Revisions to Safe Harbors Under the Anti-kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, Final Rule November 20, 2020

Eligibility for the Value-Based Safe Harbors, the Patient Engagement and Support Safe Harbor, and the Personal Services and Management Contracts Safe Harbor for Outcomes-Based Payment

Entity Type	Care Coordination Arrangements 42 C.F.R. § 1001.952(ee)	Substantial Downside Risk 42 C.F.R. § 1001.952(ff)	Full Financial Risk 42 C.F.R. § 1001.952(gg)	Patient Engagement and Support 42 C.F.R. § 1001.952(hh)	Outcomes-Based Payments 42 C.F.R. § 1001.952(d)(2)
Providers and Suppliers (e.g., hospitals, post-acute care providers, and physicians)	Eligible	Eligible	Eligible	Eligible	Eligible
Pharmacies Other Than Compounding Pharmacies	Eligible	Eligible	Eligible	Eligible	Eligible
Compounding Pharmacies (i.e., pharmacies that primarily compound drugs or primarily dispense compounded drugs)	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Manufacturer of a Device or Medical Supply (as defined in 42 C.F.R. § 1001.952(ee)(14)(iv))	Eligible, but only for in- kind remuneration that is digital health technology	Ineligible	Ineligible	Eligible, but only for tools and supports that are digital health technology	Ineligible
DMEPOS Suppliers (other than pharmacies or physicians, providers, or other entities that primarily furnish services)	Eligible, but only for in- kind remuneration that is digital health technology	Ineligible	Ineligible	Ineligible	Ineligible
Pharmacy-Benefit Managers	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Pharmaceutical Manufacturers, Distributors, Wholesalers	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Laboratory Companies	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Physician-Owned Distributors (PODs)	Ineligible	Ineligible	Ineligible	Ineligible	Ineligible
Health Technology Companies Not Otherwise Covered by an Entity Type on This List	Eligible	Eligible	Eligible	Eligible	Eligible

DISCLAIMER: This chart is current as of the date issued. It is an educational resource; it is not intended to create any rights, privileges, or benefits. Although every reasonable effort has been made to ensure the accuracy of this chart, the ultimate responsibility for complying with the Federal fraud and abuse laws lies with the party or parties seeking compliance with such laws. We refer readers to the <u>final rule published in the Federal Register</u> for additional and official information.