



## **CMS 2010 MEDICARE ADVANTAGE & PRESCRIPTION DRUG PLAN FALL CONFERENCE**

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### **Panel Discussion – 2010 Audits CMS Central Office Representatives**

I'm Brian Martin.

Good afternoon. I'm Vernisha Robinson, I work in the program compliance and oversight area.

Hello. Brenda,

Hi, good afternoon. I'm Cynthia.

Hi, James Canavan. I write and analyze enrollments and disenrollment policies for Medicare Advantage and Part D.

I'm Katherine Smith. I serve in the area of coverage determination, appeals and grievances. Good afternoon. Mike, I'm the acting director of the appeals group.

Great. Thank you everyone. We have a couple of presentations. Then what we would like to do is turn it over to questions and answers. We hope to have about 15 minutes of Q & As. I'm a person responsible for audits. If any of you have been subject to audit I'm the person that you can blame, throw things at, whatever makes you feel better. These slides will be available to you. I wanted to give a very broad overview before I turn it over, of the audit program for 2010. It probably won't be a surprise to you, just as I'm sure you are conducting your business, we do risk assessments. We did one going into the 2010 period, there were a couple of indicators that we used. Things like complaint rates and size are factors that we look at in assessing where risk is. We look at specific referrals, we determine if an audit is appropriate. When we come out on audit we're looking at all of the products that you offer and really doing a full-scale assessment of that. The other thing you should know is sometimes we're out there because we have some very serious concerns. You may have noticed earlier this year there were a couple of entities that we sanctioned or terminated based on an onsite audit.

The other thing is in addition to who we're focused, we're also focused on programmatic risk areas. This year we've had a large focus on access to drug services, exceptions and appeals, grievances and premium billing. Overall, this is something that Vernisha is our SME on, compliance plan effectiveness, we believe this is a key to getting a handle on issues. We're also doing a compliance plan effectiveness audit with we come in and audit you. Some entities we've had to audit, we've had to reaudit because they were subject to a prior desk audit review. We come out and do these onsite reviews for the compliance plan. You should also know, I think this is a trend of why it's so important to focus on compliance programs and operations, if you haven't noticed in the new legislation these mandatory compliance programs, which have been in existence for all Part B and most of Medicare Advantage life span are now on fee for service providers, Medicaid and the CHIP program. They're very interested in this, they believe this activity is the linchpin to being successful. The other thing that is really important, this goes back to the oversight, they're focused on the fraud, waste, and abuse. It has to do with focused



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activities, what are you doing specifically? Are you in high fraud counties? Are you monitoring for these activities? It's a very critical piece of the audits. I think somebody talked about the readiness check list. Look on that list and you will see that our compliance plan effectiveness and fraud, waste and abuse measures are on that list. I encourage you to look at that.

Just in terms of the audit process, some of you know that have been subbed to this, there's shortened timeframes for notice and response. We ask for documentation and data. We give you very accelerated times to respond. There's allegation a change to the -- also a change in the legislation that I wanted to bring to your attention. Congress has inserted "timely" in the provisions, which we believe is an important addition to our authority. We're asking you to pull up the systems, we're picking different things for you to walk us through. The corrective action process is another difference. We will give you a notice of deficiency and a timeframe to correct. It's not going to be a back and forth iterative process. We're looking at about 60-daytime frame to correct. We will be publishing these results on our website.

The other thing, we also will have a future listen session on audits. We want to gauge you on the process. You will be seeing something on that in the next couple of months.

I want to make a plug here. I know one question came up, another really important critical audit activities, we're beginning to connect the dots here is 1/3 financial audits. They focus on financial, Part D cost and data and et cetera. They've been completed for 2006 and 2007.

They're about to be launched for 2008. We've seen some very serious findings, findings that really concern us. If you have gotten anything other than a clean opinion you will be getting a notice, you will be given an opportunity to correct, I strongly encourage you to do that. Also the kinds of things that we're seeing is failure to maintain and provide requested documentation. Some of you are not getting documentation scripts from your PBMs. That's a really serious problem for us. We have to be able to audit your financials. I'm sure you understand why that would be critical. Lack of internal controls, nonbenefit [ Indiscernible ] expenses, highlights of what we're seeing. Again, with these findings these will become public at some point. I'm sure you can see the importance of that. Very, very important set of audits.

With that I will turn it over to Cynthia.

Thank you. I'm supposed to give another plug for this. Wanted you to know this page 14 and 15 of Medicare And You. We developed this with our office of external affairs. You will see a lot more coming your way. Ultimately plan materials will have these kinds of things for decision making. You will be seeing this from us in the future.

We sent out a memo on August 27th about a number of findings we had been seeing from the audits that Brenda talked about. One of the things we've seen is plans that don't understand some of the [ Indiscernible ] changes. That was effective January 1, 2009. In addition to using the Part D compendia, this law updated the requirement to include the use of [ Indiscernible ] drug biologics compendium when you are evaluating off-label uses. Some plans did not include incorporate it. We're suggesting you do this. December 2008 is when we gave these requirements to you. You can go back and look at that HPMS memo.

We have identified a number of sponsors not in compliens with transition requirements. Part D sponsors must provide for an appropriate transition process for new and current enrollees. The transition policy is per prescription. It's not per individual, it is not per a strength. So basically the



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transition is on different strengths of the drug, it's two different transitions that you have to give. The memo on the 27th outlined these requirements around when a beneficiary gets a transition requirement. I will not go over them again. They're in this memo, they're in the memo. I suggest you go back through the memo and read it and think about how your systems are working and you run test plans to make sure that your systems will work appropriately.

We also talked about how sponsors should expedite transitions on formularies. If you haven't done it we will identify you.

The majority of the compliance actions involved current enrollees affected by changes to their planned formulary. The sponsor intended to transition all members who were subject to a formulary change, or they improperly relied on [ Indiscernible ] to effectuate the transition, or they processed fields for only some drugs. Rather than provide the remaining enrollees with a temporary field they were rejected at the point of sale. One changed their formulary from a very broad open formulary to a more restrictive formulary and decided that providing it with the [ Indiscernible ] was sufficient notice of this change. The sponsor didn't provide continuing members with the files at the point of sale. Another sponsor -- beneficiary call the plan in advance of effect wages. More audit findings, they did not process claims with hard edits. Requiring the dispensing pharmacist to enter an override code has not generally worked. No controls were in place by the plan to make sure that this happened at the point of sale.

The second one, a beneficiary that left a plan for a year to enroll in another plan decides to reenroll in the original plan. They relied on the beneficiary's original enrollment date of two years ago, failing to recognize the beneficiary as a new enrollee.

I forget to advance these. The 2011 readiness check list, you should have gotten that last week. We basically give you the check list about this time of the year to make sure that you are aware of what is going on. It covers Part C and D this year. We don't put new guidance in here at all. We only reiterate existing guidance. You should just be seeing the current set of requirements. For sponsors we want you to review the check list in September. October you should be responding to immediate action items. November we ask you to respond to this when we reissue it. We also want you to be aware of two things that you need to tell us about immediately. One is for example, if you change PBMs or enrollment processes, you need to let us know this, we can talk about you about making sure that you are ready. It also happens us if something happens on January 1. We have to know what is going on in case we see problems. I think you will see other issues coming up as we try to review what you said in your readiness check list.

This is an actual piece of paper sent to us by a plan by mistake. This is a compliance plan that we should never see and you should never use. If you can't read it, it says compliance programming. Instructions, replace [ Indiscernible ] with plan name. We view the committee structure. This is a general template designed to meet the CMS requirements. However, your organization may have slight variations. We are neither impressed with the consultants that put this together, nor with the plan that decided that to use this.

What is on the horizon? We expect to see more oversight, more rigorous proactive data driven target monitoring much you heard about the performance assessment. We've been able to tie the star ratings system to something we call the [ Indiscernible ] green light analysis. We're tying this to auditing. We've got all of the data to read into one thing, you can expect to see more realtime monitoring of your plans.



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I think that's it. The last point, which I forgot, can you put that back up? The last point, I can't even see over here. I think part of the problems that we're seeing from auditing and when I talk to plans this is what I get. You are administering plans as if they are commercial. Medicare has a lot more requirements and a lot more benefits to its beneficiaries and enrollees than commercial plans do. Take a step back, make sure that you are following Medicare rules, not commercial plan rules. Thanks.

Thank you, Cynthia. I will spend the next few minutes just going over at a high level what to expect for the formulary portions of the audit. Give you a flavor. So to start off we'll be looking at your PDP document, the minutes and other clinical notes to ensure that you are meeting the PNP committee requirements. We'll be asking for a number of universes of Part D claims to help us identify in advance of the onsite visit areas of concern and deficiencies. For instance we'll be looking at rejected claims files and comparing those to your formulary changes to identify where you are not effectuating properly. On site we'll expect to run a number of test claims to ensure that your systems are working properly, also look at actual claims that we pull from data. I am going to talk about some of the findings and observations we've made thus far on these audits. The first has to do with the Part D compendia. This far into the program we have identified sponsors who are either not using [ Indiscernible ] or drug decks. And sponsors not updating their policies and procedures to incorporate the MIPA data.

What we're finding claims being rejected for drugs on the formulary. These are drugs that should be processing without stoppage, yet they're getting rejected. What we're finding is that the formulary is not programmed correctly, whether it's the plan for the first tier entity. It's not matching what we've approved. We're finding implementation of PA and therapy edits that were not approved by CMS, and not included on the approved formulary. This has gone so far as plans implementing age restrictions that are outside of the FDA approved labeling and stopping claims for those drugs when there is no prior authorization on the approved formulary. We've identified where a plan is implementing unapproved PA criteria. Not only did the drug not have PA, but they went ahead and adding additional lab tests and diagnostic procedures that were not -- they were clinically inappropriate and not part of the PA file that we reviewed ahead of the contract year.

And one practice that we've encountered is the use of a high-cost edit to trigger a clinical PA. We certainly understand that a high-cost edit is a good tool to help avoid fraud, waste, and abuse and identify fat finger errors. However, some of the drugs that are legitimately high cost that did not have prior authorization were hitting against this edit and kicking off a PA review. In cases therapy was delayed. This was occurring for H.I.V. drugs and cancer drugs. If you are implementing these high-cost edits these need to be resolvable at point of sale.

We're seeing a number of issues on these audits relating to drugs within the classes of clinical concern, the classes that are listed here. Just to remind you of our policy, PA and therapy requirements on these drugs have to be limited to beneficiaries who are just starting on the drug. They cannot applied to members that are currently taking the drug. Again, there are no PAs allowed on H.I.V. medications. What we're seeing is this is not the case, plans are not following this requirement, which is not a new requirement, this is unchanged since 2006. We're seeing that beneficiaries are having their therapy interrupted. Recently we encountered a sponsor approving through the end of the plan year, once January 1 hit they were subjecting them to PA for drugs within these classes, this is against our guidance, it's putting beneficiaries at risk for serious health problems.



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While we're on site we're also looking at your formulary website, your posted material and comparing that to the material that we've approved. We have identified areas, sponsors that are fail not guilty this area. Both with respect to what is posted and what we've approved through our review process. The marketing guidelines for 2010 are on our website, they're clear with respect to formulary information. One basic requirement is to have an electronic version of your form laid out posted on your website. Some sponsors are failing to do this. That comprehensive formulary is the minimum requirement. We need to you have those posted and updated regularly.

Also, just a reminder, your PA and step therapy criteria have to be posted on your website and your quality limit restrictions. Will are things you can do to help these issues from occurring. It starts with understanding the guidance, being out on audits it's surprising that there's still some misunderstandings in information that's in chapter 6. It's where all of the formulary requirements are contained. Because of the issues we've been finding on audits we did release a memo on August 27 as a reminder. We also put in that memo some examples of what we found on audit so you will not make the same mistake. It's also surprising that we're seeing plans are not overseeing their PBM. So the formulary errors are easily identifiable, but we've seen a number of plans that sort of try to put the blame on the PBM, but it is your responsibility. We really urge you to monitor your rejected claims, your complaints, to ensure that your benefit is what is adjudicated at the point of sale. Prior to January 1 it's very important to test your systems to make sure that the transition process is going to work. We're seeing that as a sticky point. Run test claims on these claims for beneficiaries that were taking the drug to ensure that transitions are being processed.

Thank you.

Good afternoon. I will just go over some high-level findings in the enrollment and the appeals area. We're concerned about organizations' ability to make timely determinations about enrollment and disenrollment requests. This includes application dates, effective dates and election periods. In some of the audits we noticed organizations having problems meeting the timeframes for transmitting data to CMS. We also noticed that some organizations aren't sending the correct CMS requirement notices to beneficiaries within the appropriate timeframes. And there's also a need among organizations to develop an infrastructure that allows employees and CMS audit teams to track notices related to enrollment and disenrollment requests. Especially the dates when the notices were mailed. A lot of times we're able to determine when the system generated the notice, but we're not able to determine when the notice was actually mailed. Organizations have also shown a need for training on some of our guidance materials, especially when determining and applying both grace periods and the out of area policy. As far as coverage determinations, appeals and grievances, the findings I will talk about relate to Part D plan sponsors. We're really concerned about these some of these findings, as a result we issued an HPMS memo over the weekend reminding plans about some of the responsibilities in this area.

For the most part we noticed that a lot of plans didn't have adequate tracking systems, or work flow processes in place to triage the requests when they're received. We also noticed that some plans were not date stamping the incoming requests. Without the procedure triaging on the front end this was preventing plans from issuing timely decisions to enrollees. This also resulted in an inability to auto forward cases through the qualified independent contractor when the plan sponsor doesn't meet a deadline.





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If a plan fails to notify an enrollee of its decision within the required timeframe the plan must forward the request to the qualified contractor within 24 hours of the expiration of the adjudication timeframe. We also noticed a failure to expedite coverage determination requests. Even when it was pretty clear that it should have been classified as an expedited request based on their statement of the life or the health of the beneficiary being jeopardized plans processed them as standard requests. Revisit our manuals. Look for key words, triggers.

A large number of plans have been identified as having insufficient processes for classifying coverage determinations and appeal requests from grievances. This is resulted in beneficiaries not receiving prescription drugs in a timely manner. I think this is a similar theme from earlier with some of the tracking systems and work flow processes in place. You can just train your CSRs to properly identify the requests when they come in, and send them to the appropriate department, I think that will really help plans process in a timely manner.

Another area is the number of deficiencies that we identified in the area of prompt e effect wages of favorable decisions. For example, Part D sponsors are failing to enter the information into the claims system, as well as notifying the enrollees of favorable decisions. This is creating unnecessary delays in cases where coverage is approved. So we just encourage sponsors to review the processes on effect wages to get these out to the beneficiaries. We're taking these findings we seriously. In the area of grievances, coverage determinations and appeals, it may impact the health of the enrollees.

That's it for my presentation. Thank you.

At this point in time if you have any questions please feel free to come down to the microphones in the aisles. We'll open up the floor. Questions? If you can't get to a microphone please raise your hand, we'll have a wireless mic passed to you. There we go. Don't forget to state your name, who you work for and if you are addressing someone.

Vernisha, training and down streaming training is an issue for us. In '09 CMS said they would have training guidelines for working with network pharmacies, they never put out the training program.

Are you talking specifically for a type of training?

Fraud, waste and abuse.

I don't have that information at this time. I can get your information and respond back. I would like to respond. If you are talking about ability to deem for some of these, I think this is the late iteration. For entities that have come to the certification process on the fee for service side, some pharmacies meet the requirements, there is an ability to deem for purposes of that. I believe they may be working on something, a baseline training that might be available.

Okay, thank you.

We have a question right here.

Dave. A common theme has been about the 2010 audit processes, data validation. Demonstrating results in the data systems, show it to me. So there's a more proactive data



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driven monitoring. I'm wondering about the new requirement for the data validation that begins in the spring, the plans need to have an external source doing the validation and how that ties in to the audits.

Generally the audit and the validations won't overlap. The validation is going pretty deep. We'll make sure that the two audits don't overlap. I think there's some areas, the grievance numbers that you still may have to show that you are classifying grievances correctly, and [ Speaker/Audio Faint or Unclear ] these kinds of issues where we go into if you are counting grievances right, and the coverage determinations.

Is it safe to say then that a thorough and successful data validation audit would be helpful for the onsite audits?

I think the data validation goes into a lot of the clinical data on the Part C side that the audits don't go into at this point. It's not clear to me that you are talking about the same level of audit for these two.

Okay.

Okay. Thank you.

All right.

We have a question over here, please.

Hi, Donovan. I had a question on the compliance program audit, plans that have the audits, what should they expect now?

All entities that have been subject to audit will go down a couple possible paths. You will be given the normal process where you have about 60 days to make correction and provide validation that you have made corrections to any deficiencies. Some entities we suspect, given what you heard today, we'll go down a different path, that will be either sanction or the possibility of termination. Depending on the severity. Most will end up in the normal path, notice of deficiencies and reasonable opportunity to correct, if you fail to correct we will go down a different path.

Thank you.

Sure.

A question over here.

My question is not related to our company, it is a question related to guidance that was put out. In our guidance we recommended that transition fields that were done as a result of claims that were failed from [ [ Indiscernible ] ] pharmacies have rejections sent back with codes. That was at the specific request of the long-term care industry. Their work flows are set up in a way that any don't recognize there may be action that needs to be done on behalf of the beneficiary, since they take on a bit of that role. I was asking for clarification. I saw a broad statement that said that transition claims should not be rejected. I would like a little feedback on that.



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I was called after that memo was released. Tracy, my deputy, is the person that deals with the MCPDP, I can take that question back to her. When you deny this, if you deny it, if there is an override done by the pharmacist -- what we said was that -- what she said is people that claim the process gave people a clear path are being disingenuous. I'm saying that you have to make sure the beneficiary gets the drug. I think it's in the long-term care arena they generally are, the pharmacist will put in the override code. In the normal retail setting that is not happening. I hope that helps.

Do you have another question?

Nancy. In the presentation you mentioned that CMS is focused on more specific data collection across plans, which we see as a positive. We know that CMS has published national averages for a while now. We're pleased to hear that CMS will be publishing some standards so plans know how they're doing in terms of the marketing surveillance console. It's very helpful for plans to get this kind of data. It allows us to benchmark ourselves against data that you are seeing, and would encourage that level of transparency. It's very helpful. I'm curious as to whether or not we can expect that kind of data in other areas.

In general you will see a lot more transparency. We've always been transparent in all of our star ratings. There are Excel spreadsheets out there. I think you will see that. Even from that you can calculate benchmarks. We can try to put those out.

I have one follow-up. On star ratings on particular, those have been transparent. One thing to note there is the time lag on stars is long. Star ratings that are earned for 2011 were dated back to plan performance up to two years ago. I'm wondering whether CMS has any design on ways of making those star ratings more current. Because truly plans have done many things in the last couple of years to improve performance.

I think if you listen to Liz Goldstein earlier, a lot of the plan ratings were from 2010, that's about as current as you will get. I think we're working, you know, CMS -- around that measure versus collect timely measures. We try to balance those two demands. I think until we can get the consensus building organizations to come up with more timely measurements that are agreed on I think it will be difficult for us to change. But we are working on it.

Thank you.

All right. Another question.

Hi, Kathy Freedman. There are two new things for 2011 that industry is still waiting for final information on. I'm wondering if everyone on the panel can provide an updated timeframe. The release of the labeler codes. The second would be the final requirements for the Part C and D data validation.

On the labeler codes, we just closed the required period for finding those last Wednesday. We will work on this list. We'll see it coming out sometime soon, not too far. The data validation, I think there's plans to get that out by the end of the month, too. I will check when I get back. Any other questions? Won't please join me in thanking this distinguished panel of experts. Thank you. [ Applause ]