

I. Coordination with Other Agencies

As mentioned previously, in developing the Shared Savings Program, and in response to stakeholder concerns, we have worked very closely with agencies across the Federal Government to facilitate participation in the Shared Savings Program and to ensure a coordinated and aligned inter- and intra-agency effort in the implementation of the program. The result of this effort is the release of three documents with which potential participants are strongly encouraged to become familiar. These documents include: (1) a joint CMS and DHHS Office of Inspector General (OIG) Medicare Program; **Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center addressing proposed waivers of the civil monetary penalties (CMP) law, Federal anti-kickback statute, and the physician self-referral law;** (2) an Internal Revenue Service (IRS) notice soliciting comments regarding the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals, participating in the Shared Savings Program; (3) a proposed Antitrust Policy Statement issued by the FTC and DOJ (collectively, the Antitrust Agencies). In addition, we are proposing to preserve the benefits of competition for Medicare beneficiaries by precluding newly formed ACOs with market power from participating in the Shared Savings Program.

1. Waivers of CMP, Anti-Kickback, and Physician Self-Referral Laws

Certain arrangements between and among ACOs, ACO participants, other owners, ACO providers/suppliers, and third parties may implicate the CMP law (section 1128A(b)(1) and (2) of the Act), the Federal anti-kickback statute (section 1128B(b)(1) and (2) of the Act), and/or the physician self-referral prohibition (section 1877 of the Act). Section 1899(f) of the Act authorizes the Secretary to waive certain fraud and abuse laws as necessary to carry out the provisions of the Shared Savings Program. Accordingly, pursuant to section 1899(f) of the Act,

CMS and OIG have jointly published elsewhere in this **Federal Register** a Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center which describes and solicits public input regarding possible waivers of the application of certain CMP law provisions, the Federal anti-kickback statute, and the physician self-referral law to specified financial arrangements involving ACOs under the Shared Savings Program. In addition, section 1115A(d)(1) of the Act, as added by section 3021 of the Affordable Care Act, authorizes the Secretary to waive the same fraud and abuse laws, among others, as necessary solely for the purposes of carrying out the provisions of section 1115A of the Act with respect to the testing of certain innovative payment and service delivery models by the Innovation Center. The notice with comment period published elsewhere in this **Federal Register** also solicits public input regarding that separate waiver authority

We expect that the waivers applicable to ACOs participating in the Shared Savings Program will be issued concurrently with our publication of the Shared Savings Program final rule. The requirements of the Shared Savings Program final rule will bear on the scope of any waivers granted for the Shared Savings Program. Because of the close nexus between the final regulations governing the structure and operation of ACOs under the Shared Savings Program and the development of waivers necessary to carry out the provisions of the Shared Savings Program, CMS and OIG may, when crafting waivers applicable to the Shared Savings Program, consider comments submitted in response to this Shared Savings Program proposed rule and the provisions of the Shared Savings Program final rule. Conversely, we may consider comments received in response to the joint notice with comment period when drafting the Shared Savings Program final rule. Members of the public submitting comment on this proposed regulation should consider commenting on the proposed waivers, as well.