Department of Health and Human Services

# DEPARTMENTAL APPEALS BOARD

## Civil Remedies Division

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| In the Case of: | ) | |
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| Keith O. Irby and Michelle P. Irby, R. Ph., | ) | DATE: July 13, 1994 |
| | ) | |
| Petitioner, | ) | Docket No. C-243 |
| | ) | Decision No. CR321 |
| - v. - | ) | |
| | ) | |
| The Inspector General. | ) | |
| | ) | |

## DECISION

On March 27, 1990, the Inspector General (I.G.) notified Petitioner Keith Irby that he was being excluded from participating in Medicare and State health care programs. On April 6, 1990, the I.G. notified Petitioner Michelle Irby that she was being excluded from participating in Medicare and State health care programs.[1] The I.G. told each Petitioner that the basis for the exclusion was that Petitioners were convicted of criminal offenses related to Medicare, within the meaning of section 1128(a)(1) of the Social Security Act (Act). The I.G. advised each Petitioner that the minimum mandatory period of exclusion for an individual convicted of an offense within the meaning of section 1128(a)(1) was five years. The I.G. advised each Petitioner, however, that based on the circumstances of that Petitioner's case, the I.G. had determined to exclude each Petitioner for 20 years.

Both Petitioners requested a hearing, and the cases were assigned to me for hearings and decisions. I decided that the cases should be consolidated for purposes of holding a single hearing, in light of facts which were common to both cases. Neither of the Petitioners nor the I.G. objected to

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

my determination to consolidate the cases.[2]

The cases were stayed by consent of all parties while Petitioners appealed their convictions of criminal offenses. I continued the stays, with the mutual consent of all parties, for various additional reasons.[3] The cases were heard in a consolidated hearing in Houston, Texas, on November 16 and 17, 1993. I received additional testimony by telephone on December 15, 1993. The parties filed posthearing briefs.[4]

I have carefully considered the applicable law, the evidence, and the parties' arguments.[5] I conclude that the exclusions

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[2] The notices of exclusion which the I.G. sent to the Petitioners refer to a corporation, Med-Equip Sales and Rentals, Inc. (Med-Equip), as a corporation wholly owned by Petitioners. The notices state that, by virtue of the exclusion, no payments will be made to this corporation during the exclusion period. In the initial prehearing conferences which I held in this case, the I.G. contended that she may have determined also to exclude Med-Equip. For that reason, I named Med-Equip as a party. In a prehearing order dated June 12, 1992, I raised the issues of whether Med-Equip had been excluded and whether the I.G. had provided proper notification of the exclusion. In a motion dated November 5, 1993, the I.G. asserted that she had not excluded Med-Equip and that the corporation should not be a party. This motion is supported by Petitioners. Accordingly, I determine that Med-Equip is not a party to this case, and I have removed Med-Equip from the caption of this decision.

[3] These reasons included the withdrawal of Petitioners' first counsel due to illness, the birth of a child to Petitioner Michelle Irby, and providing the parties with an opportunity to engage in settlement negotiations.

[4] References to the record in this decision will be cited as follows:

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| I.G.'s Exhibits | I.G. Ex. (number), p. (page number) |
| Petitioners' Exhibits | P. Ex. (number), p. (page number) |
| Hearing Transcript | Tr. at (page number) |

[5] The evidence which I received from the I.G. at the hearing included six volumes of transcripts of the criminal trial of Petitioners. I.G. Ex. 49 - 54. Counsel for Petitioners objected to my receiving these exhibits on the ground that they were voluminous and that the I.G. had not shown the relevance of these exhibits to the instant case.

(continued...)

which the I.G. imposed on Petitioners are excessive. I modify the exclusion which the I.G. imposed on Petitioner Keith Irby to a term of 10 years. I modify the exclusion which the I.G. imposed on Petitioner Michelle Irby to a term of five years.

## ISSUE

The issue in this case is whether the 20-year exclusion which the I.G. imposed and directed against each Petitioner is reasonable.

## FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. On June 9, 1989, Petitioners were each indicted in United States District Court for the Southern District of Texas for fifteen counts of mail fraud. I.G. Ex. 24.

2. Petitioners were charged with scheming to defraud the Medicare program. I.G. Ex. 24, pp. 2 - 3.

3. Petitioners were charged with fraudulently creating medical authorization forms for the purchase of durable medical equipment from a corporation which they owned and operated, Med-Equip, which contained untrue and exaggerated information. I.G. Ex. 24, pp. 2 - 4.

4. Petitioners were charged with mailing such forms to physicians, with the intent that the physicians would sign them inadvertently. I.G. Ex. 24, p. 4.

5. Petitioners were charged with using fraudulently created medical authorization forms that had been signed inadvertently by physicians to document fraudulent claims for Medicare reimbursement for durable medical equipment. I.G. Ex. 24, p. 4.

6. Petitioners were charged with delivering durable medical equipment to Medicare beneficiaries which had not been

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[5] (...continued)
In receiving the exhibits, I advised counsel for the parties that I expected that, in their posthearing briefs, they would cite to any specific excerpts of these exhibits that they contended were relevant. Tr. at 32 - 33. I told the parties that it would be unlikely that I would read these exhibits and make findings from them unless they directed my attention to specific portions of them which they wished me to consider. I have reviewed the excerpts of these exhibits cited by the parties in their posthearing submissions. I have not read the remainder of I.G. Ex. 49 - 54 and, with the exception of the excerpts cited by the parties, I have not considered these exhibits in making my decision in these cases.

requested by those beneficiaries, in order to submit fraudulent reimbursement claims to Medicare. I.G. Ex. 24, p. 5.

7. Petitioners were charged with submitting claims to Medicare for the purchase of new medical equipment when, in fact, the equipment was not new. I.G. Ex. 24, p. 6.

8. Petitioners were charged with fraudulently obtaining signatures from Medicare beneficiaries in order to further their scheme to submit fraudulent reimbursement claims to Medicare. I.G. Ex. 24, p. 6.

9. In counts 1 - 8 of the indictment, Petitioners were charged with committing mail fraud to implement their scheme to defraud Medicare, by causing Medicare reimbursement checks to be mailed to Med-Equip. I.G. Ex. 24, pp. 6 - 7.

10. In counts 9 - 15 of the indictment, Petitioners were charged with committing mail fraud to implement their scheme to defraud Medicare by causing medical authorization forms to be mailed to physicians. I.G. Ex. 24, pp. 7 - 9.

11. After a trial, Petitioners were each convicted of counts 1 - 9 and 11 - 15 of the indictment. I.G. Ex. 19 - 20.

12. Petitioner Keith Irby was sentenced to five years' imprisonment and this term of incarceration was ordered suspended by the court. I.G. Ex. 19, p. 2.

13. Petitioner Keith Irby was placed on five years' probation. I.G. Ex. 19, p. 2.

14. Petitioner Keith Irby was ordered to pay fines totalling $15,000 and to pay special assessments totalling $700, and was sentenced additionally to perform 1000 hours of community service. I.G. Ex. 19, p. 2.

15. Petitioner Keith Irby was prohibited from engaging in any form of employment relating to the billing of the Medicaid and Medicare programs for durable medical equipment, and was ordered to disengage completely from any durable medical equipment business that he and Petitioner Michelle Irby were operating. I.G. Ex. 19, p. 2.

16. Petitioner Michelle Irby was sentenced to five years' imprisonment and this term of incarceration was ordered suspended by the court. I.G. Ex. 20, p. 2.

17. Petitioner Michelle Irby was placed on five years' probation. I.G. Ex. 20, p. 2.

18. Petitioner Michelle Irby was ordered to pay fines totalling $7,500 and to pay special assessments totalling $700, and was sentenced additionally to perform 500 hours of community service. I.G. Ex. 20, p. 2.

19. Petitioner Michelle Irby was prohibited from engaging in any form of employment relating to the billing of the Medicaid and Medicare programs for durable medical equipment, and was ordered to disengage completely from any durable medical equipment business that she and Petitioner Keith Irby were operating. I.G. Ex. 20, p. 2.

20. Petitioners were convicted of criminal offenses related to the delivery of items or services under Medicare. Findings 1 - 11; Tr. at 21; Social Security Act, section 1128(a)(1).

21. The Secretary of the United States 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. 21,662 (1983).

22. The I.G. had authority to impose and direct an exclusion against Petitioners pursuant to section 1128(a)(1) of the Act. Findings 20 - 21.

23. The minimum period of exclusion which must be imposed for an individual who is convicted of a criminal offense within the meaning of section 1128(a)(1) of the Act is five years. Social Security Act, section 1128(c)(3)(B).

24. On March 27, 1990, the I.G. excluded Petitioner Keith Irby from participating in Medicare and Medicaid for 20 years, pursuant to section 1128(a)(1) of the Act. I.G. Ex. 6.

25. On April 6, 1990, the I.G. excluded Petitioner Michelle Irby from participating in Medicare and Medicaid for 20 years, pursuant to section 1128(a)(1) of the Act. I.G. Ex. 18.

26. 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).

27. The regulations include criteria to be employed by the I.G. in determining to impose and direct exclusions pursuant to section 1128(a)(1) of the Act. 42 C.F.R. § 1001.101, 1001.102.

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

29. The regulations published on January 29, 1992 governing exclusions pursuant to section 1128(a)(1) of the Act are not applicable to these cases, because the Secretary did not intend to strip Petitioners retroactively of rights vested prior to January 29, 1992.

30. Section 1128 of the Act is a remedial statute.

31. The standard to be employed in evaluating the reasonableness of the length of the exclusions which the I.G. imposed against Petitioners is whether the exclusions are necessary to protect the integrity of federally financed health care programs and the welfare of the beneficiaries and recipients of those programs from individuals who are untrustworthy.

Findings as to the reasonableness of the exclusion imposed against Petitioner Keith Irby[6]

32. Petitioner Keith Irby was convicted of 14 counts of mail fraud arising from a scheme to defraud the Medicare program. Findings 1 - 11.

33. The crimes of which Petitioner Keith Irby was convicted transpired over a period beginning in December 1985 and ending in July 1988, a period of more than one year. I.G. Ex. 19, p. 1; I.G. Ex. 24, pp. 7 - 9.

34. The total dollar amount of the crimes of which Petitioner Keith Irby was convicted was approximately $10,000. I.G. Ex. 19, p. 1; I.G. Ex. 24, p. 7.

35. The crimes of which Petitioner Keith Irby was convicted are serious offenses involving a willful scheme to defraud the Medicare program. Findings 32 - 34.

36. Petitioner Keith Irby has not completed the five-year term of probation to which he was sentenced. Tr. at 168.

37. Subsequent to his conviction and sentencing, Petitioner Keith Irby was convicted of the offense of driving while intoxicated. Tr. at 172, 201 - 203.

38. Petitioner Keith Irby withheld from his probation officer the fact of his conviction for driving while intoxicated. Tr. at 172 - 173, 201 - 203.

39. Petitioner Keith Irby did not testify credibly as to the circumstances of his being convicted for driving while

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[6] I make separate Findings concerning the reasonableness of the exclusions imposed against Petitioners Keith and Michelle Irby. For the convenience of the parties, I have captioned these findings with headings. The headings are not Findings nor are they intended to alter the meaning of any of my Findings.

intoxicated, or the reasons for his withholding the fact of his conviction from his probation officer. See Tr. at 201 - 203.

40. Petitioner Keith Irby has not completed the community service which he was sentenced to perform as a consequence of his conviction for mail fraud. Tr. at 169.

41. Petitioner Keith Irby has paid the $15,000 fine which he was sentenced to pay for his conviction for mail fraud. P. Ex. 25.

42. The I.G. did not prove that Petitioner Keith Irby caused the Medicare program to sustain losses beyond the approximately $10,000 in fraudulent claims for which Petitioner Keith Irby was convicted. See I.G. Ex. 27, 28; Tr. at 142 - 163.

43. A 20-year exclusion is excessive when measured against the seriousness of the crimes for which Petitioner Keith Irby was convicted and his conduct subsequent to his conviction. Findings 32 - 42.

44. A 10-year exclusion of Petitioner Keith Irby is reasonable in light of the remedial purposes of section 1128 of the Act.

Findings as to the reasonableness of the exclusion imposed against Petitioner Michelle Irby

45. Petitioner Michelle Irby was convicted of 14 counts of mail fraud arising from a scheme to defraud the Medicare program. Findings 1 - 11.

46. The crimes of which Petitioner Michelle Irby was convicted transpired over a period beginning in December 1985 and ending in July 1988, a period of more than one year. I.G. Ex. 20, p. 1; I.G. Ex. 24, pp. 7 - 9.

47. The total dollar amount of the crimes of which Petitioner Michelle Irby was convicted was approximately $10,000. I.G. Ex. 20, p. 1; I.G. Ex. 24, p. 7.

48. The crimes of which Petitioner Michelle Irby was convicted are serious offenses involving a willful scheme to defraud the Medicare program. Findings 45 - 47.

49. Although Petitioner Michelle Irby was sentenced to probation for a period of five years, her probation was terminated early -- after approximately two years and nine months. She has met all the terms and conditions of probation and has committed no known violations. Tr. at 166.

50. Petitioner Michelle Irby has completed the community service to which she was sentenced. Tr. at 167 - 168.

51. Petitioner Michelle Irby has paid the $7,500 fine which she was sentenced to pay for her conviction for mail fraud. Tr. at 170.

52. Subsequent to her conviction, Petitioner Michelle Irby has held jobs as a pharmacist. Tr. at 49 - 62, 88 - 96, 285 - 291.

53. In performing her duties as a pharmacist, Petitioner Michelle Irby has been entrusted with the custody of and prescription of controlled substances. Tr. at 93, 289.

54. In performing her duties as a pharmacist, Petitioner Michelle Irby has been found to be trustworthy by her supervisors and coworkers. Tr. at 52 - 54, 78 - 80, 92 - 93, 287.

55. Petitioner Michelle Irby has enrolled as a student in medical school. Tr. at 235.

56. The I.G. did not prove that Petitioner Michelle Irby caused the Medicare program to sustain losses beyond the approximately $10,000 in fraudulent claims for which Petitioner Michelle Irby was convicted. See I.G. Ex. 27, 28; Tr. at 142 - 163.

57. A 20-year exclusion is excessive when measured against the seriousness of the crimes for which Petitioner Michelle Irby was convicted and her conduct subsequent to her conviction. Findings 45 - 56.

58. A five-year exclusion of Petitioner Michelle Irby is reasonable, in light of the remedial purpose of section 1128 of the Act.

## RATIONALE

Petitioners do not dispute that they were convicted of criminal offenses related to the delivery of items or services under Medicare, within the meaning of section 1128(a)(1) of the Act. Nor do Petitioners deny that, as a consequence of their convictions, they must be excluded for a minimum of five years. However, each Petitioner contends that an exclusion of that Petitioner for more than five years is unreasonable, given the facts of that Petitioner's case. Therefore, the issue I must resolve with respect to each Petitioner is whether the 20-year exclusion imposed against each Petitioner is excessive, and if so, to what extent should I modify the term of the exclusion.

### 1. Regulations published by the Secretary on January 29, 1992 are not applicable to these cases.

A threshold issue in these cases involves the standard of review I must use in adjudicating the reasonableness of the exclusion imposed against each Petitioner. The I.G. argues that I must apply the criteria contained in regulations

published by the Secretary on January 29, 1992 at 42 C.F.R. Part 1001. Specifically, the I.G. argues that the reasonableness of the length of each exclusion must be measured only by the aggravating and mitigating factors contained in 42 C.F.R. § 1001.201. I conclude that the Secretary did not intend that the regulations in Part 1001 apply retroactively to cases pending as of January 29, 1992. Therefore, I find that the reasonableness of the exclusions must be adjudicated pursuant to the standard which prevailed as of the date the exclusions were imposed.

Appellate panels of the DAB and administrative law judges delegated to hear cases under section 1128 of the Act have held consistently that section 1128 is a remedial statute. Exclusions imposed pursuant to section 1128 have been found reasonable only insofar as they are consistent with the Act's remedial purpose, which is to protect the integrity of federally financed health care programs and the welfare of beneficiaries and recipients of those programs from individuals and entities who are not trustworthy to provide care. 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.

In Matesic, an appellate panel of the DAB discussed the kinds of evidence which should be considered by administrative law judges in hearings as to the reasonableness of exclusions. That evidence included evidence which related to:

> 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.

Matesic, DAB 1327, at 12.

On January 29, 1992, the Secretary published regulations which, among other things, governed the I.G.'s imposition of exclusions pursuant to section 1128 of the Act. 42 C.F.R. Parts 1001 - 1007. These regulations contain criteria which apply specifically to exclusions imposed by the I.G. pursuant to section 1128(a)(1). 42 C.F.R. § 1001.101 - 1001.102. The regulations state that, in the case of an exclusion imposed pursuant to section 1128(a)(1), the exclusion may be increased beyond the statutory five-year minimum exclusion period if any of specified aggravating factors are present. 42 C.F.R. § 1001.102(b)(1) - (6). Specified mitigating factors may be used to offset aggravating factors and may serve as a basis to reduce the length of an exclusion imposed pursuant to section 1128(a)(1). 42 C.F.R. § 1001.102(c)(1) - (3). However, in no event may an exclusion be reduced below the five-year statutory minimum exclusion period. This regulation makes plain that only factors which are identified

in the regulation as aggravating or mitigating may be used as a basis for lengthening or reducing an exclusion. To the extent that factors identified in Matesic as being relevant to the trustworthiness of a party do not fall within the aggravating and mitigating factors identified by the regulation, they may not be used to determine the length of an exclusion.

After the 1992 regulations were published, the I.G. contended that the Part 1001 regulations should apply to establish criteria for adjudicating the reasonableness of the length of exclusions determined pursuant to section 1128 of the Act in all cases which were pending as of January 29, 1992. However, an appellate panel of the DAB held that the Secretary did not intend that these regulations were to apply retroactively to exclusion determinations made prior to the regulations' publication date. Behrooz Bassim, M.D., DAB 1333, at 5 - 9 (1992).[7]

A central conclusion in Bassim is that the 1992 regulations effect a change in the substantive criteria by which exclusions are determined. Id., at 6, 7. The appellate panel noted that retroactivity is not favored in the law. Id., at 6. It held that the authority to promulgate rules having a retroactive effect must be granted to an agency expressly by Congress. Id. It held further that if Congress does include such a statutory grant in its enabling legislation, the promulgated rules will not be applied retroactively unless their language clearly requires this result. Id. The appellate panel found that neither the legislative history of the statute which authorized the 1992 regulations, nor section 1128 of the Act, provided any support for concluding that the 1992 regulations should be applied retroactively. Id., at 7. In so holding, it stated that:

> In our view, if the Secretary had intended to effect substantive changes in pending cases, this

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[7] At issue in Bassim was an exclusion imposed pursuant to section 1128(b)(4) of the Act. The specific section of the Part 1001 regulations which was at issue in that case is 42 C.F.R § 1001.501. That regulation establishes mitigating and aggravating factors to be used in determining exclusions pursuant to section 1128(b)(4) which are very similar to those established by 42 C.F.R. § 1001.102 for exclusions imposed pursuant to section 1128(a)(1) of the Act. The effect of 42 C.F.R. § 1001.501 is the same as the effect of 42 C.F.R. § 1001.102, in that both regulations preclude use of many of the factors identified as remedial in Matesic to determine the length of exclusions. Although technically, Bassim applies only to exclusions imposed pursuant to section 1128(b)(4) of the Act, the appellate panel's decision in that case plainly is intended to apply broadly to all exclusions imposed pursuant to section 1128. Bassim, DAB 1333, at 8 - 9.

> intent would have been expressly stated since this effect would create administrative complications in the appeals process, as well as potential prejudice for petitioners.

Id.

On January 22, 1993, the Secretary published additional regulations. These regulations include a provision which clarifies the Part 1001 regulations by stating that the Part 1001 regulations apply to establish a standard of review in adjudications of exclusions before administrative law judges, appellate panels of the DAB, and federal courts. 42 C.F.R. § 1001.1(b).[8]

This clarification was to be applied to "all pending and future cases under this authority." 58 Fed. Reg. 5618 (1993). Then-Secretary Sullivan waived the proposed notice and public comment period specified by the Administrative Procedure Act. In doing so, he cited as authority the exception for "interpretive rules, general statements of policy or rules of agency organization, procedure, or practice" at 5 U.S.C. § 553(b)(A). Id. The Secretary stated that the clarification "does not promulgate any substantive changes to the scope of the January 29, 1992 final rule, but rather seeks only to clarify the text of that rulemaking to better achieve our original intent." Id.

These cases involve exclusions which were imposed prior to January 29, 1992.[9] The I.G. asserts that the effect of the 1993 clarification is to require that these cases be adjudicated pursuant to the criteria contained in the Part 1001 regulations published in January 1992. The I.G. premises this argument entirely on the Secretary's intent to apply the clarification to "all pending cases . . . ." In effect, the I.G. would have the 1992 regulations apply retroactively to adjudicate the reasonableness of the exclusions imposed against Petitioners, based on the 1993 clarification and the commentary published with that

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[8] In a number of decisions issued between January 29, 1992 and January 22, 1993, administrative law judges held that the Part 1001 regulations did not establish a standard for adjudicating the reasonableness of exclusions. Bertha K. Krickenbarger, R.Ph., DAB CR250 (1993) (decisions summarized therein at 10). An effect of 42 C.F.R. § 1001.1(b) is to overrule these decisions.

[9] Administrative law judges have held that the 1993 clarification requires that exclusions imposed after January 29, 1992 be adjudicated pursuant to the criteria contained in the Part 1001 regulations. Jose Ramon Castro, M.D., DAB CR259 (1993).

clarification.[10]

I conclude that the Secretary did not require expressly in the 1993 clarification that the 1992 regulations be applied retroactively to cases pending as of January 29, 1992. To the contrary, the more persuasive reading of the 1993 clarification is that it did nothing to change the interpretation of the 1992 regulations prevailing as of the date of publication of the 1993 clarification, which was that the 1992 regulations were not intended to apply retroactively.

The issue of whether then-Secretary Sullivan intended the 1993 clarification to apply the 1992 regulations retroactively -- to exclusions imposed prior to January 29, 1992 -- was decided by Administrative Law Judge Steinman in Domingos R. Freitas, DAB CR272, at 37 - 40 (1993). I have considered Judge Steinman's analysis and find it to be persuasive. The I.G. has offered no arguments in these cases which were not considered and decided by Judge Steinman in Freitas.

As Judge Steinman observed in Freitas, the DAB's appellate panels are delegated authority to make final interpretations of law on behalf of the Secretary in reviewing decisions of administrative law judges. DAB CR272 at 37; Gideon M. Kioko, M.D., DAB CR256 (1993). At the time that the 1993 clarification was published, the Secretary's final interpretation of the 1992 regulations was the Bassim decision, which stated that the Secretary did not intend the 1992 regulations to apply retroactively. Nothing in the 1993 clarification or the comments to that clarification suggests that the Secretary intended to overrule this interpretation. To the contrary, the comments to the 1993 clarification state unequivocally that the 1993 clarification did not make "any substantive changes" to the "scope" of the 1992 regulations. 58 Fed. Reg. 5618. Therefore, the reasonable implication of the 1993 clarification is that it did not intend to overrule an existing interpretation on behalf of the Secretary that the 1992 regulations were not to be applied retroactively to cases pending prior to January 29, 1992.

Had then-Secretary Sullivan intended the 1993 clarification to overrule the DAB's appellate panel decision in Bassim, he would have in effect overruled his own previous interpretation of the 1992 regulations. That in turn would have constituted a substantive change in the manner in which

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[10] The I.G. did not aver that she used the criteria of the 1992 regulations to determine the length of the exclusions imposed against Petitioners. These criteria were not in effect in 1990, when Petitioners were excluded. The I.G. has not explained why the Secretary would intend that criteria first published in 1992 should be used retroactively to adjudicate exclusions which were imposed at a time when such criteria had not been adopted by the Secretary.

the 1992 regulations were applied. Such a substantive change could not have been published legitimately without compliance with the notice and comment requirements of the Administrative Procedure Act. The determination to publish the 1993 clarification as an excepted statement means that the Secretary did not intend to change his previously stated interpretation. As Judge Steinman found in Freitas:

> Since the January 29, 1992 regulations lacked retroactive effect for the reasons stated in Bassim, they could not have acquired such effect with subsequent textual clarifications that do not purport to modify the scope of the January 29, 1992 regulations and have been published without satisfying the procedures necessary under the Administrative Procedure Act for effecting substantive changes.

DAB CR272 at 40.

I conclude that the statement that the 1993 clarification applied to "pending" cases does not mean that the Secretary intended to apply the 1992 regulations retroactively to cases pending as of January 29, 1992. Given the fact that the Secretary did not overrule his own statement of interpretation in Bassim, given that the Secretary stated that he did not intend the 1993 clarification to effect any substantive change, and given further, the fact that the 1993 clarification was published under an exception to the Administrative Procedure Act which does not apply to regulations having substantive effect, I conclude that the Secretary intended the 1993 clarification to apply the 1992 regulations only to those exclusions which were imposed after January 29, 1992. Cases involving exclusions imposed before that date must be adjudicated pursuant to the standard in effect as of the date of the exclusion, which consists of the remedial criteria of section 1128 as explained in the Matesic decision.

2. The exclusions which the I.G. imposed against Petitioners are excessive.

The exclusions which the I.G. imposed against Petitioners are excessive when examined in light of the remedial criteria of section 1128 and the Matesic decision. I conclude that the exclusions must be modified to avoid an unlawful punitive effect.

Both Petitioners were convicted of the same crimes. These crimes consisted of 14 counts of mail fraud. The essence of the crimes was that Petitioners, through the vehicle of a durable medical equipment company which they owned and operated, deceived physicians into certifying that their patients, Medicare beneficiaries, qualified for certain durable medical equipment. Petitioners then used the certifications which they obtained from physicians to defraud the Medicare program into reimbursing them for durable

medical equipment for which beneficiaries did not, in actuality, qualify. Findings 2 - 11. Petitioners were convicted of mail fraud totalling about $10,000. Findings 34, 47. These are serious crimes. They were committed over a period of more than one year. Findings 33, 46. They embody elements of willfulness and intent. I infer from Petitioners' convictions that they engaged in a deliberate scheme to defraud Medicare. It is reasonable to find from the circumstances of these crimes that Petitioners are untrustworthy individuals and that federally funded programs need to be protected from the possibility that they may engage in conduct in the future which is damaging.

On the other hand, the offenses of which Petitioners were convicted do not appear nearly so serious as has been asserted by the I.G. It is evident that the I.G. premised the determination to impose 20-year exclusions against Petitioners on the conclusion that the crimes of which Petitioners were convicted were merely indicia of far more serious fraud by Petitioners. Petitioners' convictions were depicted by the I.G. as comprising merely the tip of an iceberg that consisted of a wide-ranging, massive fraud against Medicare.

In both the notices which the I.G. sent to Petitioners and at the hearing, the I.G. contended that Petitioners had engaged in fraud which resulted in approximately $1.5 million in overpayments by Medicare to entities which Petitioners controlled. However, the I.G. failed to prove, by a preponderance of the evidence, that these Petitioners engaged in fraud beyond the approximately $10,000 for which they were convicted. The I.G. did not substantiate the allegations of a broader and more damaging scheme. Consequently, exclusions cannot be premised on offenses beyond that for which Petitioners were convicted.

The evidence on which the I.G. relied to prove the alleged overpayments consisted primarily of the results of audits that Blue Cross and Blue Shield of Texas, the Medicare carrier for the State of Texas, performed of Medicare reimbursement claims that had been presented by corporations owned and operated by Petitioners. The I.G. presented the testimony of an employee of Blue Cross and Blue Shield of Texas, Debbie Lewis. Tr. at 142 - 161. Ms. Lewis testified that she is a supervisor of claims examiners. Tr. at 143. She testified that Blue Cross and Blue Shield of Texas concluded that entities controlled by Petitioners had been overpaid by Medicare by approximately $1.5 million based on an audit which consisted of a random sampling of claims presented by these entities. I.G. Ex. 27, 28; Tr. at 143 - 144, 147 - 149, 151. The claims actually reviewed by Blue Cross and Blue Shield comprised a small percentage of the total claims which were estimated to be overpaid. Tr. at 154 - 157. She characterized sampling as a "valid methodology" in determining Medicare overpayments. Tr. at 144.

I do not find Ms. Lewis' testimony to be persuasive for the

following reasons. First, the I.G.'s assertion that the sampling performed here is reliable is without foundation. The I.G. failed to establish that Ms. Lewis has sufficient expertise in statistics to certify the accuracy of the sampling performed here. The I.G. offered no evidence as to Ms. Lewis' education in statistics. Nor did the I.G. offer evidence as to the statistical validity of the sampling which Blue Cross and Blue Shield of Texas performed, except to assert without foundation that sampling (not necessarily this sampling) is a valid methodology for ascertaining the existence of overpayments.[11]

Indeed, Ms. Lewis suggested in her testimony that the sampling performed here may have been biased in favor of finding overpayments. She testified that where an inquiry to a provider produced no response, that non response would be used as a basis for finding an overpayment for the sampled claim about which the inquiry was made. Tr. at 157 - 158. I am not persuaded that a provider's failure to respond to an inquiry justifies the conclusion that an overpayment was made. Yet, based on Ms. Lewis' testimony, it appears that Blue Cross and Blue Shield of Texas would use the failure to respond to the inquiry not only to find an overpayment, but to find many overpayments, inasmuch as Blue Cross and Blue Shield of Texas would extrapolate the finding of one overpayment over the entire universe of claims from which the sample was taken.

Second, the I.G. never defined what she meant by the term "overpayment." I do not infer from the way this term was used by Ms. Lewis that Blue Cross and Blue Shield of Texas' findings of overpayments necessarily were limited to claims that Blue Cross and Blue Shield of Texas concluded to be false or fraudulent. From the context, the term could mean payments based on simple error by Blue Cross and Blue Shield of Texas or by the entities whose claims were examined. It could mean also payments based on a good faith, albeit incorrect, interpretation of payment guidelines by Blue Cross and Blue Shield of Texas or by the entities whose claims were examined. I cannot conclude that entities controlled by Petitioners were overpaid based on fraud unless the evidence establishes that the determination that overpayments were made is based on fraudulent claims.

The I.G. offered evidence to prove that Petitioners have been found to be liable in a lawsuit brought against them under the False Claims Act, 31 U.S.C. § 3729 et seq., as amended, in the amount of $180,056.76. I.G. Ex. 55. I do not find

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[11] In her posthearing brief, the I.G. asserted that sampling is a methodology for ascertaining Medicare overpayments that has been upheld in the courts. I.G.'s posthearing brief at 22. However, assuming that to be so, the I.G. offered no evidence in these cases to prove that the sampling methodology used here was the same as that upheld in the cases cited by the I.G. in her brief.

from the judgment against Petitioners that Petitioners were found to have committed fraud against Medicare in an amount greater than the approximately $10,000 of which they were convicted. The judgment was based solely on the 14 counts of mail fraud of which Petitioners were convicted. P. Ex. 21, pp. 4 - 7. The damages comprise a trebling of the dollar amount of Petitioners' fraud plus civil penalties in the amount of $150,000. Id., p. 6.

In addition, throughout this proceeding, the I.G. has contended that the criminal activity which resulted in Petitioners' convictions occurred over a period of at least five years. To support this contention, the I.G. relies on a general statement in the indictment alleging that Petitioners engaged in a criminal scheme from October 7, 1983 through the date of the return of the indictment on June 9, 1989. However, the 14 specific counts which formed the basis of Petitioner's conviction covered a period spanning from December 13, 1985 through July 15, 1988. Thus, notwithstanding the allegation contained in the indictment that Petitioners' criminal activity occurred over a period of more than five years, I find that the evidence establishes that the specific counts of which Petitioners were convicted occurred over a period of only two and a half years.

In summary, I conclude that the I.G. did not prove that the ambit of Petitioners' crimes extends beyond the 14 counts of mail fraud totalling about $10,000, of which they were convicted. These are serious crimes, and they certainly provide evidence to support the conclusion that Petitioners are not trustworthy providers of care. On the other hand, the record of this case fails to establish anything approaching the offenses which the I.G. alleges Petitioners committed. That calls into question the need for such severe exclusions as the I.G. imposed, inasmuch as the I.G. plainly premised those exclusions on the conclusion that Petitioners had committed fraud greatly in excess of that of which they had been convicted.

a. The exclusion imposed against Petitioner Keith Irby

I conclude that the offenses of which Petitioner Keith Irby was convicted are not so serious as to justify the imposition of a 20-year exclusion. An exclusion of that length is for all practical purposes, a permanent ban on claiming reimbursement from Medicare or Medicaid. Given the remedial purpose of section 1128, exclusions of such length must be reserved for those individuals and entities who have demonstrated by their conduct that they can never again be trusted to provide care or to claim reimbursement for the items or services which they provide. The 14 counts of mail fraud of which Petitioner Keith Irby was convicted, while serious offenses, simply do not amount to offenses that are so serious as to merit on their face what amounts to a permanent exclusion.

However, the evidence in Petitioner Keith Irby's case

establishes that he remains an untrustworthy individual. I conclude that, while a 20-year exclusion is excessive, an exclusion of 10 years is merited.

To begin with, Petitioner Keith Irby has not expressed remorse for his criminal misconduct. To the contrary, he asserts adamantly that he engaged in no misconduct, and that, in fact, he is not guilty of the offenses of which he has been convicted. Tr. at 209 - 210. Absent persuasive evidence to the contrary, Petitioner's intransigent refusal to admit misconduct might suggest a propensity on his part to engage in similar unlawful conduct in the future.

In addition, Petitioner Keith Irby has not yet completed the terms of his sentence. Although he has paid the fine which was imposed by the court, he has not completed the community service which he was sentenced to perform.

More significant is the fact that Petitioner Keith Irby has been less than fully compliant with the terms and conditions of his probation. He is still serving the five-year term of probation to which he was sentenced. Subsequent to his conviction and sentencing, Petitioner Keith Irby was convicted of the offense of driving while intoxicated. This subsequent conviction is a violation of the terms of his probation and it suggests a continuing propensity to run afoul of the law.

Not only was Petitioner Keith Irby convicted of the offense of driving while intoxicated, but he withheld from his probation officer the fact of his conviction. Petitioner Keith Irby's failure to disclose this conviction to his probation officer is an additional violation of the terms of his probation. It suggests a propensity on the part of Petitioner Keith Irby to be dishonest with government officials when it serves his purposes.

Furthermore, I find that Petitioner Keith Irby was not credible in his testimony at the hearing which I conducted. In his account of his conviction for driving while intoxicated, he asserted that the officer who arrested him threw out test results which showed that Petitioner Keith Irby was not intoxicated, and repeated the test three more times until he obtained a result which showed that he was intoxicated. Tr. at 202. He suggested that, as part of his plea to the charge of driving while intoxicated, it had been agreed that his conviction of this offense would not be reported to federal probation authorities. Id. This self-serving account of the events surrounding his conviction for driving while intoxicated lacks the ring of truth. I conclude that his dishonesty in the hearing which I conducted is additional evidence of his continuing lack of trustworthiness.

I modify the exclusion imposed against Petitioner Keith Irby to a term of 10 years. That is a very lengthy exclusion and it reflects my conclusion that he remains an untrustworthy

individual. It takes into account also the seriousness of the offenses of which he was convicted.

b. The exclusion imposed against Petitioner Michelle Irby

As I find with respect to Petitioner Keith Irby, I conclude that a 20-year exclusion of Petitioner Michelle Irby is not merited based on the seriousness of the offenses of which she was convicted. I find that, based on evidence pertaining to her case, the exclusion should be modified to a term of five years, which is the minimum exclusion period mandated by the Act for individuals convicted of criminal offenses, within the meaning of section 1128(a)(1).

There is substantial evidence to suggest that Petitioner Michelle Irby will soon not pose a serious threat to federally financed health care programs and to program beneficiaries and recipients. The evidence in this case establishes that, since her conviction, Petitioner Michelle Irby has conducted her life in an exemplary fashion. This is strong evidence of rehabilitation and of trustworthiness.

Petitioner Michelle Irby is a pharmacist. In the months following her conviction she obtained jobs as a pharmacist in order to support herself and her family. Her employers testified at the hearing that I conducted that she comported herself in these jobs with complete honesty and integrity. She was entrusted with filling prescriptions for controlled substances. She served as a mentor for a pharmacy student. Her exemplary performance in these jobs is indicative of trustworthiness.

Petitioner Michelle Irby has sought to continue her education. Her current enrollment in medical school suggests considerable diligence on her part and is further evidence of her rehabilitation.

Other evidence of Petitioner Michelle Irby's trustworthiness consists of the fact that she completed her five years' probation in 33 months. I infer from this that, during the period of her probation, she complied strictly with the rules and requirements established by her probation officer. She has completed the community service aspect of her sentence, as well. There is no evidence that, in the more than four years since she was sentenced for her crimes, Petitioner Michelle Irby has engaged in unlawful conduct.

I recognize that Petitioner Michelle Irby, like Keith Irby, has not shown any remorse or acknowledged the unlawfulness of her criminal misconduct. Under other circumstances, this refusal to admit wrongdoing would justify an exclusion that is greater than the minimum mandatory five-year period. However, in this case, I find that Petitioner Michelle Irby's exemplary conduct since her conviction outweighs any negative inferences which can be drawn from her refusal to admit wrongdoing. Petitioner, by her actions, has demonstrated a

strong determination to be law-abiding and trustworthy and I accord great weight to the exemplary manner in which Petitioner has comported herself since her conviction.

I find that the preponderance of the evidence establishes a strong likelihood that Petitioner Michelle Irby will remain trustworthy. Given that conclusion, there is no need in this case for an exclusion which is lengthier than the five-year statutory minimum.

## CONCLUSION

I conclude that the 20-year exclusions which the I.G. imposed against Petitioners are excessive. I modify the exclusion imposed against Petitioner Keith Irby to a term of 10 years. I modify the exclusion imposed against Petitioner Michelle Irby to a term of five years.

/s/

Steven T. Kessel
Administrative Law Judge