

What are antitrust waivers for Medicare's Shared Savings Program?

The Medicare Shared Savings Program was created as part of the Patient Protection and Affordable Care Act of 2010 (health reform legislation) and established a new type of care delivery and payment model known as an Accountable Care Organization (ACO). Designed to improve quality and reduce costs in the Medicare fee-for-service program, ACOs encourage physicians, hospitals and other health care providers to become accountable for a patient population through integrated health care delivery systems. Simply put, if the ACO saves Medicare money through certain efficiencies without sacrificing quality, then the providers that constitute the ACO may share a portion of those savings as additional income.

Providers must apply to be a Medicare ACO, and the Centers for Medicare & Medicaid (CMS) may approve for Medicare participation those ACOs that meet certain eligibility criteria, including: (1) a formal legal structure that allows the ACO to receive and distribute payments for shared savings; (2) a leadership and management structure that includes clinical and administrative processes; (3) processes to promote evidence-based medicine and patient engagement; (4) reporting on quality and cost measures; and (5) coordinated care for beneficiaries. Antitrust law, however, places very strict limitations on the ability of otherwise competing providers or provider practices to collaborate conflicting with the exact types of behavior that the formation of an ACO encourages. Moreover, some ACOs serve both Medicare beneficiaries and commercially insured patients, and thus antitrust enforcers must ensure that ACOs are structured to promote, not harm, competition.

To address the antitrust concerns raised by the formation of an ACO, the Federal Trade Commission and the Antitrust Division of the Department of Justice (antitrust enforcers) have published a Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program. In this document, the antitrust enforcers explain how federal antitrust law will be applied to ACOs, including which ACOs will be entitled to an "antitrust safety zone," also known as an ACO antitrust waiver.

The antitrust enforcers will grant waivers, and therefore agree not to open antitrust investigations, to those ACOs that are highly unlikely to raise significant competitive concerns. Waivers will be granted if the independent ACO participants that provide the same service have a combined share of 30% or less of each common service in each participant's Primary Service Area (PSA). In other words, the ACO itself cannot exceed a 30% PSA share for any common service it provides, however there is a rural exception for those above the threshold. It should be noted that failure to obtain an antitrust waiver does not mean the ACO is illegal; rather the antitrust enforcers may evaluate the competitive effects of the ACO if it does not fall within the safety zone.

For more information on antitrust, see our Myth Buster here: <http://www.healthinfo.org/article/myth-buster-antitrust-waivers-protect-anyone-participating-accountable-care-organization>. For more information about health information technology, see: <http://www.healthinfo.org/topics/90>. Follow us on Twitter at [@HealthInfoLaw](https://twitter.com/HealthInfoLaw).

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