

Modifications to Anti-Kickback Law Personal Services and Management Contracts Safe Harbor

The final rules include important modifications to the Anti-Kickback Statute Personal Services and Management Contracts Safe Harbor. Under the new rules, the OIG is replacing the current Safe Harbor requirement that the aggregate compensation payable under the services arrangement must be set in advance with a requirement that the methodology for determining the compensation paid to the agent over the term of the agreement is set in advance. Compensation must still reflect fair market value, be commercially reasonable, and not take into account the volume or value of referrals of business otherwise generated between the parties. Per the OIG, parties seeking protection under this safe harbor must evaluate the specific facts and circumstances of their arrangement to determine whether the compensation methodology over the term of the agreement is set in advance before any payment under the arrangement is made. These changes help to harmonize the Anti-Kickback safe harbor with the parallel Stark Law exception for personal services arrangements.

The OIG is also finalizing its proposal to eliminate the requirement that if any agreement provides for services on a periodic, sporadic or part-time basis, the contract must specify the schedule, length, and the exact charge for such intervals. The removal of these part-time arrangement requirements will provide parties flexibility to contract for services as-needed.

Finally, under the new rules the OIG has added a new outcomes-based payments safe harbor. This new safe harbor protects arrangements under which payments are made as rewards for achieving certain defined outcomes and/or under which payments are reduced or recouped for failure to achieve such outcomes. In order for an arrangement to be protected under the new safe harbor, the outcomes selected must be either based on clinical evidence or be tied to benchmarks related to quality of patient care, reduction in costs, or both.