Docket No. OIG-1271-N

COMMENTS

of

THE WASHINGTON LEGAL FOUNDATION

to the

OFFICE OF INSPECTOR GENERAL
DEPARTMENT OF HEALTH & HUMAN SERVICES

Concerning

RECOMMENDATIONS FOR REVISING OIG'S NON-BINDING CRITERIA FOR IMPLEMENTING PERMISSIVE EXCLUSION AUTHORITY UNDER § 1128(b)(7) OF THE SOCIAL SECURITY ACT

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 79 *FED. REG.* 40114 (July 11, 2014)

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September 10, 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
Attn: Patrice Drew

Re: OIG-1271-N: 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 79 Fed. Reg. 40114 (July 11, 2014)

Dear Inspector General Levinson:

The Washington Legal Foundation (WLF) is pleased to submit these comments in response to the Department of Health and Human Services's solicitation of information and recommendations for revising Office of Inspector General's non-binding criteria for implementing permissive exclusion authority under § 1128(b)(7) of the Social Security Act, 42 U.S.C. § 1320a-7(b)(7). WLF applauds HHS for undertaking this review of existing guidance, which dates from 1997. WLF agrees that updated guidance is appropriate in order to better reflect the state of the health care industry today.

WLF urges HHS, when contemplating revisions, not to lose sight of two considerations that should guide all HHS efforts to implement its statutory exclusion authority. First, Congress specified that even if the criteria for excluding an entity or individual from participation in federal health care programs have been satisfied, exclusion is not to be invoked automatically.

Rather, the statute makes clear that exclusion under § 1128(b)(7) is permissive only and is never required. Mandatory exclusion is reserved for the infractions set forth in § 1128(a). Accordingly, HHS should exercise its exclusion authority if and only if it concludes—based on findings that exceed a bare-bones finding of a statutory violation—that exclusion serves the interests of federal health care programs. Second, exclusion is a forward-looking remedy. It should not be a punishment for past bad acts but rather a measure undertaken to protect federal health care programs from potential future bad acts. HHS's focus should be on whether an entity or individual possesses sufficient trustworthiness to provide reasonable assurances that they and their employees will comply with federal law going forward. Of course, evidence of past violations may be *some* evidence of future untrustworthiness, but that evidence needs to be weighed against competing evidence—such as whether the entity or individual has adopted and is implement corporate compliance program.

Any reasonably diligent investigator often will have little difficulty uncovering evidence that a health care entity has violated §§ 1128A, 1128B, and 1129, the statutes whose violations trigger HHS's § (b)(7) permissive exclusion authority. Such evidence often is *not* an indication of untrustworthiness, given that the health care entity may well not have had knowledge of violations committed by others for whose conduct the provider is responsible. WLF urges HHS to adopt guidance making clear that if a corporate compliance program is in place and the provider has been acting in good faith to implement that program, the issue of permissive exclusion *will not even be on the table* as a potential sanction. Under those circumstances, the existence of isolated statutory violations provides no basis for concluding that the provider will

act in an untrustworthy manner in the future, and thus there is no logical basis for exclusion.

Unless the possibility of exclusion is taken off the negotiating table, the negotiation process often takes inappropriate turns. Because exclusion is such a draconian penalty—it effectively amounts to a death penalty for a corporation and an exclusion from the entire health care field for an individual—it should not be threatened in any case in which a compliance program is in place and being faithfully implemented. Because exclusion has such severe consequences, merely invoking it, even when its use is not appropriate, can be an irresistible negotiating tactic, used as a means for government personnel to browbeat entities into agreeing to onerous settlement terms in return for assurances that exclusion will not be considered. Yet, because untrustworthiness (and thus the possibility of exclusion) is not properly at issue when a compliance program is in place, HHS guidance should state categorically at the outset that exclusion is not in the realm of possibility in such circumstances. Not only will such assurances from HHS ensure more reasonable settlements, but they will also do much to encourage health care providers to develop and implement effective compliance programs in the first instance.

Interests of WLF

The Washington Legal Foundation is a public interest law firm and policy center with supporters in all 50 States. WLF regularly appears before federal and state courts and administrative agencies to promote economic liberty, free enterprise, a limited and accountable government, and the rule of law. WLF fully recognizes the important role that the Inspector General plays in ensuring the integrity of federal health care programs. WLF understands that maintaining that integrity requires exclusion from federal health care programs of those whose

actions have demonstrated that they cannot be trusted to comply with laws governing those programs.

WLF in no way supports violations of federal health care law, including the dissemination of inaccurate information about FDA-approved products, and it applauds the IG's efforts to prevent such dissemination. At the same time, WLF recognizes that large health care entities and their senior executives can never be 100% effective in preventing their agents from speaking inaccurately, and WLF believes that many of the extremely large sanctions recently imposed on such entities and their executives were out of proportion to the wrongdoing identified. WLF has on occasion appeared in federal court to oppose unwarranted use of OIG's permissive exclusion authority. *See, e.g., Friedman v. Sebelius*, 755 F. Supp. 2d 98 (D.D.C. 2010), *aff'd*, 668 F.3d 813 (D.C. Cir. 2012).

HHS Statutory Authority

HHS's permissive exclusion authority is set out at § 1128(b); the subsection lists 16 separate grounds upon which HHS "may" exclude individuals and entities "from participation in any Federal health care program." At issue here is the seventh listed ground, which authorizes exclusion of:

> FRAUD, KICKBACKS, AND OTHER PROHIBITED ACTIVITIES. Any individual or entity that the Secretary determines has committed an act which is described in section 1128A, 1128B, or 1129.

§ 1128(b)(7). The statutory provisions cover, among other infractions, violations of the False Claims Act and the anti-kickback statute.

The Discretionary Nature of Section (b)(7) Exclusion

As noted above, imposition of exclusion is wholly discretionary for infractions covered by § (b)(7). There undoubtedly are some violations of § (b)(7) that are sufficiently egregious to warrant exclusion. However, there will be many other cases in which the infraction perceived by OIG was quite minor and, as noted above, the violations occurred without the knowledge of senior personnel within the company. WLF urges HHS to make clear in any revised guidance it issues that there is no minimum penalty that must accompany minor § (b)(7) infractions. Under current policy, "OIG has used [existing guidance] criteria to evaluate whether to impose a permissive exclusion under section 1128(b)(7) of the Act or release this authority in exchange for the defendant entering into an Integrity Agreement with OIG." *See* 79 Fed. Reg. at 40115. WLF views that policy as misguided and overkill because it mandates that, at a minimum, an Integrity Agreement be imposed in every instance in which an infraction is identified, no matter how minor. The remedy ought to be commensurate with the violation; where the infraction is sufficiently minor, little justification exists to impose an Integrity Agreement.

Effective Compliance Programs

An increasing number of companies in the health care field have made major commitments to adopt and implement effective compliance programs. A well-designed program is likely to eliminate most infractions that could give rise to permissive exclusion under § (b)(7). But as noted previously, no program is likely to be 100% effective, and some employees of an entity are likely to commit infractions regardless of the compliance program in place. WLF urges OIG's revised guidance to make clear that permissive exclusion will never be considered for a firm whose senior management was not directly implicated in the infractions, so long as the

company had fully implemented a compliance program.

It is facile to suggest that, by definition, a compliance program was not effective if an infraction has occurred. No program can be 100% effective all the time. If OIG has questions about what constitutes an "effective" compliance program, it should become directly involved in establishing criteria for such a program. Then, once it has been determined that a compliance program meeting OIG's criteria has been put into place, the issue of permissive exclusion should be taken off the table during any negotiations between a health care entity and federal officials.

The Failure of the Current Enforcement System

The deficiencies in the current enforcement system are well documented. Even though § (b)(7) permissive exclusion is rarely imposed, the possibility of its imposition is a serious threat to the continued existence of any health care entity. Given the pervasive nature of federal programs in all aspects of health care, no health care company can hope to survive an exclusion order. The threat of exclusion thus creates asymmetric negotiating leverage between companies and enforcement officials, even for objectively minor offenses. Companies are limited in their ability to push back against government enforcement positions for fear that doing so may prompt enforcement officials to invoke their exclusion option. The result has been an ever-increasing spiral of large penalties paid by health care companies based on alleged infractions whose legitimacy is never tested in court.

By taking the threat of exclusion off the table in cases in which the company has implemented a compliance program, companies would no longer feel constrained not to turn to the courts to resolve good-faith disagreements regarding, for example, the scope of the False

Claims Act. Such litigation would serve everyone's interests. Most importantly, it would allow the courts to arrive at definitive interpretations of such statutes as the False Claims Act. More than anything else, companies seek clear guidance regarding what they can and cannot do so that they can do their best to conform their conduct to the law in advance. Once courts have construed each of the relevant federal statutes, one can reasonably expect compliance by the health care industry.

Trustworthiness Is the Key

Exclusion is a forward-looking remedy. It is not a punishment for bad acts but rather a measure undertaken to protect federal health care programs from future bad acts. It is difficult to see how any company that has undertaken a good-faith effort to implement an acceptable compliance program could ever be deemed untrustworthy. Thus, taking exclusion off the table for companies that have implemented such a program is not tantamount to giving a "free pass" to lawbreakers. Rather, it is a realization that trustworthiness can be demonstrated by one's good-faith efforts to comply with the law, and that such companies cannot be deemed any sort of threat to the integrity of federal health care programs. Some sort of penalty may be appropriate for companies that, despite the best efforts of senior management, end up being held responsible for infractions committed by their employees, but exclusion is not an appropriate penalty.

Fair Treatment for Individual Company Officials

HHS's Federal Register notice asks whether "there should be differences in the [exclusion] criteria for individuals and entities." The answer depends on what the individual is charged with. If the individual knowingly violates clear federal statutes and regulations, then it

is appropriate to treat him more harshly than his employer, whose senior officials may have been unaware of the violations. On the other hand, OIG should use identical criteria when considering exclusion for entities and individuals not directly complicit in the infractions. So long as both the company and the individuals had implemented (or followed) a good-faith compliance program, neither should be subject to exclusion proceedings. OIG acted unfairly in a number of instances in the past, imposing lengthy exclusions on senior executives under the "responsible corporate officer" doctrine despite evidence that the executives neither participated in nor had knowledge of wrongdoing. WLF urges HHS to adopt new guidance making clear that such exclusions will cease and that executives will be treated no more harshly than the companies they led.

Conclusion

WLF applauds HHS for undertaking this re-examination of its exclusion criteria and urges it to adopt reforms along the lines outlined above.

Sincerely,

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/s/ Mark S. Chenoweth
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