

Alice Lee-Martin:

Good afternoon, everybody. My name is Alice Lee-Martin, and is everyone having fun yet?

[laughter]

I'm really full of acronyms right now, but as Chris mentioned this morning, this is supposed to be a very educational and fun conference. I was going through my slides, and I don't think it would be fun if I read to you 15 sections of Part D reporting requirements to you. So what I think I'll do instead is talk about the purpose of the requirements themselves, in a very general sense but also give you an explanation of why we made some changes for 2008. I'll outline CMS's definition of what compliance is and what potential actions can be taken if non-compliance is found. And then I will just touch on 2009 Reporting Requirements because there is some good news for 2009.

Briefly, the purpose of reporting requirements – and I am proud to say that I've worked for the Part D reporting requirements collections since they were created in 2005 -- and I think that they serve many different functions, one of which is that they provide more timely information than what we can get from other sources. Some prime examples of this would be the appeals information, also GDR and, of course, grievance information. The plan report data also allows plans to update the information that they may have given us at their initial application, and I'm speaking about one new section for 2008, which talks about pharmacy access. I'll go into more detail in a little bit. Then probably most importantly, the data allows CMS to have long-term monitoring and oversight of drug benefit, itself. Certainly, as we've seen, as policy changes are implemented, new areas are identified and we add them, certainly, of course, respecting the reporting burden that is associated with these requirements.

So I'm going to move on to the four sections that have changed since 2007's requirements and they are listed here. For transition, we are collecting more specific information about what you, the plans, have in place for safe guards in both the retail and long-term care settings. To mitigate the reporting burden, as I mentioned, we also have reduced the frequency of reporting from quarterly to annually. We feel this is a more comprehensive approach to learning more about safeguards that plans have in place.

For the MTM programs, CMS is very excited to have a chance to start identifying best practices and also determining long-term outcomes from the programs that we feel are very important. In order to do that, though, we need more information than what we've been able to collect in the past. What we've collected in the past is more of a descriptive nature in terms of what percentage of your population is eligible, and of that percentage how many actually participated and how many declined, et cetera. So starting in 2008 we will be asking for plans to provide a data file that actually includes the MTM eligible beneficiary information, including things such as if they were a long-term care resident, what was the actual period of their MTMP participation, and if they stopped participating in the MTM, why did they discontinue? In addition, we will continue having those aggregate pieces of data reported to us, and we have included two more because, again, we've realized that there is some need to round out the picture, per se. For example, in the past we have had a variety of discontinuation reasons. People would just report to us these are the number that discontinued because they died, this is the number that discontinued because

they moved out. Well, we realized well there could be another reason that we did not identify, and certainly to fill the whole picture, we wanted to collect that.

Similarly, we also are creating a field where, for Period One, plans will be able to report to us the number of beneficiaries that are eligible for MTM but have not yet indicated that they're participating or they have not yet declined participation, so essentially they're in a pending status. Again, this is to round out the picture so CMS can really see the full picture.

For long-term care rebates, the purpose of this section, it was created because we wanted the plans and CMS to be able to identify when there were potential conflicts in the plans' utilization management programs to that of the long-term care pharmacies. Already we report or we collect information as the drug name. In 2008, we are going to start collecting not only drug name, but also NDC information. What that will do for CMS is allow us to identify a formulation-specific level of information on the rebates that are being received. Also two special reporting cases that were actually announced effective for 2007 and, of course, into 2008 is that there is a reporting exemption for long-term care pharmacies that serve less than five percent of long-term care beds in an area they are not required to report their rebates. We also provided instructions for in the case of a long-term care pharmacy does not provide this information to the plan, the plan can go ahead and indicate that to CMS. Again, I'm going to speak of the big picture. In a sense, you're going to have from the plans reporting rebate information from long-term care pharmacies. You're going to have a group of long-term care pharmacies that you report as "not required to report" and then lastly, you may have a group of long-term care pharmacies that you indicate are non-compliant.

For drug-benefit analyses, this is of high interest at CMS, certainly we would like to understand how our beneficiaries are moving through the drug benefit. In 2007, we had created this section to speak only to those non-LIS members. Of course you can expect in 2008 we therefore expanded it to include both LIS and non-LIS members. Again, we're reporting information for enrollees in all benefit phases, which includes a deductible phase. Now these reports were always run on a monthly basis but given to CMS on a quarterly time frame. So for 2008 we have increased the frequency of reporting to monthly, and that essentially will allow CMS to receive the information in a more timely fashion and perform the analysis.

Three new sections were added for 2008. I think I touched on a few. The pharmacy access, as I mentioned. This was information that the plans gave to CMS at their initial Part D application so certainly we want to be able to confirm that access standards continue to be met. This again speaks to retail, home infusion and long-term care. For any plans who received waivers to the any-willing-pharmacy requirement or retail pharmacy convenient access standards, they will also be required to provide more information.

The next section talks about access to extended day supplies at retail pharmacies. This is only for those plans with mail-order pharmacies that offer extended day supplies. If you are that type of plan, you will need to verify for us that that same access is provided at the retail setting. Again, keeping in mind reporting burden, we are collecting this only once a year.

I mentioned in the beginning that certainly as CMS identifies new areas of need for reporting, vaccine administration with the shift in 2008 for Part D vaccine administration to go from Part B to Part D. CMS was very interested in the ability to monitor how plans are facilitating vaccine administration. So, on a quarterly basis, contracts will give us the total number of vaccines processed and then, of that total, subset them by the type of method that they facilitated the administration.

Other changes that were made for 2008? We dropped two sections, Call Center and Reversals, specifically. We have renamed Generic Drug Reutilization previously known as Generic Drug Rate and, if you've gone through the document, you probably have seen that we have made other clarifications in the language and terminology. We've tried to provide more detail in data elements and field formats. All of this is an effort to improve the accuracy of information given to CMS.

Now here's the good news. Beyond 2008 we have determined that the 2008 reporting requirements will remain in effect for 2009. No new reporting sections will be added. I thought there'd be applause there.

[laughter]

Of course in the future we may have additional areas and changes as we find them necessary. But really, since we are now looking at the reporting requirements to be a stable set of elements for at least two years, we are moving the focus to improving the accuracy and consistency of data given to us by the plans. So in that effort, there will be a Technical Specifications document released this spring that will serve as a supplement to the Reporting Requirements document. I've listed here a few of the pieces of information that we look forward to including. This will include data elements further defined, more so than what we see in the Reporting Requirements document. If there are validation and QA thresholds that we can let you know ahead of time so you can preview and QA your own data prior to providing it to CMS, we will let you know those details. If analyses have already been determined for what we will be doing with the various sections, certainly we will include that and also any other clarifications. Certainly you may already be familiar with our Frequently Asked Questions documents in the past, all of that information will be put into one document so hopefully you can find that all very useful.

I'm going to go away from the content now and go into the analysis and the reporting by CMS. CMS is doing a great deal of work to do the initial QA of data. I've listed here just a few of the activities that is included here. Very first and foremost, we're identifying those contracts that have failed to submit their data. We are performing statistical tests to determine potential outliers, not absolute outliers, potential, and, perhaps, data entry errors. Certainly when we see a piece of data that comes in by 10 million when it should be by a thousand, perhaps, we certainly will flag that.

I think the next bullet is important because we're looking at behaviors across the program to see – contracts are sometimes providing us data by reporting deadline and then frequently asking for the opportunity to resubmit their data because they say that they have identified an error. Certainly we understand errors can occur, but if it's seen frequently that your contracts are

resubmitting data or, the second piece of that, is failing to resubmit that corrected data, that certainly would be flagged as a problem. In any regards, for any of these issues, sponsors will be contacted if identified as outliers, and we request that you review your data and verify the data are accurate as submitted. If necessary, you will have the opportunity to resubmit your data and if you verify the data and say "Nope, that's right, that's absolutely accurate what I've provided," you may be asked to give us more information just to support that information. That period of time after each reporting deadline takes about four to six weeks. After that point, we will lock the data, consider it final and ready for analysis and for CMS reporting. Any submissions after this point could be excluded from our analysis.

Quickly, because I know I'm running out of time, the compliance actions. Compliance is considered by CMS the timely submission of accurate data, not just timely submission. So we are looking at this in more detail. We are certainly listing here some of the compliance actions that could be taken including warning notices, caps, and if significantly or persistently seen, we could move into intermediate sanctions, civil monetary penalties and, ultimately, unfortunately, contract termination if non-compliance is persistent.

I've provided here the link on the CMS Web site for our Reporting Requirements documents. Here you can find the current '08 documents as well as Frequently Asked Questions and then the central in-box that we have set up for any questions you may have about reporting requirements.

There's my contact information.

I'm going to turn it over to Phil who'll talk about SNIPS.

[end of transcript]