Comments On Proposed Statement Of Antitrust Enforcement Policy Regarding ACOs Participating In The Medicare Shared Savings Program, Matter V100017

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Introduction

As lawyers focusing on health care antitrust issues for 30 and 10 years, respectively, we believe that the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Share Savings Programs (the "Policy Statement"), if not modified, may prevent development of effective and attractive ACO networks where there is no serious risk of antitrust concern. Our greatest concerns are summarized below, focusing on, respectively, the 75% primary service area test (the "75% rule"); the analysis of product markets; the 50% "mandatory review" market share test; and the nature of the review process.

Overall, we believe that the proposed standards, if not modified, will fail to be "flexible enough to allow the health care community to collaborate to improve quality and decrease costs . . ."[1] We believe that the Policy Statement needs to be substantially revised.

Below, we offer specific comments and some suggestions for changes.

I. The 75% Rule

The greatest problem with the standards appears to us to be the 75% rule. By presumptively defining antitrust markets as equal to 75% service areas, the drafters of these standards ignore essentially all the health antitrust case law and even their own practices.

First, none of the government's litigated merger cases since the mid-1990s have resulted in the use of a 75% primary service area as the sole determinant of geographic market. Similarly, the methodology formed by Kenneth Elzinga and Thomas Hogarty, the Elzinga-Hogary ("E-H") test,[2] utilized a 75% test based on both inflow of patients (the service area test)

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[1] Remarks of FTC Chairman Jon Leibowitz (October 5, 2010).

[2] See Kenneth G. Elzinga and Thomas F. Hogarty, "The Problem of Geographic Market Definition in Antitrust Suits," *Antitrust Bulletin* 9 1973), Volume XVIII, pp.45-81.

and outflow, but even that test was superseded by the authors' later work and was never adopted without modification by a court to our knowledge.[3]

The tests applied by courts tend to involve much larger areas, and only after accounting for outflow. Most importantly, the cases focused on, not merely where patients currently receive their healthcare, but where they would do so upon an effort by the merging hospitals to exercise market power. *See, e.g., Morgenstern v. Wilson*, 29 F.3d 1291, 1296 (8th Cir. 1994) (holding that a market "focused upon where …. residents actually went, as opposed to where they could practicably go" for healthcare services was impermissibly narrow); *F.T.C. v. Freeman Hosp.*, 69 F. 3d 260, 271 (8th Cir. 1995) (In rejecting the FTC's proposed geographic market, the court stated that "the FTC's expert testimony addressed only the question of where patients currently go, rather than where they could practicably go, for acute care inpatient services."); *U.S. v. Mercy Health Services*, 902 F. Supp. 968, 978 (N.D. Iowa 1995), *vacated as moot*, 107 F.3d 632 (8th Cir. 1997) ("The analysis must focus . . . on where patients . . . could practicably go should [defendants] become anticompetitive."). In fact, the FTC itself has explained that "the geographic market should determine not only the firms that constrain competitor's actions by *currently* selling to the same customers, but also those that would be a constraint because of their *ability to sell* to those customers should price or quality in the area change." *Hospital Corp. of Am.*, 106 F.T.C. 361 (1985) (emphasis added).

The most recent FTC decision, *Evanston Hospital*, criticized the use of patient origin data as a method of defining geographic markets and, instead, focused on other factors, including prices and contemporaneous documents. *In the Matter of Evanston Northwestern Healthcare*

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[3] Kenneth G. Elzinga, "Defining Geographic Market Boundaries," *Antitrust Bulletin*, Winter 1981, p. 743, ("Our test is a conservative one in that it estimates only a minimum size. The actual market may be (as it might be in Werden's example) larger than shipments data would estimate. In this sense, our test as used in antitrust is plaintiff-oriented.").

Corporation, 2007 WL 2286195, *57-58; 75-76 (F.T.C.). In its decision in *In the Matter of Evanston Northwestern Healthcare Corporation*, 2007 WL 2286195 at *76, the FTC noted that Professor Elzinga himself, who testified on behalf of the FTC at trial, stated that "the [patient flow data] was not an appropriate method to define geographic markets in the hospital sector…." The FTC concluded that it "view[ed] patient flow data with a high degree of caution…." *Id.* at 77-78.

In *F.T.C. v. ProMedica Health System, Inc.*, 2011 WL 1219281, (N.D. Oh., March 29, 2011), the court largely relied on testimony by health plans, physicians, competing hospitals and the parties' own documents in support of its conclusion on geographic market. *Id.* at *10-11. The only patient flow data analyzed in the court's decision was the fact that "[o]nly 2.1% of Lucas County residents leave the county for GAC services, and only 0.6% leave the county for OB services." *Id.* That analysis is far different from what the Policy Statement proposes with its "75% Rule."

These differences between the conclusions in the case law and the proposed 75% rule are not modest. Federal antitrust enforcement officials lost most of their antitrust challenges in the 1990s precisely because the courts found that the geographic markets that they proposed (themselves broader than a simple 75% rule) were too narrow. For example, in *FTC v. Freeman Hospital*, 69 F.3d at 268-70, the Eighth Circuit affirmed the lower court's 13-county geographic market definition, extending at least 54 miles. The district court rejected the FTC's proposed geographic market utilizing an 80% service area. In *United States v. Mercy Health Services*, 902 F. Supp. at 972, DOJ alleged a single city market, but the U.S. District Court for the Northern District of Iowa found that the evidence supported a market including regional hospitals within 70 to 100 miles of Dubuque. *See also Federal Trade Commission v. Tenet Healthcare*

Corporation, 186 F.3d at 1047, 1052-53 (8th Cir. 1999) (government proposed a market with 50 mile radius, court found a market with 65 mile radius).[4]

Indeed, the 75% test is inconsistent with basic hospital economics. Such a test implies that a provider could profitably raise prices without regard to the last 25% of its patients. Certainly, for hospitals, this is several times the percentage of patients, the loss of which is sufficient to make a price increase unprofitable under the critical loss test. For example, in *Tenet Healthcare Corporation*, 186 F.3d at 1050, the merging hospitals "presented evidence, based on [their] financial data, that the loss of only a *few* commercially insured patients to other hospitals would make a five percent price increase unprofitable" and "that it was likely that enough patients would, in fact, switch to defeat such a price increase." (emphasis added). *See also Mercy Health Services*, 902 F. Supp. at 980-1 (rejecting the government's proposed geographic market, citing among other things that an 8 percent loss of inpatients would be sufficient to make an attempted 5 percent price increase by the merging hospitals unprofitable).

Under the circumstances, a 75% test is certain – not merely probable, but certain – to understate the relevant geographic market in most cases, and to frequently result in the wrong answer on the critical antitrust questions. If a test, even a presumptive test, is to be useful and cost-effective, it should not be so tilted so that false positives are the rule, not the exception. But that is what will result from a 75% test.

There is, of course, some logic to using patient origin data as a presumptive market cut off, since other tests may well be unduly complicated to apply or too subjective and debatable to

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[4] In *United States v. Rockford Memorial Corp.*, 898 F. 2d 1278, 1284 (7th Cir. 1990), the district judge found a geographic market consisting of "Winnebago County (the county in which Rockford is located(and pieces of several other counties", from which 87% of the defendants' patients came from. Defendants proposed "a ten-county area in which it assumed (without any evidence and common sense") that Rockford residents, or third-party payors, will be searching out small, obscure hospitals in remote rural areas if the prices charged by the hospitals in Rockford rise above competitive levels." *Id.* at 1285. Given a choice between the two, the appellate court accepted the district's court "less imperfect" market definition. *Id.*

create a bright line. But if a percentage of patients is to be used, 90% would be far preferable to 75%. Since the relevant market, the area within which competition would occur in the event of a price increase, has been almost uniformly found in health care to substantially exceed any 75% service area, the use of a 90% area would provide a much closer approximation of the relevant market, though it, too, will fall short in many cases. *Mercy Health Services*, 902 F. Supp. at 977-80; *F.T.C. v. Freeman Hosp.*, 69 F. 3d at 269 (affirming lower court's rejection of proposed geographic market using a 80% service area).

II. Product Market

The Policy Statement's proposed narrowly defined services "markets" for both physicians and hospitals are also problematic, and will lead to many false positives for both physicians and hospitals.

The proposed hospital services "markets" are defined as MDCs, i.e. broad service lines such as nervous system, circulatory system and digestive system. But a high market share in a particular service line by itself is in most cases unlikely to have any antitrust significance. While in theory hospitals could price discriminate with respect to service lines, all the evidence indicates that such discrimination is extremely rare.

There are good economic reasons why such price discrimination does not frequently occur. In the absence of applicable certificate of need laws or highly specialized requirements that result in a high minimum viable scale for service, hospitals are free to switch beds or staff from one service to another and undercut any attempt by their rivals to exercise market power in a particular service in which the rival has a momentary share advantage. Hospital markets in the merger cases have as a general rule been defined to include all impatient services, not MDC-specific markets.

Other problems exist with regard to physician specialties. In many cases, defining a "service" as a physician's primary specialty will define the market far too narrowly by ignoring other specialists that provide competing services. For example, in a 1994 business review letter concerning a merger of pulmonary practices in Albuquerque, New Mexico,[5] the DOJ found that the merger raised little concern, in large part, because many other physicians provided the same services as the pulmonologists. The DOJ found that the competing specialists included general surgeons, cardiac surgeons, internists, family physicians and other primary care physicians. As a result, the DOJ concluded that the pulmonologists were competing in a much broader market. Similarly, in a recent matter, we discovered that 40% of a specialty group's cases involves diagnoses also treated by other specialties.

These considerations suggest some possible modifications to the presumptive standard. For physician specialties, since the patterns of physician practice in this regard are relatively uniform across the United States, the agencies ought to be able to make a determination as to which specialties do and do not face significant competition. Indeed, the proposed statement already references a broad primary care product market. We would suggest that other areas where such overlap is common could include pulmonology, urology, gastroenterology, pain management, colorectal surgery, pediatrics, geriatrics, hand surgery, infectious disease, and neuropsychiatry.

Similarly, there are a limited number of hospital service lines where highly specialized equipment and resource needs make price discrimination a real possibility. Generally, these are higher end tertiary services (which, of course, do not correspond to broad MDCs). These are the same services which with some frequency end up as subject to carve outs in managed care

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[5] Pulmonary Assocs., Ltd., DOJ Business Review Letter (Oct. 31, 1994), *available at* http://www.justice.gov/atr/public/busreview/0797.htm.

contracts. Those services should be identified empirically, and should be the only services which can be even presumptively considered as separate hospital product markets. Another possibility is to apply presumptions when relevant certificate of need restrictions exist, but not otherwise.

III. 50% Market Share Test

Even assuming geographic markets were properly determined, a 50% market share test will also result in wrong answers, and false positives, in a large and predictable number of cases. Moreover, it will have perverse effects – potentially increasing the dominance of existing players in a market.

A. Relevance of Entry

Fifty percent of a properly defined market can be an indicator of market power, but there are many reasons why it will not. In physician markets, market share will often be trumped by easy entry. For example, in *HTH Health Services, Inc. v. Quorum Health Group, Inc.*, 960 F. Supp 1104 (S.D. Miss. 1997), the court concluded that because of the "absence of entry barriers into the primary care market…, the … postmerger market share, whether calculated at 58.33% as the Court has done or at the higher levels endorsed by Columbia [(70%)], d[id] not establish market power on the part of the merging primary care physicians." *Id.* at 1135. This, of course, reflects well-established antitrust principles. *United States v. Calmar, Inc.*, 612 F. Supp. 1298 (D.N.J. 1985) (merger held lawful, despite post-merger market shares of 83% and 79% in two markets, because entry barriers were low); *In re Baker Hughes Inc.*, 908 F.2d 981, 983 (D.C. Cir. 1990) (merger of firms with combined market share exceeding 60% upheld because of ease of entry); *Ball Memorial Hosp., Inc. v. Mutual Hosp. Ins., Inc.*, 784 F.2d 1325, 1336-37 (7th Cir. 1986) (80% market share insufficient to establish market power where no barriers to entry). "Even a 100% monopolist may not exploit its monopoly power in a market without entry

barriers." *Image Technical Services, Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1208 (9th Cir. 1997).

Any market share test ought to take account of the entry issue. At a minimum, if in the last three years there has been appreciable entry into the specialty in the presumptive relevant geographic market, that ought to serve as an alternative safe harbor or, at least, require a higher market share before concerns are raised.[6]

B. Effect On "Smaller" Specialties

The test will have unintended consequences for "smaller" physician specialties in all but the largest markets. There are a wide range of physician specialties that are represented by only a handful of doctors in most markets. This could include, for example, pulmonology, urology, allergy, and rheumatology. As a result, even a minimally efficient practice will inevitably cross the 50% threshold in such markets.

The courts have rejected the mechanical application of market share thresholds under these circumstances. For example, in *Quorum Health Group, supra* at 1128-1130, a merger between two physician clinics led to 100% postmerger market shares in both urology (combining the only two urologists in the "market") and general surgery (combing all five general surgeons) and a 67% share in ENT (combining two of the three ENT specialists). Despite the high shares, the court refused to find that the merger would "substantially lessen competition" in violation of the Clayton Act. The court stated that it "[found] it inconceivable that Congress intended the Clayton Act to prohibit two urologists in Vicksburg, Mississippi from practicing together under the same roof." *Id.* at 1128. It also held that it "found no reason under the antitrust laws to force

[6] The new physician "entrants" should not be required to practice independently under this test. If it is possible to recruit physicians in a given specialty to a community, that is evidence that an efficient new or fringe competitor could do so in response to a market opportunity arising from the exercise of market power. Today, this often occurs through recruitment by a hospital or multi-specialty clinic which are not now employing physicians in the particular specialty in question.

the [five general surgeons] in th[e] market to compete with each other." *Id.* at 1129; s*ee also Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d 1406, 1412 (7th Cir. 1995) (clinic employing all twelve physicians in a county might be considered a "natural monopolist" – a firm that has no competitors simply because the market is too small to support more than a single firm).

To avoid an immediate triggering of the antitrust presumptions for such specialties in even medium sized markets, the tests ought to exclude any specialties which are represented by less than 10 physicians in a given metropolitan statistical area.[7]

C. Perverse Effects

The 50% rule will also encourage the use of dominant providers, thereby itself reducing competition. Under the proposed standard, an ACO can utilize a single firm with greater than a 50% share. But it cannot utilize two firms whose shares together add up to more than 50%. The net result is that an ACO desiring to utilize an attractive physician group with at or near a 50% share under the proposed standard will face the choice of attempting to add other, smaller groups, only after the time and expense of an antitrust appeal, or limiting its network to the one large group, harming the competitive position of the smaller groups. This is certainly not the purpose of these antitrust standards, but it could well be the effect.

Other perverse effects will likely result from the combination of the 50% market share test with the use of MDCs as product markets. In many markets with three to four significant

[7] Such an exemption would be consistent with both the case law, *supra*, and the Agencies' Statements of Antitrust Enforcement Policy in Health Care (the "Health Care Statements"). The Health Care Statements provide for a "safety zone" for mergers between acute-care hospitals with fewer than 100 licensed beds and an average daily inpatient censes of fewer than 40 patients. The justifications for this "safety zone" are that these types of hospitals "not compete in any significant way with other hospitals" and because smaller hospitals "are unlikely to achieve the efficiencies that larger hospitals enjoy", so "some of those cost-saving efficiencies may be realized … through a merger with another hospital." The same reasoning would apply here. Indeed, it is likely that the efficiencies arising from combining sole or small physician practices are much larger than in the small hospital context.

hospitals, every hospital will have a 50% share in some MDC, simply by virtue of the fact of specialization and decisions by some of the hospitals not to compete in every area. Does this mean that an ACO will be barred from contracting with any hospital without going through a protracted antitrust review? Certainly, an ACO could not contract with one hospital for some MDCs and another hospital for others. In the real world, patients are not so easily shuttled from facility to facility.

The only way around these problems is to eliminate the minimum market share test. This can be accomplished without antitrust concern, we believe, through alternatives. First, if providers are non-exclusively affiliated with a given ACO, there is no reason for any antitrust concern, and therefore no reason for a further inquiry. This has been established in the case law, and has been acknowledged in the past by the antitrust agencies.

For example, in *Hassan v. Independent Practice Associates, P.C.*, 698 F. Supp. 679 (E.D. Mich. 1988), more than 75% of the physicians in the relevant market were affiliated with the defendant IPA. The plaintiff argued that this meant that the IPA had market power. In rejecting the plaintiff's argument, the court noted that the IPA existed only to deal with one payor, an HMO, and that HMO had only a 20% share of the market. Therefore, the court reasoned, the IPA had no power, since it did not restrict the physicians from dealing with other payors outside of the IPA.

Indeed, in today's world in which most payors offer the broadest possible network, it is common place for commercial payors to have a (non-exclusive) network that far exceeds 50% in almost every specialty area and almost every MDC. To our knowledge, that in itself has not raised the slightest antitrust concern among any enforcement officials or commentators.

Second, even in an exclusive situation, the focus ought to be, not on the share of the providers who are exclusively signed up, but on the viability, and therefore share, of the alternative providers who are not. If these providers can provide significant competition, then the ACO will not be able to exercise market power. We would suggest a presumptive test that provides that if there are providers not exclusively affiliated with the ACO in the relevant market possessing at least a 30% share, then there are significant alternatives for other ACOs, and there ought not be any antitrust concern.

IV. Review Process

The response to many of these criticisms may be that the proposed standard is simply a presumptive one, and any decision can be reversed through the expedited review process. But, based upon what is published, the review process is a complete unknown, and there are very substantial reasons for concern.

Among the questions raised by the review process include the following:

1. Who will be the ultimate decision markers?
2. Are the agencies focusing on the right facts?
3. What appeals will be possible within the agencies? Will appeals be possible to the courts?

These are critical questions for many reasons. First, while the staff at both agencies is highly professional and competent, there are occasions when a staff recommendation to challenge a transaction are overridden by higher level officials in the agencies, even including the Federal Trade Commissioners. Will that kind of "appeal" process be possible here? If not, will the absence of such a check effectively encourage the more prosecutorial, activist, inclinations that may be possessed by some members of the staffs?

Second, once simple market shares are left behind, antitrust analysis can be very complex, involved, and expensive. A (hopefully not analogous) example is a second request on a merger, which can involve millions of dollars in expense. Obviously, that will not be practical for a party seeking for form an ACO, and if expense is too high, this will simply result in *de facto* decisions that will make the presumptive standards the actual standards.

Third, in many cases, the courts have concluded that the government as a whole is wrong in its analysis of health care markets. *See e.g. FTC v. Freeman Hospital*, 69 F.3d at 268-70; *United States v. Mercy Health Services*, 902 F. Supp. at 972 (D. Iowa 1995); Fe*deral Trade Commission v. Tenet Healthcare Corporation*, 186 F.3d at 1047, 1052-53. Without a cheap, timely and effective appeal process to the courts, any wrong decisions will have the force of law and prevent more effective ACOs from forming.

We believe that the only way to avoid these problems is to reverse the presumptions, and undertake a very different process. The (revised) standards ought to apply, not to presumptively bar the use of a provider, but to trigger a filing with the federal agencies. That filing ought to be designed to be simple and bare bones with the minimal information that the agencies need in order to decide whether to undertake a further review. After the filing, the agencies should have a specified time within which they could decide to undertake a review of the transaction. Even then, there ought to be an identified appeal process. Only in those cases would CMS approval be affected.

This, of course, is very similar to the Hart-Scott Rodino process. We believe it puts the presumptions in the proper place, requiring the agencies to act where they believe there is likely to be an antitrust problem, rather than requiring the parties to act whenever there might be an issue. The simple need to conserve to resources will then limit those actions to cases where there

is likely a real risk of market power and where the issues are important enough to really matter. The balance will be placed in the right place.