Depatment of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
James H. Holmes, M.D.,	DATE: June 7, 1993
Petitioner,	Docket No. C-93-010 Decision No. CR270
- v.-	
The Inspector General.	

DECISION

On October 15, 1992, the Inspector General (I.G.) notified Petitioner that he was being excluded from participation in the Medicare and State health care programs for three years.[1] The I.G. told Petitioner that he was being excluded under section 1128(b)(3) of the Social Security Act (Act), based on Petitioner's conviction of a criminal offense related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

Petitioner requested a hearing and the case was assigned to me. On December 29 and 30, 1992, I held a hearing in Sacramento, California. On January 22, 1993, during the period that the posthearing briefing schedule was in progress, the Secretary published regulations containing provisions described as a clarification of the exclusion regulations published January 29, 1992. I invited the parties to address the issue of the impact of these clarifying regulations on this case in their posthearing briefs.

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[1] "State health care program" is defined by section 1128(h) of the Social Security Act to cover three types of federally financed health care programs, including Medicaid. Unless the context indicates otherwise, I use the term "Medicaid" hereafter to represent all State health care programs from which Petitioner was excluded.

The parties subsequently filed posthearing briefs and reply briefs. In his posthearing reply brief, Petitioner indicated that he did not contest the authority of the I.G. to exclude him pursuant to section 1128(b)(3) of the Act, but he contended that the duration of the three-year exclusion is excessive under the circumstances of this case.

Each party submitted a proposed exhibit with their posthearing submissions. By letter dated March 17, 1993, I established a schedule which provided the parties the opportunity to object to the admissibility of the proposed exhibits and to reply to any objections.

Both parties subsequently filed objections to the exhibits and the I.G. filed a reply to Petitioner's objections. For reasons explained in Part I of this decision, I deny both parties' motions to admit these exhibits into evidence.

I have carefully considered the evidence that I admitted at the hearing, the parties' arguments, and the applicable regulations. I conclude that the three-year exclusion imposed and directed by the I.G. is reasonable pursuant to the criteria specified in 42 C.F.R. § 1001.401.

ADMISSION

Petitioner does not dispute that he was convicted of a criminal offense within the meaning of section 1128(b)(3) of the Act. He admits that the I.G. has the authority to exclude him from participating in the Medicare and Medicaid programs. Petitioner Posthearing Reply Brief at 3-4.

ISSUE

Whether it is reasonable to exclude Petitioner for a period of three years.

FINDINGS OF FACT AND CONCLUSIONS OF LAW (FFCLs)

1. Petitioner is a medical doctor who has been engaged in the private practice of medicine since 1976. Tr. at 199.[2]

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[2] The exhibits and the transcript of the hearing will be referred to as follows:

(continued...)

2. On November 13, 1991, a misdemeanor complaint was filed in the San Joaquin Municipal Court by the California Attorney General's Office against Petitioner. I.G. Ex. 2.

3. The complaint charged Petitioner with eight counts of willfully and unlawfully prescribing Tylenol with Codeine No. 3, to an undercover operator, without legitimate medical purpose and while not acting in the usual course of his professional practice. I.G. Ex. 2.

4. Tylenol with Codeine No. 3 is a controlled substance. Tr. at 43.

5. On January 6, 1992, Petitioner pled guilty to one count in the complaint. The court accepted the plea and sentenced Petitioner to "three years probation on the condition he complete 108 hours of community service, pay $6,500 for cost of investigation, not prescribe for future indications, and not prescribe without a medical diagnosis." I.G. Ex. 4.

6. Petitioner was convicted of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance within the meaning of section 1128(b)(3) of the Act. FFCLs 2-5.

7. The Secretary delegated to the I.G. the authority to determine, impose, and direct exclusions pursuant to section 1128 of the Act. 48 Fed. Reg. 21,662 (1983).

8. By letter dated October 15, 1992, the I.G. excluded Petitioner pursuant to section 1128(b)(3) of the Act for a period of three years.

9. The I.G. has authority to impose and direct an exclusion pursuant to section 1128(b)(3) of the Act. FFCLs 6-7.

10. Regulations published on January 29, 1992 establish criteria to be employed by the I.G. in determining to impose and direct exclusions pursuant to sections 1128(a) and (b) of the Act. 42 C.F.R. Part 1001 (1992).

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[2](...continued)

Hearing Transcript	Tr. at (page)
Petitioner Exhibits	P. Ex. (number at page)
I.G. Exhibits	I.G. Ex. (number at page)

11. The regulations published on January 29, 1992 include criteria to be employed by the I.G. in determining to impose and direct exclusions pursuant to section 1128(b)(3) of the Act. 42 C.F.R. § 1001.401.

12. On January 22, 1993, the Secretary published a regulation which directs that the criteria to be employed by the I.G. in determining to impose and direct exclusions pursuant to sections 1128(a) and (b) of the Act are binding also upon administrative law judges, appellate panels of the Departmental Appeals Board, and federal courts in reviewing the imposition of exclusions by the I.G. 42 C.F.R. § 1001.1(b); 58 Fed. Reg. 5617, 5618 (1993).

13. My adjudication of the length of the exclusion in this case is governed by the criteria contained in 42 C.F.R. § 1001.401. FFCLs 10-12.

14. An exclusion imposed pursuant to section 1128(b)(3) of the Act must be for a period of three years, unless aggravating or mitigating factors specified in the regulations form a basis for lengthening or shortening that period. 42 C.F.R. § 1001.401(c)(1).

15. The I.G. has the burden of proving that aggravating factors exist which justify increasing an exclusion imposed pursuant to section 1128(b)(3) of the Act beyond the three-year benchmark established by regulation. 42 C.F.R. § 1001.401(c)(2)(i)-(iv); 42 C.F.R. § 1005.15(c).

16. The I.G. did not allege that any aggravating factors specified in the regulations are present in this case.

17. Petitioner has the burden of proving that mitigating factors exist which justify reducing an exclusion below the three-year benchmark established by regulation. 42 C.F.R. § 1001.401(c)(3)(i)-(ii); 42 C.F.R. § 1005.15(c).

18. Petitioner alleged that, as a result of his exclusion, alternative sources of the type of health care items or services that he furnishes are not available within the meaning of 42 C.F.R. § 1001.401(c)(3)(ii). Petitioner Posthearing Brief at 4-5.

19. Petitioner did not allege that any other mitigating factors specified in the regulations are present in this case.

20. Petitioner's office is located in the city of Stockton. Tr. at 62.

21. The nature of Petitioner's medical practice is general and family practice. The types of medical problems he treats are diabetes, hypertension, minor heart problems, sore throats, and fevers. The majority of his patients are adults. Tr. at 178, 216-17.

22. Petitioner has more than 3,000 patients under his care. Tr. at 265. Prior to his exclusion, approximately 65 percent of Petitioner's patients were either Medicare or Medicaid patients. P. Ex. 6; Tr. at 167-68, 268.

23. There are approximately 600 physicians in the Stockton area. Tr. at 245.

24. Approximately 55 physicians or clinics in the Stockton area specialize in general and family practice. I.G. Ex. 14 at 18-19.

25. There are at least five private practitioners specializing in Petitioner's area of general and family practice in the Stockton area who have expressly indicated a willingness to accept new Medicare and Medicaid patients. At least four of these practitioners are located within a six-mile radius of Petitioner's office. Tr. at 145-49, 150, 248, 288, 290.

26. The record is devoid of evidence showing that Petitioner's former Medicare and Medicaid patients have been unable to establish a long term treatment relationship with a general or family practitioner in the Stockton area.

27. The fact that some of Petitioner's former Medicare and Medicaid patients have been unable to make an appointment with a physician at the time that they asked for one is not a basis for finding that these patients were unable to establish a long term treatment relationship with a physician. Tr. at 187-88, 287-88.

28. There are several emergency care facilities which treat Medicare and Medicaid patients located within a seven-mile radius of Petitioner's office which are available to treat medical conditions requiring immediate attention at a time that a patient is unable to obtain medical care from a personal physician. Tr. at 62, 287-88.

29. Given the general nature of Petitioner's practice, there is no basis for limiting consideration of the availability of alternative sources of health care to only general and family practitioners.

30. An endocrinologist who comes to Petitioner's office to treat Petitioner's former Medicare and Medicaid patients on a temporary basis is an alternative source of medical care for these patients until they can establish a long term treatment relationship with a physician. Tr. at 170-71, 175, 186, 201.

31. The evidence fails to establish that obtaining access to alternative sources of medical care would create an unreasonable hardship for Petitioner's former patients.

32. Petitioner has not proved that his race is an essential component of the type of medical items or services he delivers.

33. The Secretary did not intend that an otherwise reasonable exclusion be reduced because a provider's patients might be forced to obtain medical care from other comparable sources.

34. Petitioner failed to prove that alternative sources of the type of health care items or services that he furnishes are not available.

35. Petitioner did not prove the presence of any mitigating factors under 42 C.F.R. § 1001.401(c)(3).

36. There is no basis under the regulations for me to modify the three-year exclusion which the I.G. imposed against Petitioner.

37. The three-year exclusion which the I.G. imposed is reasonable pursuant to the criteria specified in 42 C.F.R. § 1001.401.

RATIONALE

Petitioner does not dispute that he was convicted of a criminal offense within the meaning of section 1128(b)(3) of the Act and that the I.G. has authority to exclude him from participating in the Medicare and Medicaid programs. What is at issue here is whether it is reasonable to exclude Petitioner for a period of three years. On January 29, 1992, the Secretary published regulations which, among other things, establish criteria to be employed by the I.G. in determining the length of exclusions imposed pursuant to section 1128(b)(3) of the Act. 42 C.F.R. § 1001.401. In considering the issue of the reasonableness of the length of the exclusion, the

threshold question is whether these regulations apply to this case.

I. I am required to apply 42 C.F.R. § 1001.401 in adjudicating the length of the exclusion in this case.

Prior to the January 29, 1992 regulations, when determining whether the length of an exclusion was reasonable, administrative law judges usually evaluated an excluded party's "trustworthiness" in order to gauge the risk that a party might pose in terms of the harm Congress sought to prevent when it enacted section 1128. Appellate panels of the Departmental Appeals Board (DAB) have approved the use of the term "trustworthiness" as a shorthand term for those cumulative factors which govern the assessment of whether a period of exclusion imposed by the I.G. is reasonable. Hanlester Network, et al., DAB 1347, at 45-46 (1992).

The January 29, 1992 regulations create substantive changes in the law with respect to the imposition of exclusions. For example, the January 29, 1992 regulations establish a benchmark of three years for all exclusions imposed pursuant to section 1128(b)(3) of the Act. 42 C.F.R. § 1001.401(c)(1). In addition, the regulations specifically preclude consideration of factors for either lengthening or shortening an exclusion imposed pursuant to section 1128(b)(3) which are not identified by the regulation as either "mitigating" or "aggravating". 42 C.F.R. § 1001.401(c)(2), (c)(3). It is undisputed that the January 29, 1992 regulations alter the substantive rights of Petitioner because they limit the mitigating factors that can be considered in Petitioner's favor and would bar Petitioner from presenting evidence which is relevant to trustworthiness to provide care.[3]

Subsequent to the publication of the January 29, 1992 regulations, administrative law judges issued a series of decisions, all of which held that the Secretary did not intend these regulations to govern administrative law judge decisions as to the reasonableness of exclusion determinations. Bertha K. Krickenbarger, R.Ph., DAB CR250 (1993); Charles J. Barranco, M.D., DAB CR187

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[3] Moreover, 42 C.F.R. § 1001.401 limits my consideration of aggravating factors to those specifically mentioned therein, and so could, under the appropriate scenario, impair the I.G.'s ability to demonstrate that a petitioner is deserving of a lengthy exclusion.

(1992); Narinder Saini, M.D., DAB CR217 (1992). The Krickenbarger decision held specifically that section 1001.401 of the regulations, governing the I.G.'s exclusion determinations under section 1128(b)(3) of the Act (which is at issue here also), did not apply in administrative hearings concerning such exclusions. In addition, an appellate panel of the Departmental Appeals Board (DAB) held that the January 29, 1992 regulations do not retroactively apply in cases involving exclusion determinations made prior to the regulations' publication date. Behrooz Bassim, M.D., DAB 1333, at 5-9 (1992).

The present case does not involve an issue of retroactive application of regulations, because the exclusion determination is dated October 15, 1992, which is subsequent to the publication of the January 29, 1992 regulations. Therefore, the question before me is whether the Secretary intended these regulations to apply as criteria for adjudication of the length of exclusions at the level of administrative hearings.

Throughout this proceeding, the I.G. has consistently maintained the position that 42 C.F.R. § 1001.401 establishes criteria by which exclusions must be adjudicated at hearings before administrative law judges. The I.G. contends that none of the factors identified as aggravating or mitigating in section 1001.401 of the regulations are present in this case, and, therefore, the regulations require that I sustain the three-year exclusion. Tr. at 6-8.

Petitioner contends that one of the mitigating factors specified in the January 29, 1992 regulations at 42 C.F.R. § 1001.401(c)(3)(ii) applies to this case. He alleges that, as a result of his exclusion, alternative sources of the type of health care items or services that he furnishes are not available. Petitioner Posthearing Brief at 4-5. I permitted both parties to present evidence on this factor at the hearing.

In addition, Petitioner contends that factors related to his trustworthiness to provide care which are not specified in the regulations should be considered in determining the reasonableness of the length of his exclusion. Tr. at 13-15, 17-18. At the hearing, I permitted both the I.G. and Petitioner to present evidence as to Petitioner's trustworthiness to provide care. My ruling permitting such evidence was based on the body of decisions issued by administrative law judges which interpreted the regulations. As of the time that I held the hearing in December 1992, these decisions holding that the regulations did not apply as criteria

for review of exclusions at the administrative hearing level constituted the Secretary's final interpretation of the regulations. Thus, I allowed the parties free rein to offer evidence at the hearing concerning Petitioner's trustworthiness to provide care, as well as evidence which falls within the ambit of the factors enumerated in 42 C.F.R. § 1001.401(c).

On January 22, 1993, the Secretary published regulations containing provisions which are described as a clarification of the scope and purpose of the exclusion regulations published January 29, 1992. These regulations state in part that:

> The regulations in . . . [Part 1001] are applicable and binding on the Office of Inspector General (OIG) in imposing and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG . . .

58 Fed. Reg. 5618 (to be codified at 42 C.F.R. § 1001.1(b)). Interpretive comments to these new regulations emphasize that the exclusion determination criteria contained in Part 1001 must be applied by administrative law judges in evaluating the length of exclusions imposed and directed by the I.G.

The clarification was made applicable to cases which were pending on January 22, 1993, the clarification's publication date. 58 Fed. Reg. 5618. It is undisputed that the present case was pending on January 22, 1993.

I must now apply to this case the criteria for determining the length of exclusions set forth in 42 C.F.R. § 1001.401. In this case, the I.G. imposed the three-year benchmark exclusion and contended that no aggravating or mitigating factors specified in the regulations are present. Citing the mitigating circumstance identified at 42 C.F.R. § 1001.401(c)(3)(ii), Petitioner asserts that the exclusion is unreasonable because alternative sources of the type of health care items or services he furnishes are not available. At issue is whether a reduction of the three-year exclusion is justified in this case on the grounds that alternative sources of the type of health care items or services furnished by Petitioner are not available.

Inasmuch as the evidence adduced at the hearing concerning Petitioner's trustworthiness to provide care

does not fall within the ambit of this factor, I may no longer consider it as relevant to my decision concerning the length of the exclusion. Therefore, I make no findings concerning that evidence.[4] I do so notwithstanding the body of administrative law judge decisions which found that the January 29, 1992 regulations do not establish criteria for administrative law judges' review of exclusions. The January 22, 1993 clarification overruled those decisions, and it overruled my ruling in this case that evidence which related to Petitioner's trustworthiness is relevant to my determining whether the exclusion is reasonable.[5]

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[4] For example, Petitioner presented the testimony of character witnesses who testified as to his trustworthiness to provide care. In addition, Petitioner testified as to his motivation for his wrongdoing. He stated that he was not motivated to unlawfully prescribe controlled substances for personal gain. Instead, he explained that he prescribed the controlled substances because he wanted to be a "good guy". Petitioner asserted that he honestly believed that the patient who received the unlawful prescription had pain from time to time and Petitioner did not want the patient to have to incur the expense of making repeated office visits. Tr. at 275, 278. Petitioner averred also that he had learned to avoid making the errors in judgment that resulted in his conviction. Tr. at 215. Had I been permitted to rely on this evidence, it might have served as a basis to reduce the exclusion. On the other hand, Petitioner admitted that he falsified his medical records when it appeared that his prescribing records might be questioned by investigators. Tr. at 274. This evidence of Petitioner's lack of trustworthiness might have served as a basis to find that the three-year exclusion is consistent with the Act's remedial purpose, had I been permitted to rely on it.

[5] A clarifying point must be made here. In cases where evidence is adduced establishing the existence of an aggravating or a mitigating factor, the regulations do not provide a clear analytic guideline that can be used to determine the weight to be given such evidence in evaluating the reasonableness of an exclusion. Consequently, in my opinion, a limited "trustworthiness" analysis should be applied in such circumstances. Thus, the evidence establishing any such factor should be evaluated to determine the length of time that is necessary for a petitioner to no longer pose a threat to the Medicare and Medicaid programs and whether the length

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Attached to the I.G.'s posthearing brief was a copy of an Accusation filed against Petitioner by the Medical Board of the State of California.[6] The I.G. moved that I admit this document into evidence. This document was not presented timely by the I.G. pursuant to the schedule that I established for the exchange of exhibits. However, the I.G. showed extraordinary circumstances justifying the failure to timely exchange this document prior to the hearing. The hearing in this case took place on December 29, 1992 and the I.G. avers that he was not aware of the existence of this document, which is dated December 22, 1992, until after the hearing.

The I.G. contends that if I decide that the former standard of trustworthiness continues to apply in determining the reasonableness of the exclusion, then this document is relevant as evidence of the seriousness of the criminal offense underlying Petitioner's exclusion. I deny the I.G.'s motion to admit this document for this purpose because such standard of trustworthiness does not apply to this case. Alternatively, the I.G. argues that this document is relevant as further evidence of the I.G.'s authority to exclude. I deny the I.G.'s motion to admit this document for this purpose because the issue of the I.G.'s authority to exclude is not in dispute. Accordingly, I deny the I.G.'s motion to admit this document on the grounds that it is not relevant to my decision in this case. Since this document is irrelevant and therefore not admissible into evidence, I need not consider the

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[5](...continued)
of the exclusion is "extreme or excessive" in light of the nature of such threat. For example, if Petitioner had established the lack of available alternative sources of medical care and the I.G. was able to counter such mitigation by providing the existence of one or more aggravating factors, then I would use the above limited "trustworthiness" analysis to determine the length of the exclusion. However, even under this approach, neither the I.G. nor Petitioner would be permitted to offer evidence of other indices of trustworthiness outside the ambit of the enumerated factors set forth in the regulations. The regulations as recently clarified no longer allow application of the former general standard of trustworthiness.

[6] The I.G. originally identified this document as "Attachment A." By letter dated March 19, 1993, the I.G. resubmitted this document as I.G. Ex. 21. I will identify this document as I.G. Ex. 21.

question of whether its admission would cause substantial prejudice to Petitioner.

Petitioner submitted a proposed exhibit subsequent to the hearing and moved that I admit it into evidence.[7] While Petitioner does not directly state why this document is relevant, it appears that he is using it to attempt to minimize the seriousness of his offense under the former standard of trustworthiness. I deny Petitioner's motion. This exhibit was not presented timely pursuant to the schedule I established for the exchange of exhibits and Petitioner offered no explanation for his failure to timely exchange it. Furthermore, this exhibit is not relevant to the mitigating circumstance regarding the availability of alternative sources of medical care, specified in 42 C.F.R. § 1001.401(c)(3)(ii), which is in dispute.

II. A three-year exclusion is reasonable pursuant to the regulatory criteria set forth at 42 C.F.R. § 1001.401.

Having determined that I am bound by the January 29, 1992 regulations, I must evaluate the evidence in this case under the regulatory criteria set forth in 42 C.F.R. § 1001.401. The I.G. imposed the three-year benchmark exclusion and contends that none of the factors for either lengthening or shortening an exclusion identified by the regulation as either aggravating or mitigating are present in this case. Petitioner contends that there are circumstances defined by the regulations as mitigating which justify reduction of the exclusion imposed against him. He asserts that the weight of the evidence establishes that alternative sources of the type of health care items or services which he provides are not available, citing the mitigating circumstance identified in 42 C.F.R. § 1001.401(c)(3)(ii).

A. The standard to be applied in interpreting 42 C.F.R. § 1001.401(c)(3)(ii) is evident from the language of the regulations, their context, the preamble to the regulations, and Congress' purpose in enacting the exclusion law.

The mitigating factor identified at 42 C.F.R. § 1001.401(c)(3)(ii), that alternative sources of the type of health care items or services furnished by the individual or entity are not available, is not defined by

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[7] Petitioner identified this document as "Attachment A." I will identify this document as P. Ex. 8.

the regulations. However, the meaning of this mitigating factor is evident from the language of the regulations, their context, the preamble to the regulations, and Congress' purpose in enacting the exclusion law.

In the absence of a regulatory definition of this factor, the words describing this mitigating factor should be given their common and ordinary meaning. The word "alternative" is defined in the Random House Dictionary of the English Language, 2d Edition (1987), as "affording a choice of two or more things, propositions, or courses of action." "Available" is defined as "suitable or ready for use or service; at hand." I conclude from these common definitions that in order for the mitigating circumstance in 42 C.F.R. § 1001.401(c)(3)(ii) to apply, the evidence must show that alternative sources (sources that can be chosen instead) of the type of health care furnished by an excluded provider are not available (suitable or ready for use or service).

Looking at the phrase "alternative sources" in this context, it is evident that the Secretary contemplated that the alternative sources would take the place of or be a substitute for the type of health care provided by the excluded provider. I conclude from this that in order to qualify as an "alternative source" within the meaning of the regulations, the alternative source must provide health care items or services that are comparable or equivalent in quality to the type of items or services provided by the excluded provider. The alternative source must be able to substitute for the items or services furnished by the excluded provider without jeopardizing the health of the recipients of those items or services.

Guidance as to the meaning of the phrase "not available" can be found from language contained in the preamble to the January 29, 1992 regulations. The preamble states:

> Comment: Proposed §§ 1001.201 through 1001.801 provided that it will be a mitigating factor if alternative sources of the type of health care items or services furnished by the excluded individual or entity are not available. A number of commentators believe that the regulations should be modified to state that it will be mitigating if alternative sources are not reasonably available.
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> Response: We believe this is implicit in the regulations. The purpose of this mitigating factor is to protect program beneficiaries, and if services are not reasonably available to them then, as a

> practical matter, they are not available. Of course in evaluating the factor, we will look to whether there are service providers who accept Medicare and Medicaid patients, rather than merely whether services are available generally.

57 Fed. Reg. 3315-3316 (1992).

As the preamble states, the alternative sources of health care items or services of the type furnished by the excluded individual or entity are not available if such sources are not reasonably available. The phrase "not reasonably available" contemplates that an alternative source is not available in circumstances where Medicare and Medicaid patients are not able to reasonably obtain the type of medical services provided by the excluded provider in a practicable manner consistent with the Secretary's objective to protect program beneficiaries and recipients from being deprived of needed health care as a result of a provider's exclusion. Under this standard, even if an alternative source of health care is identified as being present to provide the type of health care provided by the excluded provider, the alternative source would not be "available" within the meaning of the regulations if, as a practical matter, program beneficiaries and recipients cannot reasonably obtain the alternative health care.

On the other hand, merely showing that the consequence of an exclusion is a reduction in the availability of items or services is not tantamount to showing that those items or services are not reasonably available. Certainly, any provider could show that health care services to program beneficiaries and recipients are less available because the provider is excluded. However, in order for the mitigating factor at 42 C.F.R. § 1001.401(c)(3)(ii) to apply, there must be a showing that a consequence of an exclusion is a reduction in health care services to the point that obtaining alternative sources of health care imposes an unreasonable hardship on Medicare and Medicaid beneficiaries and recipients. This is a far more stringent test to meet than showing merely a reduction in the availability of health care.

In addition, the language in the preamble emphasizes that reasonable availability of alternative sources of health care must be viewed in the context of the Medicare and Medicaid programs. Alternative sources of health care items or services of the type furnished by the excluded provider are not reasonably available if Medicare and Medicaid beneficiaries and recipients cannot avail themselves of the alternative sources of health care.

For example, it does little good for a Medicare or Medicaid patient to go to an alternative health care provider if that provider does not participate in the Medicare and Medicaid programs. What matters to Medicare and Medicaid patients is to have alternative sources available to them.

For additional guidance as to the meaning of 42 C.F.R. § 1001.401(c)(3)(ii), it is instructive to look at the purpose of the exclusion law.

In 1987, Congress amended section 1128 of the Act by enacting the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, 101 Stat. 680. These amendments significantly expanded the authorities under which the Secretary could exclude individuals and entities from the Medicare and Medicaid programs. The purpose of the 1987 amendments is to protect the beneficiaries and recipients of federally funded health care programs from incompetent practitioners and from inappropriate or inadequate care. S. Rep. No. 109, 100th Cong., 1st Sess. 1, reprinted in 1987 U.S.C.C.A.N. 682.

The legislative history of the 1987 amendments suggests that the Secretary (or the Secretary's delegate, the I.G.) should consider the following factors in setting the duration of exclusions under section 1128(b):

> In the case of all exclusions other than those under 1128(a) and 1128(b)(12), the Committee intends that, in setting the period of exclusion, the Secretary will take into consideration such factors as the seriousness of the offense, the impact of both the offense and the exclusion on beneficiaries, and any mitigating circumstances, such as the availability of alternate providers of needed health care services.

S. Rep. No 109, 100th Cong., 1st Sess. 12 (emphasis added.), reprinted in 1987 U.S.C.C.A.N. 693. The January 29, 1992 regulations implemented the provisions of the 1987 amendments to section 1128. Congress' intention that the availability of alternate providers be considered in setting the duration of the length of exclusions under section 1128(b) is embodied in the regulations at 42 C.F.R. § 1001.401(c)(3)(ii), which provide that a showing that "[a]lternative sources of the type of health care items or services furnished by the individual or entity are not available" may be considered as a basis for shortening a period of exclusion.

In view of the fact that the purpose of the exclusion law is to protect Medicare and Medicaid beneficiaries and recipients from providers who render inappropriate or inadequate care, the regulation at 42 C.F.R. § 1001.401(c)(3)(ii) contemplates that the factfinder, in determining the appropriate duration of an exclusion, will consider the government interest in ensuring the protection of Medicare and Medicaid beneficiaries and recipients and balance that interest against the competing government interest in ensuring that Medicare and Medicaid beneficiaries recipients will not be deprived of needed health care as a result of a provider's exclusion.

B. Petitioner has the burden of proving mitigating circumstances, including the burden of proving that alternative sources of health care items or services of the type he provides are not available.

The regulations at 42 C.F.R. § 1001.401 do not allocate specifically the parties' respective burdens of proof in establishing the existence of aggravating and mitigating factors. Instead, section 1005.15(c) of the regulations expressly reserves the duty of allocating the burden of proof in cases governed by 42 C.F.R. § 1001.401 to administrative law judges. I conclude that it is logical and consistent with the language and structure of the regulations to place the burden of proving mitigating circumstances on Petitioner, including the burden of proving that alternative sources of the type of health care he furnishes are not available.

It is plain from the language and structure of 42 C.F.R. § 1001.401(c) that the Secretary intended the mitigating circumstances identified in those regulations to be in the nature of affirmative defenses to the imposition of a three-year exclusion that would otherwise be mandated by the regulations.[8] Logically, the burden should fall on excluded parties to prove the existence of affirmative reasons for imposing less than regulation-mandated minimum exclusions. It does not make practical sense to require the I.G. to prove a negative -- the absence of

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[8] The regulations allow excluded parties to aver also that mitigating circumstances exist to offset aggravating circumstances that might otherwise be used by the I.G. to justify imposing exclusions which exceed the minimum exclusion periods prescribed by the regulations. 42 C.F.R. § 1001.401(c).

mitigating circumstances -- in cases where he has imposed the regulation-mandated minimum exclusion.

Furthermore, my decision to place on Petitioner the burden of proof for establishing the presence of mitigating circumstances is consistent with the burdens which have been established in exclusions imposed under section 1128 of the Act prior to the promulgation of the regulations. An appellate panel of the DAB held in such a case that there is a "general principle that a petitioner has the burden of proving factors which would tend to reduce the exclusion period." Bernardo G. Bilang, M.D., DAB 1295, at 10 (January 27, 1992). In addition, placing the burden on Petitioner to establish the presence of mitigating circumstances is consistent with the burdens that have been established in other kinds of cases in which exclusion is the remedy. For example, in certain other kinds of cases brought under the Act, the non-federal party has the burden of proving the presence of mitigating circumstances which would justify reduction of a penalty, an assessment, or an exclusion. 42 C.F.R. § 1005.15(b).

C. Petitioner has not met his burden of proving that by virtue of his exclusion, alternative sources of the type of health care items or services that he provides are not available.

Based on my review of the evidence of record, I conclude that Petitioner has failed to sustain his burden of proving that alternative sources of the type of health care he provides are not available.

Petitioner is a medical doctor who has been engaged in the private practice of medicine since 1976. FFCL 1. The nature of his medical practice is general and family practice. The types of medical problems he treats are diabetes, hypertension, minor heart problems, sore throats, and fevers. The majority of his patients are adults. FFCL 21. His office is located in the city of Stockton. FFCL 20. Petitioner has more than 3,000 patients under his care. Prior to his exclusion, approximately 65 percent of Petitioner's patients were either Medicare or Medicaid patients. FFCL 22.

Evidence adduced at the hearing shows that there are approximately 600 physicians in the Stockton area. FFCL 23. Moreover, the yellow pages of the Stockton telephone directory lists approximately 55 physicians and clinics holding themselves out to the public as specializing in "Family and General Practice." I.G. Ex. 14 at 18-19. This evidence shows that medical care is available in the

Stockton area and that there are a substantial number of physicians and clinics in the area which engage in the same type of medical practice as Petitioner.

The preamble to the regulations indicates that in evaluating the availability of alternative sources of health care pursuant to 42 C.F.R. § 1001.401(c)(3)(ii), the Secretary contemplates that the factfinder "will look to whether there are service providers who accept Medicare and Medicaid patients, rather than merely whether services are available generally." 57 Fed. Reg. 3316. Evidence as to the availability of family and general practice medical services to Medicaid and Medicare patients was adduced at the hearing.

The I.G. submitted a computer printout, obtained from the California Department of Health Services (CDHS), which identifies physicians whose offices are located in the same zip code area as Petitioner and who are active Medicare and Medicaid providers. I.G. Ex. 11; Tr. at 65-70. In addition, the physicians are identified on the printout by physician specialty codes which are listed in another document produced by the I.G. I.G. Ex. 13. According to the testimony of Petitioner's office assistant, the zip code area in which Petitioner's office is located has a radius of less than a mile. Tr. at 156-57. The I.G. asserts that this evidence shows that there are at least 13 Medicare and Medicaid providers who practice family and general medicine within a mile of Petitioner's office. I.G. Posthearing Brief at 27. The I.G. contends that by enrolling as a provider of services in the Medicare and Medicaid programs, a physician indicates a willingness to treat the beneficiaries and recipients of such programs. I.G. Posthearing Brief at 31. In addition, the I.G. adduced evidence showing that there are several medical clinics within a few miles of Petitioner's office in the Stockton area which accept Medicare and Medicaid patients. Tr. at 358-65.[9]

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[9] At the hearing, a witness for the I.G. offered testimony in which he stated that approximately three miles or less from Petitioner's office there were four medical clinics which accept Medicare and Medicaid patients. Tr. at 358-65. At page 5 of his posthearing reply brief, Petitioner alleged that some of these clinics were up to seven miles from Petitioner's office. He did not cite any support for his assertion. However, even assuming for the sake of argument that Petitioner's unsupported assertions are correct, it is undisputed that there are several medical clinics within a seven-mile

(continued...)

Evidence adduced at the hearing shows also that there are three hospital emergency room facilities which accept Medicare and Medicaid patients. One of these hospital emergency room facilities is located within walking distance to Petitioner's office, and the other two are within a seven-mile radius of Petitioner's office. Tr. at 62, 287-88.

Petitioner contends that the Medicare and Medicaid provider enrollment statistics produced by the I.G. have limited significance because enrollment statistics do not guarantee that all those enrolled in the Medicare and Medicaid programs do, in fact, accept new patients. Petitioner Posthearing Reply Brief at 7.[10] In addition, Petitioner does not dispute that the Stockton area has medical clinics and hospital emergency room facilities which accept Medicare and Medicaid patients. He argues, however, that treatment rendered at these facilities is not a comparable alternative to the type of treatment he provides to his patients. In essence, he argues that the personal relationship and bond that develops between a patient and his physician is an integral component of the quality of medical care provided by a private practitioner. He states that he has medical records of some patients spanning more than a decade and that he can treat not only the physical ailments of a patient, but also his underlying needs. He asserts that hospital emergency rooms and medical clinics are not geared to providing this type of ongoing care and treatment and that they do not maintain the personalized records which are mandatory to providing this specialized care. Petitioner Posthearing Brief at 9.

Even if I frame this inquiry with the limitations urged by Petitioner, the record contains evidence showing that there are alternative sources of health care available in the Stockton area. I assume, for the sake of argument, that Petitioner is correct in his assertion that a provider's willingness to accept Medicare and Medicaid

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[9](...continued)
radius of Petitioner's office.

[10] Petitioner also takes issue with the accuracy of the provider enrollment information supplied by CDHS. During his testimony, Petitioner mentioned several perceived inaccuracies. Tr. at 233-37. However, the only inaccuracy he mentioned in his posthearing reply brief was that one of the 13 listed providers is retired. Petitioner Posthearing Reply Brief at 6.

patients cannot be inferred from provider statistics alone. In addition, I assume, for the sake of argument, that Petitioner is correct in his assertion that medical care provided by hospital emergency rooms and medical clinics is not comparable to a long term treatment relationship with a personal physician. Even operating under these assumptions, the record shows that there are several private practitioners specializing in Petitioner's area of general and family practice in the Stockton area who have offered specific assurances that they will accept new Medicare and Medicaid patients. In fact, Petitioner's own witnesses have identified five such practitioners.

One of Petitioner's witnesses, the Executive Director of the San Joaquin Medical Society, testified that based on the Society's most current information, there are three general practitioner physicians in the Stockton area who accept new Medicare or Medicaid patients: Dr. Newman, Dr. Boettger, and Dr. Punla. Tr. at 248, 261.

Another of Petitioner's witnesses, his office assistant, testified that on the day before the hearing she called the offices of all the names of individual physicians listed under "family and general practice" in the yellow pages of the Stockton telephone directory and asked whoever answered the phone if the physician would accept new Medicaid patients. Petitioner's office assistant stated that she was informed that three general practitioner physicians would accept new Medicaid patients: Dr. Newman, Dr. Tanson, and Dr. Barber. Tr. at 145-47, 150. Thus, evidence adduced by Petitioner's own witnesses shows that there are at least five general and family practice physicians in the Stockton area who have expressly indicated a willingness to accept new Medicare or Medicaid patients.[11] The record shows also

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[11] While each witness gave the names of three physicians who accept Medicare or Medicaid patients, Dr. Newman was mentioned twice. In addition, I note that one of the I.G.'s witnesses testified that there is another general practitioner, Dr. Buckingham, who has a large Medicare and Medicaid practice which is located approximately one mile from Petitioner's office. This witness testified that he was unsure if Dr. Buckingham was accepting new Medicare and Medicaid patients. Tr. at 96-98.

that at least four of these physicians are located six miles or less from Petitioner's office.[12]

While Petitioner does not dispute that there are at least five physicians practicing general and family medicine in the Stockton area who are willing to accept new Medicare or Medicaid patients, he asserts that "there are not enough physicians similarly situated to fill the void left by [Petitioner's] revocation from participation." Petitioner Posthearing Reply Brief at 11. Petitioner has the burden of proving this assertion, and he has not presented any evidence to support it. Unsubstantiated conclusory statements of this type are not sufficient to sustain Petitioner's burden of proof. While Petitioner argues that "there are really only a very limited number of doctors available to take on all of the patients form[er]ly treated by Petitioner," he does not provide any evidence showing that the general and family practitioners who are willing to accept new Medicare or Medicaid patients are unable to absorb Petitioner's Medicare and Medicaid caseload. Petitioner Posthearing Reply Brief at 8.

The Executive Director of the San Joaquin Medical Society testified that some of Petitioner's former Medicare and Medicaid patients called his office and requested the names of alternative physicians who would accept Medicare and Medicaid patients and these patients were referred to Dr. Newman, Dr. Boettger, and Dr. Punla. Significantly, this witness testified that, as far as he knew, none of Petitioner's patients called back to report that they had been unable to find a doctor to treat them. Tr. at 261.

Petitioner's office assistant testified that approximately 30 of Petitioner's former Medicare and Medicaid patients have called her office to complain that they were unable to make an appointment with another doctor at the time that they needed a doctor. Petitioner's office assistant stated that she responded to these calls by referring the former patients to Dr. Newman or Dr. Tanson and that as far as she knows, these

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[12] Dr. Newman is between four to six miles from Petitioner's office. Tr. at 148-49, 290. Dr. Barber is between two to five miles from Petitioner's office. Tr. at 148, 290. Dr. Boettger is four miles from St. Joseph's Hospital which is less than one-half mile from Petitioner's office. Tr. at 248, 288. Dr. Tanson is approximately one mile from Petitioner's office. Tr. at 290.

patients either went to these doctors or received treatment at hospital emergency rooms. Tr. at 187-88.

The record is devoid of evidence showing that Petitioner's former Medicare and Medicaid patients have been unable to establish a long term treatment relationship with a personal physician. While there is evidence that a small percentage of Petitioner's Medicare and Medicaid patients have been unable to obtain an appointment with a private physician at the time that they asked for one, there is no evidence that this occurred repeatedly to these individuals. No physician can guarantee that he or she will always be available to see patients whenever they call for an appointment. The fact that some of Petitioner's former patients had to wait to see a physician is not a basis for finding that they were unable to establish a treatment relationship with the physician. In addition, it is undisputed that there are emergency care facilities available in the Stockton area in situations where a patient has a medical problem requiring immediate attention at a time when a personal physician is unable to see a patient.

Furthermore, the evidence fails to establish that obtaining access to alternative sources of medical care creates an unreasonable hardship for Petitioner's former Medicare and Medicaid patients. The evidence shows that at least four of the five physicians specializing in general and family practice who expressly indicated a willingness to treat Medicare and Medicaid patients are located within six miles of Petitioner's office. One of these, Dr. Tanson, is only one mile from Petitioner's office. In addition, there are several emergency care facilities located within a seven-mile radius of Petitioner's office, and one hospital emergency room is only one half mile from his office. The evidence fails to establish that Petitioner's patients would be forced to travel unreasonably long distances to obtain medical care.

The record shows also that Petitioner's office is on a bus line, and that approximately one-third of Petitioner's patients travel by bus to Petitioner's office. Tr. at 179. Two of Petitioner's former Medicare and Medicaid patients testified that Petitioner's office is conveniently located for them because they are able to use a bus to get to his office. Tr. at 382, 386. While Petitioner's office has the advantage of being on a bus line, the evidence of record does not show that Petitioner's former patients would be <u>unable</u> because of a

lack of transportation to obtain alternative medical care.[13]

The burden of proving that alternative sources of health care are unavailable is on Petitioner. While Petitioner emphasizes that his office is conveniently located because it is on a bus line, there might be alternative sources of medical care which also are on a bus line. Petitioner has not shown that there are no alternative sources of medical care in Stockton which are on a bus line. Even assuming, for the sake of argument, that he is the only source of medical care in Stockton that is on a bus line, Petitioner must then show that being forced to use a different mode of transportation to obtain comparable medical care would create an unreasonable hardship for his patients. I accept that, in some instances, the unavailability of public transportation might inconvenience Petitioner's patients. Inconvenience, however, is not the standard to be used in applying the mitigating factor under 42 C.F.R. § 1001.401(c)(3)(ii). The standard to be applied is whether alternative sources are not reasonably available. There must be a showing that the absence of public transportation would not only inconvenience patients, but that it would be so impractical that it would create a barrier to obtaining access to alternative sources of medical care. Petitioner has made no such showing in this case.

Moreover, the record shows that Petitioner is attempting to accommodate the needs of his patients by making available to them an alternative source of medical care located in his own office. Petitioner's office assistant testified that, in addition to referring Petitioner's former Medicare and Medicaid patients to Dr. Newman and Dr. Tanson, who are both general and family practitioners, she referred them also to a physician named Dr. Faidi. Tr. at 170-71, 175. Dr. Faidi is an endocrinologist who is enrolled in the Medicare and Medicaid programs. Tr. at 186, 201. Petitioner testified that Dr. Faidi recently opened his own medical practice and he is trying to build it up. Since he is not very busy, he has agreed to see Petitioner's former Medicare and Medicaid patients. Tr. at 201. Dr. Faidi has his own practice at a different location, but he comes into Petitioner's office on a part-time basis to

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[13] Indeed, although one witness stated that she did not drive, she indicated that she could get a ride with friends and that her husband had a car and drives. Tr. at 383-84.

see Petitioner's former Medicare and Medicaid patients. Tr. at 171, 175.

While Dr. Faidi has a specialty in endocrinology, there is no evidence that he is not qualified to treat the types of medical conditions Petitioner treats. Indeed, it can be inferred from the fact that Petitioner allows Dr. Faidi to come to his office to treat his former patients that he views Dr. Faidi as being able to provide competent medical care which will not jeopardize the health of his patients. Given the general nature of Petitioner's practice, there is no basis for limiting consideration of the availability of alternative sources of health care to only general and family practitioners.

Petitioner testified that he did not expect his arrangement with Dr. Faidi to continue on a permanent basis. Tr. at 201. However, even if this arrangement continues for only a short period of time, the medical treatment provided by Dr. Faidi is an alternative source of medical care at least until Petitioner's patients establish a long term treatment relationship with another physician.

Petitioner's office assistant testified that Petitioner's Medicare and Medicaid patients are not happy that Petitioner is no longer treating them. She testified that many of Petitioner's patients are trying to wait before changing doctors and that those who have seen Dr. Faidi "don't care for him too much." Tr. at 171, 186. The fact that some of Petitioner's patients are not pleased with having to change doctors and elect not to avail themselves of the opportunity to be treated by another physician is not a basis for finding that alternative sources of medical care are not available. In addition, the fact that some of the patients who have used the services of other physicians still would prefer to be treated by Petitioner is not a basis for finding that alternative sources of medical care are not available. There must be an affirmative showing that the services rendered by the other physicians cannot be substituted for the services of the excluded provider without jeopardizing the health and safety of Petitioner's patients.

Petitioner argues also that as a Black family practitioner, he has an awareness of the problems associated with being an ethnic minority in a city which is as racially diverse as Stockton. Citing statistics for San Joaquin County which show high mortality rates for Black babies, high numbers of children born to teenage mothers, and high per capita rates of welfare

dependency, Petitioner contends that as a Black family practitioner he is particularly qualified to provide health services which meet the needs of the community. Petitioner Posthearing Brief at 6; Tr. at 11, 13. Petitioner acknowledges that 35 percent of his patients are Caucasian. Notwithstanding this, he argues that the 65 percent of his patients who are not Caucasian have special needs that need to addressed by a Black family practitioner. Petitioner Posthearing Reply Brief at 7. While Petitioner does not dispute that there are three other Black family practitioners who are willing to take Medicare and Medicaid patients, he argues that they are unable to handle all of Petitioner's minority patients. He points out that one of them is under criminal investigation and that the other two "have fairly large practices of their own." Petitioner Posthearing Reply Brief at 6.[14]

Petitioner's argument is unpersuasive. Petitioner cites statistics which are not in evidence to support his argument. Even if I were to accept that the problems Petitioner identifies do exist, he does not provide any evidence to support his assertion that, as a Black family practitioner, he is uniquely qualified to address these problems.[15] Although it is possible that a Black family practitioner may have an awareness of what it means to be part of an ethnic minority group, this does not mean that Petitioner's minority patients would not be able to receive comparable medical treatment from a physician who is not a Black family practitioner. In order for race to be relevant as a basis for limiting the consideration of the availability of alternative sources of medical care, Petitioner must demonstrate that being a Black family practitioner is an essential component of the medical items or services he delivers. He has made no such showing in this case. Moreover, even assuming for the sake of argument that the race of one's physician is

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[14] While Petitioner does not specifically refer to the three Black physicians by name, the record shows that Dr. Tanson, Dr. Newman, and Dr. Buckingham are Black. Tr. at 96, 178-79, 260. In addition, the record shows that one of the three physicians has been criminally indicted for involvement in an automobile accident fraud ring, but that he is still practicing medicine. Tr. at 370.

[15] It is noteworthy that the Executive Director of the San Joaquin Medical Society testified that none of Petitioner's former patients specifically asked to be referred to a Black physician. Tr. at 260.

relevant, Petitioner has proffered no evidence showing that other Black physicians in the community are not available to treat Petitioner's patients. Merely asserting that they have "fairly large practices of their own" is not sufficient to show that they are unavailable to provide medical care.

Petitioner argues that he is the "sole source of essential specialized services" in his community because he has a longstanding treatment relationship with many of his patients, spanning almost two decades. He asserts that he is "one" with the patients he treats and that he is their primary source of medical, physical, and emotional care. According to Petitioner, no other physician "can offer the same services to [his] patients because that bond took years to develop." Petitioner Posthearing Brief at 5, 9-10.[16]

What Petitioner is saying, in essence, is that no medical alternative is sufficient because it is not his care. It goes without saying that on some level the medical care provided by every physician is unique and cannot be exactly duplicated by other physicians. Certainly, the regulations do not contemplate that alternative sources of care means care that is rendered under exactly the

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[16] Although Petitioner argues that he is the "sole source of essential specialized services" in the community he serves, this is not the appropriate test to be applied as a mitigating factor for exclusions under section 1128(b)(3) of the Act. As the I.G. points out, an excluded provider's being a "sole source of essential specialized services in a community" may be the basis upon which a State may request a waiver from the I.G. of an exclusion under the mandatory provisions of section 1128(a) of the Act. 42 C.F.R. § 1001.1801(b). At pages 8-9 of his posthearing brief, Petitioner refers to guidance furnished in the preamble to the regulations on the issue of "sole community physicians." This reference is inapplicable because the "sole community physician" standard also relates to circumstances under which a State may seek, and the I.G. may grant, a waiver of an exclusion under section 1128(a) of the Act. 42 C.F.R. § 1001.1801(b). Moreover, since these standards are grounds for a waiver of exclusion rather than merely a reduction of its length, it is reasonable to conclude that, if they were to apply to this case, Petitioner would have to meet even more stringent tests on the issue of the availability of other providers than is required under 42 C.F.R. § 1001.401(c)(3)(ii).

same circumstances as that given by the excluded provider. Otherwise, the Secretary would not have used the word "alternative". Under Petitioner's reading of the regulation, the mitigating factor in section 1001.401(c)(3)(ii) would apply in every case, and remove the need for a review process altogether. The Secretary did not intend that an otherwise reasonable exclusion be reduced because a provider's patients might be forced to obtain medical care from other comparable sources during the period of the exclusion.

Petitioner has not shown that there exist mitigating circumstances as defined by 42 C.F.R. § 1001.401(c)(3). Accordingly, there is no justification to modify the three-year exclusion which the I.G. imposed and directed against Petitioner.

CONCLUSION

I conclude that the three-year exclusion which the I.G. imposed and directed against Petitioner is reasonable, pursuant to the criteria specified in 42 C.F.R. § 1001.401.

/s/

Edward D. Steinman
Administrative Law Judge