



**Scripps Accountable Care Organization, LLC
Standard Operating Procedure**

Title: Compliance with Program Requirements and Applicable Laws for Medicare Shared Savings Program

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Approved by: Scripps Accountable Care, LLC
Management Board

Approval Date: 1/20/2016

PURPOSE

The following policy applies to the Scripps' Accountable Care Organization Medicare Shared Savings Program

DEFINITION

1. ACO participant. Means an individual or group of ACO provider(s)/supplier(s), that is identified by a Medicare-enrolled TIN, that alone or together with one or more other ACO participants comprise(s) an ACO, and that is included on the list of ACO participants.
2. ACO provider/supplier. Means an individual or entity that
 - a. Is a provider or a supplier
 - b. Is enrolled in Medicare;
 - c. Bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations; and
 - d. Is included on the list of ACO providers/suppliers that is required
3. Antitrust Enforcement Safety Zone. Occurs when independent ACO participants that provide the same service have a share of 30 percent or less of the common service in each participant's Primary Service Area (PSA).

PROCEDURE

1. Applicable Law. As detailed in the Scripps ACO Participant Agreement, the ACO, ACO participants, ACO providers/suppliers and other individuals or entities performing functions or services related to the ACO's activities will, comply with all applicable laws including, but not limited to, the following:
 - Federal Criminal Law
 - The False Claims Act (31 U.S.C. 3729 et seq.)
 - The Anti-Kickback Statute (42 U.S.C 1320a-7b(b))
 - The Civil Monetary Penalties Law (42 U.S.C. 1320a-7a)
 - The Physician Self-Referral Law (42 U.S.C 1395nn)
2. Waivers. Certain ACO arrangements may be covered by waivers to the Physician Self-Referral Law, the federal anti-kickback statute and certain Civil Monetary Penalties (CMP) law provisions. These waivers are maintained by Center for Medicare and Medicaid (CMS) and the Officer of Inspector General (OIG) as necessary to implement the Medicare Shared Savings Program



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(MSSP). These waivers are limited and are not a wholesale waiver of these laws and regulations and cover the following five arrangement/activities:

- ACO Pre-Participation Waiver. This waiver protects startup arrangements that pre-date an ACO's participation agreement, so long as the parties forming the ACO are working with good faith intent to develop an ACO that will participate in the MSSP during target year.
 - ACO Participation Waiver. This waiver is available for ACOs that have entered into a participation agreement with CMS for the MSSP and remain in good standing.
 - ACO Shared Savings Distribution Waiver. This waiver is available for ACOs that are participating in the MSSP and distribute shared savings during the year in which the shared savings were earned by the ACO.
 - Compliance with the Physician Self-Referral Waiver. This waiver protects arrangements, as to applicability to the AKS or the gainsharing CMP, between ACOs participating in the MSSP and physicians that the arrangement meets a Stark Exception.
 - Waiver for Patient Inducements. The Anti-Kickback Statute (AKS) and beneficiary inducement Civil Monetary Penalty (CMP) will be waived where participating ACOs provide patients with healthcare-related incentives that meet certain criteria.
3. Antitrust. The Scripps ACO, ACO participants, and ACO provider/suppliers will avoid improper exchanges of prices or other competitively sensitive information among competing participants and will implement appropriate firewalls or other safeguards to protect against collusion among competing participants.

Examples of conduct that the Federal Trade Commission (FTC) and Department of Justice (DOJ) would consider concerning include the following:

- Preventing or discouraging private payers from directing or incentivizing patients to choose certain providers
- Exclusive contracting with ACO physicians, hospitals, ASCs or other providers which would prevent or discourage those providers from contracting with private payers outside of the ACO; and



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- Restricting a private payer from making costs, quality, efficiency and performance information available to aid enrollees in evaluating and selecting health plan providers, if that information is similar to the information used for the MSSP.

RESOURCES

- <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html#Medicare Shared Savings Program>