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Practice Group:

Health Care

CMS and OIG Issue Final Fraud and Abuse Waivers in Connection With the Medicare Shared Savings Program

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Summary

Nearly four years after introducing waivers to certain fraud and abuse laws for Accountable Care Organizations ("*ACOs*") and other entities participating in the Medicare Shared Savings Program ("*MSSP*"), the Centers for Medicare and Medicaid Services ("*CMS*") and the Office of Inspector General ("*OIG*") finalized the five waivers in a joint Final Rule published October 29.[1] The waivers create limited exceptions to the physician self-referral law ("*Stark Law*"),[2] the federal anti-kickback statute ("*AKS*"),[3] and the prohibition on beneficiary inducements in the civil monetary penalties ("*CMP*") law.[4]

The Final Rule largely tracks the waivers as set forth in the 2011 Interim Final Rule, with the following notable exceptions:

(1) The OIG eliminated the Gainsharing CMP waiver due to recent statutory changes limiting its application to only payments made as an inducement to reduce or limit clinically necessary services;[5]

(2) To become eligible for the pre-participation and participation waiver, ACO governing bodies are now required to provide the basis for determining that an arrangement is reasonably related to the purpose of the MSSP (the interim final rule was permissive on that point);

(3) The Final Rule clarifies that a "home health supplier" is a provider, supplier, or other entity that is *primarily engaged* in furnishing home health services;[6] and

(4) The Final Rule incorporates certain public disclosure standards and other guidance jointly published by CMS and the OIG earlier this year.[7]

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[1] *See* Medicare Program; Final Waivers in Connection With the Shared Savings Program, Final Rule, 80 Fed. Reg. 66726 (Oct. 29, 2015). See also, Medicare Program Final Waivers in Connection With the Shared Savings Program; Interim Final Rule, 76 Fed. Reg. 67992 (Nov. 2, 2011).

[2] 42 U.S.C. 1395nn.

[3] 42 U.S.C. 1320a–7b(b).

[4] 42 U.S.C. 1320a–7a-(a)(5).

[5] See Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), H.R. 2, 114th Cong. (2015). MACRA limited the prohibition's reach to "clinically necessary" services; whereas prior to the new law any limitation on clinical services—medically necessary or not— was prohibited. See related K&L Gates Client Alert at http://www.klgates.com/sgr-law-brings-changes-to-cmp-prohibition-on-gainsharing-04-17-2015/.

[6] *See* 80 Fed. Reg. at 66727 (emphasis original).

[7] *See* CENTERS FOR MEDICARE AND MEDICAID SERVICES, OFFICE OF INSPECTOR GENERAL, MEDICARE SHARED SAVINGS PROGRAM WAIVERS: ADDITIONAL GUIDANCE, Feb. 12, 2015, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Additional-MSSP-Waiver-Guidance.pdf (last accessed Nov. 1, 2015).

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Background: Overview of the MSSP and the Need for Waivers

The Center for Medicare and Medicaid Innovation, authorized by the Patient Protection and Affordable Care Act, is tasked with developing novel health care payment and delivery systems, including the ACO model. In its most general terms, an ACO is a group of health care providers and suppliers who coordinate to provide Medicare fee-for-service beneficiaries with high-quality care at lower costs. Since its inception in 2011, the Medicare Shared Savings Program ("MSSP") ACO program has expanded rapidly to include more than 400 participating organizations representing nearly 15,000 providers and reaching more than 7.3 million beneficiaries.[8] Clinical integration is central to the MSSP's overarching goals of achieving better individual and population health while containing growth in costs. From network development to shared savings distributions, however, "providers [that participate in the MSSP] must integrate in ways that potentially implicate fraud and abuse laws addressing financial arrangements . . . between and among providers, including those who are potential referral sources to one another."[9] The waivers are designed to allow otherwise unrelated providers the flexibility needed to fund the development of, and manage the internal funds flows within, an ACO without running afoul of fraud or abuse laws.

Description of Final Waivers and Requirements for Waiver Eligibility

ACO Pre-Participation Waiver of the Stark Law and the AKS. The Pre-participation waiver applies to startup arrangements—i.e., arrangements for items, services, facilities, or goods, used to develop an ACO— undertaken in anticipation of entering an MSSP participation agreement with CMS.[10] To qualify for the pre-participation waiver, entities must meet the following requirements:

(1) The arrangement must be undertaken by a party or parties with a good-faith intention to develop an ACO and to submit an application for participation in the MSSP in a particular year. In addition, the arrangement must include, at minimum, the ACO and/or at least one participant eligible to form an ACO as defined in 42 C.F.R. § 425.102(a). The parties may not include drug and device manufacturers, distributors, durable medical equipment ("*DME*") suppliers, or home health suppliers.

The Final Rule defines home health supplier as "a provider, supplier or other entity that is *primarily engaged* in furnishing 'home health services' . . ." This includes both free-standing home health agencies and their parent entities, so long as the parent entity is primarily engaged in providing home health services. However, the Final Rule clarifies that hospitals, skilled nursing facilities, physicians' practices, as well as other providers and suppliers that

[8] *See e.g.*, CENTERS FOR MEDICARE & MEDICAID SERVICES, Medicare Shared Savings Program Accountable Care Organizations https://data.cms.gov/ACO/Medicare-Shared-Savings-Program-Accountable-Care-O/ay8x-m5k6 (last accessed Nov. 1, 2015); CENTERS FOR MEDICARE & MEDICAID SERVICES, Medicare Shared Savings Program Accountable Care Organizations-Participants, https://data.cms.gov/ACO/Medicare-Shared-Savings-Program-Accountable-Care-O/pfam-u3vp (last accessed Nov. 1, 2015); CENTERS FOR MEDICARE & MEDICAID SERVICES , Fast Facts: All Medicare Shared Savings Program ACOs, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/All-Starts-MSSP-ACO.pdf(last accessed Nov. 1, 2015).

[9] 80 Fed. Reg. at 66726.

[10] The duration of the pre-participation waiver is contingent on whether CMS accepts an ACO's participation agreement and allows the ACO to enter the MSSP. For entities that are accepted into the MSSP, the pre-participation waiver is automatically merged into a participation waiver and no further action by the governing body is needed to continue the waiver's effect. For ACOs whose participation agreement is ultimately rejected by CMS, the pre-participation waiver expires six months after the date of the denial notice, and no new arrangements are permitted during the final six months of the term. For entities that fail to submit a participation agreement by the due date, the pre-participation waiver expires on the earlier of: (i) the application due date; or (ii) the date on which the ACO submits a statement of reasons for failing to submit an application (though ACOs may apply for an extension). *See* 80 Fed. Reg. at 66736.

provide some home health services but do not primarily engage in those services, *are not* excluded from eligibility for the pre-participation waiver. The Final Rule is silent as to whether the same logic would apply to DME suppliers and other entities currently excluded from eligibility for the pre-participation waiver.[11]

(2) The parties must be taking diligent steps to develop an organization eligible to enter a participation agreement with CMS in a target year and must satisfy MSSP governance, leadership, and management requirements as specified at 42 C.F.R. §§ 425.106 and 425.108.[12]

(3) The ACO's governing body must make and duly authorize a *bona fide* determination that the arrangement is reasonably related to the purposes of the MSSP. The Final Rule clarifies that activities that are consistent with the purposes of the Shared Savings Program include: (i) promoting evidence-based medicine and patient engagement; (ii) meeting reporting requirements for quality and cost measures; (iii) promoting care coordination; (iv) developing ACO-related clinical and administrative systems; (v) achieving MSSP-required clinical integration goals; (vi) meeting MSSP quality standards; (vii) evaluating population health for ACO-assigned beneficiaries; (viii) communicating certain health-related information to beneficiaries; and (ix) developing tools and standards to promote beneficiary access (*e.g.*, to medical records) and communication.[13]

The Final Rule clarifies that activities unrelated to the purposes of the MSSP include: (i) pay-to-play arrangements whereby providers are required to pay for ACO-related referrals; (ii) medical directorships or other personal services arrangements that provide remuneration unrelated to actual services performed; (iii) inducements to stint on medically necessary care; and (iv) free gifts in exchange for referrals.[14]

(4) The startup arrangement, its authorization by the governing body, and the diligent steps to develop the ACO must be contemporaneously documented, and such documentation must be retained for at least ten years following completion of the arrangement. At minimum, the documentation must provide: (i) a description of the arrangement, including the parties, effective date, purposes, and covered items, goods, and services; (ii) the date and manner of the governing body's authorization of the startup arrangement, which must include the basis for the governing body's determination that the arrangement is reasonably related to the purposes of the shared savings program; and (iii) a description of the diligent steps undertaken by the parties to develop the ACO.[15] The documentation must demonstrate that the ACO's governing body employed a "thoughtful, deliberative process for making a determination that an arrangement is reasonably related to the purpose of [the MSSP, and clearly articulate] the basis for the determination and authorizations."[16]

(5) The description of the arrangement—including the parties, the date and purpose, and good and services covered, but not the financial or economic terms—must be

[11] *See id.*at 66,732, 66742.
[12] *See id.* at 66742.
[13] *Id.* (Citing 76 Fed. Reg. at 68002).
[14] *See* 80 Fed. Reg. at 66731.
[15] *See id.* at 66742.
[16] *See id.* at 66734.

publicly disclosed in accordance with guidance issued by the Secretary of HHS.[17] The Final Rule incorporates the Additional Waiver Guidance jointly published by CMS and the OIG on February 12, 2015, which states that public disclosures must include a description of the arrangement for which waiver protection is sought, posted on a public website belonging to (and bearing the name of) the ACO or the individual or entity forming the ACO, within 60 days of the date of the arrangement.[18] The description should be clearly labeled to indicate that the parties are seeking waiver protection, and must include information identifying the parties to the arrangement, the effective date, and the type of item, service, good, or facility provided under the arrangement. Material amendments or modifications to previously disclosed arrangements must also be disclosed following the same procedures.[19]

(6) The ACO must file an application for participation in the MSSP by the applicable due date for the target year, or certify to CMS the reasons for its failure to timely submit an application.[20]

ACO Participation Waiver of the Stark Law and the AKS. The ACO participation agreement applies broadly to ACO-related arrangements undertaken during the term of the ACO's MSSP participation agreement with CMS, and for a limited duration after the term of the agreement. The participation waiver starts on the date that the ACO enters a participation agreement with CMS and ends six months after the earlier of the following: (i) the ACO voluntarily terminates its participation in the MSSP; or (ii) the ACO's participation agreement with CMS expires. If CMS terminates the ACO's participation agreement, the waiver period will end on the effective date of the termination. To qualify for the participation waiver, entities must meet the following requirements:

(1) The ACO must enter into a participation agreement with CMS and remain in good standing under the agreement.

(2) The ACO must meet the MSSP requirements set forth in regulations concerning its governance, leadership, and management.[21]

(3) As with the pre-participation waiver, the ACO's governing body must make and duly authorize a *bona fide* determination that the arrangement is reasonably related to the purposes of the MSSP.

(4) Both a description of the arrangement and its authorization by the governing body must be contemporaneously documented with documents retained for at least 10 years following completion of the arrangement.

(5) The description of the arrangement must be publicly disclosed following the public disclosure procedures outlined above. Again, the public disclosure must not include financial or economic terms of the arrangement.

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[17] *Id*.

[18] *See* CENTERS FOR MEDICARE AND MEDICAID SERVICES, OFFICE OF INSPECTOR GENERAL, MEDICARE SHARED SAVINGS PROGRAM WAIVERS: ADDITIONAL GUIDANCE, Feb. 12, 2015, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Additional-MSSP-Waiver-Guidance.pdf (last accessed Nov. 1, 2015).

[19] *Id*.

[20] *See* 80 Fed. Reg. at 66742. *See also* Additional Waiver Guidance at 2.

[21] *See* 80 Fed. Reg. at 66743. *See also* 42 C.F.R. §§ 425.106 and 425.108.

The most significant change to the participation waiver was a clarification that the governing body must document the basis for its *bona fide* determination that the arrangement is related to the purposes of the MSSP. Previous guidance had used permissive language on this point. CMS and the OIG also considered, and ultimately rejected, requests to: (i) grant a six-month grace period when CMS involuntarily terminates an ACO's participation agreement; and (ii) add additional requirements (*i.e.*, fair market value ("*FMV*") or commercial reasonableness) to outside party arrangements.

Shared Savings Distributions Waiver of the Stark Law and the AKS. The shared savings distribution waiver applies to distributions and uses of shared savings payments earned under the MSSP. Providers must meet the following requirements to qualify for the shared savings waiver:

(1) The ACO must enter into a participation agreement with CMS and remain in good standing under the agreement.

(2) Any shared savings covered by the waiver must be earned by the ACO pursuant to the MSSP.

(3) The shared savings must be earned by the ACO during the term of its participation agreement, even if the actual distribution or use of the shared savings occurs after the expiration of that agreement.

(4) The shared savings must either be: (i) distributed to or among the ACO participants or its providers/suppliers; or (ii) used for activities reasonably related to the purposes of the MSSP.

The most notable change to the shared savings distribution waiver was to remove the provision related to the Gainsharing CMP. The agencies stated that the recent statutory changes by MACRA, which limit the prohibition to *medically necessary services*, mean that payments to induce the reduction of medically unnecessary services will no longer implicate the Gainsharing CMP and thus no longer require waiver protection. The Final Rule also recommends that ACOs develop and retain documentation that demonstrates that payments are used for activities reasonably related to the purpose of the MSSP.

Compliance With the Physician Self-Referral Law Waiver of the AKS. ACO arrangements that implicate the Stark Law but meet an existing Stark Law exception are eligible for this waiver provided that the following conditions are met:

(1) The ACO must enter a participation agreement with CMS and remain in good standing under the agreement.

(2) The financial relationship must be reasonably related to the purposes of the MSSP, as defined above.

(3) The financial relationship must fully comply with an existing exception to the Stark Law, as defined at 42 C.F.R. §§ 411.355-411.357.

The Final Rule left this waiver unchanged, and the agencies again declined to adopt a six-month tail period in cases where CMS involuntarily terminates an ACO's participation agreement.

Patient Incentive Waiver of the Beneficiary Inducement CMP. Items or services provided by the ACO to beneficiaries for less than fair market value are eligible for this waiver of the Beneficiary Inducement CMP, provided the following four criteria are met:

(1) The ACO has entered into a participation agreement with CMS and remains in good standing under the agreement.

(2) There is a reasonable connection between the items or services and the medical care of the beneficiary.

(3) The items or services must be in-kind.

(4) The items or services are preventive care items or services, or advance one or more of the following clinical goals: (i) adherence to a treatment regime; (ii) adherence to a drug regime; (iii) adherence to a follow-up care plan; or (iv) management of a chronic disease or condition.[22]

While the Final Rule did not revise this waiver, it did provide some additional guidance on the scope of its protection. The agencies stated that ACOs should closely evaluate and monitor patient incentive programs, and reminded MSSP participants that the waiver does not cover the provision of free items or services not reasonably related to a beneficiary's medical care.

Conclusions

Other than eliminating the Gainsharing CMP waiver, which was rendered unnecessary by subsequent changes to the CMP law,[23] the Final Rule largely adopts the waivers as proposed in 2011. CMS and the OIG considered, and ultimately rejected, proposals to impose additional safeguards on outside party arrangements (such as FMV or commercial reasonableness standards), which the agencies believe are important to facilitate ACO activities.[24] Indeed, the Final Rule does not materially narrow the scope of the existing waivers at any point.[25]

The Final Rule reiterates that the waivers should not be construed "to reflect any diminution of [CMS/OIG] commitment to protect programs and beneficiaries from harms associated with kickbacks and referral payments, including overutilization, increased costs, and substandard or poor quality."[26] CMS and the OIG will continue to monitor MSSP ACOs for compliance with the fraud and abuse laws, including: (i) upcoding or billing for unnecessary services; (ii) stinting on necessary medical care; (iii) submitting false or fraudulent claims or data; and (iv) providing substandard care.[27] However, the agencies believe that the waivers created in 2011 are adequately protecting beneficiaries and health care programs while allowing entities sufficient latitude to accomplish MSSP-related activities.

Providers operating or working with ACOs should work with counsel to ensure that the substance of their ACO arrangements meet the criteria for these waivers and that the various

[22] *See id.* at 66743.

[23] *See* supra at 5. For more information on MACRA, see a related K&L Gates Client Alert at http://www.klgates.com/sgr-law-brings-changes-to-cmp-prohibition-on-gainsharing-04-17-2015/.

[24] *See id.* at 66735. "An outside party arrangement is an arrangement with an individual or entity that does not meet the definition of an ACO, an ACO participating, or an ACO provider/supplier . . . but has a role in coordinating and managing care for ACO patients." *Id*.

[25] *See id.* at 66741.

[26] *Id*. (citing 76 Fed. Reg. at 68008).

[27] *Id*.

and significant approval and documentation requirements that must be met to receive the benefit of the waivers have been properly fulfilled.

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