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FTC Issues Another Favorable Clinical Integration Program Advisory Opinion

February 19, 2013

In a February 13, 2013, advisory opinion, the Federal Trade Commission (FTC) Bureau of Competition stated that it has no present intention to recommend that the FTC challenge a clinical integration program (CIP) proposed by Norman Physician Hospital Organization, a multi-specialty physician-hospital organization (PHO) in Oklahoma..[1] The opinion is the fifth advisory opinion the FTC has issued concerning a clinically integrated managed care contracting network.[2] Four of the advisory opinions were favorable, and one was unfavorable to the respective requesting parties.

It has been almost four years since the FTC last issued an advisory opinion on CIPs, and this is the first advisory opinion the FTC has issued on CIPs since the enactment of the Affordable Care Act, the establishment of accountable care organizations (ACOs) under the Medicare Shared Savings Program (MSSP), and the FTC/U.S. Department of Justice (DOJ) Antitrust Enforcement Policy Statement Regarding ACOs participating in the MSSP (MSSP ACO Policy Statement). In this article, we summarize the Norman PHO advisory opinion and its key takeaways. We also compare the opinion to the CIPs addressed in the FTC's previous four advisory opinions on the subject.

See pages 5 and 6 for a comparison chart of key CIP elements addressed in all FTC CIP advisory opinions.

Norman PHO FTC Staff Advisory Opinion

PARTIES AND STRUCTURE

Norman Physicians Association and Norman Regional Health System founded Norman PHO in 1994. Norman Physicians Association is an Oklahoma limited liability company whose members are medical staff members of Norman Regional Health System's hospitals. Norman Regional Health System is owned by the city of Norman and a hospital authority. Norman Regional Health System owns and operates hospitals and family medicine centers in Norman and Moore, and family medical centers in Newcastle and Blanchard, Oklahoma Norman Physicians Association and Norman Regional Health System split equally the initial capital costs of Norman PHO and continue to share equally in ongoing operational and capital costs of the organization. A physician-majority board of managers governs Norman PHO.

Norman PHO has always operated as a messenger-model contracting network. Norman Regional Health System and approximately 280 primary care physicians and specialists participate in the network. Approximately 84 percent of the network's patients reside in Oklahoma and Cleveland counties, and approximately 95 percent of the network's participating providers have office locations in those counties.

PROPOSAL

Norman PHO proposes to establish a non-exclusive CIP for its members designed to ensure that participating physicians work collaboratively to establish clinical practice guidelines, create a high degree of transparency and visibility with respect to their practice patterns, and provide mechanisms for monitoring and enforcing compliance with Norman PHO's clinical practice guidelines. Norman PHO will create three committees:

- Specialty Advisory Groups responsible for developing and updating clinical practice guidelines
- Mentor's Committee responsible for approving clinical practice guidelines and monitoring their implementation and enforcement
- Quality Assurance Committee charged with establishing measures for individual and group performance benchmarking, and monitoring and enforcing individual and group compliance with the network's CIP requirements

[1] FTC Staff Letter regarding Norman PHO (February 13, 2013), available at http://www.ftc.gov/os/2013/02/130213normanphoadvltr.pdf.
[2] See FTC Staff Letter regarding MedSouth, Inc. (February 19, 2002), available at http://www.ftc.gov/bc/adops/medsouth.shtm; FTC Staff Letter regarding MedSouth, Inc. (June 18, 2007), available at http://www.ftc.gov/bc/adops/070618medsouth.pdf; FTC Staff Letter regarding Greater Rochester Independent Practice Association, Inc. (September 17, 2007), available at http://www.ftc.gov/bc/adops/gripa.pdf; FTC Staff Letter regarding TriState Health Partners, Inc. (April 13, 2009), available at http://www.ftc.gov/os/closings/staff/090413tristateaoletter.pdf; and FTC Staff Letter regarding Suburban Health Organization, Inc. (March 28, 2006), available at http://www.ftc.gov/os/2006/03/SuburbanHealthOrganizationStaffAdvisoryOpinion03282006.pdf.

Norman PHO and these three committees expect to develop evidenced-based clinical practice guidelines for as many as 50 disease-specific conditions. Norman PHO has collected and analyzed physician data for purposes of identifying high-prevalence, high-cost and high-risk chronic conditions that most affect its patient population, and has identified nine diseases for which the Specialty Advisory Groups will develop clinical practice guidelines. These diseases include diabetes, anemia, and hypo- and hyperthyroid disease.

The advisory opinion states that Norman PHO has invested substantial resources in developing an electronic platform that includes a clinical decisions support system, e-prescribing, an electronic medical records system and an electronic health interface system. The platform will allow physicians to use quality measures parameters in evaluating and treating patients, streamline submission of prescriptions and reduce errors, and facilitate communication among physicians.

Each participating provider in the Norman PHO CIP will be required to adhere to all Norman PHO CIP requirements. In addition to adhering to clinical practice guidelines, program requirements include an initial $350 membership fee, annual dues of $150 and a withhold on reimbursements from payors to support CIP infrastructure. In addition, each participating provider will be required to maintain computer equipment and applicable licenses to access the CIP's electronic platform. Each participating physician must also serve as a member of and participate on one of the three committees.

FTC STAFF CONCLUSIONS

FTC staff concluded the network's proposed contracting and network activities qualify for rule of reason analysis because the network proposes to require its members to integrate their clinical services in a manner that appears to create potential significant efficiencies that benefit patients and payors, and because pricing agreements are reasonable, necessary and subordinate to their integration. FTC staff found under the rule of reason that the network's pro-competitive benefits were likely to outweigh any anti-competitive effects.

FTC staff found that Norman PHO has identified key features and mechanisms of a CIP, and has invested or will invest in substantial resources for purposes of developing the infrastructure necessary to achieve proposed efficiencies. The opinion cites the creation of various mechanisms, including clinical practice guidelines, intended to monitor and control costs and utilization while promoting quality of care. Data capture and analysis, and monitoring and enforcement of program requirements are other key elements. FTC staff also found that Norman PHO and its participating physicians have made or will make meaningful contributions, including investments of time and money, to program development and operation.

Key Takeaways

CONSISTENT ELEMENTS OF CIPS IN FAVORABLE FTC ADVISORY OPINIONS

Norman PHO has many of the same program elements of other CIPs that the FTC has addressed in favorable advisory opinions:

- Clinical protocols
- Monetary and non-monetary investment by the physicians
- Capture and analysis of clinical data
- Ability to share clinical data through health IT
- Establishment of pro-competitive program goals (*e.g.*, improving the quality of care and reducing unnecessary costs of care) and monitoring of progress with program goals
- Enforcement of CIP requirements

Pages 5 and 6 of this article contains a chart summarizing some of the common program elements among the CIPs addressed in FTC advisory opinions, and highlights many of the structural similarities. Because this is the first advisory opinion addressing a

CIP since the MSSP ACO Policy Statement, this opinion is most significant in that it confirms that the FTC continues to apply the conceptual framework that it has set forth in prior advisory opinions and other guidance to CIPs.

ABSENCE OF VERTICAL RESTRAINTS

The FTC found in the Norman PHO advisory opinion that the proposal does not appear to include any vertical arrangements that would enable Norman PHO to use any market power the network might possess in selling certain services to limit competition in the sales of any other services. As an example, the FTC cited that Norman PHO does not propose to require payors to contract with all of its hospitals, and does not propose to prevent payors from directing or incentivizing patients to choose non-network providers. The emphasis on the lack of "anti-steering" or "anti-tiering" provisions is consistent with the guidance the FTC and DOJ set forth in the MSSP ACO Policy Statement on the types of conduct by ACOs with possible *indicia* of market power that may raise competitive concerns. Preventing or discouraging private payors from directing or incentivizing patients to choose certain providers was one of the categories of conduct identified by the FTC and DOJ in the MSSP ACO Policy Statement that potentially raises competitive concerns when engaged in by ACOs with *indicia* of market power.

NON-EXCLUSIVITY AND NON-INTERFERENCE

All four favorable FTC advisory opinions addressing CIPs have pertained to non-exclusive networks. To date the FTC has not issued a favorable advisory opinion addressing an exclusive CIP. The FTC emphasizes on the first page of the Norman PHO advisory opinion that "Norman PHO represents that it will operate as a non-exclusive network."

A central issue for CIPs is whether a network will be viewed as exclusive or non-exclusive when the network includes some contracting restrictions less than a total prohibition on entering into any contract outside of the network. In Statements 8 and 9 of their 1996 Statements of Health Care Antitrust Enforcement Policy,[3] the FTC and DOJ stated that networks may limit or condition participating physicians' freedom to contract outside the network in ways that fall short of a commitment of full exclusivity, and that if those provisions significantly restrict the ability or willingness of a network's physicians to join other networks or contract individually with managed care plans, the network will be considered exclusive.

The Norman PHO opinion refers to the Norman PHO as a non-exclusive network. Norman PHO represents that it will "clearly inform" payors and participating providers that its network is non-exclusive, and that its participating providers will remain free to contract independent of Norman PHO with any payor that chooses not to contract with the network. The opinion also states that participating providers may join other provider networks. However, Norman PHO will require its participating providers to participate in any contract that Norman PHO does hold with a payor.

FTC staff found that any concerns with the potential exercise of market power are mitigated by Norman PHO's representations that payors that do not perceive that Norman PHO offers an attractive product, or that for any reason do not wish to contract with Norman PHO, will have the ability to bypass the network and contract directly with the individual providers. FTC staff also emphasized that Norman PHO will provide antitrust compliance training to its members regarding the antitrust concerns associated with concerted refusals to deal.

CIPs determining whether their network will be viewed as non-exclusive and not exclusive should remember that the FTC and DOJ will examine whether a network is non-exclusive in fact and not just in name, and should consider the *indicia* of non-exclusivity that the FTC and DOJ set forth in the Statements of Health Care Antitrust Enforcement Policy:

- That viable competing networks or managed care plans with adequate physician participation currently exist in the market
- That physicians in the network actually individually participate in, or contract with, other networks or managed care plans, or there is other evidence of their willingness and incentive to do so
- That physicians in the network earn substantial revenue from other networks or through individual contracts with managed care plans
- The absence of any indications of significant de-participation from other networks or managed care plans in the market

[3] http://www.ftc.gov/bc/healthcare/industryguide/policy/statement8.htm and http://www.ftc.gov/bc/healthcare/industryguide/policy/statement9.htm.

- The absence of any indications of coordination among the physicians in the network regarding price or other competitively significant terms of participation in other networks or managed care plans

HOSPITAL CIP PARTICIPATION

The FTC has not addressed any proposal by competing hospitals to jointly contract on the basis of clinical integration alone in any advisory opinion request concerning CIPs. The Norman PHO advisory opinion states that the initial advisory opinion request provided that another 39-bed municipal hospital in Purcell, Oklahoma, would participate in Norman PHO's proposed CIP. Purcell is approximately 21 miles (about a 26-minute drive) from Norman Regional Health System's hospital in Norman. However, Norman PHO subsequently terminated the 39-bed community hospital's participation in Norman PHO. Consequently, the opinion does not consider the issue of clinical integration among hospital competitors.

COMPARISON OF KEY CIP ELEMENTS ADDRESSED IN FTC ADVISORY OPINIONS[4]

Network (Favorable FTC Opinion & Year)	Providers	Care Management Programs	Clinical Protocols	IT Infrastructure & Data	Monetary & Non-Monetary Investment	Monitoring & Enforcement	Exclusive Network
MedSouth (Yes – 2002 & 2007)	**75 PCPs and 205 specialists**	**Primary and specialty care coordinated and integrated through a clinical resource management program**	**Covering 80–90 percent of the prevalent diagnoses and 60 major diseases**	**Sharing of patient information via a web-based clinical data record system**	**For-profit corporation owned and funded by the physician practices of its members**	**Oversight and reporting of physicians' performance relative to established goals** **Expels physicians who do not fully participate in its CIP or adhere to its standards**	**No**
SHO (No – 2006)	**Employed PCPs of each hospital member**	**Medical management and quality management activities**	**Covering four conditions**	**Web-based technology to deliver and track patient information, implemented over 18 to 24 months, and capture and use of clinical data**	**Initial CIP investment of up to $100,000 plus annual operating costs of $300,000, but physicians not required to invest any money or significant time in CIP**	**CIP entity had no authority to discipline physicians, but each hospital responsible to motivate and discipline its employees**	**Yes**

[4] Other key elements of CIP programs the FTC has examined include, without limitation, collective motivation and in-network referrals.

Network (Favorable FTC Opinion & Year)	Providers	Care Management Programs	Clinical Protocols	IT Infrastructure & Data	Monetary & Non-Monetary Investment	Monitoring & Enforcement	Exclusive Network
GRIPA (Yes – 2007)	230 PCPs and 345 specialists	Clinical improvement services	14 initial guidelines and two to four more per month being developed	Web-based electronic clinical-information system	Physicians required to invest significant time and effort in developing CIP elements	Physicians who do not comply with its practice behavior, education and disciplinary requirements subject to expulsion	No
TriState (Yes – 2009)	212 PCPs and specialists	Medical management program	18 initial guidelines and 30 guidelines being developed	Web-based health IT system to enable the network to identify high-risk and high-cost patients and facilitate the exchange of health information to manage care	Physicians required to invest significant time and effort in developing CIP elements	Monitors achievement of physician performance targets, and physicians who do not conform to CIP parameters face discipline or expulsion	No
Norman (Yes – 2013)	280 PCPs and specialists in 38 areas	Collects and analyzes physician data to assess high-prevalence, high-cost and high-risk chronic conditions, and has identified nine conditions for practice guidelines	Covering as many as 50 disease-specific conditions	Electronic platform including a clinical decisions support system, e-prescribing, an electronic medical records system and an electronic health interface system	Physicians required to pay initial and annual dues, withholds on reimbursements for CIP activities; acquire and maintain certain IT; participate on one CIP committee; and adhere to other CIP requirements	Comprehensive review processes and ability to financially penalize and terminate any physician who does not comply with CIP requirements	No

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