

## **Health Law**

## Questions or Assistance?

If you have further questions regarding these proposed rules for accountable care organizations, please feel free to contact one of the following members of our Health Law Practice Group.

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## **Proposed Rules Regarding Accountable Care Organizations Issued**

On March 31, 2011, the Centers for Medicare and Medicaid Services ("CMS"), the Federal Trade Commission ("FTC"), the Department of Justice ("DOJ"), and the Office of Inspector General (the "OIG") issued proposed rules and the Internal Revenue Service ("IRS") issued a notice regarding implementation of the Medicare Shared Savings Program contemplated by Section 3022 of the Patient Protection and Affordable Care Act. The CMS proposed regulations provide hospitals, physicians and other providers with notice on how CMS might regulate the establishment and operation of an Accountable Care Organization (an "ACO") and the parameters by which an ACO's provider participants might be financially rewarded for lowering costs and satisfying specified quality standards. CMS is accepting comments on the proposed regulations until June 6, 2011 and a copy of the proposed regulations is available at <a href="http://www.shipmangoodwin.com/files/upload/CMSRule040111.pdf">http://www.shipmangoodwin.com/files/upload/CMSRule040111.pdf</a>.

In conjunction with the CMS proposed regulations, the FTC and DOJ issued a joint proposed statement that discusses how the FTC and DOJ are considering enforcing U.S. antitrust laws in regards to ACOs. The statement discusses: 1) the ACOs to which the rules might apply; 2) when the FTC and DOJ might apply particular antitrust analyses to those ACOs; 3) an antitrust safety zone for certain ACOs; 4) the CMS-mandated antitrust review process for certain ACOs; and 5) proposed options for ACOs to gain additional antitrust clarity if they fall outside the safety zone. The FTC and DOJ are accepting comments on the proposed statement until May 31, 2011 and a copy of the proposed statement is available at <a href="http://www.shipmangoodwin.com/files/upload/FTC\_DOJStatement.pdf">http://www.shipmangoodwin.com/files/upload/FTC\_DOJStatement.pdf</a>.

The OIG issued a proposed notice that describes and seeks comments on proposed waivers of the Stark Law, the Anti-Kickback Statute, and Civil Monetary Penalties applicable to specified financial arrangements involving ACOs under the Medicare Shared Savings Program. In conjunction with interested stakeholders, the OIG will set forth a list of waivers and the requirements for persons or entities to qualify for and satisfy a particular waiver. Please see <a href="http://www.shipmangoodwin.com/files/upload/OIGNotice.pdf">http://www.shipmangoodwin.com/files/upload/OIGNotice.pdf</a> for a copy of the notice. Once the notice is published in the Federal Register, interested parties will have 60 days to submit comments.

Lastly, the IRS issued a notice requesting comment as to whether existing IRS provisions governing tax-exempt organizations are sufficient for organizations planning to participate in the Medicare Shared Savings Program and/or other ACO arrangements. The IRS is accepting public comment on the notice until May 31, 2011 and a copy of the notice is available at <a href="http://www.shipmangoodwin.com/files/upload/IRSNotice.pdf">http://www.shipmangoodwin.com/files/upload/IRSNotice.pdf</a>.

Shipman & Goodwin will be publishing a complete analysis of these proposed regulations and notices in the near future. In the meantime, if you have any questions regarding the Medicare Shared Savings Program or ACOs in general, please contact one of the members of our Health Law Practice Group listed at left.