Analyzing the Revised AdvaMed Code: Suggested Evaluation Checklist

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Health Industry Alert

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Key Points

- Review the AdvaMed Code revisions with an eye towards other key fraud and abuse, transparency and compliance issues on the horizon: the expansion of the Sunshine Act and anticipated regulatory changes to address value-based arrangements.
- Use the Akin Gump AdvaMed Code Evaluation as a high-level guide to review and assess the recent AdvaMed Code revisions.
- Consider a comprehensive, third-party compliance program assessment to help ensure that you continue to maintain an effective and reliable compliance program.

As reported in our previous Health Industry Alert, for the first time in nearly a decade the Advanced Medical Technology Association ("AdvaMed") has updated its Code of Ethics on Interactions with U.S. Health Care Professionals (the "Revised AdvaMed Code"). These revisions, which include both substantive changes and clarifications to the AdvaMed Code's language, take effect January 1, 2020. Given the evolution in the legal and regulatory landscape the medtech industry expects in 2019, medical technology companies should consider taking advantage of the recent modifications to the AdvaMed Code to review other health care compliance program policies, practices and procedures.

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See Advanced Medical Technology Association, Code of Ethics on Interactions with Health Care Professionals in the United States (2019), available at https://www.advamed.org/issues/code-ethics/code-ethics.

For example, the 2018 SUPPORT Act expanded medical technology manufacturers' reporting obligations under the U.S. Physician Payments Sunshine Act (now renamed the Provider Payments Sunshine Act) from U.S. physicians and teaching hospitals to now include advanced practice registered nurses, nurse practitioners, certified nurse mid-wives, nurse anesthetists and physician assistants. See SUPPORT for Patients & Communities Act, Pub. L. No. 115-271, § 6111 (2018); see also 42 U.S.C. § 1320a-7h (2018). We expect the Centers for Medicare and Medicaid Services (CMS) to issue proposed (and perhaps final) regulations in 2019 implementing the expanded Sunshine provisions. Also in 2019, we anticipate revisions to both Stark Law regulations and the Anti-Kickback Statute's safe harbors to address value-based arrangements.

The Revised AdvaMed Code does not only affect medical technology companies. Hospitals and other providers should also be aware of these recent changes and should understand what they mean for interactions with industry representatives.

Akin Gump's health care and life sciences practice has reviewed and analyzed the Revised AdvaMed Code. We have prepared an AdvaMed Code Evaluation Checklist as a tool to assist medical technology companies, hospitals and health care organizations, and others in evaluating the Code's updates. The Evaluation Checklist is not intended to identify all of the changes in the Revised AdvaMed Code, but it highlights certain key revisions. In addition to updating policies, training, procedures and auditing/monitoring plans, Akin Gump also regularly conducts comprehensive, third-party compliance program assessments.

Please download a copy of Akin Gump's AdvaMed Code Evaluation Checklist here.

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