August 3, 2015

Mr. Jerry Mulcahy, Director
Medicare Parts C and D Oversight and Enforcement Group
Center for Medicare
Center for Medicare and Medicaid Services
Mail Stop C1-22-06
7500 Security Boulevard
Baltimore, Maryland 21244

Via email: jerry.mulcahy@cms.hhs.gov

Dear Mr. Mulcahy,

We are writing to express our concerns about certain aspects of the Medicare Advantage compliance program training requirements. The American Clinical Laboratory Association ("ACLA") is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. Many of ACLA's members are "first tier, downstream, and related entities" ("FDRs") with respect to Medicare Advantage plans and, as such, are subject to the requirements for general compliance training and fraud, waste, and abuse ("FWA") training in the context of the Medicare Advantage program, in addition to their own compliance training programs.[1]

Despite CMS's efforts to reduce burdens on FDRs, some aspects the Medicare Advantage compliance training requirements remain problematic, and may actually increase burdens on some FDRs. Large portions of the training are not relevant to a wide variety of FDRs, including laboratories, yet the training cannot be customized or tailored to an entity's business model and risk areas. Other portions of the training are duplicative of training FDRs already provide for employees. Additionally, CMS has not provided guidance to Medicare Advantage Organizations ("MAOs") on which FDR employees are required to participate in compliance training.

We urge CMS to consider ways for MAOs and FDRs to adjust the compliance program training while maintaining the integrity and substance of the training and to separate the general compliance training module from the FWA module. We also request that CMS issue guidance to MAOs stating that only certain FDR employees must participate in the training.

A. Background

In early 2014 when CMS proposed changes to the Medicare Advantage compliance program training requirements, it did so in part because of the burdens imposed upon FDRs who potentially had to participate in duplicative training sponsored by each MAO.[2] In service of the

[1] *See* 42 C.F.R. 422.503(b)(4)(vi)(C)(*3*).
[2] 79 Fed. Reg. 1918, 1926 (Jan. 10, 2014).

goal of decreasing burdens on FDRs such as laboratories, CMS did the following in the final rule:

- Required that all MAOs accept a certificate of completion of the CMS-developed training module as satisfaction of the general compliance program training requirement;
- Permitted only this CMS training for satisfaction of the requirement to train FDRs;
- Chose not to allow the CMS training module to be downloaded into various organizations' systems;
- Delayed the effective implementation date to January 1, 2016.[3]

We were heartened to see that CMS recently reversed its earlier decision that the web-based training module could not be downloaded for incorporation into existing compliance programs.[4] Most laboratories that are FDRs are themselves enrolled Medicare providers and, as such, have implemented their own compliance programs. Many large entities conduct compliance training online, especially those with many employees in different locations throughout the country. CMS's decision will allow laboratories and other FDRs to integrate the Medicare Advantage-required training seamlessly into existing training programs.

While CMS sought to decrease burdens on FDRs by ensuring that they would not have to complete multiple duplicative compliance program trainings from several MAOs, the agency unintentionally has increased other burdens on FDRs. It has done so both through its determinations in the final rule and through its silence on other issues.

B. Portions of the CMS training are not relevant to some FDRs, while other portions are duplicative of existing compliance training.

CMS should allow its web-based training to be tailored to the many different kinds of FDRs. Portions of CMS's web-based training are not at all relevant to some FDRs. Laboratories do partner with MAOs to provide clinical laboratory services, but generally they do not have relationships with Medicare Part D prescription drug plans. However, many parts of the training focus exclusively on issues that are specific to prescription drug plans. For example, in the section on key indicators of fraud, waste, and abuse, there are slides on potential pharmacy issues, potential wholesaler issues, and potential manufacturer issues that have no relevance to laboratories and many other types of FDRs.[5] Three of the four fraud waste and abuse scenarios

[3] 79 Fed Reg. 29844, 29853 (May 23, 3014).
[4] Memorandum from Medicare Parts C and D Oversight and Enforcement Group, to All Medicare Advantage Organizations and Prescription Drug Plan Sponsors (Jun. 17, 2015), *available at* http://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/Downloads/2016_Complaince_and_-FWA_Training_Requirement_Update.pdf.
[5] *See* slides 20, 21, 23, 24, 25, 26.

have no relevance to laboratories, either.[6] Many FDRs, including many laboratories, have well-developed compliance programs, which include training specifically tailored to the FDR and focused on the areas of highest risk to the FDR. Requiring those FDRs to use this module will either needlessly increase expense or displace other, more effective compliance training. Further, providing employees with irrelevant information can result in trainees not taking the training seriously or ignoring the training altogether.

An FDR that is enrolled in Medicare Part A or Part B is deemed to have met the FWA training and education requirement and is required to complete only the general compliance training module.[7] However, CMS has determined that the downloadable training "cannot be modified," and when taken online the training does not allow separation of the two modules. Therefore, many FDRs who otherwise would be deemed to have met the FWA training requirement will have to participate in that FWA training nonetheless.

While we are pleased that CMS has allowed the compliance program training to be downloaded, we believe that CMS unintentionally has created an additional burden on FDRs by requiring their employees to participate in some training that is not relevant and in other training that is duplicative. One simple solution is for CMS to allow FDRs to download and use the FWA and the general compliance training modules separately and to tailor the training to the specific needs of the FDR. Currently, they are distinct modules included in the same download, but they could be separated into different downloads very easily. A "deemed" FDR then could complete the general compliance training module only to satisfy the Medicare Advantage compliance program training requirement. We ask that CMS take this simple step before the January 1, 2016 effective date.

ACLA hopes that CMS will consider ways for MAOs and FDRs to tailor the training to their own business models and risk areas. While we agree that compliance program training must be complete to be effective, we believe that the most effective training is that which is targeted to the audience and relevant to their daily activities.

C. CMS should provide guidance to MAOs that limits the FDR employees who must participate in compliance training.

We ask CMS to provide clear guidance to MAOs on which FDR employees must participate in compliance training for purposes of meeting the Medicare Advantage program requirements and that make it clear to MAOs that not all FDR employees need to be involved in Medicare Advantage-related training. The principle upon which an FDR that is enrolled in Medicare Part A or B is deemed to have met the FWA training and education requirement can be applied in CMS guidance to MAOs regarding which FDR employees must participate in the general compliance training. To the extent the FDR is an enrolled Medicare Part A or B provider or supplier, the requirement to complete the general compliance training module should be limited to the FDR's management team and compliance personnel.

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[6] *See* slides 47-58.
[7] 42 C.F.R. 422.503(b)(4)(vi)(C)(*2*).

Currently, the Medicare Managed Care Manual states that a sponsor's "employees (including temporary workers and volunteers), and governing body members, as well as FDRs' employees who have involvement in the administration or delivery of Parts C and D benefits must, at a minimum, receive FWA training…"[8] The manual section on the general compliance training does not specify which employees must receive the training, nor does it limit application of the training requirement to FDR employees who are involved in activities relating to Medicare Part C or Part D benefits. Obviously, it would be nonsensical for an employee who has no responsibilities whatsoever that relate to Medicare Part C or Part D benefits to be subject to these compliance program training requirements.

By remaining silent on the issue of what classes of FDR employees are required to participate in the general compliance program training module, CMS effectively has left it up to each MAO to decide. While CMS determined that FDRs should be required to participate in only one compliance training, rather than having to navigate among various MAOs' trainings, it has left FDRs to comply with varying MAOs' requirements regarding who has to complete the training.

CMS should provide guidance to MAOs that limit the FDR employees who must participate in the compliance and FWA training to an FDR's management team and compliance personnel. These are the employees in an FDR who have leadership responsibility for fostering a culture of compliance, focusing and tailoring the FDR's own compliance training based on the business model and specific risks, and implementing policies and procedures that ensure compliance. Training this subset of an FDR's employees ensures that those with "specific governing and oversight responsibilities" have compliance training relevant to a Medicare Advantage plan, which is the standard applied to MAOs themselves.

We ask that CMS include unambiguous guidance for MAOs, in a revision of the Medicare Managed Care Manual or in another forum, stating that for FDRs that are enrolled in Medicare Part A or B, only those FDR management and compliance personnel who are involved in activities relating to Part C or Part D benefits should be required to receive the general compliance program training and the FWA training (for those FDRs that are not "deemed" entities). CMS should do this quickly, far in advance of the January 1, 2016 effective date, so that MAOs and FDRs have ample time to prepare themselves to comply.

[8] Medicare Managed Care Manual, Pub. No. 100-16, Ch. 21, Sec. 50.3.2.

D. Conclusion

Thank you for your attention to our concerns. We would welcome an opportunity to meet with you to discuss these issues in more detail. Please do not hesitate to contact me at (202) 637-9466 or glisson@acla.com if you have any questions.

Sincerely,

JoAnne Glisson, Senior Vice President
American Clinical Laboratory Association