

## *OIG Addresses The Scope of Exclusion Penalty Regarding Indirect Providers of Items and Services.*

*By Robert R. Stauffer and Sandi J. Toll*

On December 19, 2007, the Department of Health and Human Services Office of Inspector General ("OIG") issued Advisory Opinion 07-17, which provides some direction on the scope of the exclusion penalty, a topic on which there is little clear guidance. The OIG addressed whether an individual (the "Requestor") excluded from participation in federal health care programs can license a new invention to a company "completely independent of the [Requestor]" (the "Proposed Arrangement"), where the products sold by the company would eventually be the subject of claims by health care providers or suppliers for Medicare and/or Medicaid reimbursement. The OIG determined that the Requestor's Proposed Arrangement would not result in the "indirect" furnishing of items or submission of claims to federal health care programs, and thus not violate the terms of the Requestor's exclusion from participation in such programs. More importantly, the Proposed Arrangement would not subject the Requestor to sanctions under the federal anti-kickback statute.

In June 2004, the Requestor pled guilty under the Anti-Kickback statute

for knowingly and willfully making false statements for use in determining rights or benefits under a federal health care program. Under the terms of his guilty plea, the Requestor was sentenced to 3 years probation and a \$2,000,000 fine. In March 2005, the OIG also excluded the Requestor from participating in all federal health care programs for a mandatory five-year period. As a result of the Requestor's exclusion, federal health care programs cannot pay for any item or service (i) furnished directly by the Requestor during this period; and (ii) indirectly supplied the Requestor during this period, such that the Requestor cannot provide items or services to providers who will then submit reimbursement claims. The Requestor's failure to comply with the terms of his exclusion could result in additional monetary penalties, criminal liability, and/or serve as the basis for denying reinstatement after the mandatory exclusion period expires.

After his exclusion, the Requestor invented and trademarked a new product. The Requestor marketed his invention outside of the United States, and now wants to introduce his invention within the United States

without running afoul of his mandatory exclusion. In an effort to avoid additional liability, the Requestor developed the Proposed Arrangement, under which the Requestor's three adult children would create and fund a new company ("Newco") completely independent of the Requestor and with an entirely independent executive team to run Newco's operations. Newco would be responsible only for manufacturing the invention and providing it to independent distributors, who would then provide the invention to health care providers or suppliers. Of these entities, only the health care providers would submit reimbursement claims to federal health care programs.

In return, the Requestor would provide Newco with a royalty-free, non-exclusive license for his invention for sale or lease in the United States (or alternatively, agree not to sue Newco for patent infringement). After transferring the license to Newco, the Requestor would have no further involvement with Newco and never receive any fees, royalties, benefits or other payments from Newco. As further evidence of his intent to remain independent of Newco, the Requestor certified that he has not

entered into any oral or written agreements with his children providing him with any financial benefits derived from Newco during his exclusion. Finally, the Requestor certified his continuing obligation to avoid providing any services or items, directly or indirectly, to any federal health care program beneficiaries during the term of his exclusion.

Based on the terms of the Proposed Arrangement, the OIG concluded that the Requestor would not be subject to sanctions because he “would not be indirectly furnishing the [i]nvention to health care providers or causing claims for it to be submitted to Federal programs in violation of [his] exclusion.” The OIG initially noted that even though the Requestor would not directly provide or submit claims for his invention, he would still set in motion a chain of events that would cause Newco to “manufacture and lease or sell his invention to independent distributors, who would in turn lease or sell [his] [i]nvention to health care providers or suppliers who could bill Federal health care programs.” However, given the number of “intervening and independent entities” between himself and Newco, the Requestor would be sufficiently isolated from any claims submitted to federal health care programs. Further, the OIG’s concern about the Requestor’s “filial relationship” with the owners of Newco was sufficiently dispelled by the Requestor’s certification that no financial or other agreements existed between himself and his children. Accordingly, the OIG concluded that

“there is little risk that Federal funds would make their way back to you through Newco” and found that the Requestor’s Proposed Arrangement would not violate the Anti-Kickback statute.

Although the Advisory Opinion provides some guidance as to the OIG’s view of the reach of the exclusion penalty, the OIG did not address whether the Requestor could be excluded if the Proposed Arrangement did not contain several “intervening and independent entities” between himself and Newco. The scope and basis for the OIG’s authority to “indirectly” exclude an entity that provides items or services to providers or suppliers which bill federal health care programs remains an area of substantial ambiguity.

Jenner & Block LLP provides information on recent developments and general topics of interest in the field of health care law. The information presented here is not intended to be legal advice. Please address any questions or comments to:

Robert R. Stauffer  
 Jenner & Block LLP  
 330 N. Wabash Avenue  
 Chicago, IL 60611-7603  
 Tel (312) 923-2905  
 Fax (312) 840-7305  
 RStauffer@jenner.com