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MedTech update 2020 — Legal and regulatory issues to watch for in the medical technology industry in the new year: Federal health care programs

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Medical device and diagnostics companies and laboratories should anticipate significant legal, regulatory and market changes in 2020 that will have a lasting impact on the industry. From revisions to how the government regulates value-based care, to shifts in the marketplace for medtech mergers and acquisitions (M&A), 2020 will prove to be another year of evolution.

Based on recent trends and developments, Akin Gump has prepared several articles to provide the medtech industry with a landscape overview of the following issues in the year ahead: FDA regulatory developments; federal health care programs; international trade; intellectual property (IP) litigation; False Claims Act enforcement and health information and privacy and data protection.

> OIG, in particular, expressed skepticism about whether medtech companies should participate in safe harbor-protected value-based arrangements.

We plan to monitor and report on these developments and potential updates as the year unfolds.

FEDERAL HEALTH CARE PROGRAMS

HHS expected to issue final value-based rules

In 2020, the medtech industry should prepare for final rules from the Department of Health and Human Services (HHS) on value-based care, and, potentially, new proposed rules to address medtech's role in value-based arrangements.

On October 17, 2019, the HHS Office of Inspector General (OIG) and Centers for Medicare and Medicaid Services (CMS) jointly released long-awaited proposals to revise the Federal Anti-Kickback Statute (AKS) safe harbors and the Physician Self-Referral Law ("Stark Law") regulatory exceptions, respectively.[1]

Akin Gump has issued client alerts on both the AKS[2] and Stark proposals.[3]

HHS will likely issue its final rules in the first half of 2020, which may greatly expand the scope of permissible activities under the AKS and the Stark Law. Medtech companies should pay particular attention to how OIG and CMS address the industry's products, technologies and related services under the final rules.

While the proposed rule excludes pharmaceutical manufacturers, durable medical equipment suppliers and laboratories from participating in value-based enterprises that merit protection under the new safe harbors and exceptions, OIG and CMS solicited comments on whether value-based arrangements involving medical technology should be protected.

OIG, in particular, expressed skepticism about whether medtech companies should participate in safe harbor-protected value-based arrangements.

We also expect that that OIG will release a second proposed rule on value-based care. This second proposed rule will address value-based arrangements under the AKS involving pharmaceutical companies and medical device and medical technology companies, including how products are purchased and used as part of a value-based arrangement.

Clarification of Sunshine Act requirements for medical devices

In November 2019, CMS issued much-anticipated regulations on a statutorily-mandated expansion of the U.S. Physician Payments Sunshine Act.[4]

The SUPPORT Act of 2018 expands the scope of the Sunshine Act to require medical technology companies to disclose virtually all payments and transfers of value made to advanced practice registered nurses, nurse practitioners, certified nurse anesthetists, certified nurse midwives and physician assistants.

Previously, companies were only required to report payments and transfers to physicians and teaching hospitals. The 2018 law also requires companies to include a portion of the "Unique Device Identifier" or UDI as part of each line item disclosed under the Sunshine Act.

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Medical technology companies must start tracking and collecting this information on January 1, 2021. Companies should therefore begin expanding their internal reporting systems and Sunshine Act capabilities.

We also anticipate additional guidance from CMS in 2020 about how to collect this information and more of the technical specifications as to how CMS will validate such information, whether the agency will issue a list of all advanced practice registered nurses and other professionals on which companies must report, and how CMS plans to assess and review device identifier disclosures.

Codes changes go into effect

Medtech companies should also be mindful of revisions to longstanding industry codes that go into effect in January 2020. This includes changes to AdvaMed's Code of Ethics, as well as similar changes to the Medical Device Manufacturers Association Code (revised in Oct. 2019).

Notes

[1] *See* Department of Health & Human Services, Office of Inspector General, 84 Fed. Reg. 55694 (Oct. 17, 2019); *see also* Department of Health & Human Services, Centers for Medicare & Medicaid Services, 84 Fed. Reg. 55766 (Oct. 17, 2019).

[2] https://bit.ly/2OSCght.

[3] https://bit.ly/38qfGol.

[4] *See* Department of Health & Human Services, Centers for Medicare & Medicaid Services, 2020 Physician Fee Schedule, https://go.aws/38mZ0Ns.

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