

ACO COMPLIANCE PROGRAM POLICIES AND PROCEDURES MANUAL

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MEDICARE SHARED SAVINGS PROGRAM (MSSP) ACO COMPLIANCE PROGRAM POLICIES AND PROCEDURES MANUAL INTRODUCTION

As part of the regulations implementing the Patient Protection and Affordable Care Act (the “ACA”), CMS established the Medicare Shared Savings Program (“MSSP”), complete with the myriad regulations regarding the governance and structure of Accountable Care Organizations (“ACOs”) and the incentive of shared savings derived from lowering costs. While these factors of the MSSP have received much attention since final regulations were published in November 2011 and June 2015, the everyday compliance obligations have received significantly less. In fact, after successfully forming an ACO and completing the MSSP application process, many leaders in ACOs are left asking “Now what?”

This manual is designed to answer that question in a straightforward narrative, complete with sample documents necessary to effectuate a standard ACO compliance program. The manual is not intended to be a comprehensive solution to every ACO’s compliance needs, as many means of executing an effective compliance program are specific to an individual ACO. Nor does this manual establish an attorney/client privilege or relationship between NAACOS, Dentons, and any ACO participant, provider, or supplier. However, this manual will give an engaged compliance officer (and better yet, team) the tools necessary to establish a robust program with the tools to handle the baseline requirements of keeping an ACO compliant with federal law and regulations.

ACO Compliance

CMS requires ACOs to have a compliance plan.¹ The compliance regime surrounding ACOs consists of many interconnected parts. The MSSP, the program in which nearly all ACOs are enrolled, is an agreement with CMS - acceptance into the program is just the beginning. CMS expects an effective compliance program, one that prevents and detects potential compliance issues proactively rather than reactively. Ideally, a compliance team will consist of a fully engaged and informed leadership team and ACO Board of Directors. Finally, evidencing a “culture of compliance” with clear expectations of ethical and proper behavior best serves an ACO.²

As part of the MSSP, all ACOs must “agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities” to allow federal authorities to audit the ACO’s activities.³ Practically, then, documentation is the key to ACO compliance - the most

¹ 42 C.F.R. § 425.300.

² The OIG provides detailed compliance program advice, including “best practices” at its website, www.oig.hhs.gov/compliance, including specific advice for separate types of entities. A review of both ACO specific and non-ACO specific compliance guidance posted here should regularly be undertaken to ensure a complete, up-to-date understanding of compliance requirements.

³ 42 C.F.R. § 425.314.

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compliant ACO in the United States must still be able to document its compliance if CMS disputes it.

Three major sources of ACO-specific compliance guidance exist - the MSSP statute,⁴ the proposed and final rules regarding the MSSP,⁵ and the MSSP and Pioneer ACO Program sub-regulatory guidance located on the CMS website.⁶ Additionally, the generally applicable Anti-Kickback Statute, Stark law, fraud, waste, and abuse (“FWA”), antitrust, and privacy laws each pose unique challenges to ACOs.

⁴ Established under Section 3022 of the ACA, amending Title 18 of the Social Security Act by adding Section 1899, et seq.

⁵ 76 Fed. Reg. 19528 (April 7, 2011), 76 Fed. Reg. 67802 (Nov. 2, 2011), 79 Fed. Reg. 72760 (Dec. 8, 2014), and 80 Fed. Reg. 32692 (June 9, 2015).

⁶ Located at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram/>.