Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	DATE: May 11, 1992
Steven Herlich,	)	
	)	
Petitioner,	)	Docket No. C-367
	)	Decision No. CR197
- v. -	)	
	)	
The Inspector General.	)	
	)	

DECISION

On February 15, 1991, the Inspector General (I.G.) notified Petitioner that he was being excluded from participating in Medicare and State health care programs for 20 years, pursuant to section 1128(a)(1) of the Social Security Act (Act).[1] The I.G. advised Petitioner that he was being excluded as a result of his conviction of a criminal offense related to the delivery of an item or service under Medicaid.

Petitioner timely requested a hearing, and the case was assigned to me for a hearing and a decision. I held a hearing in Baltimore, Maryland, on December 18, 1991. 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 20-year exclusion imposed by the I.G. is excessive. I find that the remedial principles of the Act will be met in this case by a 10-year exclusion, and I modify the exclusion accordingly.

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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.

ISSUE

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

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Petitioner attained a degree in pharmacy and became a licensed pharmacist in 1982. Tr. at 53.[2]

2. In January 1985, Petitioner became the proprietor of a franchised pharmacy in Baltimore, Maryland. Tr. at 55.

3. On May 2, 1990, Petitioner pleaded guilty in the Circuit Court for Baltimore City, State of Maryland, to one count of Medicaid fraud. I.G. Ex. 6/1.

4. Petitioner entered his guilty plea pursuant to a plea agreement dated April 4, 1990. I.G. Ex. 4.

5. Petitioner's guilty plea to Medicaid fraud was a consequence of his involvement in a conspiracy to defraud the Maryland Medicaid program. I.G. Ex. 5/3; Tr. at 63 - 64.

6. Beginning in late 1985, Petitioner conspired with another individual to falsify prescriptions for drugs to be provided to Medicaid recipients, and to file false claims for Medicaid reimbursement based on fictitious prescriptions. I.G. Ex. 5/3; Tr. at 64.

7. Petitioner obtained blank original prescription invoices from the Maryland Medicaid program and supplied them to his co-conspirator. I.G. Ex. 5/3.

8. Petitioner's co-conspirator used the blank invoices to create fictitious prescriptions for drugs to be provided to Medicaid recipients. I.G. Ex. 5/3.

9. Petitioner provided his co-conspirator with information about drugs and prescription amounts to be used in creating fictitious prescriptions. I.G. Ex. 5/3 - 4.

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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)."

10. Petitioner's co-conspirator forged physicians' signatures on the fictitious prescriptions. I.G. Ex. 5/4.

11. Petitioner's co-conspirator used a variety of schemes to obtain Medicaid cards from Medicaid recipients. I.G. Ex. 5/4.

12. Petitioner imprinted information on claims for Medicaid reimbursement from the Medicaid cards that his co-conspirator had obtained. I.G. Ex. 5/4.

13. Petitioner created false claims for Medicaid reimbursement based on the fictitious prescriptions that had been created by his co-conspirator, and presented these false claims to Medicaid. I.G. Ex. 5/4 - 5.

14. Petitioner presented false claims to Medicaid for refills of fictitious prescriptions. I.G. Ex. 5/5.

15. Petitioner also presented false claims to private insurers for reimbursement based on fictitious prescriptions. I.G. Ex. 5/5.

16. In September 1988, Petitioner began submitting claims for Medicaid reimbursement based on computer-generated tapes. He continued to present false reimbursement claims to Medicaid via computer-generated tapes based on fictitious prescriptions. I.G. Ex. 5/5.

17. The conspiracy by which Petitioner presented false claims for Medicaid reimbursement continued until April 12, 1989, when Maryland State Police and the Maryland Medicaid Fraud Control Unit executed a search warrant at Petitioner's pharmacy. I.G. Ex. 5/7.

18. Petitioner defrauded Maryland Medicaid, the Maryland Kidney Disease Program, and private insurers. I.G. Ex. 5/8; Findings 13, 15.

19. Petitioner presented approximately $450,000 in false Medicaid claims during the three fiscal years ending June 30, 1989. I.G. Ex. 5/7.

20. Petitioner split the proceeds of his false Medicaid and insurance claims with his co-conspirator. I.G. Ex. 5/9; Tr. at 64.

21. Petitioner falsified the business records of his pharmacy in order to conceal payments to his co-conspirator. I.G. Ex. 5/10 - 11.

22. Prior to Petitioner's having entered into the conspiracy, Petitioner's pharmacy had experienced severe financial difficulties. I.G. Ex. 5/9; Tr. at 56 - 57, 61.

23. In 1987, Petitioner paid himself a salary of more than $90,000, and, in 1988, he paid himself a salary of $158,000. I.G. Ex. 5/9.

24. Between January 1, 1986, and April 12, 1989, Petitioner made payments to his co-conspirator of more than $250,000.

25. Based on his guilty plea, Petitioner received a suspended prison sentence of three years. I.G. Ex. 6/1.

26. Petitioner additionally was sentenced to reside for 18 months at Fellowship House, a psychiatric halfway house which provides transitional living for individuals who have been discharged from hospitalization for psychiatric conditions. I.G. Ex. 6/1; Tr. at 125.

27. Petitioner additionally was sentenced to five years' probation. I.G. Ex. 6/1.

28. Petitioner additionally was sentenced to pay a fine of $10,000 and court costs of $105. I.G. Ex. 6/1.

29. Petitioner additionally was sentenced to pay restitution of $290,000 to the Maryland Medicaid program. I.G. Ex. 6/1.

30. Petitioner completed his residence at Fellowship House. Tr. at 70, 127.

31. Petitioner presently is enrolled in a community support program under the continued supervision of Fellowship House staff. Tr. at 127.

32. Petitioner paid his fine, court costs, and restitution to the Maryland Medicaid program. P. Ex. 18/1 - /26; Tr. at 70.

33. As a condition of his plea, Petitioner surrendered his license to practice pharmacy. Petitioner also agreed that he would not apply for or hold a license to practice pharmacy in any other state or jurisdiction until such time, if ever, that his Maryland pharmacy license was restored. I.G. Ex. 4/4; P. Ex. 19/1 - /5.

34. As a condition of his plea, Petitioner agreed that he would disclose to Maryland authorities any information that he had about unlawful activities. I.G. Ex. 4/3.

35. Petitioner has cooperated with Maryland authorities in criminal prosecutions against other individuals, including his co-conspirator. P. Ex. 3; Tr. at 72.

36. Petitioner began abusing controlled substances as early as May 1985. P. Ex. 1/2; Tr. at 60.

37. Petitioner abused controlled substances through July 1989, when he was hospitalized for an overdose. P. Ex. 1/4; Tr. at 68.

38. The controlled substances which Petitioner abused included the medication Halcion. Tr. at 60 - 61, 97.

39. Halcion may produce side effects, including impaired judgment and memory. Tr. at 98.

40. Petitioner has undergone both in- and out-patient treatment for controlled substance abuse, beginning with his July 1989 hospitalization. P. Ex. 6/1 - /4, 7/1 -/2, 14/1 - /2; Tr. at 95, 100 - 101, 106 - 107.

41. Petitioner's out-patient treatment for controlled substance abuse has included random drug testing. Tr. at 107.

42. Petitioner has not abused controlled substances since he began treatment for controlled substance abuse. Tr. at 76, 107, 113.

43. Petitioner has been treated by a psychiatrist since his July 1989 hospitalization for controlled substance abuse. P. Ex. 4/1 - /2; Tr. at 95, 107, 111 - 112, 114.

44. Petitioner has been diagnosed to be suffering from psychiatric disorders, including depression, a generalized anxiety disorder, and a mixed personality disorder with borderline, self-defeating, and dependent features. P. Ex. 1/1 - /6, 2/1 - /5, 6/1 - 4; Tr. at 96 - 98.

45. Petitioner has manifested a tendency to become dependent on other individuals in a self-destructive manner. Tr. at 98, 103.

46. Petitioner's psychiatric problems and substance abuse were factors which contributed to his decisions to engage in criminal activity. Tr. at 108 - 109.

47. Petitioner does not manifest predatory or anti-social instincts as a result of his psychiatric problems. Tr. at 111.

48. Petitioner has made substantial progress towards rehabilitation from his psychiatric and substance abuse problems. Tr. at 113 - 114.

49. Petitioner has obtained and maintained gainful employment in a field unrelated to his pharmacy practice. Tr. at 52 - 53.

50. Petitioner has progressed to living independently in the community in a safe and appropriate way. Tr. at 127 - 128.

51. It is likely that Petitioner will not manifest substance abuse problems or criminal misconduct in the future. Tr. at 116 - 117, 120.

52. Petitioner was convicted of a criminal offense related to the delivery of an item or service under Medicaid. Finding 3; Social Security Act, § 1128(a)(1).

53. 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).

54. The I.G. had authority to impose and direct an exclusion against Petitioner. Findings 54, 55.

55. Five years is the minimum statutory period of exclusion for an individual convicted of a criminal offense within the meaning of section 1128(a)(1). Social Security Act, § 1128(c)(3)(B).

56. On February 15, 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, for 20 years. I.G. Ex. 2/1 - /2.

57. 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)(1) and (2) and (b) of the Act. 42 C.F.R. Part 1001; 57 Fed. Reg. 3298, 3330 - 3341 (January 29, 1992).

58. The Secretary did not intend that regulations contained in 42 C.F.R. Part 1001, and, in particular, 42 C.F.R. §§ 1001.101 and 1001.102, govern my decision in this case.

59. The criminal misconduct engaged in by Petitioner was willful, required planning and calculation, and establishes a high level of culpability on Petitioner's part. Findings 5 - 25.

60. Petitioner's history of substance abuse establishes that he is capable of engaging in misconduct which could jeopardize the welfare of program beneficiaries and recipients. Findings 37 - 40.

61. Petitioner's culpability for criminal conduct and his substance abuse establish that he is an untrustworthy individual and that an exclusion of greater than five years is necessary to protect the integrity of federally-funded health care programs and the welfare of program beneficiaries and recipients. Findings 61, 62.

62. In light of Petitioner's efforts at rehabilitation, an exclusion of 20 years is not remedially necessary in order to protect the integrity of federally-funded health care programs and the welfare of program beneficiaries and recipients. Findings 41 - 44, 49 - 53.

63. The Act's remedial purpose will be accomplished by an exclusion of ten years.

ANALYSIS

The parties do not dispute that Petitioner was convicted of a criminal offense within the meaning of section 1128(a)(1) of the Act, and, therefore, they do not disagree that the I.G. had authority to impose and direct an exclusion against Petitioner.[3] Nor do the parties disagree that the Act mandates an exclusion of at least five years for individuals found to have committed offenses within the meaning of section 1128(a)(1) of the Act.

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[3] The Act mandates the exclusion of any individual or entity "that has been convicted of a criminal offense related to the delivery of an item or service under . . . [Medicare] or under . . . [Medicaid] . . . ." Social Security Act, § 1128(a)(1).

The parties disagree as to the reasonableness of the length of the exclusion imposed and directed by the I.G. The I.G. contends that the 20-year exclusion is reasonable, particularly when evaluated pursuant to regulations published by the Secretary on January 29, 1992. Petitioner asserts that the new regulations do not apply to govern my evaluation of the exclusion's reasonableness. Furthermore, he contends that the exclusion which the I.G. imposed and directed in this case is excessive. Petitioner urges me to modify the exclusion to the five-year minimum period required by law.

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

On January 29, 1992, the Secretary published regulations which, among other things, establish criteria to be employed by the I.G. to determine the length of exclusions to be imposed pursuant to sections 1128(a) and (b) of the Act. 42 C.F.R. Part 1001; 57 Fed. Reg. 3298, 3330 - 3341. These regulations include a section which establishes criteria to be employed by the I.G. to determine the length of exclusions to be imposed pursuant to section 1128(a)(1). 42 C.F.R. § 1001.102; 57 Fed. Reg. 3331.

The I.G. contends that these regulations are applicable to this case. He argues that the exclusion he imposed and directed against Petitioner comports with the criteria of 42 C.F.R. § 1001.102, and that therefore, the exclusion should be sustained. Petitioner argues that the regulations are not applicable here.

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

I conclude that my review of the reasonableness of the exclusion imposed and directed against Petitioner is not governed by the new regulations' criteria for determining exclusions under section 1128(a)(1). The regulations contained in Part 1001 of the new regulations, and 42 C.F.R. § 1001.102 in particular, were not intended by the Secretary to govern hearings as to the reasonableness of exclusion determinations. Stephen J. Willig, M.D., DAB CR192 (1992) (Willig), Aloysius Murcko, D.M.D., DAB CR189 (1992) (Murcko), Charles J. Barranco, M.D., DAB CR187 (1992) (Barranco). And, even if the Part 1001 regulations do govern such hearings, they do not apply in cases involving exclusion determinations made prior to the regulations' publication date. Id.

Section 1128 is a remedial statute. Exclusions imposed under section 1128 cannot be imposed lawfully for other than remedial reasons. See United States v. Halper, 490 U.S. 435, 448 (1990) (Halper).

The Halper case decided the question of whether a punitive sanction imposed under the False Claims Act against a party who had previously been convicted of a criminal offense based on identical facts constituted a "second punishment" which violated the Double Jeopardy Clause of the United States Constitution. The Supreme Court's decision subsumes the broader questions of what constitutes a civil remedy and what constitutes a punishment. The Supreme Court observed in Halper that the aims of retribution and deterrence are not legitimate nonpunitive government objectives. It concluded:

> a civil sanction that cannot be fairly said solely to serve a remedial purpose, but rather can be explained only as also serving either retributive or deterrent purposes, is punishment, as we have come to understand the term.

490 U.S. at 448.

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 - 169 (1963). Labelling a statute as a "civil remedies" statute will not serve to insulate acts taken pursuant to that statute from analysis as to whether they are remedial or punitive. Id.

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 (1992) (Matesic) at 7 - 8; Willig at 14 - 15; Hanlester Network, et al. DAB CR181 (1992) (Hanlester) at 37 - 38. Section 205(b) of the Act guarantees parties excluded pursuant to section 1128 and who request hearings full administrative review of the reasonableness of the length of the exclusions imposed against them, measured by 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.

The Matesic, Bilang, Kranz, and Hanlester decisions all involve exclusions imposed under section 1128(b) of the Act, a section which gives the Secretary authority to impose and direct exclusions against certain individuals and entities, but which does not mandate exclusions. This case involves an exclusion imposed under section 1128(a) of the Act, a section which mandates exclusions of at least five years for individuals who are convicted of program-related offenses. Section 1128(a) embodies a legislative conclusion that such individuals and entities are untrustworthy and that, in cases falling under that section, exclusions of at least five years are necessary to accomplish the Act's remedial purpose. However, the authority to impose exclusions under section 1128(a) for more than five years is permissive, even as is the authority to impose exclusions of any duration under section 1128(b). Christino Enriquez, M.D., DAB CR119 (1991) at 11 - 12. The remedial standard for evaluating an exclusion imposed pursuant to section 1128(a) which exceeds five years -- the trustworthiness of the excluded party -- is identical to that used to evaluate the reasonableness of any exclusion imposed under section 1128(b). Id.

Section 205(b) of the Act guarantees an excluded party the right to a de novo hearing as to the reasonableness of the length of an exclusion imposed under section 1128(b) or as to the reasonableness of an exclusion in excess of five years imposed under section 1128(a). Bilang at 9; Kranz at 7 - 8; Hanlester at 39 - 43. The de novo hearing granted by section 205(b) contemplates a full administrative review of whether an exclusion comports with the Act's remedial purpose. As the appellate panels affirmed in Bilang and Kranz, an administrative law judge who conducts a hearing as to the reasonableness of an exclusion may consider all evidence which is relevant to the issue of reasonableness. Kranz at 8; see Joel Davids, DAB 1283 (1991) at 7; Vincent Baratta, M.D., DAB 1172 (1990) (Baratta) at 11.

The Act requires that, in evaluating the reasonableness of an exclusion, an administrative law judge must consider any evidence which relates to a party's trustworthiness. As the appellate panel recently held in Matesic:

> Since the reasonableness of an exclusion turns on the length of time necessary to establish that a provider is not likely to repeat the type of conduct which precipitated the exclusion, the ALJ must evaluate the myriad facts of each case. These include the nature

> of the offenses 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.

Id. at 12 (citation omitted).

The regulation at issue here, 42 C.F.R. § 1001.102, would, if held to establish a standard for reviewing the reasonableness of exclusions in excess of five years imposed pursuant to section 1128(a)(1), bar excluded parties from presenting evidence at hearings as to their trustworthiness. If applied as is urged by the I.G., the regulation would deny excluded parties the opportunity to demonstrate that exclusions imposed against them are inconsistent with the Act's remedial purpose. It would serve to insulate punitive exclusions from meaningful administrative review.

The regulation provides that no exclusion imposed pursuant to section 1128(a) of the Act will be for less than five years. 42 C.F.R. § 1001.102(a); 57 Fed. Reg. 3331. This requirement tracks the Act's mandatory exclusion provision and is not at issue here. The regulation provides further that the I.G. may consider certain "aggravating" factors as a basis for imposing an exclusion of more than five years. 42 C.F.R. § 1001.102(b)(1) - (6). These include the following: (1) the acts resulting in a party's conviction, or other, similar acts resulted in a financial loss to Medicare or Medicaid of $1,500 or more; (2) the acts resulting in a party's conviction, or other, similar acts were committed over a period of one year or more; (3) the acts resulting in a party's conviction or other, similar acts had a significant adverse physical mental or financial impact on a program beneficiary or other individual; (4) the criminal sentence imposed against a party included incarceration; (5) a party has a prior criminal, civil or administrative sanction record; and (6) a party has at any time been overpaid $1,500 or more by Medicare or Medicaid for improper billings. Id.

The regulation provides further that the I.G. may consider certain "mitigating" factors to offset the presence of "aggravating" factors. 42 C.F.R. §§ 1001.102(c)(1) - (3). These mitigating factors are expressly limited to the following: (1) a party was convicted of three or fewer misdemeanor offenses, and the total loss to Medicare and Medicaid resulting from the

offenses and from similar acts is less than $1,500; (2) the record in a party's criminal proceeding, including sentencing documents, demonstrates that the court which heard the criminal case determined that, before or during the commission of the offense, the party had a mental, emotional, or physical condition that reduced the party's culpability; and (3) a party's cooperation with federal or state officials resulted in others being convicted of criminal offenses, excluded from Medicare or Medicaid, or having civil money assessments or penalties imposed against them pursuant to section 1128A of the Act.

There is no question that the presence or absence of evidence which relates to the regulation's "aggravating" and "mitigating" factors may, in a particular case, denote the presence or absence of trustworthiness. For example, evidence which relates to the seriousness of a criminal offense (evidence as to the dollar amount of the fraud, the time period over which an offense is perpetrated, or the impact of fraud on program beneficiaries and recipients) plainly is relevant to the propensity of a party to commit future unlawful acts. John N. Crawford, Jr., M.D., DAB 1324 at 12 (1992); Hanlester at 49 - 52. Similarly, evidence as to a party's cooperation with prosecuting authorities or as to his or her mental and emotional state at the time he or she committed a crime may be relevant evidence of trustworthiness. Therefore, the "aggravating" and "mitigating" factors in 42 C.F.R. §§ 1001.102(b) and (c) may be instructive points of reference for evaluating a party's trustworthiness with respect to the reasonableness of an exclusion imposed against that party, for more than five years, pursuant to section 1128(a)(1).[4]

However, this regulation would fall short of satisfying the statutory test for measuring the reasonableness of exclusions if applied as a standard for administrative review, because if so applied it would exclude consideration of evidence which could be relevant to the

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[4] The regulation which predated this regulation, 42 C.F.R. § 1001.125 (1986), was routinely used by administrative law judges as a nonbinding guideline as to a party's trustworthiness in reviewing the reasonableness of an exclusion. That practice has been noted and concurred in by the Board's appellate panels. See Crawford at 10 n.11. However, neither administrative law judges nor the Board have ever held that this regulation established exclusive and binding criteria for review of exclusions.

issue of a party's trustworthiness. Matesic at 12. For example, evidence as to a party's mental state at the time that party committed a criminal offense is relevant to that party's trustworthiness even if that evidence was never considered by the judge who heard and decided the party's criminal case. See 42 C.F.R. § 1001.102(c)(2). Evidence as to a party's rehabilitation subsequent to that party's commission of criminal acts may also be highly relevant in evaluating that party's propensity to commit criminal acts in the future. Matesic at 12. The regulation would, if applied as a standard for exclusions in excess of five years, preclude any consideration of this evidence.[5]

I do not have authority to declare regulations to be ultra vires the Act. 42 C.F.R. § 1005.4(c)(1); 57 Fed. Reg. 3351; See Jack W. Greene, DAB 1078 (1989) (Greene) at 18.[6] If the new regulations are explicit in their instructions to me, I must apply them even though they may conflict with the letter of the Act, Congress' intent, or the Board's interpretations of the Act. On the other hand, I am required where possible to read regulations consistent with the letter and spirit of the Act and the Board's decisions. If it is reasonably possible for me to interpret these regulations in a way which avoids a clash between the regulations and congressional intent, I must do so. As the 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

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[5] Indeed, as I discuss infra, evidence as to Petitioner's rehabilitation is crucial to my decision that the 20-year exclusion imposed by the I.G. is excessive. I would be precluded from considering this evidence if I were bound by the criteria in 42 C.F.R. §§ 1001.102(b) and (c).

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

> apply the issue identified by the regulation in a legally correct manner without considering these factors as appropriate.

Greene at 17 (emphasis added).

The regulation at issue here plainly would conflict with the letter and intent of the Act and the Board's decisions, if applied as is advocated by the I.G. However, the new regulations do not mandate the interpretation advocated by the I.G. As I held in Willig, and as Judge Steinman held in Barranco, it is possible to read these regulations in a manner which is consistent with the Act and with the Board's interpretations of the Act's purpose and intent. Willig at 18 - 24; Barranco at 24 - 27.[7] I conclude that the regulations contained in Part 1001, and 42 C.F.R. § 1001.102 in particular, were not intended by the Secretary to establish criteria for the review of exclusion determinations at administrative hearings conducted pursuant to section 205(b) of the Act. While the regulations establish criteria to be employed by the I.G. in determining to impose exclusions, they do not establish criteria for evaluating the reasonableness of the I.G.'s determinations. The criteria which must be used by administrative law judges to evaluate the

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[7] In Barranco, Judge Steinman first considered whether application of the criteria in 42 C.F.R. § 1001.501 as a standard for review of the reasonableness of an exclusion would be an unlawful retroactive application in that case. He concluded that such an application would be unlawful and that it was not intended by the Secretary. He then considered, as an alternative basis for his decision, whether the Secretary had intended 42 C.F.R. § 1001.501 to establish criteria for evaluating the reasonableness of exclusions imposed under section 1128(b)(4) of the Act, at the level of the administrative hearing. He concluded that the Secretary did not intend the regulation to be applicable to the administrative review. I agree with Judge Steinman's analysis. However, here, I conclude as a first point of analysis that the Secretary did not intend the regulation to establish criteria for administrative review of a section 1128(b)(4) exclusion. My rationale for considering this issue first is, that if the Secretary did not intend the regulation to govern administrative hearings, there would be no issue as to its retroactive application at the hearing level. My conclusions as to retroactivity are thus alternative findings.

reasonableness of exclusions continue to be those criteria established by the Board's appellate panels.

Nowhere do the new regulations state that the criteria to be employed by the I.G. for determining exclusions are to serve as criteria for evaluating the reasonableness of exclusions. As I observed in Willig, the letter of these regulations only establishes criteria to be employed by the I.G. in making exclusion determinations. Willig at 19. That is underscored by the comments to Part 1001 of the new regulations, which explicitly state that the Part 1001 regulations establish criteria to be used by the I.G. in making exclusion determinations. 57 Fed. Reg. 3229. Thus, the plain meaning of the new regulations, as supported by the interpretive comments, is that the Part 1001 regulations establish criteria for exclusion determinations which are not intended to be binding as a standard for reviewing the reasonableness of exclusions.

In Willig, I held that the Board's appellate panel decisions were the Secretary's interpretations of the Act. Willig at 20. In interpreting the Act, the Board serves as the Secretary's delegate and acts for the Secretary. Id. I held that had the Secretary intended to overrule his prior interpretations of the Act by publishing the new regulations, he would have explicitly said so. Id. By not saying so, and by not anywhere stating that the Part 1001 regulations are intended to establish criteria to govern administrative reviews of exclusions, the Secretary made it evident that he did not intend to overrule his decisions interpreting the Act. Id.[8]

I also held in Willig that the Part 1001 regulations would be inconsistent with the new Part 1005 regulations (which govern hearings as to exclusion determinations) if they were found to establish criteria for review of exclusions. Willig at 21 - 23. The new Part 1005 regulations establish elaborate hearing and appeals procedures for parties dissatisfied with exclusion determinations. The right to due process accorded to petitioners by these regulations would be a hollow right if, in fact, there was no meaningful opportunity for petitioners to test the reasonableness of exclusion determinations against the Act's remedial criteria. Yet

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[8] I observed in Willig that, where the Secretary intended the new regulations to be applicable both at the initial determination and administrative review levels, he explicitly recited that in the regulations. Willig at 21; see 42 C.F.R. §§ 1003.106, 1003.107.

that would be the consequence of finding that the Part 1001 regulations established criteria governing the review of exclusion determinations. Id.

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

I conclude that it was not the Secretary's intent to retroactively apply the new regulations to unlawfully strip parties, including Petitioner, of previously vested rights. Therefore, the new Part 1001 regulations were not intended to apply to cases pending as of the date of their publication (assuming they establish criteria for administrative review of exclusions).

I held in Willig and Murcko, and Judge Steinman held in Barranco, that, assuming that the new Part 1001 regulations do establish standards to be employed at the level of administrative hearings for evaluation of the reasonableness of exclusion imposed under section 1128 of the Act, they are not applicable to cases which were pending as of the date of their publication. Willig at 24 - 27; Murcko at 7 - 11; Barranco at 19 - 24. We found that to apply these regulations to such cases, as was advocated by the I.G., would strip excluded parties of previously vested rights and operate to create manifest injustice. Id. Such an application would be an unlawful retroactive application of the new regulations which was not intended by the Secretary. Willig at 25 - 27; Murcko at 9 - 11; Barranco at 23 - 24.

The identical analysis applies here. The new regulations, if they establish a standard for reviewing exclusions of greater than five years' duration imposed pursuant to section 1128(a)(1), would strip petitioners of the right to a full review of the reasonableness of exclusions pursuant to the Act's remedial criteria. A full review of an exclusion's reasonableness requires consideration of any evidence relevant to a petitioner's trustworthiness, not just the narrower criteria contained in 42 C.F.R. §§ 1001.102(b) and (c). See Matesic at 12.

2. The 20-year exclusion which the I.G. imposed and directed against Petitioner is excessive.

The evidence in this case establishes Petitioner to have committed wholesale and massive fraud against the Maryland Medicaid program and other health care insurers. Over a more than three-year period, Petitioner, a pharmacist, conspired with another individual to present thousands of fraudulent claims for prescription drugs to Medicaid and other entities. Petitioner's fraudulent

claims during this period exceeded $450,000. He and his co-conspirator realized hundreds of thousands of dollars from their fraud.

Petitioner's scheme required elaborate planning and documentation. He and his co-conspirator created false prescriptions and fictitious Medicaid claims. Petitioner maintained false business records to conceal his crimes. The books and records of Petitioner's pharmacy became a mechanism whereby Petitioner effectively laundered the proceeds of his theft.

Petitioner's wilful fraud establishes him to be a manifestly untrustworthy individual. The deliberate nature of his crimes and the persistence with which he engaged in criminal behavior demonstrate a need to protect federally-funded health care programs from Petitioner and his larcenous acts. Were the evidence that I have just cited the only evidence relevant to Petitioner's trustworthiness, I would not hesitate to sustain the full 20-year exclusion imposed by the I.G.

However, evidence pertaining to Petitioner's criminal conduct presents an incomplete picture of Petitioner. The evidence in this case demonstrates that, notwithstanding the gravity of his crimes, Petitioner has made a commendable effort to rehabilitate himself. The evidence establishes that, given Petitioner's efforts at rehabilitation, an exclusion of 20 years is not necessary, either to protect federally-funded health care programs from Petitioner or to assure that Petitioner is no longer untrustworthy.

Petitioner's criminal acts resulted from two interrelated behavior patterns, consisting of psychiatric problems and a substance abuse disorder. In the period subsequent to exposure of his crimes, Petitioner has made substantial efforts to change both of these behavior patterns. He has undergone intensive in- and outpatient treatment. This has included hospitalization, an extended stay in a psychiatric halfway house, and continued regular participation in psychiatric and drug abuse treatment sessions. He has submitted to regular testing for the presence of controlled substances and has remained substance-free for more than two years.

More important, Petitioner freely acknowledges the gravity of his misconduct and the damage he caused by his misconduct. He has made sincere efforts to redress his acts. These efforts include prompt restitution of the money he fraudulently obtained and cooperation with law enforcement officials, leading to criminal charges and

convictions of other individuals. Since his conviction, he has secured and maintained gainful employment in a field outside of health care. He has impressed professionals, including his treating psychiatrist, with his desire to rehabilitate himself.[9]

I am not suggesting that Petitioner has now shown himself to be a trustworthy individual. Given the nature of Petitioner's crimes, a lengthy exclusion is justified in this case to protect federally-funded health care programs from even the possibility that Petitioner may at some future date engage in unlawful conduct. For that reason, I do not accept Petitioner's assertion that, in light of his efforts at rehabilitation, an exclusion of only five years (the minimum period mandated by section 1128(a)(1) for individuals convicted of program-related crimes) meets the Act's remedial purpose in this case. A longer exclusion plainly is justified by the evidence.

On the other hand, 20 years is excessive. A 20-year exclusion is tantamount to a permanent exclusion from participation in federally-funded health care programs. I conclude that, given Petitioner's efforts at rehabilitation, he will establish himself to be trustworthy in less than 20 years. I find that a ten-year exclusion is reasonably necessary to meet the Act's remedial purpose, given the evidence. An exclusion of ten years is a very lengthy exclusion. However, it acknowledges the likelihood that Petitioner will not indefinitely pose a serious risk for additional misconduct in the future and presents Petitioner with some opportunity to resume his profession at some future date, provided he does not again engage in unlawful conduct.

This case contrasts with David Cooper, R. Ph., DAB CR88 (1990) (Cooper). The petitioner in Cooper was a pharmacist who conspired to engage in unlawful sales of prescription drugs. As with this case, the petitioner in Cooper abetted the conspiracy through falsified documentation and business records. As with this case, the conspiracy in Cooper extended over a period of several years. In Cooper, I sustained a 15-year exclusion of the petitioner, based on the evidence of his crimes.

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[9] Most of the evidence offered by Petitioner pertaining to his efforts at rehabilitation would not be relevant as evidence of "mitigation" under 42 C.F.R. § 1001.102(b) and (c).

The factor which distinguishes Cooper from this case is that, in Cooper, the petitioner never accepted full responsibility for his unlawful conduct. He characterized his conduct as being "poor judgment" rather than criminal. He consistently denied his guilt of the offenses of which he was convicted. Cooper at 10. Thus, unlike Petitioner, the petitioner in Cooper demonstrated no recognition of the severity of his offenses, nor did he accept responsibility for his crimes. Under the circumstances, I felt that the 15-year exclusion was justified as a remedy. By contrast, Petitioner here has fully accepted responsibility for his crimes and has made sincere and diligent efforts at rehabilitation. Such efforts establish a greater level of trustworthiness than was established in Cooper.

CONCLUSION

I conclude that the 20-year exclusion imposed and directed against Petitioner by the I.G. is excessive. I modify the exclusion to a term of ten years.

/s/

Steven T. Kessel
Administrative Law Judge