

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

James A. Holland, M.D.,  
(OI File No. 2-07-40490-9),

Petitioner

v.

The Inspector General.

Docket No. C-10-445

Decision No. CR2169

Date: June 29, 2010

**DECISION**

I sustain the determination of the Inspector General (I.G.) to exclude Petitioner, James A. Holland, M.D., from participating in Medicare and other federally funded health care programs for a period of 15 years.

**I. Background**

Petitioner is a physician. The I.G. informed Petitioner that he had determined to exclude him from participating in Medicare and other federally funded health care programs for 15 years. The I.G. advised Petitioner that his exclusion was mandatory because Petitioner had been convicted of a criminal offense that falls within the reach of section 1128(a)(2) of the Social Security Act (Act). Additionally, the I.G. asserted aggravating factors exist, which justified imposing an exclusion of 15 years, 10 years longer than the minimum mandatory five-year exclusion period for exclusions imposed for convictions that fall within any of the subparts of section 1128(a).

Petitioner requested a hearing to challenge the I.G.'s determination, and the case was assigned to me for a hearing and a decision. At my direction, each party submitted a brief. The I.G. also submitted five proposed exhibits, which he designated as I.G. Ex. 1 – I.G. Ex. 5, and he filed a reply brief as well. Petitioner submitted a single proposed

exhibit, which he designated as P. Ex. A. I re-identify P. Ex. A as P. Ex. 1, and I receive into the record I.G. Ex. 1 – I.G. Ex. 5 and P. Ex. 1. Neither party offered proposed testimony nor did a party request an in-person hearing.

## **II. Issues, Findings of Fact and Conclusions of Law**

### **A. Issues**

The issues in this case are whether:

1. Petitioner was convicted of a crime for which exclusion is mandated by section 1128(a)(2) of the Act; and
2. The I.G.'s determination to exclude Petitioner for 15 years is reasonable.

### **B. Findings of Fact and Conclusions of Law**

I make the following findings of fact and conclusions of law (Findings).

- 1. Petitioner was convicted of a crime as is defined by section 1128(a)(2) of the Act.***

Section 1128(a)(2) of the Act mandates the exclusion of any individual:

that has been convicted, under Federal or State law, of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service.

The facts of this case unequivocally establish that Petitioner was convicted of such an offense. On April 24, 2007, a one count criminal information was issued against Petitioner in the United States District Court for the Northern District of New York. I.G. Ex. 3. Petitioner was charged with the crime of failing to maintain accurate records in violation of 21 U.S.C. §§ 331(e) and 333(a)(1). *Id.*; I.G. Ex. 5 at 1.

The information alleged that Petitioner was in charge of leading, supervising, managing, conducting, and coordinating clinical trials and studies at the Stratton VA Medical Center in New York. I.G. Ex. 3 at 9. It alleged that he wrongfully and unlawfully failed to establish and maintain adequate and accurate case histories of some patients who were being administered investigational drugs in the studies that Petitioner led. *Id.* at 9-10. The investigational drugs were certain medications that were being administered as

treatments for cancer. Specifically, the information asserted that case histories generated under Petitioner's control included materially false documentation and information that a subordinate employee provided that enabled persons who did not qualify under the study protocol to be enrolled as study subjects. *Id.* at 10. It alleged further that Petitioner:

had the responsibility, authority, and duty to ensure that adequate and accurate case histories were maintained and [to] promptly detect and correct inadequate and inaccurate case histories, but wrongfully and unlawfully failed to do so, including by failing to review or check the accuracy of . . . case histories and reports of laboratory analysis, electrocardiograms, ejections fraction testing, radiology reports, surgical reports, and operative and progress notes.

*Id.* The information cited as an example an individual who Petitioner caused to be administered certain anti-cancer drugs based on documents and records that the subordinate employee made. These documents, according to the information, falsely stated and represented the results of blood chemistry analysis and, on the basis of these false results, purported that the patient met the criteria for inclusion in the study conducted under Petitioner's authority. *Id.* at 10-11. In fact, the results did not meet these criteria and showed impaired kidney and liver function. According to the information, Petitioner did not review the actual report of laboratory analysis or check the accuracy of documents that his subordinate prepared and thus administered the anti-cancer drugs to an individual who was not qualified to receive them. The information recited that the patient died after administration of the anti-cancer drugs. *Id.* at 11.

On April 24, 2007, Petitioner entered a plea agreement, agreeing to plead guilty to the information. As part of the plea agreement, Petitioner specifically admitted to all of the facts contained in the information, which I have recited. I.G. Ex. 4. A judgment of conviction was entered against Petitioner on March 27, 2009. I.G. Ex. 5 at 1.

The elements of a crime that falls within the meaning of section 1128(a)(2) are as follows. An individual must be: convicted of a criminal offense; relating to neglect or abuse of a patient; and in connection with the delivery of a health care item or service.

Petitioner was "convicted," because he pled guilty to the criminal information. A guilty plea is defined as a conviction by section 1128(i)(3) of the Act. The conviction related to neglect or abuse of a patient. While Petitioner was convicted of improper medical records maintenance, there can be no doubt that it related to patient neglect. The term "neglect" includes any act by a health care provider that criminally violates applicable standards of professional care. Here, Petitioner caused, or allowed, false patient records to be created in a setting in which patients' safety and welfare depended on the maintenance of accurate records. That is neglect of patients under any definition, and it certainly comprises a violation of a professional standard requiring that a physician ensure that his or her patients' records are maintained accurately and honestly. Finally,

the neglect was committed in connection with the delivery of a health care item or service, because the patients whose records were falsified were sick individuals who were enrolled in a study of drugs that were being used to treat their illnesses.

Petitioner's sole defense is to dispute the accuracy of the criminal information "notwithstanding the fact that . . . [he] concedes that he did enter a misdemeanor plea on April 24, 2007 before the United States District Court for the Northern District of New York to violating Title 21, United States Code, Sections 331(e) and 333(a)(1)." Petitioner's Brief at 2. In other words, Petitioner's defense is that he is not actually guilty of the crime to which he pled guilty.

I have no authority to consider that defense. The exclusion requirement of section 1128(a)(2) of the Act derives from a conviction of the type of crime described in the section and not, strictly speaking, from the underlying facts. Consequently, I am not permitted to reopen a conviction and to decide independently whether an excluded individual is actually guilty of the crime of which he or she was convicted.

## ***2. An exclusion of 15 years is reasonable.***

The Act mandates an exclusion for at least five years of any individual who is convicted of an offense as section 1128(a)(2) defines. Act § 1128(c)(3)(B). In this case, the I.G. determined to exclude Petitioner for 15 years. That raises the issue of whether the length of the exclusion is reasonable.

Regulatory criteria exist, which must be used for determining the reasonableness of any non-mandatory exclusion. For exclusions that are imposed pursuant to section 1128(a)(2), those criteria are stated at 42 C.F.R. § 1001.102(b) and (c). They are described as potentially aggravating and mitigating factors. Evidence that relates to an aggravating factor may be considered as a basis for lengthening an exclusion beyond the five-year minimum period. Evidence that relates to a mitigating factor may be considered as a basis for reducing the length of an exclusion, but not below the statutory minimum five-year period.

The aggravating and mitigating factors function very much like rules of evidence. Evidence that relates to one of these factors may be considered in deciding whether an exclusion is reasonable. However, nothing in the regulations assigns weight to evidence that relates to an aggravating or mitigating factor. It is left to the trier of fact to decide the weight that ought to be given to relevant evidence. Nor does the regulation prescribe a formula for deciding the reasonableness of an exclusion. Thus, the presence of x number of aggravating factors does not result, automatically, in an exclusion of y duration.

What must be decided in any case where the reasonableness of an exclusion is at issue is the trustworthiness of an excluded provider to provide care to program beneficiaries and recipients of program funds. Evidence that relates to an aggravating or mitigating factor is relevant to deciding that issue. Evidence that does not relate to an aggravating or mitigating factor is irrelevant and may not be considered in deciding trustworthiness. The ultimate question that must be decided is: what does evidence relating to an aggravating or mitigating factor say about the trustworthiness of the excluded provider?

The I.G. contends that evidence exists in this case that is relevant to three of the regulatory aggravating factors. I find that there is evidence that is relevant to two, but not all three, of the aggravating factors that the I.G. cites.

First, the I.G. asserts that the acts that resulted in Petitioner's conviction caused a financial loss to one or more entities of \$5,000 or more. 42 C.F.R. § 1001.102(b)(1). The evidence unequivocally sustains this allegation. Petitioner's sentence included the requirement that he pay restitution of \$502,925.05 for the damages that his criminal neglect caused. I.G. Ex. 5 at 4.

Second, the I.G. argues that the acts that resulted in Petitioner's conviction, or similar acts, were committed over a period of one year or more. 42 C.F.R. § 1001.102(b)(2). The evidence also unequivocally supports this allegation. Petitioner pled guilty to criminal negligence that began on or about May 14, 1999 and which continued to on or about July 10, 2002. I.G. Ex. 4 at 12.

Third, the I.G. contends that the acts that resulted in Petitioner's conviction, or similar acts, had a significant adverse physical, mental, or financial impact on one or more program beneficiaries or other individuals. 42 C.F.R. § 1001.102(b)(3). The I.G. asserts that Petitioner caused an individual to be given an experimental anti-cancer medication that was contraindicated in light of that individual's medical condition. I.G. Ex. 3 at 11; I.G. Ex. 4 at 13. This criminal neglect, according to the I.G., caused the death of the patient. *See Id.*

However, neither the criminal information, Petitioner's plea agreement, nor any other exhibit establishes that Petitioner actually caused the death of a patient. The information and the plea agreement recite only that the patient who received contraindicated medication subsequently died. I.G. Ex. 3 at 11; I.G. Ex. 4 at 13. Both documents avoid drawing the conclusion that the contraindicated medication actually caused the patient's death. I am not persuaded, therefore, that the evidence establishes that Petitioner's criminal neglect caused actual harm to an individual.

However, the evidence relating to the two aggravating factors that the I.G. established provides ample support for the 15-year exclusion that the I.G. determined to impose. The extraordinarily large restitution that Petitioner was ordered to pay in this case is a measure of the damage that Petitioner's criminal neglect caused. Clinical trials of anti-

cancer medication were rendered worthless as a consequence of that neglect, establishing Petitioner to be highly untrustworthy to deal with program funds and the beneficiaries and recipients of those funds. The fact that the trials were rendered worthless meant, potentially, that valuable time was lost in developing drugs that might treat cancer more effectively. The fact that Petitioner's criminal neglect extended over a period of more than three years is further proof of his untrustworthiness, because it shows Petitioner's sustained and criminal failure to comply with professionally recognized standards of care.

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Steven T. Kessel  
Administrative Law Judge