Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:

DATE: December 8, 1992

Robert L. Alexander, M.D.,

Petitioner,

Docket No. C-255

Decision No. CR244

- v.
The Inspector General.

DECISION

This case is governed by section 1128 of the Social Security Act (Act). By letter dated February 21, 1990 (Notice), the Inspector General (I.G.) notified Petitioner that he was being excluded from participation in Medicare and all federally funded State health care programs for a period of 15 years. The I.G. informed Petitioner that his exclusion resulted from his conviction of a criminal offense related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. The I.G. further advised Petitioner that exclusions from the Medicare and Medicaid programs after such a conviction are authorized by section 1128(b)(3) of the Act (42 U.S.C. § 1320a-7(b)).

By letter dated June 12, 1990, Petitioner requested a hearing before an Administrative Law Judge (ALJ), and the case was assigned to me for hearing and decision.

I have considered the evidence of record, the parties' arguments, and the applicable law. I conclude that the I.G. had authority to exclude Petitioner, that the

[&]quot;State health care program" is defined by section 1128(h) of the Act to include three types of federally assisted programs, including State plans approved under Title XIX of the Act (Medicaid). Unless the context indicates otherwise, I use the term "Medicaid" in this decision to represent all State health care programs from which Petitioner was excluded.

15-year exclusion imposed and directed by the I.G. is excessive, and that an exclusion for 10 years is reasonable under the circumstances of the case.

BACKGROUND

In September 1988, Petitioner was convicted in federal court, by jury trial, on 12 of 15 counts brought against him.² I.G. Ex. 21 at 10/5.³ The conviction included one count of conspiracy to distribute eight controlled substances and eleven counts of distributing or aiding and abetting the distribution of four of those controlled substances.⁴ I.G. Ex. 13. Petitioner was sentenced to several concurrent four-year terms of imprisonment, a \$25,000 fine, and a three-year special parole term. Petitioner's case is now on remand.⁵ I.G. Ex. 14.

³ In addition to specific documentary references in the text of this decision, the record of this case will be cited as follows:

I.G.'s Exhibits	I.G. Ex. (number at page or
	at volume/page)
I.G.'s Brief	I.G. Br. at (page)
I.G.'s Reply Brief	I.G. R.Br. at (page)
Petitioner's Exhibits	P. Ex. (number at page)
Petitioner's Brief	P. Br. at (page)

I use the phrase "controlled substances" here to refer to those drugs included in the Federal Drug Enforcement Administration (DEA) Schedules 1-5. These drugs are controlled because they have potential for abuse, causing either physical or psychological addiction. I.G. Ex. 21 at 5/70.

Petitioner's first trial on the drug-related charges was in 1986 and ended in a mistrial. He was then tried and acquitted on charges of obstruction of justice. The instant proceeding arises out of Petitioner's conviction at his second trial on the drug-related charges.

The record in this case includes two orders from the United States Court of Appeals for the Sixth Circuit -- No. 90-1248, dated October 5, 1990 and No. 90-1525, dated July 2, 1991, which remanded Petitioner's case to the district court because of its failure to receive evidence on Petitioner's disorder. P. Exs. 18-19. By affidavit dated August 19, 1992, Petitioner stated that his new trial was still pending. P. Ex. 20.

Petitioner began his prison term on January 3, 1989, served 23 months of his sentence in prison and in a half-way house, and is currently on parole through December 31, 1996.

At the time of the above-described offenses, Petitioner was a physician licensed in the State of Michigan and serving his residency at Providence Hospital in Detroit, Michigan. Petitioner moonlighted part time as a physician at a "weight loss" clinic for approximately six months during 1982. The evidence adduced at Petitioner's federal court trial indicated that, during the course of his employment at the "weight loss" clinic, he wrote prescriptions for various controlled substances under illegal circumstances and these prescriptions were sold to drug dealers and drug addicts. See generally, I.G. Ex. 21.

On August 3, 1990 (as reaffirmed on remand by order dated August 21, 1992), the State of Michigan Department of Commerce Board of Medicine (Michigan Board) revoked Petitioner's license to practice medicine. I.G. Ex. 24.

As stated above, the I.G. issued his Notice on February 21, 1990 and Petitioner filed his hearing request on June 12, 1990. On August 23, 1990, the I.G. filed a Motion to Dismiss Petitioner's Request For Hearing (I.G.'s Motion to Dismiss), on the ground that the request was filed late without a showing of good cause for an extension. Petitioner filed a reply. I ruled that I would not decide the timeliness issue at that time. Order To Show Cause Why Petitioner's Request For A Hearing Should Not Be Dismissed Because Of Abandonment, at 1, dated April 26, 1991; Order and Notice of Hearing, at 1-2, dated October 23, 1991.

During the almost three years since the I.G.'s Notice was issued, Petitioner has asked for and has been granted several delays and continuances.

The parties submitted numerous exhibits or attachments with their briefs in this matter. In an Amended Prehearing Order (Amended PHO) at 3, dated April 17, 1992, I admitted into evidence what were at that time marked by the I.G. as I.G. Exhibits 1-12. Subsequent to that date I renumbered the I.G.'s exhibits and have admitted them into evidence as follows: I.G. Exhibits (I.G. Exs.) 1-9 are those documents that the I.G. filed with his motion to dismiss dated August 23, 1990. I.G. Exs. 10-21 are those documents that the I.G. filed as proposed exhibits 1-12 and which I admitted into evidence on April 17, 1992. I.G. Exs. 22-24 are documents that

the I.G. filed with his brief in support of the exclusion, dated September 25, 1992. Also, I have renumbered Petitioner's exhibits and have admitted them into evidence as follows. On July 28, 1992, Petitioner submitted proposed exhibits lettered A through H, plus also unnumbered portions of transcripts from Petitioner's April 15, 1992 and May 6, 1992 hearings before the Michigan Board. These exhibits were not properly numbered. Petitioner's Exhibits (P. Exs.) 1-3 are documents filed with Petitioner's response to the I.G.'s motion to dismiss, dated September 6, 1990. P. Exs. 4-16 are documents Petitioner filed as proposed exhibits on July 28, 1992. P. Ex. 17 is the Scrutchions' affidavit, dated August 25, 1992. P. Exs. 18-19 are orders from the United States Court of Appeals for the Sixth Circuit remanding the case to the district court. See note 5, supra. P. Ex. 20 is Petitioner's affidavit, which states that his new trial was still pending.

In a conference call on August 10, 1992, Petitioner waived his right to an in-person hearing if his only witness, Patricia Scrutchions, his parole officer, were allowed to submit an affidavit. The I.G. did not object to proceeding without an in-person hearing. I admitted that affidavit (P. Ex. 17) into evidence by letter dated August 27, 1992 and also ruled that this case will be decided based on the written record.

<u>ADMISSIONS</u>

Petitioner admits that he was "convicted" of a crime, that he was incarcerated in a federal prison for that crime for 23 months, and that his conviction related to the illegal sale of a controlled substance. Amended PHO at 2-3. Based on this admission, I found that Petitioner had been "convicted" within the meaning of section 1128(i) of the Act and that Petitioner was convicted of a crime relating to the "distribution, prescription, or dispensing of a controlled substance" within the meaning of section 1128(b)(3) of the Act. Amended PHO at 3.

<u>ISSUES</u>

- 1. Whether the new regulations published on January 29, 1992 govern the disposition of this case.
- 2. Whether Petitioner's request for a hearing before an ALJ was filed timely or whether Petitioner established "good cause" for filing untimely.

3. Whether the 15-year exclusion imposed by the I.G is reasonable and appropriate.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Having considered the entire record, the arguments, and the submissions of the parties, and being advised fully, I make the following Findings of Fact and Conclusions of Law (FFCLs):

- 1. I reaffirm each and every prehearing ruling and FFCL.
- 2. This proceeding is governed by section 1128 and especially subsection 1128(b)(3) of the Act.
- 3. The regulations concerning time limitations for filing appeals of exclusion determinations (to be codified at 42 C.F.R. § 1005.2(c), published at 57 Fed. Reg. 3298, 3350 on Jan. 29, 1992), were not intended to apply retroactively to appeals of I.G. exclusion determinations that were pending before ALJs at the time the regulations were published.
- 4. The regulations concerning permissive exclusion proceedings brought under section 1128(b)(3) of the Act (to be codified at 42 C.F.R. Part 1001, published at 57 Fed. Reg. 3298 et seq. on Jan. 29, 1992) were not intended to apply retroactively to proceedings which began before the regulations were published.
- 5. Petitioner's hearing request, filed June 12, 1990, was not timely filed.
- 6. According to applicable regulations, "good cause" occurs where unusual or unavoidable factors beyond a party's control prevent him from filing in a timely manner. Cf. 20 C.F.R. § 404.911.
- 7. Petitioner has shown "good cause" for submitting a late request for a hearing based on the cumulative circumstances of his medical condition, his incarceration, and his pro se and in forma pauperis status at the time he received the Notice.

Some of my statements in the sections preceding these formal findings and conclusions are also FFCLs. To the extent that they are not repeated here, they were not in controversy.

- 8. Petitioner is granted an extension of time to file his hearing request, and the request for a hearing is granted. The I.G.'s Motion to Dismiss is denied.
- 9. Petitioner, Robert L. Alexander, M.D., was licensed by the State of Michigan to practice medicine. In 1982, he worked as a resident at Providence Hospital in Detroit, Michigan. I.G. Ex. 21.
- 10. Petitioner was convicted of a criminal offense within the meaning of sections 1128(i) and 1128(b)(3) of the Act. Amended PHO at 3.
- 11. The I.G. had authority to exclude Petitioner from participation in the Medicare and Medicaid programs pursuant to the permissive exclusion provision of section 1128(b)(3) of the Act.
- 12. The remedial purpose of section 1128 of the Act is to protect federally financed health care programs and their beneficiaries and recipients from providers who have demonstrated by their conduct that they cannot be trusted to handle program funds or treat beneficiaries and recipients.
- 13. The serious nature of Petitioner's violations is reflected in the fact that they involve a criminal conviction on one count of conspiracy to distribute eight controlled substances and eleven counts of distributing or aiding and abetting the distribution of four of those controlled substances. I.G. Ex. 13.
- 14. It is an aggravating factor that Petitioner was sentenced to several concurrent four-year terms of imprisonment, fined \$25,000, and paroled on a three-year special parole term. I.G. Ex. 14.
- 15. It is an aggravating factor that the Michigan Board revoked Petitioner's license to practice medicine and imposed a \$50,000 fine which must be paid before Petitioner can apply for reinstatement of his license. I.G. Ex. 24.
- 16. An exclusion is needed in this case to satisfy the remedial purposes of the Act.
- 17. It is a neutral factor that Petitioner's crimes were not directly related to the Medicare or Medicaid programs.

- 18. Petitioner suffers from a medical condition, a chronic bipolar disorder, which manifests itself with symptoms of manic depression. P. Exs. 5, 7, and 16.
- 19. Petitioner has received continuous treatment for his disorder since he entered prison in 1989, and his prognosis is fair to good if he continues to receive medication and therapy. P. Ex. 8.
- 20. Petitioner has been involved in community volunteer services since his release from prison and has complied with the terms of his parole.
- 21. Petitioner acknowledges his actions and demonstrates remorse for them.
- 22. In light of the remedial purpose of section 1128(b)(3) and the progress Petitioner has made toward rehabilitation, a 15-year exclusion is unreasonable and excessive.
- 23. Under the circumstances of this case, the remedial considerations of the Act will be served by a ten-year exclusion.

DISCUSSION

I. The New Regulations Published On January 29, 1992 Do Not Govern The Disposition Of This Case.

On January 29, 1992, the Secretary published new regulations which effect both procedural and substantive changes with respect to exclusion cases. 42 C.F.R. Parts 1001-1007; 57 Fed. Reg. 3298 et seq. (new regulations). The I.G. argues that the new regulations should apply because they were effective upon publication. Petitioner has not addressed this issue.

In my April 17, 1992 Amended PHO, I found that the procedural aspects of the new regulations (Part 1005) should govern the conduct of the hearing and the substantive aspects of the former regulations (Part 1001) should apply to the issues in this case. An appellate panel of the Departmental Appeals Board (DAB) held on May 28, 1992 that the new regulations do not apply retroactively in cases such as this one, where the exclusion determination was made prior to the regulations' publication date. Behrooz Bassim, M.D., DAB 1333, at 5-9 (1992) (retroactive application would deprive petitioner of due process). Consistent with my

Amended PHO and the appellate panel's decision in <u>Bassim</u>, I find that, with respect to the timeliness of the request for hearing, the regulations at 42 C.F.R. § 498.40 -- not the new regulations at 42 C.F.R. § 1005.2(c) -- should apply because this issue affects the right of Petitioner to be heard. I also find that, with respect to the reasonableness of the length of the exclusion, my review is not governed by the new regulations' criteria for the I.G.'s determination of that matter and that 42 C.F.R. § 1001.401 of the new regulations was not intended by the Secretary to govern de novo hearings as to the reasonableness of the I.G.'s exclusion determinations. <u>See Anthony W. Underhill</u>, DAB CR231, at 12-13 (1992); <u>Willeta J. Duffield</u>, DAB CR225, at 9-13 (1992).

The I.G. did not rely on the new regulations at 42 C.F.R. § 1001.401(b) to determine the length of Petitioner's exclusion. But, he now argues that these criteria, published almost two years after his original Notice, are now binding on my de novo review.

The I.G. asserts that, as the new regulations were effective when they were published on January 29, 1992, they apply to any exercise of ALJ authority on and after that date. He argues that 42 C.F.R. § 1001.401 limits my review of the circumstances of this case to the specific aggravating and mitigating factors listed in the new regulations. Petitioner did not address the applicability of the new regulations to this case.

The issue of the applicability of the new regulations to cases pending when the regulations were published has been extensively considered by Administrative Law Judges of the DAB, including myself. Recently, in <u>Duffield</u> at 9-13, I found that the new regulations did not govern my review of an 1128(b)(3) case which was pending at the time the new regulations were published. In addition to relying on the <u>Bassim</u> holding with respect to application of the new regulations to pending cases, I found that:

[T]he plain language of section 1001.401 and the comments of Part 1001 indicate that this provision is to be applied to the I.G.'s determination only and does not control my determination in this case. Until an appellate panel interprets these regulations as the I.G. contends, I shall continue to apply them consistent with my obligation under the Act to consider a myriad of facts to determine the length of time necessary to establish that Petitioner is not likely to repeat the type of

conduct which precipitated the exclusion. [citation omitted].

Duffield at 12-13.

The above reasoning is equally applicable to the instant proceeding. I find that the application of the new regulations, and, in particular, the application of 42 C.F.R. § 1001.401 to this proceeding would materially alter Petitioner's substantive due process rights. The new regulations are not applicable because: (1) they were published after the date of the Notice; and (2) they are not binding on my de novo review of the reasonableness of the length of the exclusion imposed by the I.G.

II. Petitioner Has Established "Good Cause" Within The Meaning Of 42 C.F.R. § 498.40 For Not Timely Filing His Request For Hearing.

A. <u>Petitioner's Request For A Hearing Was Filed Untimely.</u>

Having concluded that the prior regulations govern this case, I must now apply those regulations to the facts at issue. As noted above, the applicable regulations require that a party requesting a hearing must file the request within 60 days from receipt of the letter from the I.G. notifying of the exclusion (Notice). 42 C.F.R. § 498.40(a)(2). However, 42 C.F.R. § 498.40(c)(2) provides that for "good cause shown" the ALJ to whom the case is assigned may extend the time for filing the hearing request.⁷

The I.G.'s Notice advising Petitioner of his exclusion is dated February 26, 1990. The records of the Federal Prison Camp (FPC) at Yankton, South Dakota, in which Petitioner was incarcerated at that time, show that the return-receipt for the Notice was signed by an agent of the FPC on March 8, 1990. Also, the official legal mail log of the FPC shows that Petitioner signed for an item

The new regulations also require filing a request within 60 days but do not specifically provide for an extension of the 60-day period based on "good cause." 42 C.F.R. § 1005.2(c), 57 Fed. Reg. 3350. Thus, there is a difference between the two regulations which could, in this proceeding, substantively affect the due process rights of Petitioner.

of mail from the Department of Health and Human Services, Washington, D.C., on March 10, 1990. I.G. Exs. 5 and 6. Petitioner requested a hearing by letter dated June 12, 1990, 94 days after he received the Notice.

Thus, the undisputed material facts establish that Petitioner did not timely file his hearing request.

B. <u>Petitioner Has Shown "Good Cause" For The</u> Untimely Filing Of His Hearing Request.

In his Memorandum In Support Of Motion To Dismiss, dated August 23, 1990, the I.G. argues that the case be dismissed pursuant to 42 C.F.R. § 498.70(c). More recently, in the I.G.'s brief, dated September 25, 1992, at 2, the I.G. specifically renews his motion to dismiss and incorporates by reference the August 23, 1990 brief and accompanying exhibits. Thus, the I.G. has not argued that the new regulations should apply on this issue. Therefore, I conclude that under the DAB ruling in Bassim, the new regulations do not apply to the issue of the timeliness of Petitioner's request for a hearing or whether Petitioner established "good cause" for not filing timely. I will consider Petitioner's request for a hearing under 42 C.F.R. § 498.40.

Since Petitioner did not file his hearing request within the 60-day period required by regulation, he is not entitled to a hearing before an ALJ. However, the applicable regulations establish circumstances where a petitioner may be granted a hearing, even though there is no right to one. In my discretion, I may extend the time for filing a hearing request upon written request for an extension stating the reasons the request was not timely filed and a showing of "good cause." 42 C.F.R. § 498.40(c).

While Petitioner does not dispute that his request for a hearing was untimely filed, he contends that he had "good cause." Petitioner argues that he was delayed in filing his hearing request because of the circumstances of his medical condition (manic-depressive bipolar mental illness and depression), his incarceration, and his prose and in forma pauperis status. See Petitioner's

This regulation provides, among other things, for dismissal of a hearing request on the motion of the ALJ or a party on the ground of failure to timely file the request. 42 C.F.R. § 498.70(c).

September 6, 1990 Response to the I.G.'s Motion to Dismiss.9

While the regulations do not define "good cause," ALJs at the DAB have looked to the examples of "good cause" set forth at the regulations governing Social Security disability hearings. 10 See John T. Clardy, M.D., DAB CR199, at 11 (1992) (proceeding dismissed for failure to establish "good cause"). These examples are enumerated at 20 C.F.R. §§ 404.911(b)(1)-(9) and include circumstances such as serious illness, receiving incorrect information regarding the request for review, the destruction of important records, failure to receive the notice, a good faith submission of the request to the wrong agency, and unusual or unavoidable circumstances preventing the individual from filing in a timely manner. These examples are not inclusive of the circumstances which would qualify for a "good cause" exemption, but they do establish a commonality indicating that "good cause" should be found when the circumstances preventing a timely filing are for reasons beyond the petitioner's Clardy at 11; see I.G. Ex. 8, David Cooper, control. R.Ph., DAB C-51, Order Denying I.G.'s Motion to Dismiss Request for Hearing, dated February 3, 1989 (imprisoned petitioner showed "good cause" due to lack of control over either his own affairs or prison mailing procedures and also due to his pro se status); I.G. Ex. 9, Rose Farias, M.D., Docket No.000-44-7-049 (SSA/OHA) (August 26, 1988) (no showing of "good cause" where respondent denied receipt of notice of exclusion although the notice was received by the respondent's agent at the address she normally received correspondence); see also David L. Golden, M.D., DAB CR55 (1989) (same holding as Farias).

In this case, there is persuasive evidence which leads me to conclude that Petitioner's failure to timely file was due to circumstances beyond his control. Petitioner has introduced several reports from physicians which establish that Petitioner has been diagnosed as having a bipolar disorder and has exhibited symptoms of manic-depressive disorder. P. Exs. 5 and 11. Bipolar disorder manifests itself through fluctuating periods of high

⁹ I accept Petitioner's Response as his written statement requesting an extension of time to file. The regulations do not require that the "good cause" statement be made at the same time as the request for hearing.

The Social Security disability case regulation governing "good cause" is 20 C.F.R. § 404.909(b).

energy and feelings of euphoria followed by periods of depression. While in prison, Petitioner was treated at the Federal Medical Center from April through June 1989 for the disorder. At that time, Petitioner received treatment for his disorder through a combination of medications. Id.; Petitioner's Response at 1. According to Dr. Joseph Daniels, Petitioner's psychiatrist, the disorder was only in partial remission in 1990, and "he was still suffering some problems." P. Ex. 16 (Deposition of Dr. Daniels at 11).

Petitioner also argues that while in prison his only income came from working for 11 cents an hour, for a total of \$13-\$14 a month. This, he states, made the required postage a major expense. In support, Petitioner introduced evidence that in 1989 a federal court found that Petitioner did "not have sufficient assets to enable him to retain appellate counsel" and granted him leave to proceed in forma pauperis. P. Ex. 2. Lastly, Petitioner states that he was incarcerated in prison at the time the Notice was received and did not have the assistance of counsel.

While none of these circumstances may have been persuasive standing alone, I find that, taken together, some of them establish "good cause." See I.G. Ex. 8, Cooper at 3-4. Petitioner received the Notice on March 10, 1990 and his request is dated June 12, 1990. Thus, his request is approximately one month late. Under the circumstances, it is not unreasonable to find that Petitioner was prevented from timely filing by a combination of forces beyond his control. Justice is not harmed by my exercise of discretion here. I accept Petitioner's "good cause" for failing to file timely, grant the extension of time, and accept the request for hearing. The I.G.'s Motion to Dismiss is denied.

See part IV.B. of this decision for a more complete discussion of Petitioner's disorder.

The I.G. alleges that Petitioner had an adequate income from Social Security and insurance disability payments. See my Order dated March 18, 1992 and Amended PHO at 2. Petitioner disputes this, contending that although he had an income, it went to support his family, and that his expenses exceeded his income. See Petitioner's letter dated March 24, 1992. I do not resolve this because my finding of "good cause" is not based on Petitioner's alleged lack of funds.

I emphasize that my finding here is based solely on the circumstances peculiar to this case. I do not find that pro se status, a disability, or incarceration, taken alone or under other circumstances, would sustain a finding of "good cause." Each case must be decided on its own merits.¹³

III. The I.G. Had The Authority To Exclude Petitioner Pursuant To Section 1128(b)(3) Of The Act.

Section 1128(b)(3) of the Act authorizes the I.G. to exclude from participation in the Medicare and Medicaid programs individuals or entities who have been "convicted, under Federal or State law, of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance."

The first criterion that must be satisfied to establish the I.G.'s authority to exclude Petitioner under section 1128(b)(3) of the Act is that Petitioner must be convicted of a criminal offense. Petitioner has admitted that he was convicted of a crime, and I have previously found that Petitioner was "convicted" of a criminal offense within the meaning of sections 1128(b)(3) and 1128(i)(3) of the Act. Amended PHO at 3.

The second criterion is that the criminal offense must relate to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. Petitioner has admitted that his conviction related to the illegal sale of a controlled substance, and thus I find that the second criterion is established. Id. Accordingly, I conclude that the I.G. was authorized to exclude Petitioner pursuant to section 1128(b)(3) of the Act.

In finding "good cause" based on the cumulative circumstances, I do not decide whether the medications Petitioner was taking at that time contributed to the delay as alleged by Petitioner or could not have affected his mental state as asserted by the I.G.

IV. The Remedial Purpose Of The Act Is Satisfied In This Case By A 10-Year Exclusion.

A. <u>Several Factors Are Relevant To Determining</u> Trustworthiness.

The exclusion laws are civil statutes designed to protect government financed health care programs from fraud and abuse by providers and to protect the beneficiaries and recipients of these programs from incompetence and dishonesty. 14 Exclusion is intended also to serve as a deterrent to future misdeeds. Congress did not, however, intend that exclusions from the Medicare and Medicaid programs be permanent; transgressors are meant to have an opportunity to rehabilitate themselves. Michelle Donaldson, D.P.M., DAB CR234, at 5 (1992). Thus, resolution of the reasonableness of Petitioner's 15-year exclusion depends on an analysis of the evidence of record in light of the remedial purposes of the Act. See id.; Arthur V. Brown, M.D., DAB CR226, at 9 (1992); Charles J. Burks, M.D., DAB CR54, at 8-9 (1989).

Therefore, in determining an exclusion, all of the circumstances should be considered. In performing this analysis, the following criteria have been found suitable by the DAB's ALJs for evaluating an excluded provider's trustworthiness and the appropriateness of the length of an exclusion: (1) the provider's degree of culpability and the seriousness of the offense; (2) the degree (if any) of the provider's willingness to place the programs in jeopardy (even if no actual harm resulted); (3) the provider's failure to admit misconduct, or express remorse, or demonstrate rehabilitation; and (4) the likelihood of future abuse. Donaldson at 5-6, citing Bhupandra Patel, M.D., DAB CR227 (1992), aff'd, DAB 1370 (1992).

In addition to the above indicia of trustworthiness, the appropriateness of an exclusion may be determined by assessing the following criteria which are incorporated

Congress enacted the exclusion law to protect the integrity of federally funded health care programs. Among other things, the law is designed to protect program beneficiaries and recipients from individuals who have demonstrated by their behavior that they threaten the integrity of the programs or that they can not be entrusted with the well-being and safety of beneficiaries and recipients. See S. Rep. No. 109, 100th Cong., 1st Sess. (1987), reprinted in 1987 U.S.C.C.A.N. 682.

in the regulations at 42 C.F.R. § 1001.125. regulations set forth criteria which have been used in setting the length of exclusions for program-related offenses. I may refer to these criteria -- but am not required to rely on them -- in determining the reasonableness of the length of the exclusion. factors include: (1) the number and nature of the offenses; (2) the nature and extent of any adverse impact the violations have had on beneficiaries; (3) the amount of the damages incurred by the Medicare or Medicaid programs; (4) whether there are any mitigating circumstances; (5) the length of the sentence imposed by the court; (6) any other facts bearing on the nature and seriousness of the program violations; and (7) the previous sanction record of the excluded party under the Medicare or Medicaid programs. These factors may be used by me as general guidance as to the type of evidence that may be relevant to determining a Petitioner's trustworthiness to be a health care provider. See, e.g., Eric Kranz, M.D., DAB 1286, at 11 (1991); Chander Kachoria, R.Ph., DAB CR220, at 13 (1992).

Finally, an appellate panel of the DAB, in adopting criteria previously outlined by ALJs in section 1128 cases, has provided a listing of some of the factors which should be considered:

the nature of the offense committed by the provider, the circumstances surrounding the offense, whether and when the provider sought help to correct the behavior which led to the offense, how far the provider has come toward rehabilitation, and any other factors relating to the provider's character and trustworthiness.

Robert Matesic, R.Ph., d/b/a Northway Pharmacy, DAB 1327, at 12 (1992).

B. The Evidence Of Untrustworthiness In This Case Supports A 10-Year Exclusion.

By not mandating that exclusions from participation in the programs be permanent, Congress has allowed the I.G. to give medical providers a second chance. An excluded individual or entity has the opportunity to demonstrate that he or she can and should be trusted to participate in the Medicare and Medicaid programs as a provider. Duffield at 13, citing Lakshmi N. Murty Achalla, M.D., DAB 1231 (1991).

By reason of section 205(b)(1) of the Act, this proceeding is de novo. Thus, all evidence relevant to Petitioner's trustworthiness or the remedial objectives of the law is admissible, even if that evidence does not pertain to the legal basis for the exclusion, and even if the I.G. did not consider it or if it was not available to the I.G. at the time the Notice was issued. <u>Duffield</u> at 13; <u>Christino Enriquez, M.D.</u>, DAB CR119, at 10-12 (1991).

The I.G. argues that a 15-year exclusion is justified in this case because of: (1) the circumstances leading to Petitioner's conviction; (2) Petitioner's sentence, which included imprisonment, a large fine, and a term of parole; (3) the revocation of Petitioner's Michigan medical license and a fine for reinstatement; and (4) Petitioner's lack of remorse or acceptance of his responsibility. The I.G. contends also that Petitioner's disability does not relieve him of his criminal responsibility. These factors, the I.G. asserts, require a conclusion that Petitioner is so untrustworthy as to justify a 15-year exclusion.

Petitioner offers as mitigating circumstances: (1) his acknowledgment of his mistake and the circumstances surrounding his actions; (2) his efforts at rehabilitation; (3) the benefit to the community of an early reinstatement; (4) his knowledge and reputation as a physician; and (5) the treatment that he now receives for his disability.

I have evaluated the evidence presented in this case and have attempted to balance the seriousness and impact of the offense with other factors which may demonstrate trustworthiness.

I find Petitioner's violations to be serious. Even taking into account the effects of Petitioner's medical disorder at that time, the evidence of Petitioner's culpability for his offenses is overwhelming. According to the trial transcript, Petitioner, while a resident at Providence Hospital in Detroit in 1982, also worked part time for several "weight loss" clinics in the area. If I.G. Ex. 21 at 8/41. Although in Michigan, at that time, it was legal to prescribe controlled substances for weight loss, strict standards for their prescription were in effect. Id. at 3/83, 5/76, and 5/87. The law

Petitioner was a resident at Providence Hospital from July 1, 1981 to June 30, 1986. I.G. Ex. 21 at 4/108 and 4/129.

required that, to dispense the "weight loss" drugs, a clinic had to have a physician on staff who had a license to dispense controlled substances (a DEA number). 16

At Petitioner's 1988 trial, the government presented numerous witnesses, including owners, employees, and clients of the clinic, undercover agents who visited the clinic, and experts who testified regarding Petitioner's handwriting on prescriptions. See I.G. Ex. 21 (trial transcript). Their combined testimony indicated that the owners had operated other "weight loss" clinics and used other doctors in the past. The owners stated that they opened this clinic for the sole reason of making money by distributing controlled substances. One of the owners testified that all that was needed at that time was a building, a receptionist, a person to take blood pressure and weights, and a physician with a DEA number. <u>Id</u>. at 1/128-29 and 1/154.

The owner stated that she met Petitioner while he was working at another "weight loss" clinic owned by an acquaintance. She hired Petitioner for \$100 per hour (plus after seeing 50 patients a day, he received an incentive of \$10 for each patient he saw). <u>Id</u>. at 1/151 and 1/155. Petitioner worked part time at the clinic for about six months. An owner stated that she opened the clinic around the days and times Petitioner was able to work there.

The trial testimony also indicated that the "patients" of the clinic were rarely overweight and received little or no medical care or examinations. Diet sheets were discontinued because the "patients" threw them on the floor. In fact, there were almost no facilities or equipment for examinations other than a blood pressure cuff and weight scale. "Patients" paid a flat \$30 fee for two prescriptions of controlled substances. 1/134-35 and 7/28. Payments for the prescriptions were in cash, and no medical insurance was accepted. 1/179, 3/25-26, and 3/32-33. After payment, the patient would fill out a chart, and an employee would take the patient's blood pressure and weight. Id. at 1/163-64 and 1/180. Sometimes the weight would be increased on the chart if the patient was too thin. Id. at 2/77, 3/28-29, and 3/98-100. The patient did not always see the doctor. Id. at 6/106. An employee would take the chart back to

This number is obtained from the DEA and permits a physician to write prescriptions for controlled substances. I.G. Ex. 21 at 3/64. See also note 4, supra.

the doctor. Either the chart would have a notation on the back regarding the type of prescription the "patient" wanted, or he or she would tell the doctor. Id. at 1/158-60. The doctor would fill out the body of the prescription (the medication, his name, and DEA number), send out the chart and prescription, and the clinic employees would fill in the name(s) the "patient" was using. Sometimes, a "patient" would pay for and receive several prescriptions under different names or for "friends" or "relatives." An owner stated that they saw about 100 people a day. To keep things moving, she had to remind the doctor not to take too long with each "patient." These prescriptions would be taken to a pharmacy by the "patient," who would then use or sell the controlled substances. <u>Id</u>. at 1/219-20, 2/111-12, 3/158, 3/171, 4/15-16, 4/21, 4/132, and 4/148-49.

There was also testimony that Petitioner signed his name to pads of prescriptions for certain controlled substances. He would be paid \$15 per prescription for the Schedule II drugs such as Desoxyn, Preludin, Percodan, and Percocet, with a prescription for Valium or cough syrup "thrown in" without charge. If all at 6/112-13 and 7/23. Petitioner vigorously denied this at his trial. Id. at 8/69.

The government agents were able also to survey 21 of the 914 pharmacies in the area. I.G. Ex. 21 at 4/227-28. An analysis of half of the 11,500 prescriptions sampled showed that Petitioner had prescribed 15,360 tablets of Desoxyn; 1,260 tablets of Preludin; 3,630 tablets of Percodan; 150 tablets of Quaaludes or methaqualone; 6,750 tablets of Valium; 3,480 doses of Talwin; 540 doses of Tuinal; 88 doses of Tylenol #4 with codeine; and 560 ounces of Tussionex. Id. at 4/238-40. Thus, a small sample of area pharmacies turned up 1,156 prescriptions written by Petitioner during his six months of part-time work at the clinic. Id. at 5/45. Petitioner left the clinic in June 1982, and, shortly thereafter, the owners opened a new clinic. Several of the owners and employees were also indicted and convicted in separate trials.

In his defense at the trial, Petitioner testified that he always examined each patient fully and prescribed only what was medically necessary. He stated that many of the patients came for weight loss, but that others came for pain -- for example, for back pain from shoveling snow.

Schedule II drugs have a high potential for abuse but have currently accepted medical uses. 21 U.S.C. § 812. I.G. Ex. 21 at 5/70.

He argued, and the government agreed, that some of the prescriptions were forgeries written by the clinic's owners or others. However, the jury convicted Petitioner on 12 of the 15 counts, and the judge sentenced him to several concurrent terms of four-years' imprisonment, a \$25,000 fine, and parole ending December 31, 1996. Petitioner served 23 months of his sentence.

As stated previously, I find that Petitioner's actions had the potential for serious harm to his patients, and his criminal behavior lasted for several months. As a result of these actions, Petitioner was convicted and his sentence was substantial. The evidence also establishes that Petitioner's conduct was motivated by considerations of unlawful and personal gain. Testimony at the trial indicated that, based on clinic receipts, Petitioner was paid about \$500 to \$800 a day and received between \$9,000 and \$10,000 for his work. I.G. Ex. 21 at 1/169-70 and 8/85. Petitioner stated that he had worked at the clinic approximately 19 days. Id. at 8/98.

As Petitioner notes, his actions were not directly related to the Medicare or Medicaid programs, and there is no evidence that any Medicare or Medicaid beneficiaries or recipients were "patients" of the clinic. The clinic accepted only cash. Therefore, there are neither aggravating nor mitigating considerations with respect to this factor.

It is an aggravating factor that the Michigan Board considered Petitioner's conduct to be so serious that it revoked his medical license for an indefinite period of time and ordered that he pay a fine of \$50,000 prior to applying for reinstatement to the Michigan Board. 18

In an effort to explain the circumstances leading to his conviction, Petitioner offers evidence of his medical disorder. See generally P. Exs. 5, 7-8, and 11. Petitioner states that the stresses caused by this illness were a strong factor leading to his inability to

The original August 3, 1990 revocation of Petitioner's license was vacated and remanded by the Ingham County Circuit Court. Following a subsequent administrative hearing on the issue, by decision dated August 21, 1992, the Michigan Board reaffirmed its previous order of revocation and in addition assessed the \$50,000 fine. I.G. Ex. 24.

tell right from wrong. 19 Petitioner is considered to be 100 percent disabled. P. Ex. 7. He has been under the care and treatment of Dr. Joseph Daniels, M.D., a certified psychiatrist, since 1990. Dr. Daniels has diagnosed Petitioner as having a medical condition known as a "bipolar disorder mixed." P. Ex. 16 (Dr. Daniels' deposition at 11); P. Ex. 5. This medical condition is considered to be an affective mood disorder caused by a chemical disturbance within the body, which is usually hereditary. Untreated, it produces mood swings which move from a period of elation and energy which may result in bad judgment or poor insight to a downslide into a state of depression with crying spells, lethargy, and lack of motivation and self-worth. Id. at 11-13. Also, Dr. Daniels stated that, when not treated, an individual with this disorder may exhibit dishonesty inconsistent with one's normal set of values. Id. at 21-22. Petitioner's diagnosis of a manic-depressive illness is supported by the psychiatric evaluation made on August 8, 1989 while Petitioner was in prison. P. Ex. 15. At the time the criminal actions were committed, Petitioner states that he was not receiving treatment for the disorder.

Although it appears that the period during which the offenses occurred was an extremely difficult period in Petitioner's life, I am still troubled that Petitioner dealt with these stresses by failing to take his medications and by committing criminal acts. This raises questions about his trustworthiness because it indicates that it could happen again should Petitioner fail to take his medication. Thus, were this the only evidence relevant to Petitioner's culpability, I would not find it sufficiently mitigating to reduce the exclusion imposed by the I.G.

However, there is considerable evidence that Petitioner has made commendable progress toward rehabilitation. The record shows that Petitioner's incarceration in 1989 was a turning point for him. Although Petitioner was aware of his disorder and had taken medication for it in the past, it appears that it was not until he was

In discretionary exclusion cases, petitioners are permitted to introduce evidence concerning lack of culpability, even if this amounts to challenging findings (other than the conviction itself) reached in the actions underlying the exclusion, since the degree of culpability directly affects the length of the exclusion. <u>Donaldson</u> at 6-7; <u>see Bernardo G. Bilang, M.D.</u>, DAB 1295, at 8-9 (1992).

incarcerated that he realized the seriousness of the disorder and started to obtain regular medical counseling and medication. Dr. Daniels testified on April 15, 1992, during Petitioner's rehearing on his medical license, that Petitioner was being treated with lithium carbonate and Prozac and was being seen almost weekly. He stated also that Petitioner now was functioning well and that he understands the necessity of continued treatment. P. Ex. 16 (Dr. Daniels' deposition at 19-20).

Dr. Daniels noted that many people -- including physicians, attorneys, and accountants -- are able to live normal lives with this disorder as long as they receive treatment. Id. at 20. In a report from earlier this year, Dr. Daniels stated that he believes Petitioner's prognosis is fair to good if he continues with his medication and therapy. P. Ex. 8. Thus, the evidence indicates that Petitioner has responded reasonably well to treatment and appears determined to continue to take steps to retain the progress he has made.

This case is markedly different from that of <u>Timothy L. Stern, M.D.</u>, DAB 1314 (1992), in which an appellate panel of the DAB found that an unsubstantiated drug addiction was not a mitigating factor in a civil money penalties and exclusion case. There, Dr. Stern argued, first, that he had not committed fraud on the Medicare and Medicaid programs for three years, but alternatively, if he had, it was because of his drug addiction. The appellate panel found that Dr. Stern had introduced no evidence of his addiction as a disease or whether it was a contributing factor in his commission of the fraudulent acts. ²⁰ Id. at 20-25.

In contrast, there is substantial evidence to support a finding that Petitioner's disability is not substance abuse, but a chemical imbalance, the origins of which are beyond his control. He has admitted that at the time of the actions he did not have the disorder under control, and his psychiatrist has stated that the disorder could have adversely affected his actions at that time. Also, while the effective regulations do not specifically make provision for disease as a mitigating factor, neither do

The panel also noted that in federal sentencing guidelines, drug or alcohol abuse is not a reason for imposing a sentence below the guidelines. Stern at 25.

they preclude it. 21 The Petitioner here has admitted his actions and his remorse for them. Thus, I find that Petitioner's disorder, combined with the rehabilitative steps he has taken to control the disorder, is a mitigating factor.

Petitioner introduced other evidence regarding his activities since his release from prison which support his argument that he has realized the extent of his problems and the need to correct them. For example, he introduced evidence of his continuing medical education (CME) as a mitigating factor. P. Ex. 9. Petitioner has taken 186 CME credits in the last two years. While CME credits do not, on their own, demonstrate trustworthiness, in Petitioner's case I find that they indicate the seriousness of his attempts at rehabilitation and his interest in pursuing his medical career in the face of numerous obstacles.²²

Petitioner asks also that I consider as a mitigating factor his community involvement since his release from prison. Petitioner states that he volunteers at the Boys and Girls Club of Kalamazoo and has been active in his church. This is supported by the August 25, 1992 affidavit of Patricia A. Scrutchions, his parole officer. P. Ex. 17. I find this to be a mitigating factor. Ms. Scrutchions states also that Petitioner has complied

While not applicable to this case, the new regulations, provide that, in exclusions based on convictions of specified offenses (other than 1128(b)(3) offenses), a disease may be considered a mitigating factor in determining the length of the exclusion. The record in the criminal proceeding must demonstrate, however, that the court determined that the individual had a mental, emotional, or physical condition, before, after, or during the commission of the offense that reduced the individual's culpability. 42 C.F.R. §§ 1001.102(c)(2), .201(b)(3), and .301(b)(3). While Petitioner's disorder was not a factor in his 1988 trial, the Sixth Circuit remand is based, in part, on the failure of the district court to receive evidence on Petitioner's disorder. See note 5, supra.

Petitioner's argument that he should be reinstated because the country needs medical doctors who are willing to provide services to the poor cannot be considered a mitigating factor. The beneficiaries and recipients of Medicare and Medicaid are entitled to receive medical care from a physician who is fully qualified to participate in the programs.

with the conditions of his parole which involve bimonthly home visits. She states that he is a "changed and improved individual" who admits his guilt, continually expresses remorse, and has actively participated in community affairs as an additional repayment of his debt to society.²³

Petitioner asserts that, in light of his efforts at rehabilitation, and, considering the remedial purpose of the Act, he should be reinstated into the Medicare and Medicaid programs immediately. The I.G. suggests, however, that none of the above are mitigating factors but are more likely a "callous attempt to obtain quicker reentry as a full-fledged medical practitioner in good standing." I.G. R.Br. at 7. The I.G. argues also that Petitioner has not admitted his guilt because he has relied on his "alleged" disorder as an excuse. Finally, the I.G. asserts that I must find the 15-year exclusion reasonable to protect the beneficiaries and recipients of Medicare and Medicaid, especially in the event Petitioner should fail in his rehabilitation.

I have found that Petitioner has established that he has a chronic medical disorder which was not adequately treated until 1989. While Petitioner cannot be held responsible for having a hereditary chemical imbalance, he is responsible for his reckless behavior or failure to take his medication to control his disorder prior to 1989. He must be held responsible for his actions with respect to his failure to adequately treat the disorder, especially in light of his medical education. Petitioner has made great steps toward his rehabilitation, and these are mitigating factors which I must consider because of the remedial nature of section 1128.

The actions at issue happened during a period of several months over 10 years ago. Since that time, Petitioner

I note that under the new regulations at 42 C.F.R. § 1001.401(c)(3), Petitioner's cooperation with the investigating grand juries would be a mitigating factor. See I.G. Ex. 21 at 8/77, 8/111, and 8/129.

Although the I.G. refers to Petitioner's "alleged bipolar disorder" in his briefs, he states also that "[o]ther evidence in the file shows that he [Petitioner] was diagnosed with this disorder [bipolar disorder] long before his crimes at the KAI Clinic, and that he had taken lithium long before that time." I.G. R.Br. at 5. Thus, the I.G. appears to recognize that Petitioner's medical condition is more than "alleged."

has paid a severe price for those actions and the effects on his life and his career have been extensive. He has been through several trials, imprisonment and parole, and has lost his medical license. He has not been able to practice medicine since his incarceration in 1989 -- almost four years ago. Nor will he be able to practice unless and until his license is reinstated. He will be on parole until the end of 1996.

I do not find Petitioner's attempts at rehabilitation to In light of evidence provided by the be "callous." affidavits and statements of Petitioner, his physicians, and his parole officer, it is difficult to see what more Petitioner could do to prove his remorse and his progress toward rehabilitation. Petitioner has expressed his remorse for his actions in several arenas. And, contrary to the I.G.'s allegations, it is not unreasonable for Petitioner to condition his remorse and acceptance of his responsibility by reference to his disorder, especially considering the statements of his physicians regarding the nature of his disorder and the Sixth Circuit remand. It is unrealistic to demand that a petitioner state that he is 100 percent guilty with no extenuating circumstances when his criminal conviction is on remand, based, in part, on the failure of the lower court to hear evidence on those extenuating circumstances.

The remedial nature of section 1128 of the Act requires exclusion to protect the programs and their beneficiaries and recipients from future misconduct. But the sanction may not be so extreme and disproportionate that it bears no rational relation to the remedial goals. To do so would raise it to the level of prohibited punishment. See U.S. v. Halper, 490 U.S. 435, 447-51 (1989).

My duty, therefore, is to balance the myriad factors and determine whether the length of the exclusion imposed by the I.G. is reasonable under the circumstances -- whether its length will serve the remedial purposes of the Act.

Having considered all the evidence, I find that the I.G. has not met his burden of proof that an exclusion of 15 years is reasonable. I am satisfied that Petitioner has stabilized his condition as long as he continues to take his medication and that he is strongly motivated to do so. Petitioner was released from prison and is now on parole and living with his family. Thus, he has shown that he can control his disease outside the confines of a prison. Based on Petitioner's continued rehabilitation, the chance that he would repeat his criminal actions is minimal. Under these circumstances, I find that an exclusion of 15 years is unreasonable and excessive.

On the other hand, I do not accept Petitioner's assertion that the evidence establishes that he should be entrusted with caring for Medicare and Medicaid patients immediately. I am persuaded that Petitioner has made great strides in his rehabilitation and that his illness is currently under control. However, there has not been a sufficient period of time to gauge Petitioner's trustworthiness with respect to the Medicare and Medicaid programs and their beneficiaries and recipients. evidence indicates that Petitioner is at risk should he cease taking his medication. Furthermore, there is a potential of danger to Petitioner's future patients should Petitioner relapse. Under these circumstances, an exclusion for a period of 10 years is necessary to determine that Petitioner's unlawful conduct will not recur.25 Petitioner has been excluded almost three years already. Assuming that Petitioner continues to adhere to his current program of rehabilitation, when he is eligible to apply for reinstatement he will have been off parole for over three years. Ten years is long enough, given Petitioner's determination to fully comply with the law, to establish that he no longer constitutes a risk to the integrity of the programs or to the welfare of the programs' beneficiaries and recipients. See S. Rep. No. 109, 100th Cong. 1st Sess. 2 (1987), reprinted in 1987 U.S.C.C.A.N. 682.

The remedial purposes of the exclusion law will be served in this case by a 10-year exclusion. This exclusion will provide a sufficient period of time to test Petitioner's assurances that he will be trustworthy in the future.

CONCLUSION

Based on the law and the evidence, I conclude that the 15-year exclusion imposed against Petitioner is excessive and unreasonable, and I modify it to 10 years.

/s/

Charles E. Stratton Administrative Law Judge

Should Petitioner obtain a reversal of his conviction in the remand to the district court, he would be reinstated retroactively to the date of the Notice. 42 C.F.R. § 1001.3005(a)(1).