November 1, 2017

FTC Staff Notice of COPA Assessment:
Request for Empirical Research and Public Comments

Summary:

Staff from the Federal Trade Commission's Office of Policy Planning, Bureau of Economics, and Bureau of Competition seek to enhance our ongoing study of the impact of certificates of public advantage ("COPA") on prices, quality, access, and innovation for healthcare services. To complement this continued inquiry, we also seek to better understand the effects of other state-based regulatory approaches intended to control healthcare prices and improve quality ("state-based regulatory approaches"). We encourage empirical research by academics and healthcare industry stakeholders regarding these topics, as well as suggestions regarding potential case studies and data sources. In addition, we invite public comments regarding the benefits or harms that have resulted from COPAs or other state-based regulatory approaches. We anticipate hosting a public workshop in the fall of 2018, to provide an opportunity for invited researchers to present their empirical findings, and to facilitate discussion among researchers, state policymakers, regulators, law enforcers, and industry stakeholders regarding their experiences with COPAs and other state-based regulatory approaches.

Background Information:

Beginning in the 1990s, several states passed COPA laws and regulations intended to allow healthcare providers to enter into cooperative agreements that might otherwise be subject to antitrust scrutiny. Historically, the stated purpose of these laws has been to reduce "unnecessary" duplication of healthcare resources and control healthcare costs. These laws purport to immunize certain activities and transactions under the state action doctrine.[1] COPA laws have been applied to various forms of provider collaboration, and also have been extended to shield provider mergers that might otherwise attract the attention of antitrust enforcers.[2]

[1] In order to obtain antitrust immunity for conduct that might otherwise violate the federal antitrust laws, the state action doctrine requires both a clear articulation of the state's intent to displace competition in favor of regulation and that the state provide active supervision over the regulatory scheme or body. *See* N.C. State Bd. of Dental Exam'rs v. FTC, 135 S. Ct. 1101,1114 (2015); FTC v. Phoebe Putney Health Sys., Inc., 133 S. Ct. 1003, 1013 (2013).

[2] Although a number of state COPA laws extend in theory to cover hospital mergers that otherwise might violate the antitrust laws, in reality few hospital mergers have ever been approved under COPA regulations. To the best of our knowledge, the following hospital mergers have been permitted to proceed pursuant to COPA oversight: HealthSpan Hospital System (Minnesota, 1994); Mission Health System (North Carolina, 1995); Benefis Health System (Montana, 1996); Palmetto Health System (South Carolina, 1998); Cabell Huntington Hospital/St. Mary's Medical Center (West Virginia, 2016); and Mountain States Health Alliance/Wellmont Health System (Tennessee and Virginia, 2017).

In addition, in 1997, United Regional Health Care System was formed when the only two general acute-care hospitals in Wichita Falls, Texas – Wichita General Hospital and Bethania Regional Health Care Center – sought an exemption from the Texas state legislature. However, this transaction does not appear to have involved a COPA regulatory scheme.

In recent years, we have observed a resurgence in the passage and use of COPA laws to immunize provider transactions from antitrust scrutiny.[3] In some situations, we have observed that state legislatures have appeared to pass COPA legislation with the intent of exempting specific proposed hospital mergers from anticipated antitrust challenges. In these and other situations, hospitals have claimed that they need an antitrust exemption because consolidation is the only way to achieve the size, scale, and degree of clinical integration necessary to participate in new delivery and payment models, such as population health initiatives and value-based payment models.

Typically, COPA statutes allow hospitals and other healthcare providers to enter into cooperative agreements if the state determines that the likely benefits outweigh any disadvantages attributable to a reduction in competition.[4] State departments of health – often in consultation with state attorneys general offices – are delegated the responsibility of drafting and implementing COPA regulations, reviewing all submitted COPA applications, approving or denying particular applications, and actively supervising any approved COPAs.

As a condition for COPA approval, states often impose conduct remedies on the COPA recipient, which are intended to mitigate the potential for anticompetitive harms. Such remedies may include rate regulation, prohibitions on certain contracting practices, and commitments to improve quality, or guarantees to return cost savings to the local community. Accountability and enforcement mechanisms may include requiring the COPA recipient to submit annual reports and comply with data audits, as well as termination of the COPA if the state later determines that the benefits no longer outweigh the harms.

In recent years, FTC staff have issued several advocacy comments raising concerns about whether COPA regulations actually achieve the states' intended policy goals; in some situations, FTC staff have explicitly recommended the denial of particular COPA applications.[5] FTC staff

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[3] Three of the seven COPAs granted for hospital mergers occurred in the last two years. *See id.* In addition, the Staten Island Performing Provider System in New York recently received a COPA for certain collaborative activities. *See* https://www.health.ny.gov/facilities/public_health_and_health_planning_council/meetings/2016-11-17/docs/copa-sipps_staten_island_pps.pdf.

[4] Benefits may include quality improvements, population health improvements, preserving existing hospital operations, cost efficiencies, and increased access. Disadvantages may include price increases and an inability of health plans to negotiate reasonable contracts with providers, as well as reduced competition, quality, and access.

[5] *See, e.g.*, FTC Staff Submissions Regarding the Proposed Merger and COPA Applications of Mountain States Health Alliance and Wellmont Health System, https://www.ftc.gov/enforcement/cases-proceedings/151-0115/wellmont-healthmountain-states-health; FTC Staff Comment to Hon. Mike Pushkin, West Virginia State Senate, Concerning S.B. 597, Intended to Exempt Health Care Providers Subject to Cooperative Agreements from the Antitrust Laws (Mar. 9, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-west-virginia-house-delegates-regarding-sb-597-competitive-implications-provisions/160310westvirginia.pdf; FTC Bureau of Competition Staff Submission to the West Virginia Health Care Authority Regarding Cooperative Agreement Application of Cabell Huntington Hospital (Apr. 18, 2016), https://www.ftc.gov/system/files/documents/public_statements/945863/160418virginiahealthcare.pdf; FTC Staff Comment to New York State Department of Health, Concerning Certificate of Public Advantage Applications, Intended to Exempt Performing Provider Systems from the Antitrust Laws (Apr. 22, 2015),

have also issued several advocacy comments regarding other types of state action antitrust exemptions for healthcare providers, which in FTC staff's view raise similar concerns as COPA statutes.[6] In these advocacies, FTC staff have acknowledged the potential benefits of procompetitive collaboration among providers. FTC staff have repeatedly taken the position that the antitrust laws do not stand in the way of beneficial collaboration. Rather, the antitrust laws seek only to prohibit activities that would substantially reduce competition and harm consumers, without countervailing benefits sufficient to outweigh the harm. The FTC has issued extensive guidance about the types of provider collaboration and clinical integration that can be achieved without running afoul of the antitrust laws.[7] For these reasons, FTC staff have consistently argued that COPAs and other state action antitrust exemptions for healthcare providers are unnecessary, because they only serve to immunize precisely the types of conduct most likely to cause harm.

A significant volume of empirical literature demonstrates that competition among healthcare providers leads to reduced costs and prices, as well as improved quality and access. FTC staff are not aware of any empirical evidence demonstrating that COPA statutes and regulations produce better results for consumers than market-based competition. We recognize, however, that there is limited empirical research on the impact of COPAs on prices, costs, and quality of healthcare services, patient access to services, or innovations in care delivery models.

Beyond COPA statutes and regulations, some states have pursued other regulatory approaches intended to control healthcare prices and improve quality, including setting reimbursement rates

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https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-center-health-care-policy-resource-development-office-primary-care-health-systems/150422newyorkhealth.pdf.

[6] *See, e.g.*, FTC Staff Comment to Hon. Larry C. Stutts, AL State Senate, Concerning HB 241 and SB 243, Intended to Exempt Collaboration Among Public Universities and Health Care Providers from the Antitrust Laws (May 2, 2016), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-alabama-state-senate-regarding-alabama-house-bill-241-senate-bill-243/160504commentalabama.pdf; FTC Staff Comment to Sen. Michael H. Ranzenhofer and Assemblyman Thomas Abinanti, N.Y. State Legislature, Concerning S.B. 2647 and A. 2888, Intended to Exempt Certain Public Health Entities from the Antitrust Laws (June 5, 2015), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-new-york-state-senator-ranzenhofer-new-york-state-assemblyman-abinanti-concerning/150605nypublichealthletter.pdf; FTC Staff Comment to Sen. Chip Shields, Or. State Legislature, Concerning S.B. 231-A, Intended to Exempt Certain Collaborations Among Competing Health Care Providers and Payers Participating in a Primary Care Transformation Initiative (May 18, 2015), https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-oregon-senate-bill-231a-which-includes-language-intended-provide-federal/150519oregonstaffletter.pdf.

[7] HEALTH CARE DIVISION, BUREAU OF COMPETITION, FED. TRADE COMM'N, TOPIC AND YEARLY INDICES OF HEALTH CARE ANTITRUST ADVISORY OPINIONS BY COMMISSION AND STAFF (Apr. 2017), *available at* https://www.ftc.gov/system/files/attachments/competition-policy-guidance/topic_and_yearly_indices_of_health_care_advisory_opinions_april_2017.pdf; FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, STATEMENT OF ANTITRUST ENFORCEMENT POLICY REGARDING ACCOUNTABLE CARE ORGANIZATIONS PARTICIPATING IN THE MEDICARE SHARED SAVINGS PROGRAM, 76 Fed. Reg. 67026 (Oct. 28, 2011); FED. TRADE COMM'N AND U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (2004), *available at* http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf; U.S. DEP'T. OF JUSTICE & FED. TRADE COMM'N, STATEMENTS OF ENFORCEMENT POLICY IN HEALTH CARE (1996), *available at* http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf.

and implementing quality initiatives.[8] The effects of these state-based regulatory approaches may be analogous to the effects of some of the conduct remedies often imposed with COPAs.

Request for Empirical Research and Public Comments:

This notice is intended to facilitate a rigorous discussion of ways to study the impact of COPAs and other state-based regulatory approaches, including suggestions regarding potential case studies and data sources. FTC staff's goal is to encourage academics and health policy experts to consider these areas for empirical research projects and, ultimately, to share ideas that will lead to the development and execution of useful research that can inform future policy development.

In addition, FTC staff seek information from healthcare providers, payers, consumers, state officials, policy experts, academics, economists, and other interested parties regarding the effects of COPAs and other state-based regulatory approaches. In particular, we invite comment on the following questions and related topics:

- What information is available regarding the effects of COPAs or other state-based regulatory approaches in terms of price, cost, and quality of healthcare services; access to healthcare services; innovations in healthcare delivery models; or other dimensions of healthcare competition?

- What has been done to address the changes that occur over time in healthcare markets subject to COPAs or other state-based regulatory approaches (*e.g.*, changes in the competitive landscape, transformation of delivery and payment models, and healthcare professional shortages), as well as changes in the structure and operation of the providers that are regulated (*e.g.*, expansion by the regulated entity or operational changes that result in higher/lower costs)? Are COPA agreements or other state-based regulatory approaches, including price and quality commitments, modified to address these types of changes? To what extent are healthcare providers, payers, state health departments, state attorneys general, state legislators, or other stakeholders involved in this process?

- What information is available regarding the impact to healthcare markets following the expiration of COPAs or other state-based regulatory approaches, when price and quality commitments are no longer in effect or enforceable?

[8] For example, Maryland has implemented an all-payer hospital rate regulation system that, among other price and cost requirements, commits hospitals to achieving certain quality improvements. CENTERS FOR MEDICARE & MEDICAID SERVICES, https://innovation.cms.gov/initiatives/Maryland-All-Payer-Model/. Until recently, West Virginia's Health Care Authority had some ability to establish hospital rates in West Virginia. WEST VIRGINIA HEALTH CARE AUTHORITY, http://www.hca.wv.gov/ratereview/Pages/default.aspx. In addition, some courts and state agencies have entered into consent decrees with merging hospitals that contain some form of post-merger price regulation and other contract term commitments. *See, e.g.*, Butterworth Health Corp. v. FTC, 946 F. Supp. 1285 (W.D. Mich. 1996); Commonwealth of Pennsylvania v. Jameson Health Sys., Inc., No. 15-CV-1706 (W.D. Pa. Mar. 25, 2016), https://www.acms.org/wp-content/uploads/2016/03/signedorder.pdf.

- How much time, and what commitment of resources, is required to fully implement and monitor COPAs or other state-based regulatory approaches? To what extent do healthcare providers, state health departments, state attorneys general, or other stakeholders attempt to measure and quantify these resources? What metrics and methodologies do they use?

- Is competition more or less effective than certain forms of regulation in lowering prices, costs, and health expenditures; improving quality and access; promoting efficient resource allocation; and fostering innovations in care delivery models in healthcare provider markets?

    - Are there any special considerations for assessing competition versus regulation in environments with evolving reimbursement methodologies (*e.g.*, value-based payment models), which may involve more complex contracting practices than traditional fee-for-service payment models? Are rate regulation schemes flexible enough to allow for these more complex contracting practices?

- What existing empirical studies (including working papers) evaluate the effects of COPAs or other state-based regulations?

- How might existing research on conduct remedies, rate regulation, or other regulatory economics inform our understanding of COPAs and other state-based regulatory approaches?

- What additional types of research would be useful? Are there natural experiments that would be particularly relevant to understanding the effects of COPAs? What data are available for this research?

Instructions for Filing Public Comments:

Interested parties are invited to submit written comments on the topics described above to the FTC electronically or in paper form. FTC staff will consider these comments when developing potential research projects or a public workshop agenda, and may use these comments in subsequent reports or policy papers, if any. Comments should refer to "COPA Assessment, Project No. P181200."

Comments filed in electronic form should be submitted using the following web link: https://www.regulations.gov/docket?D=FTC-2019-0016 and following the instructions on the web-based form.

A comment filed in paper form should include the "COPA Assessment, Project No. P181200" reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex X), 600 Pennsylvania Avenue, NW, Washington, DC 20580. Because paper mail addressed to the FTC is subject to delay due to heightened security screening, please consider submitting your comments in electronic form or by courier or overnight service, if possible.

Please note that your comment – including your name and state – will become part of the public record of this project. In addition, comments may eventually be included on a publicly accessible FTC website in connection with a public workshop. Because comments will be made public, they should not include any sensitive personal information, such as an individual's Social Security Number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, comments should not include "trade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential," as provided in Section 6(f) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 C.F.R.§ 4.10(a)(2). Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c).[9] For any copyrighted material, please provide authorization (signed by the publisher or author if they retain the copyright) so that the material may be republished on the Agencies' websites.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, available at http://www.ftc.gov/ftc/privacy.htm.

For Further Information Contact:

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Revised March 27, 2019, to reflect new process for submitting public comments.

[9] The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* FTC Rule 4.9(c), 16 C.F.R. § 4.9(c).