

BJC HEALTHCARE ACCOUNTABLE CARE ORGANIZATION POLICY

APPLIES TO:	BJC HealthCare Accountable Care Organization
TITLE:	BJC HealthCare Accountable Care Organization MSSP Waiver Policy
NUMBER:	No.2
PURPOSE:	To describe the requirements of certain waivers available when participating in a MSSP and to define the process BJC HealthCare Accountable Care Organization Board of Managers will use to review and approve programs and activities to take advantage of the waivers.

I. Statement of Policy

The purpose of this policy is to: (1) describe the requirements of certain waivers available in connection with BJC-ACO's participation in the Medicare Shared Savings Program ("MSSP"), including, without limitation, the Participation Waiver and Waiver for Patient Incentives, as defined and described more fully below; and (2) define the process and parameters the BJC-ACO's Board of Managers (the "Board") will use to review and approve proposed BJC- ACO programs or activities seeking to take advantage of these waivers.

The BJC-ACO, as with all BJC-affiliated organizations, is committed to conducting business in compliance with all applicable laws, regulations, and BJC-ACO policies and according to the highest standards of ethical conduct and integrity.

II. Scope of Policy

The policy applies to all members of the ACO Board of Managers and BJC ACO Participants.

III. Background of the Waivers

The MSSP is a Medicare program designed to achieve three goals: (1) better health for populations, (2) better care for individuals, and (3) lower growth in expenditures. It is expected that accountable care organizations ("ACOs") participating in the MSSP will help foster a new approach to delivering care that reduces fragmented or unnecessary care and excessive costs for Medicare Fee for Services (FFS) Beneficiaries and other patients.

In order to carry out the provisions of the MSSP, the Centers for Medicare and Medicaid Services (“CMS”) and the Office of Inspector General (“OIG”) have jointly issued a Final Rule (the “Waiver Rule”) waiving application of certain provisions of the Physician Self-Referral Law and the Federal Anti-Kickback statutes:¹ the Civil Monetary Penalty (“CMP”) law prohibiting hospital payments to physicians intended to induce certain practice behaviors (the Gainsharing CMP), and the CMP law prohibiting inducements to beneficiaries (the Beneficiary Inducements CMP) to ACOs formed in connection with the MSSP. Certain criteria for use of these waivers ensures that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or Federal health care programs.

The Waiver Rule outlines five waivers consisting of the following:

1. Pre-participation Waiver - Waiver of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP that applies to ACO-related start-up arrangements in anticipation of participating in the MSSP.
2. Participation Waiver - Waiver of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP that applies broadly to ACO-related arrangements.
3. Shared Savings Distribution Waiver- Waiver of the Physician Self-Referral Law, Federal anti-kickback statute, and Gainsharing CMP that applies to distributions and uses of shared savings payments earned under the MSSP.
4. Physician Self-Referral Waiver- Waiver of the Gainsharing CMP and the Federal anti-kickback statute for ACO arrangements that implicate the Physician Self-Referral Law and meet an existing exception.
Patient Incentives- Waiver of the Beneficiary Inducements CMP and the Federal anti-kickback statute for medically-related incentives offered by ACOs under the Shared Savings Program to beneficiaries to encourage preventive care and compliance with treatment regimes.

IV. Participation Waiver

1. Requirements To Meet The Participation Waiver:
 - a. In order to qualify for protection under the Participation Waiver, the following conditions must be met:
 - i. BJC-ACO must remain in good standing under its MSSP Participation agreement.
 - ii. BJC-ACO must continue to meet the MSSP requirements concerning its governance, leadership, and management
 - iii. The Board must make and duly authorize a bona fide determination that the arrangement is reasonably related to the purposes of the MSSP.
 - iv. Both the arrangement and its authorization by the Board must be

¹ See 80 FR 66725, “Medicare Program; Final Waivers in Connection with the Shared Savings Program,” published October 29, 2015 and available here: <https://www.govinfo.gov/content/pkg/FR-2015-10-29/pdf/2015-27599.pdf>.

documented. The documentation of the arrangement must be contemporaneous with the establishment of the arrangement, the documentation of the authorization must be contemporaneous with the authorization and all such documentation must be retained for at least 10 years following completion of the arrangement and promptly made available to the Secretary of the U.S. Department of Health and Human Services upon request. The documentation must identify at least the following:

1. A description of the arrangement, including all parties to the arrangement; date of the arrangement; the purpose of the arrangement; the items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods); and the financial or economic terms of the arrangement.
 2. The date and manner of the governing body's authorization of the arrangement. The documentation should include the basis for the determination by the Board that the arrangement is reasonably related to the purposes of the MSSP.
 - v. The description of the arrangement must be publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary. Such public disclosure shall not include the financial or economic terms of the arrangement.
2. Evaluation Of Whether Arrangement Is Reasonably Related To The MSSP
- a. As used in the Waiver Rule, the purposes of the MSSP means one or more of the following purposes:
 - i. Promoting accountability for the quality, cost, and overall care for a Medicare patient population as described in the MSSP;
 - ii. Managing and coordinating care for Medicare FFS Beneficiaries through an ACO;
 - iii. Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries.
 - b. The arrangement need only be reasonably related to one enumerated purpose of the MSSP, although it is expected that many arrangements would relate to multiple purposes. These purposes may include, for example:
 - i. Promoting evidence-based medicine and patient engagement; meeting requirements for reporting on quality and cost measures; coordinating care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies; establishing clinical and administrative systems for the ACO; meeting the clinical integration requirements of the MSSP; or meeting the quality performance standards of the MSSP.
 - ii. Evaluating health needs of the ACO's assigned population; communicating clinical knowledge and evidence based medicine to beneficiaries; and developing standards for beneficiary access and

- communication, including beneficiary access to medical records.
 - iii. ACO operating activities, as well as performance-based compensation ("results-based" compensation) that is dependent upon achieving quality thresholds or efficiency measures of the MSSP.
 - c. CMS has indicated that arrangements with specialists or nursing facility staff members to engage in care coordination for ACO beneficiaries or implement evidence-based protocols could be reasonably related to the purposes of the MSSP even if the arrangement were to reflect a likelihood that the patient might be referred to or within an ACO; however, BJC-ACO and any other parties to the arrangement remain obligated to comply with the provisions at 42 CFR 425.304(c) that prohibit certain required referrals and cost-shifting.
3. Procedures for Consideration and Adoption of Waiver-based Arrangements
- a. Submission of Arrangement to Board for Consideration. If BJC-ACO or an ACO Participant of BJC-ACO desires to implement an arrangement for which protection under the Participation Waiver is sought, it must first subject a description of the arrangement to the Board for review and approval. Submissions must be made in writing to the Board and must describe and provide relevant detail, to the satisfaction of the Board, how the arrangement is reasonably related to the purpose of the MSSP.
 - b. Board Review and Determination. The Board shall review submissions in a timely manner and may request additional information concerning the arrangement as necessary to make a bona fide determination as to whether the arrangement is reasonably related to the purposes of the MSSP.
 - i. Within a reasonable time period after the Board obtains all the materials necessary to evaluate the arrangement, the Board shall issue a written response to the submitting party setting forth the following:
 - 1. The Board's findings concerning whether the arrangement is reasonably related to the purposes of the MSSP (the Board should articulate clearly the nexus between the arrangement and the purposes of the MSSP so that the reasonable relationship between the arrangement and purposes of the MSSP can be clearly identified);
 - 2. The Board's written authorization to carry out the arrangements, if granted, and;
 - 3. If the arrangement is authorized by the Board, the dates during which the arrangement may be implemented.
 - c. Documentation. Documentation concerning the arrangement's submission and the Board's review process must be maintained for ten (10) years following completion of the arrangement. Although the Participation Waiver does not require an agreement signed by the parties, such an agreement is a best documentation practice (and would typically be required for compliance with the Physician Self-Referral Law if a waiver does not apply). The core characteristics of the arrangement should be evident from the documentation with sufficient clarity that the government or another third party reviewing the documentation would be able to ascertain the material terms of the arrangement, including the

information listed in Section C.3 above. Material amendments and modifications to the arrangement should be similarly documented and subject to Board approval and disclosure. At minimum, the documentation must include:

- i. The arrangement's purpose;
 - ii. The items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods);
 - iii. The financial or economic terms of the arrangement
 - iv. The date and manner of the Board's review and authorization; and
 - v. The basis for the Board's determination that the arrangement is reasonably related to the purposes of the MSSP.
- d. Public Disclosure. CMS issues public reporting templates for each performance year which ACOs are required to customize with ACO-specific information, including the use of applicable waivers considered in this policy, and post on their public website in the proscribed manner. The BJC ACO will comply with this requirement, including as relates to MSSP Participation.
- e. The Participation Waiver period will end on the date CMS issues its termination notice to BJC-ACO

V. Waiver for Patient Incentives

Under the MSSP, CMS permits ACOs to offer to certain patients under specific circumstances a limited set of incentives for treatment or care-related behaviors, including in-kind items and services as well as monetary incentives. CMS sets forth strict protocols for developing, approving, implementing, and documenting ACO programs utilizing programs of this type.

1. Requirements for In-kind items and services. Certain items or services provided by BJC-ACO, its ACO participants, or its ACO providers/suppliers to Medicare FFS Beneficiaries (even if they are not assigned to BJC-ACO) for free or below fair-market-value will qualify for protection under the Waiver for Patient Incentives. Examples of permitted incentives include, among other things, items such as blood pressure cuffs for hypertensive patients, smoking cessation treatment and free home visits to coordinate in-home care during a post-surgical patient's recovery period. The following requirements apply to the Patient Incentive Waiver:
 - a. BJC-ACO remains in good standing under its MSSP participation agreement.
 - b. There is a reasonable connection between the items or services and the medical care of the beneficiary.
 - c. The items/services are in-kind, and are for preventative care 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;
 - iv. Management of a chronic disease or condition.
2. Requirements for monetary incentives. Effective for performance years beginning July 1, 2019, CMS will permit MSSP-participating ACOs to provide certain Medicare fee-for-service beneficiaries with monetary incentives to carry out specified behaviors according to an ACO's formal plan submitted to and approved by CMS in accordance with

procedures described below.² CMS will approve such arrangements that conform with the following criteria:

- a. The ACO participates in the one of the applicable risk-sharing MSSP tracks, including without limitation the Enhanced Track in which the BJC ACO currently participates.
 - b. The ACO elects Preliminary Prospective Assignment or Prospective Assignment of beneficiaries and makes available the monetary incentives to only those beneficiaries so assigned.
 - c. The monetary incentive program must begin on January 1 of the applicable Performance Year (PY) and last the full duration of that year.
 - d. The incentives are given only for CMS-designated primary care services furnished by applicable ACO Participants
 - e. The payment meets the following specifications:
 - i. Is made for each qualifying service;
 - ii. In the form of a check, debit card, or other traceable cash equivalent;
 - iii. The value of the payment does not exceed \$20 adjusted annually for inflation as published by CMS
 - iv. Is provided by the ACO to the patient no later than thirty days after the qualifying service is received
 - f. The ACO tracks and retains records of each such payment including:
 - i. Name and Medicare Beneficiary Identifier of the recipient
 - ii. The type and amount of each payment
 - iii. The date of the qualifying service, including the relevant HCPCS code and the ACO provider/supplier that furnished it
 - iv. The date the payment was made to the beneficiary
 - g. ACOs may not fund monetary incentives through any entity or organization outside of the ACO
 - h. ACOs implementing a monetary incentive program must notify ACO-assigned beneficiaries of the program
 - i. Except for this notification, ACOs are prohibited from using monetary incentive programs to market ACO participation or the services of ACO Participant providers/suppliers to beneficiaries.
 - i. Covered Period for In-kind items and services. The Waiver for Patient Incentives will cover arrangements involving the provision of covered items or services for free or below fair-market-value so long as BJC-ACO participates in the MSSP. If BJC-ACO ceases participating in the MSSP, Medicare FFS Beneficiaries will be permitted to keep items they previously received, as well as the remainder of any service initiated, while BJC-ACO was participating in the MSSP.
3. Public Disclosure. CMS issues public reporting templates for each performance year which ACOs are required to customize with ACO-specific information, including the use of applicable waivers considered in this policy, and post on their public website in the proscribed manner. The BJC ACO will comply with this requirement, including as relates

² The Patient Incentives waiver was expanded to include monetary incentives in the “Pathways to Success” Final Rule, 83 FR 67816, published December 31, 2018 and available here: <https://www.govinfo.gov/content/pkg/FR-2018-12-31/pdf/2018-27981.pdf>.

to patient incentives, both in-kind and monetary.

4. Limitations. The Waiver for Patient Incentives is limited in two respects:
 - a. Prohibited Activities. The MSSP regulations prohibit BJC-ACO, the providers and suppliers who participate in BJC-ACO's network and other individuals or entities performing functions or services related to BJC-ACO activities from providing gifts or other remuneration to Medicare FFS Beneficiaries as inducements for receiving items or services from, or remaining in, BJC-ACO or with providers in BJC-ACO or receiving items or services from BJC-ACO's participants or providers/suppliers participating in BJC-ACO's network.
 - b. Items/Services Not Covered. The Waiver for Patient Incentives will not cover financial incentives such as waivers of co-payments and deductibles, gifts, cash, sporting or entertainment event tickets, jewelry, household items, beauty products, or gift certificates for non-health care related retail items. Subject to the prohibitions on patient inducement described above, arrangements which involve the provision of these items/services for free or below fair-market-value, or the provision of monetary incentives as proscribed, may nonetheless comply with applicable fraud and abuse laws
5. Covered Period for monetary incentives. The Waiver for Patient Incentives will cover arrangements involved monetary incentives for the single performance year for which the ACO has applied and CMS has approved. Subsequent years require recertification by CMS of the ACO's use of monetary incentives.
6. Procedures: The BJC-ACO Board shall follow the procedures in this Section II.D when determining whether a particular arrangement meets the Waiver for Patient Incentives:
 - a. Submission of Arrangement to Board for Consideration. If BJC-ACO or an ACO Participant of BJC-ACO desires to implement an arrangement covered by the Waiver for Patient Incentives, it should submit a description of the arrangement to the Board for review and approval. Submissions shall be made in writing to the Board and describe how the arrangement is "reasonably connected to Medicare beneficiaries' medical care."
 - b. Board Review and Determination. The Board will review submissions in a timely manner and may request additional information concerning the arrangement as necessary to make a determination as to whether the arrangement is reasonably connected to Medicare beneficiaries' medical care.
 - c. Within a reasonable time after the Board obtains all the materials necessary to evaluate the arrangement, it will issue a written response to the submitting party setting forth the following:
 - i. The Board's findings concerning whether the arrangement is reasonably connected to the Medicare beneficiaries' medical care (the Board should articulate clearly the nexus between their arrangement and the purposes of the MSSP so that reasonable connection can be clearly identified);
 - ii. The Board's written authorization to carry out the arrangements, if

- granted, and the dates during which the arrangement may be implemented;
- iii. Notwithstanding the foregoing, failure to submit an arrangement to the Board does not prohibit the arrangement from qualifying for protection under the Patient Incentive Waiver, However, such submission is encouraged as a best practice to ensure that the requisite elements under the waiver have been satisfied prior to the arrangement being implemented.
- d. For Monetary Incentives, Board approval will initiate the CMS application process, to be carried out by the BJC ACO Compliance Officer or BJC ACO Program Director, as may be proscribed by CMS.
 - i. Final decision from CMS will be reported to the board for review. A positive finding by CMS and final approval by the Board of Managers will initiate implementation per CMS regulations.

VI. Responsibility of All BJC Employees and all Employees of ACO

All ACO participants and their respective employees or agents are responsible for being aware of, and complying with ACO policies and procedures. Questions or issues regarding the policies shall be directed to the ACO Program Director or the ACO Compliance Officer

VII. Legal Services Department Review, Approval and Assistance

Any exception, change or deviation from this Policy must be reviewed and approved by the ACO Compliance Officer. The ACO Compliance Officer or ACO Program Director will be available to answer any questions and to provide assistance and advice to ACO members concerning this Policy.

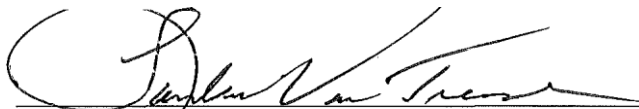
RECOMMENDED BY: BJC HealthCare ACO Board of Managers

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