



CMS 2010 MEDICARE ADVANTAGE & PRESCRIPTION DRUG PLAN FALL CONFERENCE

Real Time Caption Transcript

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Mandatory Compliance Program – Requirements & Effectiveness Vernisha Robinson, CPC/PCOG/DCE

Vernisha Robinson

Good morning, everyone. My name is Vernisha Robinson, I'm here to speak on the mandatory compliance program, the requirements specifically. Just taking you through some of the important -- um, requirements as well some observations from this summer.

Next slide. There's four points I will touch on. The first will give you an overview of the mandatory compliance requirements. I will also give updates on the CMS mandatory compliance regulation requirements and the focus of the audits and talk about compliance plan effectiveness.

Again, effective compliance programs is a requirement of a contract for CMS for Part C and D. There are seven elements implemented, they work together. Some industry experts will say there's an 8th element. They should prevent, detect and respond to violations of non-compliance. Also you should have a proactive versus a reactive approach to compliance. This is something that -- if you have a proactive approach you will be able to respond to CMS and to beneficiaries, as well as your subcontractors appropriately. Also your compliance program should have Medicare specific provisions, you should talk about the false claims act, and some other specific acts within the Medicare guidelines. They must be incorporated into policies and procedures and standards of conduct. At your program should demonstrate your program's compliance. The culture of compliance comes from the head, as we all know. Your compliance program should require engagement, support and communication.

Additionally, your compliance program should define expectations for employees. This is very, very important. Your employees and everyone that you contract with should know your guidelines in regards to your line of business for Medicare. What do your standards of conduct say? Also your compliance programs should be identifying risks and responding in a proactive and comprehensive manner. This is very important to CMS and your providers, your compliance program should be detecting issues, it's all about identifying risks and responding.

Again, the compliance program is very focused on fraud, waste, and abuse. The programs should address noncompliance and also fraud, waste, and abuse issues internally and externally. I will go into updates. They have changed. Effective June 7 there were some final regulations that were updated. They're specifically made in the compliance program. They become effective January 1, 2011. There's existing ones that are current, there are some updates that take immediate place on 1/1/2011. The updates require compliance programs to be effective.

Updates provide more details requirements on each of the seven elements. We will go through each one of the elements.

Again, this is very important, not only must you have a plan, but you must be able to adopt and implement. I know there's a lot of verbs that have a lot of weight. I looked up the definition for



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adopt and implement. You are taking up a practice, which is your compliance program, you move it to your organization, you also apply it consistently throughout the organization and operations. We're looking to see an effective compliance program. Again, I looked up "effective." The ability to produce, or the capability of producing an intended result, or having an striking effect. You are taking up a practice, molding it, applying it, and producing a product for an intended result. That's what we're looking for you to do, to have an effective program. I always say if I were an compliance officer in your industry, in the compliance department take these three action word, your employees should know prevent, detect and respond. Those are three of the verbs that are very crucial to the requirements. At a minimum, at a minimum, you must include the seven required elements that are outlined in the regulations. Again, you can additionally add more. But they must contain the seven required elements.

Element one is about procedures. The organization must have written policies and procedures that the MA and Part D sponsors comply with standards. What we're looking for is that they specifically state your organization's commitment with CMS and whatever state that you contract with the standards. They should be very specific about your expectations for your employees, subcontractors, and beneficiaries. How should they behave? Your employees should know the consequences for not reporting fraud, waste, and abuse. We're looking for you to be very specific. Again, you have to work in the implementation of your compliance operations. We're looking to see if your policies and procedures provide guidance to your employees and others on how to deal with and respond to and correct potential issues. We're also looking for you to identify how to communicate issues to the compliance personnel. Let's say a CSR receives a call from a Medicare beneficiary specifically stating that an agent or broker showed up at their house and asked for their Social Security number without an appointment. You need to ensure that your CSRs understand the process and access to policies and procedures and get that to the compliance department to investigate. We're also looking for your policies to be descriptive on how issues are investigated and resolved. You can't just generally state that these issues will be followed up, we're looking for timeframes. There needs to be prompt response to issues. We're looking for very specific information. An employee should be able to pick up the procedures and know their job and the flow of the process. As well as this is very, very important, just from my audits this summer, your employees should feel very forthcoming with an issue. A particular employee witnessed someone in the claims department upcoding a particular claim, so in a discussion we asked do you feel comfortable talking to the next level, or your hotline? They stated "no." It's very important that employees receive the message that is very clear that there will be no retaliation. I know a lot of companies now have policies on the internet. Make it very, very easy for your employees, subcontractors and beneficiaries -- for your subcontractors and employees to have access to your internet to know what the policies and procedures are. I have seen some situations where it's very difficult to weed through the Medicare line of business. Make sure that the policies and procedures are easy to read and be understood and be accessible.

Element two is all about the compliance office and compliance community. It talks about the designation of a compliance officer and the committee that they report to directly. The committee and the compliance officer are directly reporting and are accountable to the organization's chief executive, versus who are accountable to senior management. This is where the language has changed. The compliance officer may bring an issue of concern that has true risk to the organization and may be talked out of reporting that to the board, the compliance officer and the committee must have a direct link to talk about compliance issues for Part C and D. The compliance officer must be an employee of the parent organization, corporate affiliate. The compliance officer may not be an employee of a first tier. The committee must periodically report directly to the governing body of the organization on activities and the



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status of the program, including issues identified, investigated and resolves. Whatever the issue is if it's policy and procedures that need to be directly communicate today the board, those meetings and discusses must be documented. We understand there are some conversations that are informal. When we come to audit or review your program we're looking specifically for minutes that are very detailed that will tell the story of how the department is reporting on specific issues.

The governing body must be knowledgeable about content and operation of the compliance program. I would say from my experience this is something that is very troubling when you talk to a CEO that does not understand, or does not know, doesn't know what the compliance program is for the Part C and D line of business. This gets lost when you have a parent organization that has other lines of business. We understand that. But we're looking to how does your compliance program address Part C and D? Very crucial.

Element three is about effective training and education. Each plan sponsor must establish, implement, and provide effective training and education between the compliance officer and the organization's employees, including the CEO and other senior administrators. This is new language. There's a huge job of training and education. You have to provide, you have to test that it's affective. There's some creative ways that I have seen, there's some industry experts that have ways on testing the effectiveness. Training and education must occur annually at a minimum. When you in a bring in a new first tier, down stream, when there's a new appointment, there must be training.

Just a little note on effective training. You need to develop mechanisms to test whether or not employees are obtaining the information. Let's take a common area that has some problems or operational risks, enrollment and disenrollment. Once you provide training, once you provide the training you need to document who was there, who conducted it, what materials were used, and how you go back in three months to test if employees obtained some of the crucial information that is important to the process? How do you test that? Do you go back and ask a couple of questions from the previous training? Do you look at stats to see if your numbers for enrollment applications have increased or decreased? That's ways that you show to CMS that you conducted the training and that it was effective.

Element four. This is one of my favorite. Establishment, you have to give the structure, and implementation, putting it into action, effective lines of communication. Here we go again. Ensuring confidentiality between the compliance officer, members of the compliance committee, employees, managers and governing body. Pretty much this is everybody that you do business with, and also you have to have lines of communication for your beneficiaries to report noncompliance and fraud, waste, and abuse issues. You have to have a structure in place to ensure that customer service representative reports that to the compliance department. These lines of communication must be acceptable to all. Chapter 9 goes into detail about mechanisms. If you have a hotline make sure it's anonymous, it should not go to your direct phone where you have caller ID and you can see who is calling. That may prevent someone from calling in. If you have boxes in the cafeteria, or in meeting rooms make sure that they're checked and that you follow up on these investigations. You have to use other creative mechanisms that are available to you. All meetings, this is another observation, all meetings meetings you need to document on a non-compliance issue. You need to be able to show CMS how you funneled that issue, whether it's it was potential fraud, waste, or abuse, or if there's an a concern about operational work. You need to be able show CMS that you funneled it through the process and there was promote follow-up. If you are a large organization, or a small, you may have other lines of



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business, you need to ensure that you have your hotline or whatever mechanism that you have for employees to communicate that is distributed throughout your organization. Create a flyer that may catch someone's eye, and beneficiaries need to receive reminders that if you appreciate any one of the five issues in the last month please make to sure this number. Element five, has to do with disciplinary guidelines. You have to have them, they must be well publicized in your organization. Whether it's the internet or email service, they have to be well publicized and accessing to employees and your subcontractors. They must be well publicized through the implementation of procedures which encourage good and safe participation in the compliance program by all effected individuals. This is another element that has new language. You should be communicating to the employees what compliance or noncompliance looks like in their areas. Also your disciplinary guidelines should identify noncompliance and nonethical behavior, what does that look like? I have seen the best ways that employees understand it is they know what it means for their particular line of work. Also your bottom lines should provide for timely, consistent and effective enforcement of standards when this is detected. When we come out to audit we're looking to see if someone received a disciplinary action was it fair? Was that action distributed to all employees? Make sure that the guidelines are fair and consistent.

Element six, effective monitoring. This is a huge area. This is one that takes a lot, a lot of work to be effective in this particular element. This is specifically establish, get the structure in place, and implement, an effective system for routine monitoring and identification of compliance risks. This is totally new language. Here you are looking to identify compliance risks within the organization. I have been at several places where I asked for the compliance risks. All of the operations. Okay, you if you all of Part C and D you need to be conducting a risk assessment to see the areas that will effect beneficiary access and beneficiary right to medical services. There's additional requirements for this particular element. You have to have a system in place that has monitoring of areas by business units. Internally monitoring and auditing are separate. Monitoring is day-to-day work. Make sure that beneficiaries are receiving access to their services and drugs, your grievances are not off the scale, you have to have a Rick assessment of your -- risk assessment of your areas. Your system must also include periodic internal audits to confirm results of the monitoring. The monitoring is a proactive analysis. The auditing is the reactive piece of it. You should also be conducting external audits as appropriate. I see a lot of organizations struggle with this. If you have a delegation department that has handles that, that's a huge task. The compliance program should be working with the delegation area to ensure that they're complying. You conduct audits internally and externally. Also an evaluation of overall effectiveness. Element six is very huge. I have seen organizations break down because of the lack of knowing what their risks are for the Part C and D requirements.

Element seven is all about prompt response. Are you responding timely and in a reasonable way to all levels, including your sponsor, the organzal level to your beneficiaries, so your first tier and down stream related entities? This element is establish the structure and implement the action. You have two things to do. Promptly respond to issues as they're raised, investigate potential issues, correct such problems promptly, and reduce the potential for reoccurrence and ensure ongoing compliance with CMS requirements, huge. Not only are you -- you should not be waiting on CMS to identify issues for you. By that time it's too late. Once you are doing that day-to-day monitoring and you conduct an audit how quickly are responding to the issues and areas that you identify to ensure that those are followed up on. There was one instance that I have seen where an employee left a specific department. As a result there was no day-to-day monitoring, we came to review this organization, this person's workload was out of bounds, they had a huge workload for a particular area of the Part C and D operations. Once we identified



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that issue we expect immediate response. Make sure when employees leave that those specific areas that they work on are followed up on and handed off to someone else to conduct. Any time you discover evidence of miss conduct related to payment or prescription drugs, under the contract you must conduct a timely reasonable inquiry. Again, you know, if an employee calls your hotline or the compliance department don't just sit there. You need to work it appropriately to ensure that not only your employee -- show your dedication to the process. Your employees need to know if they report an issue that you will do something about it. Prompt response.

Correcting the actions. You need to respond quickly to the issues and to ensure that all pieces of the puzzle have been dealt with. You need to ensure that those specific issues are funneled and you are self-reporting. Hey, I found this issue, this is what we're doing about it. That's showing us that you have a compliance program that is able to prevent, detect and deal with issues within your organization.

For 2010 CMS conducted actions based on deficiencies in compliance plan requirements. There were three actions. There's a link to the specific actions. I hope you don't fall into this category. Again, that's why your compliance program is very, very important.

The focus of the actions, I wanted to tell you how an organization is selected, it's all about their risk to the beneficiaries and to the Part C and D program. Sponsors are chosen for audits based on a risk analysis. It's very detailed. We're not just picking on you. You present a risk to the program or to beneficiaries. Any sponsors chosen will also receive a compliance plan effectiveness audit.

Let me go into detail about the audits that we've conducted. They're onsite. Very intensive process. It's not just a paper exercise. One of my directors talks about print a plan, post it, and just pray that someone from CMS doesn't come. Not the case anymore. We ask you to demonstrate the effectiveness of your program. My favorite phrase is "show me." We're looking at data, personnel and documentation. We're not just relying on one piece of the puzzle, what data can you provide? Show me what you have, the analysis, what went into this particular audit, walk me through the process, walk me through your dashboard, is there validation of data? Another key point that I have seen is make sure that the data you receive from the operational areas, if you are a compliance officer, that information is validated. What prevents the grievance department from deciding to give a 97% number today or this week? There should be someone to validate that data. Make sure that someone is validating the data that you receive from the operational areas. We talk to personnel in regards to the culture of the organization. We're judging your commitment to the compliance of Medicare. Can you show you have a system for proactively finding issues? Let's walk through the process. It's a very intensive audit process. It's really up to you to determine straight your program -- demonstrate your program. Also it includes focus on requirements to implement programs to control fraud, waste, and abuse. How does the compliance program work in your organization? Where does it live? How does it communicate with your operational areas? How does it communicate with your subcontractors? How does it communicate with your employees and beneficiaries? The focus is also on fraud, waste, and abuse. The compliance program is a huge entity. But if you have it work within your organization you should have something good.

These are deficiencies that we've discovered. How does your first tier know what your ethical code is? Very, very, very important. Another finding is that the written policies and procedures are out of date, haven't been updated in years, or they're not Medicare specific. We understand if you have other lines of business, commercial or Medicaid, but you receive a lot of money from



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us, we expect you to have Medicare-specific policies and procedures. It should not be buried. Your employees and subcontractors should know exactly where to find it. With the Healthcare Reform Act you need to ensure that you have a mechanism to ensure that the updates are incorporated within the PDPs. We're seeing seeing that the -- or not exercising proper oversight of Medicare operations. I have personally seen this myself. We ask general questions to some senior executives, they have no idea if they've received compliance training. If you service one of the five counties that have been identified in highest Medicare fraud, you don't know if you operate in that area, that's very disturbing. You need to ensure that your senior level people receive training and there's proper oversight.

Again, we're seeing that the compliance officer and the committee are not communicating to the governing body. If you have the compliance committee reporting to legal counsel they should have a direct link with the governing body. Training and education programs are not measured, how do you know if you are spending the appropriate money, or if you are spending too much money and people are not getting the information, maybe you need to change your mechanism. Risk assessment, huge, I don't understand how people can start a work plan of auditing without doing a risk assessment. How do you know which areas pose a risk to your organization? We're not seeing that, we need to see that. Monitoring and auditing is sometimes pretty much nonexistent. When it comes to fraud, waste and abuse you need to be more proactive, target efforts. If you rely on your Part D to conduct this work you need to ensure that someone is validating that data and that you are feeding that. What is the most overprescribed drug for this county? You need to know what they're feeding you and how that works within your organization.

This is the little diagram that helps me to understand compliance plan effectiveness. You have the leadership, compliance committee and officer. These people are at the head.

Communication 360, you have people communicating up and down and across. Documentation, how well are you documenting your meetings? This is a good way of seeing the structure of it all.

The compliance program is three buckets. There's a structure. You have to have this in place. Structure, culture, it's your policies and procedures, reporting mechanisms, education and training. You have to have the structure in place before you move on to the process of showing or having an effective compliance program. Next you have your process. How does your system work? You are looking at your monitoring, you are incorporating new changes in policy, it's all about your response and prevention. How well to you correct systemic problems? Accountability of operational areas. This is all about the process within your organization. Last, it's all about the outcomes. What are your trends and reports telling you? It's all about the monitoring and auditing results. Those should trigger to you there's a need to update policies and procedures, or there's a need for additional employees. You need to ensure there's controls in place and identify risk areas. Proper internal controls. Internal controls is used widely and overused, you need to find out what do you need as a compliance officer or the head of a program to ensure that you are not waiting until the last minute to respond to operational issues? It's all about employee engagement. Are your employees discussing issues and asking questions? That's a way to see if employees are engaged. Are you having increase or decrease in complains? Another outcome is how you're able to evaluate your compliance.

Compliance program effectiveness is a top CMS priority. There's heightened focus on enforcement activities. You know it's very visible. At any time we can ask for you to demonstrate



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to us how your compliance program is effective. The focus of CMS oversight entities, you need to ensure that it's working. There's Congressional focus, the Affordable Care Act requires plans for organizations. Again, I don't have anything else to add. I hope you that you take away that the compliance program is very important, very visible. If you have questions we will take them at the panel discussion, thank you. [Applause]