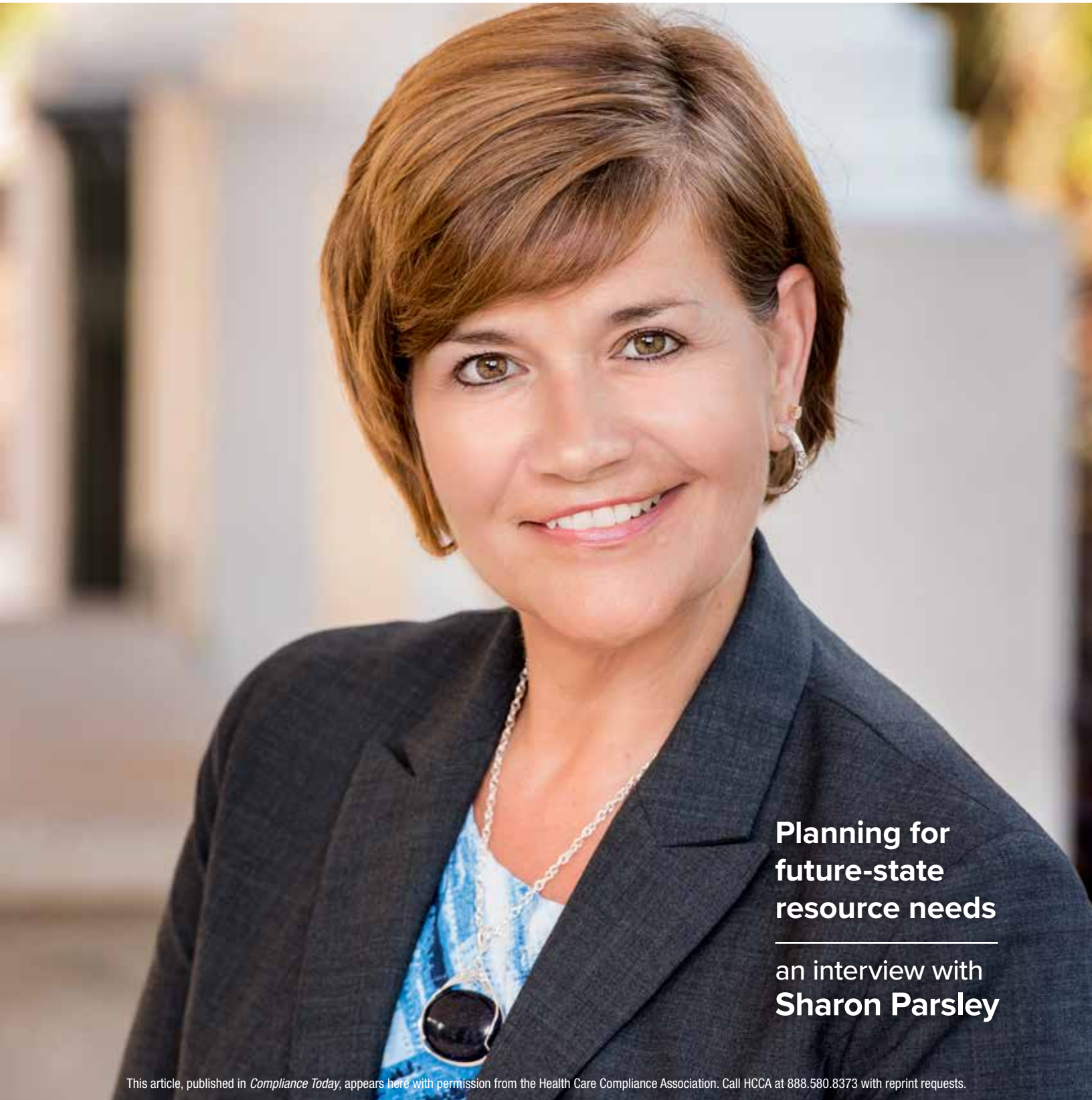
HCCA
hcca-info.org

Compliance TODAY

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

OCTOBER 2018



Planning for future-state resource needs

an interview with **Sharon Parsley**

ARTICLES

Compliance TODAY

Compliance Today (CT) (ISSN 1523-8466) is published by the Health Care Compliance Association (HCCA), 6500 Barrie Road, Suite 250, Minneapolis, MN 55435. Subscription rate is $295 a year for nonmembers. Periodicals postage-paid at Minneapolis, MN 55435. Postmaster: Send address changes to Compliance Today, 6500 Barrie Road, Suite 250, Minneapolis, MN 55435.

VOLUME 20, ISSUE 10

by Joan W. Feldman, Esq., and Stephanie M. Gomes-Ganhão, Esq.

New compliance training requirements for Medicare Advantage

» Medicare Advantage organizations were required to ensure that their contractors annually completed general compliance training for Medicare program requirements and fraud, waste, and abuse issues.

» This often resulted in duplicative training requirements and confusion regarding which employees were required to complete the training.

» CMS has eliminated the contractor training requirement, effective June 15, 2018.

» Medicare Advantage organizations will continue to be required to establish and implement compliance training for their own organizations.

» Providers should not be surprised if they continue to see Medicare Advantage organizations include compliance training requirements in their agreements.

Joan W. Feldman *(jfeldman@goodwin.com) is a Partner and* ***Stephanie M. Gomes-Ganhão*** *(sgomesganhao@goodwin.com) is an Attorney at Shipman & Goodwin LLP in Hartford, CT.*

The Centers for Medicare & Medicaid Services (CMS) imposes strict standards on all Medicare Advantage (MA) organizations that contract with Medicare for the provision of medical care services to beneficiaries enrolled in Medicare Advantage plans. Among the considerable range of requirements that these participating Medicare Advantage organizations (sponsors) have been required to comply with are the requirements to implement and maintain effective corporate compliance programs, which contain seven core measures to prevent, detect, and correct non-compliance with CMS's program requirements, as well as fraud, waste, and abuse, in accordance with 42 CFR § 422.503(b)(4)(vi). Presumably, the objective of these measures is to ensure the integrity of the Medicare Advantage Program and protect Medicare beneficiaries and program funds. Although Medicare Part D plan sponsors are also required to implement and maintain compliance programs, this article focuses on providers that contract with Medicare Advantage Organizations only.


Feldman


Gomes-Ganhão

Until recently, one of these core measures required sponsors to ensure that their first tier, downstream, and related entities (FDRs) completed annual training regarding compliance with CMS program requirements (general compliance training) and fraud, waste, and abuse (FWA) training, collectively, the CMS training requirements. CMS defines FDRs to include all parties with which the sponsor contracts, directly or through intermediaries, to provide healthcare or administrative services to

beneficiaries enrolled in a Medicare Advantage plan.[1] However, CMS recently eliminated this requirement due to ongoing concerns from the industry that satisfying this compliance training requirement imposed an unreasonable financial and administrative burden on both sponsors and their FDRs.

Before the recent amendment of 42 CFR § 422.503, sponsors not only had to validate to CMS that their own employees received the required compliance training, but they also had to verify and certify to CMS that their FDRs received such training.[2] Sponsors would typically attempt to address the CMS training requirements by inserting language into their provider contracts that required the provider to represent that all individuals involved in the delivery of clinical care or administration of the Medicare Advantage Plan had completed general compliance and FWA training. Providers participating in the Medicare Advantage program found the CMS training requirements to be very burdensome and time-consuming. In response to questions and concerns from both sponsors and FDRs, CMS modified the training requirements several times over the years.

In response to questions and concerns from both sponsors and FDRs, CMS modified the training requirements several times over the years.

Given that most providers are already required to conduct regular corporate compliance training by virtue of their participation in governmental payer programs, providers complained to CMS that they were expending significant resources trying to satisfy multiple corporate compliance training requirements, many of which were duplicative. Specifically, FDRs raised concerns that the FWA training was redundant, because many FDRs are required to certify understanding the FWA rules through their enrollment in the Medicare program.

In response to such concerns, in 2010, CMS amended the CMS training requirements to eliminate the FWA annual training requirement for FDRs that are enrolled as Medicare providers.[3] However, this exemption created greater confusion, because FDRs were still required to receive the general compliance training, and some sponsors continued to require the FWA training despite the exemption, because it was difficult to track down which of their FDRs were subject to the exemption and not all of the FDRs' employees were enrolled as Medicare providers.

Sponsors and FDRs continued to complain that the CMS training requirements were burdensome and duplicative, because several types of FDRs (e.g., physicians and pharmacies) generally provide services to Medicare beneficiaries under multiple sponsors. Because CMS required each sponsor to ensure that all of its FDRs satisfied the CMS training requirements, FDRs that contract with multiple sponsors were often required by their sponsors to complete similar trainings on multiple occasions so that each sponsor could ensure satisfaction of the CMS training requirements.

In order to address these concerns, in 2014, CMS developed its own web-based, standardized, compliance training modules available on the Medicare Learning Network.[4] CMS again revised the CMS training requirements such that each sponsor was required to ensure that its FDRs completed the new CMS training modules and to accept the certificate of completion of the CMS-developed training from their FDRs as satisfaction of the CMS

training requirements.[5] Furthermore, sponsors were "prohibited from developing and implementing their own training or providing supplemental training materials to fulfill this requirement."[6]

Notwithstanding the new standardized CMS training modules, CMS continued to receive questions and complaints related to the CMS training requirements. In 2015, CMS issued a memorandum that provided that, although the CMS training content could not be modified, sponsors and FDRs could "add to the CMS training to cover topics specific to their organization."[7] Furthermore, in 2016, CMS issued another memorandum that: (1) clarified that sponsors and FDRs could incorporate the content of the CMS-developed training modules into their organizations' existing compliance training materials/systems or written documents distributed to providers (e.g., Provider Guides); (2) provided guidance as to which entities qualify as FDRs and which employees within an FDR were required to complete the training; and (3) indefinitely suspended CMS's enforcement of the requirement that sponsors obtain certificates of completion of the CMS training modules from their FDRs.[8]

On April 16, 2018, in response to ongoing complaints from providers regarding the burdensome compliance training requirements, CMS published final regulations, effective June 15, 2018, that eliminate the requirement that sponsors ensure that their FDRs complete the CMS training requirements.[9] CMS's rationale for removing this regulatory requirement was due in part to CMS recognizing that the CMS training requirements did not promote the "effective and efficient administration of the Medicare Advantage and Prescription Drug programs."[10] CMS further acknowledged in the commentary to the final regulations that "delegated entities range in size, structure, risks, staffing, functions, and contractual arrangements which necessitates the sponsoring organization have discretion in its method of oversight to ensure compliance with program requirements."[11]

In addition, CMS explained that CMS contracts with the sponsor, and not with the FDR entity, and the sponsor is "ultimately responsible for compliance with all applicable statutes, regulations and sub-regulatory guidance, regardless of who is performing the work."[12] CMS, therefore, emphasized that it "will continue to hold sponsoring organizations accountable for the failures of their FDRs to comply with Medicare program requirements, even with these proposed changes."[13]

CMS, therefore, emphasized that it "will continue to hold sponsoring organizations accountable for the failures of their FDRs to comply with Medicare program requirements...

Despite the fact that the CMS training requirements no longer apply to FDRs, existing regulations still require sponsors to specify in their contracts with FDRs that "FDRs must comply with all applicable federal laws, regulations and CMS instructions."[14] Furthermore, CMS's routine compliance audits include evaluations of sponsors' "monitoring and auditing of their FDRs as well as FDR oversight."[15] Lastly, CMS recognized that "[i]f sponsors choose to include a compliance program training requirement as part of their contract with FDRs, that is a private contractual matter between the FDR and the sponsoring organization" and that "[s]uch training would not be prohibited by these rules as amended."[16]

Conclusion

This is good news for providers, but providers should not be surprised if they continue to see sponsors include a compliance program training requirement in their agreements. However, it is now a negotiable matter and, because most providers already have well-established corporate compliance training programs, each provider will need to evaluate the most efficient and effective manner in which it can satisfy its contractual obligations for compliance training. Therefore, it is important that the individuals responsible for contracts with sponsors communicate the provider's compliance obligations to the provider's corporate Compliance department so that compliance with these contractual obligations is satisfied and not overlooked. In essence, understand your contractual obligations, the operational implications, and the risk you are assuming.

1. See definitions of "first tier entity," "downstream entity," and "related entity" at 42 C.F.R. § 422.500.
2. See Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19678, 19810 (April 15, 2010).
3. Id. at 19688, 19689-91.
4. See Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29844, 29853-54 (May 23, 2014).
5. Id. at 29854.
6. Id. at 29958-59.
7. CMS Memorandum: "Update—Reducing the Burden of the Compliance Program Training Requirements" (June 17, 2015).
8. CMS Memorandum: "Additional Guidance—Compliance Program Training Requirements and Audit Process Update" (Feb. 10, 2016).
9. See Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 Fed. Reg. 16440, 16618 (April 16, 2018).
10. Id.
11. Id. at 16619.
12. Id.
13. Id.
14. Id.
15. Id.
16. Id.at 16620.