

## TRANSCRIPT

### CMS 2012 Maryland Room Session 1

Good afternoon. Welcome back from lunch for those of you who were at lunch this afternoon here on the East Coast. For those of you viewing on the webcast, hello. This is the Compliance Program Guidance Break Out Session. You are in the Maryland Ballroom. We'll get to that at the end when it's time to submit feedback on today's session.

My name is Abe Hollander. I'm from the Central Office at CMS. And I'm here to introduce a couple of my colleagues from the Division of Compliance Enforcement – Marianne Bechtle, Philip Sherfey, and Beth Brady will all be speaking to you today. Please welcome them.

Thank you. Good afternoon and thanks for coming today. As Abe just said, my name is Marianne Bechtle, and I'm at Central Office in the Program Compliance and Oversight Group, Division of Compliance Enforcement. The purpose of today's presentation is to give you an overview of the highlights of the new Compliance Program Guidelines. We won't be going into detail today on the individual elements; however, I will tell you that we are planning detailed training on the individual elements starting later this fall. So keep an eye out on HPMS and we'll be announcing it.

As Abe said, joining me in today's presentation is Philip Sherfey, also of the Division of Compliance Enforcement. And I'm pleased to be joined by Beth Brady from the Center for Program Integrity, Division of Plan Oversight and Accountability.

Our agenda for today will be the overview, as I just described. In addition, we're going to give you a little bit about the background on how we came to the final version of the Compliance Program Guidelines. We will be leaving time at the end for questions and answers. And in addition, we have developed a process for those of you who want to ask a question at any time – not just at the end of this presentation – to send it to our Compliance Division mailbox and we will provide an answer.

As you know, Chapter 9 has existed since 2006. However, we are referring to it as a new chapter because there are marked differences between the Chapter 9 as it exists now and Chapter 9 from 2006. First of all, old Chapter 9 was devoted to fraud, waste, and abuse only and only applied to Part D. The new Chapter 9 also covers in addition to fraud, waste, and abuse, Medicare Program Compliance. And in addition, we now have Chapter 21 of the Medicare Managed Care Manual, indicating that Chapter 9 and Chapter 21 Program Compliance Guidelines also apply to Medicare Advantage Plans as well as Part D Plans. The two chapters are identical, and they are effective immediately.

As to the background on the final version, I'd like to take this opportunity to thank everyone in the industry who submitted comments. We found the comments to be very thoughtful and very helpful to us in drafting the final version. The final version of Chapters 9 and 21 is the result of our review of over 900 comments. The topics that were the subject of most comments were FDR oversight,

content, and other requirements surrounding policies and procedures and standards of conduct; the role of the governing body and senior management in the Compliance Program oversight; compliance training of deemed providers and whether it's required; and the frequency of the requirements for checking the OIG and GSA Exclusion Lists. The final version was published on July 27, 2012.

I'm going to go through – in fact the whole presentation will go through the chapter in order. First thing, the introduction talks about – what is the definition – when we talk about something “must” be done or when we talk about something “should” be done in the chapter, or that something is a best practice, what do we mean by that? There was a lot of industry question about it. “Must” means mandatory. It means that the requirement is either stated expressly in the regulations, or it's stated by necessary implication. It indicates a required action or condition that must be carried out by the Sponsor in order to be compliant. If it says “must,” there is no discretion.

“Should” indicates an action or condition that CMS thinks is necessary to meet the statutory or regulatory requirement. However, a “should” isn't a must because maybe you have another way of meeting that statutory requirement. And if you do, that's fine – as long as whatever you're doing is effective, because what we're striving for is an effective Compliance Program. So we will leave that discretion to you, but we will – when we come to audit you – see whether what you're doing allows you to have an effective compliance program.

Best Practices – there was some talk about that this morning. Best practices are practices that we have learned in the course of our oversight that some Sponsors use to have an effective compliance program. It doesn't mean that these necessarily are best practices for every organization because organizations come in all shapes and sizes. It's just something for you to consider, depending on the configuration of your organization, as something that may work for you.

Now, I've skipped Section 20 of the chapter because that's our definitional section. And while there are some new definitions, I think they speak for themselves.

Section 30 identifies the seven elements of the Compliance Program, but I think the most important aspect of this is it talks about and defines what we mean when we say that a Sponsor must have adequate resources. Adequate sources are defined by reference to the activities that a Sponsor must have the resources to conduct. So for example, you must have adequate resources to oversee your FDR's compliance, to identify risks, to audit and to monitor on a routine basis, and to respond to findings of non-compliance and fraud, waste, and abuses. These are things that you must have adequate resources to accomplish.

Okay, on the subject of FDRs, we got a lot of questions around, “How do I identify which organization that we've delegated functions to as an FDR or not? And it's important because FDRs have certain compliance requirements that they have to meet. Because Sponsors are ultimately responsible for compliance by their FDRs, we have left it up to Sponsors to determine which delegated entities qualify as an FDR and which do not. The Guidelines to help you in making that determination – we have given you a list of certain functions that we believe are clearly related to the Medicare benefit. And therefore, if the delegated entity is performing one of these functions, then chances are extremely high that that delegated entity will qualify as an FDR.

Now, just because a delegated entity may not be performing one of those functions, however, does not mean that it is not an FDR. If it's not clearly an FDR that is performing one of these functions – or not clearly not an FDR, such as maybe your lawn crew or something like that – then the Sponsor should go through an analysis of the facts and circumstances to determine who is an FDR. And we've given you certain factors that you can consider in making that determination.

Element I, Standards of Conduct and Policies and Procedures – We have defined Standards of Conduct. They are the overarching principles by which the Sponsor conducts its business. Many organizations have their own what they often call “Code of Conduct.” And we got the question, “Well, are Standards of Conduct as referred to in Chapter 9 and Code of Conduct the same thing?” Essentially, the concept is the same. And so the Standards of Conduct that you may have for your Medicare Program may be inserted into your organization-wide Code of Conduct.

Also where the old guidelines were silent, the new guidelines now make it clear that if you have Medicare content for your Standards of Conduct, that may as I said be inserted as part of your corporate Code of Conduct or it may be in a separate document, but you don't have to have a separate document for your Medicare Standards of Conduct.

When we talk about policies and procedures in Element I, we're talking about compliance policies and procedures. We have, as I said, required content in the regulations; but it may be in either Standards of Conduct or in Policies and Procedures. It does not have to be in both.

One thing that we have clarified is that in order to have an effective Compliance Program, your Standards of Conduct and Compliance Policies and Procedures must be distributed. It's not enough to have them sitting in a book on a shelf. They have to go out and be distributed to your employees and to your FDR's employees. However, we leave the method of distribution up to you. And this chart gives you some examples of methods of distribution and also the timing requirements.

Another change that we hope will be helpful is that Sponsors do not have to require FDRs to distribute their own Standards of Conduct. Having a Sponsor make that requirement of an FDR that has multiple sponsors as clients became troublesome for FDRs. So therefore, the new requirement is that the FDRs have to have some Standards of Conduct. They can be either the FDR's own Standards of Conduct, they can be that Sponsor's Standards of Conduct, or they can be the Standards of Conduct of some other Sponsor as long as they are comparable and meet CMS requirements.

Element II -- Compliance Officer, Compliance Committee, and High-Level Oversight – We have clarified that Sponsors do not have to have a separate dedicated Medicare Compliance Officer. If you have Medicare business and other government business and/or Medicare business and commercial business, you can have the same Compliance Officer that for example oversees your commercial business also oversee your Medicare business. I think Sponsors have to make a decision in whether or not they're going to have a dedicated Compliance Officer by reference to the facts and circumstances.

We think at CMS that it's a good idea to have a separate Compliance Officer dedicated to your Medicare business if only because the Medicare requirements are so different from commercial business. So we do have that recommendation. It is not a requirement necessarily.

The regulations speak in terms of a direct reporting relationship between the Compliance Officer and the CEO. When we talk about reporting relationship, we don't mean an administrative reporting relationship – that is, that the Compliance Officer does not have to report to the CEO, and the CEO doesn't have to check the Compliance Officer's travel vouchers and things of that nature. When we're talking about a reporting relationship, we're talking about the reporting of information. So there has to be a direct reporting of information relationship between the Compliance Officer and the CEO. We want the information to go unfiltered from the Compliance Officer to the CEO because we don't want it to get stuck midlevel. The CEO needs to know about compliance activities and compliance information in your Medicare operation.

The reporting can go from the Compliance Officer if not directly to the CEO; it can go through the Division or Business Unit President. The information, however, should not be filtered through operational personnel. So it's not okay to have it go from, for example, the Compliance Officer to the President and Head of Marketing. It has to be more direct than that.

As to reporting to the Board, we have clarified that the Compliance Officer must also report either directly to the Board or that the reporting may go through the compliance infrastructure. So that would mean the Compliance Officer – if there's a Medicare Compliance Officer – could report it to the Corporate Compliance Officer, who would then report it to the Board. Or it could go through the Compliance Committee. The Compliance Officer could report it to the Compliance Committee, who would then report it to the Board.

Similarly to the Compliance Officer, you do not have to have a dedicated Compliance Committee dedicated to Medicare only. If you have a regular corporate Compliance Committee, your Medicare information can be considered and overseen by that committee.

Also, we've clarified that when the Compliance Committee makes reports to the Board – and also this would apply to the Compliance Officer – reports may be made to a committee of the Board. So it wouldn't have to be to the full Board of Directors. It could be to, say, the Audit Committee or some subset of the Board of Directors.

If there's anything that the 5-Star Plans said this morning, it was the importance of engagement by the senior leadership and the Board in the Compliance Program. We've had questions in the past about, "Okay, if the Medicare contract holder is a subsidiary, which Board is it that's supposed to be conducting oversight? Is it the subsidiary Board or is it the Board of the parent company?" Previously we required that the Board of the parent company oversee the Medicare Compliance Program. The new guidelines make it clear that this is going to be from here on out up to the Sponsor itself. If you are a subsidiary, the oversight of the Medicare Compliance Program can be either by the subsidiary's Board or it can be by the parent. It's up to the Sponsor.

Also again, while the full governing body remains ultimately responsible for the Compliance Program, we've clarified that the full Board may delegate certain Board oversight responsibilities to

a smaller committee of the board, such as an Audit Committee. And in addition, it may also delegate some responsibilities previously required of the Board to senior management.

Like the governing body, previously it had to be the CEO of the parent company that had to conduct the oversight of the Medicare Compliance Program where the contract holder was a subsidiary. Now it can be the CEO of the subsidiary contract holder or it can be the CEO of the parent.

I'm going to turn the presentation now over to my colleague, Phil Sherfey, who will go over some of the next elements for you.

Thank you, Marianne.

And good afternoon, everyone. We appreciate you selecting this particular breakout session. We hope it will be informative and enjoyable for you.

Moving on, briefly I'm going to continue now with Element III, which are the Requirements for Effective Training and Education. The revised guidelines reemphasize the training and education requirements for all employees who are involved in the Medicare Program, as well as senior management and Board members. We remain concerned that particular Sponsors still are not implementing training requirements for their Board members which, as has been emphasized in this session this morning, the Board oversight is critical to an effective compliance program.

The Guidelines also provide various methods/examples of how the particular training requirements can be accomplished, such as structured training through classroom training environments, online training modules, and distribution of the Compliance Policies and Procedures and Standards of Conduct with accompanying attestations that the employees, Board members, senior managers have indeed accepted, read, and agreed to comply with those Policies and Procedures and Standards of Conduct.

Also a quick note – the Guidelines define the requirement that's in the regulations for the training to occur at orientation. The Guidelines define that to be within 90 days of hire -- within 90 days of hire in the case of employees, or within 90 days of being appointed to the Board in the case of a Board Member.

Moving on to Training and Education for First-Tier, Downstream, and Related Entities -- In regards to the compliance training aspect of those education requirements, the Guidelines confirm that which is required. The requirements and principles, which is emphasized in Element I and Element IV, that is, that the compliance information must be communicated to first-tier, downstream, and related entities and compliance expectations – that is, compliance information such as the reporting mechanisms that the Sponsor has established for reporting incidences of non-compliance and potential fraud, waste, and abuse and compliance expectations – such as expectations regarding investigating, responding to, and correcting instances of non-compliance and again, potential fraud, waste, and abuse.

The Guidelines also provide various methods/examples of how this training requirement may be satisfied – such as, again, distributing -- as Marianne was talking about – distributing the Sponsor's

Standards of Conduct, policies and procedures to the first-tier, downstream, and related entities, providing those through provider guides, business associate agreements, contracts, etc. So again, the theme is that we're providing various methods of how these particular requirements might be satisfied by the Sponsor in order to accommodate your particular program.

Beth Brady is going to briefly touch upon the fraud, waste, and abuse aspects of training. And then I'll return and continue with the Element IV Effective Lines of Communication.

Again, good afternoon. As Phil mentioned, I'm just going to speak the next couple slides on fraud, waste, and abuse training. I'm only going to address the highlights since much more detailed information is contained in the chapters.

The new Guidelines clarify that Sponsors must provide fraud/waste/abuse training to all FDRs, not just pharmacies. As you can see, we've indicated the who, the when, and the FDRs. I do want to stress that with the when, it is to be provided within 90 days of hire and then annually thereafter. One of the things I do also want to mention, if you'll recall that in May of this year we issued an HPMS Memo and we introduced a fraud, waste, and abuse training module. That module that is available through the Medicare Learning Network does satisfy the fraud, waste and abuse training requirement.

The Deeming for FDRs – FDRs that meet the fraud, waste and abuse certification throughout Part A and B enrollment or accreditation, as such with the DMEPOS, those suppliers are deemed to have met the fraud, waste and abuse training requirement. However, in the case of chain pharmacies, each individual location must be enrolled in order to have met the fraud, waste and abuse training requirement. And as Phil mentioned, he's going to turn back to the presentation and continue with Element IV.

Thank you, Beth.

Moving on to Element IV, which are Effective Lines of Communication -- The Guidelines provide more clarification and guidance regarding how the Compliance Officer/Compliance Department must establish effective lines of communication between the Compliance Department and all other employees, senior managers, Board members, first-tier or downstream or related entities, and enrollees. Now, the Guidelines also provide various examples of how Sponsors might achieve this; such as, posters, desk props, emails, fax blast, agreements and contracts, etc., as well as ways to educate enrollees – such as through emails, mail systems – again, reemphasizing that the Sponsor must maintain effective mechanisms of communication which are anonymous, confidential, and which encourage good faith reporting of non-compliance or potential fraud, waste and abuse.

Moving on to Element V, Well-Publicized Disciplinary Standards – Again, the Guidelines confirm that the Sponsors must establish, implement, and maintain disciplinary standards that are clear, specific; that clearly outline the inappropriate behaviors that they will be applied to; and that are indeed applied consistently. Those disciplinary standards then – the Sponsors must be able to confirm to CMS that they have indeed implemented and applied those standards. And the Guidelines provide various methods of how the Sponsor may be able to demonstrate to CMS that they have adopted those. One way is to ensure that the Sponsor is maintaining records of all

disciplinary actions that have been imposed upon any of their employees or any employee or entity of their first-tier, downstream, and related entities. Remind Sponsors that those records must be maintained for a period of ten years and should include information such as the specific breach or violation, the punishment imposed, and all other information regarding that particular disciplinary action.

We'll move on to an element which has multiple components of course, and that is the Element VI, which is Effective System for Monitoring and Auditing. All of the best practice Sponsors this morning mentioned this aspect specifically, and that is the importance of effective monitoring and auditing. A couple of points regarding this – the Guidelines distinguish between monitoring and auditing. And I won't read those definitions, but it's important to understand those distinctions and the requirements around those, and also outline the importance of monitoring and auditing across the board. That is, that Sponsors are obligated to monitor each and every operational area, their first-tier entities, and also must monitor and audit the effectiveness of their Compliance Program.

Now, we've noticed throughout the past audit years and this audit year not excluded, that some Sponsors still are having difficulty understanding the importance of monitoring and auditing their Compliance Program effectiveness. So we would refer Sponsors to the details provided in the revised guidelines regarding this component.

The Guidelines also provide information in regards to establishing a formal baseline assessment in order to properly structure your monitoring and auditing work plans and in order to actually implement your monitoring and auditing efforts. This would include FDRs, which I'll get to in a moment. We would note also that auditing and monitoring must be conducted by independent entities; that is, the operational area being monitored and audited should not be auditing and monitoring themselves, except to check for quality improvement and quality control, of course. But as far as independent audits, they must be conducted by components which are independent to the operational area.

It is not necessary for Sponsors to establish a specific auditing program or auditing division. The Compliance Program, as long as they have the appropriate knowledge and experience in particular operational areas, may conduct those audits. And as to the Compliance Program effectiveness, of course those audits have to be independent as well. And that is that the Compliance Officer and associated Compliance Department employees should not be conducting the internal audit of the Compliance Program effectiveness -- so again, just emphasizing the principle of independent auditing and monitoring in order to maintain the integrity of those efforts.

I've already touched upon the principles here emphasizing the operations and Compliance Program.

Moving on to Monitoring and Auditing FDRs – The regulations require monitoring and auditing of first-tier entities for their Compliance Program requirements. Now, the Guidelines provide specific clarification regarding how you can accomplish these monitoring efforts. Again, this is in regards to monitoring and auditing the first-tier entities' compliance with the Compliance Program.

Now, we understand that many Sponsors have numerous first-tier entities, and it may not be practical and it may be cost prohibitive, to attempt to perform a specific audit of all of those first-

tier entities within any specified time period. So the Guidelines clarify that in regards to monitoring first-tier entities for Compliance Program requirements, the Sponsors may conduct a baseline risk assessment of their first-tier entities and determine and categorize and prioritize which ones should be audited first and which ones should receive the most emphasis. In that regard, Sponsors will ensure the compliance of those entities.

The Guidelines also emphasize that the auditing and monitoring results must be tracked and reported. Now, Marianne touched upon the requirements of Element II, which is that the Board and senior management are accountable for Compliance Program oversight. And some of the reports that must be received by and must be distributed to the Board and senior management include the results of monitoring and auditing efforts, both by compliance and by the operational area. Now, those reports may be in the form of dashboards, scorecards, self-assessment tools, etc. And all issues of non-compliance and fraud, waste and abuse should also be included in those assessment tools and, again, must be shared with the Board and with senior management as conducted and frequently.

I'm now going to turn the time back over to Beth Brady, who will complete Element VI and Element VII with the components regarding fraud, waste and abuse.

Thank you.

I'm going to start off with the OIG/GSA exclusion. The new Guidelines provide detail as to requirements for both the OIG and the GSA exclusion checking. The checking must occur prior to hiring or contracting, and then monthly. Now, the categories of persons and entities to be checked are stated in the chapter. For example, it does include conclude consultants and volunteers. Now, we have provided in Appendix A of both chapters the links to the instructions for accessing both the OIG and the GSA websites.

Use of Data Analysis for Fraud, Waste and Abuse Prevention and Detection – We provide that Sponsors must effectively monitor for potential fraud, waste, and abuse and must use data analysis. Data analysis should factor the particular prescribing and dispensing practices of both the providers who serve the particular population -- for example, long-term care providers or assisted living facilities. Use of data analysis may include monitoring the pharmacy and the medical billing. And that way, you can detect potential unusual patterns. Sponsors should routinely generate and review reports of pharmacy billing, medical claims, etc., based on data analysis performed. And that way, again, you can identify pharmacies and other FDRs that may require further review.

Special Investigation Units or SIUs – The new Guidelines now provide more detail on the use of special investigation units. Now, depending upon the size and the resources available within an organization, Sponsors may either have a dedicated SIU or ensure that the SIU responsibilities are handled through the Compliance Department. Sponsors must ensure that suspicions of fraud, waste, and abuse can be reported anonymously to the SIU or whoever is performing those functions. And in addition, the new chapters now specify that you have to have coordination between the SIU and the Compliance Department. And that's necessary to be very effective.

What to do if potential fraud, waste and abuse is detected – and now I’ve moved into Element VII. The new chapters clarify that the required reasonable inquiry of a potential fraud, waste and abuse incident must be commenced no later than two weeks after that incident has been identified. It’s also now clear in the chapters that if the issue does appear to be potential fraud, waste and abuse and you do not have the resources or the time to investigate, that you can refer the matter to the NBI Medic. And I’m going to talk about the National Benefit Inquiry Medic in a few slides. The referral, however, should occur within 30 days of the date the potential fraud and abuse was identified. And that’s necessary because you don’t want to let that problem continue without know what the resolution may be.

Corrective Actions – Our revised Guidelines provide that corrective actions are designed to correct underlying problems and prevent future non-compliance. There are also now additional details in the new chapters regarding FDR corrective actions. The Sponsors must ensure that FDRs have corrected their deficiencies. When developing corrective actions for fraud, waste and abuse or program non-compliance by an FDR, the elements of that corrective action should be detailed, it should be in writing, and it should include the ramifications if the FDR fails to implement the corrective actions to your satisfaction.

Also, your contract between the Sponsor and the FDR should include language that details the ramifications of failing to maintain compliance or perhaps engaging in fraud, waste and abuse. And that could be contract termination. In order to ensure that the FDR has implemented the corrective action, the Sponsor should conduct independent audits or review the FDR’s monitoring and audit reports. Sponsors must continue to monitor these corrective actions after their implementation to ensure that they are effective.

I mentioned the National Benefit Integrity Medic. The Medicare Drug Integrity Contractor is an organization contracted by CMS to perform specific program integrity functions for Medicare Parts C and D under the Medicare Integrity Program. The National Benefit Integrity Medic’s function is to identify potential fraud and abuse within Medicare C and D.

Moving on to Fraud Alerts – The Guidelines now include a section on fraud alerts, and it clarifies the action the Sponsors should take in response to those fraud alerts. Now, these fraud alerts are alerts that we issue because these schemes have been identified by law enforcement officials. When a provider has a history of complaints, as we mentioned back in Element V, you should maintain your files for a period of ten years – and that’s both on in-network and out-of-network providers who have been the subject of complaints, investigations, violations, or perhaps prosecutions.

And now I’m going to turn it back over to Marianne, who will conclude with some closing remarks.

Thank you.

Thanks, Beth.

We hope that the content of the final Chapters 9 and 21 will be helpful to you in building an effective Compliance Program. As I mentioned before, we’re happy to take questions from you to our mailbox and we will provide answers. And also before I turn this over to the audience for

*FALL 2012 CMS CONFERENCE*  
*CMS 2012 Maryland Room Session 1*

questions, I want to have a little advertisement because we're going to be having a website for our program compliance and oversight group on cms.gov. One of the other speakers mentioned it, and it should be coming up this fall – in fact, pretty shortly as far as I know. So stay tuned. And when we have that up, we'll be putting additional compliance information on it to help you achieve an effective compliance program.