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FTC Staff Takes Positive Second Look at MedSouth's Clinical Integration

An important and often vexing issue for health care provider joint ventures is determining when the venture is sufficiently clinically integrated so that if it contracts collectively with providers, its activities will be tested under the more forgiving antitrust rule of reason. One touchstone in the limited amount of guidance that has emerged since clinical integration was first added to the U.S. Department of Justice's and Federal Trade Commission's Antitrust Health Care Guidelines¹ in 1996 was the FTC's 2002 staff advisory opinion in MedSouth, Inc.² At that time, the FTC staff indicated that it reserved the right to come back and monitor MedSouth's activities in practice. The staff has now done so, and on June 18, 2007 issued a follow-up letter to MedSouth that indicated that the staff had no reason to rescind or modify the views it expressed in 2002.

Clinical Integration

To the FTC, clinical integration in a provider network involves a degree of interaction and interdependence among the provider participants in their provision of medical services, in order to jointly achieve cost efficiencies and quality improvements in providing those services, both individually and as a group. Successfully achieving clinical integration requires the establishment and operation of active and ongoing processes and mechanisms to facilitate, encourage, and assure the necessary cooperative interaction.

As the FTC follow-up letter to MedSouth put it:

Typically, clinically integrated programs will involve some or all of the following aspects or characteristics, development of adoption of appropriate performance standards or goals, referral guidelines or requirements, or other performance criteria and measures for the

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9255 Towne Centre Drive San Diego, California 92121 858 320 3000 858 320 3001 fax

The Rectory 9 Ironmonger Lane London EC2V 8EY England +44 (0) 20 7726 4000 +44 (0) 20 7726 0055 fax participants, both individually or as a group; establishment of mechanisms, including information systems that permit collection and analysis of relevant data to monitor and evaluate both individual and group performance relative to the established standards, goals and measures; and provision for appropriate educational, behavior modification, and remedial action, where warranted, to improves both individual and overall group performance.... The test [of integration] is what the participants, through the network, actually do-i.e. how they use those tools to create cooperation and interdependence in their provision of medical care, thereby facilitating their efforts to jointly reduce unnecessary costs, improve quality of care, and otherwise increase their efficiency in the provision of medical care.

It is important to underscore that the achievement of clinical integration (or financial integration for that matter) by a provider network does not create an exemption from antitrust scrutiny. Instead, it will allow network activity, such as collectively negotiating prices with a provider and collectively deciding not to contract with a provider, which in other contexts might be considered *per se* illegal under the antitrust laws, to be analyzed under the more forgiving rule of reason standard. Importantly, "rule of reason" does not mean automatically legal. But it does allow for a broader inquiry into marketplace impact. In analyzing the competitive effects of a provider network under the rule of reason, two key areas of potential anticompetitive effects are:

- the potential misuse of collected price information to facilitate unjustified and unlawful price agreements by the network participants when doing business outside the joint venture; and
- 2. the exercise of market power by the joint venture itself, due to its size or methods of doing business.

The FTC Staff Follow-up Letter to MedSouth

The FTC staff's recent "check-up" focused on three main areas: "(1) integrative activities by the MedSouth physicians through MedSouth's operations and programs; (2) the extent to which potential efficiencies had resulted from, and were continuing to be attained, as a result of that integration; and (3) aspects of MedSouth's makeup and operation that were relevant to ascertaining its ability to exercise market power or otherwise adversely affect competition in the market."

The staff reported that MedSouth currently has clinical guidelines or screening protocols in place regarding 60 major diseases, periodically

reviewed and updated by a clinical integration committee; each individual physician is required to review and sign off on relevant guidelines. Annually, with payer participation, MedSouth selects 10 guidelines as its focus for that year's efficiency activities, setting its performance goal at the national HEDIS goal level or at the community performance goal set by a payer. "Stretch goals" are set at up to 15% above current performance. Physicians receive an individual report card. Additionally, one major payer contract has pay-for-performance provisions, where additional financial incentives are paid where the network as a whole reaches or exceeds certain goals.

MedSouth has an electronic-data system where physicians receive and share data in HIPAA complaint form. The data system has new software and certain additional efficiency-enhancing features.

MedSouth reported observing improvement in both individual physician performance and network performance *vis-à-vis* its goals and that physicians' performance has been rewarded under the pay-for-performance programs with small fee increases over the last three years.

The staff felt comforted that spillover anticompetitive price effects were minimized because MedSouth had an outside contractor collect fee information from individual members who used the information to develop MedSouth's contracting fee structure, and that neither MedSouth members nor its board had access to any individual fee information.

As to market power issues in the south Denver area where MedSouth operated, MedSouth now has substantially fewer participating physicians than at its inception in both the primary care and specialty physician categories. MedSouth attributed this, inter alia, to the fact that some physicians did not want to make the capital investment in technology connections in their offices, and physicians retiring or leaving the area. The staff observes that this reduction "may well be indicative that a program of clinical integration requires very serious commitment and effort by physicians to engage in the activities that are necessary to achieve the beneficial objectives of such a program, as well as physicians' weighing of the economic costs and benefits of participating in such a program. This may be instructive for other provider networks, particularly one involving large numbers of physicians, regarding the practical realities and potential difficulties inherent in coordinating and clinically integrating the care provided to numerous enrollees through a network comprising many independent physician practices."

Some other notable "take-aways" from the letter:

• In this area, as in many areas of antitrust analysis, non-

exclusive arrangements are given more breathing room by the antitrust agencies. The MedSouth arrangement is non-exclusive, and, therefore, payers wishing to deal with individual MedSouth physicians outside of MedSouth's programs are able to do so. The FTC staff labeled this fact as important and opined that it reduced concerns about possible exercise of market power.

- MedSouth had lost some physician specialists, and also had no members in certain specialities. In theory, these gaps could potentially adversely affect its ability to monitor and coordinate patients' care, and thereby undercut the program's ability to achieve efficiency and quality-improvement goals. The staff, however, accepted MedSouth's statement that the gaps were not a problem, particularly since most of its practice guidelines focused upon chronic conditions and diseases, which did not require the participation of specialists not in the network (using open-heart surgery as an example of the latter).
- Notably, there was no direct discussion or evaluation of what protocols, if any, MedSouth has to identify where changes need to be made to improve individual performance or what steps MedSouth takes when a physician's performance or adherence to guidelines falls short.

The MedSouth follow-up letter does not represent a pronouncement of the minimum or the necessary elements required to establish a clinical integration program acceptable to the federal antitrust agencies. The agencies have repeatedly indicated that they would never provide an exhaustive list and that each situation should be evaluated against the general standards. Instead, the letter represents a real-world example, in an area where there has been little formal guidance, where the FTC staff has looked at a set of clinical integration practices and has found no reason to object or intervene.

¹ U.S. Department of Justice and Federal Trade Commission, *Statesments of Antitrust Enforcement Policy in Health Care* (1996), available here.

² February 19, 2002 staff advisory opinion issued to MedSouth, available here.

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If you wish to discuss the contents of this Alert, or for assistance with issues raised by the legal developments that are the subject of this Alert, please contact the Mintz Levin lawyers listed below or any other member of Mintz Levin's Antitrust or Health Care practice groups.

> Bruce D. Sokler 202.434.7303 | BDSokler@mintz.com

> Fernando R. Laguarda 202.434.7347 | Laguarda@mintz.com

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