



[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.]

Issued: May 19, 2009

Posted: May 26, 2009

[Name and address redacted]

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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General

DISTRIBUTION LIST

NOTICE OF MODIFICATION OF OIG ADVISORY OPINION 08-11

[Name and address redacted]