DEPARTMENT OF HEALTH AND HUMAN SERVICES

Departmental Appeals Board

Civil Remedies Division

In the Case of:	
Jose Ramon Castro, M.D.,	DATE: April 28, 1993
Petitioner,	Docket No. C-92-132
- v. -	Decision No. CR259
The Inspector General.	

DECISION

On June 17, 1992, the Inspector General (I.G.) notified Petitioner that he was being excluded from participation in the Medicare and State health care programs for three years.[1] The I.G. told Petitioner that he 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 January 14, 1993, I held a hearing in Savannah, Georgia. On March 4, 1993, I received additional testimony from Petitioner by telephone and admitted exhibits in addition to those which I had admitted at the January 14, 1993 hearing.[2]

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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 Petitioner was excluded.

[2] The March 4, 1993 session was held for the limited purpose of permitting the parties to address issues raised by the publication of a new regulation on January 22, 1993. See 58 Fed. Reg. 5617, 5618 (to be

(continued...)

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 regulations require that I sustain the three-year exclusion imposed and directed by the I.G.

ISSUE

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

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Petitioner is a physician.

2. From 1969 until 1980, Petitioner practiced medicine in Puerto Rico as a pathologist. Tr. I at 90 - 91.

3. Since 1980, Petitioner has conducted a general practice in Alma, Georgia. Tr. I at 91.

4. Petitioner's practice in Alma, Georgia, has included obstetrics, gynecology, pediatric medicine, and geriatric medicine. Tr. I at 92.

5. Petitioner has also served as laboratory director at the Bacon County, Georgia, hospital, where he directed that hospital's pathology services. Tr. I at 92.

6. Petitioner is also a practitioner of clinical hypnosis and behavioral modification techniques, which he uses to treat conditions including smoking addiction, obesity, and other behavior-related illnesses. Petitioner's Exhibit (P. Ex.) 11.

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[2] (...continued)
codified at 42 C.F.R. § 1001.1(b)). I discuss this new regulation, and its effect on my decision in detail, infra. The parties consented to the taking of testimony from Petitioner by telephone on March 4, 1993. In this decision, I refer to the transcript of the January 14, 1993 hearing as Tr. I at [page] and to the transcript of the March 4, 1993 telephone proceeding as Tr. II at [page].

7. Petitioner speaks Spanish, and his practice includes the treatment of Spanish-speaking migrant workers. Tr. II at 15 - 16.

8. On August 19, 1991, Petitioner was convicted by a jury in United States District Court for the Southern District of Georgia on four counts of the crime of knowingly, intentionally, and unlawfully dispensing controlled substances outside the usual course of professional practice and without medical purpose, in violation of 21 U.S.C. § 841(a)(1). I.G. Exhibits (I.G. Exs.) 1, 2.

9. Petitioner's conviction was based on a Drug Enforcement Administration (DEA) investigation in which Petitioner prescribed valium to agents of the DEA. I.G. Ex. 7, at 2 - 4.

10. Petitioner was convicted of a criminal offense under federal law relating to the unlawful distribution, prescription, or dispensing of a controlled substance. Findings 8 - 9; Social Security Act, section 1128(b)(3).

11. 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).

12. The I.G. had authority to impose and direct an exclusion pursuant to section 1128(b)(3) of the Act. Findings 10, 11.

13. 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).

14. 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.

15. On January 22, 1993, the Secretary published a regulation which directs 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 upon administrative law judges, appellate panels of the Departmental Appeals Board, 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).

16. My adjudication of the length of the exclusion in this case is governed by the criteria contained in 42 C.F.R. § 1001.401. Finding 15.

17. An exclusion imposed pursuant to section 1128(b)(3) of the Act must be for a period of three years, unless aggravating or mitigating factors form a basis for lengthening or shortening that period. 42 C.F.R. § 1001.401(c)(1).

18. Aggravating factors which may form a basis for lengthening an exclusion imposed and directed pursuant to section 1128(b)(3) of the Act may consist of any of the following:

> a. the acts that resulted in the conviction of an offense within the meaning of section 1128(b)(3) or similar acts were committed over a period of one year or more;
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> b. the acts that resulted in the conviction of an offense within the meaning of section 1128(b)(3) or similar acts had a significant adverse physical, mental, or financial impact on program beneficiaries or other individuals or the Medicare or Medicaid programs;
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> c. the sentence imposed by the court for the offense upon which the exclusion is based included incarceration; or
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> d. the excluded party has a prior criminal, civil, or administrative sanction record.

42 C.F.R. § 1001.401(c)(2)(i) - (iv) (paraphrase).

19. Mitigating factors which may be a basis for shortening an exclusion imposed and directed pursuant to section 1128(b)(3) of the Act are limited to the following:

> a. the excluded party's cooperation with federal or State officials resulted in others being convicted of criminal offenses or excluded from participating in Medicare or Medicaid, or the imposition of a civil money penalty against others; or

b. alternative sources of the type of health care items or services furnished by the excluded party are not available.

42 C.F.R. § 1001.401(c)(3)(i) - (ii) (paraphrase).

20. The I.G. has the burden of proving that aggravating factors exist which justify increasing an exclusion imposed pursuant to section 1128(b)(3) of the Act beyond the three-year standard established by regulation. 42 C.F.R. § 1001.401(c)(2)(i) - (iv); 42 C.F.R. § 1005.15(c).

21. The I.G. did not allege that any aggravating factors are present in this case.

22. Petitioner has the burden of proving that mitigating factors exist which justify reducing an exclusion imposed pursuant to section 1128(b)(3) of the Act below the three-year standard established by regulation. 42 C.F.R. § 1001.401(c)(3)(i) - (ii); 42 C.F.R. § 1005.15(c).

23. Petitioner alleged that, as a result of his exclusion, alternative sources of the type of health care items or services that he furnishes are not available.

24. Petitioner did not allege that any other mitigating factors are present in this case.

25. Petitioner did not allege, nor did he offer evidence, that he would cease practicing medicine because of his exclusion.

26. Petitioner did not prove that, as a consequence of his exclusion, he would be precluded from providing items or services to patients.

27. Petitioner is one of four general practice physicians currently practicing in Alma, Georgia. Tr. I at 37, 87 - 88.

28. Alma, Georgia, could benefit from the services of additional primary care physicians. Tr. I at 87.

29. Petitioner failed to prove that, as a result of his exclusion, alternative sources of general practice physician services would not be available. Findings 25 - 28.

30. Petitioner is the only pathologist residing in Bacon County, Georgia. Tr. II at 12; P. Ex. 11.

31. As a result of his exclusion, Petitioner no longer performs pathology services for Bacon County Hospital, and no longer serves as the hospital's laboratory director. Tr. II at 12 - 13.

32. Since Petitioner's exclusion, Bacon County Hospital has obtained pathology services from a pathologist in Augusta, Georgia. Tr. II at 12.

33. Petitioner failed to prove that, as a result of his exclusion, Bacon County Hospital would be unable to obtain pathology or laboratory services. Findings 30 - 32.

34. Petitioner is the only Spanish-speaking general practice physician residing in Bacon County. Tr. II at 15.

35. Bacon County and surrounding counties have a large population of Spanish-speaking migrant farm workers. Tr. II at 16.

36. Petitioner is the only Spanish-speaking physician who, at present, provides care to the migrant farm worker community in Bacon County and surrounding counties. Tr. II at 16; P. Ex. 11.

37. Petitioner failed to prove that, as a result of his exclusion, Spanish-speaking individuals would be deprived access to medical care. Findings 34 - 36.

38. Petitioner is the only member of the American Society of Clinical Hypnosis within 100 miles of Alma, Georgia, practicing behavioral modification. Tr. II at 26 - 27.

39. The fact that Petitioner is the only member of the American Society of Clinical Hypnosis practicing within 100 miles of Alma, Georgia is insufficient to prove that, as a result of his exclusion, patients would be denied treatment for cigarette addiction, obesity, or other behavior-related illnesses. Finding 38.

40. Petitioner failed to prove that alternative sources of the types of health care items or services that he furnishes are not reasonably available. Findings 25 - 38.

41. The facts proved by Petitioner are insufficient to establish that, as a result of his exclusion, alternative sources of the type of health care items or services that he furnishes are not available. Findings 25 - 40.

42. Petitioner did not prove the presence of any mitigating factors under 42 C.F.R. § 1001.401(c)(3)(i) - (ii). Findings 23 - 41.

43. Neither aggravating nor mitigating factors are present in this case. Findings 18 - 42.

44. Evidence as to Petitioner's remorse for his unlawful conduct, his rehabilitation, and his reputation for honesty and integrity, is not relevant to deciding whether the length of the exclusion imposed and directed against him is mandated by 42 C.F.R. § 1001.401(c).

45. The three-year exclusion which the I.G. imposed and directed against Petitioner is mandated by regulation. Findings 18 - 43; 42 C.F.R. § 1001.401(c).

ANALYSIS

Petitioner does not dispute that he 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 him from participating in the Medicare and Medicaid programs. What is at issue here is whether regulations require me to sustain the three-year exclusion which the I.G. imposed and directed against Petitioner without considering whether the exclusion is reasonably necessary to meet the remedial concerns which are the basis for section 1128 of the Act. I conclude that regulations require me to sustain the exclusion. Therefore, I make no findings in this decision as to whether the exclusion is reasonable or whether Petitioner is trustworthy to provide care to program beneficiaries and recipients.

1. Background

I ruled initially in this case that both the I.G. and Petitioner were entitled to present evidence as to Petitioner's trustworthiness to provide care. Tr. I at 6 - 10. My ruling was grounded on the Act and on decisions by Departmental Appeals Board (Board) appellate panels and administrative law judges which interpreted the Act and regulations on behalf of the Secretary.

Board appellate panels 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 program beneficiaries and recipients from

providers 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. The United States Constitution prohibits the application of civil remedy statutes in a way that produces punitive results, in the absence of traditional constitutional guarantees such as the right to counsel, the right to 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, a Board appellate panel 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 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 by Board appellate panels 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. 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.

Under the Act, the burden of proof is on the I.G. to establish that the length of any exclusion imposed

against a party is reasonable. An excluded party has the statutory right to rebut evidence presented by the I.G. in a de novo hearing, or to introduce affirmative proof that is relevant to the issue of his or her trustworthiness to provide care. The criteria identified by the Board's appellate panel in Matesic for evaluating the reasonableness of permissive exclusions apply to all permissive exclusions, including those imposed pursuant to section 1128(b)(3).[3]

On January 29, 1992, the Secretary published regulations which, at 42 C.F.R. Part 1001, established criteria for the I.G. to apply in determining, imposing, and directing exclusions pursuant to section 1128 of the Act. The I.G. has argued since then that the exclusion determination criteria contained in Part 1001 of these regulations apply also as criteria for adjudication of exclusions' length at administrative hearings. Administrative law judges have held consistently that these regulations do not establish criteria for adjudication of the length of exclusions. Bertha K. Krickenbarger, R.Ph., DAB CR250 (1993); Tajammul H. Bhatti, M.D., DAB CR245 (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). The Krickenbarger decision held specifically that section 1001.401 of the regulations, governing the I.G.'s exclusion determinations under section 1128(b)(3) of the Act, which is at issue here also, did not apply in administrative hearings concerning such exclusions.

The decisions in these cases were based on two conclusions. First, the Part 1001 regulations were not intended by the Secretary to strip parties retroactively of rights vested prior to January 29, 1992. Therefore, the Part 1001 regulations did not apply to any cases arising from exclusion determinations made prior to that

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[3] The Act does not require consideration of the Matesic criteria for evaluating the reasonableness of exclusions imposed pursuant to sections 1128(a)(1) and (a)(2) of the Act for terms of five years. Congress mandated exclusions of at least five years for all exclusions imposed pursuant to sections 1128(a)(1) and (a)(2). Social Security Act, sections 1128(a)(1), (2), 1128(c)(3)(B).

date. Behrooz Bassim, M.D., DAB 1333, at 5 - 9 (1992).[4] Second, the Secretary did not intend Part 1001 of the regulations to establish criteria for administrative hearings as to the length of exclusions.[5]

The present case does not involve an issue of retroactive application of regulations, because the exclusion determination is dated May 12, 1992, which is subsequent to the publication of the January 29, 1992 regulations. Therefore, the only question concerning the regulations' application is whether the Secretary intended these regulations to apply as criteria for adjudication of the length of exclusions.

The administrative law judge decisions which addressed the issue of applicability, including Krickenbarger, found that the Part 1001 regulations, if applied as criteria for review of exclusions, would place the

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[4] Central to the appellate panel's holding that the regulations did not apply retroactively was a finding that the I.G.'s interpretation of the January 29, 1992 regulations represented a departure from policy previously enunciated by the Board. The appellate panel considered and rejected the I.G.'s argument that, in requiring most exclusions based on State license revocations and suspensions to be coterminous with such revocations and suspensions, 42 C.F.R. § 1001.501(c) merely restated the Board's interpretation of section 1128(b)(4) on the Secretary's behalf:

> [T]here is no merit to the I.G.'s argument that his interpretation of the 1992 Regulations comports with prior Board decisions, with respect to prohibiting review of matters considered during the state licensing proceeding and requiring a coterminous exclusion.

DAB 1333, at 8 (footnote omitted).

[5] The I.G. filed a notice of appeal with the Board in Willig, but then withdrew it. Krickenbarger was the first of the administrative law judge decisions to examine an exclusion determination made after January 29, 1992. Thus, Krickenbarger was the first decision to present the issue of the applicability of the Part 1001 regulations independent of the issue of retroactive application of the regulations that had been addressed by the appellate panel in Bassim.

Secretary in opposition to the requirements of the Act. If applied at the level of the administrative hearing, the regulations would conflict squarely with the remedial criteria of the Act. 42 C.F.R. § 1001.401(b), for example, mandates that exclusions imposed pursuant to section 1128(b)(3) be for a term of three years.[6] This is in direct conflict with the Act, as interpreted by the Board's appellate panels in Kranz, Bilang, and Matesic. The gravamen of those decisions was that the Act did not direct exclusions of any particular length under section 1128(b). Furthermore, the Part 1001 regulations would strip parties of their rights to de novo hearings guaranteed to them by section 205(b) of the Act, because these regulations, if applicable as criteria for administrative adjudications of the reasonableness of exclusions, would bar parties from presenting evidence which is relevant to their trustworthiness to provide care.[7]

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[6] The regulation provides very narrow exceptions to this mandate, which I shall discuss infra.

[7] Although the I.G. did not raise the argument here, he has asserted in other cases that the new regulations are similar to those found lawful by the United States Supreme Court in Heckler v. Campbell, 461 U.S. 458 (1983). The Campbell decision involved regulations adopted by the Social Security Administration to facilitate the processing of disability cases under the Act. The regulations simplified the processing of disability cases by resolving certain medical-vocational issues that were common to many cases. The Supreme Court held that the regulations were not ultra vires the Act. In holding that the regulations were not ultra vires, the Supreme Court found that they determined issues that did not involve case-by-case consideration in a manner which was consistent with that which Congress had intended. 461 U.S. at 467. Furthermore, the Supreme Court noted that: "The regulations here . . . state that an administrative law judge will not apply the rules contained in the guidelines when they fail to describe a claimant's particular limitations." 461 U.S. at 468 n.11. Thus, these regulations were held not to be ultra vires because: (1) they promoted outcomes which were consistent with congressional intent, and (2) they permitted claimants to argue that the regulations did not resolve the issues as uniquely applied in their particular cases. By contrast, the Part 1001 regulations would direct outcomes based on criteria which are inconsistent with congressional intent, as found by the Board's appellate panels in Kranz, Bilang, and Matesic,

(continued...)

The administrative law judge decisions concluded that the Secretary did not intend to publish regulations which might conflict with the requirements of the Act. They found support for this conclusion on several grounds. First, the decisions found that the Part 1001 regulations neither stated nor suggested that they applied at the level of the administrative hearing. The decisions held that the plain meaning of the Part 1001 regulations was to establish criteria for the I.G. to use in making exclusion determinations. Thus, the Part 1001 regulations did not, on their face, apply to administrative hearings. Krickenbarger, DAB CR250, at 15 - 16.

Second, the administrative law judge decisions found that there was nothing in the Part 1001 regulations or the commentary to those regulations which either stated or suggested that the Secretary intended the regulations to overrule the Board's interpretations of the Act. Even as administrative law judges are delegated authority to hear and decide cases on the Secretary's behalf, and to interpret law and regulations for the Secretary, the Board is delegated authority to make final interpretations of law on behalf of the Secretary. The decisions concluded that, had the Secretary intended to supersede the Board's appellate decisions by his enactment of regulations, he would have said so. Id. at 16.

Third, the decisions concluded that 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 length of exclusions. The Part 1001 regulations are part of a broader enactment which includes regulations which

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[7] (...continued)
and would prohibit petitioners from offering evidence to show that the regulations did not resolve the issues as uniquely applied in their particular cases.

More recently, the United States Supreme Court has held that regulations promulgated pursuant to the Social Security Act are ultra vires where they impose standards for relief which are stricter than those embodied in the Act, or where they deny claimants for benefits the opportunity to show that the regulations should not direct an outcome given the unique circumstances which pertain in particular cases. Sullivan v. Zebley, 493 U.S. 521 (1990). Zebley involved the lawfulness of regulations which directed the outcomes of applications for disability for children eligible for benefits under the Supplemental Security Income program.

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 42 C.F.R. Part 1005. 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 become meaningless when the Part 1001 regulations are applied as a standard for reviewing the length of exclusion determinations. For example, the Part 1005 regulations include sections which establish and define the authority of administrative law judges, and sections which define the parties' rights to present evidence in administrative hearings. Id. at 16 - 17.

Finally, the administrative law judge decisions concluded that the Part 1001 regulations could be read as codifying I.G. policy, without construing them as being applicable at all levels of review. Id. at 18. In so holding, the administrative law judges noted that there had 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.

As of January 14, 1993, when I held the in-person hearing in this case, these decisions constituted the Secretary's final interpretation of the January 29, 1992 regulations. As I note above, the I.G. did not elect to pursue appeals of any of these decisions. Consequently, I permitted both the I.G. and Petitioner to present evidence in the in-person evidentiary hearing which was relevant to the evidentiary factors identified by the Board in Matesic. Petitioner availed himself of this opportunity by presenting the testimony of 10 witnesses, who testified as to his trustworthiness to provide care. Tr. I at 25 - 88. Petitioner also testified on his own behalf. Tr. I at 89 - 102. The evidence Petitioner offered on his behalf might have served as a basis to find the three-year exclusion which the I.G. imposed and directed to be contrary to the Act's remedial requirements, and might have served as a basis to modify that exclusion, had I been permitted to rely on that evidence.[8]

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[8] For example, Petitioner expressed remorse for his unlawful conduct and averred that he had learned to avoid making the errors in judgment that resulted in his being convicted of a criminal offense related to the unlawful distribution of controlled substances. Tr. I at 95, 97 - 99; see Matesic, DAB 1327, at 12.

2. The effect of the January 22, 1993 regulations on my authority to hear and decide exclusion cases

On January 22, 1993, the Secretary published new regulations.[9] These regulations state in part that:

> The regulations in . . . [Part 1001] are applicable and binding on the Office of Inspector General (OIG) in imposing and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG . . . .

58 Fed. Reg. 5618 (to be codified at 42 C.F.R. § 1001.1(b)). Interpretive comments to these new regulations emphasize that the exclusion determination criteria contained in Part 1001 must be applied by administrative law judges in evaluating the length of exclusions imposed and directed by the I.G.

The regulations were made applicable to cases which were pending on January 22, 1993, the regulations' publication date. 58 Fed. Reg. 5618. The present case is a "pending case" inasmuch as the exclusion determination was made on May 12, 1992, subsequent to the January 29, 1992 effectuation date of the Part 1001 regulations.[10]

I must now apply to this case the criteria for determining the length of exclusions set forth in 42 C.F.R. § 1001.401. That regulation establishes a benchmark of three years for all exclusions imposed pursuant to section 1128(b)(3) of the Act. 42 C.F.R. § 1001.401(c)(1). It also specifically precludes consideration of factors for either lengthening or shortening an exclusion not identified by the regulation as either "mitigating" or "aggravating." 42 C.F.R. § 1001.401(c)(2), (c)(3). In this case, the I.G. imposed the three-year benchmark exclusion and did not contend that any aggravating factors were present. Inasmuch as the evidence Petitioner offered at the January 14, 1993 hearing concerning his trustworthiness to provide care

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[9] The new regulation was approved by then-Secretary Louis W. Sullivan on December 18, 1992. 58 Fed. Reg. 5618.

[10] I make no findings here as to whether the Part 1001 regulations apply to cases in which exclusion determinations were made prior to January 29, 1992.

does not fall within the ambit of any of the factors identified by 42 C.F.R. § 1001.401(c)(3) as "mitigating," I may no longer consider it as relevant to my decision concerning the length of the exclusion. See Finding 19. Therefore, I make no findings concerning that evidence. I do so notwithstanding the fact that the Board held in Matesic that the Act itself requires that excluded parties be permitted to offer evidence as to their trustworthiness to provide care. I do so also notwithstanding the administrative law judge decisions which found that the Part 1001 regulations do not establish criteria for administrative law judges' review of exclusions. The January 22, 1993 regulations overruled those decisions, and they overruled my ruling in this case that I would consider evidence which related to the factors identified in Matesic.[11]

Petitioner argues that, notwithstanding the January 22, 1993 publication, I am not required to apply 42 C.F.R. § 1001.401(c) in adjudicating the length of the exclusion imposed and directed by the I.G. He argues that the January 22, 1993 regulations are ultra vires the Administrative Procedure Act because they are a substantive change in the Secretary's interpretation of the Act and were implemented without providing the public with notice and the opportunity to comment. He argues

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[11] One consequence of the new regulations being applied as criteria for adjudication of the length of exclusions imposed pursuant to section 1128 of the Act is that administrative law judges now have considerably less authority to review the length of exclusions than the I.G. has to determine the length of exclusions. The regulations do not preclude the I.G., in a given case, from deciding not to exclude a party even though authority may exist under the Act to impose and direct an exclusion. The I.G. may exercise discretion in a particular case not to exclude a party. However, once the I.G. exercises discretion to exclude, administrative law judges may consider only the factors identified by the regulations in reviewing the length of exclusions imposed by the I.G. Furthermore, since 1992, the regulations have barred administrative law judges from reducing exclusions imposed under section 1128 to zero, even if parties could show that they are trustworthy to provide care. 42 C.F.R. § 1005.4(c)(6) (1992). The authority to review exclusions which these regulations confer on administrative law judges is thus not the de novo review authority mandated by section 205(b) of the Act, or by the Board's appellate panels in Bilang, Kranz, and Matesic.

also that, in participating in the preparation of the January 22, 1993 publication, the I.G. violated the delegation of authority granted to him by the Secretary. Petitioner argues also that the January 29, 1992 regulations, including Part 1001, are ultra vires the Act if applied as standards for administrative adjudication of the length of exclusions.

I have no authority to consider these arguments, whatever their merits. The regulations expressly deny me authority to consider whether regulations are ultra vires. 42 C.F.R. § 1005.4(c)(1). I have no authority to decide whether the I.G. exceeded the authority which the Secretary delegated to him. Therefore, I make no findings or conclusions as to whether either the Part 1001 regulations or the January 22, 1993 regulations are ultra vires or as to whether the I.G. exceeded the authority delegated to him by the Secretary.[12]

3. The absence of circumstances which are mitigating, as defined by regulations

Petitioner contends that there are circumstances defined by the regulations as mitigating which justify reduction of the exclusion imposed and directed against him. He asserts that the weight of the evidence establishes that alternative sources of the type of health care items or services which he provides are not available, citing the mitigating circumstance identified in 42 C.F.R. § 1001.401(c)(3)(ii). He argues that the I.G. had the burden of proving that alternative sources of health care were available, and that, in the absence of such proof, I must assume that such sources were not available. He contends, alternatively, that he has proved that alternative sources of health care are not available.

The Part 1001 regulations do not allocate specifically the parties' respective burdens of proof in establishing

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[12] Petitioner submitted three documents (Petitioner's attachments A, B, and C) to his posthearing brief and moved that I admit them into evidence. Attachments A, B, and C are documents which Petitioner contends support his argument that the January 22, 1993 publication and the Part 1001 regulations are ultra vires. I deny Petitioner's motion. These documents were not presented timely by Petitioner pursuant to the schedule that I established for the exchange of exhibits. Furthermore, they are not relevant to issues which I have the authority to hear and decide.

the presence of aggravating and mitigating circumstances. The duty of allocating the burden of proof in section 1128 exclusion cases is reserved expressly to administrative law judges. 42 C.F.R. § 1005.15(c). I conclude that it is both logical and consistent with the structure and language of the regulations to place on Petitioner the burden of proving mitigating circumstances, including the burden of proving that, by virtue of his exclusion, alternative sources of health care of the type that he provides are not available.

It is plain from the language and structure of the Part 1001 regulations that the Secretary intended the mitigating circumstances identified in those regulations to be in the nature of affirmative defenses to the imposition of exclusions that would otherwise be mandated by the regulations.[13] Logically, the burden should fall on excluded parties to prove the existence of affirmative reasons for imposing less than regulation-mandated minimum exclusions. It does not make practical sense to require the I.G. to prove a negative -- the absence of mitigating circumstances -- in cases where he has imposed the regulation-mandated minimum exclusion.

Furthermore, my decision to place on Petitioner the burden of proof for establishing the presence of mitigating circumstances is consistent with the burdens which have been established in other kinds of cases in which exclusion is the remedy. For example, in cases brought under the Civil Money Penalties Act, the respondents have always had the burden of proving the presence of mitigating circumstances which would justify reduction of a penalty, an assessment, or an exclusion. Social Security Act, section 1128A; 42 C.F.R. § 1005.15(b); see 42 C.F.R. §§ 1003.106, 1003.107.

I am not convinced from the evidence offered by Petitioner that his exclusion would result in the unavailability of the types of health care services that he provides.[14] Petitioner currently engages in the

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[13] The regulations also allow excluded parties to aver that mitigating circumstances exist to offset aggravating circumstances that might otherwise be used by the I.G. to justify imposing exclusions which exceed the minimum exclusion periods prescribed by the regulations.

[14] Petitioner points out that the preamble to the January 29, 1992 regulations explains that the phrase "alternative sources of the type of health care items or

(continued...)

general practice of medicine, with at least some of that practice being devoted to obstetrics, gynecology, pediatric medicine, and geriatric medicine. Finding 4. His background includes training and work as a pathologist, and he has provided pathology services to the Bacon County, Georgia hospital, serving as that hospital's laboratory director. Finding 5. Petitioner is also a practitioner of clinical hypnosis which he uses in the treatment of a variety of emotional conditions, including obesity and smoking addiction. Finding 6. Petitioner speaks Spanish and provides medical care to Spanish-speaking migrant workers in his community. Finding 7.

Petitioner did not prove that his exclusion will result in any of these medical services becoming unavailable in his community. He has not averred that, as a consequence of his exclusion, he will cease practicing medicine or that he will cease providing any of the health care items or services which he currently provides.

It may be that as a consequence of Petitioner's exclusion he will cease providing treatment during the exclusion period to Medicare beneficiaries and Medicaid recipients. However, the exclusion will not preclude Petitioner from treating other members of his community who are not program beneficiaries or recipients. Petitioner has not alleged nor is there any evidence that the exclusion will so impair his practice as to require him to cease treating non-program patients.[15]

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[14] (...continued)
services furnished by the excluded individual are not available" should be read to mean that such services are not reasonably available. P. Br. at 7, 18; 57 Fed. Reg. 3315 - 16. In concluding that Petitioner has failed to establish this mitigating factor, I have determined that alternative sources of the services provided by Petitioner are reasonably available.

[15] The consequence of Petitioner's exclusion is that he will not be able to seek or obtain reimbursement for any Medicare or Medicaid items or services which he provides during the period that he is excluded. Petitioner may, as a practical consequence of his exclusion, cease treating Medicare beneficiaries and Medicaid recipients during this period. But he is not precluded from treating these individuals. Furthermore, the exclusion does not preclude Petitioner from treating any individuals who are not Medicare beneficiaries or
(continued...)

Furthermore, Petitioner did not prove that even if he were to cease practicing medicine as a consequence of his exclusion, the health care items or services that he provides would be unavailable. At most, Petitioner demonstrated that such items or services would become less available than they are presently. But proving that the consequence of an exclusion might be a reduction in the availability of items or services is not the same as proving that the consequence of an exclusion would be that those items or services are not available.

Even if Petitioner were to cease practicing medicine entirely as a consequence of his exclusion, there would still be other physicians in the vicinity of Alma, Georgia, who would be in a position to provide items or services to patients. There are at least three physicians besides Petitioner practicing in the Alma area. Finding 27. Although Petitioner is the only pathologist in Bacon County, Georgia, pathology services are provided presently at the Bacon County Hospital on a contract basis by another pathologist from Augusta, Georgia. Finding 32. Although Petitioner may be the only physician in Alma, Georgia, who speaks Spanish who currently provides medical services to Spanish-speaking migrant workers, there is no evidence to show that these patients would be deprived of the opportunity to obtain medical treatment in the Alma area (as opposed to medical items or services provided by a Spanish-speaking physician) if Petitioner ceased his practice of medicine. While it may be, as Petitioner asserts, that he is the only physician in Alma, Georgia, who provides clinical hypnosis as a treatment for obesity, smoking, and other emotional problems, Petitioner has not shown that patients who might be deprived of these services by virtue of his exclusion could not find adequate treatment for their conditions elsewhere. Furthermore, Petitioner has not established that clinical hypnosis is the only adequate treatment for obesity or smoking, or that his patients could not obtain some other effective mode of therapy for these problems.

Petitioner has not shown that there exist mitigating circumstances as defined by 42 C.F.R. § 1001.401(c)(3). There is no basis under the regulations for me to modify the three-year exclusion which the I.G. imposed and directed against Petitioner. Therefore, I sustain it.

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[15] (...continued)
Medicaid recipients, nor does it preclude him from obtaining reimbursement from such individuals for the items or services he provides to them.

CONCLUSION

I conclude that the three-year exclusion which the I.G. imposed and directed against Petitioner is mandated by 42 C.F.R. § 1001.401.

/s/

Steven T. Kessel
Administrative Law Judge