

Questions and Answers
Supplement to the Compliance Program Guidelines Focused Training
Element 1: Written Policies, Procedures, and Standards of Conduct
January 30, 2013

Background

The following Questions and Answers (Qs&As) are a supplement to the Compliance Element I Focused Training conducted by CMS via webinar on January 30, 2013. The training elaborated on Element I of the Compliance Program Regulations and Guidelines: Written Policies, Procedures, and Standards of Conduct. Participants submitted questions prior to, during and following the presentation. Following are questions related to Element I, with answers from CMS. These answers are provided in the context of the Compliance Program Guidelines (Chapter 9 of the Medicare Prescription Drug Benefit Manual and Chapter 21 of the Medicare Managed Care Manual) only. Clarification provided may not reflect other CMS program area policies, which should be considered as well. Please note that some questions received pertain to other Compliance Program Elements, and will be addressed in more detail in future focused trainings.

Questions and Answers

- 1. Q: The “Standards of Conduct” content requirements are typically very similar to and redundant of “Compliance Policies”. Will CMS allow plans to use the Compliance Program Policies for the dual purpose as the de facto “Standards of Conduct”, so long as the content is there?**

A: Sponsors may combine their Standards of Conduct and Compliance Policies and Procedures into one document, as long as the document contains all of the content required by the Compliance Program regulations and guidance. The portion of any such document that reflects the “Standards,” should be approved by the full governing body.

- 2. Q: CMS requires plans to “distribute” the Compliance Policies and Standards of Conduct. Does “distribute” mean we can send it out via email with instructions to read it, or must we have individual employee confirmation of receipt?**

A: Sponsors have discretion regarding how they distribute Compliance Policies and Standards of Conduct, but they must ensure their choice of distribution is effective, and sponsors must be able to demonstrate to CMS that each of their employees has received the Standards of Conduct and Compliance Policies and Procedures.

3. Q: Could you provide some guidance on policy and procedure updates where rule changes occur? Since there are logistics to making these changes, is a 60 day compliance timeframe a reasonable expectation that would meet the CMS standards in cases where no specific implementation date is provided in the memo or guidance?

A: Sponsors must ensure that policy and procedure updates occur within a reasonable time and are effectively implemented. Reasonable timeframes must be determined on a case-by-case basis.

4. Q: Are there policy and procedure requirements for all of the Medicare program areas (i.e. enrollment, sales, OEV, claims)? Should these requirements be in a Compliance Program?

A: Each Medicare program area has specific requirements governed by regulation and guidance, and overseen by individual components within CMS. At the sponsor level, policies and procedures for each program area should be developed, updated and overseen by the respective experts and departments for those specific program areas. Compliance Policies and Procedures must be detailed, specific and describe the operation of the Compliance Program, which includes policies regarding Compliance Department monitoring and auditing of operational areas; however, specific policies for each individual program/operational area are generally housed within that specific program/operational area, separate and apart from the Compliance policies and Procedures.

5. Q: Given the multitude of FDRs that "RutRo" [referring to fictional Sponsor used as a case study in the training] must oversee, could you please provide an example of how "RutRo" could effectively distribute their own Standards to FDRs or review their FDRs' comparable Standards?

A: Sponsors have discretion regarding how they distribute Standards to their FDRs. The Compliance Program Guidelines provide numerous examples of how this might be accomplished, such as through FAX Blasts, posting of sponsor's Standards on a sponsor's FDR portal, or incorporating specific language into contractual arrangements with FDRs, regarding compliance expectations. Sponsor's contracts with FDRs will determine specifics regarding communicating compliance expectations. For purposes of the Compliance Program requirements, CMS does not have direct authority over FDRs and does not interfere with contracts between sponsors and FDRs, but rather CMS establishes requirements and guidance for sponsors regarding oversight of their FDRs. Sponsors must determine how to satisfy those oversight requirements.

The principle of "distributing" Standards to FDRs is to ensure that sponsors are communicating compliance expectations to their FDRs, and that FDRs are abiding by compliance principles. Most FDRs already adopt their own organizational Standards, consistent with compliance

principles, thus those FDRs could demonstrate to the sponsor that compliance expectations are already being communicated at the FDR level.

For those sponsors that may have a large number of FDRs, sponsors may consider distributing Standards to their first tier entities, then in turn require their first tier entities to distribute Standards to their respective contracted entities (sponsor's "downstream" entities). Again, the critical principle is that all are aware of and are abiding by compliance expectations and efforts are documented.

6. Q: Can you give a clear definition and give an example of Volunteer?

A: For purposes of the Compliance Program Guidelines, a volunteer is any individual who performs work for the sponsor related to the Medicare program, but is not employed by or contracted with the sponsor in any fashion, and not otherwise compensated for their work. An example is an unpaid student intern. Although sponsors rarely utilize "volunteers" in the Medicare program, some sponsors who did use volunteers in the past, were not providing their volunteers with compliance and fraud, waste and abuse (FWA) training and education, even though these volunteers performed work in areas with risks of non-compliance and FWA. These sponsors incorrectly reasoned that because the Compliance Program regulations refer only to "Employees" generally, and do not specifically mention "volunteers," the sponsor did not have to apply Compliance Program requirements to the volunteers. CMS determined it was necessary to include "volunteers" in the Compliance Program Guidelines, to clarify that the Compliance Guidelines apply to unpaid volunteers performing work for the sponsor in Medicare program areas.

7. Q: Are FDRs required to provide signatures confirming receipt of a sponsor's Standards of Conduct?

A: Sponsors have discretion regarding how they distribute Standards of Conduct to FDRs (or otherwise ensure that FDRs have comparable Standards) and how they confirm that FDRs have received and will apply such standards. Please refer to answer number five (5) above for more details regarding this principle.

8. Q: Can you please clarify the Compliance Officer's role in operational policies and procedures?

A: Operational policies and procedures for each program area should be developed, updated and overseen by the respective experts and departments for those specific program areas. In addition to operational policies, each operational area should establish and implement its own compliance policies specific to their respective area, to include the compliance and FWA risks of that area. The Compliance Officer may provide support in these efforts. In turn, the

Compliance Officer should solicit input from operational department leaders when developing organization-wide Standards of Conduct and Compliance Policies and Procedures.

9. Q: Are FDRs required to distribute Compliance Policies and Procedures and/or Standards of Conduct to all employees upon hire, within 90 days, and annually thereafter?

A: CMS does not have direct authority over FDRs (for purposes of the Compliance Program requirements) and does not interfere with contractual arrangements between sponsors and FDRs, but rather CMS establishes requirements and guidance for sponsors regarding oversight of their FDRs. Standards of Conduct and compliance distribution timeframes of “upon hire and annually thereafter” are requirements specific to the sponsor’s employees. The principle of sponsors “distributing” Standards to FDRs is to ensure that sponsors are communicating compliance expectations to their FDRs, and that FDRs (including FDR employees) are abiding by compliance principles. FDRs may have their own comparable Standards that they communicate to their employees. The sponsor’s contracts with its FDRs will determine specifics regarding communicating compliance expectations.

10. Q: Can an attestation from FDRs on Code of Conduct be acceptable as to meeting or exceeding those of a Plan Sponsor?

A: Sponsors have discretion regarding how they ensure that FDRs have comparable Standards of Conduct (A.K.A. “Code of Conduct”). The sponsor’s contracts with its FDRs will determine specifics regarding communicating compliance expectations through Standards of Conduct. Examples of proof of receipt and compliance may include attestations and electronic certification from FDRs.

11. Q: Since our Compliance Policies & Procedures are to be distributed to FDRs as well as employees, should they be written in general terms, or can they be distributed as they are currently directed to our own employees?

A: The principle of “distributing” Standards of Conduct and Compliance Policies and Procedures to FDRs is to ensure that sponsors are communicating compliance expectations to their FDRs, and that FDRs are abiding by compliance principles. The sponsor’s Compliance Policies and Procedures are detailed, specific and describe the operation of the compliance program. The sponsor’s Standards of Conduct state the overarching principles and values by which the company operates. While FDRs and their employees must understand compliance expectations (as generally embodied within Standards of Conduct), they do not necessarily need to receive and review the specifics of each individual sponsor’s Compliance Policies and Procedures. When a sponsor chooses to make its own Standards of Conduct available to FDRs (as opposed to ensuring the FDRs have their own comparable Standards), the sponsor must

determine what components of the sponsor's Standards/Compliance Policies should be provided to the FDRs, in order to effectively communicate compliance expectations.

12. Q: Given that one provider/vendor may contract with dozens of sponsor organizations (SO) and would therefore be considered a First Tier contract for all of the SOs, is it realistic that they must distribute different Compliance Policies and Procedures from dozens of SOs to all of their employees and governing body?

A: The principle of "distributing" Standards of Conduct and Compliance Policies and Procedures to FDRs is to ensure that sponsors are communicating compliance expectations to their FDRs, and that FDRs are abiding by compliance principles. Sponsors have discretion regarding how they ensure that FDRs communicate compliance principles to their employees, as long as the method is effective. One method may be for sponsors to confirm that the FDRs establish, distribute and apply their own comparable Standards of Conduct, thus FDRs need not necessarily distribute different compliance policies and procedures and Standards of Conduct from the various sponsor organizations with which they may contract, if the sponsors accept the FDRs' own Standards.

The sponsor's contracts with its FDRs will determine specifics regarding communicating compliance expectations through Standards of Conduct. CMS does not interfere with these contracts; however, CMS is aware of the potential burden placed upon FDRs that may be required to fulfill compliance requirements for each of the various sponsors with which they may contract.

As such, CMS has granted sponsors with discretion regarding how to effectuate and conduct FDR oversight (for purposes of the Compliance Program requirements), and has continuously messaged to sponsors (through guidance, trainings, etc.) that such oversight should be reasonable, and should take into consideration potential burdens faced by FDRs in fulfilling the sponsor's compliance requirements. CMS has also responded to this burden by actions such as developing the CMS Fraud, Waste and Abuse (FWA) training module, which may be used universally to satisfy the FWA training requirement component of the Compliance Program regulations, therefore preventing FDRs from necessarily having to take individual FWA trainings from each of the sponsors with which they may contract (details regarding training will be provided in a future Element III Focused Training session). For more information on requirements for contracts with FDRs, see Pub. 100-16, Medicare Managed Care Manual, Chapter 11, §110.

13. Q: If Providers are considered FDRs, then is Dr. X required to distribute Compliance Policies and Procedures and Standards of Conduct to the front office staff?

A: Sponsors have discretion regarding how they ensure that FDRs communicate compliance principles to their employees, as long as the method is effective. The sponsor's contracts with

its FDRs will determine specifics regarding communicating compliance expectations through Standards of Conduct.

14. Q: Has CMS already instructed CMS and contracted auditors to begin evaluating Plans on the effectiveness of programs? If so, what has CMS done to train auditors on how to evaluate the effectiveness of Plan's efforts to implement the standards, given that Plans have significant discretion, or to evaluate the effectiveness of Plan processes?

A: CMS and contracted auditors undergo extensive training in regulations, policy guidance, audit processes, etc. prior to participating in Compliance Program audits. All audit teams include CMS subject matter experts, and all audit work papers, associated documents and audit reports are reviewed and approved by CMS subject matter experts. Compliance Program audit protocols, methods of evaluations, and associated audit documents are specifically designed to conform to the principles articulated in the Compliance Program regulation and guidance.