



MAY 19 2009

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Johns Hopkins Bloomberg
School of Public Health
Department of Epidemiology
Room W5010
615 N. Wolfe Street
Baltimore, MD 21205

SEE ALSO ATTACHED DISTRIBUTION LIST

Re: Notice of Modification of OIG Advisory Opinion No. 08-11

Ladies and Gentlemen:

We are writing in response to your request to modify Office of Inspector General ("OIG") Advisory Opinion No. 08-11, which we issued on September 17, 2008, by adding you to the list of requestors to which the opinion applies.

OIG Advisory Opinion No. 08-11 addressed the waiver of Medicare cost-sharing obligations by certain providers, practitioners, and suppliers (the "Original Requestors") participating in a particular clinical trial sponsored by the National Heart, Lung, and Blood Institute and the Centers for Medicare and Medicaid Services. In the opinion, we concluded that the Proposed Arrangement (as further defined in the opinion): (i) would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act, and (ii) while it could potentially generate prohibited remuneration under the anti-kickback statute (if the requisite intent to induce or reward referrals of Federal health care program business were present), the OIG would not impose administrative sanctions on the Original Requestors or the data coordinating center in connection with the Proposed Arrangement under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act).

The parties listed on the distribution list attached to this notice (the "Additional Requestors") have asked to join in OIG Advisory Opinion No. 08-11. The Additional Requestors are additional providers, practitioners, and suppliers participating in the same

clinical trial under the same terms and conditions. They are similarly situated to the Original Requestors and have certified that all of the information provided in the original request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties. The Additional Requestors will participate in the Proposed Arrangement in exactly the same way as the Original Requestors.

Based on our review of the Additional Requestors' submissions, we conclude that the modification to add the Additional Requestors to the opinion would not affect our conclusion in OIG Advisory Opinion No. 08-11. Accordingly, OIG Advisory Opinion No. 08-11 is modified to add the Additional Requestors to the "Distribution List" of requestors attached to the opinion.

Pursuant to 42 C.F.R. § 1008.45(a), this letter serves as final notice of OIG's modification of OIG Advisory Opinion No. 08-11, effective as of the date hereof. The modification of OIG Advisory Opinion No. 08-11 means that the advisory opinion continues in full force and effect in modified form. See 42 C.F.R. § 1008.45(b)(3).

Sincerely,

A handwritten signature in cursive script, appearing to read "L. Morris".

Lewis Morris
Chief Counsel to the Inspector General

DISTRIBUTION LIST

NOTICE OF MODIFICATION OF OIG ADVISORY OPINION 08-11

Regional Clinical Centers:

1. Brigham and Women's Hospital, Inc.
75 Francis Street
Boston, MA 02155
2. University of Pittsburgh Medical Center (UPMC) Presbyterian Shadyside
200 Lothrop Street
Pittsburgh, PA 15213

Satellite Sites:

1. Boston Medical Center
One Boston Medical Center Place
Boston, MA 02118
2. Drexel University College of Medicine
245 N. 15th Street
Philadelphia, PA 19102
3. Fallon Clinic, Inc.
630 Plantation Street
Worcester, MA 01605
4. Geisinger Health System/Geisinger Clinic
100 North Academy Avenue
Danville, PA 17822
5. The Institute for Respiratory and Sleep Medicine
1205 Langhorne-Newtown Road, Suite 301
Langhorne, PA 19047
6. Lung Health and Sleep Enhancement Center, LLC
4745 Ogletown-Stanton Road
Medical Arts Pavilion 1, Suite 220
Newark, DE 19713

7. Mission Internal Medical Group
Mission Medical Plaza, Suite 305
26800 Crown Valley Parkway
Mission Viejo, CA 92691
8. National Jewish Health
1400 Jackson Street
Denver, CO 80206
9. Peninsula Pulmonary Medical Associates
23550 Hawthorne Boulevard, Suite 180
Torrance, CA 90505
10. University of Kentucky
Chandler Medical Center
740 South Limestone Street
L543 Kentucky Clinic
Lexington, KY 40536-0284
11. University of Maryland Baltimore
Pulmonary and Critical Care Division (a Division of UMD School of Medicine)
685 W. Baltimore Street
Baltimore, MD 21201