

## Summary Chart of Changes to Electronic Health Records (EHR) Donation Rules Under Stark and Anti-Kickback Statute (AKS)

Current Stark Exception	New Stark Exception (effective on Jan. 19, 2021)	Current AKS Safe Harbor	New AKS Safe Harbor (effective on Jan. 19, 2021)
(1) The remuneration is nonmonetary and consists of EHR items and services.	Expanded to include cybersecurity software and services.	(1) The remuneration is nonmonetary and consists of EHR items and services.	Expanded to include cybersecurity software and services.
(2) The items and services are provided by an entity (other than a laboratory company) to a physician.	Same as prior rule.	(2) The items and services are provided to (i) an individual or entity (other than a laboratory company) that provides services covered by a federal healthcare program or (ii) a health plan.	Same as prior rule.
(3) The software is interoperable at the time it is provided to the recipient.	The Updated Stark Rule clarifies the term “interoperable” to mean (i) able to securely exchange data with and use data from other health information technology and (2) allows for complete access, exchange and use of all electronically accessible health information for authorized use.	(3) The software is interoperable at the time it is provided to the recipient.	The Updated AKS Rule clarifies the term “interoperable” to mean (i) able to securely exchange data with and use data from other health information technology and (2) allows for complete access, exchange and use of all electronically accessible health information for authorized use.
(4) The donor does not limit or restrict the use, compatibility or interoperability of the items or services with other EHR systems.	Eliminated this provision. <i>*Information blocking rules still apply but are not enforced under this authority.</i>	(4) The donor does not limit or restrict the use, compatibility or interoperability of the items or services with other EHR systems.	Eliminated this provision. <i>*Information blocking rules still apply but are not enforced under this authority.</i>
(5) Before receipt of the items and services, the physician pays 15 percent of the donor’s cost for the items and services.	(i) Before receipt of the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor’s cost for the items and services, and (ii) with respect to items or services received from the donor after the initial donation, the physician pays 15 percent of the cost at reasonable intervals.	(5) Before receipt of the items and services, the physician pays 15 percent of the donor’s cost for the items and services.	The Updated AKS Rule now requires (i) before receipt of the initial donation of items and services or the donation of replacement items and services, the physician pays 15 percent of the donor’s cost for the items and services, and (ii) with respect to items or services received from the donor after the initial donation, the physician pays 15 percent of the cost at reasonable intervals.
(6) Neither the physician nor the physician’s practice makes the receipt of the donation a condition of doing business with the donor.	Same as prior rule.	(6) Neither the recipient nor the recipient’s practice makes the receipt of the donation a condition of doing business with the donor.	Same as prior rule.

Current Stark Exception	New Stark Exception (effective on Jan. 19, 2021)	Current AKS Safe Harbor	New AKS Safe Harbor (effective on Jan. 19, 2021)
(7) Decisions to donate to a recipient are not determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.	Same as prior rule.	(7) Decisions to donate to a recipient are not determined in any manner that directly takes into account the volume or value of referrals or other business generated between the parties.	Same as prior rule.
(8) The arrangement is set forth in a written, signed agreement.	Same as prior rule.	(8) The arrangement is set forth in a written, signed agreement.	Same as prior rule.
(9) The physician does not possess equivalent technology.	Eliminated this provision.	(9) The physician does not possess equivalent technology.	Eliminated this provision.
(10) For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict or take any action to limit the physician's right or ability to use the items or services for any patient.	Same as prior rule.	(10) For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict or take any action to limit the recipient's right or ability to use the items or services for any patient.	Same as prior rule.
(11) The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the physician's medical practice.	Same as prior rule.	(11) The items and services do not include staffing of the recipient's office and are not used primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations.	Same as prior rule.
(12) The EHR software contains electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system, which meets the applicable Part D standards.	Same as prior rule.	(12) The EHR software contains electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system, which meets the applicable Part D standards.	Same as prior rule.
(13) The arrangement does not violate the AKS or other law.	Same as prior rule.	(13) The donor does not shift the costs of the items or services to any federal healthcare program.	Same as prior rule.
(14) The transfer of the items or services occurs and all conditions are satisfied on or before December 31, 2021.	Eliminated this provision.	(14) The transfer of the items and services occurs and all conditions have been satisfied on or before December 31, 2021.	Eliminated this provision.