hole.” Although there is low-income assistance, it may not be adequate for all patients. There is an intention that there be some cost sharing with patients to make them cost sensitive about their drugs, but there also is the issue of simply locking people out of adequate therapy.

**“The Pink Sheet”:** *How can manufacturers help patients in this regard?*

**Bagley:** Manufacturers have always had programs in which they attempted to assist patients who are not able to afford medications and their medical care. One of the challenges that industry is going to have under Part D is to find a way to make that happen within the confines of the program’s intended cost-sharing and the various provisions of the anti-kickback statute and the other enforcement actions the governments can take.

## Internal Coordination Is Key To Success

**“The Pink Sheet”:** *How should pharmaceutical companies frame their reimbursement strategy approach?*

**Bagley:** Pharmaceutical companies are organized in different ways, so it’s going to depend. But the critical thing is that however they organize the internal components that are dealing with this issue, they must recognize that the implementation of the Medicare Part D program – which makes Medicare suddenly a much more important program for all pharmaceutical companies – will change the way they look at those internal relationships. In the past, many companies paid less attention to the Medicare program if they didn’t have a large portfolio of products that were covered by Medicare, such as oncology drugs that were paid for as Part B drugs or as inpatient services paid by Medicare. Suddenly, that’s not the case.

**“The Pink Sheet”:** *So, what should companies consider in terms of integrating their Medicare-related operations?*

**Bagley:** You have the business units, which are doing marketing, sales and pricing and dealing with competitive issues. You have the general counsel’s office, which has typically been responsible for regulatory issues and compliance. And now, in virtually all companies, you have a separate office of compliance which is dealing with ethical issues, integrity and compliance with government programs. Now all of those components have an important role in Medicare. These roles may be organized differently in different companies, but they all need to talk to each other.

In the companies we deal with, it has become clear that the internal compliance and ethics function, the general counsel’s office and the sales/marketing/promotion function – and perhaps even the government relations part of the company – all need to be integrated in terms of doing their strategic planning and thinking about their products. This is imperative because as soon as one of these components operates in isolation, it might cause problems for the others.

**Maxwell:** I’d like to add that...digesting [the Part D final rule] will be a daunting task. At the same time, CMS is continually coming out with new subregulatory guidance documents that companies have to look through, and they need to identify anything of interest and concern in those documents as well as the USP [U.S. Pharmacopeia] guidelines. It’s a big job that needs to be shared and coordinated appropriately, and that is going to be tough.

## New Considerations Of Cost, Comparability Data

**“The Pink Sheet”:** *What types of data do you think will come to be expected as part of a standard Medicare coverage decision under Part D?*

**Bagley:** Under Parts A and B, CMS is playing a much more active role in considerations of cost. It’s worthwhile to look at the experience that the Australians had when they started looking at costs and comparisons of pharmaceuticals reimbursed under their single-payer program. What they found to be the most limiting was the lack of literature or any studies that looked at direct comparability of products. Such studies aren’t required by the FDA, they aren’t typically done by research institutions and they aren’t typically funded by industry. There are a lot of reasons for this. One, it’s not the primary question that the FDA looks at. Two, they are studies that are difficult to do because they have to be incredibly large in order to have any meaningful results at all.

**“The Pink Sheet”:** *In which direction do you see CMS moving on this issue?*

**Bagley:** Considering the limitation that the Australian pharmaceutical pricing authority ran into, I think CMS is initiating activities that are aimed at conditioning their coverage of a new product to the ongoing collection of information on performance, whether it is performance of one product or performance compared to other products. We may see CMS taking on more of a role in the design of clinical trials and even requiring that clinical trials continue as a condition of being reimbursed under Medicare Parts A and B.

Does that directly influence the PDPs and how prescription drugs will be dealt with? Well, it’s CMS that will be looking at plans and looking at their activities, so I think the activities that CMS undertakes for the drugs they pay for more directly may have an influence on the activities of PDPs.

**Maxwell:** Serious questions exist about whether CMS has the legal authority to do that sort of thing in the traditional Part A and Part B programs. Clearly the MMA does not envision that sort of role for CMS in the Part D context.

**Bagley:** There’s no question of that. The creation of Part D did not envision CMS making decisions about those sorts of issues. In fact it points in the other direction: CMS is not to make those decisions.

**“The Pink Sheet”:** *More broadly, how do you think the new requirements will affect drug development?*

**Bagley:** The goal of pharmaceutical research is to come up with innovative products – that is all there is to it; the more innovative it is, the better. For the major pharmaceutical companies, that is their mission and their future. They will continue to do research looking for innovative products. People can say they do it because it is their business, but it goes deeper than that – for the people who do research, that is their profession, their passion and their life. If they didn’t do it in this industry, they’d have to do it somewhere else. Innovation will continue in the pharmaceutical industry.

Is it going to be harder or easier in the future? It depends on how successful the Part D program is. If it does everything it is supposed to do, it will foster innovative research. To the extent that drug companies have the return on capital, research is stimulated because you have to have return on capital to be able to put research and development money back in.

**Maxwell:** It will be important for CMS to reassure manufacturers that if they are thinking about a drug for a smaller patient population, particularly one that is heavily represented by Medicare patients, that those kinds of drugs will not get overlooked because they are designed for special populations, and that plans will not be able to just ignore those for formulary purposes.

### Pros And Cons Of AWP Reform

**“The Pink Sheet”:** *Who benefits from average wholesale price reform? What should manufacturers be addressing in their operations as a result of this change to ensure compliance moving forward?*

**Bagley:** I think getting rid of an AWP-based payment has caused a fair amount of displeasure within some of the provider community – primarily the oncology community – because it was such an inherent part of the economic structure of the delivery of oncology services. There’s been a lot said about why oncology services have been designed around the economic model that they had imposed upon them, and much of the service they’ve been able to provide would have been uncompensated otherwise. That was part of the structure, so it’s requiring a tremendous amount of readjustment in that and perhaps a few other parts of the provider industry.

On the other hand, manufacturers have always had an impossible dilemma in trying to deal with AWP. It was the basis on which their products were reimbursed and they were given absolutely no direction or guidance on what it meant. To make things worse, AWP became the major area of criticism against their business practices and they were powerless to do anything about it.

To that extent, I think the industry is happy to see it go away in the Medicare arena. They didn’t know what AWP was, they didn’t know how to deal with AWP, and they had no guidance from the government. They were frequently criticized – no, even more than criticized, they were subject to enforcement actions – over how AWP was reported. They didn’t violate any regulations because there aren’t any. They didn’t go contrary to any guidance because there hasn’t been any. They did nothing wrong, yet there are claims being asserted against them. There have been settlements based on the fact that the risks are just too great to have challenged the issue. So, with the exception of providers, I think everyone is glad to see it go away.

**Maxwell:** Of course, the next issue is whether the system that replaced AWP works well. We are just starting to see how the ASP system works. I think we have to monitor the situation to see if problems emerge, to what extent and where.

**Bagley:** It’s worth observing that even though we have to see how the system that replaces it works, one of the greatest failings of the AWP-based system was that there was a complete lack of guidance from the agency on how to live in an AWP world. That has not been the case with the new system. Given short timelines and an incredible amount of work needed to implement a new program, CMS has done a great job adjusting to a new way of price reporting and reimbursement for the Part B drugs. And while there may have been a lack of guidance on AWP, that certainly has not been true in the current system. CMS has been extremely responsive in this area.

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**Maxwell:** They’ve done a much better job, but I can’t tell you that all of the questions I have about the calculation of ASP are answered.

**Bagley:** All the questions are not answered, but at least we’ve got places to ask the questions and every expectation to think that answers are forthcoming. That is a tremendous amount of progress.

### Will Part B Drugs Be Folded Into Part D?

**“The Pink Sheet”:** *Some in the industry have asserted that Part D soon will subsume Part B. Do you think this will happen? If so, are there advantages to such a scenario?*

**Maxwell:** I do not see that happening in the short term because it will complicate the implementation of Part D. Over the longer term, CMS might recommend to Congress that some of the Part B drugs – but not all – be folded into Part D, but that remains to be seen.

**Bagley:** For Part B drugs to be subsumed into Part D, Congress would have to act. CMS is supposed to issue a report on this to Congress and I think there will be attention over this issue as long as we have two separate programs to pay for drugs.

In order for Congress to take the action to move Part B drugs into Part D, a number of things would have to happen. For example, as long as there are inequities in the payment, such as the “donut hole” in Part D, it would be very difficult to take Part B drugs – many of them expensive cancer drugs or drugs for expensive, chronic diseases – out of Part B and into Part D. That would result in removing an entitlement from the program, which Congress is not likely to do.

The second issue is that if you take a lot of expensive drugs in Part B and put them into Part D, you run the risk of seriously increasing the Part D premium, which is not going to help to win support for the Part D program.

But having said those things, there’s still going to be a certain amount of tension over this issue moving forward. Part B coverage policies could become very restrictive, so that drugs currently covered under Part B no longer are, which would suddenly make them Part D-eligible drugs. So even if drugs weren’t moved by statute, they still could be moved in a number of ways, one drug at a time, using coverage polices. This would be very unpopular in both the provider and the beneficiary communities.

**“The Pink Sheet”:** *Are Part B drugs harder to define under the MMA?*

**Maxwell:** The way that things work right now, it’s a little bit complicated. Under the statute, a drug that otherwise qualifies as a Part D drug is not considered as such if payment is available under Part B “for that individual.” Although we often speak loosely of “Part B drugs,” there are all sorts of complexities and uncertainties associated with Part B coverage in many cases.

A claim for a drug that’s typically thought of as a Part B drug might be denied in some cases for various reasons, such as local medical carriers having different coverage policies or coming to different conclusions about whether a certain drug is “usually self-administered” by patients.

So there are a lot of uncertainties that can pop up about Part B coverage. A drug that you think of as a Part B drug is not assured coverage in the context of any particular claim. The way that the statute is set up now with its definition of a covered Part D drug and how a Part B drug falls outside that definition only if payment is available for that patient, Part B is essentially the primary payer vis-a-vis Part D in cases where a drug is potentially covered by both programs.

This is another area where it will be very important for CMS to avoid confusion for patients. They need to come up with seamless procedures so that the patients don’t need to worry about the complexities of Part D coverage and how it interacts with Part B drug coverage.

### Manufacturers And Physicians May Partner For Appeals

**“The Pink Sheet”:** *The appeals process certainly will be an important element in the Part D implementation. What role do you think manufacturers will play in appeals?*

**Bagley:** We’re going to have to see how the PDPs, the appeal mechanisms and all the safety valves that are supposed to prevent discrimination and allow for access to needed drugs work in practice. Much of that we don’t know yet, but

we know that although the PDPs have formularies and they'd be allowed to use utilization and cost-containment mechanisms, protections must be in place to ensure that Medicare beneficiaries will get needed medications.

Depending on how these protections play out, it is always going to fall to the physician, as the prescriber and as the patient advocate, to make those mechanisms work. In many ways it's going to be the responsibility of the manufacturer of products, to a certain extent, to provide support for those kinds of activities.

**“The Pink Sheet”:** *How would you characterize that kind of support?*

**Bagley:** To the extent that physicians make determinations about the necessity of particular drugs for categories of patients, they need to be based on evidence, based on the indications and a lot of information. So as a physician assists a patient in going through the appeals process, manufacturers may be called upon to make that information available to physicians. I think providers are going to look to manufacturers to help them assemble the literature for evidence-based appeals.

### Model Formulary Is Guide, But CMS Review Process Is True Test

**“The Pink Sheet”:** *The USP's revised formulary guidelines released Jan. 3 still call for 146 drug classes. Who benefits from this scenario?*

**Maxwell:** Patient groups and manufacturers hoped to see more categories and classes created. However, between the time USP came out with its draft guidelines and its final guidelines, CMS came out with draft subregulatory guidance saying essentially that the agency would be looking at actual populated formularies.

According to CMS, the fact that you have two drugs in each category or class – even assuming you have an acceptable nondiscriminatory category or class structure – would not necessarily mean that the formulary would pass CMS' review. It would look at the actual populated drugs and might require more than two drugs in categories or classes in order to ensure that the formulary was nondiscriminatory and adequate. So ultimately, much will be determined by how CMS conducts its formulary reviews.

However, it's a little bit difficult to understand exactly what they are going to do because their draft subregulatory guidance lacks specificity. The final formulary guidance should give us a more concrete sense of how they are going to review proposed formularies. There are a lot of complicated questions, such as how the review of the drugs on the formulary is going to interact with CMS' review of the proposed cost-sharing structure and proposed utilization management tools. There are a lot of variables in play there.

I don't think the USP final guidelines had the improvements that people wanted to see, but the ultimate impact of the final guidelines is going to be determined, to a large degree, by CMS and what it does in its formulary review process.

**Bagley:** That's right, and I think it's clear that no matter what the role of the USP formulary is, CMS will have some sort of a review process. It will be the review process that people are going to have to take a hard look at. That review process is going to be critical to ensuring an adequate and nondiscriminatory benefit.

**“The Pink Sheet”:** *CMS' proposed formulary review plans seem pretty labor intensive. Do you think that the agency has adequate resources to conduct all of these reviews in a thorough manner?*

**Bagley:** CMS is an incredibly small agency given the magnitude of the task it has. Last I checked, CMS had responsibility for one-sixth of the federal budget, and they do that with 5,000 to 6,000 employees. How do they manage at all? A lot of the functions – including most of the claims administration – are done by private contractors, and that is part of the reason why Medicare works as well as it does.

**Maxwell:** But of course the contractors do not do any of the Part D work.

**Bagley:** That's right. Plus, the MMA is a lot more than Part D. There is just an incredible implementation effort. CMS cannot do everything and they have to set

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priorities. Obviously Part D is one of the largest priorities. So yes, I think CMS will see that the program is implemented – they’ll do it but it will be tough.

For example, CMS will get formularies from PDPs and will review them to see if they pass muster. We don’t know how many they’ll have, but there will be quite a few. As we’ve seen for a group such as USP, which has experience in these issues, it’s a difficult task. CMS is going to have just 30 days to go over the formularies for the PDPs. How thoroughly they’ll do it remains to be seen. Is it going to be a flawless, seamless implementation? We all know it’s not, but I think CMS will do it. We’ll have to see what the budget heralds for CMS. They certainly need more resources.

### Trying To Hit A Moving Target

**“The Pink Sheet”:** *CMS has indicated the Part D final rule will be subject to annual revision and to interpretation at the subregulatory level. With so much change and uncertainty, manufacturers may feel like they are trying to hit a moving target. What advice would you give drug companies attempting to both plan for the future and still remain flexible?*

**Maxwell:** Part of it is that you have to follow activity closely – not just the rule, but all of the subregulatory guidance coming out – to understand how CMS envisions this process working and what it means for your products. You need to call to CMS’ attention problems in the procedures they are contemplating for implementing various statutory provisions. The agency needs a lot of help in reviewing all of these documents and seeing practical problems that might exist.

CMS has a daunting task, and the agency’s normal practice is to rely very heavily on subregulatory guidance, so although it will be great to see regulations, manufacturers need to follow that subregulatory guidance carefully.

**“The Pink Sheet”:** *Based on your experience, what is the biggest obstacle manufacturers face in shepherding in the new Part D drug benefit?*

**Bagley:** Industry has always shown itself to be able to adapt to changing markets and changing situations. The big unknown here, the dilemma, is that we can’t adapt to the changing market until we know what it is. There are so many unknowns, for good reasons, sometimes, but often the explanation industry really needs in order to adapt comes a little too late. It’s very difficult to adapt to a changing market when you don’t know what it is and, if you’re waiting for a definition, the definition comes at the last minute or is not adequate. The tough part is trying to predict how the program is going to shape up in advance, and that’s where the industry is right now.

If you guess wrong, you have to back up and you’ve lost a lot of strategic positioning. So, people are trying to second-guess what the agency is going to do, and that’s not a trivial exercise. It’s particularly frustrating because for a lot of reasons – indecision, lack of expertise due to being short-staffed and having inadequate resources – the agency often is not giving the guidance as early as people would like.

**“The Pink Sheet”:** *PDPs and drug companies will be entering into new relationships as Part D is implemented. What should drug companies be paying special attention to as they negotiate and work with PDPs?*

**Maxwell:** When you are dealing with plans that are delivering Medicare benefits specifically, more issues probably will come up where manufacturers and plans will need guidance from the HHS Office of Inspector General about structuring arrangements to ensure compliance with the anti-kickback statute.

**Bagley:** The overarching issue is that in the past you’ve dealt with one health plan at a time– it might have been big or it might have been little. But Medicare is truly the 800-pound gorilla of health plans, so when you deal with Medicare, even in the context of individual PDPs, it may affect other plans as well.

**Editor’s Note:** *Grant Bagley’s practice focuses on representing drug and device manufacturers on reimbursement and regulatory matters. Bagley, a physician, is the former director of the coverage and analysis group in the Health Care Financing Administration’s Office of Clinical Standards and Quality. Rosemary Maxwell focuses on Medicare and Medicaid reimbursement, health care compliance and public policy issues, Medicaid rebate calculations and related price reporting requirements.*

– Gretchen Parisi

