Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
	DATE: January 13, 1993
Bertha K. Krickenbarger, R.Ph.,	
Petitioner,	Docket No. C-92-113
	Decision No. CR250
- v. -	
The Inspector General.	

DECISION

On May 11, 1992, the Inspector General (I.G.) notified Petitioner that she was being excluded from participation in the Medicare and State health care programs for three years.[1] The I.G. told Petitioner that she was being excluded under section 1128(b)(3) of the Social Security Act (Act), based on Petitioner's conviction of a criminal offense related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

Petitioner requested a hearing, and the case was assigned to me for a hearing and a decision. On September 21, 1992, I held a hearing in Columbus, Ohio. Both parties filed posthearing briefs. I have carefully considered the evidence that I admitted at the hearing, the parties' arguments, and the applicable law and regulations. I conclude that the I.G. had authority to exclude Petitioner under section 1128(b)(3) of the Act. I conclude that the three-year exclusion imposed and directed by the I.G. is unreasonable, and I modify it to a term of 18 months.

---

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

ISSUES

The issues in this case are whether:

1. My decision as to the reasonableness of the exclusion imposed and directed against Petitioner by the I.G. is governed by regulations published on January 29, 1992.

2. 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 pharmacist. Tr. at 43.[2]

2. Petitioner received licenses to practice pharmacy in the States of Ohio and West Virginia. Tr. at 44.

3. On September 28, 1990, Petitioner pled guilty in an Ohio court to a bill of information charging her with the criminal offense of illegal processing of drug documents. I.G. Ex. 2/1.

4. The offense to which Petitioner pled is a felony under Ohio law. I.G. Ex. 2/1.

5. Petitioner had been charged with intentionally making, uttering, or knowingly possessing a false or forged prescription for the drug Fioricet, a barbiturate, and a controlled substance under Ohio law. I.G. Ex. 1/1; see I.G. Ex. 4/3.

6. Petitioner was convicted of a criminal offense related to the unlawful prescription or dispensing of a controlled substance. Findings 3 - 5; Social Security Act, section 1128(b)(3).

7. The offense to which Petitioner pled resulted from her unlawfully writing a prescription for Fioricet, in her ex-husband's name, on July 7, 1990. Tr. at 45 - 47.

---

[2] I refer to the I.G.'s exhibits as "I.G. Ex. (exhibit number)/(page)." I refer to Petitioner's exhibits as "P. Ex. (exhibit number)/(page)." I refer to the transcript of the hearing as "Tr. at (page)."

8. Petitioner's purpose in unlawfully writing a prescription for Fioricet was to obtain possession of the drug for her own use and to obtain compensation for the drug from her health insurance company. Tr. at 47.

9. Petitioner was sentenced to incarceration for one and one-half years, which was suspended, conditioned on her satisfactory completion of a five-year term of probation. I.G. Ex. 3/2.

10. The terms of Petitioner's probation included the requirement that she pay a fine of $1000 and that she subject herself to drug analysis whenever requested to by her probation officer. I.G. Ex. 3/2.

11. On December 18, 1990, the Ohio State Board of Pharmacy (Ohio Pharmacy Board) suspended indefinitely Petitioner's license to practice pharmacy in Ohio. I.G. Ex. 4/4 - 5.

12. The Ohio Pharmacy Board found that Petitioner had been convicted of a felony and had engaged in dishonest or unprofessional conduct in her practice of pharmacy. I.G. Ex. 4/4.

13. The Ohio Pharmacy Board found that Petitioner had been addicted to or had abused liquor or drugs or had been impaired physically or mentally to such a degree as to render her unfit to practice pharmacy. I.G. Ex. 4/4.

14. The Ohio Pharmacy Board based its conclusion that Petitioner had been addicted to or had abused liquor or drugs in part on a finding that Petitioner had been observed abusing drugs and being under the influence of drugs during the performance of her duties as a pharmacist. I.G. Ex. 4/3 - 4.

15. The Ohio Pharmacy Board made Petitioner eligible to apply for reinstatement of her license after a suspension of one year, provided that Petitioner: enter into a five-year contract with an acceptable drug rehabilitation program and provide the Ohio Pharmacy Board with quarterly progress reports which included copies of results of random urine screens for drugs, evidence of attendance at meetings of a support group, and descriptions of her progress toward rehabilitation. I.G. Ex. 4/4 - 5.

16. On November 1, 1990, Petitioner signed a contract with Pharmacists Rehabilitation Organization, Inc. (PRO). P. Ex. 4/2 - 4; Tr. at 49.

17. On January 9, 1991, Petitioner entered into an additional agreement with PRO. P. Ex. 5/1 - 2; Tr. at 53.

18. Petitioner's agreements with PRO require her to attend three weekly meetings of a substance abuse rehabilitation program. P. Ex. 5/1.

19. Petitioner's agreements with PRO require that she submit to random urine screens, at least monthly, for controlled substances. P. Ex. 5/1.

20. Petitioner's agreements with PRO remain in effect until January 1996. P. Ex. 5/2.

21. Between September 1990 and May 1991, Petitioner underwent drug and alcohol counseling with a therapist at North Central Mental Health Services in Columbus, Ohio. P. Ex. 8/3; Tr. at 57 - 58.

22. Petitioner received psychiatric treatment in October 1991. Tr. at 58 - 59.

23. Petitioner has attended meetings of Alcoholics Anonymous since October 1990. P. Ex. 7/3, 8/2; see Tr. at 59.

24. Petitioner has attended at least three meetings of Alcoholics Anonymous per week since October 1990, except for the period between December 24, 1990 and January 7, 1991, when Petitioner was recovering from surgery. P. Ex. 7/3, 8/2, 13.

25. Petitioner has been subject to random urinalysis for the presence of drugs since her conviction of a criminal offense. P. Ex. 7/3 - 6, 8/2, 8/4 - 7, 13, 14; Tr. at 51.

26. All urinalysis tests conducted of Petitioner since her conviction of a criminal offense have been negative for the presence of controlled substances. P. Ex. 7/3 - 6, 8/2, 8/4 - 7, 13, 14; Tr. at 51.

27. Petitioner has not consumed any controlled substances or alcohol since October 16, 1990. Tr. at 57; see Finding 26.

28. Petitioner has expressed remorse for the unlawful conduct which resulted in her criminal conviction. Tr. at 59, 62.

29. Petitioner is sincere in her efforts to abstain from consuming controlled substances and alcohol and to refrain from engaging in conduct that is unlawful or which might endanger the welfare of other persons. Findings 16 - 28.

30. On August 13, 1992, the State of Ohio discharged Petitioner from probation. P. Ex. 18.

31. Petitioner was discharged from probation in advance of the discharge date established by her criminal sentence. Findings 9, 30.

32. The decision to discharge Petitioner from probation was based on the conclusion that Petitioner had complied with the rules and regulations of her probation and was no longer in need of probation supervision. I.G. Ex. 18.

33. On March 10, 1992, the Ohio Pharmacy Board reinstated Petitioner's license to practice pharmacy in Ohio, subject to conditions. I.G. Ex. 11/3 - 4.

34. The conditions which the Ohio Pharmacy Board attached to reinstatement of Petitioner's license to practice pharmacy in Ohio included the requirement that Petitioner continue her relationship with PRO until January 14, 1996. I.G. Ex. 11/3.

35. The Ohio Pharmacy Board specified that, as conditions for Petitioner being licensed to practice pharmacy in Ohio, Petitioner must, for the remainder of her relationship with PRO:

> a. submit to random observed urine screens at least once every three months;
>
> b. continue regular attendance at Alcoholics Anonymous, Narcotics Anonymous, or a similar support group meeting;
>
> c. report immediately to the Ohio Pharmacy Board any violations of her contract with PRO; and
>
> d. continue to submit quarterly progress reports to the Ohio Pharmacy Board documenting her activities and her recovery progress.

I.G. Ex. 11/3 - 4.

36. The Secretary of the United States Department of Health and Human Services (the Secretary) delegated to the I.G. the authority to determine, impose, and direct exclusions pursuant to section 1128 of the Act. 48 Fed. Reg. 21,662 (1983).

37. The I.G. had authority to impose and direct an exclusion pursuant to section 1128(b)(3) of the Act. Findings 3 - 6; Social Security Act, section 1128(b)(3).

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

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

40. The Secretary did not intend that regulations contained in 42 C.F.R. Part 1001 (1992) and, in particular, 42 C.F.R. § 1001.401 (1992), govern my decision in this case.

41. The remedial purpose of an exclusion under section 1128 of the Act is to protect federally funded health care programs and beneficiaries and recipients of those programs from individuals and entities who have established by their conduct that they are untrustworthy to provide care.

42. In writing a false prescription for a controlled substance for her own consumption, Petitioner engaged in conduct which endangered the health and safety of other individuals. Findings 7, 8, 12 - 14.

43. Petitioner has demonstrated by her conduct that she is untrustworthy to provide care. Finding 42.

44. Petitioner has shown by her admissions of misconduct, her remorse for her misconduct, and her efforts at rehabilitation that it is likely that she will soon become trustworthy to provide care. Findings 16 - 29.

45. The three-year exclusion which the I.G. imposed and directed against Petitioner is excessive in light of Petitioner's admissions of misconduct, her remorse for her misconduct, her efforts at rehabilitation, and the

likelihood that she will soon become trustworthy to provide care.

46. If Petitioner abstains from alcohol and controlled substances until November 1993, she will have abstained from the use of alcohol and controlled substances for more than a three-year period. Finding 27.

47. Given Petitioner's remorse and efforts at rehabilitation, a three-year period of abstinence by Petitioner from the use of alcohol or controlled substances will be sufficient to establish that she is trustworthy to provide care.

48. An 18-month exclusion is sufficient in this case to achieve the Act's remedial purpose.

ANALYSIS

Petitioner does not dispute that she was convicted of a criminal offense within the meaning of section 1128(b)(3) of the Act and that the I.G. has authority to exclude her from participating in the Medicare and Medicaid programs. What is at issue here is the reasonableness of the three-year exclusion that the I.G. imposed and directed against Petitioner.

The salient facts of this case are not disputed by either party. Petitioner is a pharmacist. In July 1990, Petitioner unlawfully wrote a fictitious prescription in her ex-husband's name for the drug Fioricet, a barbiturate. She did so in order that she could obtain the use of the drug for herself and to deceive her health insurer into paying for it. Her crime was detected; she was charged under Ohio law with a felony; and she pled guilty to the crime. She was sentenced to five years' probation in lieu of incarceration. Her license to practice pharmacy in Ohio was suspended by the Ohio Pharmacy Board.

Petitioner entered a program of substance abuse and alcohol rehabilitation, both as a condition of her probation and in order to regain her license to practice pharmacy in Ohio. Her rehabilitation included therapy, regular attendance at Alcoholics Anonymous meetings, and periodic random urinalysis for controlled substances. Thus far, her efforts at rehabilitation have been successful. Petitioner has expressed remorse for the misconduct which led to her conviction and has resolved to remain sober. Petitioner has faithfully attended meetings of Alcoholics Anonymous. She has refrained from

any use of alcohol or controlled substances since October 1990, and her sobriety is attested to by the fact that all of her drug tests have been negative.

Petitioner's efforts at rehabilitation have satisfied the State of Ohio that she is no longer in need of supervision by that State's criminal justice system. She was discharged from probation on August 13, 1992, approximately three years before the discharge date established by her sentence of probation. On March 10, 1992, the Ohio Pharmacy Board conditionally restored to Petitioner her license to practice pharmacy. That action was premised on Petitioner's agreement to remain in rehabilitation for alcohol and substance abuse and to continue to report regularly to the Ohio Pharmacy Board.

The I.G. asserts that regulations published by the Secretary in January 1992 mandate that I sustain the exclusion. He argues, further, that the exclusion is a reasonable remedy in view of the facts of this case. Petitioner contends that the three-year exclusion is not mandated by regulation and that it is not reasonably related to the Act's remedial purpose.

1. Regulations published by the Secretary on January 29, 1992 do not mandate that I sustain the exclusion which the I.G. imposed in this case.

The I.G. contends that my decision as to the reasonableness of the exclusion imposed against Petitioner is governed by regulations published by the Secretary on January 29, 1992. 42 C.F.R. Part 1001 (1992). 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)(3) of the Act, also apply at the level of administrative hearings to establish mandatory criteria for adjudicating the reasonableness of exclusions imposed pursuant to section 1128(b)(3). 42 C.F.R. § 1001.401 (1992).[3]

---

[3] Neither party to this case submitted extensive briefs on this issue. I advised the parties at the hearing that I had issued several decisions in which I found that the new Part 1001 regulations did not establish criteria governing administrative law judges' adjudications of the reasonableness of exclusions. I did not instruct the parties that they should not brief the issue of the regulations' applicability, but I made it clear that I was unlikely to change my decision based on

Section 1001.401 of these regulations directs that exclusions imposed pursuant to section 1128(b)(3) of the Act be for three years, absent proof of factors which the regulation designates as being either "aggravating" or "mitigating." Aggravating factors (none of which are asserted by the I.G. to be present here) will justify imposition of an exclusion for a period that exceeds three years. Mitigating factors will justify imposition of an exclusion for less than three years. Mitigating factors are specifically limited by subsection 1001.401(c)(3) to the following:

> (i) the . . . [excluded party's] cooperation with Federal or State officials resulted in --
>
> > (A) Others being convicted or excluded from Medicare or . . . [Medicaid],
> >
> > (B) The imposition of a civil money penalty against others; or
>
> (ii) Alternative sources of the type of health care items or services furnished by the . . . [excluded party] are not available.

Petitioner does not contend that any of the factors identified by the regulation as mitigating are present here.[4] If section 1001.401 of the new regulations had governed my decision in this case, I would have had no choice but to sustain the three-year exclusion imposed and directed by the I.G. Indeed, there would have been no purpose for holding a hearing in this case, because Petitioner did not contest the I.G.'s authority to exclude her. If this regulation had governed my decision, none of the evidence offered by Petitioner concerning the reasonableness of the exclusion would have been relevant, inasmuch as it did not pertain to any of the mitigating factors specified by the regulation.

---

a revisiting of arguments which I had already heard and decided. I advised the I.G. that, to the extent he disagreed with my decision as to the regulations' applicability, his disagreement would be noted and his rights to appeal would be preserved.

[4] Petitioner's crime did not involve other individuals. Therefore, Petitioner could not have performed any of the acts which the regulation designates as "mitigating" even if she wanted to do so.

The formula for determining exclusions established by section 1001.401 of the new regulations is generally duplicated by the other sections contained in Part 1001 of the new regulations. A purpose of these regulations is to establish a narrow framework of factors that may be considered as relevant by the I.G. and his agents in determining to impose exclusions pursuant to section 1128 of the Act. They are intended to exclude from consideration any factors not specifically identified by the regulations as being aggravating or mitigating. For all practical purposes, the regulations establish minimum mandatory exclusion periods for most exclusions imposed pursuant to section 1128.

Depending on how they are applied, the Part 1001 regulations may affect much more than the outcome of this case. If the Part 1001 regulations were held to govern administrative law judge decisions under section 1128 of the Act, they would eliminate all basis for administrative hearings in many cases. In such cases the role of the administrative law judge would be reduced to ruling, on the face of the request for a hearing, that the petitioner had not raised a justiciable issue.

I, along with other administrative law judges, have held in numerous decisions that these regulations do not establish criteria for administrative law judges' review of exclusions imposed and directed by the I.G. Tajammul H. Bhatti, M.D., DAB CR245 (1992); John Cleveland Turley, III, M.D., DAB CR236 (1992); Narinder Saini, M.D., DAB CR217 (1992); Sukumar Roy, M.D., DAB CR205 (1992); Steven Herlich, DAB CR197 (1992); Stephen J. Willig, M.D., DAB CR192 (1992); Aloysius Murcko, D.M.D., DAB CR189 (1992); Charles J. Barranco, M.D., DAB CR187 (1992). We have grounded our decisions on two conclusions. First, these regulations were not intended to strip parties retroactively of rights vested prior to January 29, 1992. Therefore, the regulations did not apply to any cases arising from exclusion determinations made prior to that date. Behrooz Bassim, M.D., DAB 1333, at 5 - 9 (1992). Second, the Secretary did not intend Part 1001 of the regulations to establish criteria for administrative hearings as to the reasonableness of exclusions.

There is no issue of retroactivity here. This case differs from those which we have decided previously in that here, the I.G. determined to exclude Petitioner on May 11, 1992, after the new regulations' publication date. This case raises unequivocally the question of whether the Secretary intended Part 1001 of the regulations to govern administrative hearings arising

from exclusion determinations made after the regulations' publication date.

If the Part 1001 regulations were held to govern an administrative law judge's review of an exclusion imposed under section 1128 of the Act, they would change fundamentally the way in which exclusions are evaluated for reasonableness. Up until now, section 1128 of the Act has been interpreted to permit the imposition of exclusions which achieve the Act's remedial purpose. Exclusions which are punitive have been held to be unreasonable. Up until now, excluded parties have been permitted to present any evidence which is relevant to the issue of whether exclusions are remedial. They have not been limited arbitrarily to presenting evidence which relates only to factors defined by the regulations as "mitigating" or "aggravating," nor have they been precluded from presenting evidence not considered by the I.G. in making his exclusion determinations.

Section 1128 is a civil remedies statute. Its purpose is not to punish excluded parties, but to provide the Secretary with a remedy to be used to protect the integrity of federally funded health care programs and their beneficiaries and recipients from individuals who have established by their conduct that they are not trustworthy. Robert Matesic, R.Ph., d/b/a/ Northway Pharmacy, DAB 1327, at 7 - 8 (1992). Exclusions which do not comport with this remedial purpose may be punitive, and, therefore, unlawful. 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). Labeling an action taken pursuant to a civil remedies statute as "remedial" does not immunize that action from scrutiny as to its effect. An action taken pursuant to a civil remedies statute may be punitive in effect, and therefore, unlawful, if it does not comport with that statute's remedial purpose.

In Matesic, an appellate panel of the Departmental Appeals Board (Board) discussed the kinds of evidence which should be considered by administrative law judges in hearings as to the reasonableness of the exclusion. That evidence includes evidence which relates to:

> 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.

Matesic, DAB 1327, at 12.

Hearings before administrative law judges as to the reasonableness of exclusions have been held to be de novo, and not appellate, hearings. Bernardo G. Bilang, M.D., DAB 1295 (1992); Eric Kranz, M.D., DAB 1286 (1991). Any party excluded pursuant to section 1128 of the Act is entitled to an administrative hearing as to the exclusion's reasonableness. Section 1128(f) of the Act provides that an excluded party's hearing rights shall be those conferred by section 205(b) of the Act. That section provides for de novo hearings.[5] An excluded party may offer evidence at a hearing under sections 1128 and 205(b) which is relevant to the issue of reasonableness, even if that evidence was not considered by the I.G. in making his exclusion determination.

The right to present evidence at a hearing under sections 1128 and 205(b) is not unlimited, however. As with any hearing, evidence which is not relevant should not be admitted or considered in adjudicating the case. Evidence which is offered in a case brought pursuant to section 1128 is relevant to the issue of an exclusion's reasonableness if it addresses the issue of whether the exclusion conforms to the Act's remedial purpose.

Exclusions imposed pursuant to sections 1128(a)(1) and (a)(2) of the Act, which are based on convictions for program-related crimes or for patient neglect or abuse, are required by the Act to be for no less than five years. Social Security Act, sections 1128(a)(1), (a)(2), (c)(3)(B). Exclusions imposed pursuant to sections 1128(a)(1) and (a)(2) are distinguishable from exclusions imposed pursuant to section 1128(b) of the Act, in that in the case of exclusions mandated by sections 1128(a)(1) and (a)(2), Congress itself has made a legislative determination that mandatory exclusions of a minimum five-year duration are remedially necessary. Thus, in hearings concerning exclusions imposed pursuant to sections 1128(a)(1) and (a)(2), the issue of reasonable-

---

[5] Section 205(b) also governs hearing rights for applicants for Social Security benefits, including Social Security disability benefits. A party excluded under section 1128 of the Act has the same hearing rights as has any applicant for Social Security benefits.

ness arises only if the exclusions are for periods in excess of five years. By contrast, Congress did not mandate minimum exclusions for parties excluded pursuant to section 1128(b) of the Act. Neither in the Act nor in the legislative history to the Act is there support for the I.G.'s position that the Secretary was authorized to establish minimum exclusions for parties excluded pursuant to section 1128(b).

In this case, the exclusion was imposed pursuant to section 1128(b)(3) of the Act, a section which neither mandates the imposition of an exclusion nor requires that an exclusion of a particular length be imposed against an excluded party. The measure of the reasonableness of any exclusion imposed under this section is the Act's remedial criteria.

The new Part 1001 regulations, and, in particular, section 1001.401, plainly would strip excluded parties of the statutory right recognized in Matesic to present evidence which relates to the Act's remedial criteria, if those regulations were found to govern administrative hearings as to the reasonableness of exclusions. Furthermore, the new regulations would render meaningless parties' rights to de novo hearings as to the reasonableness of exclusions, because the regulations would declare the evidence which relates to reasonableness to be irrelevant. Under the new regulations, assuming they were to apply to administrative law judges' hearings as to the reasonableness of exclusions, the role of administrative law judges would be confined to an appellate review of whether the I.G. had considered the factors delineated by the regulations in reaching his exclusion determinations. Thus, the Part 1001 regulations, assuming they were held to govern administrative law judges' hearings as to the reasonableness of exclusions, would place the Secretary in opposition to the Act as interpreted in prior decisions by appellate panels of the Departmental Appeals Board.[6]

---

[6] This potential conflict was implicitly recognized by the appellate panel in Bassim. Although the panel declined to address the issue of the applicability of the Part 1001 regulations, it held that those regulations could not be applied retroactively to exclusion determinations made prior to January 29, 1992. The gravamen of the decision in Bassim was that if the Part 1001 regulations applied to administrative adjudications, then they stripped parties of rights which the Board's appellate panels had found previously were vested by the Act.

I do not have authority to declare regulations to be ultra vires the Act. 42 C.F.R. § 1005.4(c)(1) (1992); see Jack W. Greene, DAB 1078, at 18 (1989), aff'd, Greene v. Sullivan, 731 F. Supp. 835.[7] If the Part 1001 regulations are intended to govern administrative law judges' hearings as to the reasonableness of exclusions, I must apply them to my decisions, even though they may conflict with the Act or the Board's interpretations of the Act. Therefore, I make no findings here as to whether the Part 1001 regulations are ultra vires the Act.

However, I am required to interpret regulations so that they are consistent with the letter and spirit of the Act and the Board's decisions, to the extent that I do not contravene the regulations' plain meaning. If it is reasonably possible for me to read these regulations in a way which avoids a clash between the regulations and congressional intent, I must do so. As the Board's appellate panel held in Greene:

> In order to consider the "issues" as stated by the regulation [the version of 42 C.F.R. § 1001.125 which predates the January 29, 1992 publication] the A.L.J. must apply the underlying statutory provisions that the issues were designed to address. The A.L.J. must consider the meaning of the pertinent statutory provision as well as related provisions, relevant legislative history, the effective date of the statute, case law interpretations, and implementing regulations and policy issuances. It would literally be impossible to apply the issue identified by the regulation in a legally correct manner without considering these factors, as appropriate.

Greene, DAB 1078, at 17 (emphasis added). Therefore, in interpreting the regulations, I must, where possible, read them consistent with the Act and the Board's decisions interpreting the Act. Furthermore, to the extent that the regulations are unclear or ambiguous, I must look to the Act and case law interpreting the Act as a controlling statement of intent. In the final analysis, the operative principle I must apply -- unless explicit language in the regulations prohibits me from doing so -- is to interpret regulations in a manner which

---

[7] I also do not have authority to overrule decisions by the Board's appellate panels.

avoids creating conflicts between the Secretary's applications of the Act and the Act itself.

The Part 1001 regulations neither mandate nor suggest the interpretation advocated by the I.G. The regulations may be read fairly in a manner which is consistent with the Act and the Board's interpretations of the Act. I conclude here, as I and other administrative law judges have concluded previously, that the Part 1001 regulations do not establish criteria for administrative law judges' review of exclusion determinations imposed pursuant to section 1128 of the Act. The criteria which must be used by administrative law judges to evaluate the reasonableness of exclusions continue to be those required by Congress and identified by the Board's appellate panels in their decisions, including Matesic.

There are several bases for my conclusion that the Part 1001 regulations do not establish criteria for the evaluation of exclusions by administrative law judges, apart from my conclusion that the Secretary would not willingly publish regulations which are in conflict with the Act. First, the Part 1001 regulations neither state nor suggest that they apply at the level of the administrative hearing. The plain meaning of the regulations contained in Part 1001 is to establish criteria for the I.G. to use in making exclusion determinations.

The Part 1001 regulations establish criteria to be employed only by the I.G. in making exclusion determinations. Each subpart of Part 1001 refers only to "the OIG." "OIG" is defined by 42 C.F.R. § 1001.2 (1992) to mean "Office of Inspector General of the Department of Health and Human Services." The comments to Part 1001 of the regulations provide that "[t]he basic structure of the proposed regulations in this part set forth for each type of exclusion the basis or activity that would justify the exclusion, and the considerations the OIG would use in determining the period of exclusion." 57 Fed. Reg. 3298, 3299 (1992) (emphasis added). Nowhere do the regulations state -- either in Part 1001 or elsewhere -- that they are intended to establish criteria for de novo adjudications of the reasonableness of exclusions.

The I.G. has argued previously that a portion of the commentary to the Part 1001 regulations expresses the Secretary's intent that the regulations establish criteria for administrative law judges' adjudications of the reasonableness of exclusions. I considered this argument in Saini and found it to be without merit. Saini, DAB CR217, at 14 - 16. I will not reiterate my

analysis here, except to note that the "comment" and "response" cited by the I.G. in his arguments in Saini are, at best, ambiguous, and furthermore, they do not state that the Part 1001 regulations are intended to serve as criteria for adjudications of exclusions' reasonableness.

Second, there is nothing in the Part 1001 regulations or the commentary to those regulations which either states or suggests that the Secretary intended the regulations to overrule the Board's interpretations of the Act. The Board is vested with authority to interpret the Act on behalf of the Secretary. Its decisions carry the same weight as do regulations. Had the Secretary intended to supersede the Board's decisions by his enactment of regulations, he would have said so.

The Secretary's decision not to overrule or supersede Board interpretations of the Act establishing the standard for review of section 1128 exclusions stands in contrast to specific instances where he has, through the new regulations, explicitly established standards of review of I.G. determinations which are binding on administrative law judges and the Board's appellate panels. For example, the new regulations containing criteria for determining civil money penalties, assessments, and exclusions apply to "the Department" and not to the I.G. only. 42 C.F.R. §§ 1003.106, 1003.107 (1992).

Third, the Part 1001 regulations would conflict with other regulations adopted by the Secretary on January 29, 1992, if they were held to establish criteria for adjudication of the reasonableness of the exclusion by administrative law judges. The Part 1001 regulations are part of a broader enactment which includes regulations which explicitly establish the authority of administrative law judges to conduct hearings pursuant to section 1128 of the Act (and pursuant to other sections, as well). These are contained in Part 1005 of the new regulations. The Part 1005 regulations also make explicit certain rights which inure to parties in hearings held pursuant to the Act.

The Part 1005 regulations contain many sections which would be meaningless if the standard for determining exclusions contained in Part 1001 were construed to be a standard for reviewing the reasonableness of exclusion determinations. The Part 1001 regulations all but mandate exclusions of predetermined length in most cases. By contrast, the Part 1005 regulations envision adversary hearings where the review of exclusions by administrative

law judges is not bound rigidly by the criteria and evidence employed by the I.G. to make exclusion determinations.

Specific sections in the Part 1005 regulations plainly envision a much broader scope to administrative hearings than would result from holding that the Part 1001 regulations establish criteria for adjudication of the reasonableness of exclusions. For example, 42 C.F.R. § 1005.15(f)(1) (1992) provides that evidence which may be considered by an administrative law judge in reviewing an exclusion determination shall not be limited to that on which the I.G. relies in his notice of exclusion. As another example, 42 C.F.R. § 1005.20(b) (1992) provides that an administrative law judge may "affirm, increase or reduce the penalties, assessment or exclusion proposed or imposed by the IG, or reverse the imposition of the exclusion." Nowhere does this section or the other Part 1005 regulations state or suggest that this authority is subject to the criteria contained in the Part 1001 regulations.

The Part 1005 regulations also establish comprehensive procedural safeguards for the conduct of adversary hearings pursuant to section 1128 of the Act, which would become meaningless if the Part 1001 regulations were construed to establish standards for adjudication of the reasonableness of exclusions. For example, discovery of documents is provided for by 42 C.F.R. §§ 1005.3, 1005.7 (1992). The regulations mandate prehearing exchanges of lists of witnesses, as well as witness statements and exhibits. 42 C.F.R. § 1005.8 (1992). The regulations provide a mechanism to subpoena witnesses to testify at hearings. 42 C.F.R. § 1005.9 (1992). They provide for on-the-record hearings which may include the testimony of witnesses and the cross-examination of witnesses. 42 C.F.R. §§ 1005.15, 1005.16 (1992). They contain standards governing the admission of evidence at hearings. 42 C.F.R. § 1005.17 (1992). They provide for recorded and transcribed hearings. 42 C.F.R. § 1005.18 (1992). None of these regulations would be needed if, in fact, nearly all cases brought under section 1128 of the Act were to be decided summarily pursuant to the Part 1001 regulations.

The I.G. has argued that any decision by an administrative law judge which interprets the new regulations in a manner different from that contended to be correct by the I.G., or which differs with the I.G.'s determination as to what is a reasonable exclusion in a particular case, constitutes an impermissible interference with the I.G.'s discretion. He bases this

argument on 42 C.F.R. § 1005.4(c)(5) (1992), which forbids administrative law judges from reviewing the I.G.'s exercise of discretion to exclude a party under section 1128(b) of the Act or to determine the scope or effect of the exclusion. The meaning of section 1005.4(c)(5) is not apparent from its language or its context, and it is not explained in the preamble or comments. However, it plainly does not vest authority in the I.G. to interpret and apply regulations as "exercises of discretion" which are immune from review by administrative law judges and the Board's appellate panels. Furthermore, if the regulation were read to mean that administrative law judges could not independently decide whether an exclusion is reasonable in a particular case, it would make meaningless all hearings under section 1128 of the Act. Under the I.G.'s asserted interpretation, I would lack even the authority to decide whether the I.G. had complied with the Part 1001 regulations.

Finally, it is reasonable to read the Part 1001 regulations as codifying I.G. policy, without construing them as being applicable at all levels of review. There has never been a particular nexus between the criteria employed by the I.G. to make exclusion determinations and criteria employed by administrative law judges or the Board's appellate panels to evaluate the reasonableness of such determinations. For example, the I.G.'s agents have testified routinely in cases involving section 1128(b)(4) exclusions that the I.G.'s policy is to make exclusions under that section coterminous with license suspensions or revocations imposed by State licensing authorities. However, the Board's appellate panels and administrative law judges have held that the purpose of the administrative hearing is to objectively adjudicate the reasonableness of an exclusion determination pursuant to the remedial criteria contained in the Act. The I.G.'s internal policies and adherence to them have not been standards by which the reasonableness of exclusions have been adjudicated.

The Part 1001 regulations therefore can be read to make explicit a previously inchoate policy governing the I.G.'s internal operations. However, neither administrative law judges nor the Board's appellate panels have ever concluded that it was the Secretary's intent to direct them to apply the law in a manner consistent with the I.G.'s internal policy. The fact that these regulations codify policy which is applicable to the I.G. does not require that they be read as a directive to administrative law judges and the Board in the absence of any expression of intent by the Secretary

to make that policy applicable at the level of the administrative hearing.

2. The three-year exclusion which the I.G. imposed and directed against Petitioner is excessive.

I conclude that the three-year exclusion imposed and directed against Petitioner by the I.G. is excessive because an exclusion of that duration is not necessary to protect the welfare of beneficiaries and recipients of federally funded health care programs.

Applying the criteria established in Matesic, I reach the following conclusions. First, Petitioner's offense was serious and it demonstrates that Petitioner was a highly untrustworthy individual at the time she committed that offense. There is no question that her conduct merits an exclusion in order to protect the welfare of program beneficiaries and recipients. Second, Petitioner has expressed recognition of the nature of her misconduct, remorse for it, and has made sincere and dedicated efforts at rehabilitation. Third, Petitioner's efforts at rehabilitation have so far been successful. When viewed in combination, these factors demonstrate the need for an exclusion, but not for the lengthy exclusion imposed by the I.G.

There is no question that Petitioner committed a serious offense which established her to be an untrustworthy provider of care. Petitioner abused her position as a pharmacist to unlawfully obtain possession of controlled substances. Further, Petitioner potentially endangered the welfare of individuals whose welfare she had the duty to protect. By abusing controlled substances and alcohol, Petitioner created the possibility that she might make judgment errors in filling prescriptions for controlled substances and other medications, thereby placing other individuals' health and safety in jeopardy.

Had the I.G. imposed the exclusion at issue here in September 1990 when Petitioner pled guilty to an offense involving controlled substances, I would have had no difficulty in sustaining it. At that point, Petitioner was addicted to controlled substances and alcohol and had not yet begun the process of rehabilitation. I would have held then that a three-year exclusion would have been reasonably necessary to protect the welfare of beneficiaries and recipients.

Intervening events demonstrate that it is not now necessary to impose a three-year exclusion against

Petitioner. Beginning in October 1990, Petitioner underwent intensive, and, so far, successful efforts to refrain from substance and alcohol use and to rehabilitate herself. She has remained free of both controlled substances and alcohol for more than two years. She has involved herself actively in rehabilitation efforts. Her dedication to rehabilitation is demonstrated by her faithful attendance at Alcoholics Anonymous meetings.[8]

Petitioner has demonstrated an understanding of the harmfulness of her past substance and alcohol abuse. She has expressed remorse for her past conduct and has asserted, credibly and sincerely, that she intends to remain substance and alcohol-free.

Petitioner's efforts at rehabilitation plainly have impressed State authorities in Ohio. She was discharged early from her probation. Her license to practice pharmacy in Ohio has been restored, albeit on a probationary basis.[9]

The I.G. imposed his three-year exclusion of Petitioner in May 1992. Under the terms of that exclusion, Petitioner would not be eligible to apply for reinstatement prior to May 1995. Assuming she remains faithful to her pledge to rehabilitate herself, by then Petitioner will be substance-free for nearly five years. I do not believe that such a long term of abstinence is a

---

[8] Petitioner had surgery in December 1990. Notwithstanding, she attended an Alcoholics Anonymous meeting the following week. P. Ex. 7/3.

[9] The I.G. could have excluded Petitioner pursuant to section 1128(b)(4) of the Act, based on the suspension of Petitioner's license to practice pharmacy in Ohio. Had the I.G. done so, and had the I.G. followed his policy of making the exclusion coterminous with the license suspension, Petitioner would now be eligible for reinstatement. The Act does not require the I.G. to impose exclusions which operate to the advantage of excluded parties. There is no requirement that the I.G. elect to exclude under section 1128(b)(4) where there exists an option to exclude under another subsection of section 1128(b). On the other hand, the fact that Petitioner would now be eligible for reinstatement, had the I.G. chosen to exclude her under section 1128(b)(4), underscores my conclusion that the Act does not suggest that minimum exclusions are required for any subsection of 1128(b).

reasonable precondition for eligibility for reinstatement in this case, given Petitioner's diligence and sincerity. In light of Petitioner's efforts at rehabilitation, I conclude that a three-year period of abstinence from alcohol and controlled substances would establish Petitioner to be trustworthy to provide care. Therefore, I modify the I.G.'s exclusion to a term of 18 months. Under the terms of the modified exclusion, Petitioner will be eligible to apply to the I.G. for reinstatement in November 1993, more than three years from the date when Petitioner last consumed alcohol or controlled substances.[10]

CONCLUSION

For the foregoing reasons, I conclude that the three-year exclusion imposed and directed against Petitioner by the I.G. is excessive. I modify the exclusion to a term of 18 months.

/s/

Steven T. Kessel
Administrative Law Judge

---

[10] The fact that Petitioner is eligible to apply for reinstatement after 18 months does not obligate the I.G. to grant her application. If Petitioner should relapse during the period between this decision and the date of her becoming eligible for reinstatement, then, presumably, the I.G. could factor such a relapse into his determination as to whether Petitioner is in fact trustworthy to provide care as of the date of her application for reinstatement.