

Generic Substitution in Medicare Part D Plans

Jack Hoadley, Ph.D.

Thank you. Thank you for the opportunity to speak here today. And first I want to acknowledge my coauthors, Katie Merrell, Elizabeth Hargrave, and Laura Summer, who are all very much a part of this project. And also, I don't have any conflicts to declare but I do want to acknowledge my funders, the Robert Wood Johnson Foundation. HCFA program is the primary funder for most of the research we're presenting here, although some of the other related work is funded by the Kaiser Family Foundation and by MedPAC. And all of the reports that we have done are available on our website.

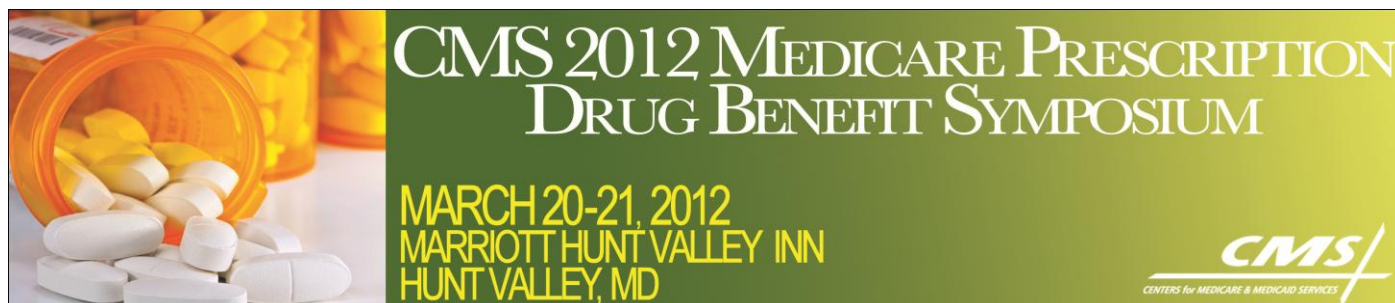
Today we want to talk about the most important factors drug plans are using to maximize generic use by their plan enrollees and really want to start out with the question of why does generic use matter? And I think for this audience it's probably pretty obvious, but I always like to sort of start here to ground things. And, clearly, generic use is something that should be a win-win all around the program. It generates savings, it saves money for the beneficiaries, it saves money for the government, it saves money for the plan, and it also should have an advantage in better health because we have studies that suggest that adherence is better when people's spending is lower when people are using generics, and that may, in fact, lead to better health outcomes, although adherence can vary by drug class. We know from a study by Congressional Budget Office that generic use, in fact, has reduced costs for Part D by a large amount, and, you know, if we simply had no generics, the cost overall would be a lot greater.

So, again, just things that should be obvious to this crowd, the cost we're going to focus here mostly on statins, but the cost of the brand statins, just the list price out there, is substantially higher than the parallel statins that are generics in the same class, and this is obviously as of 2008, which is the date of our study, and brand status is changing since that date, as many of you know.

So there are different strategies that plans can use to try to influence generic use. They can exclude some of the drugs, particularly the brand drugs from the formulary, and thereby encourage people to use generic drugs that are available in the class. They can apply, as many plans do, tiered cost sharing to try to accentuate the cost difference between the brands and generics and alternatives in a particular drug class. And they can also use various utilization management factors, especially prior authorization step therapy, to try to encourage the generics to be used.

We do know that generic use does vary quite a bit by plans. According to the CMS data in 2008, the generic use varied from 54% to 76% depending on what plan somebody's enrolled in. So something's going on that's different. There's different generic use depending on what plan you're in.

Now I want to go back and just talk a little bit about those tools and give you a little bit of descriptive background. In terms of the formularies we know overall that most drugs for most plans are on formulary. The average plan has about in the most recent year we're presenting here 84% of all drugs on formulary, but that still shows that they do exclude drugs from formulary. So they are using these tools to pick and



choose and determine which drugs are covered on their formularies. Of course, people who want to use an off formulary drug have options to using the exceptions process and so forth.

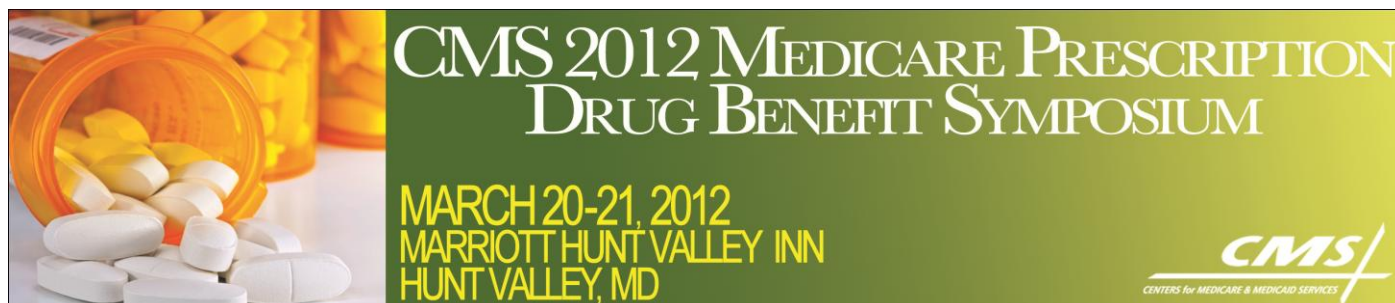
We also know that tiered cost sharing is broadly used. The blue sections of those bars are the relatively few plans -- these are weighted by enrollment -- that are using the defined standard benefit with the 25% coinsurance. That's never been a very popular approach by plans, and it's actually become substantially less popular over time. It's now down to 6% of enrollees are in plans that use a defined standard benefit. Most plans most of the time, since Part D started, have been using a three-tier formulary plus a specialty tier, so a generic tier, a preferred brand, and a non-preferred brand tier. Although as of the last couple of years we have seen a substantial growth in four tiers plus a specialty tier, where the generic is put into two different, a preferred and a non-preferred generic tier.

So, again, the main point here is that tiered cost sharing approaches are really the norm out there in the Part D world, as they are the private sector and elsewhere. We also can say that in those tiered cost sharing arrangements that cost sharing is substantially different. If you just look at the average median cost sharing across the Part D plan, there's really a ten to one ratio between the typical preferred brand copay and the generic copay, and it's actually widened a little bit in the last year, and so what we're really seeing is plans using this tool to create a pretty sharp differential in the cost to the patient for getting a generic as opposed to a brand. Compared to the non-preferred brands, it's a much even wider gap. It's a twenty-to-one differential using those non-preferred brands and the generic. So, again, you see pretty strong differences. And these are actually stronger differentials than you typically see in the private sector, which we've presented in other work.

The utilization management tools are also broadly used. We've actually seen a growth over time in the amount of prior authorization tools, and step therapy has gone up a little bit, although it dropped a little bit in the last year or so, quantity limits as well. But there is a substantial share of drugs and a typical plan's formulary for which these utilization management tools are used. So, again, they're used for a lot of reasons. They're used for safety considerations. They're used to distinguish between preferred brands and non-preferred brands. They're for payment criteria to try to distinguish whether a particular drug should be paid under A and B. But they're also used, in part, to try to encourage generic use.

So there's a fair amount of literature here that's relevant. We do have literature that suggests that the adherence, as I mentioned earlier, is higher for people who are using generics than when they're using brands. There's literature that actually does hint at the possibility of some outcome improvements when generics are being used, a number of articles that suggest that as that copay difference that I was describing increases, that people do use generics more often, something you would expect to be true, but we do have a set of studies to go along with that.

So the questions on our particular project were to look at, specifically, is generic use within a drug plan influenced by benefit or formulary design? So our real goal here is plans are using all those tools to differentiate themselves from other plans to try to influence what's going on with their utilization patterns, and the question we want to know is how much does it matter in terms of this one outcome of generic use? Does a greater differential in those copays, does leaving drugs off formulary, which, in effect,



creates even a greater cost difference because somebody would have to pay out of pocket to use the off-formulary drug, or does prior authorization make a difference?

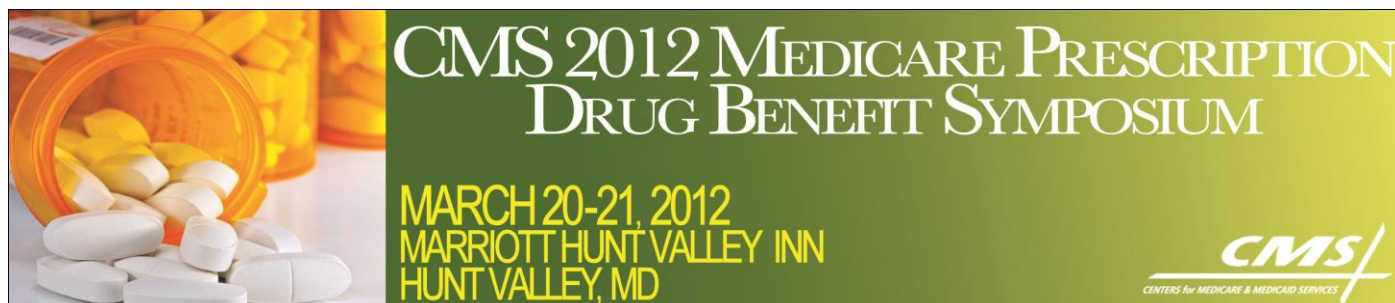
We also want to ask whether these effects vary by drug class. And so we do think that there are reasons that might happen. First of all, there's just different generic options in different drug classes. There are different plan policies. Plans may take a more aggressive stance in one class versus another. There are, of course, some rules that are imposed in terms of protective classes, and then there's simply the beneficiary and prescriber willingness to make switches. There are some drug classes where doctors are less quick to be willing to switch to a generic among a set of available options in the class and some classes where patients may be less willing to switch. So we know all those things matter.

We also would like to look at, although we haven't really done much yet on this, at whether the impact of plan design differs for the low income subsidy beneficiaries versus others, because obviously we know that the law has different posturing requirements and does not allow the same amount of differential for these beneficiaries as it does for non low income beneficiaries. Unfortunately we haven't gotten any new results on that yet, but I do want to put that as part of the focus of our overall research process.

And I do want to emphasize here that really what we're interested in most is therapeutic substitution not just straight generic substitution. We know that when the brand, as has happened in recent months, when Lipitor suddenly has generic option available, that kind of conversion happens pretty rapidly. That a lot of that happens simply at the pharmacy because the pharmacist can make that substitution except where a doctor specifies brand-only, so that kind of transition, that kind of substitution happens pretty automatically. So we're really interested in the extent to which therapeutic substitution happens within the broader drug class. So when Zocor first had generic alternatives in the statin class, how many of the Lipitor users and the Crestor users went over and switched to the generic Simvastatin? Now that Atorvastatin is available generically how many of the Crestor users might switch over and use Atorvastatin who were previously using brand Crestor.

And, again, we know that this is going to be a slower rate of change than the straight generic substitution, and of course it's partly of that because it requires you going back and getting a new prescription. You can't just have the pharmacist make the substitution. And obviously the factors of just willingness to substitute are going to vary here. Okay. There we go.

So the model for our analysis, our dependent variable is whether the individual's last prescription of the year in this particular drug class was a generic, and I'll come back and talk a little bit more about that definition in a minute. The primary independent variables we're interested in are those plan benefit design variables, the copay for the generics, the copay for the brands, and the use of step therapy and prior authorization. The off formulary factors really picked up through the copay because we treat the copay for an off formulary drug as being the full price, and so that really becomes kind of a subset of that copay analysis, but that's factored in as well.



We have a variety of control variables we're looking at. We're looking at the individual's overall drug use, their propensity to use generics as measured across their use of generics in other drug classes outside of our particular class of interest, individual characteristics like age and race, rural location. We also look at whether the state that you live in has some of the different variations in state laws on the ability to make generic substitutions, that picks up some of the difference in the straight substitution, although not for therapeutic. And then we use date of residence as a dummy variable just to pick up any geographic variations. And then we're going to repeat this analysis, potentially for different drug classes and for beneficiaries with LIS or non-LIS status.

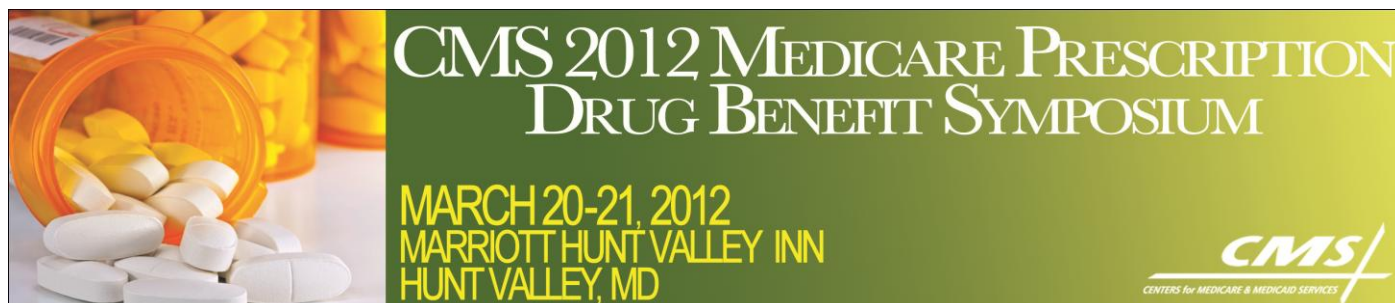
For data source here, the CMS PDE data, we had 20% sample of data, and we included all beneficiaries who were age 65 and over who were enrolled in a standalone PDP. For this analysis we didn't want to mix in the Medicare Advantage people. We figured different factors are going on there. That would be subsequent analysis, but we haven't done that yet. And then, of course, we needed to have beneficiaries with at least one prescription in a particular target class, drug class that we're looking at, and I'll show you the classes a little bit later.

We excluded any beneficiaries who were not in a single plan all year, anybody who made a mid-year switch, that's not very many people, anybody who died during the year. We skipped people who were in Medicare solely based on ESRD, and anybody in the territories. And again, as I said before, the LIS and the non-LIS show up in different models, so we're only looking at one group at a time.

So in defining our generic use variable, we did find that we got about 700,000 non-LIS beneficiaries who took a statin. That constituted our sample of non-LIS, and about 400,000 LIS beneficiaries. As I said, the variable we're using is our dependent variable, is if whether your last drug taken in this drug class was a generic, and that's true for about 58% of the people in this drug class.

We did take a look at alternate measures. We did find that most people use only -- most of this 58% group are using generics throughout the year. So, really, very few people are making a brand of generic switch within any given year. Now if we look at the year during which a big drug went generic we might see a different pattern there, and that would allow a different kind of analysis. But we're looking at a year here, 2008, where there were no big patent expirations in mid year, so it's a nice clean year just to look at straight effects of your use not looking at particular changes in use. We did find a few people that started with a brand and ended up with a generic, so they get classified as being generic users. But we do find that overall about 89% are stable in their brand, not just in generic but actually are using the exact same drug for the entire year, so it does sort of support the idea of using this as a simple dichotomous variable.

We did see results here that kind of support what we have seen in the literature, that the adherence rate, we did look at alternate measures like adherence. And adherence rate is a bit higher for generic users over brand users, very similar to what we have seen in the literature, so that's just a nice little side result. The median user in our sample used about 270 days worth of medication, so, of course, some people may have started early, that shows some lack of complete adherence, and some people may have no longer needed the prescription at some point during the year.



So this is -- where am I at here -- the statin market. These are the drugs that we're looking at, and you can see that the use in this drug class is pretty skewed to a few certain drugs. There's three different generics in 2008, and they each have a decent amount of use. The highest use is for Simvastatin by far, and you can see the median prices and the median copays that people face for these different drugs.

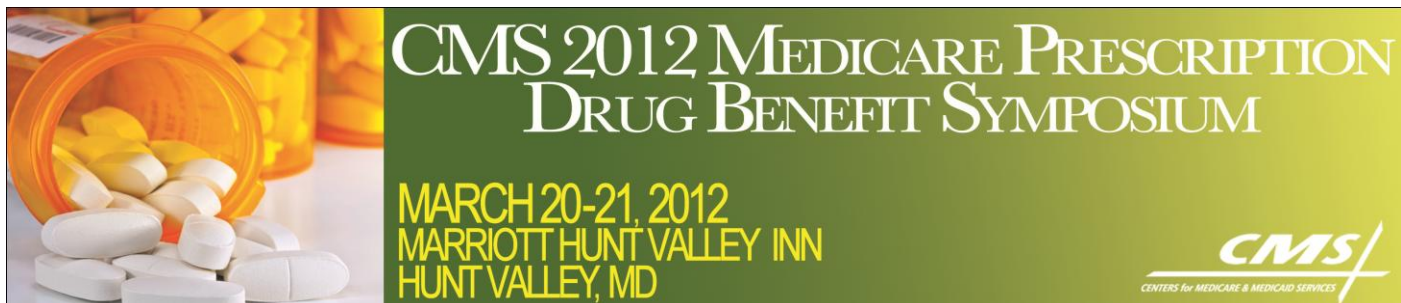
The three brand drugs that were commonly used in the sample, Lipitor was by far the most common. We did include the Vytorin, which is a combo drug, and Crestor, and those led pretty substantially. And then there was a set of additional drugs and included, for example, brand version of Simvastatin and a few of the other drugs that are much less commonly prescribed, and we lumped all of those together into an all-other-brands category, and you can see that that is about 3% of all users.

So these are the characteristics of our independent variables and, in general, the mean value for our generic copay. So, again, this is the environment that the beneficiary is facing that's driving this behavior. They're seeing a \$5 copay on average for if generic options. They're seeing a \$33/\$34 average for Lipitor, a somewhat higher copay for Crestor because that drug is more often on non-preferred tiers, and you can see the other value. The other brands has got the high average copay because, again, those are the drugs that are most commonly either not on formulary at all, and thus, maybe have more of the \$100 kind of price in this class or they're on non-preferred tier, so on average that's the highest. So that's kind of the array that people face.

You see that they do face some degree of prior authorization and step therapy, and then we have some of the other plan variables that we conclude as controls in our model.

These are the more detail on the independent variables that we use that are not part of the core study but are really control categories for enrollee characteristics, total days supply that people have for all drugs that they're using, their generic rate for other drugs outside of the statin class and so forth, dispenses written, use, age, sex, race, and then the state laws, so you see the values for those kinds of variables.

So here we're looking at results. Now we didn't put the results on the version that you have in your package. This paper is under review by a journal for publication, so I didn't want to end up having those posted with the results, but I was willing to put them up here and show you. And the one thing I would say is we tried different versions of looking at the generic copay variable. We tried a continuous version. It looked like some non-linear things were going on. So we ended up splitting the generic copays into four copays; a zero copay category, which, in this case, is our control group; and then \$1 to \$4, \$4 to \$6, and more than \$4. And one of the first things you see there is that, A, you get some very significant results here for the generic copay, but it's actually a pretty similar odds ratio. This is logistic progression, a dichotomous dependent variable, pretty much the same result regardless of the copay category you're in.



So in this drug class at least, it seems that the important difference is between the zero copay and any of the other copay levels that we identified. It doesn't seem to have a greater effect to have a \$6 or more copay than it does to have a \$1 to \$4 copay. We don't know whether that's the result of a hold up regulating other drug classes, but at least in this instance that's the pattern that we saw. So if you look at the marginal probabilities here, you're seeing about a 13 or 14% reduction in the generic use rate as that copay goes up above zero into one of these other categories. So the marginal probabilities are not displayed here, but we've done those separately.

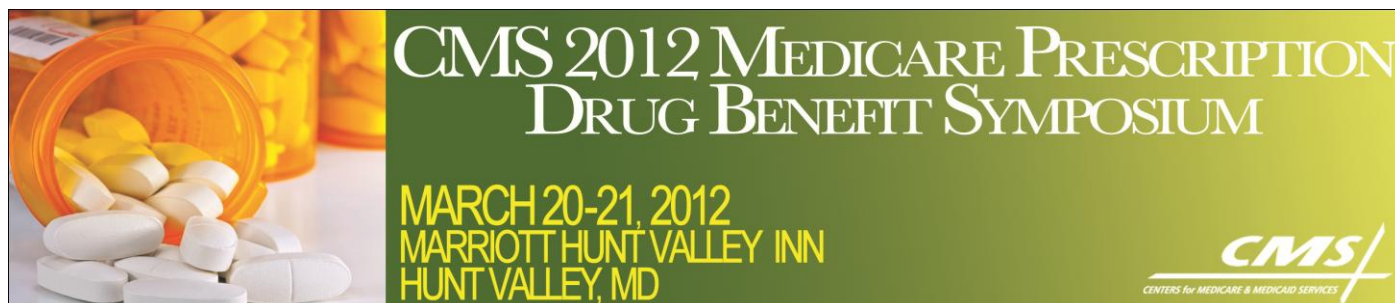
Again you see statistically significant effects for three of the four brand copays, so, again, as brand copays are higher people are more likely to use generics. Again, these are logical results. They're not shocking, but they're things that we really don't know, haven't known before, how much effect these would have. Again, to use the marginal probabilities to give you a sense of the magnitude of these effects, for a \$20 change in the brand copay rates, say, for Lipitor, you get about an 8% -- a \$20 increase in the brand copay, you get about an 8% increase in generic use rate. So the higher that Lipitor copay goes up the more likely people end up using a generic. The effects are smaller, really quite small for the other brand drugs, the Lipitor (INAUDIBLE), the biggest drug is the one people are most likely to consider as realistic alternative. But as it gets more expensive, it seems that they're less likely to go ahead and use Lipitor and more likely to move onto the generic.

Similarly, we get statistically significant results for prior authorization and step therapy. If there's prior authorization applied to at least one of the brands in that drug class, or step therapy applied to at least one of the brands in the drug class people are more likely to use generics. And, again, the marginal probabilities are about 5%, so with that going on there's about a 5% difference.

Another way to look at this is to sort of say what happens at a plan level. So, you know, a plan is going to have a particular array of characteristics that it applies, so we took an average beneficiary and we identified five hypothetical plans with different sets of copays and prior authorizations that you can see up here, and over in the right-hand column you can see the predicted generic use for people who are enrolled in that plan varied at one extreme at only 51%, and at the other extreme to 88%. So the message here to me is that it really does matter.

If you put together the right array of plan design characteristics you really are going to move a lot more utilization to generics. And, you know, you could for your own interest you could try different combinations of copays and prior authorizations and so forth and you get different results, but the biggest point here is that it makes a lot of difference. You can get very different result depending on what goes on.

We wanted to try to look at this same analysis in a couple of other drug classes. Due to limitations in our funding we didn't get very far in this. We were particularly interested in trying to apply this in one of the protected classes and in a class where both for the legal reasons of it being a protected class but also for reasons of beneficiary or patient and physician preference the willingness to substitute may be substantially less, so we looked at antidepressants. You see the set of antidepressants here that we considered. In structure it's a similar class. There's a set of generics that are pretty widely used. There's a couple of brands, two or three brands that are still pretty well used, and then some other additional



brands that are not commonly used. So, again, in sort of structure we had the good fortune to kind of look similar and similar kind of cost differences, \$100 typical cost if brands versus \$10 to \$20 costs, and again, that's not the copay that's the raw cost.

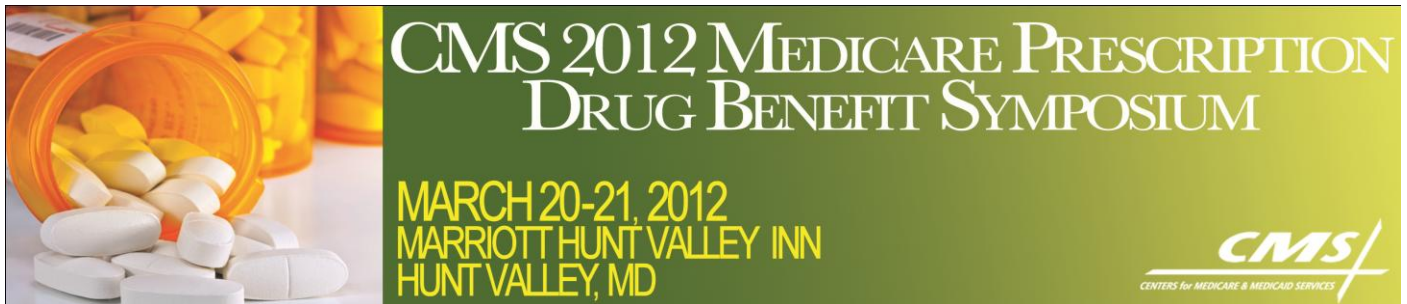
So we only have preliminary results from this drug class, and I'll just describe generally that the relationships are a lot weaker. You know, we really see a difference and understand on this basis that it's going to matter what kind of class drug class you're in. We definitely saw only a weak relationship to the generic copays, and some of the relationships are actually in the counterintuitive direction. We did see the high brand copays were associated with higher generic use, so that's in the direction we expected, and significant effects for prior authorization step therapy, but in that case kind of in the opposite predicted direction. This is something we've got to dig deeper in and try to understand what's going on here.

We know that the use of prior authorization in step therapy in a protect it had class is much more restricted so it may be that even though it's there it can only be used for new starts, that it really is kind of irrelevant to what's going on. And so the real question that we need to explore further is sort of why is this happening? Is it just the willingness to substitute in this class? Is it the protected class rules that limit what plans to do, but there's some really interesting questions here.

We also, as I mentioned, wanted to try to take a look at low income subsidy variables. We know there that the copay levels are much reduced and there's a lot less ability to differentiate. Plans do have some tools but it really is a question of whether the tools available allow them to influence generic use. We know overall that generic use by low income beneficiaries is a lot less than for non low income beneficiaries, so this is a really important question to look at for the future.

So to summarize the results, we do see an important impact of cost sharing utilization management associated with increased generic use. It looks like, at least in this one class, that the zero copay is particularly important, particularly effective, and as I showed you before, we can see a predicted generic rate for sample plans. It ranges quite a bit. But we also have a sense that it's going to matter what drug class we're looking at and that there are potentially different results for LIS enrollees.

Some important limitations -- and I won't have time to really talk much about these -- we can't see any claims that occur for off formulary purchase, so if somebody decides to pay cash and buy a drug off formulary, that's not something we're able to see, so that would not show up in the data. We know there are selection of facts that individuals who want to continue taking brands may seek out the plan that is more generous in its treatment of brands, and so there may be some reverse effect. But because this was 2008 and beneficiaries are relatively sticky, we actually think this is less likely to be a strong effect than it might otherwise be. We know there are other factors; the position has to play an intermediary roll. Plans use strategies that we're not measuring here like mailings and other kinds of publicity to encourage generics. We also can't control for income if there's an income effect, other than the fact that we're using all non-LIS folks.



You know we do think there is a significant impact on spending here that plan designs and increased generic use can yield savings. Obviously those are savings that are then shared by government, by enrollees in the plans, and there are some limitations in the savings. We did try to take a little bit of the look at the potential savings here, and if we just took these 2008 patterns and we assumed a 10% overall use in statin use, which given that I showed you a 30% potential range of variation among plan design models seems actually a modest thing, that would actually yield a billion dollars in net savings across the system, government enrollees and plans combined.

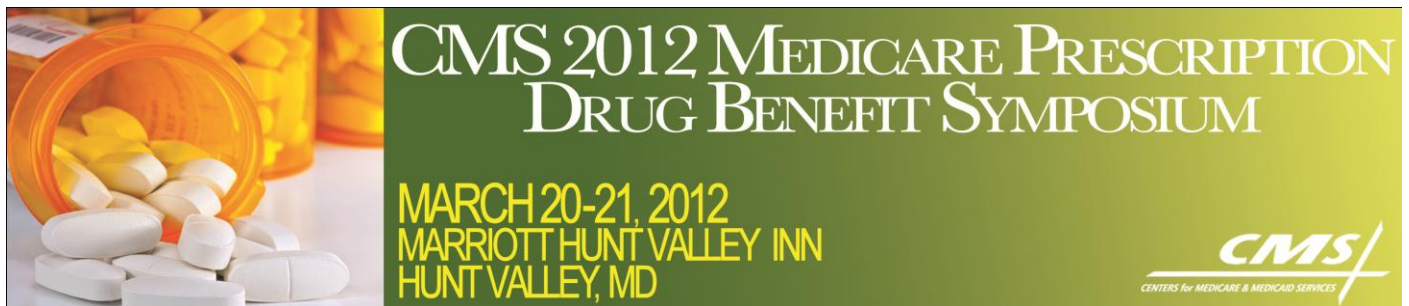
Obviously, some of this will have happened this year with Lipitor going off patent and a lot of the Lipitor users going to generic already, so plans wouldn't have to take additional steps to do that. But, obviously, they could go beyond that. The recent study that suggests no real clinical advantage between Crestor and Lipitor suggests the kinds of situation that allows people to be encouraged to move off of brand Crestor and creates a savings.

If you go beyond the statin class, you know, we're somewhat convinced that savings may not be broadly available on all classes, the mental health drugs for example, the HIV, some of the protected classes may be less likely. Both because they're protected classes but also simply the nature of those classes, the nature of those kinds of drugs that are involved in those classes. But we do think there are some of these other classes that really do have the potential to yield savings. So we do think, you know, generic substitution already plays a large roll in keeping Part D costs lower than the original expectations for the program but that there are policy tools that could further increase generic use, whether this is a matter of just plans moving to adopt better practices, adopt best practices out there in the industry, some plans clearly already try to go that, or whether there are thing that is CMS could do to mandate or encourage with performance measures and other kinds of things more use of these best practices is something that is a policy option, and, obviously, we need to think about policies for low-income beneficiaries, something that MedPAC has already addressed in this year's report.

Finally, future research, we really want to know more about results across more drug classes. We would love to be able to run this across a variety of drug classes and see if the statin results hold up consistently, and particularly see if the things like this zero-dollar copay effect holds up consistently when we look at a variety of other drug classes. Maybe that was something unique to this class, as well as to look at, as I said several times, what goes on with the low-income beneficiaries.

With that, it's time for assessments, so I'll find the piece of paper that has these instructions. So the first thing is you need to pick channel 61 if you haven't already done so, which you do by hitting the channel button, hitting 61, and hitting the channel button the second time. That was the part I forgot the other day. So if you haven't already done that, you can do that.

And so our first assessment question says, "Based on the presented analysis, which is the most important factor to maximize use of generics; one, allow full flexibility for physicians to prescribe the drugs they prefer; two, set a zero-dollar copayment for generic drugs; three, play some brand drugs on a preferred tier and others on a non-preferred tier; or four, require prior authorization for brand name drugs?



And please vote now. You have ten seconds. The poll is now closed. Look at the results. And that is the correct result, 84%.

We'll go on to the next question. "What share of prescriptions for Medicare beneficiaries were filled as generic drugs in 2008?" Answer one is 32%; answer two, 54%; answer three, 69%; answer four, 88%. Please vote now, you have ten seconds. The poll is now closed. Let's put the results. And the correct answer is actually 69%. We showed that there was a range from about 50-something to as high as 88 in what we were getting. And actually the more recent results from 2008 forward that I think Cynthia presented yesterday showed that Part D is up over 70% in more recent years. With all the new generic conversions that continues to increase. So that's it.