

Drug Adherence in the Coverage Gap ***Rebecca DeCastro, RPh., MHCA***

Good morning. The title of my presentation today is Prescription Drug Adherence in the Coverage Gap Discount Program.

Okay, to get started, first I'd like to thank Jonathan Smith, subject matter expert on Part D data and \INAUDIBLE\ programming in the Medicare payment group, and contractors Acumen Foo & Vitch (sp) for providing data for this analysis.

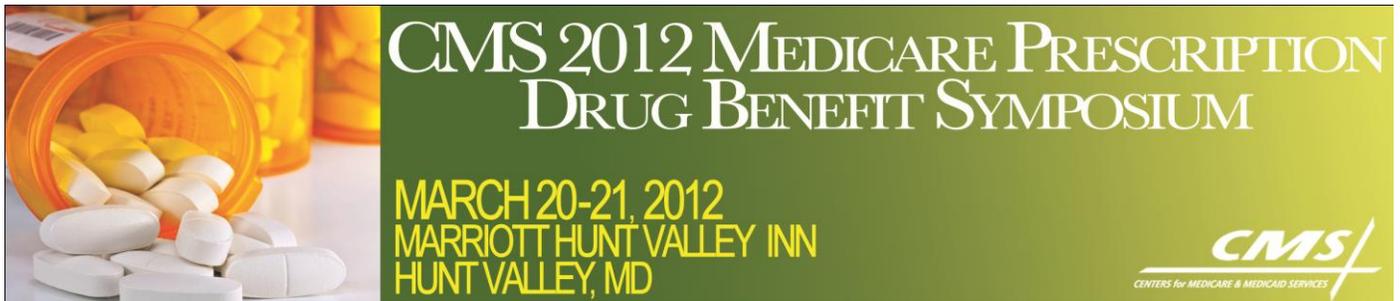
Calendar year 2011 marked a beginning of the Coverage Gap Discount Program. This gave – this program gave certain Medicare Part D beneficiaries in the coverage gap a 50% discount on brand drugs. Today to observe beneficiary drug utilization behavior along with the implementation of the Coverage Gap Discount Program, I'm going to compare prescription drug adherence rates within the initial coverage limit, coverage gap, and catastrophic benefit phases of years 2009 through 2011, along with highlighting some statistics of the Coverage Gap Discount Program. These highlights include reviewing the top ten therapeutic use classes and their Coverage Gap Discount dollar amounts and average Coverage Gap Discount amount per beneficiary.

We will also look at statistics of Medicare Part D populations adherent and not adherent to prescription drugs. We will divide these populations into four chronic disease cohorts, dementia, diabetes, hyperlipidemia and hypertension. And looking through results of a regression analysis, we will compare the likelihood of a beneficiary being adherent based on variables such as gender, race, enrollment in an MAPD versus a PDP, plans with supplemental coverage and beneficiaries with other health insurance coverage.

Furthermore, with the implementation of the Coverage Gap Discount Program in mind, we will observe generic prescription drug dispensing rates of each cohort in each Part D benefit phase.

Okay, with the main topic of this presentation being Prescription Drug Adherence in Part D Beneficiaries With Chronic Diseases, I'd like to first define adherence and chronic disease. Now the World Health Organization defines adherence as the extent to which a person's behavior taking medication and/or executing lifestyle changes corresponds with agreed recommendations from a healthcare provider. The World Health Organization further defines chronic diseases as diseases which have one or more of the following characteristics: permanently residual disability caused by non-reversible, pathological alteration, require special training of the patient for rehabilitation, or may be expected to require a long period of supervision, observation or care. Therefore it's no surprise that chronic diseases are very expensive. According to the CDC, diabetes, which is a leading cause of kidney failure, lower extremity amputations and blindness, cost more than \$116 billion in medical costs in 2007 in the United States. Additionally, the costs of cardiovascular disease was estimated to be around \$475 billion in 2009. Addition to this devastation, Healthy People 2020 reported that in 2008 almost one out of two adults in the United States has at least one chronic disease such as cardiovascular disease, arthritis, dementia, asthma, cancer or dementia.

Aside from the economic cost, chronic diseases are the leading cause of death and disability in the United States causing seven out of ten deaths each year. It's also estimated that one-quarter of persons



living with a chronic disease experience significant limitations in daily activities. Besides the fact that chronic diseases cost or account for about 75% of \$2 trillion spent on Medicare in 2009, chronic disease is responsible for high morbidity and high mortality rates too. Therefore managing chronic diseases is very important to patients, healthcare providers, medical insurance plans, and federal policy makers. In fact, this past fall, the Affordable Care Act created other initiatives such as the Community Transformation grants and the Comprehensive Primary Care initiative aimed at combating chronic diseases through better coordination of care and patient education and disease self-management. In fact, the AHRQ reported that prescription drugs are a main component of disease self-management. They further went on to say that prescription drugs will not promote better health outcomes or reduce costs unless the patients take the medications as prescribed. So to repeat, medication adherence is an integral part of patient self-management of chronic diseases. Further emphasizing the importance of adherence, analysis results published in a 2011 *Health Affairs Journal* article found that patients with chronic diseases that are adherent to prescription drugs have better health outcomes, have less emergency room visits – excuse me, I’m sorry. I think we got off. There. And use less inpatient hospital services and overall have lower total healthcare costs.

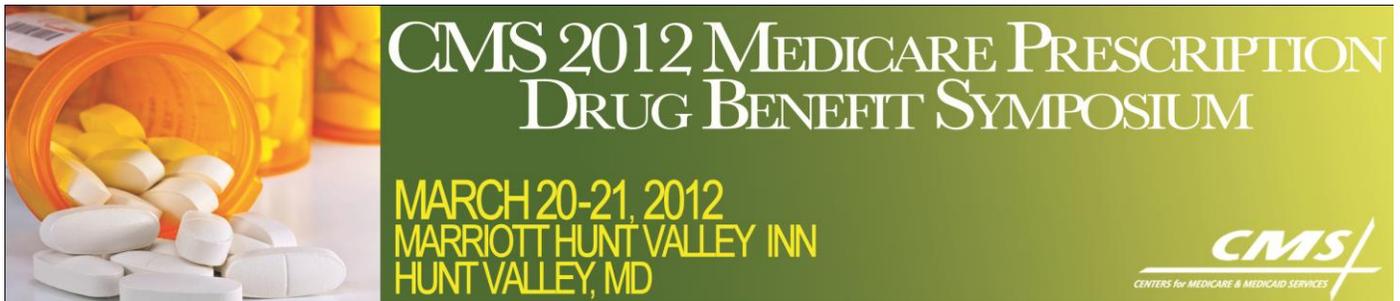
Let’s look back for a moment to a 2010 Medicare Part D symposium presentation about Medicare Part D costs related to non-adherence to prescriptions given by Dr. Iris Wei. In this presentation we learned that Medicare Part D beneficiaries who entered the coverage gap in 2006 were 34% more likely to experience cost-related non-adherence to prescription drugs compared to those who did not enter the gap. With over three million non-low income subsidy beneficiaries hitting the gap in 2010, this would mean that a little over one million beneficiaries experienced cost-related non-adherence to critical drug therapy. However, this all changed in 2011 when certain beneficiaries hitting the gap saw savings. To make Medicare Part D drug benefits more affordable, the Affordable Care Act has lowered drug costs for beneficiaries entering the gap and will gradually close the gap by 2020. The Act included a 50% discount on brand drugs and a 93% coinsurance on generic drugs in the coverage gap in 2011.

Okay, now we’d like to turn our attention to look at our research results. First we focused on beneficiaries taking prescription drugs to treat dementia, diabetes, hyperlipidemia and hypertension. The cohorts were limited to Part D enrollees within years 2009 through 2011. They were adherent to prescription drugs within the ICO. They were the non-low income subsidy population. Entered the gap prior to October 31st. Had at least two prescriptions for one drug category prior to entering the coverage gap and we excluded PACE plans and employer group waiver plan enrollees.

This slide describes the drug classes used to identify beneficiaries taking prescription drugs for the four chronic diseases in this analysis. Examples include acetylcholinesterase inhibitors for dementia, dipeptidyl peptidase-4 inhibitors for diabetes, statins for hyperlipidemia, and angiotensin II blockers for hypertension.

This slide just shows the sources used to extract data for this analysis. For time’s sake I won’t read all the sources.

This slide outlines how we identified the benefit phase for each prescription drug event. Instead of splitting up the day’s supply on PDEs that overlap benefit phases, we assigned all the day’s supply to the benefit phase where the fill originated. This method prevents the cost sharing and the ICL from impacting adherence in the gap. It also gives a more accurate measure of adherence in the gap by preventing any weight out-of-pocket costs in the gap may have on the catastrophic benefit phase.



For this analysis we used a metric developed and endorsed by the Pharmacy Quality Alliance, known as proportion of days covered to calculate adherence. For example, in the scenario on the slide, the beneficiary filled the same drug four times, three for a 90-day supply and one for a 60-day supply, with the first fill on January 1st. To calculate the proportion of days covered, we divide the total day supply, which is 330 in this case, by the total number of days in a measurement period, which ends up being 365 days. Times it by 100 and we get 90.4%. Now if the proportion of days covered is greater than or equal to the 80% Pharmacy Quality Alliance established threshold, the beneficiary is considered to be adherent. So in this example the beneficiary would be considered adherent.

This slide shows the initial cohorts for our analysis. After all the restrictions were applied, except for being adherent in the initial coverage limit. Note that some beneficiaries have overlapping chronic diseases but are only counted once. So we have roughly 1.8 to 2 million beneficiaries each year which we started our analysis.

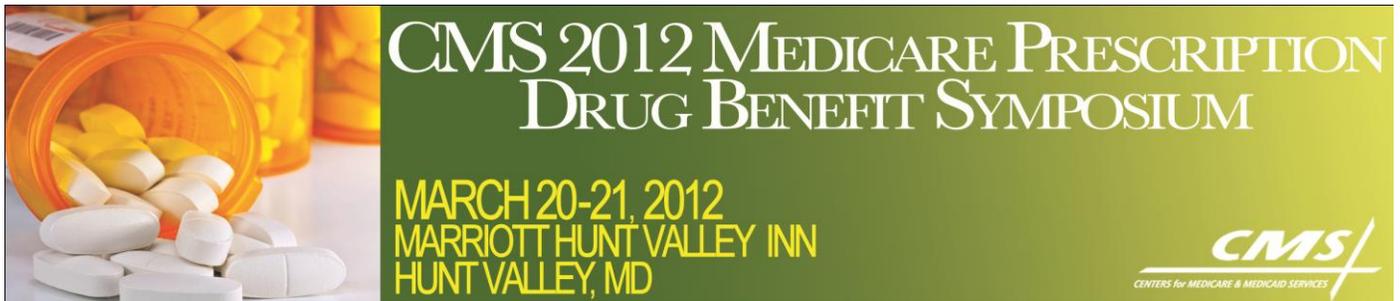
On this chart you can visualize the breakdown of the initial cohorts by chronic disease. 2009 in blue, 2010 in red, and 2011 in green, you can see that over the past three years the number of beneficiaries within each chronic disease category is roughly the same with most beneficiaries falling in the hyperlipidemia and hypertension categories and dementia representing the smaller cohort.

Of the initial cohorts on the previous slide, the above chart represents a percentage of beneficiaries adherent in the initial coverage limit. Here you can see that higher adherence rates are in the dementia chronic disease category. Take notice though, that the adherence rates in the initial coverage limit within each chronic disease category remained steady over the past three years.

So far we've seen that the cohort size for each chronic disease category through the years has relatively – excuse me – has relatively been the same. We've also seen that adherence rates to prescription drugs for each chronic disease category in initial coverage limit has also been pretty steady. It is on this chart that we start to see more dramatic increases in adherence rates. Unlike the initial coverage limit, adherence rates in the gaps are not steady over the past three years. From 2009 to 2010, the average increase in adherence rates for all four chronic disease cohorts combined is 6.7%. Even greater, we saw an average increase of 14% in adherence rates from 2010 to 2011. I'd like to point out here that the largest increase in adherence rates is with the dementia chronic disease category, which was 16.1% from 2010 to 2011. This is worth noting, especially with the first of the baby boomers turning 65 in 2011 along with the facts that the presence of dementia doubles every five years for adults age 65 and older. It's the sixth leading cause of death, and costs \$172 billion a year in healthcare. Therefore adherence to medication for dementia could never be more important.

The trend that we saw on the previous slide with adherence rates more than doubling in the gap from 2010 to 2011 continues in the catastrophic benefit phase. The average increase in adherence rates for chronic diseases from 2009 to 2010 is 5.7%. However we saw an average increase of almost 17% in adherence rates from 2010 to 2011 in the catastrophic phase. So it appears that the adherence behavior in the gap carried over to the catastrophic benefit phase.

We are now going to take a deeper look at some demographics and other plan variables that describe each chronic disease cohort that are adherent in the coverage gap. Specifically I'll just point out some outliers that are boxed in red.



Starting with gender, the dementia cohort had fewer males. The dementia cohort also had fewer beneficiaries less than 65 years of age. However the tables turned at ages 75 to 84, where there is a much higher percentage of beneficiaries in a dementia cohort. This would make sense as we just learned that the presence of dementia doubles every five years for adults age 65 and older.

The other outlier falls within the diabetes cohort. Looking at the variable the Medicare Advantage prescription drug plans, the diabetes cohort had a significantly larger proportion of beneficiaries enrolled in MAPDs.

We then did a regression analysis on the demographic and plan variables of beneficiaries adherent in the coverage gap and non-adherent in the coverage gap to predict adherence. With a 95% confidence interval, we plotted the odds ratios and corresponding upper and lower confidence limits. Note that the dotted vertical line is at one. An odds ratio of one implies that adherence is equally likely between the variable and its reference variable, such as male versus female. An odds ratio greater than one implies adherence is more likely to occur with that variable. An odds ratio less than one implies that adherence is less likely to occur with that variable. Also I'd like to point out that the range of the upper and lower confidence limits around each odds ratio was small, meaning that the estimates are reasonably precise. Please make a correction here. Change the variable age 75 to 84 on this and the next three slides to age over 84.

So, for example, beneficiaries with non-troop eligible other health insurance payers – payers that are taking prescription drugs for dementia are 1.6 times more likely to be adherent than beneficiaries taking prescription drugs for dementia without other health insurance payers. As a second example, beneficiaries under the age of 65 are .7 times as likely to be adherent as beneficiaries age 75 to 84. Lastly, with the focus on the Coverage Gap Discount Program, we see that beneficiaries are 3.3 times as likely to be adherent in 2011 in the coverage gap than in 2009.

For diabetes, for the non-troop eligible other health insurance payers, they are 1.5 more times likely to be adherent. And again, with the focus on the Coverage Gap Discount Program, beneficiaries are 2.4 times more likely to be adherent in 2011 in the coverage gap than in 2009.

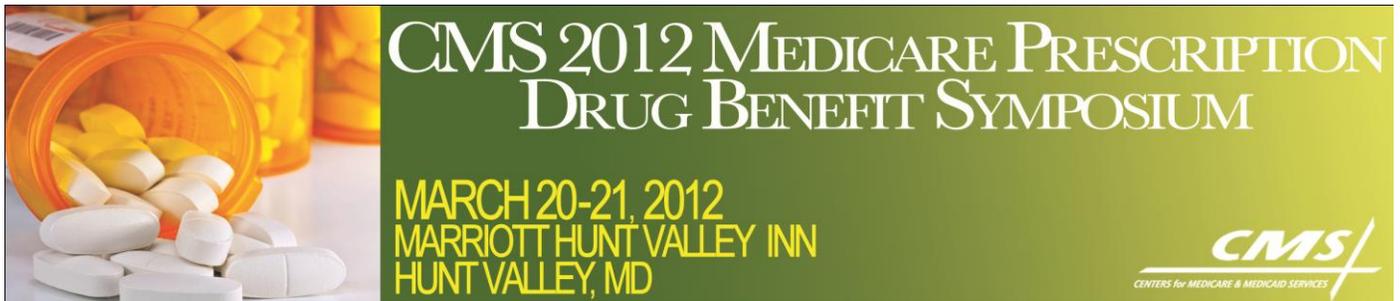
For the hyperlipidemia cohort, beneficiaries, again, with a non-troop eligible other health insurance payers are 1.4 times more likely to be adherent. And with the Coverage Gap Discount Program year 2011, we see that beneficiaries are 2.7 times as likely to be adherent than – in the coverage gap – than in 2009.

For the hypertension cohort, we see the same. The non-troop eligible other health insurance payers are 1.4 more times likely to be adherent. And in 2011 we see that beneficiaries are 2.9 times more likely to be adherent than in 2009 in the coverage gap.

So combining all the chronic disease cohorts, we saw one, the older you are, the more likely you are to be adherent. We also saw that the more financial help in paying for drugs in the coverage gap, the more likely you are to be adherent.

It's interesting that enrollment in a MAPD had a negative effect on adherence.

Summing up this analysis, adherence in the coverage gap increased over the past three years, with beneficiaries more likely to be adherent in 2011 compared to 2009 and 2010.



So far we've focused on the population that is here in the coverage gap. Now we're going to look at some statistics of the total population. Beneficiaries adherent in the initial coverage limit that are one, adherent in the coverage gap and two, non-adherent in the coverage gap. Just from this slide, you can see that in 2009 there was a 60/40 split in the percent adherent versus non-adherent in the coverage gap, and by 2011, this split went to 80/20.

Before we start on the next three slides, please correct the age variable age less than 64 to age less than 65. So on this and the next three slides.

Here we're going to examine adherence and non-adherence by several variables across the years. Most results were statistically significant. I boxed in the probabilities that were not statistically significant. For example, this dementia table shows that in 2011, males and beneficiaries age less than 65 make up a higher proportion of the non-adherent population than the adherent population.

For diabetes in 2011, we saw a higher proportion of males, non-white beneficiaries, beneficiaries enrolled in an MAPD, and beneficiaries with supplemental benefits are non-adherent.

For hyperlipidemia in 2011, a higher proportion of non-white beneficiaries, beneficiaries enrolled in MAPDs, and age less than 75 years of age were more likely to be non-adherent.

And finally, for hypertension, a higher proportion of males, non-white beneficiaries, beneficiaries enrolled in MAPDs, disabled beneficiaries, and beneficiaries with other types of coverage for supplemental benefits are non-adherent in 2011.

Now we are going to move on to our next objective, to contrast generic prescription drug dispensing rates on the next five slides of all cohorts combined in each chronic disease cohort within all three Medicare Part D benefit phases.

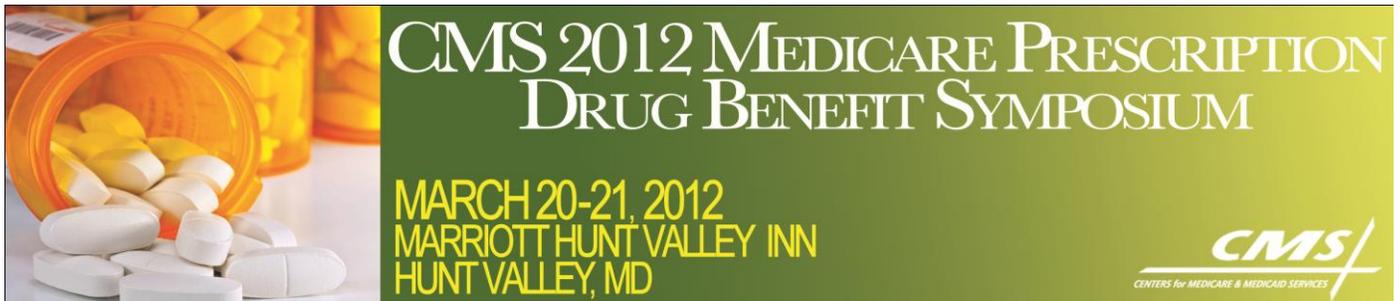
On this slide we see a trend where the generic dispensing rates have increased over the past three years within each benefit phase. We also see that generic dispensing rates each year increase from the ICL to the coverage gap and decrease from the coverage gap to the catastrophic benefit phase.

The next four slides just break down the generic dispensing rates for each chronic disease individually. Just like we saw on the previous slide, we see a spike in generic dispensing rates in the coverage gap and the lowest generic dispensing rates in the catastrophic benefit phase.

See the same trends again for diabetes. Same trends again for hyperlipidemia. And the same trends again for hypertension.

At the end of calendar year 2011, over 3.5 million beneficiaries received savings from the Coverage Gap Discount Program. This is represented by the blue column on the far right. Coverage gap discount dollars totaled over \$2.1 billion, represented by the red data line. The average Coverage Gap Discount amount saved by beneficiaries was \$603.75. Note as we move closer to the end of the year, the red line maintained a steady increase in slope corresponding with the increasing amount of beneficiaries entering the coverage gap and experiencing savings from the Coverage Gap Discount Program.

This slide is a picture of our Coverage Gap Discount Program Drug Therapeutic Use pie chart. This chart is updated monthly, and can be found at www.cms.gov/plan-payment. By the end of 200 – by the end of



December 31, 2011, drugs used in the treatment of diabetes had the largest Coverage Gap Discount amount totaling over \$300 million. Drugs used to treat hyperlipidemia had the second largest Coverage Gap Discount Amount totaling over \$263 million. Drugs used to treat hypertension and dementia were also in the top ten on this pie chart, each totaling over \$100 million in Coverage Gap discounts.

To conclude, we definitely saw a greater adherence rate in the coverage gap in 2011, the implementation year of the Coverage Gap Discount Program versus 2009 and 2010. We also saw this trend carry over to the catastrophic benefit phase with greater adherence rates, too. Thank you.

Now it's – it's time to conduct the assessment. Please get out your ARS cards. I hope all of you can participate. I tried to be really clear with the learning objectives. And as a reminder, just remember that if you're looking for the CPE credit, you need to respond to all the assessment and evaluation questions.

After I read the questions and responses, you'll have ten seconds to respond. You can see the timer. And then I'll let you know when the ten seconds is up.

Okay, the first question. The largest increases in the prescription drug adherence rate for all chronic diseases in the coverage gap occurs during which time span? Number one was it from 2009 to 2010 or number two, 2010 to 2011. Please vote now. You have ten seconds.

The poll is closed. Let's take a look at the results. Good. The – the message is driven home. Ninety-seven percent of you chose 2010 to 2011. That's correct.

Okay, and our second question, number two. Prescription drugs used in the treatment of dementia, diabetes, hyperlipidemia and hypertension are found on the 2011 Total Gap Discount Amount by Drug Therapeutic Use graph, pie chart. Which chronic disease has the largest Coverage Gap Discount amount totaling over \$300 million for 2011? Is it one, dementia, two, diabetes, three, hyperlipidemia, or four, hypertension? Please vote now. You have ten seconds.

Okay, the poll's closed. Let's take a look at the results. Okay. good. Message is driven home. That's right. The answer is diabetes. Although diabetes has the third largest adherence rate in the gap and the third largest cohort size, diabetes had the largest Coverage Gap Discount dollar amounts. This may be due to multiple drug therapy, more brand utilization, maybe less available generics. That's another study in itself there we'd have to look at.

Thank you.