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CLIENT ADVISORY

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OIG Finalizes ACO Fraud and Abuse Waivers with Only Minor Adjustments

On October 29, 2015, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") and Centers for Medicare and Medicaid Services ("CMS") (collectively, the "Agencies") jointly published the Final Waivers in Connection with the Shared Savings Program ("Final Rule"), which finalized the waiver of various fraud and abuse laws for Accountable Care Organizations ("ACOs") formed as part of the Medicare Shared Savings Program ("MSSP"). The Final Rule continues to waive, with technical adjustments, various provisions of the Federal anti-kickback statute ("AKS"), Stark law, and Beneficiary Inducements CMP; however, it does not continue to waive the Gainsharing CMP.

I. Background

On November 2, 2011, the Agencies published an Interim Final Rule with comment period (the "IFC") that established waivers of the application of certain provisions of the Stark law, AKS, Gainsharing CMP, and Beneficiary Inducements CMP for MSSP participants. The IFC set forth five different waivers:

1) Pre-participation waiver for ACO-related start-up arrangements.
2) Participation waiver applicable during the period when the entity is actively participating in the MSSP and for a specified time thereafter.
3) Shared savings distribution waiver for distributions and uses of shared savings payments earned under the MSSP.
4) Stark law waiver that protected arrangements that already met a Stark exception.
5) Patient incentive waiver for medically-related incentives offered to beneficiaries.

II. Changes to the ACO Fraud and Abuse Waivers

Gainsharing CMP

Due to recent legislative changes to the Gainsharing CMP as part of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), the OIG no longer considered waiver of the Gainsharing CMP necessary for the operation of the MSSP. MACRA revised the Gainsharing CMP to prohibit hospitals from knowingly making payments, directly or indirectly, to induce physicians to reduce or limit "medically necessary" services provided to Medicare or State health care program beneficiaries under the physician's direct care. Because of this statutory change, payments by hospitals to induce physicians to reduce or limit medically unnecessary services no longer implicate the Gainsharing CMP, so the Agencies determined that a waiver of the Gainsharing CMP is no longer necessary.

Pre-Participation and Participation Waivers

The Agencies finalized the inapplicability of the pre-participation waiver to home health suppliers, durable medical equipment suppliers, and drug and device manufacturers. In response to comments, the agencies clarified the definition of "home health supplier" as a "provider, supplier, or other entity that is *primarily engaged* in furnishing 'home health services.'" This definition includes freestanding home health agencies ("HHAs") and their parent

entities that may own one or more freestanding HHAs, if the parent entity is primarily engaged in the delivery of home health services. Hospitals, skilled nursing facilities, physician practices, and other providers or suppliers are not included as long as they are not primarily engaged in providing home health services.

The Agencies also clarified the requirements that ACO governing bodies must meet when making a bona fide determination and authorization that pre-participation and participation waivers are reasonably related to the purpose of the MSSP. As in the IFC, the Agencies note that the process for making determinations and authorizations will differ by ACO; however, a bona fide determination requires more than "rubber stamping" the arrangement. The governing body must employ a thoughtful, deliberative process for making a determination and clearly articulate the basis for the determination and authorization.

The Agencies further clarified that documentation of the governing board's bona fide determinations and authorizations must include the basis for the determination that the arrangement is reasonably related to the purposes of the MSSP. While it is best practice to have a written resolution to document this determination, it is not required. The ACO must, however, maintain an audit trail of contemporaneous documentation that identifies the core characteristics of the arrangement for a minimum of 10 years.

Shared Savings Distribution Waiver

The Agencies reminded ACOs that, although not required, they would be well advised to maintain documentation explaining how shared savings distribution payments would be and are being used for activities reasonably related to the purpose of the MSSP. Distributions within and outside the ACO that do not satisfy the "reasonably related to" requirement are not protected by the waiver and would need to qualify under another waiver or fit within an existing safe harbor or exception.

Compliance with the Stark Law Waiver

The OIG continues to believe that specific safeguards in the MSSP minimize many of the typical fraud and abuse concerns associated with the AKS. In response to comments, the Agencies declined to extend the waiver to cover a period of time after the expiration or termination of the ACO's participation agreement. As such, the waiver applies until the participation agreement, or any renewal, expires or terminates.

Waiver for Patient Incentives

The OIG reiterated its strong belief that beneficiary compliance with care management programs is critical to the success of ACOs and that ACOs should have more flexibility than what may be permitted under current law to develop incentives. As long as safeguards in the existing waiver are satisfied, ACOs may continue to provide free or below-fair market value items and services to beneficiaries.

The OIG further clarified that the Final Rule permits an ACO, its providers/suppliers, and its participants to provide local transportation (or pre-paid transportation vouchers) as an in-kind item or service under the patient incentives waiver. The waiver protects only in-kind incentives that satisfy the conditions of the waiver, such as transporting beneficiaries to a medical appointment or picking up prescriptions. The waiver does not protect transportation to recreational events, running errands unrelated to medical care, or cash reimbursement for transportation costs (e.g., bus or taxi fare).

III. Practical Takeaways

The approach taken by CMS and the OIG in the Final Rule to preserve the breadth of the ACO fraud and abuse waivers is a positive development for ACOs participating in the MSSP. The waivers will continue to provide significant flexibility to providers seeking to develop innovative arrangements that allow them to deliver on the Triple Aim. There is plenty of reason to suggest that, despite the continued availability of these broad waivers,

CMS and the OIG will closely scrutinize arrangements structured pursuant to the waivers. ACOs must ensure their compliance with the technical requirements for governing body authorization, public disclosure, contemporaneous documentation, records retention, and other requirements to receive waiver protections. We recommend that ACOs incorporate oversight and verification of compliance with the waiver requirements into their ACO compliance program.

For more information about the ACO fraud and abuse waivers and how your ACO should incorporate these changes into its compliance program, please contact Mary Malone, Jim Daniel, or Corbin Santo by phone at (866) 967-9604, or by email at mmalone@hdjn.com, jdaniel@hdjn.com, or csanto@hdjn.com. Additional information about Hancock, Daniel, Johnson & Nagle, P.C. is available on the firm's website at www.hdjn.com.

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