

Plan Benefit Generosity Adherence to Statins and Hospitalizations Under Medicare Part D

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Today I'm going to be talking about plan benefit generosity, adherence to statins, and hospitalizations under the Medicare Part D program. I do not have any conflicts of interest to declare. And our two primary learning objectives for today are first, to identify the data elements needed for the prescription drug event data, the PDE data, and the plan characteristics file for purposes of creating the measure of Part D plan generosity, and second, to assess the impact of Part D plan benefit generosity on adherence to statin drug therapy and the likelihood of subsequent hospitalizations for cardiovascular reasons.

The general outline I'm going to follow for today's presentation is I'm going to start off with a few quick slides to give you kind of the policy and project background. Then I'm going to discuss the specific research objectives for the paper that the findings are drawn out of. Then I'll provide greater detail on our adherence and hospitalization models. And finally then discuss policy implications from these models for the current ACA policy environment, and then end with just a brief discussion of where we're heading with this project.

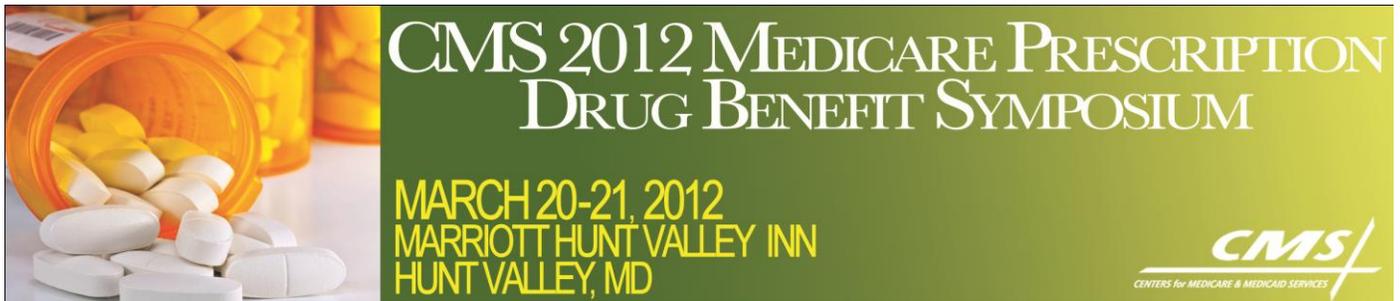
So, basically these policy slides that I put in here are kind of to re-orient you back to that first initial implementation period back in 2006. And also to like then highlight the things that affected our key research design decisions that we made.

So as you recall, the Medicare Part D program started in January 2006, and that initial enrollment period was open through mid-May of that year. Participation was optional and approximately 50% of the Medicare population did enroll in the Part D program in that first initialization period. Beneficiaries had the option of enrolling in stand-alone Prescription Drug Plans, PDPs, or in Medicare Advantage Prescription Drug Plans, the MAPDs. It's a phased benefit design where essentially they have a deductible, the pre-ICL, Initial Coverage Limit, the ICL, more commonly known as the Coverage Gap or the donut hole, and then the catastrophic coverage phase, or the reinsurance phase. And beneficiaries track through these different phases through the calendar year based on their out-of-pocket spending and the total drug costs that they incurred with their utilization.

And plans have options in structuring their coverage and their benefits many different ways in terms of like they can have a deductible or not have a deductible, the way that they structure their formulary in terms of tier structure, and so there's a large variability that way in terms of looking at plans.

And then for reference purposes I put on here the PDP region map where you can see that essentially there's 25 PDP regions that are single states. Six of them are two states combined together. And then there's three PDP regions that are three or more states combined.

The Low Income Subsidy program offers different levels of premium subsidies and cost sharing amounts for Medicare beneficiaries that are best – based on their income and asset level qualification levels.



The Medicare and Medicaid duals are the large majority of LIS program enrollees, and the – the key thing for research design purposes is LIS beneficiaries do not encounter that coverage gap phase and so they don't have the same phase benefit as non-LIS beneficiaries.

Both PDPs and MAPDs are required to submit administrative prescription event data to CMS for reconciliation purposes, and the federal legislation that allows us to use that PDE data for research purposes does not allow the release of commercially-sensitive data. And so how this affects us is essentially what we have to do is we have to construct a utilization formula based on actual prescription drug fills that we get in our data file. And this will be key to how we're constructing our benefit generosity by plan measure that we'll deal in more in upcoming slides here.

So then for the general project background, the funding for this project came from the University of Minnesota Academic Health Center Faculty Development Grant. The principal investigator on the project is Pinar Karaca-Mandic and Jean Abraham is the co-investigator.

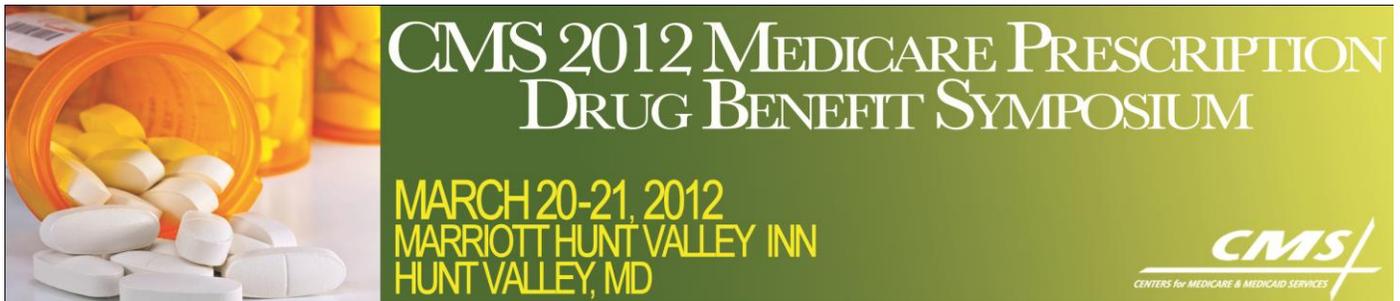
The purpose of the project is that we're examining regional variations in the benefit design of formulary characteristics and how they affect Part D drug utilization and spending. We were focused in on three broad therapeutic drug classes for analysis, and today's presentation is really from projects focusing on our first cut, or our first draft, looking specifically at statin adherence. And the co-authors of this project are Pinar and Jean, and also Bob Kane at the University of Minnesota.

So in this first statin project that we're looking at, we have essentially two hypotheses that we're testing. And our research objective with this paper is to estimate the role of plan benefit generosity towards statins on adherence with cholesterol-lowering medications and the subsequent risk of cardiovascular hospitalization. And our first hypothesis, then, is we're looking at benefi – we're proposing that beneficiaries with less generous benefit design will have lower statin adherence. And then the second related hypothesis that beneficiaries with less generous benefit design will be more likely to have a cardiovascular hospitalization. And just a point of clarification here, when I say less generous benefit design, I mean that the beneficiary has higher out-of-pocket costs, and so more generous benefit design, the beneficiary would have less out-of-pocket costs during that calendar year.

The background literature that we're drawing from is essentially that statin medications account for close to ten percent of all Part D expenditures, and that this is really building on a project that Pinar started with Dana Goldman and Geoffrey Joyce in 2006. In that paper they're using commercial prescription drug event data for the adult population, and they found that full compliance with cholesterol-lowering medication reduced the risk of hospitalizations by about 25% among high risk patients.

So the data that we're using for this project are drawing from the five percent enhanced Medicare sample. We're using the 2006 through 2008 prescription drug PDE data, the 2007 plan characteristics file, the 2006 through 08 denominator file, and the 2007 through 2008 medPAR file. And then we're merging in drug characteristics from the Medi-Span drug database.

The PDE data is, of course, from the prescription drug utilization information. The plan characteristics file contains several sub-datasets within it that are relationally related that gives us variables on the plan, variables about the tier structure within the plan, information on the premiums, as well as the service area covered by the plan.



The denominator file is the enrollment information for the beneficiary, and then the medPAR contains the hospitalization information.

So our analytical sample, then, we start off with approximately 5.2 million beneficiaries in the 2007 and 2008 five percent enhanced Medicare sample. We then limit that to we're looking at the aged Medicare beneficiaries only, or those over 65. Furthermore we're looking at the non-LIS Part D enrollees. And then we're focusing on PDP enrollees only, and the reason for that is essentially because we're looking at adherence as well as hospitalization. We needed to make sure that we can capture that hospitalization in the fee-for-service claim data.

And then furthermore we're restricting it to they have to have at least a statin fill during those cohort years, and so that results in that we have approximately 347,000 beneficiaries in our analytical cohort.

The functional model then that we have is that essentially if you look at adherence for beneficiary, I, time T, 2007 or 2008, that we're proposing that this is a function of plan design characteristics, demographic characteristics, risk adjustors, and time and regional fixed effects.

We're estimating a logistic regression of adherent and non-adherent behavior, and then we're correcting those model findings for the panel effects that we may observe the same beneficiary in both 08 and 07 cohorts.

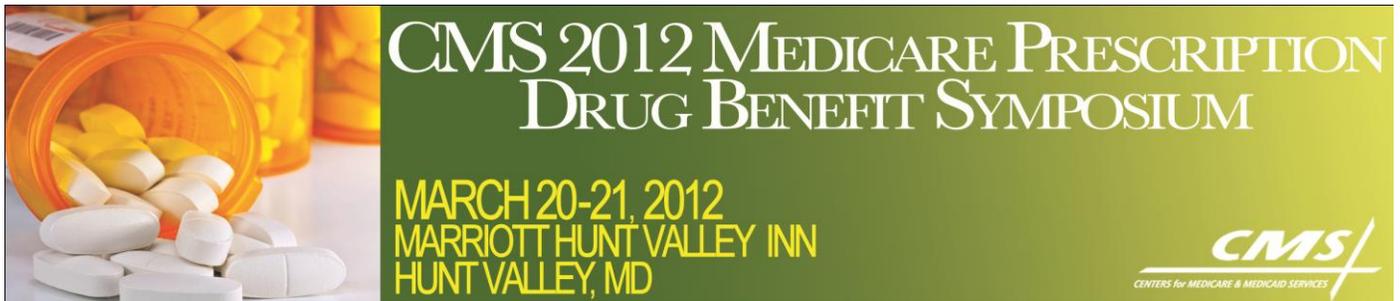
So our adherence measure that we're using is kind of a standard demonstrative adherence measure looking at the proportion of days covered, or the PDC, and we're indexing that by January 1st and December 31st, so we're looking at a calendar year adherence data. We're using the prior year's drug claims, so like for the 2007 cohort, we're using the 2006 PDE data in order to see if the person has a stock – or has a statin filled on January 1st of that year. And then we're also adjusting our PDC for if the beneficiary experiences a hospitalization during that year.

And so, just for reference purposes, on this slide I also include that essentially PDCs of .08, or roughly 80%, are generally considered adherent behavior during the year.

So on average what we find for our statin cohorts is that the average level of adherence was 0.82, so in general, they're very adherent considering these two cohorts. And then if you look at that distribution-wise, we have approximately 67% of the sample that can be classified as adherent.

And then I put this just to give you kind of a quick perspective of how this plays out over geography. You'll see that lower adherence rates are kind of in the southeast portion of the country. Better adherence rates in the northwest and north central areas looking at it by PDP regions. And I'd also just like to make a quick note that this is just a purely descriptive map here where essentially it's just the quintiles are 20%, 20%, 20%. Not saying clinically being in the fourth quintile is any different from being in the fifth quintile. This is just for pure descriptive snapshot of the data.

So the plan design characteristics that we're using is we're looking at essentially whether the PDP plan had a deductible, and we find that approximately 76% had a zero deductible. And then on average, for those plans that did have a deductible, the non-zero average is around \$264.00 for those plans. Approximately 16% of them had some gap coverage. And then the other measure that we constructed is the plan expected out-of-pocket for a representative basket of statins – or basket out-of-pocket measure.



And this the one that I'll spend a little bit more time here on to describe kind of the algorithms that we followed for constructing this measure and giving you kind of the broad details so you can see how everything fits together.

So conceptually, what we're going to measure with the basket out-of-pocket or our plan generosity measure is we want to look at the average out-of-pocket costs for a representative market basket of statins for each plan. To do this we need two key pieces of information. We need to know what the out-of-pocket is for each statin for each plan, and then we need to know weighted overall distribution of each statins for the Part D population. So, for example, say if we had a clinical classification that had only two drugs in it. Our basket out-of-pocket for Plan P would be equal to the out-of-pocket amount for drug number one for Plan P times the share of drug number one, plus the out-of-pocket costs for drug number two for Plan P times the share of drug number two. And it's just simple arithmetic from that.

The challenge though, however, is because we're having to construct a utilization formula, we have to develop an algorithm for how to substitute in when we don't observe a fill for a particular active ingredient. So, for example, say we're missing the out-of-pocket costs for drug number one or the out-of-pocket costs for drug number two. So in order to do that, we construct a utilization formula. And there's two key pieces of information we use, or two datasets that we're drawing on, to look at this part. The first dataset that we're going to be using is the plan characteristics file. And from this file we get information on all plans on all of their tier structures. So essentially we have the universe here for all plans. And the key variable within this is we have a tier ID, like tier number one, tier two, tier three, but then we also have for each of those separate tiers, what tier type that plan classified that as. So, for example, in 2007, essentially plans could have like a generic or a preferred generic or non-preferred generic, etc. for their different tier types. By far the most common plan tier structure is a generic tier, a preferred brand, and a non-preferred brand. Three tiers that way.

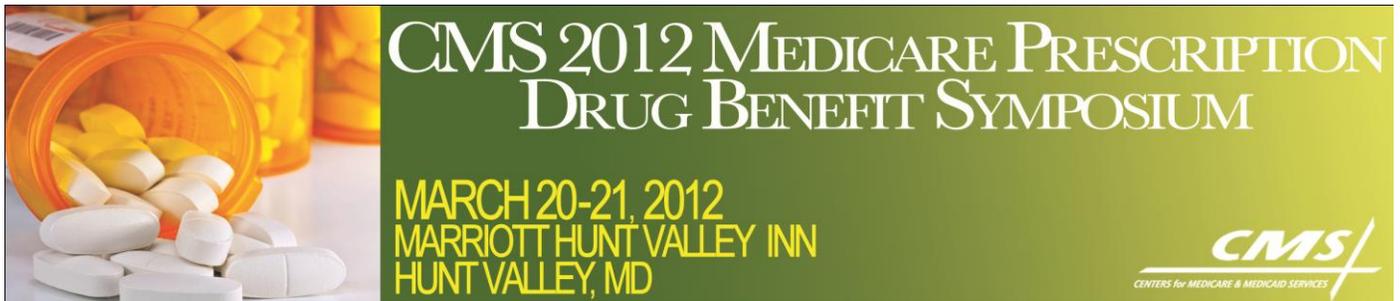
But then what else we get from the information is for each of those tiers then, we know what the coinsurance or co-pay value is for that particular tier.

Then the second data that we need for the utilization formula is the information from the PDE data, or the actual utilization information. So within the tier data – PDE data, we have the tier ID for that particular fill. We have an active ingredient from information that we've merged in from Medi-Span, we have the data supply and we have the out-of-pocket. And so the first thing we have to do is standardize all fills to 30-day equivalent fills so that we're summing up accurate measures that way. But then using the PDE data for all beneficiaries, we're able to get that distribution by active ingredients for the Part D population. So we know that roughly ten percent of them had fills for Lipitor, ten – another 20% had Simvastatin, etc. So we know that broad distribution for those weights.

And so using the summarized information from the PDE files and the plan characteristics files, we can then create our out-of-pocket measure.

So the first step, then, for creating our actual plan generosity measure then is that if the plan has a fill for statin active ingredient J, we then know what essentially the pre-ICL and copayment or coinsurance and tier structure was for that plan.

The second step, though, is the more complicated one, and that's when we observe the plan does not have a fill in our utilization data. We then have to use a separate algorithm for imputing the information for what we would expect that out-of-pocket fill for that active ingredient to be for that plan. And so



essentially what we end up having to do is that we impute then the out-of-pocket by assigning a pre-ICL copay and coinsurance mode using the information from the plan characteristics file and what we know from the tier structure from the utilization data.

So, for example, say that we're looking at Lipitor, and that we know from our utilization, the PDE data, that essentially that Lipitor was most commonly covered under these tier types, 87% preferred brand, 7% of the plans had it just in a generic brand tier, 6% had it in a non-preferred brand tier. So using this information we then can go to the plan characteristics file and for this particular plan, if they covered preferred brands and non-preferred brands as two different tiers, we then know the distribution that we'll use for that active ingredient in that part. And so for this example, then, the weights that we would assign for that active ingredient would be some in the preferred brand and then the non-preferred brand portion for those two tiers.

And so essentially it's just going step by step then and following the algorithm to get our overall broad measure that we then summarize into the out-of-pocket plan generosity \INAUDIBLE\.

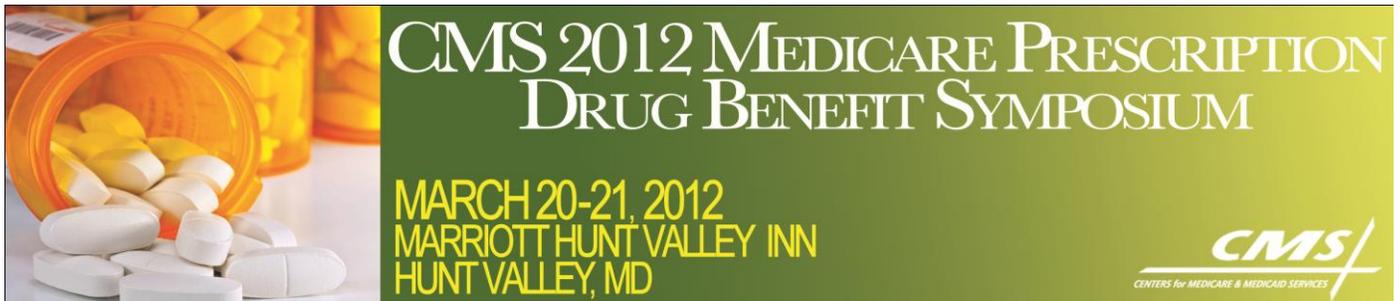
And so what we find then is that for our pre-ICL basket of out-of-pocket measures, we have that on average for a month of filled pre-ICL it is about \$15.00 per month, on average using our standardized baskets. And looking at the distribution, that most of the plans fall within a range of about \$12.35 up to about \$19.00. Most frequently the plans do.

The geographical distribution then of this is essentially that we find that like within the southeast corner, as well as in the north central, that those tend to have the most generous benefit baskets for the pre-ICL, and that the coastal region and northeast England have the least generous in terms of looking at just that pre-ICL basket.

So now that we constructed the pre-ICL basket, we then repeat that to construct a gap phase out-of-pocket basket as well. This is somewhat simpler from the standpoint that plans without any gap coverage, we simply have to assign the total cost of that active ingredient as the monthly out-of-pocket gap basket for that amount as well. But then we follow a similar process of reconstructing that basket for the gap phase. And what we find looking at on average for one month gap out-of-pocket for statin basket, that that averages around \$41.00, but that greatly varies between whether they have any gap coverage or not in that part.

And so then the final step that we take in constructing the generosity measure is we then look and see, we want to have the standard market basket of statin drugs was constructed using individual weights for the expected time spent in each benefit phase in terms of how long we expect the person to be in the pre-ICL phase as well as what they're expecting the amount is in the gap phase as well. Then on average the PDP statin user spent approximately nine-and-a-half months in the pre-ICL phase and one-and-a-half months in the gap phase. And then you can roughly assume the other month is pretty much in that deductible phase for some of them. And so our plan generosity measure is then equal to a weighted annual out-of-pocket expenses for the pre-ICL and gap phases combined based on those weighted expected times in each phase for the beneficiary.

Thus we find that on average the annual out-of-pocket for statin basket using the pre-ICL and gap combined averaged about \$200.00 for the beneficiaries in our analytical cohort. And that this then ranged between whether the person was in a plan with gap coverage or not gap coverage. And then we also looked in terms of like looking at low medication use or high medication use. High medication use



\INAUDIBLE\ are the ones that are expected to hit the gap phase. So the high range then is those that were expected to hit the gap, on average had a market basket of around \$274.00 for the year.

We also then had other variables that we coded from the administrative data to look at age, race and sex. We included socioeconomic measures that we merged in by zip code and then had fixed effects for the regional variables as well.

The risk adjuster that we used was from their drug utilizations with the concurrent adjuster based on their – the Medi-Span therapeutic classes that we controlled for.

And the findings that I present here, I just pull out the odds ratios for those variables of interest that we're studying. On the first set is the overall general population model. And then there's subpopulation models that look at those beneficiaries that are high and low cardiovascular risk, and that's defined as beneficiaries that also – excuse me – beneficiaries with high cardiovascular risk have co-morbidities of diabetes and hypertension or a previous hospitalization in the previous year for cardiovascular-related condition. And low cardiovascular risks do not have those co-morbidities.

But what I'll concentrate on is just the overall findings, and so what we find is that the plan generosity measure that we constructed does have a significant effect and results that plans that are less generous are – have poorer adherence rates. Or plans that are more generous have better adherence rates from beneficiaries. The relative magnitude of that finding is relatively small from the standpoint that like it's expected that essentially a plan would not have moved the adherence rate by expected eight percent based on moving the basket by hundred dollar equivalents, which is a large variance. But when you look at it by the subpopulation analyses, we find kind of very similar effects on those parts.

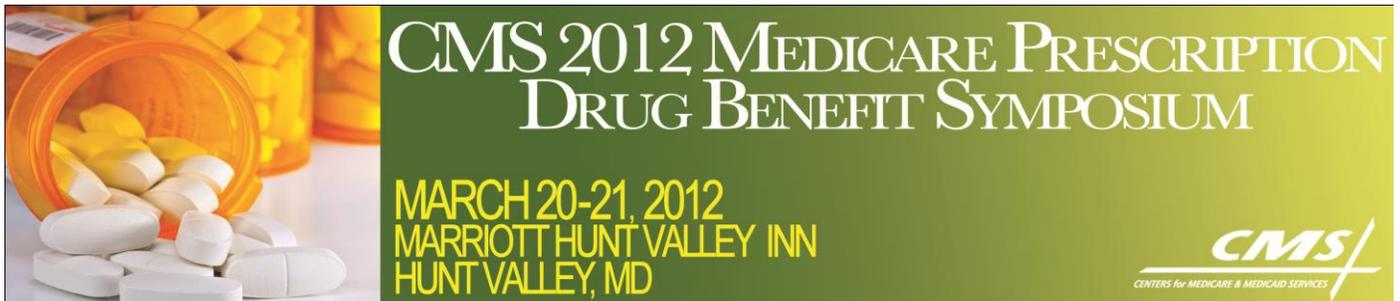
And so the high medication, low medication use are those that are expected to hit the gap versus those that are not expected to hit the gap. What we find is that those with low medication use, there's no significant effect from the plan generosity measure on that part.

So the next part of our research then that we looked at was we examined cardiovascular hospitalizations, or the risk of cardiovascular hospitalizations. So essentially we applied the same framework, but just changed the dependent variable on that part, so we're still using the \INAUDIBLE\ regression, but the dependent variable is now the risk of cardiovascular hospitalization. And the way that we define the cardiovascular hospitalization is that we looked at the MDC classification of the DRG for the hospitalization. And so we used it as an indicator variable for if they had any hospitalization due to cardiovascular conditions or not during that year.

So what we found is approximately with our analytical cohort, roughly 7.4% of them did have a cardiovascular hospitalization.

Geographically, the way that this kind of like spreads out, just looking at it descriptively, is that the western coast states, less likely to have a cardiovascular hospitalization. Northeastern, more likely to have hospitalization.

And our findings then support that plans that are more generous have a decreased risk of cardiovascular hospitalization. Plans that are less generous have an increased risk of cardiovascular hospitalization on that part.



And that essentially that what we would expect in overall models and that this is a statistically significant effect that we're finding.

So overall, it increases the likelihood of having a cardiovascular hospitalization by about ten percent controlling for all other independent variables that we have in the model.

And then we look at it, then also for subpopulations of high and low medication use, we found a significant finding for those that are likely to hit the gap and no significant findings for those that are not expected to.

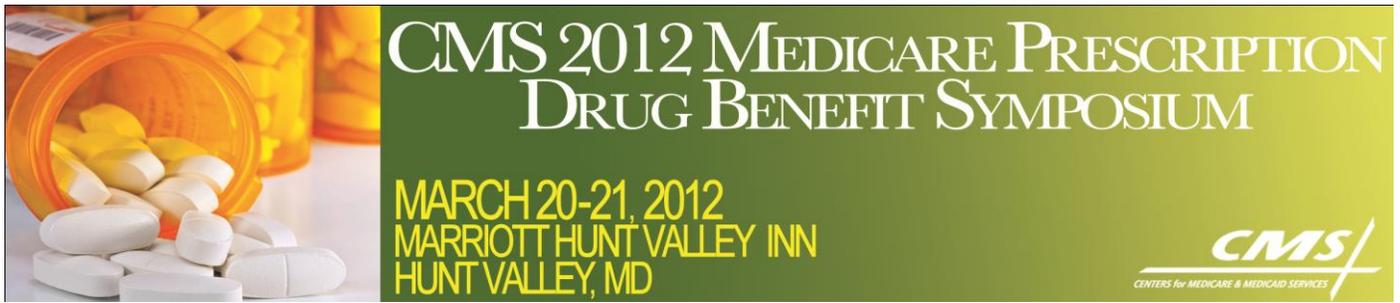
So then what we did then is like now that we knew what our model findings were based on the 06 through – the 07 and 08 cohorts, we then used our model findings to examine what we expect for the implications in the current policy environments with the Affordable Care Act. Specifically we wanted to model what are we expecting to see for effects if using the discounted brand and generic drugs that are available with ACA current policy environment. So in 2012, the beneficiary out-of-pocket in the coverage gap phase is roughly they're responsible for 50% of the brand name drug purchases or 86% of the generic purchases. And so we used that information to estimate what we expect for the annual out-of-pocket costs that would be for a representative basket of statins using these discounted rates. And then we focused on those high medications \INAUDIBLE\. Those that would be most affected because they're expected to hit that gap phase.

And our findings show that the adjusted rates of adherence increased from expected 70.6% to 73%, and the adjusted risk for cardiovascular hospitalizations decreased from 8.9% to 8.2%. And so they do have a considerable benefi – beneficial effect for the Medicare population.

So in conclusion, what we find is that less generous plan benefits for coinsurance and copayments are associated with lower statin adherence rates, and that overall the plan deductible did not have a statistically significant effect on statin adherence. And then we find that less generous plan benefits are associated with increases in the likelihood of a cardiovascular hospitalizations, and again that the plan deductible does not have a significant effect.

Future researchers where the project's going is essentially will look at those other therapeutic classes that we defined in the project outline, and the copart that we're looking at for the diabetes cohort, that's going to be presented at the upcoming Ash Conference in Minneapolis in June if any of you are going to be attending that as well. And then we're going to follow that up by looking at that final cohort of gastrointestinal agents. In my dissertation research I'm specifically looking at the \INAUDIBLE\ subsidy program and the regional variation for those same three clinical cohorts on those results. And then finally we'll also then begin looking at just drug adherence in general, comparing the PDP and the MAPD populations for those three clinical cohorts as well.

So now it's time for the assessment questions. Please get out your ARS response cards and we would like to encourage all of you to participate. As a reminder, if you're seeking CP credit, you must respond to all assessment and evaluation questions. After the questions and responses are read, you will have ten seconds to respond and you will see a timer on the screen. And then I guess I'm supposed to also note to make sure that you have entered in that you have channel 41 on your ASR responder, and that that will start.



So the first assessment question that we have is which of the following variables are not used in the construction of the market basket measuring Part D plan generosity. Number one, drug tier identifier. Two, the beneficiary out-of-pocket amount. Three, the beneficiary date of birth. And four, the drug tier type. That is generic brand or preferred brand. Please vote now. You have ten seconds.

So the correct response was the beneficiary date of birth. It doesn't – is it going to put up the percent that were correct? Okay.

So the second assessment question that we have then, are the study findings suggest that less generous Part D plan benefits, that is higher out-of-pocket expenses, are associated with the following effects of statin adherence levels and the risk of cardiovascular hospitalizations. One, lower adherence levels and increased risk of hospitalization. Two, higher adherence levels and no statistically significant effect on hospitalization. Three, no statistically significant effect on adherence and decreased risk of hospitalization. And four, no statistically significant effect on either. Please vote now. You have ten seconds.

The poll is now closed. Let's look at the results. So, of course, number one is the correct response. I think compared to some of the questions at the end of sessions, these were probably a little bit too easy, but it's almost the end of the symposium.