

Medicare ACO Participation Waiver of Fraud and Abuse Laws: How It Works and Why ACOs Should Use It

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Accountable care organizations (ACOs), established under the Affordable Care Act, are the marquee health care delivery system reform initiative of the federal government. The Centers for Medicare & Medicaid Services (CMS) administer two ACO programs—the Medicare Shared Savings Program (MSSP) and the Pioneer ACO Program (a precursor to the MSSP that was reserved for providers with significant experience in providing coordinated care). Medicare ACOs now cover approximately 15% of Medicare fee-for-service beneficiaries. In the view of the federal government, since their implementation in 2012, Medicare ACOs have met their goals of improving patient care while generating “shared savings” for Medicare and participating providers.¹ In the first year of the MSSP, 58 ACOs held spending \$705 million below their targets and earned shared savings payments of more than \$315 million.² This means, however, that 162 ACOs (or 74% of all MSSP ACOs) generated no shared savings.³

Critics of the MSSP have noted the various challenges of providing “accountable” care in connection with the limitations imposed by the Medicare fee-for-service program, including the unrestricted freedom of choice of providers enjoyed by Medicare beneficiaries and the resulting impact it has on the stability of the Medicare beneficiary population assigned to an ACO.⁴ Other critics have noted that Medicare fraud and abuse laws, which are designed to protect the Medicare program and beneficiaries from decision making that is unduly influenced by the providers’ financial incentives under fee-for-service payment arrangements, act as barriers to the type of clinical and operational integration that is needed to build high-functioning ACOs. With respect to this potential barrier, little has been written about perhaps the most powerful tool available to ACOs participating in the MSSP and Pioneer ACO program, which is the complete waiver of several

restrictive health care fraud and abuse laws for arrangements among an ACO, its participating providers, and certain other third parties (the so-called “Participation Waiver”). This article discusses the Participation Waiver and aims to give the reader a high-level understanding of its mechanics as well as an appreciation for its broad scope and potential for creative applications.

Description of Participation Waiver and Analysis of Its Elements

The U.S. Department of Health and Human Services (HHS) established the Participation Waiver with respect to MSSP ACOs in an Interim Final Rule, and with respect to Pioneer ACOs in a notice, each published in 2011 (collectively, the “Waiver Regulations”).⁵ The Participation Waiver waives the federal Stark Law (the “Stark Law”),⁶ the federal anti-kickback law (the “Anti-Kickback Law”),⁷ and the federal civil monetary penalties law provisions addressing hospital payments to physicians to reduce or limit services (the “Gainsharing CMP”)⁸ with respect to any arrangement of the ACO, one of more of its ACO participants, or one or more “outside providers and suppliers,” such as hospitals, specialist physicians, or post-acute care facilities, that do not participate in the ACO but have a role in coordinating and managing care for ACO patients, if the relevant Waiver requirements are satisfied. Once the Waiver requirements are satisfied for a particular arrangement, the Participation Waiver is self-implementing—no special action, such as applying for an individualized waiver, is required.⁹ The Participation Waiver requirements are as follows:

1. The ACO has entered into an agreement with CMS to participate in the MSSP or Pioneer ACO program and remains in good standing under the agreement.¹⁰
2. The ACO meets the requirements set forth in the MSSP regulations or Pioneer ACO participation agreement concerning its governance, leadership, and management.¹¹
3. The ACO’s governing body has made and duly authorized a *bona fide* determination, consistent with the governing body’s fiduciary duty to the ACO, that the arrangement is “reasonably related” to the purposes of the MSSP or Pioneer ACO program.¹²

The Waiver Regulations define the purposes of the MSSP or Pioneer ACO program as one or more of the following: (a) promoting accountability for the quality, cost, and overall care for a Medicare patient population; (b) managing and coordinating care for Medicare fee-for-service beneficiaries through

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a MSSP or Pioneer ACO; and (c) encouraging investment in infrastructure and redesigned care processes for high-quality and efficient service delivery (i.e., cost reduction) for patients, including Medicare beneficiaries.¹³ Purposes (a) and (b) are limited to Medicare beneficiaries, while purpose (c) is not. Therefore, “encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery” for all patients, so long as it includes Medicare beneficiaries, is a legitimate purpose of the MSSP and Pioneer ACO program.

HHS does not define what constitutes a “bona fide” determination of the governing body in the context of the Participation Waiver. Arguably, any governing body vote taken in accordance with the charter documents of the ACO (e.g., quorum and voting rules) would be a bona fide determination, because it would represent a bona fide action of the governing body from a corporate governance perspective. However, HHS stated in the preamble to the Interim Final Rule to the MSSP Participation Waiver (which also applies to the Pioneer Participation Waiver) that the “governing body would be well advised to exercise diligence in ensuring that arrangements are reasonably related to one or more purposes of the [MSSP or Pioneer ACO program] and to articulate clearly the bases for their determinations and authorizations.”¹⁴ HHS also advised the governing body to scrutinize proposed arrangements “with care to ensure that the reasonable relationship . . . can be clearly identified.”¹⁵ Finally, HHS noted that “[w]here a reasonable relationship exists, it should not be difficult . . . to articulate clearly the nexus between [the] arrangement and the purposes of the [MSSP or Pioneer ACO program].”¹⁶

In light of this guidance, it seems reasonable to conclude that HHS would likely not consider an action of the governing body taken in accordance with required corporate formalities but without any regard to the degree of reasonableness of the relationship between the arrangement and the enumerated purposes to be a bona fide determination. However, it seems equally clear that a bona fide determination need not be reasonable in accordance with some objective measure. If HHS had intended an objective reasonableness standard, it would have been a simple matter to incorporate such a standard into the Interim Final Rule. As HHS stated in the Interim Final Rule, the approach taken “interposes the ACO’s governing body as an intermediary responsible, in the first instance, for ensuring that all protected arrangements are in furtherance of ACO purposes . . .”¹⁷ While the reference to “in the first instance” suggests some ability for HHS to review, and accordingly reject, the determination of the ACO governing body, it does not seem reasonable to interpret this language as permitting a de novo HHS review of ACO governing body determinations. Meaningful deference to the determination of the ACO governing body is consistent with the rationale, articulated by HHS, that transparency (as opposed to objective correctness) is one of the primary safeguards against abuse built into the Participation Waiver, because “transparency creates an incentive for ACOs to exercise due diligence when arrangements are being established to ensure that they are waiver compliant and

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otherwise consistent with the ACO’s mission . . .”¹⁸

Taken together, HHS’ statements suggest that it would likely consider a determination to be bona fide if the ACO governing body discharges its responsibility in a manner consistent with each governing body member’s fiduciary duty of due care. Under the fiduciary duty of due care, each governing body member is obligated to exercise the proper level of care in the decision-making process, by acting: (1) in “good faith” (i.e., in the absence of any personal benefit or self-dealing); (2) with that level of care that an ordinary prudent person would exercise in like circumstances (e.g., the obligations to be informed and to exercise reasonable inquiry); and (3) in a manner the governing body member reasonably believes is in the best interests of the ACO.

4. Both the arrangement and its authorization by the governing body are documented. The documentation must be contemporaneous with the establishment of the arrangement or authorization, as the case may be. Documentation of the arrangement must describe the arrangement (including the parties, date, purpose, items, services, facilities and/or goods covered by the arrangement (including non-medical), and the financial terms of the arrangement). Documentation of the authorization by the governing body must identify the date and manner of the authorization and the basis for the governing body’s determination that the arrangement is reasonably related to the purposes of the MSSP or Pioneer ACO program. The ACO must retain all such documentation for at least 10 years following completion of the arrangement and must make such documentation available to the Secretary of HHS upon request.¹⁹

HHS recommends, but does not require, that documentation of the arrangement take the form of a signed agreement by the parties.²⁰ Documentation of the governing body’s determination would typically take the form of a resolution by the governing body in compliance with all relevant corporate governance formalities.

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5. The ACO must publicly disclose a description of the arrangement at a time and in a place and manner established in guidance issued by the Secretary of HHS. HHS directs that such disclosure must not include the financial terms.²¹

As described above, HHS intends that public disclosure act as a safeguard against abuse of the Participation Waiver. HHS has not issued guidance on this public disclosure standard. However, the Interim Final Rule states that HHS does “not expect that the disclosure requirements . . . will be onerous.”²² In addition, the Interim Final Rule provides that, until the disclosure guidance is issued, ACOs “should” meet the disclosure requirements by: “posting information identifying the parties to the arrangement and the type of item, service, good, or facility provided under the arrangement on a public Web site belonging to the ACO or an individual or entity forming the ACO, clearly labeled as an arrangement for which waiver protection is sought, within 60 days of the effective date of the arrangement. The Web site must include the name of the ACO (or, if the name of the ACO is not known, the parties forming the ACO) and other identifying information sufficient to allow individuals conducting an electronic internet search using a widely available search engine to readily locate the Web site.”²³

Discussion

The Participation Waiver is, by its terms, a very broad waiver of several restrictive health care fraud and abuse laws, with fairly simple requirements to satisfy. The Waiver’s breadth and low administrative burden is consistent with HHS’ design goals. In explaining the limited fraud and abuse safeguards of governance responsibility, transparency, and public disclosure built into the Participation Waiver, HHS stated that the Participation Waiver “rel[ies], as a threshold matter, on the programmatic requirements of the [MSSP and Pioneer ACO program] to safeguard Medicare beneficiaries and the Medicare program.” HHS further acknowledges the breadth of the Participation Waiver in recognizing that it, along with the other ACO waivers, may be restricted in the future. In particular, the Interim Final Rule states that: “We plan to narrow the waivers established in this [Interim Final Rule] unless the Secretary [of HHS] determines that information gath-

ered through monitoring or other means suggests that such waivers have not had the unintended effect of shielding abusive arrangements.”²⁴ That is, in the absence of affirmative evidence that there is no abuse, HHS intends to narrow the waivers. Such an approach seems to acknowledge implicitly that the waivers were drafted to be broad, and somewhat imprecisely defined, in scope. If the waivers were carefully defined and circumscribed, the opposite approach (i.e., that changes would only be made if there is affirmative evidence of abuse) would be expected.

Despite this breadth and ease of use, our analysis of available mandatory public disclosures suggests that ACOs infrequently use the Participation Waiver. In particular, despite extensive efforts to identify the mandatory public disclosures using internet search engines (and recall that the Participation Waiver requires that such disclosures be made on websites in such a manner to “allow individuals conducting an electronic internet search using a widely available search engine to readily locate the Web site”²⁵), we were only able to locate evidence of arrangements implemented under the Participation Waiver for 31 MSSP and Pioneer ACOs—approximately 9% of the 360 current MSSP and Pioneer ACOs. Even if our internet searches failed to identify a significant number of disclosures, this result suggests that only a small minority of ACOs are availing themselves of this powerful tool.

Even where ACOs do take advantage of the Participation Waiver, they typically use it for straightforward arrangements that do not reflect the full scope of the Waiver’s potential applications. For instance, we found that ACOs typically use the Participation Waiver for donation of electronic health records (EHRs) and other information technology infrastructure, where such donations would not otherwise meet the restrictive requirements of the fraud and abuse laws governing donation of EHR hardware and software. The relationship between these arrangements and the enumerated MSSP and Pioneer ACO program purposes (e.g., fostering care coordination among ACO participants) is obvious and straightforward.

ACO executives and their advisers could consider satisfying their operational and strategic goals through more creative uses of the Participation Waiver. If ACOs are to succeed, it is crucial to align the financial incentives of their participating providers in such a manner that encourages the delivery of more efficient, high-quality care. The Participation Waiver can protect such arrangements, even if an arrangement “reflect[s] a likelihood that [a] patient might be referred to or within [the] ACO.”²⁶

Additional clarity around the scope of the Participation Waiver may be forthcoming because HHS is obligated to publish a final rule for the MSSP Participation Waiver prior to 2016.²⁷ (HHS originally was obligated to publish a final waiver rule prior to 2015,²⁸ but the agency recently opted to extend the regular timeline for publishing a final waiver rule through November 2, 2015 to ensure that the final waiver rule aligns with a proposed rule regarding the MSSP generally that HHS is actively developing²⁹). As discussed above, in the Interim Final Rule, HHS stated its intent to closely monitor ACOs and

narrow the Participation Waiver as appropriate. Nevertheless, it appears that many Medicare ACOs currently are failing to take advantage of the Participation Waiver—an extraordinary tool, with potentially far-reaching impact, for re-shaping the incentives that surround health care delivery. 

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Endnotes

- 1 Department of Health and Human Services (HHS), Press Release, NEW AFFORDABLE CARE ACT TOOLS AND PAYMENT MODELS DELIVER \$372 MILLION IN SAVINGS, IMPROVE CARE, *available at* www.hhs.gov/news/press/2014pres/09/20140916a.html.
- 2 CMS, Fact sheets, MEDICARE ACOs CONTINUE TO SUCCEED IN IMPROVING CARE, LOWERING COST GROWTH, *available at* www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-11-10.html.
- 3 CMS notes that an additional 60 MSSP ACOs reduced costs compared to their benchmarks, but did not qualify for shared savings because they did not meet the minimum savings thresholds. *Id.* Presumably, this means that 102 ACOs (or nearly half of the total) had costs above their benchmarks, although only one ACO was responsible for making a payment to CMS for shared losses. See CMS MEDICARE SHARED SAVINGS PROGRAM ACCOUNTABLE CARE ORGANIZATIONS PERFORMANCE YEAR 1 RESULTS, *available at* <https://data.cms.gov/ACO/Medicare-Shared-Savings-Program-Accountable-Care-O/yuq5-65xt>.
- 4 See, e.g., J. Michael McWilliams et al., *Outpatient Care Patterns and Organizational Accountability in Medicare*, 174 JAMA INTERN. MED. 6, 938–45 (2014).
- 5 See Medicare Program; Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992 (Nov. 2, 2011) (hereinafter "Interim Final Rule"); HHS, Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Pioneer ACO Model (Dec. 8, 2011) (hereinafter "Pioneer Waiver Notice"). The Waiver Regulations include additional waivers of the same or additional health care fraud and abuse laws. Such waivers include the Pre-Participation Waiver (similar to the Participation Waiver but for start-up arrangements of ACO applicants), Shared Savings Distribution Waiver (waives the Stark Law, the Anti-Kickback Law, and the Gainsharing CMP with respect to distributions or use of shared savings earned by an ACO), Compliance with the Physician Self-Referral Law Waiver (waives the Anti-Kickback Law and Gainsharing CMP for certain arrangements that comply with a Stark Law exception), and Waiver for Patient Incentives (waives the Anti-Kickback Law and civil monetary penalties law provisions addressing inducements to beneficiaries, 42 U.S.C. § 1320a-7a(a)(5), with respect to provision of certain free (or below market) items or services to ACO patients).
- 6 42 U.S.C. § 1395nn.
- 7 42 U.S.C. § 1320a-7b(b).
- 8 42 U.S.C. §§ 1320a-7a(b)(1)–(2).
- 9 Interim Final Rule at 67999.
- 10 Interim Final Rule at 68001; Pioneer Waiver Notice at 2.
- 11 *Id.*
- 12 *Id.*
- 13 Interim Final Rule at 68002; Pioneer Waiver Notice at 1.
- 14 Interim Final Rule at 68004.
- 15 *Id.*
- 16 Interim Final Rule at 68002.
- 17 Interim Final Rule at 68003.
- 18 Interim Final Rule at 68004.
- 19 Interim Final Rule at 68002; Pioneer Waiver Notice at 2–3.
- 20 Interim Final Rule at 68004.
- 21 Interim Final Rule at 68002; Pioneer Waiver Notice at 2–3.
- 22 Interim Final Rule at 68004.
- 23 Interim Final Rule at 68004–68005.
- 24 Interim Final Rule at 68008.
- 25 Interim Final Rule at 68005.
- 26 Interim Final Rule at 68004.
- 27 79 Fed. Reg. 62356 (Oct. 17, 2014).
- 28 Interim Final Rule at 68009.
- 29 79 Fed. Reg. 62356 (Oct. 17, 2014).