

## Current Start of Part D: 2006-2012

*Cynthia Tudor, Ph.D.*

I'm very pleased to be here today. As John said, I'm Cynthia Tudor. I'm Director of the Medicare Drug Benefit and C&D Data Group at CMS. And we have a great program planned for you over the next couple of days with both CMS staff and external researchers who've done a lot of work on examining the program and sharing best practices.

I'm pleased to share my perspective on the program. When the program started, we had lots of cartoons out there; and my staff had a great time trying to find ones that sort of presented the cynical view of what Part D looked like. And here's a Wheel of Fortune slide where it looks like a 1-800 CSR is spinning the wheel to give advice on what program to join. But they keep coming – a great labyrinth of Part D in trying to figure out what's right with the program and what's wrong.

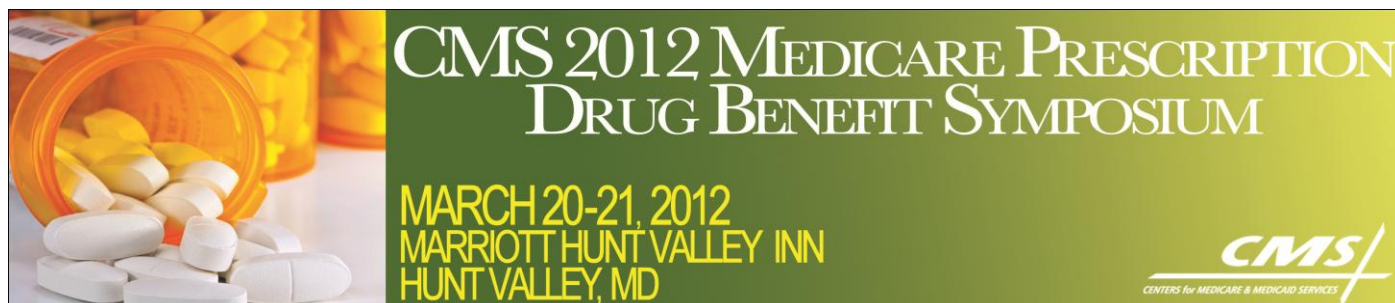
But now we have the strongest formulary review process I think in the United States. We've proactively worked to ensure that enrollees have plenty of Plans to choose from that are both simplified and differentiated. And we're rewarding quality and improving our plan finder tools so that beneficiaries have the information they need to choose the plans that are right for them, based on their quality first and cost second.

The learning objectives are here; I won't go over those. I'm going to talk about the program successes in terms of formulary review, medication therapy management, complaint tracking, Plan ratings and the Coverage Gap Discount Program, and then end with overall trends and future challenges.

On formulary review – CMS review of drug plan formularies is an unprecedented process. When we started this, we had to make up the kinds of edits we were looking for; and we tried to make them meaningful. And over time, we've been able to simplify these and to cover more areas. It's rigorous and ensures that Part D beneficiaries have appropriate access to drugs and avoid discrimination in those Plans. We not only ensure that the formularies meet the statutory requirements (two drugs per class and category), but they also include other formulary protections, such as the inclusion of long-term-care dosage forms, home infusion drugs and drugs to treat rare diseases. And to date, we've seen a number of commercial insurers have adopted CMS's review standards.

In 2006, over 500 formularies were submitted; and 387 ended up being associated with Part D plans. And since then, we've seen the number of formularies decrease each year until 2012, when they started increasing again.

Our formularies are robust with broad coverage of Part D drugs. The average number of distinct drug entities covered continues to increase; and by "distinct drugs," we mean distinct Rx norm ingredients. Today, on average, the formularies cover 988 distinct drugs and many, many more NDC codes. The percentage of Plans utilizing three- and four-tier formularies is decreasing, while the percentage using five tiers is increasing. The inclusion of specialty tiers on formularies remains fairly constant. The rate of PA and utilization management techniques has increased from about 12% in 2011 to over 14% in 2012. Step therapy requirements are unchanged. We encourage appropriate drug utilization management techniques including PA, step therapy and quantity limits. We review each to make sure that they are



appropriate. Initially, these techniques were limited; but we have continued to decrease the number of steps allowed, but encourage step therapy for the use of generics of the brand coverage.

Moving to MTM – we had very few requirements initially in Medication Therapy Management. The regulations provided a basic framework, and industry practice influenced the direction that CMS took. After an extensive analysis, the requirements were expanded in 2010 for increased consistency among the programs; and we pushed the industry forward. Significant changes were made to the targeting criteria, and CMS required a minimum level of MTM services that had to be offered to Part D beneficiaries who qualified. For the coming years, we expect increase standardization and industry consensus around what the best techniques are. We would like to expand access and be able to better target beneficiaries who most need MTM. And through expanded data collection, we would be better positioned to evaluate the impact of MTM at the beneficiary level.

We're showing enrollment trends here. Beneficiaries must meet three targeting criteria to be eligible for MTM. The drugs Plan sponsors have some discretion in defining those criteria for CMS requirements. The percent of Part D enrollees eligible for MTM who opted out of these programs has decreased over time to 13% in 2010. But the percent eligible has declined as well, driven by PDPs and we think primarily for budgetary reasons. We're conducting analyses on the eligibility practices and will not tolerate restrictive practices. And these data do not reflect Plans who are offering MTM to all of their Plan's enrollment.

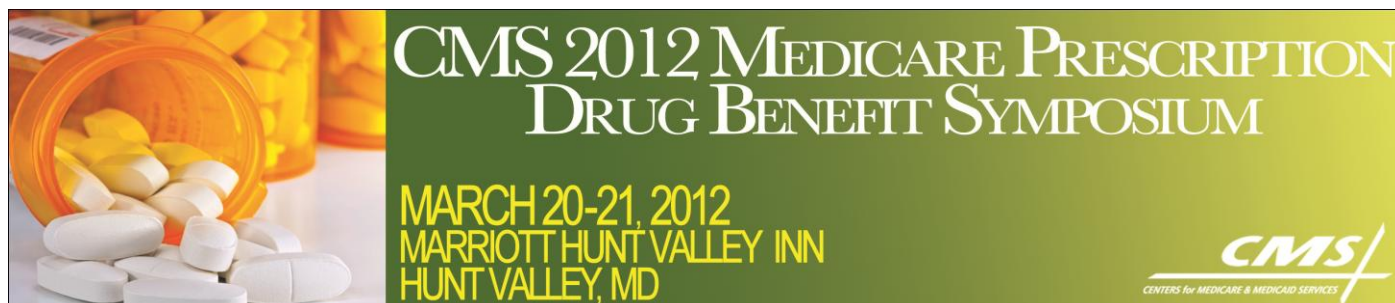
For the first time in 2010, Plans were required to offer an interactive, person-to-person comprehensive medication review to MTM enrollees. In 2010, over 8% received a CMR. We expect this percentage increase with improved beneficiary awareness of the value of MTM and considering CMS's proposed a CMR plan rating moving from offered CMR to actually being delivered a CMR.

On average, the beneficiaries enrolled in the MTM Program have a higher annual drug cost, more chronic conditions, and more drug fills than the general Part D population. While beneficiaries are targeted for enrollment based on cost and utilization criteria, these findings are still remarkable. If you look at the MTM eligibles and you look at the average number of fills, it's 83.2% per year – and that's about 12 per month – I'm sorry, it's about 8 per month.

Almost 82% of MTM-eligible individuals enter the coverage gap, and this includes low-income subsidy people who may not experience an actual gap in care; and almost one-third entered catastrophic. A higher percentage of these people are LIS.

Per the Affordable Care Act, we are required to develop a standardized format for the individual written summary delivered to beneficiaries after they get a comprehensive medication review. We developed the format with a lot of industry input and beneficiary input as well. The format will include a beneficiary information letter, a medication action plan and a personal medication list. The format is consistent with industry score elements, focuses on the beneficiary's needs and is a dynamic document. It will reinforce certain levels for the CMR; and Plans have to start using this no later than January 1, 2013.

CMS is focused on identifying potential opportunities to improve the awareness of MTM among beneficiaries, and we're expanding the language included in the Medicare and You handbook that will go out this fall and on the Medicare Plan Finder as well. We proposed a CMR rate for the Plan ratings which should increase the number of beneficiaries who receive CMRs. And we are evaluating the impact of



MTM to drive further improvements. We hope that Plans and beneficiaries – everyone – share in this commitment to educate beneficiaries and publish data on the value of MTM.

Moving to complaint tracking – the implementation of the Complaint Tracking Module was instrumental to Part D. For the first time, Medicare tracked beneficiary complaints and opened the industry to issues. The initial collection didn't include beneficiary identifiers, but we soon expanded that to a better address and track issues. We could more individually assess what was happening to each beneficiary. And then we expanded this effort to include MA plans.

The CTM is a centralized repository of complaints data that allows CMS to review and assess trends in complaints. Receiving beneficiary complaints often involves multiple, timely and accurate electronic data exchanges among federal agencies, private health plans, providers and pharmacies. In 2011, we expanded this access through a web-based complaint form.

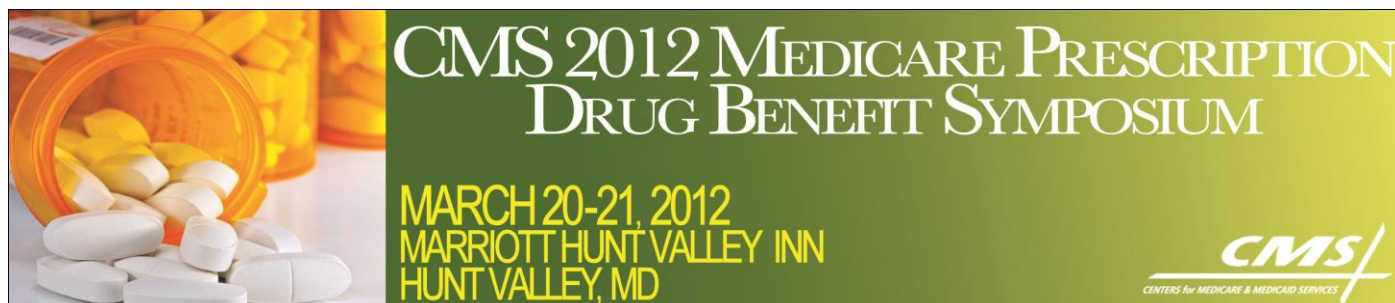
This graph shows you sort of the complicated logic that involves the knowledge exchange that has to happen with our CTM. We either have complaints coming in through the CMS online complaint form, through 1-800, through one of CMS's vibrant regional offices or through a Plan sponsor. And they go into the tracking module, and they are handled by either the CMS regional offices or the Part D Plans; and that leads to complaint resolution.

We encourage beneficiaries to contact their Plans directly when they have a problem. Many of those people have those complaints handled then, and they never enter CTM. But for those that do, we work towards resolution in a timely manner.

Why is CTM so important? Well, it provides an early warning of potential operational problems with a Plan. We monitor data, including calculating the complaint rates; the resolution times for each Plan sponsor; and the categories of complaints. The information helps us on both operational issues and compliance problems with Plans. We use these complaints data in our Plan ratings. And I'll show you a slide later that shows you the average number of complaints and how they've decreased over time.

And here we are. So if you look at this slide – you've got lots of lines on it – the top line is the 2006. It's the blue line. And you can see that we started in about May of the year. We still had a very high rate of complaints going on at that time. But you can see how they fell dramatically by the end of the year. The little line at the very bottom – I think -- it looks like it's a light blue – it's the 2012 line, and you can see that it actually is below every other line in there. So we're very thankful that the number of complaints continues to drop. I think Plans may pay a lot more attention to what's in CTM now than they used to, so we have a lot of cooperation in getting the complaints down.

Moving on to Plan ratings – the progress in the Star ratings is phenomenal. We created these ratings in 2006, as it was very clear that beneficiaries needed more information than just annual cost in order to choose the best plans. Process measures were the foundation of CMS's Plan ratings. We started this with things like Call Center hold times, 1-800 complaints, appeals, and Plan finder suppression – those process measures that we simply had around. Over the past couple of years, there have been significant changes in these Star ratings. With the calculation of a combined Part C and D overall rating, the continuing incorporation of National Quality Forum endorsed patient safety measures for Part D and the differential weighting of outcomes and beneficiary satisfaction measures. Changes are constantly made to ensure that we focus on quality improvement and, whenever possible, measuring clinical outcomes or beneficiary experiences. /INAUDIBLE/ simple attainment of CMS's administrative goals.



With our work to emphasize clinical quality measures and meet the Affordable Care Act's requirements for quality bonus payments, we're moving closer to measuring Plans on how they can improve the health outcomes of Medicare beneficiaries.

Next slide shows how stable this has been. And certainly, in terms of Part D, we've had very little change in how many measures we have had. We've had the retirement of measures, where Plans have reached a 95% consistency goal. We've kept our roots in what we measured though – be it complaints logged with 1-800 Medicare to the percent of breast cancer screenings for the betterment of Plans if they develop long-term quality improvement as well as for beneficiary's who monitor their current Plan's performance relative to others in the marketplace.

Plans have responded to public reporting. This is one of the most powerful slides I think you'll see. When we first measured the availability of TTY/TDD services in foreign language, we had only about half of Plans complying with our regulations. By year three that had improved by over 50%, to 78% for NAPDs and 76% for standalone PDPs. We've seen similar changes in beneficiary hold time. These numbers are number of seconds; so you can see that number of seconds for hold time has dropped from 62 in NAPDs to about 37. So you see a lot of progress. When we measure Plans on something, they improve.

The Coverage Gap Discount Program, as John mentioned, is one of our most recent success. The slide shows the standard benefit prior to 2011, and it clearly shows the coverage gap where the beneficiaries were responsible for 100% of the cost.

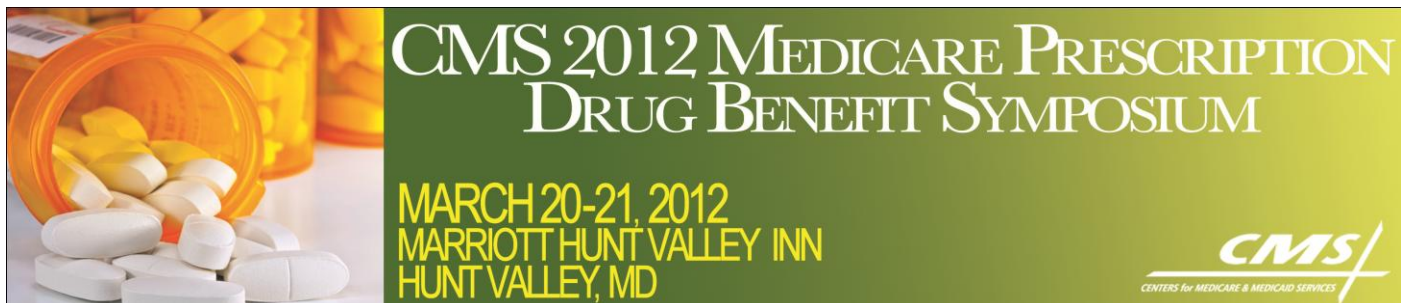
In 2011 and 2012, the standard benefit changes to having the beneficiary pay only about 50% of the cost of brand name drugs while in the coverage gap; and in 2012, the beneficiary pays about 86% of the cost of generics.

The approach to closing the coverage gap – these implemented in stages. In 2010, beneficiaries who entered the coverage gap received \$250 rebate checks. Over 3.78 million beneficiaries were issued a check, and to date over 95% have cashed their checks. The point-of-sale discounts were available as of January 1, 2011; and virtually no drugs were excluded from the Discount Program. And incrementally, the coverage gap will close between 2012 and 2020.

The beneficiaries' cost sharing will gradually decrease to 25% when in the coverage gap, and Medicare contributes more to the cost of brand new drugs, and will continue to do so until brand new drugs also have only 25% co-insurance. And that happens as soon as this begins in 2013.

In 2011, over 3.5 million people entered the gap and benefited from the Coverage Gap Discount Program. The average savings were about \$568 per beneficiary, and that's represented by the red line on this graph. Early in the year, the average discount is higher. Beneficiaries who enter the gap in the first quarter tend to be sicker. If they already have a total covered drug spend of \$2,930 that early in the year, they rapidly move through the coverage gap and hit catastrophic.

Most beneficiaries enter the gap later in the year, as you can see here. For the past three years, an average of 1% of the beneficiaries entered the gap in January, whereas an average of 12% enter the gap in December. We'll give you some more information later in this symposium about the gap.



This is a slide that is out on the web and is published every month and shows you what drugs are discounted by therapeutic class in 2011. The largest identifiable therapeutic class was blood-sugar-lowering drugs, hypoglycemics for diabetes (which is what those are, represented by the dark blue), followed clockwise around the pie graph by triglycerides and cholesterol-lowering drugs that are in the dark red.

Overall trends – I think they gave me this to do so that all these slides would be out there for people to use, and we wouldn't have to run them every time anybody asked. So I'm going to run through these pretty fast since it says I have a minute/twenty-five left. This slide is the average standard benefit adjustments and simply is a slide that just puts together all the benefit adjustments over time. Part D enrollments – I think this is an interesting slide. We've increased enrollment from about 24 million in 2006 to 31 and a half million today. That's about 60% of the Medicare population being enrolled in Part D. One-third of the enrollees receive the low-income subsidy.

This slide shows the number of Part D Plans. It's gone down every year. The blue bar is the Part D Plans that are part of Medicare Advantage, and the red bar is the standalone Part D Plans. We've struggled mightily to get these down to a number where beneficiaries can distinguish among Plans, can understand that an enhanced offering by a standalone PDP is significantly different from a defined standard or basic Plan.

Average PDP Plans by Region – beneficiaries will continue to have broad access to Part D Plan choices in 2012. The average number of standalone Part D Plans in each region is about 31 – 16 basic and 15 enhanced. And no region has less than 25 Plan offerings.

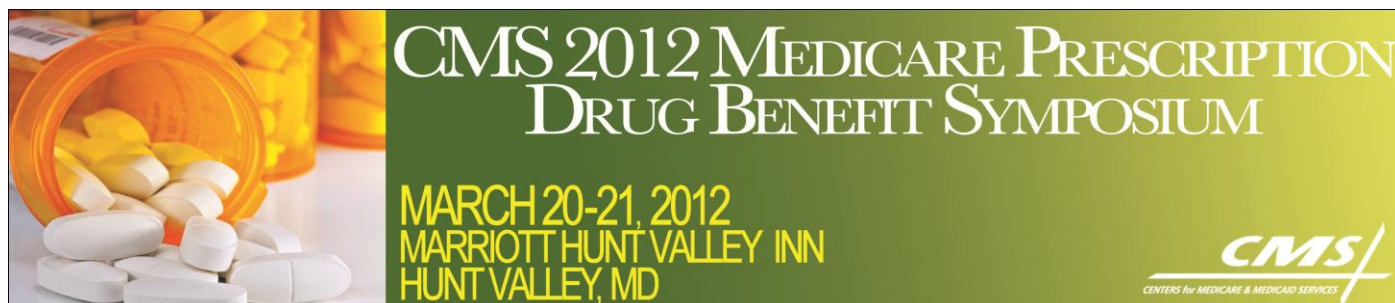
Part D trends and Part D Benefit Types – you can still see that we have a large number of Plans in both PDP and MA of different types. Enhanced alternative plans remain popular. Almost 54% of all enhanced alternative PDPs continue to offer additional gap coverage for 2012 that is beyond the generic coverage and the brand name coverage that is standard. Most of the decrease that we saw in 2011 was the result of Plan consolidation rather than actual decrease in a level of care.

It says I'm over now, so we'll just ignore it.

Beneficiaries filled about 3.3 prescriptions per month on average since 2007. It sounds low, but we get over 1.2 billion claims in total for the number of people enrolled in Part D. Average monthly total drug costs have increased each year, but the year-over-year difference is decreasing. In 2006, there were over \$51 billion on total drugs cost, and in 2010 about \$76 billion.

As far as total fills, there were over 800 million drug fills in 2006; in 2010, over a billion. Average monthly cost in utilization from 2006 to 2010 -- LIS beneficiaries and PDPs, where most of the LIS beneficiaries are enrolled, have on average a higher number of fills and total drugs cost per beneficiary per month. Again, this is the percentage of non-utilizing people in Part D. We were very surprised that 10% of the people enrolled in Part D in 2006 were non-utilizers. The number still is pretty high; it's 7.3%.

This is very difficult to see, but most of the utilizing beneficiaries are in their late 60s and 70s. Generic dispensing rate continues to go up. Changes in how generics are identified has also changed; therefore, the results in 2010 are difficult to compare to previous trends. A generic drug is defined as a drug for which an abbreviated new drug application (or ANDA) is approved by the FDA. The FDA data available to identify drugs at the NDC level are being approved under an ANDA is the NDC Directory. However,



prior to initiatives such as this, the FDC's NDC data repository was lacking many of the products existing in the marketplace and included incomplete or conflicting listing information. Therefore, these data couldn't be relied upon to evaluate generic dispensing. So we hope we're getting this right now; but we are using the NDC Directory, so some of these data points were not directly comparable.

This slide describes the top drugs and drug classes used by Part D enrollees, and we're basically including them for your reference. Again, we have cardiovascular drugs that are most popular. Drugs by cost show the share of cardiovascular drugs has been decreasing as more generics are available. Psychotherapeutic drugs are the second most top drug class.

In terms of fills, Simvastatin and Sinopril (two cardiovascular drugs) are the two most utilized drugs in 2010. Plavix and Lipitor are the two top drugs by cost, and they've been the top drugs by cost consistently between 2009 and 2010.

Since 2006, we've conducted extensive studies of Part D drug pricing using prices submitted for the Medicare Plan Finder. We examined prices in aggregate for the program as well as sponsor-specific differences. We've also looked from the point of view of the individual beneficiary, using market basket analyses to gauge how one person's cost could fluctuate throughout the year.

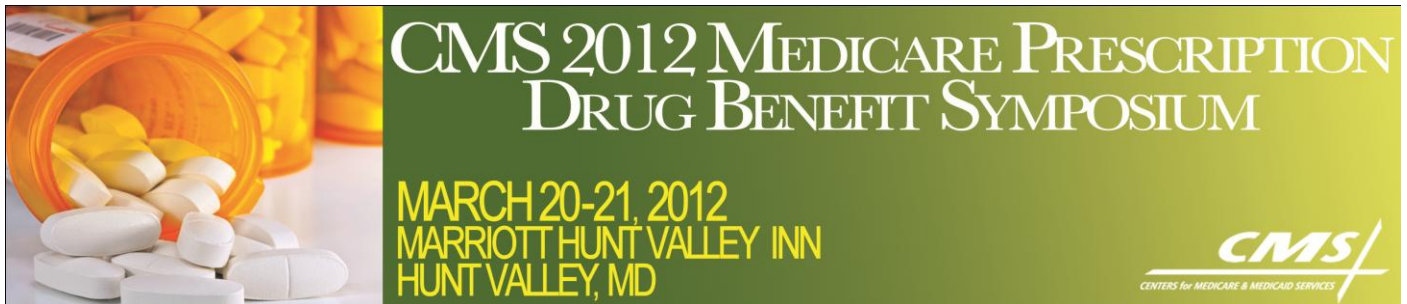
Certainly changes to the program have modified our studies. For example, we monitored whether manufacturers increased drug prices in anticipation of the Discount Program. With recent AWP changes, CMS transitioned from average wholesale price to wholesale acquisition cost (or WAC) as the primary cost amount for both the Medicare Plan Finder and our analyses.

In previous studies, we've consistently seen that Part D prices followed commercial trends and of course are not immune to market changes. The program offers savings; however, we do realize beneficiaries may be receiving drugs not captured through the prescription drug event data that we have. Cost analyses via the sample drug regimens have shown that prices for specialty meds tend to increase at a much higher rate, and unfortunately there is not much protection in Part D against these increases.

In 2010, the metric shifted from AWP to WAC. For Part D sponsors that had higher price indices compared to WAC, differences were usually less than 1% higher than WAC. This small /INAUDIBLE/ is very similar to our previous studies comparing changes to AWP. As WAC prices are almost always higher than AWP, this appears acceptable; but we'll continue to monitor this.

There's been some variability between out-of-pocket costs over the years, although some of the variation can be explained by data changes. For example, the AWP to PDE changes, methodology changes or programming fixes. For the first time we've made the OOPC model (the Out-of-Pocket Cost model) available in SAS software via the CMA website to help sponsors calculate out-of-pocket cost values for each of their plan offerings in 2012. This slide basically says the ratio of PDP out-of-pocket costs of fee-for-service out-of-pocket cost has gone from about 0.64 in a defined standard plan to about 0.49.

Future challenges – I think one of the biggest issues for us is the transition of care – how to make sure that the physicians are cooperating with Part D in terms of transitioning people from one level of service to another and making sure their drugs are reviewed as those transitions occur. We want to increase access to MTM and the number of Comprehensive Medication Reviews that are delivered. And we've not seen improvements in some Plan ratings measures. We believe that the number of cases forwarded to the IRE continues to be difficult because some Plans cannot comply with CMS's required timeframes.



We've seen these rates increase instead of decline; and only for MAPDs recently did performance return to the original level of performance.

We're looking at improved outcome measures. The average percent of enrollees with diabetes and hypertension receiving the recommended class of antihypertensives has remained in the low to mid-80s. So we're hoping to see improvements in this along the lines that John mentioned.

Assessments – it is time to conduct the assessment. Please get out your ARS response cards. We would encourage all of you to participate. As a reminder, if you're seeking CPE credit, you must respond to all assessment and evaluation questions. All right, after the questions and responses are read, you'll have ten seconds. You'll see the timer on the screen.

*What was first implemented for the first time in Medicare to track and resolve issues reported by beneficiaries: (a) HPMS, (b) MTM, (c) CTM, or (d) none of the above?*

Say, "Please vote now. You have ten seconds."

The poll is now closed. Let's look at the results. Okay, the results say that 4% thought HPMS. That's not right; HPMS has been there for a long time – since probably the mid-90s. Medication Therapy Management was not a Part D invention; it has been there as well. CTM is the right answer, and 90% of you got it. Congratulations.

*Which of the following is an example of a program improvement in the Medicare Drug Benefit: (a) implemented a standard complaint resolution process; (b) developed more robust MTM service requirements with standardized action plans; (c) enhanced the Plan ratings to drive performance improvement and aid in enrollment decisions; (d) implemented the Coverage Gap Discount Program; (e) all of the above?*

Please vote now. You have ten seconds. There you go; you're down to six. I'm not very good at this.

The poll is now closed. Let's look at the results. We have 95% of you getting the right answer with (e) all of the above.