

## Impact of Part D Coverage Gap on Adherence to Diabetes Medications

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Good morning. Welcome to my presentation. So today I'm going to talk about the impact of coverage gap reforms on adherence to diabetes medications. As you may know, in 2009 Congress has passed Affordable Care Act, ACA, so one of the key clauses in ACA is to gradually shrink the coverage gap. So today the topic we're going to study how the reform in 2011 might influence the adherence to diabetes medication.

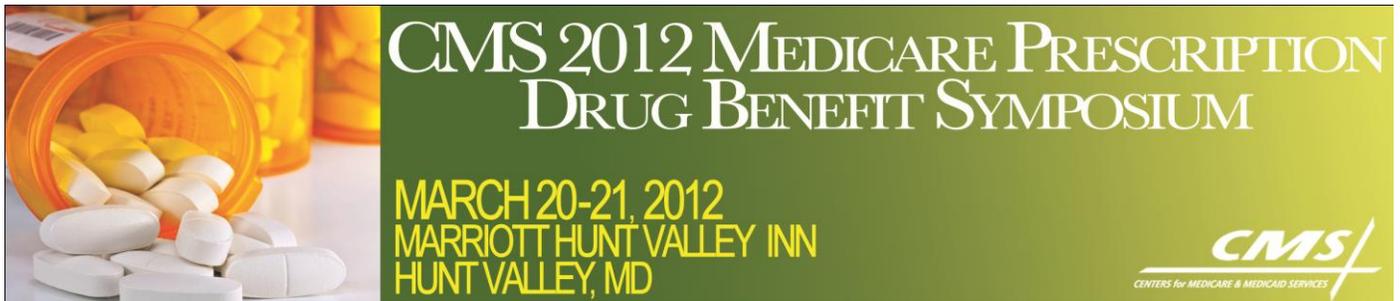
Okay, disclosure statement. Okay. We have two learning objectives here. So after this presentation you should be able to identify Part D coverage gap reform stipulated in ACA, and also you should be able to understand the impacts of coverage gap on adherence to diabetes medications.

So let's start by talking about coverage gap. So coverage gap, commonly referred to as "doughnut hole," is a unique feature in the Part D benefit design. So it's a difference between the initial coverage limit and the catastrophic coverage limit. And the coverage gap beneficiaries would have to pay 100% copay. So here's the graphic illustration of the doughnut hole in 2010. So we have a 310 deductible, and after that beneficiary needs to pay 25% of copay for their medications. And after total pharmacy spending reached 2,830, the patient would enter the doughnut hole, or the coverage gap, in which patients would need to pay 100% copay. And when the total pharmacy spending reached 6,440 a patient will reach catastrophic limit, and after that patient would need to just pay \$2.5 for each prescription. Okay.

So Part D coverage gap is a unique benefit design, and it was designed this way because the Congress wanted to encourage patients to save more money, to economize the pharmacy spending, and in a way I think it has achieved its objectives. The actual Part D spending in the first few years are actually much lower than the projected spending, which is pretty remarkable for a government program. However, at the same time, the center rise in the copayment in the coverage gap was raised a lot of concern. And there are already a couple of researches done on this issue. People concerned about the rise in copayment might have a negative impact on patients' outcomes.

So here are some of those researches. And we can see that the increased copayment in coverage gap might decrease drug spending and lower the adherence to diabetes medications, and also lower adherence to other chronic illness such as diabetes, hypertension, and dislipidemia, and also the rise in copayment; also, delayed cardio vascular medications.

So in response to all those concerns about rise of copayment in the doughnut hole, in 2009, the Congress has passed ACA and to mandate coverage gap reform. So starting from 2011, patients would receive a discount of 50% for brand medications when they reach the doughnut hole. At the same time, they also will receive a 7% discount for generic medication in the doughnut hole. And the discount for brand medication and generic medication will also apply to patients who have full coverage in the coverage gap.



So suppose a patient have full coverage in the coverage gap with a \$20 copayment for brand medication, in 2011, when these patients reach the doughnut hole this copayment would be \$12.5 instead of \$25 because of the 50% discount.

Okay. All right. So the 2011 reform will be just a down payment for the future reform, and, as time goes by, the coverage will continue to improve. So right now we are here. So in 2012 the brand name coverage drug is 50%. In 2013, the copayment will be decrease to 47.5 and will continue to decrease until it reaches 25% in 2020. And the generic copayment will continue to decrease at a rate of about seven percentage points each year until it reaches 25% in 2020. So in 2020, that will be the time when the doughnut hole is completely – doughnut hole is completely gone.

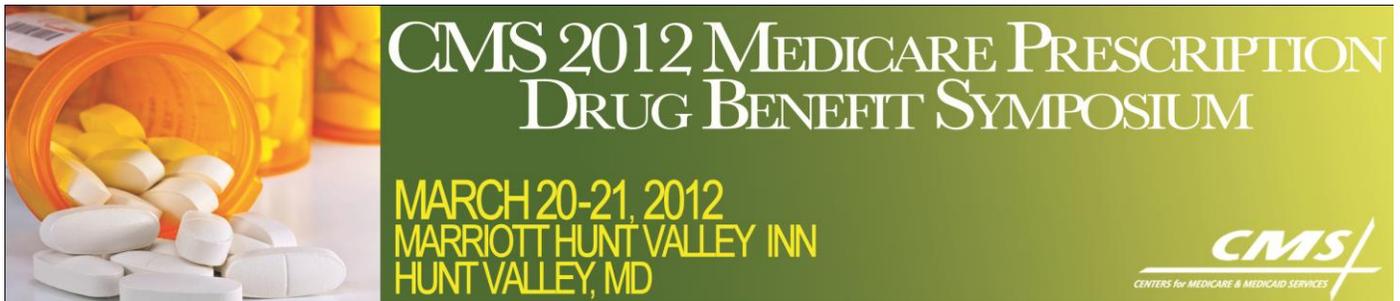
So the research question here is what is the impact of coverage gap reform on adherence to diabetes medications? So why do we focus on diabetes? Because diabetes is a highly prevalent disease within Medicare population, so as we can see, the blue line here is the Medicare population, age 65 to 74, and the yellow line here is 65 and above. So here is the projection of diabetes prevalence rate within the US population. So I just picked the two Medicare populations for your reference. So we're here about 2020. So, as you can see, the diabetes prevalence rate is about 20%. So in the next 40 years the prevalence rate, I expect, will increase steadily until it reaches over 30% in 2050. So this is very high prevalence rate. Obviously, we all like Medicare to be there when we want it, so successful management of diabetes is critical to the long-term health of Medicare.

Okay. So outcome variable would be an adherence to diabetes medication, and, as we all know, adherence is critical because poor adherence is a major contributor of poor glycemic control, and extensive research has shown that poor adherence to diabetes medication can increase morbidity or adverse events such as in-patient hospitalization and mortality, et cetera.

So the research method, we're going to use the pharmacy claim data from MedImpact. So MedImpact is a large national PBM with clients across the country. And we'll build two data cohorts to identify the impact of coverage gap reform. So one cohort would be the 2010 cohort. That would be the last year before the ACA reform. And the second cohort would be the 2011 cohort. That will be the first year after the ACA reform. So the idea is that we just make some comparison of patients' behavior for those two cohorts to see what kind of impact the ACA reform might have on patient's adherence. Okay.

So here we'll take a look at the coverage gap limit in the two years. So as you can see, those two years are pretty much comparable, and because CMS is supposed to adjust the coverage gap limit every year based on inflation, so between 2010 and 2011 there's little inflation going on, and, as a consequence, the adjustment is minimal. So, as you can see, the deductible, 310 in 2010, 310 in 2011. So the initial coverage limit, the limit that patients should go to doughnut hole, is only about a ten-dollar difference. The catastrophic limit is about \$7.5 difference.

Okay. So here's the data inclusion and exclusion criteria. So we focus on typical Medicare population would require them to be age 65 and older, and we also require them to continuously enroll in the Part D plan for two years, so one year prior to the cohort year in the cohort year. So you might wonder why we require patients to also have continuously enrolled in the one year prior to the cohort year; that's for two



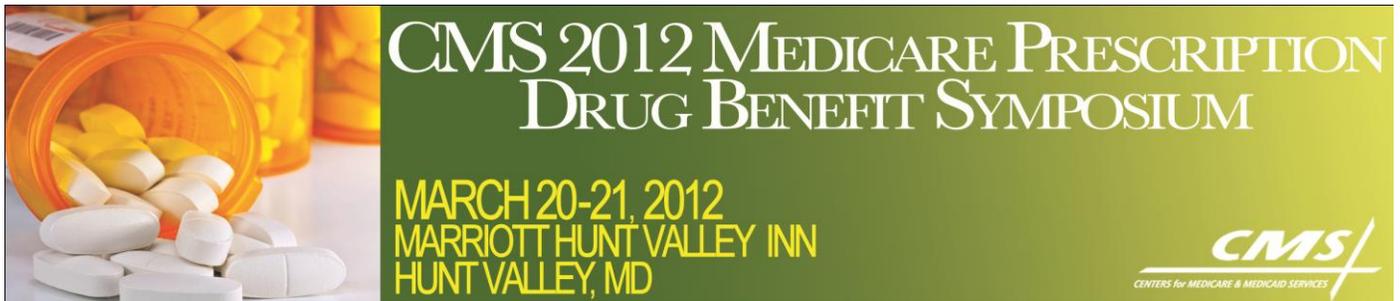
reasons. So one reason is that we want to make sure that those patients start using diabetes medication before their cohort year. So the second reason is that we need to get a comorbidity data to do comorbidity adjustment based on the one-year utilization prior to the cohort year. And so the third criteria is that they are not eligible for (INAUDIBLE), that's for obvious reasons because the patient have copayment structure that's very different from other patients. And we also require them to have two diabetes medication claims in both years so that we could have a full year to measure their adherence in diabetes medications.

And here the diabetes medicine, we include both insulin and oral medication, which is different from the CMS star rating, which is limited to oral medications only. So we try to be more inclusive in this research in the definition of diabetes medication, and that's also (INAUDIBLE) of our old study. So, but just as to check that – to show that our method is not that different from the CMS star rating, we also do a robust check by removing patients with insulin use history from the sample, and from this step we identify about 20,000 patients in the 2010 cohort and the 2011 cohort, so both cohorts are about 20,000 patients.

Okay. So within each cohort, within the 20,000 patients we identify, we are focused on a patient who reached the doughnut hole but not catastrophic. It's mainly for the convenience of research. The nice thing about all those patients who reach the doughnut hole, not the catastrophic limits, that we have two observations; so one observed prior to the doughnut hole, one observed after the doughnut hole so that we can compare their adherence before and after. So for those patients who – about 59% of those patients who did not reach the doughnut hole, we only observe what they did before the coverage gap. We don't have their observations after the coverage gap. So for the 11% who reach catastrophic, they have three observations we need to identify, so which made the modeling more difficult. So for the convenience of research we only focused on the 30% of patients who reached doughnut hole but not catastrophic limits. So, in the end, we identified about 6,800 patients for the 2010 cohort, and 6,100 observations in the 2011 cohort.

So the outcome variable is adherence to the diabetes medication. Adherence in this research is measured by PDC per person that is covered. So they speculate based on (INAUDIBLE) and the data supply, and for overlapping – (INAUDIBLE) overlapping, we'll remove the second claim so that the (INAUDIBLE) will connect with the first (INAUDIBLE). And adherence is defined as being greater or equal than 80%, which is consistent with the CMS star rating. Okay.

So for each cohort we'll divide a patient by their type of coverage in the coverage gap. So the first type of coverage is the no coverage. Those patients have zero coverage in the doughnut hole. They need to pay 100% out of who pay when they reach the doughnut hole. Patients in this group come from Defined Standard Benefit, DSB, and basic alternative, BA, and actually (INAUDIBLE) Enhanced Alternative, EA. And the second group would be those patients who have partial coverage, those patients who have coverage for generic drugs but not brand name drugs in the coverage gap. So those patients essentially come from EA, which they are paying a higher premium for better coverage. So the last group are the patients who have full coverage. So they have full coverage for both generic and brand name drug medications in the coverage gap, and those patients also come from EA, Enhanced Alternatives. Okay.



So here's some modern detail, if you're interested. So, essentially, the research method is a difference in different methods. So we are essentially comparing the difference of adherence before and after the coverage gap in comparison with patients who have full coverage for their adherence before and after the coverage gap. So why here is the outcome variable, and equal the (INAUDIBLE) the control variable, series control variable, and then we'll have a series fixed effect, doughnut hole fixed effect, and a generic and a no coverage fixed effect, the generic coverage fixed effect in the year 2011 (INAUDIBLE) coverage effect.

And the beta five here will indicate the impact of coverage gap on patients who have no coverage at all in the coverage gap. And the beta six is the interaction of the doughnut hole, and the generic coverage indicates the impact of coverage gap on patients who have generic coverage only. So the beta seven is the interaction of the doughnut hole in the year 2011. It's the impact of doughnut hole coverage reform in 2011 on patients who have full coverage. So the next one, beta eight, is the interaction of doughnut holes, no coverage, in year 2011; these will indicate an impact of coverage gap reform on patients who have no coverage in 2011. And the next one is the interaction of doughnut hole, generic coverage, and year 2011 will indicate an impact of coverage gap reform on patients who have generic coverage only in 2011.

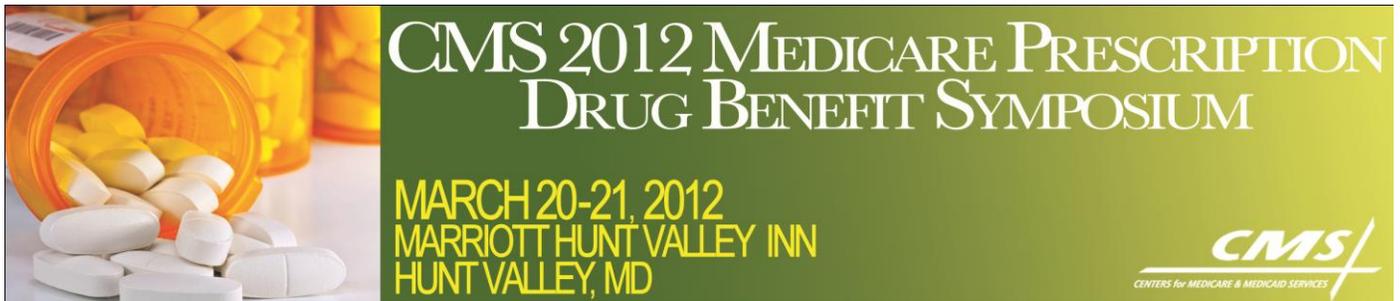
Okay. So the x (beta) control variable include a series variable like age, gender, and history of incident use in the previous year, and geographic locations, and also comorbidity index measured by (INAUDIBLE) risk based on the drug use in the previous year. Okay.

So I think we are done with the methods, so here are the descriptive statistics; right. So of the amount of populations, male and female are roughly evenly split, so the male ratio in our sample is higher than the national one, I believe. The national one is about 46, 47, something like that. Okay. So here's age, so patients who under age 65 to 70 account for about 25%, and 71 to 75 account for 27%. So these two groups account for about half of the patients. So the next group accounts for 22%.

And here's geographic location, so based on our client distribution, and the largest group in patients in the Midwest account for 52%, and patients in the West, which include Pacific and Mountain, account for, like, 40%, and East accounts for 7%. Okay. So patients in this sample have a lot of comorbidity, obviously, especially diabetes-related comorbidities, so about – okay. So more than 85% of patients in our sample have either hypertension or dyslipidemia, so the comorbidity rate is pretty high.

So here's the distribution by the type of coverage in the doughnut hole. So in the year 2010, as you can see here, the large group actually are the patients with full coverage, 62%. And the patients with no coverage at all is the second group, and the patient with generic coverage only account for 15%. So in the 2011, after the coverage gap reform, as you can see, the patients with full coverage, the percentage actually decreased to 55%. And the patient with no coverage at all increased to 32%. And patients with generic coverage only decreased slightly, 2%, to 13% in 2011. Okay.

So now we look at the patients' characteristics across different groups, as you can see. So the objective looking at it is to see whether there is any pattern. So, as you can see, from the table, patients' age and history of insulin use, and the percentage female pretty comparable. The only big difference is in the



insulin use in the previous year. So the last group we have 39%, the other two groups about 50%, so we need to do a robust new check for that.

So here's the impact of coverage gap on generic drugs in 2010. As you can see, for the group with no doughnut hole coverage, before the coverage gap the copayment is about \$6 for generic drug, that increased to \$10 in the coverage gap, that's in 2010. The other two groups with generic coverage only and full coverage, essentially no improvements.

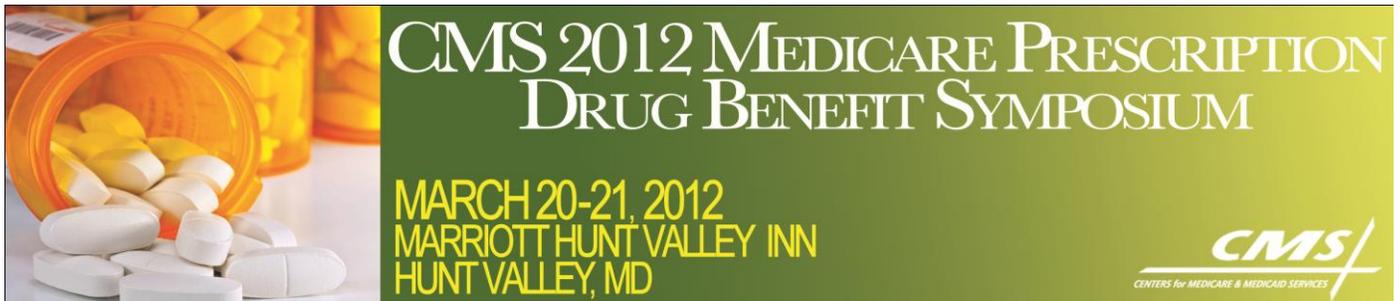
So now let's look at – bring the 2011 data in to see what kind of thing – how the coverage gap might influence the copayment for generic drugs. So as you can see, in the 2011, after, for the first group, no coverage. After they reached doughnut hole the copay still jumped from 5.9 to 8.9. However, the magnitude increase is smaller here. In 2010 it's from ten, and in 2011 it's about nine. For the other two groups, essentially, no influence. So, remember, those patients in those groups all received a 7% discount, but perhaps because the discount is too small it cannot show in this graph.

So here's the copayment for brand medications. As you can see, in 2010, that's the copayment before the coverage gap, which is pretty low, about 30 for both generic no coverage group and generic coverage only. And after they reached the doughnut hole it jumped to about 150 for both groups. For this group, full coverage, no change.

And now let's bring in 2011 data. You can see that the 50% discount instituted in 2011 have big impact. So as we can see, in the copayment for brand medication decreased from about 150 to about 90-something for the no-coverage group in 2011. For the patients with generic coverage only it decreased from 166 to about \$70, so big decrease. Even for the patients with full coverage, they also experienced substantial decrease from 50 before the coverage gap to 33, so mainly because of discount.

So here's the adherence data. And as you can see, again, the blue bar adherence before coverage gap, and yellow adherence after doughnut hole. And as you can see, it decreased by about 40 percentage points after the patient reached the doughnut hole. And for patients with generic coverage only, it reached, like, 11 percentage points. For patients with generic and brand coverage, in 2010, essentially no change. Okay.

So now let's look at patients in 2011. In 2011, as you can see, adherence decreased much smaller, decreased by about six percentage points. And for the no-coverage group, for the generic coverage group it decreased by four percentage points. For the patients with generic and brand coverage, essentially no change. Okay. Now we look at (INAUDIBLE) results. So the first two variables would be impact of doughnut hole on patients with no coverage and patients with full coverage. The default group are patients with full coverage. So (INAUDIBLE) ratio (INAUDIBLE) of being adherent in comparison with patients in the default group which is with full coverage. So both X ratio is smaller than one, so it indicates that in comparison with patients with full coverage, those patients with no coverage and patients with generic coverage only are less likely to be adherence to diabetes medications, and both coefficients are significant. And we also did statistics of those coefficients, whether they are significantly different, and they are not, so indicates that providing generic coverage only might not be substantial difference for patients with diabetes in terms of adherence.



So here's the main outcome of the research. So here's the first one, coverage gap reform in 2011. So this indicates the impact of coverage gap reform in 2011 on patients with full coverage is 1.01, and it's not significant. So in the case that copay reduction for patients with full coverage has no impact for patients with full coverage, despite a 50% discount. And the other two coefficients, 1.3 and 1.24, 1.3 is for patients with no coverage, and 1.24 is patients with generic coverage only. So those coefficients are both highly significant and they are bigger than one, 1.3 and 1.24, so indicates that after 2011 reform patients in these two groups are significantly more likely to adherence to diabetes medication.

So we also do a robustness check based on – by removing patients who – by removing patients who have history of using insulin. So we see the five key coefficients here. So they're essentially similar to what we presented in the previous two slides. Essentially, patients have – doughnut hole have a significant impact on patients with diabetes when they reach the doughnut hole, and the 2011 reform has a significant impact on patient's adherence. Okay.

So I know a lot of practitioners here would like to know what kind of impact on the full year of adherence because I just presented the adherence before and after doughnut hole, and so here's the full year data for our specific example. So the blue bar is 2010 data, and the yellow bar is 2011 data. So for patients with no coverage the 2011 reform improved their adherence by four percentage points. And for those patients with generic coverage only, it increased by about two percentage points. For patients with the generic and brand coverage, essentially no change. So for these patients, even if you have four percentage points pretty big enough to sway the star rating, so for these patients, even if you do nothing, and those patients are going to benefit from the doughnut hole reform and have improved adherence in the doughnut hole. Okay.

So here's the conclusion. So the coverage gap has a negative impact on adherence to diabetes medication (INAUDIBLE), and availability of brand name medication is important, and the coverage gap reform in 2011 decreased copayments for patients with diabetes dramatically, and coverage gap reform improved adherence to diabetes medication for patients with no coverage and generic coverage only substantially.

(INAUDIBLE) assessment questions (INAUDIBLE). Next slide.

So the question is what's the percentage of discount for brand name medications in the coverage gap in 2011? C is the right answer. So in the percent research, which group of patients have improved adherence to diabetes medication in the coverage gap in 2011? Is it A, both patients with no coverage and patients with generic coverage only; and B, patients with no coverage only; and C, patients with generic drug coverage only; and neither group? Okay. A is the right answer.