



**BILL McCOLLUM**  
**ATTORNEY GENERAL**  
**STATE OF FLORIDA**

OFFICE OF THE ATTORNEY GENERAL  
Antitrust Division

Lizabeth A. Brady  
Chief Multistate Antitrust Enforcement  
PL-01 The Capitol  
Tallahassee, FL 32399-1050  
Phone (850) 414-3300 Fax (850) 488-9134  
<http://www.myfloridalegal.com>

March 31, 2010

**Antitrust No Action Letter**  
**Number NAL 10-01**  
**Subject Voluntary Cancer Clinical Trial Compact**

Michael W. Garner, Ph.D.  
FAHP President and CEO  
Florida Association of Health Plans  
200 W. College Avenue, Suite 104  
Tallahassee, FL 32301

RE: Florida Health Care Community Guidance Act-  
Antitrust No Action Letter Voluntary Cancer Clinical Trial Compact

Dear Mr. Garner:

On behalf of the Florida Association of Health Plans, Inc. ("FAHP") you have requested an antitrust no action letter pursuant to the Florida Health Care Community Antitrust Guidance Act<sup>1</sup> regarding a proposed voluntary cancer clinical trial compact to be entered into by, among others, health care payors in Florida ("Compact"). The Compact was developed in conjunction with Florida Senator Dan Gaetz, individual health plans, the Florida Medical Association and several patient advocacy groups ("Proponents"). Attorney General Bill McCollum has asked us to respond to your request.

The Compact states that those who sign will not limit health care coverage normally provided to a subscriber under a signatory health plan's benefit schedule upon that subscribers entering and participating in cancer clinical trials. Parties to the agreement are health plans providing group coverage in Florida and self insured governmental health plans in the State. The Compact will not become effective until you have received an Antitrust No-Action Letter from this office. You have asked us to determine whether our office would pursue an action against any of the participating organizations based on the terms of the Compact.

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After reviewing your request it is this Office's conclusion that, under the circumstances you have presented, the Compact is not likely to be anticompetitive in overall effect. Accordingly, it is the present intention of this Office not to take antitrust enforcement action against any signatory to the Compact.

You have provided this office with the following information in support of your request:

1. A description of the FAHP
2. A description of how the Compact was developed
3. A copy of the Florida Senate Issue Brief on the Voluntary Compact
4. A copy of the Compact language that health plans have been asked to sign
5. Copies of similar compacts available from other states
6. A response dated February 2, 2010 to this Office's request for additional information dated January 14, 2010.
7. A response dated March 1, 2010 to this Office's request for additional information dated January 14, 2010.

You have advised that clinical trials<sup>2</sup> are research studies on patients designed to test the safety and effectiveness of new medical treatments.<sup>3</sup> Those who sponsor clinical trials and others have expressed concern that patients may decide not to enroll in these clinical trials because of a lack of health insurance coverage for care related to the clinical trial.<sup>4</sup>

While clinical trial sponsors usually cover the cost of the drug or treatment being studied as well as other related diagnostic and testing costs, the sponsor generally does not cover this cost for routine patient care. Routine patient care includes doctor visits, tests and x-rays.<sup>5</sup> Health insurance plans may limit or deny coverage for trial related routine care if a policy holder is enrolled in a clinical trial.<sup>6</sup> Several states have legislatively mandated coverage that requires health insurers to cover routine patient care for policy holders enrolled in cancer clinical trials.<sup>7</sup> Others have mandated health insurance coverage for clinical trials more broadly.<sup>8</sup>

Current Florida law does not directly regulate the clinical-trial-research process.<sup>9</sup> Nor does it mandate insurance coverage for routine patient care for those enrolled in clinical trials.<sup>10</sup> Although legislation to require insurers to cover routine patient care costs in connection with clinical trials, has been proposed, it has not been enacted.<sup>11</sup>

In order to address the issues raised by the gap in health care coverage for those participating in cancer clinical trials, the Proponents have proposed the Compact as a solution.

The Compact, by its terms, applies only to cancer clinical trials that meet certain "well defined parameters." The Compact also defines Routine Patient Care Costs.<sup>12</sup> Importantly, the Compact does not dictate a reimbursement rate and FAHP has assured this Office that the Compact does not fix or set reimbursement rates:

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The Compact does not in any manner fix or set reimbursement amounts to any provider or premiums or copays to any individual or group policy holder. Insurers will continue to employ their current methodology to determine payments to providers and premiums or copays to policyholders.

Each insurer currently has a methodology it uses to determine the amount to reimburse a provider for a medical service. These methodologies are independently developed using both internal and external experts and are considered confidential. Insurers will continue to use that same methodology to determine the appropriate reimbursement for services provided under the compact<sup>13</sup>

Additionally, the Compact does not require a set percentage of insurer's participation in order to be effective. Thus, all who sign the Compact will be bound by its terms. There is no set expiration date and insurers can withdraw from the Compact at any time. If, however, an insurer decides to withdraw from the Compact, that insurer would be required to provide notice as is required under the Florida Insurance Code for the discontinuance of this coverage. Under the Code, change to coverage may only occur at the renewal date provided that 45 days prior notice was given.<sup>14</sup>

The proposed Compact, the key provisions of which are described above, is not manifestly anticompetitive. On its face, it does not appear to set or fix prices. Rather, it requires signatories to the Compact to cover the Routine Patient Care Costs as that term is defined in the Compact, incurred by an insured who participates in a clinical cancer trial if those services, including drugs, items and devices, "would otherwise be covered under the plan or contract if those drugs, items, devices and services were not provided in connection with an approved cancer clinical trial program."<sup>15</sup> Therefore, in evaluating the lawfulness of the Compact under the Florida Antitrust Act and Section 1 of the Sherman Antitrust Act, this Office will apply the rule of reason standard. In a rule of reason analysis, an agreement is deemed unlawful only if it is likely to result in an unreasonable restraint of trade, that is, if under the circumstances, it is likely the anticompetitive economic effects of the restraint will outweigh its likely procompetitive effects in a relevant market.<sup>16</sup>

None of the contractual relationships that will be created by the Compact will necessarily result in an anticompetitive agreement between or among competitors. In particular, the Compact does not dictate the amount of reimbursement, premiums or copays to be paid by any individual or group policy holder for the routine patient care costs incurred by a subscriber who is a participant in a cancer clinical trial. Moreover, the signatories to the Compact may withdraw at any time provided they adhere to the requirements of the Florida Insurance Code. Health plans will continue to independently set reimbursement, premium and co-pay amounts.

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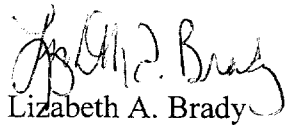
The Compact does appear to offer several potential pro-competitive effects which include, (1) improving coverage for clinical trial participants and (2) increasing competition among health care payors for providing coverage for cancer clinical trials.

Weighing the potential pro-competitive justifications and effects from the Compact against possible anticompetitive effects, it appears, on balance that the Compact is not likely to have a substantial adverse effect upon competition in any relevant market. Accordingly, based upon the information you have provided and the specific facts presented thereby, it is the present intent of this Office not to take antitrust enforcement action with respect to the Compact.

This letter expresses this Office's present enforcement intention only. It applies only to the Compact presented to this Office, summarized above. This Office reserves the right to bring an enforcement action in the future if actions taken by signatories to the Compact shall prove anticompetitive in purpose or effect.

Sincerely,

Patricia A. Conners  
Associate Deputy Attorney General



Lizabeth A. Brady  
Chief Multistate Antitrust Enforcement

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<sup>1</sup> § 408.18 Fla. Stat.

<sup>2</sup> Clinical trials are generally biomedical or health related research studies in human beings that follow a defined research protocol.

<sup>3</sup> Id.

<sup>4</sup> Id. at 2-3.

<sup>5</sup> Id. at 3.

<sup>6</sup> Id.

<sup>7</sup> Arizona, California, Connecticut, Georgia, Florida, Louisiana, Maine, Missouri, New Hampshire, New Mexico, Rhode Island, Tennessee, Vermont, Virginia, Wisconsin, see Id. At note 5 and 26.

<sup>8</sup> Delaware, Washington, D.C., Indiana, Maine, Maryland, Nevada, North Carolina, Ohio, Oregon, West Virginia, Wyoming. See Id. At Note 6 and 26.

<sup>9</sup> Id. at 6.

<sup>10</sup> Id. at 7.

<sup>11</sup> Id.

<sup>12</sup> "Routine patient care costs, for the purposes of this Agreement is defined as those costs associated with the provision of health care services, including drugs, items, devices, and services that would otherwise be covered under the plan or contract if those drugs, items, devices and services were not provided in connection with an approved cancer clinical trial program including the following:

A. Health care services covered absent a cancer clinical trial.

B. Health care services required solely for the provision of the investigational drug, item, device or service.

C. Health care services required for the clinically appropriate monitoring of the investigational item or service.

D. Health care services needed for the reasonable and necessary care arising from the provision of the investigational drug, item, device, or service including the diagnosis or treatment of the complications." Florida Clinical Trials Agreement at § 1.0.3 at §1.

<sup>13</sup> Letter dated February 10, 2010 to Lizabeth A. Brady from Michael Garner, President and CEO of Florida Association of Health Plans.

<sup>14</sup> Id.

<sup>15</sup> Compact at § 1.0.3.

<sup>16</sup> Leegin Creative Leather Products, Inc. v. PSKS, Inc., 127 S.Ct. 2705 (2007).