September 9, 2014

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Office of Inspector General
Department of Health and Human Services
Attention: OIG-1271-N, Room 5296, Cohen Building
330 Independence Avenue SW, Washington, DC 20201
www.regulations.gov

Attn: Ms. Patrice Drew

Re:  OIG-1271-N: AdvaMed Comments on Solicitation of Information and Recommendations for Revising OIG’s Non-Binding Criteria for Implementing Permissive Exclusion Authority Under Section 1128(b)(7) of the Social Security Act

Dear Inspector General Levinson:

The Advanced Medical Technology Association (“AdvaMed”) is pleased to comment on the Department of Health and Human Services, Office of Inspector General’s (OIG’s) solicitation of information and recommendations for revising OIG’s non-binding criteria for implementing permissive exclusion authority under Section 1128(b)(7) of the Social Security Act (the “(b)(7) Permissive Exclusion Criteria”).1 We appreciate OIG’s interest in engaging industry to consider possible changes to the (b)(7) Permissive Exclusion Criteria and look forward to working with OIG regarding any refinements to or clarifications of these criteria. We believe this open dialogue is critically important, in part, due to the proposed revisions to the regulations implementing OIG’s exclusion authority that are currently under consideration by the agency.2 If the proposed revisions are adopted, there would be no limitations period on OIG’s ability to impose exclusions under Section 1128(b)(7) – a regulatory change that AdvaMed believes would be highly inappropriate and wholly unwarranted.3 However, given this potential for increased exposure for individuals and entities, it is more critical than ever that affected entities understand the applicable (b)(7) Permissive Exclusion Criteria and how OIG would propose to apply them.

Below, we first provide in Section I, background information regarding AdvaMed and our membership. In Section II, we comment on specific aspects of the existing (b)(7) Permissive Exclusion Criteria and offer suggestions for additional criteria; specifically, we request that OIG:

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1 79 Federal Register 40,114 (July 11, 2014).
2 See Medicare and State Health Care Programs; Fraud and Abuse; Revisions to the Office of Inspector General’s Exclusion Authorities, 79 Federal Register 26,810 (May 14, 2014).
3 See id. at 26,815.
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- Specifically evaluate whether exclusion of an entity could harm beneficiaries by impeding access to life-saving and innovative medical technologies;

- Revise the existing criteria under the “Defendant’s Response to Allegations/Determination of Unlawful Conduct” category to better account for “affirmative exclusions,” which are not based upon actions previously taken by a court or other law enforcement or regulatory agency;

- Continue to include criteria that weigh the effectiveness of an entity’s compliance program; specifically consider whether the entity follows relevant industry guidelines (e.g., the AdvaMed Code); and consider whether the compliance program is appropriately tailored to the particular entity; and

- Incorporate additional criteria that evaluate the exclusion of individuals who work on behalf of an entity that is involved in an enforcement action.

Our comments and recommendations addressed in Section II are driven by guidance and examples provided by our member companies.

I. Background

AdvaMed is the world’s largest trade association of medical device manufacturers, which produce the medical technologies that are transforming health care through earlier disease detections, less invasive procedures, and more effective treatments. AdvaMed represents manufacturers of medical devices, diagnostics, and health information systems, ranging from the largest to the smallest medical technology innovators and companies.

AdvaMed is dedicated to the advancement of medical science, the improvement of patient care, and, in particular, the contributions that high quality, innovative medical technologies make toward achieving these goals. The medical technology industry is highly heterogeneous and is fueled by intense competition, a commitment to scientific research and the innovative energy of our member companies. Our constant innovation leads to the introduction of new and improved technologies that prevent illness, allow earlier detection of diseases, and treat patients effectively and efficiently.

It is AdvaMed’s mission to advocate on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation. We recognize our industry’s obligation to facilitate ethical interactions between companies and health care providers, and we are recognized worldwide for our industry code of ethics and global compliance leadership, which we discuss further in Section II below. AdvaMed and its member companies are concerned about fraudulent behavior in the health care system, especially in relationship to the Medicare and Medicaid programs, and work to instill a corporate culture that focuses on compliance and ethical business practices.
II. Comments on the (b)(7) Permissive Exclusion Criteria


In addition to protecting the Federal health care programs and their beneficiaries from untrustworthy health care providers, OIG has a significant interest in guaranteeing that no substantial harm comes to program beneficiaries as a result of a permissive exclusion. To that end, OIG appropriately considers waivers of exclusions pursuant to a formal request submitted by a State health care program. There is no reason that this consideration should be delayed until after the imposition of a permissive exclusion — OIG can and should engage in this line of inquiry as part of its decision-making process. Therefore, we recommend that OIG add a fifth general category of criteria to the (b)(7) Permissive Exclusion Criteria that evaluates whether the exclusion would not be in the public interest. Within the Public Interest category, we further recommend that OIG include the following criterion:

- Could the exclusion harm beneficiaries by impeding access to life-saving and innovative medical technologies?

The medical technology industry is fueled by intense competition and the innovative energy of medical technology manufacturers — firms that drive very rapid innovation cycles among products, in many cases leading to new product iterations every 18 months. This constant innovation leads to the introduction of new technologies that prevent illness, allow earlier detection of diseases, and treat patients as effectively and efficiently as possible. Medical technology manufacturers also regularly partner and collaborate with physicians and other health care providers to address a specific need in the continuum of care and create an improvement or a solution addressing that need. In some cases, the resulting solution may be used across the United States, but only be available from a single entity or as a result of the contributions of a single individual.

As a result, exclusion of a single entity, or individual who serves a vital role, could preclude or impede beneficiary access to medical technologies developed by that entity or individual. These technologies may be critical to the care of a particular disease state or injury, and only available through a single entity or individual.

With respect to new and emerging medical technology manufacturers, an exclusion, even for an abbreviated period of time as OIG considers a formal waiver request, may foreclose the entity’s ability to continue operating, thereby potentially impeding patient access to critical medical technology indefinitely. Therefore, given OIG’s significant interest in ensuring no harm comes to beneficiaries as a result of an exclusion, we recommend that OIG add a Public Interest general category and specifically evaluate whether exclusion of an entity or individual could harm beneficiaries by impeding their access to life-saving and innovative medical technologies.

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4 See 42 C.F.R. § 1001.1801(c).
2. OIG Should Revise Existing Criteria to Better Account for “Affirmative Exclusions.”

In its recent proposed revisions to the regulations implementing OIG’s exclusion authority, OIG described permissive exclusions as either “derivative” or “affirmative.” “Derivative” exclusions are those based on actions previously taken by a court or other law enforcement or regulatory agency. By contrast, “affirmative” exclusions are those based on OIG-initiated determinations of misconduct. For all derivative and many affirmative exclusions, individuals and entities are only entitled to post-exclusion hearings to challenge OIG’s actions. However, for the following affirmative exclusions, individuals and entities are entitled to pre-exclusion hearings: false or improper claims, fraud and kickbacks and other prohibited activities, violations of the limitations on physician charges, and billing for services of assistant at surgery during cataract operations. Therefore, for permissive exclusions falling within these categories, an exclusion is not imposed until after an administrative law judge has found that OIG proved the misconduct by a preponderance of the evidence.

Notably, the criteria set forth under “Defendant’s Response to Allegations/Determination of Unlawful Conduct” generally assume that either unlawful misconduct has already been proven (as in the case of a derivative exclusion) or admitted to by the individual or entity. In fact, many of the criteria are entirely inapplicable to a situation where, for example, OIG is weighing an affirmative exclusion arising out of alleged false or improper claims, which the individual or entity disputes and plans to appeal to an administrative law judge prior to the exclusion taking effect. For example, in this situation, the individual or entity likely has not: (1) made or agreed to make full restitution to the Federal and/or State health care programs; (2) paid or agreed to pay all criminal, civil, and administrative fines, penalties, and assessments resulting from the improper activity; (3) taken steps to undo the questionable conduct or mitigate the ill effects of the misconduct; or (4) acknowledged its wrongdoing and changed its behavior.

In light of the existing (b)(7) Permissive Exclusion Criteria, it is unclear how OIG evaluates its permissive exclusion authority with respect to an individual or entity that disputes OIG’s allegations. In fact, it appears that these individuals and entities may actually be disadvantaged for doing so even though they are entitled to a pre-exclusion hearing in some cases. A better understanding of OIG’s decision-making process in these circumstances is also critical given that there may be no limitations period on OIG’s ability to exclude an individual or entity under Section 1128(b)(7) if OIG’s revisions to existing regulations are adopted as proposed (a concept which, as stated above, we

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5 79 Federal Register at 26,811.
6 42 C.F.R. § 1001.2003(c).
7 42 C.F.R. § 1001.2003(a).
8 42 C.F.R. § 1001.2007(c).
9 Most medical technology manufacturers do not submit claims for payment to the Medicare and Medicaid programs. Therefore, in this context, the OIG’s allegations typically involve whether the manufacturer “cause[d false or improper claims] to be presented,” which involve additional elements of proof that may be disputed.
believe is inappropriate and unwarranted). Therefore, we recommend that OIG revise existing criteria and incorporate new elements to more appropriately outline how OIG evaluates whether to exercise its exclusion authority in circumstances where the allegations remain disputed.

For example, where applicable, we recommend that OIG consider whether payments or other transfers of value associated with the alleged misconduct have been appropriately reported to the Centers of Medicare & Medicaid Services pursuant to the regulations implementing section 6002 of the Affordable Care Act (the “Open Payments program”). Similar to the existing (b)(7) Permissive Exclusion Criteria, complete and accurate reporting under the Open Payments program has bearing on the trustworthiness of the entity and negates any improper intent on the part of the disclosing entity, which the OIG should take into account when evaluating whether to impose a permissive exclusion. Therefore, we specifically recommend the following criterion:

- **Were any payments or transfer of values associated with the alleged misconduct, reported to a Government agency or official in compliance with applicable reporting obligations?**

3. OIG Should Continue to Include Criteria Regarding the Effectiveness of an Entity’s Compliance Program

OIG specifically requested recommendations and suggestions regarding whether and how it should consider an entity’s compliance program. We agree that OIG must consider an entity’s compliance program when evaluating whether to exercise its permissive exclusion authority. In particular, the existence of a robust and effective compliance program should foreclose the necessity of an exclusion altogether. To help guide OIG’s assessment of an entity’s compliance program, we recommend the following criteria:

- **Does the entity follow relevant industry guidelines as part of its compliance program?**

First, we recommend that OIG’s (b)(7) Permissive Exclusion Criteria specifically include whether an entity follows relevant industry guidelines as part of its compliance program. AdvaMed and our member companies recognize that strong ethical standards are critical to ensuring appropriate interactions among the medical technology industry and health care professionals.

AdvaMed and our member companies take very seriously our responsibility to ensure ethical interactions with our physician and other health care professional partners, recognizing that adherence to ethical standards is essential to the industry’s ability to continue its collaboration with health care professionals across the board. These are among the reasons that, as early as 1993, AdvaMed (then known as the Health Industry Manufacturers Association, or HIMA) developed a code of ethics, which was revised and restated in 2003 as the Code of Ethics on Interactions with Health Care Professionals (the “AdvaMed Code” or “Code”).10 The Code distinguishes interactions

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10 Available at: [http://www.advamed.org/MemberPortal/About/code/](http://www.advamed.org/MemberPortal/About/code/).
that result in bona fide contributions to the advancement of medical technology, from interactions that may inappropriately influence medical decision-making. AdvaMed has revised and strengthened the Code via FAQs since then, including the most recent Code revision in 2009. We take aggressive steps on an ongoing basis to educate the industry and health care professionals about the Code, ethical interactions, and compliance. For example, in 2011 we released, in collaboration with Eucomed, the Joint Guidance on Ethical Third Party Sales and Marketing Intermediary (SMI) Relationships and implementing tools,\(^\text{11}\) to provide guidance on interactions with third party distributors. In 2013, we published Guiding Principles for Product Communications, which focused on off-label promotion.\(^\text{12}\) We also strongly encourage that industry participants structure arrangements among medical technology manufacturers and health care professionals in accordance with and reliant on definitions set out in the AdvaMed Code. To that end, we have recently published Illustrative Best Practices Tools\(^\text{13}\) to assist with implementation of the Code. These tools, in conjunction with the Code, provide a solid foundation for an effective compliance program. Therefore, we recommend that OIG’s consideration of an effective compliance program include an analysis of whether an entity follows the AdvaMed Code, or other relevant industry guidelines.

- *Is the entity’s compliance program appropriately tailored to mitigate the compliance risks faced by the entity?*

Second, not every effective compliance program will look the same or incorporate the same elements. Instead, entities will have differently-scaled compliance programs that reflect the size and available resources of the entity, and that are specifically tailored to address the risk areas faced by the entity. It is important for OIG to take this into account when evaluating the effectiveness of a compliance program and not impose a “one size fits all” requirement. Therefore, we recommend that OIG further clarify that its consideration of an effective compliance program is both flexible and scalable to the particular entity being evaluated.

### 4. OIG Should Incorporate Additional Criteria Applicable to the Possible Exclusion of an Individual Working on Behalf of an Entity that Is Involved in an Enforcement Action

We agree that OIG should incorporate additional criteria that guide OIG’s decision-making process when it is evaluating whether to exclude an individual who works on behalf of an entity that is involved in an enforcement action. In particular, we recommend the following criteria:

- *Did the individual have actual knowledge of the alleged misconduct and fail to take any corrective actions?*

\(^\text{11}\) Available at: [http://advamed.org/issues/28/distributor-guidance.](http://advamed.org/issues/28/distributor-guidance.)


• Did the individual rely on guidance from a Government agency or official or legal counsel regarding the legality of the alleged misconduct?

The alleged misconduct of an entity should only serve as the basis for excluding a single individual working on behalf of that entity if the individual had actual knowledge of the alleged misconduct and took no corrective actions. An individual’s actual knowledge should also be evaluated in light of any guidance received from a Government agency or official or legal counsel regarding the legality of the alleged misconduct. An actual knowledge standard may also be appropriate in light of OIG’s recent proposed revisions to the regulations implementing the exclusion authority. If adopted as proposed, there will be no limitations period on OIG’s ability to exclude an individual or entity under Section 1128(b)(7). Given the significant potential for increased exposure for individuals in particular, OIG should weigh carefully whether an exclusion of an individual is truly warranted under these circumstances and focus on the information actually known to that individual regarding the alleged misconduct.

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AdvaMed appreciates the significant complexities associated with OIG exercising its permissive exclusion authority and is grateful for the opportunity to engage OIG in any efforts to revise or clarify the (b)(7) Permissive Exclusion Criteria. We thank you for your consideration of these comments.

Sincerely,

Christopher White, Esq.
Senior Executive Vice President, General Counsel

cc: Stephen J. Ubl, AdvaMed
    Andrew Van Haute, AdvaMed