

Antitrust Issues of Patient-Centered Medical Homes

Law360, New York (August 30, 2010) -- While the existence of patient-centered medical homes is not a new reality, their prominence in the Patient Protection and Affordable Care Act and the national discussion regarding delivery system reform has catapulted these entities into the limelight.

The National Committee for Quality Assurance has identified and provides certification for patient-centered medical homes and has taken time to identify and define the characteristics of a medical home. In addition the American College of Physicians, American Academy of Family Physicians and the American Academy of Pediatrics have developed precepts for use in the delivery of care within a medical home.



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A medical home is a health care setting that fosters partnerships between individual patients and their personal physicians and, when appropriate, the patient's family. Care is facilitated by registries, information technology, health information exchange and other means to assure that patients receive the indicated care when and where they need it and want it in an appropriate manner. Conceptually, the medical home is a physician-driven model in which the physician leads a team that takes collective responsibility for a patient. Typical characteristics involve open scheduling, expanded access hours, e-mail communication, patient tracking, care management, test tracking and performance reporting and improvement.

Medical homes typically are discussed in the context of chronic care management, including within PPACA. Providers can receive a per patient management fee for phone calls, e-mails and other types of patient contact that normally are not covered under standard fee-for-services arrangements.

As hospitals and physicians together seek alignment strategies, the creation of a patient-centered medical home may be an appropriate first step on the accountable payment pathway. As entities move in this direction, antitrust issues, among a number of legal issues, may be raised when bringing together otherwise competing entities, including payors.

Generally, antitrust law treats "naked agreements" among competitors that fix prices or allocate markets as per se illegal. The Sherman Act prohibits agreements that unreasonably restrain competition. When collaborative ventures are created between otherwise competing entities, lawyers seek to assure that the collaborative venture is not evaluated under the per se illegality test, but rather that the venture contains the essential criteria or indicia worthy of evaluation under what is known as the "rule of reason" test of the Sherman Act, and that such venture would, in fact, withstand such an evaluation.

Where competitors, such as hospitals, individual physicians or physician groups, join together in a venture or affiliation for purposes of creating a medical home, such antitrust issues should be taken into consideration. What does that mean? The key analysis is weighing whether any potential competitive harm is caused by the venture in relation to the efficiencies or consumer benefits likely to be created by the arrangement.

The health care industry has relied on guidance relating to this issue historically, but the guidance is outdated. Congress identified that much of delivery system reform initiatives contained within PPACA will require the relaxation or waiver of the laws that currently might work to stifle innovation. Many in the industry have called on the Federal Trade Commission and the U.S. Department of Justice Antitrust Division to provide updated guidance.

In the interim, we have the FTC/DOJ Statements of Enforcement Policy in Healthcare (1996), Statements #8 and #9 (regarding physician joint ventures and multiprovider networks). Both statements highlight that ventures will be analyzed under the rule of reason if they contain adequate integration — either clinical integration or financial integration — sufficient to produce efficiencies that benefit consumers.

We know that financial integration can be accomplished through capitation — this was clear from the early 1990s when the creation of physician-hospital organizations was all the rage. In today's environment, financial integration also can be accomplished by bundled payment, partial capitation (contemplated in the PPACA shared savings model) or some form of fixed payment for care coordination.

However it is to be achieved, it is incumbent upon a collaborative to share financial risk in such a way that members have economic incentive to ensure that the group as a whole produces the material efficiencies that will benefit consumers.

Most likely, however, the focus that will arise in the creation of a medical home is whether there is sufficient clinical integration to withstand the antitrust "rule of reason" analysis. We have examples of ventures, evaluated in a number of advisory opinions and in the statements that have been "blessed" by the agencies. Critical criteria include the adoption by the collaborative of a number of elements, including the use of bona fide systems to improve quality and efficiency, the use of clinical protocols, clinical information systems, referral requirements or guidelines, a selective network which is limited to committed providers, case management/disease management systems and significant capital investment, including human capital.

From a legal perspective, we ask whether the integration is sufficient to satisfy the pro-competitive effect test of the rule of reason under the Sherman Act. If so, antitrust is no barrier. If integration is not sufficient and competition is significantly reduced, then antitrust may become a barrier.

There are no bright line tests currently, yet the incentives and the payment drivers of PPACA all push providers to collaborate and consolidate fairly rapidly. Recently, Mark McClellan, who, together with Elliott Fisher, is credited with creating and pursuing the accountable care payment initiatives, wrote in Health Affairs that accountable reforms really should serve to inform antitrust policy, since the purpose of accountability is to increase transparency, aide in consumer protection and enact enhanced quality measurements and payments for quality. McClellan seemed to hint at the creation of an exception for accountable payment mechanisms since at their very core, such mechanisms incentivize quality care and care coordination, all meant to benefit the consumer in a transparent environment.

If we take this argument further, we could argue that the necessary indicia involved in the creation of a medical home, "recognized" by NCQA, would serve to "deem" such an entity as having satisfied the antitrust rule of reason test such that it would exempt the entity from antitrust scrutiny.

Thus far it seems unlikely, based upon the public comments of officials from the FTC and DOJ that an overt exception would be provided. The agencies have provided minor hints in public speaking engagements that the existing guidance should serve the new environment well, although there was an indication that both the DOJ and the FTC would work closely with the U.S. Department of Health and Human Services to offer whatever guidance is needed.

Antitrust is but one of a number of legal issues and potential barriers that could be raised when nonrelated entities, such as hospitals and physicians or other competing entities seek to align their interests to create a medical home or other accountable care entity.

While providers should be mindful of the antitrust issues, movement forward should not be stifled by such potential barriers. Assurance can be provided within the context of existing guidance, assuming the venture or collaboration is established carefully with the appropriate financial or clinical integration necessary to satisfy the rule of reason test.

Patient-centered medical homes that are recognized by NCQA and that follow existing precepts set forth for primary care should satisfy many of the required indicia under existing antitrust guidance.

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