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Alerts

Accountable Care Organization Waivers

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Health Care Alert

This Hinshaw Health Law Alert describing ACO waivers is the fourth in a series of advisories regarding accountable care organizations (ACOs).

As the development of accountable care organizations (ACOs) progresses, key stakeholders have raised several concerns related to forming ACOs while complying with several laws that inherently appear to impede the development of ACOs and their participation in the Medicare Shared Savings Program (MSSP). In recognition of these concerns, various federal regulatory agencies have attempted to provide more flexibility for ACOs to form. This alert will focus on the fraud and abuse waivers and tax-exempt organization waivers that have been proposed to assist in further development of ACOs.

Waivers of Fraud and Abuse Laws for ACOs
Section 3022 of the Patient Protection and Affordable Care Act, codified at Section 1899(f) of the Social Security Act, authorizes the Secretary of the U.S. Department of Health and Human Services to waive certain fraud and abuse laws as necessary to carry out the MSSP. On April 7, 2011, the Office of the Inspector General (OIG) and the Centers for Medicare and Medicaid Services (CMS) issued a combined notice (Notice) which proposes waivers targeted toward the application of the federal Anti-Kickback Statute, the Stark Law and civil monetary penalties (CMP) provisions or "gainsharing" laws that prohibit a hospital's payment to a physician to reduce or limit care to a Medicare or Medicaid beneficiary. Key stakeholders served as the impetus for the Notice as concerns were raised that many ACOs that participated in the MSSP would be impeded by the federal fraud and abuse laws.

The proposed waivers relate to the distribution of shared savings received by an ACO from CMS under an MSSP. As a prequalification for a waiver, the ACO would be required to have an agreement with CMS to participate in the MSSP. The ACO, ACO participants and providers/suppliers would be required to comply with that agreement and Section 1899 of the Social Security Act and the regulations implementing the program.

The application of the federal Anti-Kickback Statute and Stark Law would be waived for distributions of shared savings earned through an MSSP but solely for those activities that are *necessary for and directly related* to the ACO's participation in the MSSP. The waiver is somewhat limited as it does not apply to financial relationships other than distributions of shared savings. Instead, those financial relationships that are not distributions of shared savings would need to meet some Anti-Kickback Statute safe harbor or Stark Law exception. Another significant limitation gleaned from the Notice is that the waiver would not apply to an ACO that distributes shared savings from an agreement with non-Medicare and Medicaid third-party payers.

The application of the CMP or "gainsharing" laws to distributions of shared savings would be waived in situations where the distributions are made from a hospital to a physician, provided that the payments are not made to knowingly induce the physician to reduce or limit *medically necessary* items or services. The Notice, however, fails to define what constitutes *medically necessary*. Application of the CMP will also be waived in any financial relationship directly related to the ACO's participation in the MSSP that implicates the Stark Law and complies with a Stark Law exception.

Tax-Exempt Organization Waivers/Internal Revenue Service Notice 2011-20

The Internal Revenue Service (IRS) issued a notice on March 31, 2011, which offers guidance on the tax implications to those tax-exempt organizations seeking to form an ACO and participate in the MSSP (Notice 2011-20). The two main areas where tax-exempt status would be jeopardized when forming an ACO include *private inurement/private benefit and unrelated business taxable income (UBTI)*.

In Notice 2011-20, the IRS asserts that it does not anticipate a tax-exempt organization's participation in the MSSP through an ACO to result in private inurement/private benefit, if the following criteria are met:

- The ACO has been accepted into and has not been terminated from the MSSP;
- There is a written agreement that delineates the terms and conditions of the tax-exempt organization's participation in the MSSP through the ACO;
- The tax-exempt organization's share of economic benefits derived from the ACO is proportional to the benefits or contributions the tax-exempt organization provides to the ACO. If the tax-exempt organization receives an ownership interest in the ACO, the ownership interest received is proportional and equal in value to its capital contributions, allocations, distributions and return of capital;
- The tax-exempt organization's share of losses does not exceed its share of income or gain; and
- All transactions between the ACO and its taxable participants are at fair market value.

Further, tax-exempt organizations will need to determine whether any income they receive from the MSSP through the ACO could be treated as UBTI. In Notice 2011-20, the IRS states that any MSSP payments received by a tax-exempt organization through an ACO will not be subject to UBTI, so long as the ACO meets all the eligibility requirements to participate in the MSSP. Instead, the IRS will treat such payments as payments related to the performance of the charitable purpose of lessening the burdens of government.

While the guidance from the OIG, CMS and the IRS provides stakeholders some comfort, there are many open issues that remain. For instance, with respect to fraud and abuse, whether the final federal regulations will preempt state enforcement under consumer protection and unfair trade practices or whether certain capital contributions within the ACO arrangement would be prohibited by the federal fraud and abuse laws. Additionally, it is still unclear whether the IRS will treat non-MSSP activities through an ACO as unrelated to the health care organization's tax-exempt purpose.

For more information, please contact your regular Hinshaw attorney.

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