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There Is Potential Federal Inconsistency Over ACOs

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On June 4, 2015, the Centers for Medicare & Medicaid Services issued final revisions to regulations governing accountable care organizations participating in the Medicare Shared Savings Program ("MSSP"). Among them is one explicitly requiring the formation of an ACO as a formal, separate legal entity for governance purposes whenever there are two or more ACO participants with unique tax identification numbers.[1] In its revised state, CMS' requirement now appears to be at odds with certain positions taken by the Federal Trade Commission and U.S. Department of Justice. For example:

- The FTC has consistently maintained that the goals of the Affordable Care Act can be achieved through coordination of health care services, and does not in fact require or encourage providers to merge or otherwise consolidate. That position, however, appears to be undercut by CMS' newly explicit mandate that multiparticipant ACOs participating in the MSSP must be governed by a separate legal entity that directs the ACO's activities.

- The FTC's insistence in merger enforcement that claimed health care efficiencies are not merger-specific whenever they can be achieved by means other than a merger appears to be inconsistent to the extent that CMS' mandate reflects its conclusion that whenever two or more participants wish to coordinate care pursuant to the MSSP, they must do so through the formation of the ACO as a separate legal entity for governance purposes.

- The FTC/DOJ-issued joint guidance for MSSP ACOs clearly stating that joint negotiations with private payers by a multiparticipant ACO will also be analyzed under the rule of reason when the ACO meets the eligibility requirements for MSSP ACOs and employs the same mechanisms to serve patients in commercial markets. But it now remains to be seen whether private ACOs, if

any, that coordinated care through informal means short of forming a separate legal entity will still be accorded rule of reason treatment.

CMS' Revised Regulation

The MSSP was enacted pursuant to Section 3022 of the ACA, with the aim of encouraging groups of providers to form ACOs to coordinate care for Medicare fee-for-service beneficiaries in order to improve quality and lower costs.

CMS initially promulgated regulations governing ACOs participating in the MSSP in 2011. Among them was 42 C.F.R. § 425.104(b), which required the formation of a legal entity separate from any of the ACO participants whenever an ACO was formed by two or more "otherwise independent" ACO participants.

The now-final revision to Section 425.104(b), in comparison, removes the reference to "otherwise independent," instead mandating that whenever an ACO is formed by two or more participants, "each of which is identified by a unique TIN [tax identification number]," it must be governed by a legal entity separate from any of the individual ACO participants.

According to CMS, this change is intended to address valid questions previously raised by industry participants as to the precise meaning of "otherwise independent." It was unclear, for example, whether or not multiple ACO participants who belonged to the same integrated health system were considered "otherwise independent" so as to require formation of the ACO as a separate legal entity. The revised regulation answers this question in the affirmative, requiring the formation of a separate legal entity to govern the ACO even when the ACO participants all belong to the same integrated health system or IPA. According to CMS, this requirement is necessary "to ensure that the interests of individuals and entities other than the ACO do not improperly influence decisions made on behalf of the ACO."

During the comment period before CMS' proposed regulation became final, the new requirement was criticized as: (1) overly intrusive; (2) creating unnecessary administrative burdens on the ACO and its multiple participants; and (3) creating the potential for inconsistencies in the application of policies and procedures within the ACO.

CMS finalized its proposed revision without change. In addressing the above criticisms, CMS explained that the requirement of a separate legal entity is "essential to promote program integrity broadly ... and to ensure the ACO is accountable for its responsibilities under the [MSSP]." CMS was also unpersuaded that the formation of a separate legal entity was overly burdensome, citing to the fact that all ACOs participating in the MSSP to date had satisfied this requirement.[2]

CMS' Revised Regulation Appears to be Inconsistent with Certain Positions of Federal Antitrust Enforcement Agencies

CMS' revised regulation now appears to be inconsistent with certain positions taken by the FTC and DOJ, and senior officials at the agencies, with respect to antitrust enforcement of multiprovider health care collaborations.

First, both the FTC and DOJ consistently uphold and encourage a wide array of legitimate collaborative activities within the health care sector, so long as the conduct is likely to promote consumer welfare through lower cost and/or improved quality. For example, the 1996 Statements of Antitrust

Enforcement Policy in Health Care issued jointly by the FTC and DOJ, as well as a collection of FTC advisory opinions to date, explicitly recognize that pro-competitive collaborations are often achieved through clinical integration or financial risk-sharing, short of creating new, formal legal entities. This inclusive endorsement of all types of pro-competitive health care collaborations has remained unchanged in recent years despite passage of the ACA.

Relying on its prior endorsement of pro-competitive collaborations short of creating formal legal entities, just this past year, FTC Commissioner Julie Brill disputed the accuracy of a widely held notion among many health care providers and their counsel that the ACA encourages, and in fact requires, ever-increasing consolidations among providers. Rather, according to Brill, the ACA encourages providers to "coordinate" (not "consolidate") the provision of patient care services, and ACOs may in fact be formed through "contractual arrangements that are well short of a merger."[3] Similar sentiments have been echoed by other high-ranking officials within the FTC, including the director of the bureau of competition, Deborah Feinstein, as well as Chairwoman Edith Ramirez.[4] The FTC has also explicitly noted that the ACA does not mandate a particular structure.[5]

The FTC's position on whether the ACA encourages consolidation now appears to be at odds with the CMS regulation requiring the formation of an ACO as a formal, separate legal entity whenever two or more participants with different TINs are involved. The CMS regulations now appear to rule out the possibility of a multiparticipant MSSP ACO collaboration by other, less formal means.

Second, the FTC's insistence in merger investigations and challenges that any claimed efficiencies must be merger-specific is likewise undercut to a certain extent by CMS' revised regulation. In the FTC's recent significant victory on this front in St. Alphonsus Medical Center-Nampa Inc. v. St. Luke's Health System Ltd., (9th Cir. 2015), the Ninth Circuit agreed with the FTC that in order to rebut a prima facie case of anti-competitive effects, claimed efficiencies had to be merger-specific. In arguing its case, the FTC did not dispute the potential benefits of integrated care generally, but did argue that the claimed efficiencies from the merger between St. Luke's Health System and the Saltzer Medical Group could have been achieved in many different ways short of merger, including through the use of clinical practice protocols to ensure consistent treatment and/or financial incentives for meeting quality of care goals.[6]

CMS' final ACO regulation appears to undercut the FTC's position on merger-specificity to some degree. At a minimum, merging parties should now be entitled to observe (in response to FTC contentions that claimed efficiencies are not merger-specific) that a formal legal structure for ACO governance is now required by law at least in order to participate as an ACO in the MSSP.

Third, in what former FTC Chairman Jon Leibowitz described as an "unprecedented, collaborative effort among all of the agencies responsible for developing guidance for ACOs,"[7] the FTC and DOJ issued a 2011 Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, in close conjunction with CMS' original ACO regulations issued the same day.

The FTC and DOJ's goal in issuing the ACO policy statement is to "ensure that health care providers have the antitrust clarity and guidance needed to form pro-competitive ACOs" that participate not only in the Medicare market, but also in the commercial, private payer market. Pursuant to that goal, the policy statement makes clear that the FTC and DOJ will apply a rule of reason analysis to any ACO that: (1) meets eligibility requirements for, and participates in, the MSSP; and (2) employs the same legal and governance structures, and clinical and administrative processes to serve patients in commercial

markets. The ACO policy statement also explicitly adopts the eligibility standards set forth in CMS regulations as broadly consistent with the indicia of clinical integration identified in prior FTC advisory opinions dealing with health care collaborations.

When now read in conjunction with CMS' revised regulation, however, it is unclear whether rule of reason treatment would be accorded to multiparticipant ACOs participating in the commercial market short of forming the ACO as a separate legal entity. This is all the more pertinent given that the term "accountable care organization" is increasingly being used generically to describe various structures and process for taking either "upside" or "full" risk in agreements with private payers in the commercial market. Indeed, many commercial-only ACOs have been formed since the beginning of the MSSP, and it is now unclear whether those commercial-only ACOs — to the extent they are not in compliance with CMS' new mandate for separate legal entities — will still be accorded rule of reason treatment by the antitrust enforcement agencies.

Conclusion

The development of such potential inconsistencies between CMS' revised regulation and the treatment of ACOs under the antitrust laws may create an additional level of risk or uncertainly for providers contemplating ACO formation. And additional uncertainty in the marketplace will surely not help the federal government's goal of "maximize[ing] and foster[ing] opportunities for ACO innovation"[8] in order to improve the ailing health care system, particularly at this still early stage of ACO development.

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[1] 42 C.F.R. § 425.104(b), available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-14005.pdf.

[2] To the extent that CMS' initial 2011 regulations already functionally required the formation of a separate legal ACO entity whenever there were two or more ACO participants with unique TINs because that was CMS' practice, then the inconsistencies between CMS, the FTC and DOJ discussed below have existed for quite some time. CMS' revised regulation, nevertheless, formalizes the tensions on the face of the regulation.

[3] Commissioner Julie Brill's Keynote Address: Competition in Health Care Markets, at the 2014 Hal White Antitrust Conference (June 9, 2014), available athttps://www.ftc.gov/system/files/documents/public_statements/314861/140609halwhite.pdf (Competition in Health Care Markets).

[4] Director Deborah Feinstein's Antitrust Enforcement in Health Care: Proscription, Not Prescription, Fifth National Accountable Care Organization Summit (June 19, 2014); Chairwoman Edith Ramirez's Antitrust Enforcement in Health Care — Controlling Costs, Improving Quality, The New England Journal of Medicine, Dec. 11, 2014.

[5] Competition in Health Care Markets, supra note 3, at 8.

[6] Answering Brief of Appellees at 51-57, St. Alphonsus Medical Center — Nampa Inc. v. St. Luke's Health System Ltd., No. 14-35173 (9th Cir. Aug. 13, 2014), ECF Doc. 72.

[7] FTC, DOJ Seek Public Comment on Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (Mar. 31, 2011), available athttps://www.ftc.gov/news-events/press-releases/2011/03/ftc-doj-seek-public-comment-proposed-statement-antitrust.

[8] FTC and DOJ, Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, at 2 (Oct. 20, 2011), available at http://www.justice.gov/atr/public/health_care/276458.pdf.