

ACO Waivers Final Rule Issued

On October 29, 2015, the *Centers for Medicare and Medicaid Services* (CMS) issued its much-anticipated final rule regarding waivers of federal healthcare fraud and abuse laws for participants in the *Medicare Shared Savings Program* (MSSP).¹ The MSSP, established through the *Patient Protection and Affordable Care Act* (ACA), is a key component of recent healthcare reform initiatives² and utilizes *accountable care organizations* (ACOs)³ “to facilitate coordination...among providers [and] to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries” [emphasis added].⁴ CMS has received comments from MSSP participants advocating for waivers of these fraud and abuse laws, noting that “stakeholders have expressed concern that the restrictions these laws place on certain coordinated care arrangements may impede some of the innovative integrated-care models envisioned” by the MSSP.⁵ After considering stakeholder feedback as well as early performance measures by participating MSSP ACOs, CMS created five waivers of federal healthcare fraud and abuse laws for MSSP participants: (1) the ‘pre-participation’ waiver; (2) the ‘participation’ waiver; (3) the ‘shared savings distribution’ waiver; (4) the ‘compliance with the physician self-referral law’ waiver; and, (5) the ‘patient incentive’ waiver.⁶ This Health Capital Topics article will detail the requirements of the five waivers, discuss how the finalized waivers may impact the MSSP, and address the continuing duties of the Board of Directors of an ACO to maintain compliance with federal standards in today’s heightened regulatory environment.

ACOs are groups of doctors, hospitals, and other healthcare providers, who join together through various integration models to provide high quality care to Medicare patients.⁷ ACOs work to ensure patients receive quality medical care in a timely manner while avoiding unnecessary services and medical errors.⁸ To support this increase in quality, in contrast to quantity, of services provided within ACOs, physicians either receive financial bonuses for satisfying quality measures, or face penalties for failing to achieve a benchmark level of quality care.⁹ Without a waiver, ACO arrangements developing unique models of care delivery could violate federal healthcare fraud and abuse laws, such as the *Anti-Kickback Statute* (AKS) and the *Stark Law*, which seek to achieve “financial separation” between “sources of Federal health care program referrals and those seeking such referrals.”¹⁰

After four years of interim rulemaking, CMS finalized five waivers, effective immediately, in its October 29th, 2015 rule: (1) the ‘pre-participation’ waiver, (2) the ‘participation’ waiver, (3) the ‘shared savings distribution’ waiver, (4) the ‘compliance with the physician self-referral law’ waiver, and (5) the ‘patient incentive’ waiver.¹¹ Both CMS and the *Office of the Inspector General* (OIG) stated that further rules and modifications may be promulgated in the future as both groups continue monitoring the development of MSSPs and ACOs to ensure beneficiary protection.¹² By providing for these waivers, CMS and the OIG recognize the need for flexibility in regulations in order to promote beneficial arrangements between ACO participants in the MSSP, while balancing protections for beneficiaries and Federal healthcare programs.¹³ MSSP participants who satisfy any of the five finalized waivers are not required to comply with the AKS; however, only four of the five waivers (excluding the ‘compliance with the physician self-referral law’ waiver) waived the requirement of compliance with the *Stark Law*.¹⁴ Notably, the final ACO waivers rule eliminates the *Gainsharing Civil Monetary Penalty* (Gainsharing CMP) waiver included in previous interim rules. The Gainsharing CMP “prohibited a hospital from providing a physician with anything of value that could induce that physician to reduce or limit services to Medicare or state health care program beneficiaries.”¹⁵ However, after the passage of the *Medicare Access and CHIP Reauthorization Act* (MACRA) in April 2015 – which limited the scope of the Gainsharing CMP law to *medically necessary* services – CMS cut the waiver to comply with the language of MACRA.¹⁶

The ‘pre-participation’ waiver applies to “ACO-related start-up arrangements in anticipation of participating in the [MSSP].”¹⁷ To be eligible for the ‘pre-participation’ waiver, an ACO-related start-up arrangement must satisfy the following requirements:

- (1) “The arrangement is undertaken by a party or parties acting with the good faith intent to develop an ACO that will participate in the Shared Savings Program starting in a particular year (the ‘target year’) and to submit a completed application to participate in the Shared Savings Program for that year;”

- (2) *“The parties developing the ACO must be taking diligent steps to develop an ACO that would be eligible for a participation agreement that would become effective during the target year;”*
- (3) *“The ACO’s governing body has made and duly authorized a bona fide determination...that the arrangement is reasonably related to the purposes of the Shared Savings Program;”*
- (4) *“The arrangement, its authorization by the governing body, and the diligent steps to develop the ACO are documented;”* and,
- (5) *“The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by”* the U.S. Department of Health & Human Services (HHS).¹⁸

If an ACO start-up does not submit an application within the required timeframe, the ACO start-up must submit a statement to CMS describing the reasons it was unable to submit the application.¹⁹ The ‘pre-participation’ waiver is limited on the duration and types of parties covered.²⁰ The waiver defines “start-up arrangements” as applicable to arrangements for facilities, goods, etc., that are to be used to create an ACO and is provided by such ACO, ACO participants, or ACO providers/suppliers.²¹ In order to be eligible for the ‘pre-participation’ waiver, the parties to the arrangement must include, at a minimum, at least one ACO participant, and the arrangement cannot include drug or device manufacturers, distributors, home health suppliers, or durable medical equipment suppliers.²² Compliance with the requirements of the ‘pre-participation’ waiver allows an ACO start-up to avoid regulatory scrutiny under the AKS or the Stark Law.²³

The ‘participation’ waiver “applies broadly to ACO-related arrangements during the term of the ACO’s participation agreement under the [MSSP] and for a specified time thereafter.”²⁴ To be eligible under the ‘participation’ waiver, an MSSP participant must satisfy the following requirements:

- (1) *“The ACO has entered into a participation agreement and remains in good standing under its participation agreement;”*
- (2) *“The ACO meets the requirements of 42 CFR [§§] 425.106 and 425.108 concerning its governance, leadership, and management”* (which are detailed in the 3rd installment of the Health Capital Topics Series on Commercial Reasonableness and ACOs from October 2015, entitled “Commercial Reasonableness: Why It Matters to an ACO’s Board”);
- (3) *“The ACO’s governing body has made and duly authorized a bona fide determination...that the arrangement is reasonably related to the purposes of the Shared Savings Program;”*
- (4) *“Both the arrangement and its authorization by the governing body are documented;”* and,
- (5) *“The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by”* HHS.²⁵

Notably, the documentation requirement under the ‘participation’ waiver requires ACOs to maintain the following documentation for a period of ten years:

- (1) *“A description of the arrangement, including all parties to the arrangement;”*
- (2) *“[The] date of the arrangement;”*
- (3) *“The purpose of the arrangement;”*
- (4) *“The items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods);”* and,
- (5) *“The financial or economic terms of the arrangement.”*²⁶

Like the ‘pre-participation’ waiver, the ‘participation’ waiver eliminates the requirement of compliance with the AKS as well as the Stark Law.²⁷

The ‘shared savings distributions’ waiver applies to “distributions or use of shared savings [payments] earned” under the MSSP.²⁸ The conditions required under the ‘shared savings distributions’ waiver are:

- (1) *“The ACO has entered into a participation agreement and remains in good standing under its participation agreement;”*
- (2) *“The shared savings are earned by the ACO pursuant to the Shared Savings Program;”*
- (3) *“The shared savings are 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;”* and,
- (4) *“The shared savings are”* either:
 - (a) *“Distributed to or among the ACO’s ACO participants, its ACO providers/suppliers, or individuals and entities that were its ACO participants or its ACO providers/suppliers during the year in which the shared savings were earned by the ACO;”* or,
 - (b) *“Used for activities that are reasonably related to the purposes of the Shared Savings Program.”*²⁹

Compliance with the requirements of the ‘shared savings distributions’ waiver allows an ACO to avoid regulatory scrutiny under the AKS or the Stark Law in regards to its distributions of shared savings earned under the MSSP.³⁰

The ‘compliance with the physician self-referral law’ waiver was included for ACO arrangements that may violate the Stark Law prohibition but already satisfy the conditions of an existing exception.³¹ In order to be eligible under the ‘compliance with the physician self-referral law’ waiver, the following conditions must be satisfied:

- (1) *“The ACO has entered into a participation agreement and remains in good standing under its participation agreement;”*
- (2) *“The financial relationship is reasonably related to the purposes of the Shared Savings Program;”* and,

- (3) “The financial relationship fully complies with an exception at 42 CFR [§§] 411.355 through 411.357.”³²

An ACO’s satisfaction of the ‘compliance with the physician self-referral law’ waiver allows an ACO to avoid regulatory scrutiny under the AKS.³³

Finally, the ‘patient incentive’ waiver applies to “items or services provided by an ACO, its ACO participants, or its ACO providers/suppliers to beneficiaries for free or below fair market value.”³⁴ In order to be eligible under the ‘patient incentive’ waiver, the following conditions must be satisfied:

- (1) “The ACO has entered into a participation agreement and remains in good standing under its participation agreement;”
- (2) “There is a reasonable connection between the items or services [provided] and the medical care of the beneficiary;”
- (3) “The items or services are in-kind;” and,
- (4) “The items or services—
 - (a) “Are preventive care items or services;” or,
 - (b) “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.”³⁵

An ACO’s satisfaction of the ‘patient incentive’ waiver allows an ACO to avoid regulatory scrutiny under the AKS as well as the beneficiary inducements CMPs.³⁶

While the finalized waivers provide some security and comfort for ACO participants in the MSSP,³⁷ CMS and OIG have stated that each organization plans to monitor the development of ACOs, with the potential that the waivers be modified in the future.³⁸ Considering this backdrop, along with a stated push by the OIG and the U.S. Department of Justice (DOJ) to penalize individuals responsible for corporate violations,³⁹ it may be prudent for ACOs relying on a federal fraud and abuse waiver to evaluate their financial agreements and enterprise arrangements for potential noncompliance with the Stark Law, AKS, and False Claims Act. As the leadership for an ACO, the board of directors may feel more comfortable with also obtaining a certified opinion prepared in compliance with professional standards by an independent credential valuation professional (under the advice of legal counsel), and supported by adequate documentation as to whether each of the proposed elements of the transaction are both at *Fair Market Value* and *commercially reasonable*, so as to establish a risk adverse, defensible position that the transactional arrangement can withstand regulatory scrutiny should the waivers be modified in the future.

1 “CMS Issues Final Rule for Fraud and Abuse Waivers in MSSP” The National Law Review, November 6, 2015, <http://www.natlawreview.com/article/cms-issues-final-rule->

fraud-and-abuse-waivers-medicare-shared-savings-program (Accessed 11/12/15).

2 “Shared Savings Program” Centers for Medicare & Medicaid Services, June 12, 2015, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharesavingsprogram/index.html?redirect=/sharesavingsprogram> (Accessed 11/12/15).

3 The National Law Review, November 6, 2015.

4 CMS, “Shared Savings Program,” June 12, 2015.

5 “Medicare Program; Final Waivers in Connection with the MSSP” Federal Register Vol. 80, No. 209 (October 29, 2015) p. 66726.

6 *Ibid*, p. 66742-43.

7 “Accountable Care Organizations (ACO)” Centers for Medicare & Medicaid Services, January 6, 2015, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/index.html> (Accessed 11/12/15).

8 *Ibid*.

9 “Accountable Care Organizations: What Providers Need to Know” Centers for Medicare & Medicaid Services, April 2014, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharesavingsprogram/Downloads/ACO_Providers_Factsheet_ICN907406.pdf (Accessed 11/20/15), 3-4.

10 “Medicare Program; Final Waivers in Connection with the MSSP” October 29, 2015, p. 66726-27.

11 *Ibid*, p. 66742-43.

12 *Ibid*, p. 66727.

13 “CMS & OIG Finalize Waivers for ACOs in the Medicare MSSP” By Kenya S. Woodruff & Jennifer S. Kreick, Haynes Boone, November 2, 2015, <http://www.haynesboone.com/news-and-events/news/alerts/2015/11/02/cms-and-oig-finalize-waivers-for-acos> (Accessed 11/12/15).

14 “Medicare Program; Final Waivers in Connection with the MSSP” October 29, 2015, p. 66742-44.

15 “Limited Modifications in Final ACO Fraud & Abuse Waivers Most Notably Include Cut of Gainsharing CMP Waiver” By Emily H. Wein and Catherine A. Martin, Ober Kaler, 2015, <http://www.ober.com/publications/3073-limited-modifications-final-aco-fraud-abuse-waivers-most-notably-include> (Accessed 11/23/15).

16 *Ibid*.

17 “Medicare Program; Final Waivers in Connection with the MSSP” October 29, 2015, p. 66727-28.

18 *Ibid*, p. 66742.

19 *Ibid*.

20 *Ibid*, p. 66742-43.

21 *Ibid*, p. 66733.

22 *Ibid*, p. 66742.

23 *Ibid*.

24 *Ibid*, p. 66728.

25 *Ibid*, p. 66743.

26 *Ibid*.

27 *Ibid*.

28 *Ibid*.

29 *Ibid*.

30 *Ibid*.

31 *Ibid*.

32 *Ibid*.

33 *Ibid*.

34 *Ibid*.

35 *Ibid*.

36 *Ibid*.

37 “CMS and OIG Issue Final Fraud and Abuse Waivers in Connection with the Medicare Shared Savings Program” By John M. Kirsner, Esq., David W. Grauer, Esq., et al., Jones Day, November 2015, <http://www.jonesday.com/cms-and-oig-issue-final-fraud-and-abuse-waivers-in-connection-with-the-medicare-shared-savings-program-11-13-2015/> (Accessed 11/17/15).

38 “Medicare Program; Final Waivers in Connection with the MSSP” October 29, 2015, p. 66727.

39 “Individual Accountability for Corporate Wrongdoing” By Sally Quillian Yates, Memorandum (September 9, 2015), <http://www.justice.gov/dag/file/769036/download> (Accessed 11/20/15).



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