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COMMENTS SUBMITTED ON BEHALF OF THE HEALTH LAW SECTION on I.D. No. HLT-38-13-00007-RP (Addition of Subpart 83-1 to Title 10 NYCRR)

Health #5 September 26, 2014

We appreciate the opportunity to submit comments on the revised proposed regulations issued by the Department of Health ("DOH") on August 27, 2014 implementing Article 29-F of the Public Health Law (the "COPA Statute"). These proposed regulations seek to add a new Subpart 83-1 to Title 10 NYCRR addressing issuance of Certificates of Public Advantage.

Section 83-1.2(a): Certificate of Public Advantage: Effect

The legislative intent expressed with the enactment of the COPA Statute is instructive:

> § 50. Legislative findings. The legislature finds that integration and coordination of health care services is essential to the improvement of health care quality, efficiency, access and outcomes. The federal Patient Protection and Affordable Care Act creates several health system demonstration and pilot programs, intended to promote and assess delivery system and payment reforms, that require integration of services, coordination among providers, or a combination of the two. In addition, collaborative arrangements among, or consolidation, mergers or acquisition, of providers may be necessary to preserve access to essential services in some communities, and improve the quality of the services they provide and the efficiency of their operations, as well as minimize unnecessary increases in the cost of care.
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> ***Federal and state antitrust laws may prohibit or discourage such collaboration or consolidation beneficial to residents of New York state, given their potential for, or actual, reduction in competition. The legislature finds that such agreements where they meet the standards of this section, should be permitted and encouraged. Under these circumstances, competition as currently mandated by federal and state antitrust laws should be supplanted by a regulatory program to permit and encourage mergers, acquisitions, and cooperative, collaborative and integrative agreements among health care providers, and others, that are beneficial to New York residents when the benefits of such agreements outweigh any disadvantages caused by their potential or actual adverse effects on competition.*** Regulatory oversight of such arrangements should be provided to ensure that the benefits of such agreements outweigh any disadvantages attributable to any reduction in competition that may

> result from the agreements. Accordingly, the legislature intends to authorize a regulatory program to permit and oversee merger, acquisition, integration, consolidation, collaboration, and coordination among providers, where necessary to assure access to essential health care services, to improve health care quality and outcomes, to enhance efficiency, or to minimize the cost of health care. (Emphasis added). Chapter 59 of the Laws of 2011, p. 146-147.

Given this legislative intent, our concerns with the draft regulation include the following issues.

A. Retroactivity and regulatory uncertainty. Section 83-1.2 (a) of the proposed COPA regulations does not specify that the Attorney General's ability to seek relief under the state antitrust law is limited to prospective relief. We suggest that the proposed COPA regulations be revised expressly to address this issue.

If DOH intended to take the position that this important legal protection can be revoked retroactively, not only would that position be novel, but it is not in any way compelled by the wording of the COPA Statute, which makes no reference to retroactive revocation. The legislative findings preceding the new statute (see §50 of Chapter 59 of the Laws of 2011) clearly state that the statute is intended to provide protection under state antitrust laws as well as under federal antitrust laws. PHL §2999-aa also contains two explicit references to intended protections under state antitrust laws. There would effectively be no protections under state antitrust laws if the Attorney General can second guess the value of the COPA on a retroactive basis after reviewing the results of the project.

Moreover, if DOH and the Attorney General were to take the position that a COPA could be revoked retroactively, it could undermine the very purposes that DOH seeks to promote in the COPA regulations. It is very possible that potential provider applicants would not utilize the regulations if a COPA could be retroactively revoked, and thus the purposes of health reform, the MRT and DSRIP will almost certainly be severely curtailed.

The COPA provides no meaningful protections if the Attorney General can contest it at any time and effectively nullify the COPA on a retroactive basis. By definition, under a COPA the parties will have proceeded to undertake actions that arguably or definitely violate usual antitrust rules and thus will have exposed themselves to considerable liability if the Attorney General decides to contest the actions of the parties. The wording of the proposed regulation includes situations where the results of the initiative simply did not come to fruition as planned, despite the best efforts of the parties, and even when conducted in full compliance with the terms of the COPA. Even if no monetary liability were to attach to actions taken under the COPA, undoing a merger or some other arrangement that was covered by a revoked COPA may be, for all intents and purposes, a practical impossibility.

B. Considering the impact on competition: The proposed COPA regulations include several references regarding assessing the impact of the COPA on competition.[1] While likely unintentional, we believe that these references could subvert the legal basis for asserting state action, and thus may undermine the very purposes for issuing a COPA.

[1] *See, e.g.,* Section 83-1.5(b), (d)(4), (e), .

The fundamental premise of the state action exemption to the antitrust laws is that the state must have enunciated a clear state policy to supplant use of the competitive model (which it did by issuing the COPA Statute), and have taken actions to implement and monitor that state policy (which is the purpose of the proposed COPA regulations). The premise is that the clearly enunciated and implemented public policy has been determined to be sufficient to supplant competition. Any indications that the State is retreating from that assertion could jeopardize the validity of the state action protection. A suggestion that the State should somehow "balance" the use or benefits of the COPA as against the value of "competition" is inherently inconsistent with the COPA concept.

That said, the state may certainly balance the costs and benefits of a COPA compared to the costs and benefits of not having a COPA (the latter, by definition, means the conventional marketplace). The regulatory focus should be on the impact on health care costs and on the prices charged for health care—not necessarily on competition. The intended effect of granting a COPA is so that the long-term trend of rising costs and prices will be moderated from what it is currently occurring in the marketplace. The framing of any evaluation (whether in granting, monitoring, or revoking the COPA) should be that it produces better results (prices to payors and consumers, as well as better quality care for consumers) than the current competitive model system. There is no need to frame the evaluations by their impact on competition, since competition *per se* is not the focal point for the analysis under this statute and, as noted above, has been supplanted by other policy considerations.

Section 83-1.2(b)(3): Certificate of Public Advantage for a Planning Process

The proposed COPA regulations laudably intend to provide state action immunity for Health care providers engaged in a "Planning Process." However, the procedures DOH proposes for obtaining a COPA for a Planning Process will make obtaining such protection too late to be of use because the application requires submission of a "detailed letter of intent." In our experience, Health care providers engaged in a Planning Process will have a need to meet and share information of a competitively sensitive nature *before* they sign a "detailed letter of intent." Therefore, this section of the regulations should be revised.

Section 83-1.1: Definition of "Cooperative Agreement."

The proposed definition of a "Cooperative Agreement,"[2] as currently written, is not consistent with corporate law. For example, there is no such thing as a "lawful purchase of assets pursuant

[2] The proposed COPA regulations currently define a "Cooperative Agreement" as follows:

"(c) "Cooperative Agreement" means an executed agreement among a health care provider and one or more persons or entities, including other health care providers, governing any of the following:

(1) The sharing, allocation, or referral of patients, personnel, instructional programs, information technology resources, support services and facilities, or medical, diagnostic, or laboratory facilities or equipment, or procedures or other services traditionally offered by health care providers or health care-related entities, including but not limited to, the implementation of clinical integration programs and payment mechanisms that involve the sharing of data and resources to develop, implement, and monitor

to a merger." Moreover, it is not clear whether the definition is intended to or would include certain agreements among Health care providers to establish entities such as Independent Practice Associations ("IPAs").[3]

We suggest that subsection (2) of the definition of a "Cooperative Agreement," be revised – at the very least - to be consistent with the terms used in corporate law. For example, the following language could be used instead for subsection (2):

(c) "Cooperative Agreement" means an executed agreement among a health care provider and one or more persons or entities, including other health care providers, governing any of the following: (1)…or (2) a merger, consolidation, purchase of stock or assets, partnership, joint venture or any other transaction or affiliation among one or more health care providers (or one or more entities that own or control such health care providers) and any other person or entity, including other health care providers.

In conclusion, we appreciate the opportunity to submit comments on these important proposed regulations.

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the effectiveness of, and adherence to, performance standards, clinical protocols and evidence-based practices; or

(2) A lawful purchase of assets pursuant to a merger or sale, a partnership, a joint venture, or any other affiliation by which ownership or control over all or substantially all of the stock, assets, or activities of one or more health care providers, or health care-related entities, are transferred to another entity who controls a health care provider or health care-related entity."

[3] For example, the current definition of a "Health care provider" includes "a lawful combination of such health care professionals" but fails to include "a lawful combination of health care providers."