Stark Law Exceptions and Anti-Kickback Safe Harbors

Waiver of Beneficiary Coinsurance and Deductible Amounts

Stark [No comparable exception]	**Anti-Kickback** Safe harbor for reduction or waiver of a federal or state health program beneficiary's obligation to pay coinsurance or deductible amounts
	If the coinsurance or deductible amounts are owed to a hospital for inpatient hospital services for which Medicare pays under the prospective payment system, the hospital must comply with all of the following three standards: a) the hospital must not later claim the amount reduced or waived as a bad debt for payment purposes under Medicare or otherwise shift the burden of the reduction or waiver onto Medicare, a State health care program, other payers, or individuals; b) the hospital must offer to reduce or waive the coinsurance or deductible amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for Medicare reimbursement is filed; c) the hospital's offer to reduce or waive the coinsurance or deductible amounts must not be made as part of a price reduction agreement between a hospital and a third-party payer (including a health plan), unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy.
	If the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under titles V or XIX of the Social Security Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under title V of the Act, the health care center or facility may reduce or waive the coinsurance or deductible amounts for items or services for which payment may be made in whole or in part under part B of Medicare or a State health care program.

Warranties

Stark [No comparable exception]	**Anti-Kickback** Safe harbor for any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer
	The buyer must fully and accurately report any price reduction of the item (including a free item), which was obtained as part of the warranty, in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.
	The buyer must provide, upon request by the Secretary of HHS or a State agency, the information required to be provided by the manufacturer or supplier.
	The manufacturer or supplier must fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations; and/or where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.
	The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.
	The term warranty means either an agreement made in accordance with the provisions of 15 U.S.C. 2301(6), or a manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item (which is covered by

	an agreement made in accordance with this statutory provision), on terms equal to the agreement that it replaces.

Personal Services and Management Contracts

Stark Stark exception to the referral prohibition related to compensation arrangements for personal services or management	**Anti-Kickback** Safe harbor for remuneration from an entity under an personal service arrangement or management contract
The arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.	The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
The arrangement(s) covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity. This requirement is met if all separate arrangements between the entity and the physician and the entity and any family members incorporate each other by reference or if they cross-reference a master list of contracts that is maintained and updated centrally and is available for review by the Secretary of HHS upon request. The master list must be maintained in a manner that preserves the historical record of contracts. A physician or family member can "furnish" services through employees whom they have hired for the purpose of performing the services; through a wholly-owned entity; or through locum tenens physicians (as defined at Sec. 411.351, except that the regular physician need not be a member of a group practice).	The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).	If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
The term of each arrangement is for at least 1 year. To meet this requirement, if an arrangement is terminated during the term with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original term of the arrangement.	The term of the agreement is for not less than one year.
The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at Sec. 411.351 of this subpart), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.	The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.
The services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.	The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any state or federal law.
A holdover personal service arrangement for up to 6 months following the expiration of an agreement of at least 1 year that met all of the above conditions satisfies the requirements, provided that the holdover personal service arrangement is on the same terms and conditions as the immediately preceding agreement.	
	The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Sale of Practice

Stark **[No comparable exception]**	**Anti-Kickback** Safe harbor for payments made to a practitioner by another practitioner where first practitioner is selling a practice to the second practitioner
	The period from the date of the first agreement pertaining to the sale to the completion of the sale is not more than one year.
	The practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner for which payment may be made in whole or in part under Medicare or a State health care program after one year from the date of the first agreement pertaining to the sale.

	Remuneration under this provision does not include any payment made to a practitioner by a hospital or other entity where the practitioner is selling his or her practice to the hospital or other entity, so long as the following four standards are met: a) the period from the date of the first agreement pertaining to the sale to the completion date of the sale is not more than three years; b) the practitioner who is selling his or her practice will not be in a professional position after completion of the sale to make or influence referrals to, or otherwise generate business for, the purchasing hospital or entity for which payment may be made in whole or in part under Medicare or a State health care program; c) the practice being acquired must be located in a Health Professional Shortage Area (HPSA), as defined in Departmental regulations, for the practitioner's specialty area; d) commencing at the time of the first agreement pertaining to the sale, the purchasing hospital or entity must diligently and in good faith engage in commercially reasonable recruitment activities that may reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice within a one year period and will satisfy the conditions of the practitioner recruitment safe harbor.

Referral Services

Stark Stark exception to the referral prohibition related to compensation arrangements for referral services	**Anti-Kickback** Safe harbor for payments between an individual or entity ("participant") and another entity serving as a referral source ("referral service")
Remuneration that meets all of the conditions in the anti-kickback safe harbor for referral services.	The referral service does not exclude as a participant in the referral service any individual or entity who meets the qualifications for participation.
	Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by either party for the other party for which payment may be made in whole or in part under Medicare or a State health care program.
	The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charge the person referred at the same rate as it charges other persons not referred by the referral service, or that these services be furnished free of charge or at reduced charge.
	The referral service makes the following five disclosures to each person seeking a referral, with each such disclosure maintained by the referral service in a written record certifying such disclosure and signed by either such person seeking a referral or by the individual making the disclosure on behalf of the referral service: a) the manner in which it selects the group of participants in the referral service to which it could make a referral; b) whether the participant has paid a fee to the referral service; c) the manner in which it selects a particular participant from this group for that person; d) the nature of the relationship between the referral service and the group of participants to whom it could make the referral; and e) the nature of any restrictions that would exclude such an individual or entity from continuing as a participant.