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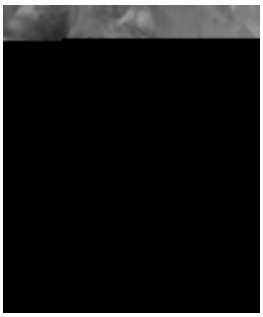
HEALTHCARE

Affordable Care Act Signals New Direction for Antitrust Enforcement in Healthcare



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The enactment of the 2010 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, represents the most significant and comprehensive attempt to manage healthcare coverage for Americans since the creation of the Medicare program in 1965.

The main goal of the Act is to reform the delivery of healthcare services by changing the way healthcare providers are paid and by providing incentives toward greater integration between healthcare providers to use resources more efficiently. The Act seeks this goal through implementation of a Medicare Shared Savings Program that encourages provider groups to come together as Accountable Care Organizations (''ACOs'') and qualify for the Program's new payment structure.

By virtue of its emphasis on integration and cooperation between otherwise competing providers, the Act has generated considerable debate in the antitrust community as to the proper role of antitrust law in the healthcare sector. Proponents of the reforms have argued that absent a relaxing of antitrust scrutiny the Act's desired efficiencies cannot be achieved. Similarly, some of the county's largest health systems that were supposed to be spearheading the push towards greater

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integration have stated that they will not participate in the ACO framework absent a reduction of bureaucratic oversight, including of antitrust scrutiny.[1]

The purpose of this article is to review recently proposed regulations by the agencies tasked with antitrust enforcement to determine whether the new ACO framework does in fact weaken the traditional role antitrust law plays in the healthcare sector. Two important regulations under the Act were proposed in March of this year. The first, by the Centers for Medicare & Medicare Services (''CMS'') — the administrative agency chiefly tasked with implementing the Shared Savings Program — sets out a Proposed Rule on how the new ACO framework will be structured. The second, issued jointly by the Department of Justice (''DOJ'') and Federal Trade Commission (''FTC''), sets out a Proposed Statement of their policy for antitrust enforcement regarding the ACOs participating in the new Program.[2]

As set out below, an initial review of the Proposed Rule and Statement does indeed suggest a shift in focus by the Administration in the regulation of concerted activities by healthcare providers. First, the traditional analysis of whether cooperating providers are sufficiently medically integrated to avoid per se treatment under the antitrust law has broadly been taken from the agencies — the FTC in particular — and given to CMS. Second, there appears to be a greater willingness than in the past to allow provider cooperation among entities with a degree of market power. Indeed, both the Proposed Rule and Statement explicitly afford room for significant ACO growth — the former by encouraging ACOs to expand their footprint and grow their membership through their joint ventures and the latter by expanding the agencies' traditional antitrust ''safety-zone'' to include larger entities. Third, the Proposed Statement exhibits and reinvigorates focus on abuse of market power by dominant entities, particularly the use of vertical restraints such as exclusive dealing or contracting arrangements between large ACOs and insurance companies. As demonstrated in the final section of this article, this appears to be broadly consistent with recent Agency enforcement decisions.

In sum, our preliminary review of both the CMS and Agencies' proposals suggests an Administration willing to encourage ACO consolidation and tolerate greater market power with the goal of cutting and streamlining healthcare costs.[3] The Act's priorities do reflect a significant shift away from the Agencies' traditional role in the healthcare sector and a partial surrendering of antitrust oversight, particularly as it relates to joint ventures between competing entities with market power.

Such a shift raises concerns from an antitrust perspective. However, particularly in certain healthcare markets that are fragmented, it may be that cooperation between providers in an ACO could limit duplicative medical services without causing adverse economic consequences. To the extent that such a limited relaxing of traditional antitrust standards can lead us to an effective and much needed reform of the healthcare system, it may be a path worth considering.

Moreover, as set out in the Proposed Statement, and as demonstrated by recent enforcement activity, the Agencies have made it a priority to ensure that ACOs or other entities with significant economic power will be unable to exercise such power in an anticompetitive fashion. They have done so by stepping up enforcement of abuse of dominanc11111.1ted rel1.1(enfouk2T*(ber(ACO)-250.3

signed care processes,'' and attain ''high quality and efficient service delivery.''[4]

The HHS has delegated this task to CMS,an operating division of HHS. To this end, CMS submitted its Proposed Rule entitled ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations'' (''Proposed Rule'') on April 7, 2011.[5] This Proposed Rule sets out the specific standards that must be met by entities wishing to quality as an ACO and participate in the Shared Savings Program. Comments that were submitted before June 6, 2011, in response to the Proposed Rule will be considered by CMS before it issues its Final Rule.

In addition to HHS and CMS, the DOJ and the FTC (collectively the ''Agencies'') are involved in the execution and oversight of the Medicare Shared Savings Program. The DOJ, as an administrative agency, is responsible for implementing the administration's priorities with respect to antitrust enforcement related to the Program. The FTC, an independent agency, has historically taken the lead in considering issues of clinical integration in the health care sector and will continue to be involved in the review and enforcement of ACOs.[6] Notwithstanding traditional allocations of tasks between the Agencies, it appears that both will simultaneously be involved in the review and enforcement of the ACO Program.[7]

Historically, the DOJ and FTC have provided active oversight with respect to innovations in health care delivery systems, often by issuing advisory opinions, guidelines and policy statements. The FTC/DOJ 1996 *Statements of Antitrust Enforcement Policy in Health Care* (''1996 Health Care Statements'') have been the primary source of antitrust guidance for multiprovider networks[8] and more specifically for physician network joint ventures[9]. On March 31, 2011, the Agencies responded to the Medicare Shared Savings Program and the ACO framework by issuing their *Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (''Proposed Statement'').[10] The Proposed Statement, discussed in detail below, is an extension of the DOJ/FTC analysis under the 1996 Health Care Statements.

II. CMS PROPOSED RULE REGARDING ACOs

CMS's Proposed Rule sets out the Administration's goal for the Shared Savings Program: ''(1) better care for individuals; (2) better health for populations; and (3) lower growth in expenditures.''[11] To achieve this, HHS and CMS attempt to generate incentives for providers

Third, the Proposed Rule recognizes that the patients covered by the ACOs will not be limited to Medicare beneficiaries but that ACOs will likely also be negotiating collectively with commercial insurers.[16] Although the current Program itself applies only to savings in the Medicare fee-for-service market,[17] it is understood that providers are more likely to form ACOs if they can simultaneously or subsequently reap the benefits of increased efficiencies in the provision of care for commercially insured patients. In short, if the Program ultimately is successful, it will result in a permanent shift in the health care delivery paradigm for a much larger category of patients — regardless of payment source.

2. Role of Antitrust Law in ACO Framework

The Proposed Rule is also relevant from an antitrust perspective in that it specifically sets out CMS' position concerning the role of antitrust law in the new ACO framework. The Rule does so in two ways. First it addresses the question of potential *per se* liability for collaboration between competing providers. Second, it sets out CMS' position for limiting the exercise of ACO market power.

The Proposed Rule clearly recognizes that the incentives provided by the ACO framework will necessarily involve competing provider collaboration. Pursuant to both the CMS Proposed Rule and the FTC/DOJ Proposed Statement, it is CMS, not the Agencies, that will be responsible for determinations of whether the members of the ACO are sufficiently integrated to protect against antitrust scrutin

termining the level of clinical integration required by ACO to be considered a bona fide joint arrangement. Second, the traditional antitrust zone thresholds, including the threshold for the ''Antitrust Safety Zone,'' are expanded for newly formed ACOs compared to the similar zones identified under the Agencies' 1996 Health Care Statements. Finally, the Proposed Statement places specific emphasis on an Agency review of potential abuses of market power by large ACOs — specifically through vertical restraints entered into between ACOs and health insurance companies.

1. Clinical Integration of ACOs

As explained above, the Proposed Rule specifically identifies the Agencies as being responsible for reviewing any ACO that has a greater than 50 percent share of a market. That said, under the Agencies' Proposed Statement, *the determination of whether an ACO is sufficiently integrated to avoid an allegation of per se price fixing is left in the hands of CMS*. The Agencies' coordination efforts with CMS involved a review of CMS's proposed eligibility criteria for ACOs and a determination that such criteria are ''broadly consistent with the indicia of clinical integration that the Agencies previously set forth in the Health Care Statements'' they issued in 1996.[24]

This represents a significant shift from prior practice. The FTC previously specialized in making case-by-case determinations as to whether sufficient clinical integra-

ing in the Shared Savings Program. These ACOs are presumed to be ''highly unlikely to raise significant competitive concerns.''[33]

The Agencies' Proposed Statement diverges from its 1996 Health Care Statements in two important respects. It increases the safety zone threshold to ACOs with independent ACO-participants combining for a 30 percent PSA share from the previous 20 percent share of a traditionally defined relevant market (which could use concepts of market definition other than PSAs).[34] It also introduces a new ''Dominant Provider Limitation'' clause to the safety zone analysis, whereby an ACO with a provider-participant with a greater than 50 percent share in its PSA of any service that no other ACO participant provides to patients in that PSA may fall within the safety zone so long as (1) the dominant provider-participant contracts with the ACO on a non-exclusive basis, and (2) the ACO does not require commercial payers to contract exclusively with the ACO or otherwise restrict the commercial payer's ability to deal with other provider networks.[35] These provisions tacitly acknowledge both the potential need for ACOs to have larger footprints in their respective markets as well as the fact that many provider markets already suffer from high levels of provider concentration.

The Proposed Statement also appears to echo the growth incentives in the CMS's Proposed Rule by shielding organic growth from antitrust review where it is driven by business acumen rather than anticompetitive considerations. For instance, an ACO starting below the 30 percent share mark that later exceeds that threshold solely because it attracts more patients will not lose its safety zone status and protection.[36] Indeed, even an ACO with a share greater than 50 percent will be permitted to grow if solely by attracting more patients without attracting additional review by the Agencies[37]—so long as it does not abuse that dominant position under antitrust laws.

B. ACOs That Require Mandatory Review

The second distinct zone contemplated by the Proposed Statement is the Antitrust Mandatory Review Zone for ACOs with PSA shares exceeding the 50 percent threshold for any common service that two or more independent ACO participants provide to patients in the same PSA, unless the ACO qualifies for the narrow Rural Exception.[38] If the ACO is of sufficient size to reach the Mandatory Review Zone, during the application process the ACO must provide CMS a letter from the FTC or DOJ indicating that it has no intention to challenge or recommend challenging the ACO.[39]

Here, the Agencies recognize that while the 50 percent share threshold provides ''a valuable indication of the potential for competitive harm,'' it will consider ''any substantial procompetitive justification for why the ACO needs that proposed share to provide high-quality, cost-effective care.''[40, 41]

The Agencies also provide specific guidance as to the type of conduct that may raise flags in their review. They state that ACOs with greater than a 50 percent PSA share can reduce the likelihood of antitrust concern by avoiding such conduct, which is identified in the Proposed Statement's description of its review of ACOs falling within the ''Gray Zone'' (below).

C. ACOs In the Antitrust Gray Zone

The final distinct zone contemplated is for ACOs that do not qualify for the Antitrust Safety Zone and are below the 50 percent threshold. We call this the Gray Zone. If the ACO falls within the Gray Zone, mandatory review by the Agencies is not necessary, but available.[42]

More importantly, this section sets out ''additional antitrust guidance'' for ACOs fitting within the Gray Zone–as well as those with greater than a 50 percent share—including specific examples of potentially anti-

contract with all the hospitals in the same network as the hospital that belongs to the ACO)

3. With an exception for primary care physicians, contracting with other ACO physician specialists, hospitals, ASCs, or other providers on an exclusive basis, thus preventing or discouraging them from contracting outside the ACO, either individually or through other ACOs or provider networks
4. Restricting a commercial payer's ability to make available to its health plan enrollees cost, quality, efficiency, and performance information to aid enrollees in evaluating and selecting providers in the health plan, if that information is similar to the cost, quality, efficiency, and performance measures used in the Share Savings Program
5. Sharing among the ACO's provider participants competitively sensitive pricing or other data that they could use to set prices or other terms for services they provide outside the ACO.[45]

Notably, of the five types of conduct identified, 4 are aimed at the vertical relationship between the ACO and insurance companies and are stated to be ''important to facilitate payers' ability to offer insurance products that differentiate among providers based on cost and quality.''[46] Only one is aimed at conduct typically targeted by the Agencies when reviewing *horizontal* agreements between competitors, namely avoiding collusion on pricing or other competitively sensitive data.

The five types of anticompetitive conduct highlight the Agencies' particular concern with vertical restraints between health care providers and insurance companies. While the Proposed Statement is aimed specifically at ACO conduct in this regard, the Agencies enforcement record—as well as recent actions brought by private plaintiffs—suggests that such practices will also be subject to investigation when initiated by independent providers or large insurance companies. The Proposed Statement's emphasis on a review of vertical restraints appears consistent with the Agencies' recent enforcement activity. In particular, both the Proposed Statement and the enforcement activity suggest that vertical restraints, including exclusive dealing arrangements and other vertical exclusionary contracting practices, will receive special attention from the Agencies as the ACO framework unfolds.

IV. RECENT ANTITRUST CASES IN THE HEALTH CARE SECTOR

1. United States v. United Regional Health Care System

On February 25, 2011, the DOJ and the State of Texas filed a complaint against United Regional Health Care System alleging a violation of Section 2 of the Sherman Act.[47] The complaint provides an indication of the DOJ's position on certain types of conduct in the health care environment mere weeks before the DOJ/FTC Proposed Statement was issued. Here, the DOJ claimed that the defendant, an alleged ''must-have''[48] hospital in the region, had monopoly power in the markets for ''(1) the sale of general acute-care inpatient hospital services to commercial health insurers, and (2) the sale of outpatient surgical services to commercial health insurers,'' maintaining unlawfully a market share of approximately 90% and 65%, respectively.[49]

Critically for present purposes, the DOJ alleged that United Regional entered into exclusive contracts with commercial health insurance companies, whereby the insurance companies had to pay a ''substantial pricing penalty,'' ranging from 13% to 27%, if the insurers also

DOJ.[72] On June 7, 2011, the court denied Blue Cross Blue Shield's motion to dismiss.[73]

4. West Penn Allegheny Health System, Inc. v. UPMC

In a recent private[74] case, *West Penn Allegheny Health System, Inc. v. UPMC*, 627 F.3d 85 (3d Cir.

particularly exclusive dealing and other exclusionary contracting practices that fail to ensure competition. A serious economic analysis on a case-by-case basis of the net benefits to market competition and consumer welfare of such vertical restraints in the health care context is necessary to determine whether or not to permit such arrangements given the concerns with anticompetitive effects.

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