Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
Narinder Saini, M.D.,	DATE: July 23, 1992
Petitioner,	Docket No. C-425
- v. -	Decision No. CR217
The Inspector General.	

DECISION

On April 18, 1991, the Inspector General (I.G.) notified Petitioner that he was being excluded from participating in Medicare and State health care programs pursuant to section 1128(b)(4) of the Social Security Act (Act).[1] The I.G. advised Petitioner that he was basing his decision to exclude him on a decision by the Board of Medical Examiners of the State of Iowa to suspend Petitioner's license to practice medicine in Iowa. The I.G. further advised Petitioner that he had determined to exclude Petitioner until Petitioner obtained a valid license to practice medicine in Iowa.

On July 8, 1991, the I.G. notified Petitioner, that, in light of information which Petitioner had supplied to the I.G., the exclusion was being modified to a term of three years. The I.G. told Petitioner that he was modifying the term of the exclusion based on the fact that Petitioner had obtained a license to practice medicine in the State of Wisconsin.

Petitioner requested a hearing, and the case was assigned to me for a hearing and a decision. I held a hearing in

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[1] "State health care program" is defined by section 1128(h) of the Act to include any State Plan approved under Title XIX of the Act (such as Medicaid). I use the term "Medicaid" hereafter to represent all State health care programs from which Petitioner was excluded.

Madison, Wisconsin, on March 10, 1992. With the parties' consent, I received additional testimony by telephone on March 27, 1992. The parties submitted posthearing briefs and reply briefs.

I have carefully considered the evidence, the applicable law, and the parties' arguments. I conclude that the three-year exclusion imposed and directed by the I.G. is reasonable. I therefore uphold the exclusion.

ISSUE

The issue in this case is whether the three-year exclusion which the I.G. imposed and directed against Petitioner is reasonable.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Petitioner is a psychiatrist. Tr. at 34.[2]

2. Petitioner was employed as a staff psychiatrist at Mendota Mental Health Institute, in Madison, Wisconsin, from February 24, 1986 to September 26, 1986. He was employed again at Mendota Mental Health Institute as a forensic psychiatrist, beginning January 29, 1990, and he is presently employed in that capacity by Mendota Mental Health Institute. P. Ex. 18/4; Tr. at 34.

3. From September 29, 1986 until May, 1989, Petitioner was employed as Medical Director and psychiatrist at the Mental Health Center of Mid-Iowa, in Marshalltown, Iowa. P. Ex. 18/4.

4. Petitioner also served as the Clinical Director in Psychiatry at Ellsworth Hospital, in Iowa Falls, Iowa, from November, 1987 to February, 1988. P. Ex. 18/4.

5. From May, 1989 until August, 1989, Petitioner was employed as a psychiatrist at the Mental Health Center of North Iowa, in Mason City, Iowa. P. Ex. 18/4.

6. On August 7, 1990, the Board of Medical Examiners of the State of Iowa (Iowa Board of Medical Examiners) issued an order directing that Petitioner's license to

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[2] I refer to the Inspector General's exhibits as "I.G. Ex. (number)/(page)." I refer to Petitioner's exhibits as "P. Ex. (number)/(page)." I refer to the Transcript as "Tr. at (page)."

practice medicine and surgery in Iowa be indefinitely suspended. I.G. Ex. 29.

7. In ordering that Petitioner's license to practice medicine and surgery be suspended, the Iowa Board of Medical Examiners accepted the Findings of Fact, Conclusions of Law, and Proposed Decision of a panel, consisting of three members of the Iowa Board of Medical Examiners and a State administrative law judge, which had conducted an evidentiary hearing in Petitioner's case on May 31, 1990. I.G. Ex. 28; I.G. Ex. 29.

8. The Iowa Board of Medical Examiners found that, while employed at the Mental Health Center of North Iowa, Petitioner had experienced a psychotic episode. I.G. Ex. 28/3; I.G. Ex. 29.

9. The Iowa Board of Medical Examiners found Petitioner's mental condition affected his practice of medicine and compromised the care of his patients. I.G. Ex. 28/3; I.G. Ex. 29.

10. The Iowa Board of Medical Examiners found that, although Petitioner had received treatment for his mental condition, there remained the possibility that Petitioner could experience an additional psychotic episode in the future which would compromise the care of his patients. I.G. Ex. 28/15; I.G. Ex. 29.

11. The Iowa Board of Medical Examiners found that Petitioner was unable to practice medicine with reasonable skill and safety as a result of a mental or physical condition. I.G. Ex. 28/16; I.G. Ex. 29.

12. The Iowa Board of Medical Examiners found that Petitioner's practice of psychiatry had been harmful or detrimental to the public. I.G. Ex. 28/16; I.G. Ex. 29.

13. The Iowa Board of Medical Examiners suspended Petitioner's license to practice medicine and surgery in Iowa for reasons bearing on Petitioner's professional competence or performance. Findings 6 - 12.

14. On February 21, 1991, the State of Wisconsin Medical Examining Board (Wisconsin Medical Examining Board) issued a decision and order concerning Petitioner's license to practice medicine and surgery in Wisconsin. P. Ex. 1.

15. The Wisconsin Medical Examining Board found that Petitioner suffered from a bipolar mental disorder (manic-depressive illness). P. Ex. 1/2.

16. The Wisconsin Medical Examining Board found that Petitioner's illness was reasonably related to his ability to practice medicine and surgery. P. Ex. 1/2.

17. The Wisconsin Medical Examining Board found that Petitioner's illness could reasonably be accommodated by placing appropriate conditions on Petitioner's license to practice medicine and surgery in Wisconsin. P. Ex. 1/2.

18. The Wisconsin Medical Examining Board restricted Petitioner's license to practice medicine and surgery in Wisconsin, subject to conditions which included the following:

> a. Petitioner is prohibited from practicing or attempting to practice medicine or surgery in Wisconsin as a sole practitioner;
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> b. Petitioner must remain in treatment with Ronald Diamond, M.D., his treating psychiatrist, and follow that physician's recommendations for diagnostic testing, evaluation and treatment;
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> c. Dr. Diamond or his successor must submit reports every 90 days to the Wisconsin Medical Examining Board, concerning Petitioner's treatment program and his progress in that program;
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> d. Petitioner shall notify the Wisconsin Medical Examining Board prior to commencing any practice of medicine or surgery in Wisconsin and shall identify an individual satisfactory to the Wisconsin Medical Examining Board who will supervise Petitioner's practice and who will report any conduct by Petitioner which may impact upon patient health, safety or welfare, or Petitioner's ability to practice medicine or surgery with reasonable skill and safety to patients.

P. Ex. 1/3.

19. On March 6, 1992, the Wisconsin Medical Examining Board renewed that the conditions which it had imposed on Petitioner's license to practice medicine and surgery in Wisconsin. P. Ex. 25.

20. In January, 1992, Petitioner received neuropsychological testing at the University of Wisconsin Hospital and Clinics in Madison, Wisconsin. I.G. Ex. 31.

21. Testing established that Petitioner had a continuing impairment on the nonverbal aspects of the Wechsler Adult Intelligence Scale, with a Performance IQ in the Borderline Range. I.G. Ex. 31/2.

22. Petitioner demonstrated impairment of naming and visual attention. I.G. Ex. 31/2.

23. Petitioner demonstrated impairment in performing nonverbal abstraction tasks which required flexibility of thinking and ability to shift problem solving set. I.G. Ex. 31/2 - 3.

24. Petitioner demonstrated difficulty on a task requiring him to spontaneously recall complex verbal material. I.G. Ex. 31/3.

25. Petitioner continues to manifest mental impairments, consisting in part of mild bilateral cerebral impairment. I.G. Ex. 31/3.

26. Petitioner's present mental impairments affect his ability to perform nonverbal abstraction tasks and to engage in tasks which require flexibility of thinking. Findings 21 - 25.

27. Petitioner's present cerebral impairments might affect his ability to make complicated decisions concerning the management of patients in the context of his present work as a psychiatrist. Findings 21 - 26; Tr. at 100.

28. Petitioner has suffered from mental illness, diagnosed as bipolar affective disorder, in addition to his cerebral impairments. Findings 8, 15; I.G. Ex. I.G. Ex. 20/3; P. Ex. 12/1; Tr. at 36.

29. Petitioner's mental illness has been successfully treated with medication. P. Ex. 4/2; P. Ex. 7.

30. Recently, Petitioner has appeared at times to be withdrawn and to display diminished energy, but he has not displayed clinical signs of active mental illness. Tr. at 96.

31. A significant minority of individuals who suffer from bipolar affective disorders experience recurrences of symptoms, despite treatment, which can be disabling for a period of time. P. Ex. 12/1.

32. There is no guarantee that Petitioner will not, at some future date, experience a relapse of his bipolar affective disorder. Findings 28, 31.

33. Petitioner presently practices psychiatry at Mendota Mental Health Institute under the supervision of another psychiatrist on the staff of that facility. Tr. at 93 - 94.

34. Petitioner's present duties include evaluating patients for mental competency and providing treatment for some of them. Tr. at 40 - 41.

35. Petitioner is seen by his supervisor on a daily basis and also meets with his supervisor for one hour each week to discuss his work. Tr. at 94.

36. Petitioner has performed his present duties at Mendota Mental Health Institute in a satisfactory manner. Tr. at 94 - 96.

37. Petitioner's current duties can be monitored closely because he works in a closed environment with a fixed number of patients, in close contact with his supervisor and with coworkers, including other health care professionals. Tr. at 103.

38. Petitioner is capable of competently performing his current duties as a psychiatrist at Mendota Mental Health Institute, provided that he continues to work in a closed environment, in close contact with coworkers, including other health care professionals, and under the close supervision of another psychiatrist. Tr. at 124 - 125.

39. Petitioner is not trustworthy to provide care to patients outside of the setting of his current employment at Mendota Mental Health Institute or a setting with an equivalent level of supervision. Findings 25 - 37.

40. The Secretary of the Department of Health and Human services (Secretary) delegated to the I.G. the authority to determine, impose, and direct exclusions pursuant to section 1128 of the Act. 48 Fed. Reg. 21662 (May 13, 1983).

41. The I.G. had authority to impose and direct an exclusion against Petitioner. Findings 13, 40; Social Security Act, § 1128(b)(4)(A).

42. On April 18, 1991, the I.G. advised Petitioner that he had determined to exclude Petitioner from participating in Medicare, and to direct that he be

excluded from participating in Medicaid until Petitioner obtained a valid license to practice medicine from the State of Iowa. I.G. Ex. 1.

43. On July 8, 1991, the I.G. advised Petitioner that he had determined to modify Petitioner's exclusion from participating in Medicare and Medicaid to a term of three years. I.G. Ex. 3.

44. 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; 57 Fed. Reg. 3298, 3330 - 3341 (January 29, 1992).

45. 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)(4) of the Act. 42 C.F.R. § 1001.501; 57 Fed. Reg. 3332.

46. The Secretary did not intend that regulations contained in 42 C.F.R. Part 1001 and, in particular, 42 C.F.R. § 1001.501, govern my decision in this case.

47. I do not have authority to decide whether any exclusion imposed and directed by the I.G. must reasonably accommodate an excluded party's medical impairments. See 29 U.S.C. § 794(a).

48. I do not have authority to impose an exclusion which applies to some, but not to all, services for which Petitioner potentially could file Medicare or Medicaid reimbursement claims. Social Security Act, § 1862(e)(1). See Findings 38 - 39.

49. The Act's remedial purpose will be accomplished by excluding Petitioner for three years.

ANALYSIS

Petitioner is a psychiatrist. Finding 1. Prior to 1989, he had practiced successfully in various settings. Findings 2 - 4. However, in 1989, Petitioner experienced a psychotic episode while serving as a psychiatrist on the staff of the Mental Health Center of North Iowa in Mason City, Iowa. Finding 8. Petitioner's illness was manifested by a host of bizarre behaviors. Petitioner experienced hallucinations, both auditory and visual. I.G. Ex. 20. He fantasized that he was the victim of a conspiracy involving other physicians in his community.

I.G. Ex. 11. He engaged in assaultive behavior towards his wife. I.G. Ex. 20. His mental problems affected his practice of psychiatry and prompted complaints from his coworkers. I.G. Ex. 9; I.G. Ex. 13. Eventually, Petitioner was hospitalized for his mental problems. I.G. Ex. 20. He was treated with medication, his condition improved, and he was discharged. Id. Petitioner was diagnosed to be suffering from a bipolar affective disorder, which is amenable to treatment with medication. Id.

The Iowa Board of Medical Examiners, responding to complaints concerning the manner in which Petitioner was practicing psychiatry, investigated the facts of Petitioner's case and conducted a hearing. Finding 7. On August 7, 1990, it issued an order based on the evidentiary record of that hearing, indefinitely suspending Petitioner's license to practice medicine and surgery in Iowa. Findings 6, 7. It concluded that Petitioner was suffering from a mental impairment which affected Petitioner's practice of medicine and compromised the care of his patients. Findings 11, 12. It also expressed concern that Petitioner's mental problems might recur at some future date. Finding 10.

The Wisconsin Board of Medical Examiners initiated a proceeding concerning Petitioner's license to practice medicine and surgery in Wisconsin, based on the action taken by the Iowa Board of Medical Examiners. In February, 1991, the Wisconsin Board of Medical Examiners issued an order which permitted Petitioner to continue to practice medicine in Wisconsin, but under strict limitations. Finding 17. These limitations included requirements that Petitioner remain under the regular care of his treating psychiatrist and that his psychiatrist report regularly concerning Petitioner's mental status and his response to treatment. Finding 18. The Wisconsin Board of Medical Examiners also required Petitioner to notify it of any practice arrangement which he intended to enter. Id. Finally, it required, as a condition for Petitioner practicing in Wisconsin, that he be supervised in his practice by an individual satisfactory to the Wisconsin Board of Medical Examiners. Id. The Wisconsin license restrictions were renewed in March 1992. Finding 19.

Beginning in early 1990, Petitioner has practiced at the Mendota Mental Health Institute in Madison, Wisconsin. Finding 2. He practices under the close supervision of another psychiatrist. Finding 33. His practice consists of evaluating individuals for mental competence and treating some of these individuals. Finding 34. His job

performance while at Mendota Mental Health Institute has been satisfactory. Finding 36.

Petitioner is not at this time manifesting clinical signs of a bipolar affective disorder. Findings 29, 30. However, neuropsychological testing performed in January, 1992, establishes that he continues to manifest some deficits in his thinking. I.G. Ex. 31; Findings 21 - 25. These deficits, which may be attributable to some organic cause other than Petitioner's bipolar affective disorder, affect Petitioner's ability to engage in nonverbal abstraction and to perform tasks which require flexibility of thinking. Findings 26 - 27.[3] Petitioner's supervisor has also noted that Petitioner has recently manifested some decreased energy. Finding 30.

The parties do not dispute that Petitioner's license to practice medicine and surgery in Iowa was suspended for reasons relating to his professional competence and performance. They do not disagree that the I.G. had authority to impose and direct an exclusion against Petitioner pursuant to section 1128(b)(4)(A) of the Act.[4]

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[3] Petitioner testified that his performance on his most recent tests was adversely affected by cultural factors. Petitioner is a native of India, and he asserts that some of the tasks he was asked to perform during his testing involved concepts that he is not familiar with. Tr. at 56 - 57; 79 - 80. I conclude that Petitioner's explanation for his performance on these tests does not credibly account for the deficiencies which he manifested. The tests were performed by a professor of neurology at the University of Wisconsin Hospital and Clinics. I.G. Ex. 31. The test report notes Petitioner's cultural background and the fact that English is Petitioner's second language. However, the report finds that Petitioner manifests cerebral impairments notwithstanding his background. I conclude that the tests performed in January 1992 represent an accurate measure of Petitioner's performance at that time.

[4] Section 1128(b)(4)(A) provides that the Secretary (or his delegate, the I.G.) may exclude a party:

> whose license to provide health care has been revoked or suspended by any State licensing authority, or who otherwise lost such a license or the right to apply for or renew such a license, for reasons bearing on . . . [that

The parties disagree as to whether the three-year exclusion imposed and directed against Petitioner by the I.G. is reasonable.

1. Regulations published by the Secretary on January 29, 1992 are not applicable to this case.

A threshold issue in this case is whether regulations published by the Secretary on January 29, 1992 establish criteria by which I must adjudicate the reasonableness of the exclusion which the I.G. imposed and directed against Petitioner. 57 Fed. Reg. 3298, 3330 -41 (to be codified at 42 C.F.R. Part 1001). The I.G. asserts that these new regulations, which contain a section establishing criteria for the I.G. to employ in determining to impose and direct exclusions pursuant to section 1128(b)(4) of the Act, also apply at the level of administrative hearings to establish mandatory criteria for adjudicating the reasonableness of exclusions imposed and directed pursuant to section 1128(b)(4). 57 Fed. Reg. at 3332 (to be codified at 42 C.F.R. § 1001.501). The I.G. asserts that the regulations in effect require that I sustain the exclusion which he imposed and directed against Petitioner without considering evidence offered by Petitioner as to the exclusion's reasonableness. According to the I.G., 42 C.F.R. § 1001.501 directs me to sustain any exclusion, imposed and directed under section 1128(b)(4) of the Act, which is coterminous with a State license suspension or revocation.[5]

I conclude, as I have on several previous occasions, that these regulations do not establish criteria which govern administrative law judges' reviews of exclusion determinations. Furthermore, it is now settled that the regulations do not apply to I.G. determinations made prior to the regulations' publication date.

> party's] professional competence, professional performance, or financial integrity . . . .

[5] I note that, although the exclusion originally imposed and directed by the I.G. is coterminous with the license suspension ordered by the Iowa Board of Medical Examiners, that exclusion was modified by the I.G. to a term of three years. The I.G. has not explained how I am to evaluate the reasonableness of this modified exclusion under the new regulations, assuming that the new regulations establish criteria which govern reviews of exclusions by administrative law judges.

a. Regulations contained in 42 C.F.R. Part 1001 do not establish criteria for review of exclusion determinations.

The new regulations' criteria for determining exclusions under section 1128(b)(4) do not govern my review of the reasonableness of the exclusion imposed and directed against Petitioner. The regulations contained in Part 1001 of the new regulations, and 42 C.F.R. § 1001.501 in particular, were not intended by the Secretary to establish criteria to govern hearings as to the reasonableness of exclusion determinations. Stephen J. Willig, M.D., DAB CR192 (1992) (Willig); Charles J. Barranco, M.D., DAB CR187 (1992) (Barranco). See Sukumar Roy, M.D., DAB CR205 (1992) (Roy); Steven Herlich, DAB CR197 (1992) (Herlich); Aloysius Murcko, D.M.D., DAB CR189 (1992) (Murcko).

The cited decisions explain in detail why the new regulations do not establish criteria to be used by administrative law judges at hearings. It is not necessary for me to repeat verbatim the analysis contained in these decisions. It is sufficient to state that these decisions are grounded on two conclusions. First, the new regulations, if applied to establish criteria at the hearing level, would serve to strip excluded parties of rights guaranteed by Congress in sections 205(b) and 1128 of the Act. Second, interpreting the new regulations as inapplicable at the hearing level is fully consistent with their plain language and moreover avoids any possible conflict with congressional intent.

The first ground for concluding that the new regulations are inapplicable at the hearing level is that their application would strip excluded parties of rights guaranteed by sections 205(b) and 1128 of the Act. The rights which would be extinguished include the right to a de novo review of an exclusion determination, measured against the remedial criteria of the Act.

The legitimate remedial purpose for any exclusion imposed pursuant to section 1128 is to protect federally-funded health care programs and their beneficiaries and recipients from parties who are not trustworthy to provide care. Robert Matesic, R. Ph., d/b/a/ Northway Pharmacy, DAB 1327 at 7 - 8 (1992) (Matesic); Willig at 14 - 15; Hanlester Network, et al., DAB CR181 at 37 - 38 (1992) (Hanlester). Exclusions which do not comport with this remedial purpose may be punitive, and, therefore,

unlawful.[6] Section 205(b) of the Act guarantees parties excluded pursuant to section 1128 and who request hearings de novo hearings as to the reasonableness of the length of the exclusions imposed against them. The standard for evaluating the reasonableness of exclusions at such hearings is the remedial criteria implicit in section 1128. Bernardo G. Bilang, M.D., DAB CR141 at 9 (1991), aff'd DAB 1295 (1992); Eric Kranz, M.D., DAB CR148 at 7 - 8 (1991), aff'd DAB 1286 (1991); Hanlester at 39 - 43. Thus, in hearings as to the reasonableness of exclusions imposed pursuant to section 1128, the Act requires administrative law judges to entertain any evidence which either party offers which reasonably relates to the excluded party's trustworthiness.

The new Part 1001 regulations, including 42 C.F.R. § 1001.501, narrowly state the criteria which the I.G. may consider in deciding the length of any exclusion he determines to impose. If these regulations were held to constitute a standard by which to measure the reasonableness of exclusions, they would bar administrative law judges from considering evidence which relates to an excluded party's trustworthiness. For example, 42 C.F.R. § 1001.501(b) all but mandates that exclusions imposed pursuant to section 1128(b)(4) of the Act be coterminous with State license suspensions or revocations. The regulation forbids the I.G. from considering evidence which might establish that a party would be trustworthy at a time other than the date when a State licensing authority decides to restore a license to that party. Application of the new regulations to establish criteria for review of exclusions would prevent excluded parties from contesting the reasonableness of their exclusions, even if the exclusions are punitive, when measured against the Act's remedial criteria. They would, if applied as a standard for review of exclusion determinations, mandate outcomes which are contrary to congressional intent and are, therefore, unlawful.

Second, although I have no authority to declare regulations to be ultra vires the Act, I do have the duty to interpret regulations in a manner which is consistent with legislative intent, insofar as I can do so in a way which does not contravene the Secretary's explicit

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[6] Civil remedy statutes cannot be applied constitutionally to produce punitive results in the absence of traditional constitutional guarantees such as the right to counsel, the right to a trial by jury, or the right against self-incrimination. Kennedy v. Mendoza-Martinez, 372 U.S. 144, 168 - 69 (1963).

directives. The new regulations can be read unambiguously in a way which does not create conflict with congressional intent, but which provides excluded parties with the continued right to de novo review of the reasonableness of their exclusions. Herlich at 14; Willig at 18 - 24; Barranco at 24 - 27.

The plain language and the context of these regulations demonstrate that they establish criteria to be used by the I.G. in making exclusion determinations. The regulations neither state nor suggest that they establish standards for review of exclusions' reasonableness by administrative law judges.[7] Furthermore, as I held in Herlich and Willig, if the Part 1001 regulations were held to establish criteria for review of exclusions, they would render meaningless the new Part 1005 regulations, which establish procedures governing hearings for parties excluded under section 1128. I am not prepared to find that the rights established under Part 1005 are hollow.

As I observed in both Herlich and Willig, the Departmental Appeals Board, including its administrative law judges, is the Secretary's delegate for purposes of interpreting the Act and its implementing regulations. Decisions by the Board's appellate panels and administrative law judges which interpret the Act and set forth standards for administrative review of exclusion determinations are therefore the Secretary's final interpretation of the Act. Herlich at 15; Willig at 20. The Secretary may publish regulations which overrule his interpretations of the Act. However, as I held in Herlich and Willig, that would require an unambiguous statement of intent, particularly where the interpretations at issue hold that Congress conferred specific rights on excluded parties.

Had the Secretary intended that the Part 1001 regulations establish criteria which extinguished a party's right to a de novo hearing, or the right to have the exclusion measured against the Act's remedial criteria, he would

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[7] The I.G. has contended in numerous cases, in addition to Roy, Herlich, Willig, Barranco, and Murcko, that the Part 1001 regulations establish criteria for review of exclusions by administrative law judges. I have routinely invited the I.G. and excluded parties to brief the issue of applicability. The I.G. has filed many briefs on this issue. The I.G. has never identified language in the regulations which would even arguably establish the Part 1001 regulations as criteria for review of the reasonableness of exclusions.

have said so explicitly. He could have published a regulation in either Part 1001 or Part 1005 of the new regulations which stated such an intent. By the same token, the Secretary could have published a comment to the regulations which plainly established the Part 1001 regulations as criteria for deciding the reasonableness of exclusions at the hearing level. It is significant that the Secretary did none of the foregoing, especially in light of the plain and unambiguous language of the new regulations, and the equally plain and unambiguous decisions by the Board's appellate panels which establish the standard of review for deciding whether exclusions are reasonable.

The I.G. makes two arguments concerning applicability of these regulations which he did not forcefully advocate in Willig and Herlich. First, he contends that a portion of the commentary to the new regulations proves that the Secretary intended that the regulations apply as a standard for review of exclusion determinations. Second, the I.G. seems to argue that the interpretation of the regulations which he advocates is an act of discretion which is immune from any review by an administrative law judge. Neither of these arguments persuades me that there is error in the administrative law judges' analysis of these regulations.

The new regulations are preceded by a lengthy commentary. 57 Fed. Reg. at 3298 - 3329. As I observed in both Willig and Herlich, nowhere does this commentary state that the Part 1001 regulations are intended to establish criteria which govern hearings as to exclusions' reasonableness. Furthermore, as the regulations themselves are plain and unambiguous, the commentary is of only limited value in interpreting them. It would not be appropriate to give a regulation a meaning, which would contravene its plain meaning, based on a commentary about that regulation.

The commentary relied on by the I.G. is contained in a section of "comments" and "responses" pertaining to Part 1001 of the new regulations entitled "Aggravating and Mitigating Factors." 57 Fed. Reg at 3314. The "comment" states:

> Commenters stated that an ALJ should be free to consider any factors whatsoever in determining whether the length of an exclusion should be reduced, and that the mitigating factors included in the regulations should be examples rather than an exhaustive list.

Id.

The "response" to this "comment" is:

> The legislative history directs the Secretary to consider any mitigating circumstances in setting the period of exclusion. The Secretary has the authority to determine what circumstances are mitigating. Moreover, these factors only relate to the length of the exclusion. The OIG considers many factors in deciding whether to impose an exclusion in the first place.

Id.

The comment and response do not state that the criteria to be employed by administrative law judges to decide as to exclusions' reasonableness must consist of the "aggravating" and "mitigating" factors which are set forth in the new regulations as criteria for determining the length of exclusions imposed and directed by the I.G. The comment and response suggest, first, that administrative law judges are not "free" to consider any factors whatsoever in deciding whether to reduce the length of an exclusion. That statement is entirely consistent with the authority delegated by the Secretary to administrative law judges, pursuant the Act, and pursuant to the Board's appellate panel decisions interpreting the Act. Neither the Act nor appellate panels have ever suggested that administrative law judges are free to invent criteria by which to adjudicate exclusions. Rather, the Act and the decisions of appellate panels establish a standard by which exclusions must be adjudicated. That standard is trustworthiness. Adjudications which do not comport with this standard are in error and are subject to reversal. Therefore, the first conclusion which is to be drawn from the comment and response is that it repeats the obvious truth that administrative law judges are not free to invent their own criteria by which to evaluate exclusions.[8]

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[8] The I.G. has the delegated authority to determine and impose exclusions. DAB administrative law judges and the Chair and members of the DAB have the delegated authority to hear and decide cases in which the reasonableness of exclusions is challenged. At the level of the administrative hearing, the administrative law judge is "the Secretary." An essential element of the authority which has been delegated to DAB administrative law judges and to the Chair and members of the DAB is the

Second, the comment and response make it plain that administrative law judges are not free to identify "mitigating" factors in addition to those specified by the regulations. That is not a controversial statement. Administrative law judges do not have authority to amend or enlarge regulations. But the issue here is not whether administrative law judges may amend or enlarge regulations, but whether the regulations contained in Part 1001 contain criteria to be employed by administrative law judges in deciding whether exclusions are reasonable. The comment and response are silent on this issue.

The I.G. contends that administrative law judges are obligated to follow the Secretary's determinations as to the meaning of the Act, citing Association of Administrative Law Judges v. Heckler, 594 F. Supp. 1132 (D.D.C. 1984). That is certainly true. My decision that the new Part 1001 regulations do not establish criteria to be employed by administrative law judges in deciding whether exclusions are reasonable does not constitute a departure from the Secretary's past decisions as to what are appropriate criteria for administrative law judges to employ. It is entirely consistent with those decisions.

Thus, the comment and response on which the I.G. relies must be read against the regulations themselves, which are not ambiguous, and which do not suggest the interpretation advocated by the I.G. It also must be read in light of the Secretary's interpretations of the Act, and his previous instructions to administrative law judges, which have not been overruled either expressly or impliedly by the new regulations. This comment and response must also be read in the context of other commentary to the new regulations which makes it plain that the new Part 1001 regulations are intended to establish criteria whereby the I.G. would make exclusion determinations. 57 Fed. Reg. at 3299. Finally, the language of the comment and response do not support the I.G.'s sweeping assertions as to the meaning of the new regulations.

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authority to make interpretations of the Act and regulations which are binding on all components of the Department, including the I.G. While administrative law judges may not be "free" to invent criteria by which to evaluate exclusions, they have the duty to interpret the Act and regulations so as to identify the criteria which must be applied to such evaluations.

The I.G. also appears to assert that his interpretation of the Part 1001 regulations is an "exercise of discretion" which is in and of itself not reviewable by an administrative law judge. See I.G.'s Post-Hearing Brief at 6.[9] The I.G. relies on 57 Fed. Reg. at 3351 (to be codified at 42 C.F.R. § 1005.4(c)(5)), as support for this apparent contention.

The regulation in question provides that administrative law judges do not have authority to:

> Review the exercise of discretion by the . . . [I.G.] to exclude an individual or entity under section 1128(b) of the Act or determine the scope or effect of the exclusion.

The I.G. seems to contend that his interpretation and application of the new Part 1001 regulations in an exclusion case constitutes an "exercise of discretion" which is not reviewable by an administrative law judge.

Of course, if the phrase "exercise of discretion" were read as broadly as is advocated by the I.G., then any exercise of judgment by the I.G. or his agents would be immune from review by an administrative law judge. That interpretation would render utterly meaningless the hearing rights conferred by Part 1005 of the new regulations. It would also render meaningless the Part 1001 regulations -- even under the I.G.'s expansive interpretation of those regulations -- because every exclusion determination by the I.G. could be characterized as an immune "exercise of discretion." Thus, under the I.G.'s apparent interpretation, I would not have the authority in an exclusion case even to decide whether an exclusion comported with the criteria for I.G. exclusion determinations expressed in Part 1001 of the new regulations.

The regulation would have troublesome implications if my authority in an exclusion hearing were limited to appellate review of the I.G.'s determinations. If my authority consisted of appellate -- rather than de novo -- review authority, then, arguably, the new regulation could immunize from review virtually all of the I.G.'s actions taken in connection with exclusion determina-tions. However, my authority is not appellate.

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[9] This is not explicitly stated in the I.G.'s Post-Hearing Brief. I infer that is the I.G.'s argument, given the context of the I.G.'s citation to 42 C.F.R. § 1005.4(c)(5).

Section 205(b) of the Act plainly requires that I conduct a de novo review of exclusions in cases where exclusions are challenged. The hearings which I conduct under sections 205(b) and 1128 are not reviews of the I.G.'s "exercise of discretion" or of his judgment in deciding to impose exclusions. Rather, they are de novo evaluations of exclusions in light of the Act's requirements. In conducting such evaluations, I necessarily must exercise the delegated authority to interpret and apply the Act and regulations. Such interpretations and applications are in no sense a review of the I.G's determinations, but are independent decisions as to the Act's and regulations' meaning. Therefore, 42 C.F.R. § 1005.4(c)(5) does not reserve to the I.G. nonreviewable authority to interpret and apply the Act and regulations.

The I.G.'s arguments as to the meaning and applicability of the new regulations to the hearing process betray a fundamental misconception of the purpose of the hearing and the role of administrative law judges in hearing and deciding exclusion cases under section 1128(a) or (b) of the Act. Under the I.G.'s analysis, administrative law judges are appellate reviewers whose function is limited to certifying whether or not the I.G.'s exclusion determinations comply with the I.G.'s internal policies or the regulatory criteria which govern the I.G.'s exclusion determinations. Under the I.G.'s analysis, I should affirm any exclusion which was made in compliance with such policies or the regulatory criteria. And, under that analysis, I should reject any evidence which was not considered by the I.G. For that reason, the I.G. persists in calling as witnesses his special agents, for the purpose of certifying that exclusion determinations were made in compliance with policies and regulations.

I have repeatedly and forcefully ruled that this analysis is incorrect. The purpose of the hearing in an exclusion case is not appellate, it is de novo. Section 205(b) of the Act, as consistently interpreted and applied by the Board's appellate panels, requires me to provide excluded parties with nothing less than a de novo hearing, governed on the issue of reasonableness by statutory criteria which mandate that I independently decide excluded parties' trustworthiness to provide care. The Act does not direct me to limit the evidence received at hearings to that which was considered by the I.G. and his agents in determining to impose exclusions. There is nothing in the new regulations which can be read rationally as a directive by the Secretary to transform a

statutorily-mandated de novo hearing process into an appellate review.

b. The Part 1001 regulations do not apply retroactively to pending cases.

In Roy, Herlich, Willig, Barranco, and Murcko, DAB administrative law judges found that it was not the Secretary's intent to retroactively apply the new regulations to unlawfully strip parties of previously vested rights. We concluded that to apply the Part 1001 regulations as is advocated by the I.G. would strip excluded parties of previously vested rights contrary to the Act's letter and intent. Therefore, we found that, assuming the Part 1001 regulations did establish criteria for review of I.G. exclusion determinations, they did not apply to those determinations that were made prior to January 29, 1992. An appellate panel of the Departmental Appeals Board recently reached the same conclusion in Behrooz Bassim, M.D., DAB 1333 at 5 - 9 (1992). Thus, even if my conclusion that the Part 1001 regulations do not establish criteria for review of exclusions by administrative law judges is incorrect, those regulations would not govern cases in which exclusion determinations were made prior to January 29, 1992.[10] The exclusion determination in this case was made on April 18, 1991. Therefore, the Part 1001 regulations cannot be applied retroactively to establish a standard for adjudicating the reasonableness of the exclusion in this case.

2. A three-year exclusion of Petitioner is reasonable.

The exclusion which the I.G. originally imposed against Petitioner would have excluded him coterminously with his Iowa license suspension. In July, 1991, the I.G. modified that exclusion to a term of three years. Therefore, what is now at issue is whether the three-year exclusion imposed against Petitioner by the I.G. is reasonable.

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[10] In a recent hearing, counsel for the I.G. attempted to distinguish Bassim as applying only to cases where the hearing occurred prior to January 29, 1992. Under that analysis, the new regulations would apply to cases where the determination predated January 29, 1992, but where the hearing took place after January 29, 1992. I see no merit in this argument. Whatever substantive rights inure to an excluded party spring from the I.G.'s determination to exclude that party and not from the hearing.

I conclude that a three-year exclusion is reasonable here. The evidence in this case establishes that Petitioner is suffering from medical conditions which affect his trustworthiness to provide care. Findings 25 - 37, 39. Although Petitioner is not culpable for his medical problems, they nonetheless render him less than fully trustworthy to provide care. An exclusion is therefore necessary to protect federally-funded programs and their beneficiaries and recipients.

There is no evidence that Petitioner is presently manifesting clinical signs of the bipolar affective disorder which incapacitated him in 1989. Finding 30. That condition appears to have been successfully treated with medication. Finding 29. But the credible expert evidence of record in this case is that in some instances, the manifestations of bipolar affective disorder may recur, even where a person has received appropriate treatment with medication. Finding 31. Recurrences happen in thirty percent or more of those individuals who have a bipolar affective disorder. P. Ex. 12. There is no guarantee that Petitioner's disorder will not recur, notwithstanding the fact that he is presently not manifesting clinical signs of the condition. Finding 32. An exclusion can be justified in this case based on the significant possibility that Petitioner's bipolar affective disorder may recur, because, if that happened, Petitioner's judgment could be affected in a way which might endanger his patients.

However, there is a more compelling reason to exclude Petitioner. The medical evidence of record in this case establishes that Petitioner presently is suffering from diminished mental functioning which affects his ability to engage in tasks which require flexibility of thinking. Findings 20 - 27. His impairment may affect his ability to make complex analyses and judgments relevant to his duties as a psychiatrist. None of the evidence, including the testimony of Petitioner's supervisor, who is a psychiatrist, proves that Petitioner is currently capable of performing the duties of a psychiatrist without restriction. To the contrary, the evidence shows that Petitioner is only trustworthy to perform such duties in a highly controlled setting under close supervision. Findings 37 - 39.

Petitioner bears no fault for his medical condition, and he appears to be functioning reasonably well within the constraints of his present work arrangement. However, the fact that Petitioner may be functioning successfully under close supervision does not support an argument that he should not be excluded. To the contrary, the need for close supervision of Petitioner is strong evidence that he potentially could engage in conduct that is harmful to beneficiaries and recipients of program funds. Petitioner's impairments and his need for close supervision are evidence of Petitioner's lack of trustworthiness and are grounds to justify the exclusion which was imposed in this case.

I cannot conclude that Petitioner is trustworthy to treat all program beneficiaries and recipients. The three-year exclusion which the I.G. imposed against Petitioner is necessary, if only to protect program beneficiaries and recipients from the dangers posed by Petitioner were he to attempt to provide care outside of his presently closely supervised and constricted working environment.

Petitioner argues that the current restrictions on his license to practice medicine and surgery in Wisconsin assure that he could not attempt to practice outside of his currently restricted work environment. This is so, according to Petitioner, because the restrictions require him to obtain permission from the Wisconsin Board of Medical Examiners prior to changing his practice arrangements. I agree with Petitioner that this restriction does serve as a restraint on any attempts by him to change his practice arrangements. However, there is no guarantee that Petitioner would not violate the terms of his license restriction. The three-year exclusion in this case is necessary to preclude the possibility that, during that time, Petitioner might attempt to seek reimbursement from Medicare or Medicaid for items or services furnished to patients outside of his current practice arrangement, in violation of the restrictions imposed by the State of Wisconsin. Even though such risk may be very slight, imposing an exclusion to protect program beneficiaries and recipients is a legitimate remedial purpose.

Petitioner asserts that whatever his trustworthiness may be to provide care outside of his present work environment, he is trustworthy within that environment. He argues from this that the exclusion should at least be modified to accommodate his present work arrangement. He also argues that he is an "individual with handicaps" within the meaning of the Rehabilitation Act of 1973, as amended, 29 U.S.C. § 794(a), and its implementing

regulations. He asserts that the Department is obligated to modify his exclusion to comply with the Rehabilitation Act's requirement that employers provide reasonable accommodation to individuals with handicaps.

I am without authority to order that the exclusion be modified to permit Petitioner to claim reimbursement for items or services which he provides to program beneficiaries and recipients in his present work arrangement. Sections 1128 and 1862(e)(1) of the Act require that an exclusion apply equally to all federally-funded health care programs. An exclusion cannot lawfully be tailored to permit an excluded party to claim reimbursement for particularized items or services. Walter J. Mikolinski, Jr., DAB 1156 (1990). Thus, I cannot order that his exclusion be modified to allow him to claim reimbursement for program-related items or services which he may provide while employed at Mendota Mental Health Institute.

I am without authority to order that Petitioner's exclusion be modified to accommodate his medical condition, assuming that it is a handicapping condition under the Rehabilitation Act of 1973.[11] There is nothing in the language or history of section 1128 which states or suggests that Congress intended that exclusions be modified to accommodate handicapping conditions. In the context of section 1128 exclusion hearings, I have not been delegated authority by the Secretary to consider issues which might properly be raised under the Rehabilitation Act of 1973.

I must uphold an exclusion determination which I determine to be reasonable in light of the evidence in that case. An exclusion is "reasonable" if it is not extreme or excessive. 48 Fed. Reg. 3744 (1983). The evidence in this case convinces me that the exclusion is reasonable because Petitioner will not be trustworthy to provide care to program beneficiaries and recipients for at least three years. The evidence establishes that there is a significant risk that Petitioner's bipolar affective disorder may recur, even if Petitioner complies with his medication regimen and remains under a psychiatrist's care. Finding 31. Moreover, neuropsychological testing of Petitioner, as recently as January 1992, established that Petitioner continues to manifest mental impairments which might affect his

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[11] I make no findings as to whether or not Petitioner is an "individual with handicaps" within the meaning of the Rehabilitation Act of 1973.

ability to practice psychiatry. Findings 20, 21, 27. There is no evidence of record to suggest that either Petitioner's bipolar affective disorder or his cerebral impairments are likely to resolve within the near future. The I.G. determined to exclude Petitioner for three years, a period which is not extreme or excessive on the facts of this case. Therefore, I conclude that the three-year exclusion imposed and directed by the I.G. is reasonable, and, accordingly, I uphold it.

CONCLUSION

For the foregoing reasons, I conclude that the three-year exclusion imposed and directed against Petitioner by the I.G. is reasonable. I therefore uphold the I.G.'s determination to impose and direct a three-year exclusion against Petitioner.

/s/

Steven T. Kessel
Administrative Law Judge