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TRANSCRIPT

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CMS

Good morning everyone. So, thank you all for coming back this morning. We're very happy to have you all here again and for braving the downpour. I'm very happy to have all my colleagues with me this morning. And we're hoping that we can pick up sort of where John Blum left off yesterday with his remarks, talking about some of the priorities that CMS has, particularly in regards to compliance and audits moving into this year, and focusing on some of the guidance that I know he left you all with yesterday.

I'll be presenting a little bit about the 2010 audits and the tiny bit that we know so far about 2011. My colleague Vernisha Robinson will then be speaking about focusing on compliance plan audits and some of the best practices that we established over this past summer. And then my other colleagues will be happy to take some questions from you about particular areas of focus for the audit.

So let's go ahead and get started. Great. So, again, I'm going to spend most of my time, again, speaking about the audits, and, as I said, we're looking forward to taking your questions. So 2010, let me say a little bit about where we started, where we got to, and the roadmap in between. We audited for 2010 at the parent organization level, as opposed to the contract level that I know had been done in years past. So, in most cases, when we arrived on site, we would be auditing several if not all of the H, S, or R numbers associated with the parent organization. We felt like this really gave us the best impression of the organization, the best picture of what was going on within the company.

The plans were selected for audit based on risk assessment. And this was, as opposed to 2009 and prior where there was sort of a random – it would spin every three years, and now it's your turn to get audited. This was a departure from the way we had done things in the past. We really focused on Part D access this year. And the audits, we attempted to look really at outcomes as opposed to a policies and procedures audit or looking at processes.

We felt like one of our main goals of the audits were really that, how should I say this, to be collaborative while on-site, and I know that that is probably going to get some laughs from people that got audited this past year because we did hear some feedback about a different stance from CMS, that maybe we felt like more regulators as opposed to friends or partners. But we did, believe it or not, want the audits to be a positive experience, and we wanted, after we left, that sponsors would feel like they learned something from the audit, they learned about what CMS was focused on, and they were able to act on the information that was provided to them. And I think, actually, we were able to succeed in that respect.

We did 33 audits last summer. We covered about 60% of the enrollees in the MA and Part D programs. There were 11 audits that were compliance plan only, and those we conducted for a couple of reasons; one, we were sort of cleaning up some old work that had been done in the past, and sort of taking a new look at compliance and compliance programs.

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And then we did an additional 22 performance plus compliance audits, and those were driven by the risk assessment that we conducted, and I can say more about that in a second.

Reports were issued for both of these sets of audits. I will admit that it did take us quite a while to get the audit reports out after the conclusion of the audits, but the compliance plan-only audits were – reports were issued in January, and the reports for the performance plus compliance plan audits were issued in February.

Some of the audits led directly to some very eventful outcomes for a few of the sponsors. Number one, we did end up terminating a contract from the program that was a direct result of one of our audits this past summer. Five sponsors were subject to marketing and enrollment sanctions that were either directly or partly related to the information that we found onsite during the audit. And it was our conclusion that there were ineffective compliance programs in place at all of these organizations where we took a compliance action, or an enforcement action I should say, and that's really been a focus of our efforts this past year, and it is also a major focus of our remediation and validation activities moving forward.

So who were the lucky few to get audited this past year? Well, it was a little bit of everybody, as the next two slides will demonstrate. We were, you know, thinking about some of the themes or characteristics of the plans that were audited, and really it was all over the map, I would say, in one aspect. But, again, it was driven by a risk assessment, both, number one, of areas within the program that we felt presented the greatest risk to beneficiaries and to the program, and then number two, driven by risks suggested by the performance of the plans themselves. And we did receive a lot of questions about how did I get selected from an audit, am I going to get selected again for 2011? And really it's all driven by this risk assessment.

And you can read all of the details about what would go into the criteria for this risk assessment, it was published. And our methodology is consistent with the methodology that's used by MCAG and the drug benefit group when they're assessing or evaluating whether or not to allow a plan to expand or submit new applications. And that methodology was published in an HPMS memo from Cynthia Tudor and Danielle Moon back in December of 2010, and I think it was entitled the "Past Performance Methodology." And if you're familiar at all with that, that is entirely consistent with the assessment that we used to choose plans for audit.

So, again, we had large and small organizations. We had plans that were brand new to the program, plans that have been around for a long time. We, you know, visited plans that only have Medicare business, that have an enormous commercial business but, you know, have Medicare – one of our major concerns was Medicare sort of "buried," and we can talk more about that in a minute. But really, again, all over the map, really driven by sort of who popped up on our radar screen for the risk assessment.

So let's talk a little bit about the areas, the performance areas that we audited this year. Again, it was focusing on the areas within the program that we felt presented the greatest risk, number one, to beneficiaries, and number two, to the program. A variety of issues we audited under formulary administration, and I will say that, you know, going into the 2010 audits, to be quite honest, I don't think that we confident that this was an area we were going to look at. But very, very early on, from the first audit, we realized that almost – I would say it was almost a surprise to us to realize or to discover how many issues we would find when looking – sort of looking under the hood and looking into this area of performance.

And I can say that the single biggest issue that we found onsite was sponsors not appropriately providing transition fills to beneficiaries, and so it would result in beneficiaries arriving at the pharmacy and leaving the pharmacy without the medications that they need and without medications that they're entitled to. And John Blum alluded to this yesterday when he was talking about findings from the audit, and he said that he didn't want to put a percentage up with each of the findings. This would have been the highest one.

So a big lesson learned for those of you in the room who didn't get audited, this was a disturbingly common issue, and Brian will say a little more about that in a minute. But if you have any doubts about the performance of your PBM or about, you know, your in-house performance in terms of evaluating rejected claims, evaluating beneficiary complaints, and making sure beneficiaries are provided transition fills, lots and lots of your colleagues were getting this wrong. And

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after, you know, five years of this requirement being around, again, it was quite disturbing to find what we did. So, please, if I can give you one piece of parting advice, please go back and look at your rejected claims.

The other areas that we looked at this past year were prescription drug coverage determinations, appeals, and grievances; that was another very common area for findings. We looked at premium billing, enrollment, disenrollment, and then compliance. And, again, for all of the 33 audits, every sponsor that we audited got a compliance plan audit.

So what was the process like? It was very, very different, as I mentioned, from 2009 and the years previous to that. We built the 2010 process around a few key points. First, it was really important to us that the most senior-level executives of the organization be engaged and part of the process. And so, for us, that meant that we, you know, got to interact with some new folks, new names, new faces to us.

But, again, this is sort of a repeat of one of John Blum's points yesterday, we really, really saw a difference in the outcome of the audit, in the ability of the organization to quickly correct issues that were identified when their CEO, their Chief Compliance Officer, their Corporate Compliance Officer, the most senior-level executives at the organization were engaged. And we've had the opportunity throughout this process to speak with ultimately the CEOs at all of the 33 entities that we audited. And it's really, really been a meaningful exchange both for us at CMS, and I think for the sponsors as well because, again, I think for them and for us, it's really been eye-opening to learn what we have.

And I was having a conversation with one of the CEOs of one of the audited plans last week, and it was really interesting to speak to him and ask him, "Okay, so for all of your, you know, colleagues that are potentially going to be audited for 2011, what would you tell them? What would you sort of – you know, what advice would you give them?" And his response was, I'm glad to say, consistent with some of the lessons that we've learned at CMS. And one of the things he said was, "As a CEO, as the leader and most senior level leadership of the organization, it's not enough to just sort of trust that things are going well. It's not enough to 'kick the tires'," and he said, "But you have to, you know, pick up the hood and dig the engine apart and pull things apart and have confidence and be convinced yourself, be confident yourself that the organization is operating in compliance and performing consistent with CMS requirements."

And so to the other CEOs in the room, I would suggest that, you know, please heed that advice and take it from someone who had a – I would say, was put in a position over this past summer and fall that I don't think if he could do it again he would want – I don't think he would want to do it again. So, like I said, it's really, really been meaningful to us, and it's very important for us to see the CEO and Chief Compliance Officer engaged with us starting at the beginning of the process.

As opposed to the way we operated in the past, we really tried to target our data requests this past year. And when and if problems were found onsite, particularly access problems, we asked for an immediate response from the plan, in most of those cases, while we were still onsite. And, you know, like I said – as I've said a couple of times, it really was eye-opening to us, and I think to the plans as we were out there finding some of the access problems that we did. And, you know, I'm sure that the audited sponsors would agree, we didn't feel like we could leave – depart the audit knowing that these issues still existed, so we tried to work together as quickly as we could to make sure that access issues were addressed right away.

Similarly, there a few fundamentals that we focused on with regard to the corrective action process. Again, this is not the old way of doing business. I don't know if people will be relieved or not, but for the corrective action process, at least for this year, we're not asking anybody to upload anything into HPMS. We are not asking for reams and reams of binders of information. We're really attempting to be very targeted in terms of what we ask for. The process involves a couple of key documents that we are requesting. And for those sponsors that were audited over the summer, we're in this sort of corrective action validation phase now.

Two of the key documents that we're asking for, number one, is an attestation from the CEO. And that is confirming two things for us; number one, that the deficiencies identified in the audit report have been corrected and are not likely to recur; and then number two, attesting that the sponsor's compliance program has been modified and is now in compliance with CMS requirements.

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The second document we're asking for is a resolution to be adopted by the board of directors outlining a commitment to meet at least quarterly to discuss Medicare compliance issues. And we're asking for these two documents after 60 days or within a 60-day timeframe from when the audit report was issued. We actually have added one additional document to this list because we thought it would hopefully make the process a little more efficient and easier, and that is we are providing every sponsor a customized template that outlines all of the areas where we identified a deficiency, and then asking for a very, very high level overview of a root cause identification of the source of the problem, and then a very high level description of steps that were taken to correct the problem. But, again, it's those three things that we're asking for and that's it.

The sort of second part of the corrective action phase is validation. And this part of the corrective action phase is sort of kicked off after we receive the three documents that I just described. And I don't think anybody that got audited has started down into this process yet. So I would say something that I said to every sponsor that we had on the phone is that for those of you who are entering this phase with us for the first time, please be patient because we are – I won't say we're making it up as we go along, but I will say we're refining it as we go along. And so we're really trying to be sensitive. We heard your feedback about, come on, CMS, you asked us for an awful lot of information and you gave us about three days to turn it around. So we're really trying to be sensitive to that. So we're refining our process. So if it feels at all like guidance is changing, it's because we're trying to do a better job. And I would continue to invite your feedback. If it feels like we're not actually hitting the mark on that one, please let us know.

So, again, once this validation phases kicks off, we sort of start down two parallel tracks, and that's; one, we'll provide the sponsor very specific guidance on the type of validation exercise we would like them to undertake, and that would include submitting a universe to CMS. We'll provide you instructions on what kind of targeted sample we'd like you to pull. And CMS will undertake a similar activity. We will conduct data analysis. Hopefully at the end of all of this our outcomes are consistent and we've discovered that you've corrected your problems and we can confirm the same thing. If the results diverge, well then we're going to have a different conversation. I hope that that is not the case. We are asking for an attestation that you followed our instructions, that you passed the exercise. And we are identifying within those instructions what we're considering failure thresholds, so the criteria for passing or failing.

So process improvements: We learned a lot from the 2010 process, and I think, hopefully, sponsors did as well. Let me talk about a few lessons learned from our perspective. First of all, we heard you. And I guess I should be pleased to say that when we got feedback from sponsors who were audited, we really didn't get any challenges or concerns about the content of the audit, about the subjects that we looked at, and I think that was reassuring to us that at least, you know, we feel and you feel like we're looking at the right things and that we all have our priorities, you know, in check.

What we did hear a lot of feedback about was the process, and so I do want to acknowledge that, you know, we were quite sincere when we asked you for your feedback about the process, and we're very sincere when we say, you know, we are going to make changes to how we're conducting things in 2011, and I hope that you'll see a difference.

You asked us to give you more notice in terms of when we let you know when we're coming on audit and in terms of the turnaround time for requesting documentation. We will be providing more time, but frankly, we think that in tandem with that, another to sort of get at that issue would be, again, to ask you for less information, to be more targeted in terms of what we're asking for. And we're constantly asking ourselves, "Is this something we really need? Is this something we really need the sponsor to provide us?," and if we can't come up with a good answer, we're not going to ask for it. So hopefully you'll see this concern addressed in a variety of ways.

You asked us to be more clear about our expectations. I think that's some very fair feedback, and I hope that sponsors are seeing us do a better job of this as we moved into the corrective action phase. We held conference calls with every sponsor after we issued all of the 33 audits to walk through the corrective action process, to walk through the validation part of the process, to give folks a time and an opportunity to ask questions and to express concerns. And so I really hope that, you know, that you have already seen improvements in this area already.

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You asked us to make your life easier in terms of how you uploaded or provided information to us, and so we very quickly started to put a solution in place so that hopefully for the 2011 audits, instead, again, of shipping CDs and CDs and binders and binders, you can upload your data to a secure facility, and we can access the information that way.

And then finally, the last two items, folks asked if we could update or provide audit guides and asked if we could – we would allow either a draft report or the ability to dispute findings. And so to the first item about audit guides, I don't think you'll – I don't think you'll be seeing, at least while I'm around, audit guides anymore, and I don't mean to say that we want to keep you in the dark because that's not the case at all, but I think we're really moving away from publishing audit guides, publishing methods of evaluation, and instead we'd, frankly, be very, very clear about what do we want to ask you for, what are we looking for when we do our analysis, and what's the threshold for failure.

Now I guess you could say, well, frankly, Michelle, that sounds like an audit guide, or that sounds like what the old audit guide was. But, you know, I just feel like we have a very different perspective on the types of information we're asking for, you know, now I'm moving forward, and so I don't think you'll be seeing audit guides in the old form, you know, up on the web or up in HPMS anymore. But in the absence of that, again, we will be as transparent and as upfront as we can in terms of what we're asking you for, what our expectations are, and what our requirements are.

And then in terms of an ability to respond or dispute findings, again, I do want to point out that we had calls with all 33 sponsors, allowed all of them to submit questions, to submit their concerns to us in writing or over the phone, and we did end up revising a couple of reports. Now the risk is that can be a good and a bad thing. In one case I would say that that was definitely to the sponsor's benefit. In the other case it was sort of, again, a very eye-opening process of talking through the audit report and the findings, and it actually resulted in additional findings for the sponsor. So if you want to go down that road you have to be willing to take the news, good, bad, or otherwise. But you can't say that we weren't at least open to considering it.

So let me talk a little bit about 2011. We're very much in the sort of planning and development phase now. Again, we are planning to conduct a risk assessment. That's going on as we speak. And I would say, again, please, if you're not familiar with the past performance methodology that was published in December of last year, we would be happy to provide you with a link to that, or if you want to email me, we'll go ahead and send you the memo. But that should not be new news for this year. We are taking your feedback very much to heart, and I hope that you'll see some differences moving into 2011.

In terms of two new items that I think you'll see for this year, number one has to do with due diligence. And I know that because it was a very different approach this year, CMS, lots of times, came onsite with lots of questions, and typically we would spend a half a day, maybe the first day, sitting down with you and getting information and making sure that, you know, the information we had was consistent with what was actually going on onsite with the organization. And so we had a different approach, we asked for different information, and we want to do a better job of talking with you and getting our due diligence done upfront so that when we show up onsite, everybody is ready to run, and we don't have to take the time onsite to have that kind of conversation.

And then, secondly, we're going to be asking plans who are getting audited to conduct a self-assessment ahead of the audit. CMS will provide tools for this self-assessment, and we'll ask you to sort of identify what your biggest performance and compliance concerns are in advance of us arriving onsite. And our hope with this is really that it would enable us to have some very meaningful conversations when we arrive onsite. We'll obviously be doing our homework and assessment of plan performance, and we would ask that you do the same. Honestly, you know, we hope that this is something that you're conducting on a regular basis, not just in advance of a CMS audit. But we're hoping that by, you know, doing this homework, again, upfront, it will give us time to really focus while we're there onsite with you in terms of these performance areas, and hopefully moving very quickly to take action and to respond to issues while we're still onsite.

I'm very happy now to turn it over to my colleague, Vernisha Robinson, who is going to talk to you about compliance programs, the compliance plan audits that we conducted. And when she's finished, we're all happy to take questions about any of the audit areas or about the audits in general. Thank you.

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Vernisha: Good morning everyone. So on to the good stuff. All right. Actually, it's fun stuff actually, I think, anyway. There's three areas which we're going to cover in the next few slides. I won't – just in the essence of time, I won't go over each slide, but I hope that we provided some information that will be useful to the ones that have been audited this year, as well as future auditees.

So the three areas that I will focus on are key audit findings. As Michelle stated earlier in her presentation, we audited 33 organizations last year in 2010, and there was a mix of entities, privately-held, publically-traded, I think one-third of the auditees were Blues Plans, not-for-profits. So there were 14 categories that all of the findings seemed to fall into, so I want to share that information with you, as well as speak very briefly on effectiveness, and give some best practices for the compliance officer, as well as some organizational improvements in best practices that you can use based on our conversations with the CEOs of the 33 that we spoke to during this audit process.

Okay. So there were 14 recurrent themes that spread across the 33 compliance program audits. And as you see here, this particular slide is about leadership and corporate governance. So what we saw was that the compliance officer, there was indirect or infrequent reporting relationship to the CEO and the board. And how we tested this onsite was we asked for – we held interviews with a compliance officer, various managers at the senior level, and also looked at communications between the compliance officer, the CEO, or other senior management, and board minutes. And we were very, I would say, shocked to see that there was little to no detail about Medicare compliance.

Another finding was that the compliance officer had direct reporting relationships to the general counsel, the legal counsel, or actually performed orals. And you will actually see this particular finding in some of the sanction materials – sanction letters, rather, that are on the web where the compliance officer – the Medicare Compliance Officer or Chief Compliance Officer served as either the general counsel or perhaps the Chief Financial Officer or a director of an operational area. And definitely that is not a good practice to have, because as a compliance officer you need that level of independence.

There was a lack of sufficient leadership level and board-level involvement and just lack of awareness of the Medicare Compliance rules and regulations. You know, I have so many stories to share, but just in regards to anything I can give to you is that if you are part of an organization that has multiple lines of business, you really need to make sure that the Medicare line of business has a reporting structure to -- if it's your audit compliance committee and also to your full board. We don't care if, you know, Medicare is 5% of your total business, Medicare needs to be escalated and get the attention of your other products.

The next slide really deals with endorsement code of ethics, your standards of policies and procedures. All of your compliance policies and procedures should be approved by your senior management. They need to endorse their level of commitment in regards to ethics and the companies' policies and procedures around, you know, compliant with federal regulations and various fraud-related acts and laws; that needs to be very escalated within your policy and procedures. And also, again, when you have a large organization that serves multiple lines of business, your policies and procedures and your code of conduct need to be specific to Medicare laws and rules. That was a huge finding that we saw throughout the audit process.

And this was the second item. I think we saw this at almost every organization, is that, you know, if you have a tracking mechanism for your policy and procedures, just make sure that you have a reporting system and a system that works for your organization to ensure that the policy and procedures for your compliance program, as well as your operational areas; that there's a tracking system to ensure that policies and procedures are updated; that they're identified as the business owner, and the main thing is ensuring that your FDR is your first tier down simulated entity, so that includes your PBM, your physicians, and any providers have access to your policies and procedures.

And I know a lot of organizations use an Internet or a web device to do that, and so our next question would be, like, how do you know that your FDRs and your employees are actually accessing your policies and procedures through this vehicle? Do you have a tracker or do you have a ticker? Is there someone that evaluates or calls up the FDR system to say, you know, does this mechanism work for you all? So that's something definitely to keep in mind.

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This next slide deals with – there was a lack of awareness around reporting mechanisms, your hotline, or let's say if you have a drop box in your lunchroom, that it was confidential, that you stated that there's – that the employee will not be retaliated against for reporting compliance or fraud, waste, and abuse incidents. And, again, this includes reporting mechanisms for your first tier down-related entities as well as your beneficiaries. What mechanism do you give them to report--let's say an incident of their troop balance is incorrect, and they're calling your customer service to say, "I didn't receive this drug, but it's, you know, on my EOB." What reporting mechanisms do you give beneficiaries to report fraud, waste, and abuse or any non-compliance issues?

This second bullet deals with that fraud, waste, and abuse training and compliance training, were not up-to-date and were not targeted to specific job duties. So, let's take for instance, if you – you know, I work in enrollment and disenrollment department, you need to kind of tailor – we've seen best practices of training that is tailored to that specific department so that I know what fraud, waste, and abuse looks like in my department and in my world, as well as non-compliance. What does non-compliance look for me with me handling an application or inputting information into an informational system? So that is definitely – you may have a broad or general fraud, waste, and abuse or compliance training, but it really, really works, and it is most effective when you tailor it to the specific job duty of the individual.

And then the last piece of it, there's a lot of attention around this with the OIG, GAO, as well as CMS, in regards to you have to ensure it's a requirement that the training is effective. And I know we've gotten into a lot of discussion with plans in regard to this, and we're open to any best practices you have, is how do you measure effectiveness? You have to have a benchmark, so you have to start somewhere. So, like, once you complete a training, do you, let's say in two weeks or so, conduct a quiz, or do you look at what your complaints looked like a month ago and you go a month late and see if your complaints have dropped down, or is this some – you have to have some benchmark in order to measure whether or not the training is actually working, and maybe you need to adjust it or make it more tailored to the individual.

This was a huge area in regards to monitoring auditing. There was a lack of a risk assessment for fraud, waste, and abuse and your compliance area, and this includes the operational units. You know, we asked a simple question and, you know, what type of risk assessments do you conduct? And, you know, a couple organizations will say, "Well, all of our Medicare operations are risk." Yeah, but how do you know which areas present the most risk to your organization? Is it your billing area? Is it your formulary division? Is it your delegation oversight? And it needs to be a risk assessment for each bucket of requirement, so the fraud, waste, and abuse, and we're also looking for a risk assessment of your operational areas.

The second bullet -- Michelle talked about this also -- is that the major functions were not being looked at by the area that was responsible for delegating oversight. And specifically the PBM, I know, was interesting for me. I went on, I think, ten audits last year, and where one organization no one even knew who was the primary contact between the parent organization and the PBM. And we were there for – I think this was, like, on the second day. It took into the fourth for someone to recognize, okay, this is the lead person. But there was just a total disconnect. And so I would just say if it's your PBM or provider unit or if you have a vendor that conducts your processing of your ANOCs or EOCs, like, you need to have extreme oversight over your entities to ensure that they are performing functions that are not only your contract between them but if they're submitting any information on your behalf to CMS, or just to ensure the ultimate we're trying to get to is that the beneficiaries are administered their due right service. So this is one that you really need to focus on that a lot of organizations struggle with.

These two areas deal with, you know, just tracking and ensuring that your reporting and responding timely to any incident that you receive of non-compliance. If you're receiving something from your operational areas or anything related to ethics or fraud, waste, and abuse, that you're not sitting on in, that you – once you receive it, that you're, you know, responding to the employee or to your first downstream-related entity, and ensuring that you are letting them know, I received your complaint, we're investigating this issue, and that you also, you know, make it aware that if – we've had some organizations that actually post, like, their disciplinary actions. They remove all the identifying information, but it shows – you know, it displays to the employees that, yes, they do take non-compliance seriously and these are – you know, this is how they will handle any type of disciplinary actions for non-compliance or fraud, waste, and abuse.

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And the second bullet here is, again, what we've seen with an enormous amount of entities that we audited this year. This is in regards to their compliance model that they currently had in place, did not support the requirements for Medicare Advantage and prescription drug. So, again, where Medicare was, you know, a small percentage of their business and was buried way, way, way down within the organization, and that definitely is not going to work. So it's really difficult to use a commercial business compliance model for your Medicare line of business. And I will say, this was actually confirmed through – when Michelle talked about our validation process, we have a new validation process for the compliance program piece of it, which is, like, the first part of it. We have invited the CEOs, as well as any senior management that they would like to bring with them, as well as a compliance officer, into our office, and they meet with Michelle, Brenda Tranchida, who is the director of our group, as well as others from our compliance team, to actually walk through the before and after picture of their compliance program.

And it's just been interesting to see directly from the CEO's mouth, the second bullet, how they tried to treat their Medicare line of business like their commercial. And many, they had to actually institute a lot of different reporting structures and oversight over this particular line of business.

Another area where organizations struggle with is with the OIG, provided exclusion list just failing to implement and oversee this process. I know it's a huge and daunting process, but it has to be done. And you have to ensure -- of course you know to screen our providers that have been disbarred from the Medicare program. So this is something that we will actually ask for proof that you have conducted this activity, and it's something that you need to really think about when forming your compliance program and you're approving it.

Failure to report fraud, waste, and abuse to the Medic, we just saw a disconnect between if you have an SIU department or the compliance department, just, were not talking to each other or were not forwarding appropriate cases to the fraud, waste, and abuse medic, as well as a lack of specific mechanisms to target fraud, waste, and abuse. So those that were audited this year, I know we really focused on, aside from just a general fraud, waste, and abuse requirements, a specific monitoring that you conduct in the high-fraud counties. And we're looking, again, if you have your PBM that conducts oversight over your PBM or, you know, trends and analysis, and you receive reports, what do you do with that information? How do you ensure that beneficiaries or providers are not billing inappropriately or exercising the over-utilized drugs, like, what do you do with that information, and how do you feed that into your organization to improve your processes?

So compliance program effectiveness, you know, it's up in the – a lot of people have, okay, what is effectiveness, but we have indicators of what is not, so you can just look through this. I won't really talk through all of this, just in the essence of time. But you see here when – just the bottom line, when a compliance officer does not have the authority to report to the board or the Chief Executive Officer. They just bury it down within the organization. There's four levels that they have to go to to say, "Hey, we have a problem here or a potential compliance issue in the Medicare line of business," and they just don't get the attention that they need. So it's really to help you all out in the industry.

Here, this, you don't have the reporting mechanisms as well as adequate and consistent disciplinary actions, and allegations are not effectively investigated. So some best practices that we've seen communicated with other organizations. You have to meet with your management and attend business operation meetings. You know, some – we've talked to some organizations, and one of the best practices that we thought that was really good was that the compliance officer actually rotated and sat in some staff meetings of the various operational areas, or they embed a compliance professional from the compliance department within the operational area. So they assign that person to the marketing department so that compliance person can, you know, focus on the marketing or the marketing guidelines and regulations and know, whoa, you can't do that, and keeps everybody, you know, the internal controls and keeps them in check.

Observe operations personnel during their jobs; so sit – you know, as a compliance officer of the compliance department, sit in at various operational areas, sit in appeals and grievances and see how they do their job, and see if it's possibly a broken system that you could provide technical or, you know, from a compliance perspective, a better solution.

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Coordinate with your Human Resources in regards to exit interviews. Using exit interviews, you know, you're more willing to give out, you know, what didn't work, you know, or how they can better improve their systems or infrastructure. So that is some great, great data that you can use with that.

And then celebrate improvements with the operations. We had one organization that told us – gave an example of, they had a marketing and agent problem, and so, you know, for a couple of months, and this one particular month their complaints were down in CTM and, you know, everybody was feeling good, so they actually celebrated and had, like, a 15-minute party with some cake and punch. But that way people feel – you know, you feel engaged, you feel energized, like you're actually making a difference, and you can actually see the work. So that's just a best practice that was shared.

At the organizational level, board agenda. I can't stress this more. Your minutes in any conversation, specifically small organizations, we know that you have – you know, I can just go to so and so's office and we'll hash out that issue. You have to document in regards to non-compliance or if it's in any of the operational areas or program issues – program areas that were evaluated, how was that – once you became aware of that issue or formulary issue or a CDAC issue, how did you communicate that to the respective areas and escalate that, if need be, to your Chief Executive Officer?

And educate your board on the line of business. We've met with many boards throughout this process, and we've actually one-on-ones with them, and they just did not know that this particular organization for which they sit on the board did not – that they did offer Medicare. So they need to really know what line of business that they're in.

Again, I talked about publicizing disciplinary actions, and business leaders need to be held accountable for compliance. I know Brenda says to us all the time that the compliance officer is really not responsible for compliances, it's really the business leaders within the organization and operational areas. So, again, institute – you know, talk with your CEO about how you can institute performance – or how they can really, institute performance evaluations and incorporate compliance within that. And also, offer incentives for people to – you know, when they're doing a better job or their performance has increased in regards to compliance or fraud, waste, and abuse.

This is just a slide just to give more information about your FDRs and education. It's just not enough to change behavior, you have to put your – you have to get down in the – you know, in the grind, and also, you know, let the organization, let employees know what happens, what's the consequence if I choose to up-code a particular procedure. You know, if that's the tone of the organization, you know, you're going to have those results, so really focus on that area.

And that is it at this time. I kind of rushed through just so we could have some time for questions and answers, but if you have any questions, my compliance team, we're actually definitely holding webinars as well as looking to get some training out there for you all. But if you would like to have just a one-on-one session, just to explain any regulations or best practices, you're definitely welcome to call me, we can get that going. Thank you.

Michelle: Thanks, Vernisha. So I think I'm just going to do the job of introducing Brian Martin who is going to talk to you about some findings from the formulary administration-focused area. Thank you.

Brian: Thanks, Michelle. So just to take a few minutes to talk about some of the things we found last year and, you know, more so we can help assure that these things aren't continuing to happen with other plans. We can't overstate enough the number of issues we found with transition, the effectuation of transition requirements. You know, we can hypothesize that this is, you know, maybe due because in your commercial line of business this is not – you know, this is not a requirement, so it's somewhat new or unique to Medicare, certainly not new as Michelle alluded to; nothing's really changed with our requirements.

And even specifically with transition, the most common sort of area in that topic has been the problems with transitioning members across the contract year who experienced a formulary change, and that, you know, it could be because that requires additional programming and having a look back in place and so on to identify effected members. But that was really the key area that we were finding.

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Other things that we found with respect to transition was, you know, we spoke of and issued a guidance – sort of a reminder guidance memo in August of last year about transition requirements, but it was the fact that some sponsors were implementing this hard edit at the point of sale. So when a member came in, that was perhaps affected by formulary change across the contract year, the claim was getting rejected with messaging going back to the retail farms and saying this is -- you know, could be a transition fill, call such and such phone number to get authorization to process the claim. You know, that certainly wasn't outside of our guidance, but what was the fact that there was no oversight or monitoring of this, so pharmacies, for whatever reason, weren't calling the plan, so what, in effect, was happening was that beneficiaries were leaving the pharmacy, numerous beneficiaries leaving without their transition fill.

So while that was a common practice that we were seeing, we didn't think that that's sort of the best way to operate the transition policy, because of this sort of inability to have that real time monitoring and communication with pharmacists. So we've seen a lot of sponsors switch to more of a soft messaging alert at the point of sale, notifying the pharmacist that this was a transition fill, but going ahead and processing the claim.

The sort of other common formulary area that we see problems with is just the failure to adjudicate the formulary that CMS approved. And this is ranged from just failing to program a drug appropriately; so a drug that did not have step therapy on your approved formulary was being adjudicated with step therapy requirements, down to sort of in the weeds where there was a drug that was previously on our non-match list, but was not on – was removed from the latest update of the non-match list, but that particular NDC was still rejecting at point of sale for – you know, the NDC for the drug was on the formulary.

So, you know, what was discussed yesterday, and what Michelle mentioned today as well was the importance of looking at your rejected claims. There's a wealth of knowledge that can be had from doing this activity and it's not – you know, not a terribly complicated activity, but looking at it on a regular basis daily would, you know, help you identify things as they're happening, system breakdowns, because that's pretty much all the findings that we've found in this area, were looking through your rejecting claims and identifying issues and then going onsite and looking at specific claims that rejected and shouldn't have rejected, and it sort of leads us down this, you know, additional path of finding other deficiencies related to your formulary administration.

So, again, if I could just, you know, for the sake of the Medicare beneficiaries and receiving their medications at the point of sale, to review your rejected claims on a regular basis because, again, it is a very critical activity that we're finding does truly help identify problems. So I think that's just what I wanted to share today. Thanks.

Michelle: And now Kathryn McCann-Smith is going to be speaking about coverage determinations appeals and grievances. Thanks.

Kathryn: Thanks, Michelle. And I'll just, again, go over some of the more common findings in the area of coverage determinations, appeals and grievances. Primarily what we saw, which we were, you know, a little bit surprised about, are findings related to inadequate systems and processes for doing some basic things like tracking when the request comes in, having a means for daytime stamping that request so you know when it comes in, and having a tickler system, which tells you when the enrollees should be notified of a decision.

We also saw some problems with situations where if the request was maybe received in the wrong department, there was no means for triaging that request to the appropriate department for processing. So, again, I mean being able to take a look at your processes for how that request is managed when it comes in the door is critical because then that flows down to everything else related to it. When is the notice due to the enrollee? Do you need to solicit supporting documentation from the prescriber in order to make a substantive decision in the case? And if you are, you know, doing your due diligence and soliciting that information, are you properly documenting that you're making those efforts?

And related to that were some findings around exceptions requests, which, of course, are coverage determinations. They're a subset of coverage determinations. These would be, for example, a request for an off-formulary drug. And it's really critical that you have a means for identifying those requests, because in that case your adjudication timeframe starts when you receive the necessary prescriber supporting statement. So, again, it's critical to, you know, one, identify that

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request as an exception, and then proceed with soliciting and obtaining the prescriber's supporting statement, and, again, being able to track, then, when the notice is due to the enrollee.

And, again, kind of how some of these problems trickle down to other areas, if you're not properly tracking when your decision is due to the enrollee, then we also found situations where plans were not following our rules to auto-forward cases to the independent review entity. If you miss your adjudication timeframe, that case has to then be auto-forwarded to the Part D independent review entities. So it's really critical kind of to be looking at those front-end processes and how you're managing those requests when they come in. And these same issues were identified at the redetermination level, at the appeal level as well.

Some of the other items that we identified were failure to expedite requests if, say, the enrollee's prescriber noted that the decision – the need for decision was urgent or life-threatening or if there was an immediate need. We also identified some issues with improper classification of grievances versus coverage determinations and identified some areas where the plan wasn't necessarily providing an appropriate resolution to a grievance. We had one instance where the plan had determined that the enrollee got frustrated with the plan CSR and terminated the call, and that was considered a resolution to the grievance, and we would not consider that a proper resolution.

So, you know, you should be taking a look at your grievance logs; that will help you identify some of the things that may be going wrong in your processes. Just as Brian mentioned, that you should be looking at your denied claims. Another area to be reviewing periodically would be your grievance logs and your denied coverage determinations.

The other area related to effectuation of favorable decisions, we found some instances where even if you issued a timely favorable decision to the enrollee, that was not effectuated in a timely manner in your claims system. So you should, you know, have proper linkages between, you know, making those decisions and ensuring that those decisions are properly effectuated.

So just really to wrap up, the message we want you to take away is that we would consider material deficiencies in the area of coverage determinations, appeals and grievances, to pose risk to the enrollees to the extent that it's impeding access to necessary prescription drugs and that we would encourage you before we come on-site for you to do some internal audit activities and take a look at your processes related to in taking requests and how those are triaged and your processes related to timely auto-forwarding cases to the independent review entity, again, your systems issues with respect to ensuring timely effectuation, and reviewing your grievance logs to, you know, help you do some early identification of problems.

And I think now, last but not least, we're going to hear from Tawanda Holmes who's the director of our audit division.

Tawanda: Good morning. We received three questions in advance, so I just want to share those questions with you and respond appropriately. Question one, why did it take so long to get my audit report? The answer to that is, as Michelle and Vernisha pointed out, this was a brand new process for 2010. We also hope that those lucky winners found that as an opportunity to improve their operations. However, the delay in the reports, we had to kind of stand down on the reports for a minute to focus on beneficiaries who did not receive access.

As Michelle pointed out, this was a new process, and at the beginning of 2010 we were not sure if we were going to look at formulary administration. But as we started going through the audit process and we found that beneficiaries indeed, were not receiving drugs that they were entitled to, beneficiaries' coverage determination requests were not handled appropriately, we had to focus our attention to those.

Second question is when will the 2011 begin and what is the focus to 2011 audits? When will they begin and what will be the focus? As Michelle pointed out, after the risk assessment is completed, those new lucky winners will be identified and we will know what we will focus on for 2011, the specific areas.

And lastly, how to prepare for the 2011 audit process? Well, as Vernisha pointed out, please keep your senior management involved, keep them aware of your issues, and lastly, please oversee your PBM. I cannot tell you how many

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times during the audit process we had to have calls with sponsors and they didn't have a clue to what their PBM was doing. We get the idea that you all pay them, you have this contract with this PBM, but ultimately, the sponsors are responsible for the contract that they have with CMS. Thank you.

Michelle: And I think we do have some time, if there were any other questions from the audience, I think we'd be happy to have those. Thanks.

Jill: We have one right up front.

Audience Question: I'm [Audience Member's Name Withheld] and I found this session very helpful, very informative. In the compliance context, it appears as if your requirements are evolving and getting more specific, and my question has to do with is your plan to include a lot of this – in a sense it's new, and in a sense it's not new information, but the more detailed information in the revised chapter nine that will apply both to MA and to Part D, and if so, what's your timeframe for that, and is chapter nine going to be sort of re-titled "Compliance" with a subpart "Fraud, Waste, and Abuse," or is it going to keep the same title?

CMS Panelist: Sure, I can answer that. In regards to – we're working endlessly on chapter nine, and it will include the compliance program, the non-compliance piece of it as well as fraud, waste, and abuse. So stay tuned. I know we've been saying it, but we actually have a working draft. It's just I will tell you the persons that are working on this particular project, we've just completed so much research. There are so many resources that are out there, articles and different positions, that we've consulted with various entities to include some best practices and things like that. So just stay tuned. We're really, really working on that. So hope – we're praying, have our fingers crossed by the summer time that you'll have that released to you all.

We're also putting together a resource list of all the articles and resources that we've used to provide additional guidance to organizations. So stay tuned for that also. Hope to get that out really soon. And Michelle talked about a self-assessment tool. We're putting that together also to release to the industry to help you identify the self – yourself – your compliance program. It will be similar. I know OMIG – the New York OMIG has one on their website, as well as the Health Care Compliance Association has one that we've used as a basis too. So until we get ours out there, those are two resources that you can use in the meantime. But we're working on it.

Jill: Good. There we go.

Audience Question: Hi. I'm [Audience Member's Name Withheld] from [Organization Name Withheld]. Unfortunately compliance officers, on a daily basis have an issue with a group of folks called lawyers, and the legal team at many of our health plans don't consider it any type of conflict between compliance and legal. Their comment has been that the OIG in 1999 had in a note published in the Federal Register as part of its guidance to Medicare Plus Choice organization stated that they didn't think it was a great idea to report to the legal department. But according to lawyers, that didn't that it was really a rule, that it wasn't that they could point to as a regulation.

The last number of years, more and more CMS has gone to an attitude that the compliance officer should not report to legal counsel at all. Unfortunately, in large organizations like HMOs with multiple lines of business, the compliance officer has a straight line to the board of directors in the way of reporting but dotted line to either the president of the line of business or the Chief Compliance Officer was also part of legal department. What would be your attitude about that line of reporting?

Vernisha: I would – again, this is Vernisha. Are you aware of our new regulation that became effective on January 1st, 2011?

[Audience Member's Name Withheld]: Why don't you describe it.

Vernisha: Okay. Sure. The news regs that were released that became effective in regards to implementation on January 1st, 2011, specifically speaks to the compliance officer, not just the reporting, but having that access to the governing

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body of your organization, as well your – the senior management or, you know, your Chief Executive Officer, as well as – I'm just looking here at the reg that I have in front of me – that the governing body of the MAO or PDP sponsor must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance program. So I know this is something I was going to speak to in regards to we've had some conversations with plans with your issue with compliance officers reporting to general counsel. Our position with that is that we've seen that information has – or reports have been edited, there's not a –

[Audience Member's Name Withheld]: Understood.

Vernisha: There's unfiltered information, you know, you don't get the direct of what's actually going on. But we're open to a discussion. We've had two discussions with plans in regards to this issue. So if you would like to, you know, schedule a call with us or with your senior management or with your general counsel to explain our position and why it's not a good practice, we're open to that.

[Audience Member's Name Withheld]: Well, no, as a compliance officer, I understand it's not a great practice. That is well within. What I'm trying to do is convince general counsel that it's not a great practice.

Vernisha: Exactly. And we've done that. We'd be happy to have that conversation with you. I mean, their point is fair in that it's not an out and out requirement at this point.

[Audience Member's Name Withheld]: Correct. And that's what they keep telling me over and over and over again. And they feel that my ability to report directly to the board of directors gives me enough reach to be able to report any situation. But there is, in fact, a conflict according to what I look at. But they said there's no rule or regulation, there's just guidelines. And you can guide all you want, but, you know, their lawyers – I hope there's no lawyers here – they're the legal department, and I have that issue. So we'll be calling you.

Vernisha: Sure.

[Audience Member's Name Withheld]: Great.

Vernisha: Thank you.

Jill: That's great. We have a question right up here, Jack.

Audience Question: Hello. Good morning. I'm [Audience Member's Name Withheld]. I have a question regarding risk assessment. There is one sentence in an October 2010 memo from CMS that discourages drug plan sponsors from using the high-dollar trigger at the point of sale because it just might restrict access. We actually use – I know that drug plan sponsors would like to use the high-dollar trigger really as a risk assessment, and we can set that at some -- maybe two times what commercial is and so on and so forth, but a lot of drug plan sponsors now, they actually have shied away completely from having that added. And we are seeing, you know, potential FWA at the point of sale.

So if CMS could provide some guidance that you would not interpret that strictly. And I think that you really don't, you really are not asking drug plan sponsors not to use that, but you just don't want the drug plan sponsors to use that as a way to impose more PA guidelines, right, that are approved. So if you could give some clarity to this discouragement, I think it would be very helpful. And the other issue also is related to over-utilization.

Again, a lot of drug plan sponsors are under the impression that lockdowns are prohibited. You know what I mean by "lockdown." Can you also provide some guidance as to the threshold that CMS would tolerate if we want to implement a lockdown.

CMS Panelist: Okay. Thanks, [Audience Member's Name Withheld]. First, with respect to the high cost or high dollar edit, it's not – certainly not outside of our guidance, and that's a common practice and a good practice to identify anything

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from over-utilization, like you're mentioning, or fat finger errors at the pharmacy. The problem that we saw, I can speak to a couple, you know, audits, one was a high-dollar edit on, you know, any drug, HIV drugs particularly came up, where the reject was coming back prior authorization required, so they rejected under a 75, or also for cancer drugs, Glevet, for instance, and then the drug didn't have PA on the approved formulary, but yet it rejects with this PA required. The beneficiary went through the PA process despite already being on Leveck, so that's another sort of error that, you know, shouldn't be PAing the drug anyway because the member has already been on it. And then the request for – you know, for the approval was denied. So that's sort of one extreme of how not to do a hide cost edit.

Another that we've seen recently is a threshold set so low across the board that drugs were just left and right rejecting without any sort of messaging to the pharmacist to advise as to what the rejection was or what the – you know, what to do to have the claim process successfully. So there's – it's not outside of our guidance. It's a good tool to use, it's just it needs to be implemented in a way that really basically uses common sense. And I think what would be ideal is the edit at specific drug level so you're not, you know, rejecting every drug with a claim of \$500, but rather, adjusting it appropriately for the drug at which is being requested.

And then your second question related to –

[Audience Member's Name Withheld]: Lockout.

CMS Panelist: Oh, yeah, lockout, which, you know, I don't – I can't – policies not – I can't really speak on behalf. But, you know, pharmacy lock-in is not permitted under Part D, but you certainly have a lot of tools that you can use. So over-utilization should be identified by therapeutic duplication or early refill edits at point of sale, for instance. So there are other things in your toolbox to sort of prohibit just wide open access to Part D drugs.

When we're seeing multiple doctor shopping, provider shopping, you know, this behavior or utilization pattern like that. We have reasonable cause to believe that maybe there is some potential abuse there, but it's just – drug plan sponsors are just scared to death that if we put a lockdown, that CMS would consider that restriction to access, and you end up just kind of letting it go.

Mm-hm. Yeah, I mean, again, you know, concurrent DUR edits can be used to identify these issues, as well as reviews, retrospective reviews, and, you know, referral to the medic, and, you know, communications with the providers and so on. So those are some of your other tools besides a pharmacy lock-in.

And I would just like to add, we definitely – the medic, we definitely want to take that kind of call. If you have suspicion of doctor shopping, they can then further investigate the issue.

Audience Question: I'm Bobbi Nickman from CPI, Center for Program Integrity.

Jill: Okay. Thank you. We have a question over here.

[Audience Member's Name Withheld]: My name is Levi Miller. I'm with Geisinger Health Plan. I have two questions. The first thing I wanted to say was thank you very much for your presentation, and I found it to be very informative. My first question is about audits in general and the scheduling of them. We have recently – we close out an audit of financial activity in January, and before the exit conference, we were informed of another activity audit for the following year. We are presently involved in a RADV audit and have already been identified as an organization that will participate fully in that RADV audit.

And my question is with respect of these audits, are there internal discussions within CMS about the burden, administrative and otherwise, that's placed on organizations who are repeatedly selected for these audits; and in particular, does your area, Ms. Turano, engage in those discussions so that organizations aren't stretched too thin with respect to responsive resources? That's the first question. Would you like me to ask the second?

Michelle: Well, I can answer the first one. Sure, I'll go ahead.

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[Audience Member's Name Withheld]: Okay.

Michelle: And the answer is yes, absolutely we are engaged in those conversations. Those other two audit activities, the 1/3 financial audits and the RADV audits are not – they're not conducted out of my group; however that's not an excuse for me to be ignorant of their processes. And so obviously the 1/3 financial audits are governed by – you know, that's a different decision-making process in terms of who is going to be audited and when. You know, that's a statutory requirements that 1/3 of the plans get audited every year. So I can't tell you that that one is – I have any impact on whether or not you're going to get chosen for that one.

And RADV is obviously run under a different process as well. Ours is then governed and driven by risk assessment. So I appreciate – you might also get GAO and OIG come by while you're at it as well. So we absolutely are aware of the fact that there's quite a bit that's imposed by these audits. And to the extent possible, we do attempt to coordinate and at least be aware of it so that – you know, we have to be sensitive to that fact because it's not doing us or you any favors to have, you know, a summer that's entirely taken up by responding to CMS audits. I don't think that's a good way for you to spend resources, and I'm sure you don't either. So we are sensitive to that fact. To the extent that we can be reasonable and minimize the burden, we are attempting to do that.

But I would say that if you – if and when you are or others find yourself in that position, you know, we can do our best to be aware of it, but please call, and you're welcome to call me, even if you're not one of the lucky few to get a performance audit. If you feel like CMS is being blind to the fact that you've had eight different, you know, entities in to audit your over the past three weeks, I think it's perfectly reasonable for you to raise your hand and let us know and give us a chance to make some modifications to the schedule for you.

[Audience Member's Name Withheld]: Thank you. I'd like to raise my hand and say that (INAUDIBLE).

Michelle: Duly noted. Thank you.

CMS Panelist: Before you ask your second question I just want to just expand on Michelle's response. We actually work coordination with the Office of Financial Management. As they wrap up their 1/3 audit results, they sent them to our shop, where we are responsible for coordinating with the plans as far as reviewing their corrective action plan. Just recently, within the last month or two – we haven't told the boss yet – within the last month or two we have been kind of creating a grid, so to speak, to try to identify all the audits that – the specific audits that specific plans are currently being audited for. This includes, like, the OAC audits, the bid audits, as well as the 1/3 financial audits, our audits. That way we are able to assess in some type of collaboration, and it may be possibly – I know this will be good news – possibly all of us may be going out at the same time if possible, if that would work with some people. For some people that would work. Oh, is that a round of applause? I'm liking that. If that would work for some plans we're open to that, but that's just that we need to discuss—we have to discuss that with the boss, but we are looking into that.

We're sensitive to the issue.

[Audience Member's Name Withheld]: Thank you very much.

CMS Panelist: Thanks.

[Audience Member's Name Withheld]: Very quickly, the second question. With respect to the potential for conflict of interest when a compliance professional also serves in a counsel capacity, if I'm understanding correctly, there is actually no regulation at this time. The gentleman from Blue Cross mentioned that. Yet, CMS would still note a deficiency, and I assume it would be an official deficiency where that potential exists within an organization. Where is the authority for making that sort of finding in the absence of regulation? Thank you.

CMS Panelist: You're correct. There were instances over the summer where we did note and observe that there were – where a compliance officer did serve in that sort of dual capacity, and we did note it as an observation and a finding. And

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while I appreciate and am sensitive to the fact that there's no specific statutory or regulatory prohibition on a compliance officer serving in that official function, we really feel very strongly, and will be updating our sub-regulatory guidance to reflect this, that those two positions, the general counsel and the compliance officer, there's just an inherent conflict of interest in trying to serve that dual function because – and I think even the gentleman from California was sort of agreeing with this point that, you know, our sense is that general counsel's first obligation is to protect and advise the company.

The compliance officer, I'm not always – probably some compliance professionals would disagree with me, but their first priority is different, and they can be put in an extremely uncomfortable position at times. And so while I'll concede the point that it's not within regulation right now, based on best practices, based on our research and interpretation and our own CMS sub-regulatory guidance, we feel strongly that this creates such a conflict of interest that we feel compelled to note it as a finding. So I don't – and I don't think we'll – I don't think we see ourselves changing that position. In fact, we'll be moving in the other direction to strengthen our guidance and to strengthen, maybe not the regulations at this point, but all the sub-regulatory guidance to support that fact.

His question was do we anticipate compelling organizations to separate those functions. Well, you know, if we don't have the authority, we don't have the authority to mandate such a move. However, I will say that we did have several conversations over the course of the summer where sponsors, in response to the conversation and response to a discussion – a very fruitful discussion of the issue, did choose to make that split, and I'm very pleased to report that. So I can't mandate that an organization would do that. All I can do it strongly recommend it. And, you know, I'm pleased when an entity chooses to take CMS recommendations on the issue. Thank you.

Jill: We have a question in the back.

Audience Question: [Audience Member's Name Withheld] from [Organization Name Withheld]. We have been using the audit guide as a tool for our monitoring and auditing. It has some useful worksheets and so forth that I know have a long history but had continued, and we use them. And given the new direction that CMS seems to be going in and the decline in the emphasis in the audit guide for areas that CMS hasn't given us an alternative for, what would you suggest we use to do our monitoring and auditing, specifically pulling universals, looking at samples, are there other mechanisms that we should be using in lieu of the audit guide?

CMS Panelist: Sure. Let me answer in a couple of ways. Number one, I don't want to give the impression that the old audit guide, you know, is a dinosaur now and completely useless. I think that it's a useful guidance document in terms of just the way you described it; in terms of sort of guiding your internal audit; however I would not use that tool in isolation. I would suggest that there are a variety of ways for you to target internally areas of risk for your own organization. I mean, obviously, the ones that we listed off that we covered in audit for 2010. You know, you could expect that CMS would likely want to cover those same areas moving forward, because we obviously had so many issues over the summer and so many findings that they all, I would say, continue to be areas where we want to, you know, focus our efforts.

So I would say – let me make two more points. I'm, like, thinking ahead before – I'm thinking faster than I can talk. Number one, the tools that we used this past summer, both in terms of conducting the audits and the documents that are out now in terms of how we will conduct corrective action and validation, while we haven't posted them on the website or issued them through HPMS, they're out there. Ask your colleagues in the room. If you're part of one of the associations, you can get to those documents. So I would say, get a copy of that updated guidance from 2010 and use that for monitoring and auditing.

Number two, in terms of the other areas that weren't covered by the more recent guidance, I do think – and we worked with our regional office colleagues around these topics because they, frankly, asked the same question, what tools are there to do monitoring for the areas that aren't audited? I do think you can use the old audit guides for that purpose. But, again, those guides tend to be focused on policies and procedures, and I think we all have larger concerns than policies and procedures at this point.

I would focus, to the extent that you can, on drilling down into your complaints within the complaints tracking module, I would drill down into your grievances as Kathryn was saying, into your own call center and the complaints that you receive

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internally that CMS never gets; I would really target your monitoring and auditing efforts around those areas of risk. And in the absence of anything else, I would continue to use the audit guide to direct your internal auditing and monitoring.

And I'm sorry, I want to be sensitive with the time, I know we've gone over the time allotted for our session and I'm getting the queue to wrap up, but we'll all be around at least for a little while afterwards. So we can stay here and take some more questions or you can grab us in the hallway, whatever people are most interested in. Were there anymore questions at this point?

Jill: We have one right there.

Michelle: One. There was one more?

Audience Question: I'll make it quick.

CMS Panelist: Sure.

[Audience Member's Name Withheld]: Okay. It's two questions. One is about the OIG exclusion list. And we would love to be able to meet the requirements of using the exclusion list except that what the OIG and CMS has said about the timing is not true. So the exclusion list is not updated 15 days before the effective date. There are retroactive adjustments to the effective date to the provider's exclusion as well as their reinstatement. And also, the OIG exclusion list uses a UPIN, which is basically a dinosaur number that the industry doesn't use, and there are actually doctors with the same name. So when we are trying to coordinate the information that's on the OIG exclusion list with finding a real doctor or finding a real pharmacy, we have received a lot of heat from physicians who are saying, "Well, you're saying I'm excluded, and I'm not."

And then there's apparently a magical type of exclusion where you're not officially excluded if you're, for example, a doctor in a remote part of Pennsylvania that's the only cardiologist in the area. And they have these exclusion exception letters where they can be written by a governor or someone, and that doctor is allowed to practice even though they show up on the exclusion list. And the regional offices are telling us that we have to find a mechanism for allowing that doctor to provide for a certain type of medication, but we have no way of knowing who they are, and since we can't impose new prior auth criteria, there's no way for us to really do that. So that's one.

And number two, I know that this is not your team, but, would CMS – or could you let us know where we should – who we should contact to make recommendations about the 1/3 financial audits? We're PBM, and we've seen four of the five contracted auditors. We've identified some opportunities for improvement, especially with regard to the auditor's understanding of the pharmacy industry, and there are things that we think could speed up the audits and improve CMS's ability to, you know, find opportunities for improvement and do general oversight. And so is there an opening or is there an opportunity to discuss that with CMS and who should we contact?

CMS Panelist: Well let me answer the first half of the question because that's the easiest one. Even though we're not responsible for the 1/3 financial audits, you're welcome to contact me, and instead of me throwing out somebody's name to you right now, please go ahead and contact me and we can facilitate that conversation. And Bobbi, do you want to –

CMS Panelist: As far as the OIG exclusion list, we know that there's, you know, like you mentioned, the lag and things like that. We are working on getting you more information on a more regular basis from the Medicare exclusion database, which is something that we maintain in-house. You can always call the MEDIC if you have an issue with a particular provider and, you know, they can check and find out if, you know, that person's got a waiver or whatever. We can certainly investigate that, because we do grant waivers, especially for underserved areas. So we know that's a conflict, so we're working to get more information to you sooner rather than later. We recognize that there's, you know, some vulnerabilities there. Okay.

Thank you. And let's give a round of applause to Michelle and her team.