Federal Trade Commission
Office of the Secretary
Room H-113 (Annex W)
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017

DaVita, Inc. (DaVita) is pleased to provide these comments to the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice (collectively, the Antitrust Agencies) regarding the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Proposed Statement).[1]

ABOUT DAVITA

DaVita is a leading provider of kidney dialysis services in the United States to patients suffering from End Stage Renal Disease (ESRD). We serve our approximately 125,000 patients through 1,612 outpatient dialysis facilities located in 42 states and the District of Columbia. The vast majority of our patients are Medicare beneficiaries (around 80%), and the remainder are beneficiaries of other government-based programs (approximately 9%) and patients covered by commercial payors (approximately 11%).

OVERVIEW OF OUTPATIENT DIALYSIS SERVICES MARKETS

Outpatient dialysis services markets are highly competitive. Besides DaVita, there is one other large dialysis organization (LDO), followed by many medium dialysis organizations (MDOs) and small dialysis organizations (SDOs). Competition among these market participants is for scale (e.g., acquisition of dialysis centers), for qualified physicians that can act as medical directors of the centers (a federal requirement), and for individual patients.

COMMENTS

DaVita believes that ACOs provide a significant opportunity for the Medicare program to improve quality of care while reducing the cost of dialysis services furnished to ESRD patients. Therefore, we are examining innovative ways to form and otherwise participate in ACOs through mechanisms that will promote competition in services furnished both to Medicare beneficiaries and commercially-insured patients. DaVita commends the Antitrust Agencies for their collaborative efforts with CMS to provide additional clarity on the antitrust analysis of ACOs seeking to participate in the Medicare Shared Savings Program (MSSP). In particular, we

[1] 76 Fed. Reg. 21894 (Apr. 19, 2011).

applaud the application of the Rule of Reason analysis to ACOs that satisfy certain conditions (e.g., CMS eligibility criteria) and operate in the Medicare and commercial markets.

Other aspects of the Proposed Statement, however, are likely to create significant barriers to ACO formation and participation. For DaVita, the most significant issue that arises from the Proposed Statement is a unique problem created by the confluence of non-exclusivity with the 50% screen for mandatory antitrust review. The union of these two provisions effectively creates a "no-win situation" in the outpatient dialysis services market that could result in significant barriers to participation and innovation.

The "no-win situation" is as follows: Participate on an exclusive basis in an ACO and risk antitrust investigation if PSAs for outpatient dialysis services exceed 30%; or participate in an ACO on a non-exclusive basis along with other providers of outpatient dialysis services and be subject to the mandatory antitrust clearance requirement. Neither option is appealing and both may result in ACOs forming without seeking the participation of dialysis organizations. Such an outcome would mean that ACOs would not have the opportunity to coordinate the care of ESRD patients, which account for 10% of Medicare's overall spend. Moreover, ESRD populations typically suffer from complex health problems often resulting in co-morbidities like diabetes, hypertension, and vascular disease. Even if the Antitrust Agencies believe they can resolve market concentration issues relative to dialysis organizations rather summarily, DaVita believes that ACOs will be hesitant to include LDOs if they would potentially be subject to the expense of mandatory review.

Regarding ACOs that choose to include only one provider of outpatient dialysis services on an exclusive basis, besides the 30% threshold, DaVita is concerned about the potential deleterious impact that such exclusivity would have on ESRD patients. These patients must undergo dialysis treatments three times a week for four hours each time. Because of the intensity of dialysis treatments, patients must go to a facility that is easily accessible and close to home. We believe that, by potentially forcing patients to change dialysis providers to maintain exclusivity and stay under the 30% threshold, the Antitrust Agencies may preclude the potential benefits of ACOs for this vulnerable population.

Under the Proposed Statement, ACOs with shares above 30% can significantly reduce the likelihood of antitrust investigation by, among other things, contracting with ACO physician specialists, hospitals, Ambulatory Surgery Centers (ASCs), *or other providers*[2] on a non-exclusive basis, thus allowing these providers to contract outside of the ACO either individually or through other ACOs or provider networks. While it is not expressly required by the Proposed Statement, DaVita expects that most ACOs will operate on a non-exclusive basis as a way to mitigate antitrust risk. The Antitrust Agencies have stated that operating on a non-exclusive basis must be "in fact" and not just "in name." In other words, there must be evidence that the ACO actually does, or otherwise is willing and able to, contract with other providers.

Non-exclusivity is often favored with provider networks because it enables payors (and enrollees) to include or access other providers in the market without contractual restraints.

[2] We assume that the term "other providers" would be interpreted to include outpatient dialysis providers.

Under the Proposed Statement, however, a "norm" of non-exclusivity could have a perverse impact in markets with a high concentration of large national-level health care providers. Specifically, the result of non-exclusivity is the inclusion of more providers in an ACO, thus raising the ACOs shares for a common service furnished by the providers. When coupled with the 50% share threshold for mandatory antitrust review, as provided for in the Proposed Statement, the purported benefits of non-exclusivity in this instance are thwarted.

This scenario is likely to play out many times over when ACOs wish to include an LDO like DaVita. Including DaVita—and/or its national competitor—along with other MDOs and/or SDOs in an ACO (because of the desire to satisfy the norm of non-exclusivity) will, in many markets, result in PSA shares that exceed the 50 % threshold for mandatory review. As a result, DaVita is concerned that participation by outpatient dialysis organizations in non-exclusive ACOs will require mandatory antitrust review in most cases, which, as discussed above, creates an incentive to exclude dialysis organizations, especially LDOs, as participants.

DaVita is concerned that the impact of routine mandatory review for ACOs that include outpatient dialysis organizations could be profound. ACOs may decide not to invite dialysis organizations to participate if doing so will trigger mandatory antitrust review. If this occurs routinely, ESRD patients may be excluded from the clinical and economic efficiencies expected to result from ACOs. Such decisions could undermine the ultimate goal of the MSSP. Or, ACOs may not make provider participation decisions on clinical and service merits, but instead on a preference for avoiding mandatory antitrust review. This is not a procompetitive incentive. Alternatively, ACOs that include LDOs be may saddled with the cost of a mandatory review process over and over and over again, a highly burdensome proposition not only for the providers, but also for the Antitrust Agencies.[3]

DaVita is cognizant of the risks to competition that may arise when an ACO of independent providers possesses market power for common services. However, when an ACO's PSA shares are driven up for the sake of non-exclusivity, the same non-exclusivity should militate, to a certain degree, against the need for any mandatory market share screening from the Antitrust Agencies. DaVita, therefore, suggests that the Proposed Statement be changed to eliminate or modify the mandatory antitrust agency review requirement when the only outpatient dialysis service category that exceeds the 50% PSA is outpatient dialysis services so long as the arrangement is non-exclusive (as to the network and to payors) for such outpatient dialysis providers and the other safeguards listed in the Proposed Statement are in place.

Alternatively, the Antitrust Agencies could also consider establishing a streamlined review process that applies to LDOs or MDOs that are likely to participate in ACOs in numerous geographic areas across the country. A streamlined process eliminates the need for, or at a minimum, reduces the burdens associated with repeated and numerous mandatory antitrust reviews, and may allay concerns about including outpatient dialysis providers in ACOs.

[3] It is not clear what data the Antitrust Agencies considered in estimating the numbers of ACOs that would desire or require antitrust agency review. If the data did not contemplate services like outpatient dialysis that are furnished by large national organizations, the estimates of the Agencies' workloads could be off by a significant margin.

We appreciate the opportunity to submit comments on the Proposed Statement. We hope our comments are helpful in highlighting some of the unique effects the Proposed Statement could have on providers of outpatient dialysis services. If the Proposed Statement is implemented without consideration of the unique issues addressed herein, the guidance may fail to meet the Antitrust Agencies' stated goal of maximizing and fostering opportunities for ACO innovation.