## Department of Health and Human Services

## **DEPARTMENTAL APPEALS BOARD**

### Civil Remedies Division

In the Case of:

DATE: April 30, 1992

Stephen J. Willig, M.D.,

Petitioner,

Docket No. C-362

Decision No. CR192

- v. 
The Inspector General.

### DECISION

On March 22 1991, the Inspector General (I.G.) notified Petitioner that he was excluding him from participating in Medicare and directing that he be excluded from participating in State health care programs, pursuant to section 1128(b)(4) of the Social Security Act (Act). Petitioner timely requested a hearing. The I.G. moved for partial summary disposition on the issue of whether he had authority to exclude Petitioner pursuant to section 1128(b)(4)(B) of the Act. Petitioner opposed the motion and cross-moved for summary disposition on the issue of authority to exclude. Petitioner also requested oral argument. I conducted oral argument by telephone on August 2, 1991. I reserved judgment on the parties' motions, however, because of new evidence which Petitioner sought to introduce immediately prior to the oral argument.

I conducted a hearing on September 4, 1991, in St. Louis, Missouri. I took supplemental testimony from Petitioner by telephone on December 5, 1991. The parties filed post-hearing briefs in which they addressed both the disputed issues of fact and the question of whether new regulations promulgated by the Secretary on January 29, 1992 should be applied in this case. I have carefully considered the evidence adduced at the hearing and in the supplemental telephone proceedings, as well as the applicable law. I have also considered the parties' arguments expressed in their motions for summary disposition and post-hearing briefs. I conclude that the I.G. had authority to exclude Petitioner pursuant to

section 1128(b)(4)(B) of the Act. I further conclude that the Secretary did not intend for the new regulations to establish criteria to govern administrative review of exclusions imposed pursuant to section 1128(b) of the Act, and did not intend the new regulations to be applied retroactively in cases such as this one. I conclude that an indefinite exclusion of Petitioner until he regains his license to practice medicine in Missouri is not reasonable in this case.

#### **ISSUES**

The issues in this case are:

- 1. Whether the I.G. had authority to exclude Petitioner pursuant to section 1128(b)(4)(B) of the Act;
- 2. Whether new regulations promulgated on January 29, 1992 are applicable to this case;
- 3. Whether the indefinite exclusion imposed by the I.G. is required by regulation or, if not, whether an indefinite exclusion until Petitioner regains his license to practice medicine in Missouri is reasonable.

#### FINDINGS OF FACT AND CONCLUSIONS OF LAW

- 1. Petitioner is a physician who was licensed to practice medicine in Missouri. P. Ex. 5.
- 2. Petitioner resided at 1402 Barger Place, St. Louis, Missouri from about July of 1984 until about July of 1987. Tr. I/143.
- 3. Petitioner is also licensed to practice medicine in Illinois, where he has resided since July 1987. Tr. I/96, 143.
- 4. During the period September 1987 through May 1989, Petitioner was attending law school at Washington University School of Law in St. Louis, Missouri. Tr. I/96.

Petitioner's ExhibitP. Ex. (number)
I.G. Exhibit I.G. Ex. (number)
Transcript Volume ITr. I/(page)
Transcript Volume IITr. II/(page)

Citations to the record in this case are noted as follows:

- 5. During the period September 1987 through January 1989, Petitioner worked part-time as an emergency room physician at St. Louis Regional Medical Center in St. Louis, Missouri. Tr. I/138-39.
- 6. During the period September 1987 through February 1989, Petitioner worked on a temporary basis at other hospitals and health care facilities in Missouri as an employee of Healthline, a firm which supplies physicians to hospitals on a contract basis. Tr. I/56.
- 7. To prescribe controlled substances in Missouri, a physician must be licensed by the State Board of Healing Arts and registered with the State Bureau of Narcotics and Dangerous Drugs and with the United States Drug Enforcement Agency. Tr. I/48-49.
- 8. To obtain registration with the Missouri Bureau of Narcotics and Dangerous Drugs, a physician must provide that agency with a Missouri practicing address. Tr. I/49.
- 9. Petitioner's registered address on file with the Missouri Bureau of Narcotics and Dangerous Drugs was 3663 Lindell Boulevard, St. Louis, Missouri, the corporate address of Healthline, the agency for which Petitioner worked on an intermittent basis. P. Ex. 5.
- 10. Beginning in about March 1989, investigators of the Missouri State Board of Registration in the Healing Arts and the Missouri State Bureau of Narcotics and Dangerous Drugs began investigating Petitioner's prescription of controlled substances for his wife. Tr. I/50, 55.
- 11. The investigators found that on fourteen occasions between September 1987 and February 1989, Petitioner had written prescriptions for Schedule II controlled substances for his wife which either failed to recite a registered address for Petitioner or recited a false registered address. I.G. Ex. 5; Tr. I/60.
- 12. The prescriptions in question listed Petitioner's former residence address, 1402 Barger Place, St. Louis Missouri, as his registered address.
- 13. In an interview with investigators, Petitioner acknowledged that he had used a false Missouri registered address on the prescriptions, and thus had obtained controlled substances by fraud, a felony. I.G. Ex. 5; Tr. I/60-61.

- 14. On May 9 1989, the Missouri Bureau of Narcotics and Dangerous Drugs terminated Petitioner's Missouri Controlled Substances Registration based on Petitioner's failure to notify that agency of a change in his professional status and address and for writing prescriptions for controlled substances which contained incorrect information. P. Ex. 1.
- 15. On October 20 1989, the Missouri State Board of Registration for the Healing Arts (Missouri Board of Healing Arts) issued an administrative complaint against Petitioner which was based on the investigation and on the termination of Petitioner's controlled substances registration by the Bureau of Narcotics and Dangerous Drugs. P. Ex. 2.
- 16. The complaint charged that Petitioner's acts or omissions fell within sections of Missouri law which provided for disciplinary actions against physicians who had violated Missouri drug laws or rules or regulations, or whose controlled substance authority had been subject to revocation, suspension, limitation, or restriction of any kind. P. Ex. 2; Mo. Rev. Stat. §334.100.2(13), (23) (Supp. 1988).
- 17. On January 8 1990, Petitioner and the Missouri Board of Healing Arts entered into an agreement to resolve the administrative complaint against Petitioner concerning his Missouri license to practice medicine. I.G. Ex. 2.
- 18. The agreement recited that Petitioner signed prescriptions for controlled substances which either did not recite a registered address for Petitioner, or which recited an address which was not Petitioner's registered address, in violation of Missouri law. The agreement also recited that cause existed for discipline against Petitioner's license to practice medicine. I.G. Ex. 2.
- 19. Under the terms of the agreement, Petitioner must wait until January 8, 1992 to apply for reinstatement of his license to practice medicine in Missouri. I.G. Ex. 2.
- 20. The conduct which gave rise to the investigation and administrative complaint does not represent a mere technical violation by Petitioner.
- 21. Petitioner surrendered his license to practice medicine while a formal disciplinary proceeding was pending before a State licensing authority which concerned Petitioner's professional competence,

professional performance, or financial integrity, within the meaning of section 1128(b)(4)(B) of the Act.

- 22. The Secretary of the Department of Health and Human Services (Secretary) has authority to impose and direct an exclusion against Petitioner from participating in Medicare and Medicaid, pursuant to section 1128(b)(4)(B) of the Act.
- 23. 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. 21662 (May 13, 1983).
- 24. By letter dated March 22, 1991, the I.G. excluded Petitioner from participating in Medicare and directed that he be excluded from participating in Medicaid, pursuant to section 1128 of the Act, effective 20 days from the date of the letter.
- 25. The I.G. excluded Petitioner from participating in Medicare and directed that he be excluded from participating in Medicaid until Petitioner obtained a valid license to practice medicine in Missouri.
- 26. Section 1128(b)(4)(B) of the Act does not establish a minimum or maximum term of exclusion.
- 27. The regulations concerning permissive exclusions pursuant to section 1128(b), to be codified at 42 C.F.R. § 1001, subpart C, promulgated at 57 Fed. Reg. 3298, 3330-42 (January 29, 1992), were not intended to govern administrative review of I.G. exclusion determinations.
- 28. The regulations concerning permissive exclusions pursuant to section 1128(b), to be codified at 42 C.F.R. § 1001, subpart C, promulgated at 57 Fed. Reg. 3298, 3330-42 (January 29, 1992), were not intended to apply retroactively to appeals of I.G. exclusion determinations that were pending before ALJs at the time the regulations were promulgated.
- 29. During the period September 1987 to February 1989, Petitioner's wife suffered pain due to extensive dental problems and following a caesarean section. Tr. I/110-112.
- 30. During the period September 1987 to February 1989, Petitioner treated his wife's pain by prescribing controlled substances for her. Tr. I/110.

- 31. Petitioner did not maintain medical records documenting his physician-patient relationship with his wife. Tr. I/59-60.
- 32. During the period September 1987 to February 1989, Petitioner overprescribed controlled substances for his wife. Tr. II/242.
- 33. Petitioner now recognizes that his wife has a substance abuse problem and that he enabled her to abuse drugs by writing the prescriptions at issue in the Missouri proceedings. Tr. II/227, 233.
- 34. Under Illinois law, prescriptions for controlled substances must be prepared on triplicate forms. Tr. I/114, 150.
- 35. Petitioner wrote the prescriptions for controlled substances for his wife in Missouri because he believed he would be unable to obtain the triplicate forms required by Illinois law, since Petitioner did not maintain a practice in Illinois. Tr. I/114.
- 36. Petitioner used a false registered address on the prescriptions because he knew that he was prescribing improperly. Tr. II/230-31.
- 37. Petitioner has demonstrated a number of instances of poor medical judgment and dishonesty by overprescribing controlled substances for his wife and by obtaining those controlled substances by using a false registered address on the prescription. This conduct demonstrates that Petitioner is not a trustworthy provider of medical care.
- 38. Petitioner has recognized that he acted improperly and has sought support from Alanon in dealing with his wife's substance abuse problem. Tr. II/230, 233.
- 39. Petitioner has recommended to his wife that she seek treatment for her substance abuse problem. Tr. II/229.
- 40. Petitioner testified that, in the future, he will not prescribe controlled substances for his wife or any other family members. Tr. II/233, 245.
- 41. Petitioner agreed to surrender his license to practice medicine in Missouri because he no longer resided in Missouri and no longer wished to practice there. Tr. I/136, II/249.
- 42. The I.G. has not shown that an exclusion until Petitioner regains his license to practice medicine in

the State of Missouri is reasonably necessary to satisfy the remedial purpose of section 1128 of the Act.

43. The remedial purpose of the section 1128 of the Act will be satisfied in this case by modifying the exclusion imposed and directed against Petitioner to the shorter of either: 1) a two-year exclusion; or 2) an exclusion until such time as a State licensing agency reviews all the factual and legal issues that were before the State of Missouri when Petitioner surrendered his license, and based on the result of that review, either a) grants Petitioner a license, or b) if such a review is undertaken by the Illinois agency, that agency takes no significant adverse action against Petitioner's existing license.

#### ANALYSIS

1. The I.G. had authority to exclude Petitioner pursuant to section 1128(b)(4) of the Act.

The I.G. excluded Petitioner pursuant to section 1128(b)(4)(B) of the Act. This section provides that the Secretary of the Department of Health and Human Services has the authority to exclude an individual or entity:

who surrendered . . . a license [to provide health care] while a formal disciplinary proceeding was pending before . . . [a State licensing] authority and the proceeding concerned the individual's or entity's professional competence, professional performance, or financial integrity.

There is no dispute that the Missouri Board of Healing Arts is a "State licensing authority" within the meaning of this section. Nor do the parties dispute that a formal disciplinary proceeding was pending before the Missouri Board of Healing Arts concerning Petitioner's license to provide health care. The parties do not dispute that Petitioner "surrendered" his license to practice medicine while the formal disciplinary hearing was pending.

What is disputed is whether the disciplinary proceeding against Petitioner was a proceeding which concerned Petitioner's professional competence or performance.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> The I.G. does not assert that the disciplinary proceeding concerned Petitioner's financial integrity.

Petitioner argues that the proceeding was based entirely on the recision of Petitioner's Missouri controlled substances registration. This action was in turn, according to Petitioner, based solely on Petitioner's failure to maintain a Missouri office or residential address which he could identify as a registered location, as is required by Missouri controlled substance laws and regulations. Thus, according to Petitioner, the Missouri disciplinary proceeding was an action based entirely on the "technical" failure of Petitioner to comply with Missouri law and not on anything having to do with his professional competence or performance.

I disagree with Petitioner's characterization of the basis of the Missouri disciplinary proceeding concerning Petitioner's license to practice medicine in that State. I conclude that the disciplinary proceeding concerned Petitioner's professional competence or performance. Therefore, the I.G. had authority to exclude Petitioner pursuant to section 1128(b)(4)(B).

The terms "professional competence" and "professional performance" are not defined in section 1128(b)(4) of the Act.<sup>3</sup> The plain meaning of these terms encompasses the ability or willingness of a provider to practice a licensed service with reasonable skill and safety consistent with the requirements of State law and regulations. Bernardo G. Bilang, M.D., DAB CR141 (1991), aff'd DAB 1295 (1992) (Bilang); see also Richard L. Pflepsen, D.C., DAB CR132 (1991).

It is apparent from review of the administrative complaint filed against Petitioner by the Missouri Board of Healing Arts and the investigative report incorporated by reference in that complaint that the disciplinary proceeding against Petitioner related to his ability to practice medicine in Missouri with reasonable skill and safety consistent with the requirements of Missouri law.

<sup>&</sup>lt;sup>3</sup> Section 1128(b)(4) has two subparts. Subpart (A) applies to circumstances where a party's license to provide health care is revoked or suspended by a State licensing authority, or where such license is otherwise lost. Subpart (B) applies to circumstances where a party surrenders a license to provide health care while a formal disciplinary hearing is pending. Both subparts require that the disciplinary action concerning the party's license to provide health care concern the party's professional competence, professional performance, or financial integrity. Social Security Act, section 1128(b)(4)(A),(B).

The investigative report referred to by the complaint recites that:

Preliminary investigation revealed various technical violations on the part of . . . [Petitioner] which, if viewed collectively and from a strict legal point of view, could be construed as having obtained controlled substances by fraud and deceit, a felony.

I.G. Ex. 5. The investigators found that Petitioner had written prescriptions for controlled substances (including Percodan, Percocet, Valium, Tylox, and Demerol) for his wife over a period of more than one year, which either failed to recite Petitioner's registered address, or which recited a registered address at which Petitioner neither worked nor resided. <u>Id</u>.

Thus, while the administrative complaint against Petitioner may state as cause for disciplinary action the revocation of his Missouri controlled substance registration, the allegations of misconduct which underlay both the revocation and the administrative complaint pertained to fraudulent and deceitful prescription of controlled substances. Such allegations bear directly on the question of whether Petitioner performed his profession with reasonable skill and safety and in compliance with law. Therefore, the proceeding concerning Petitioner's license to practice medicine brought against Petitioner by the Missouri Board of Healing Arts related to his professional competence or performance.

Petitioner contends that the allegations against Petitioner which the Missouri Board of Healing Arts investigated were not the basis of the administrative complaint against Petitioner. It is apparent from the investigative report which was referred to in the administrative complaint that some allegations were made against Petitioner that were not pursued to the point of being made the basis for an administrative complaint. For example, it appears from the investigative report that some allegations had been made concerning the quality of services provided by Petitioner. It can also be inferred from the report that the investigators at least considered the possibility that Petitioner and/or his wife had abused controlled substances and that Petitioner had facilitated such abuse. Such allegations were not stated as the basis for disciplinary action by the Missouri Board of Healing Arts. However, the allegations stated in the administrative complaint, which I have described above, and which were described in more

detail in the investigative report, are in and of themselves related to Petitioner's professional competence or performance. Therefore, the I.G. had authority to exclude Petitioner, notwithstanding the fact that other more serious allegations were not used as a basis for a State disciplinary proceeding against Petitioner.

Petitioner argues that the surrender of his Missouri license to practice medicine is "not of a type that the [Act] was intended to encompass." Petitioner's Brief in Response to the I.G.'s Motion for Partial Summary Disposition at 15. Petitioner seems to argue that I should infer from the settlement agreement between Petitioner and the Missouri Board of Healing Arts that the disciplinary proceeding against Petitioner did not concern his professional competence or performance. Id. I have examined the settlement agreement. I find nothing in that document which suggests that Petitioner and the Missouri Board of Healing Arts agreed that the disciplinary proceeding did not pertain to Petitioner's professional competence or performance. The administrative complaint against Petitioner unambiguously recites allegations which fall within the purview of section 1128(b)(4)(B). The parties did not agree that those allegations were incorrect or that they were improperly filed. Rather, they agreed to settle the case against Petitioner. That is precisely the type of agreement which Congress intended to be covered by section 1128(b)(4)((B).

Petitioner appears to argue that the revocation of his Missouri controlled substance registration falls within the scope of conduct which Congress did not intend to be a basis for exclusion under section 1128(b)(4)(B). Essentially, Petitioner argues that his alleged misconduct is of such a minor or technical nature as to be exempted from the exclusion authority conferred by the Act. I disagree with this argument. Congress plainly concluded that any State license disciplinary proceeding which related to a provider's professional competence or performance could provide the jurisdictional authority for the Secretary to impose or direct an exclusion. Congress did not suggest that some behavior relating to professional conduct or performance was too insignificant to pass the threshold of authority to exclude.<sup>4</sup>

<sup>4</sup> On the other hand, it is appropriate to evaluate the scope and effect of provider misconduct in order to assess the reasonableness of the length of any exclusion.

(continued...)

Legislative history to section 1128(b)(4) does suggest that the Secretary should use his discretion to not exclude those parties disciplined by State professional boards for minor infractions not related to quality of care, such as failure to pay licensing fees or violation of strict advertising requirements. S. Rep. No. 109, 100th Cong., 1st Sess. 1-2, reprinted in 1987 U.S. Code Cong. & Admin. News 682, 688. However, the Secretary has discretion to impose and direct exclusions where, as here, the basis for the disciplinary proceeding against a provider relates to that provider's professional competence or performance. That discretion exists regardless of how "minor" the infraction may be upon which the disciplinary complaint is based, so long as it relates to the provider's professional competence or performance. Moreover, it is apparent that the revocation of Petitioner's controlled substance registration was not based on any of the minor grounds alluded to by Congress in the legislative history of the Act.

# 2. Regulations published on January 29, 1992 do not establish criteria which govern my decision in this case.

Having concluded that the I.G. has authority to exclude Petitioner, I must next consider whether regulations published by the Secretary on January 29, 1992 establish criteria to be employed by administrative law judges to decide the reasonableness of exclusion determinations made by the I.G. pursuant to section 1128(b)(4) of the Act. The new regulations contain sections which govern the I.G.'s determination of exclusions under section 1128 of the Act. 42 C.F.R. Part 1001, 57 Fed Reg. 3298, 3330-42 (January 29, 1992). The I.G. contends that these regulations mandate the indefinite exclusion imposed and directed by the I.G. He asserts that evidence concerning Petitioner's trustworthiness is irrelevant under the new regulations and must be disregarded by me in deciding whether the I.G.'s exclusion determination is reasonable.

The I.G. contends that 42 C.F.R § 1001.501, 57 Fed. Reg. 3332, establishes criteria which govern not only the I.G.'s determination of exclusions imposed pursuant to

<sup>4(...</sup>continued)
The fact that the Secretary may have authority to impose and direct an exclusion under section 1128(b)(4) does not by itself suggest that an exclusion of any particular length is reasonable. Bilang, DAB 1295 at 8; Eric Kranz, M.D., DAB 1286 at 11 (1991).

section 1128(b)(4) of the Act, but also govern my review of those exclusions. He asserts that I must affirm the exclusion at issue here, because it is coterminous with the license revocation imposed against Petitioner by the State of Missouri, and because there exist no factors which would qualify under 42 C.F.R. § 1001.501(b) or (c) to reduce the exclusion to a term which is less than coterminous with the State license revocation. The I.G. also argues that the Secretary intended the new regulations to apply to cases which were pending at the date of the regulations' publication. Application of the regulations to this case, according to the I.G., is a lawful prospective application intended by the Secretary.

Petitioner argues that the regulations do not establish criteria which administrative law judges must use in deciding as to the reasonableness of exclusions. He contends also that the new regulations were not intended to apply retroactively to exclusion determinations made prior to the regulations' date of publication.

Section 1001.501 of the new regulations establishes criteria to be employed by the I.G. (identified in the regulations as "the OIG") to determine the length of exclusions to be imposed and directed pursuant to section 1128(b)(4) of the Act. This regulation requires that, in most cases involving license suspension or revocation by State authorities, any exclusion imposed by the I.G. be of a duration which is at least as long as the term of the State license revocation or suspension. 42 C.F.R. § 1001.501(b)(1)-(3). The regulation permits the I.G. to impose an exclusion for less than the duration of a State suspension or revocation only in the limited circumstance where a second State authority, being fully apprised of the action by a State authority, grants a license to a party or elects not to take significant adverse action against that party's license in the second State. 42 C.F.R. § 1001.501(c).5

<sup>&</sup>lt;sup>5</sup> This section does not appear to permit the I.G. to impose an exclusion which is less than coterminous with a State license revocation or suspension in the circumstance where a State authority reviews all of the circumstances of a case and decides not to revoke or suspend a license and another State authority subsequently decides to revoke or suspend the party's license to provide health care in that State based on identical evidence.

a. The Part 1001 regulations do not establish criteria which govern review of the reasonableness of exclusions.

If I accept the I.G.'s interpretation of 42 C.F.R. § 1001.501, I would sustain the exclusion imposed against Petitioner solely because its duration is coterminous with the indefinite duration of his surrender of his license to practice medicine in Missouri. I would have no choice but to reject evidence offered by Petitioner as to his culpability and his motivation for engaging in the misconduct which resulted in his license surrender. 6 In short, application to this case of 42 C.F.R. § 1001.501 would mandate an indefinite exclusion of Petitioner -possibly, under the I.G's interpretation, for a period which is longer than the five-year minimum period mandated for program-related crimes under section 1128(a)(1) of the Act -- even if Petitioner could prove that the indefinite exclusion is not remedially necessary.

The I.G.'s asserted interpretation of the regulation plainly conflicts with the Departmental Appeals Board's (the Board) and administrative law judges' decisions as to the meaning of sections 205(b) and 1128(b) of the Act. If I find that this regulation establishes the criteria by which I must review the I.G.'s exclusion determinations under section 1128(b)(4) I would have no choice but to sustain exclusions which could, in light of Board decisions interpreting section 1128(b)(4), be considered to be punitive, and not remedial. Under the I.G.'s advocated interpretation, the new regulation would strip excluded parties of review rights which the Board

Indeed, in future cases under section 1128(b)(4), assuming that 42 C.F.R. § 1001.501 establishes criteria for reviewing the I.G.'s exclusion determinations, I would be required to reject as irrelevant evidence offered by a petitioner concerning his or her trustworthiness, unless the I.G. determined that "aggravating" factors existed justifying imposition of an exclusion of longer duration than the State license suspension or revocation on which the exclusion was premised. Thus, notwithstanding the I.G.'s contention that I would continue to have authority to conduct de novo review of exclusions' reasonableness, there would be nothing for me to review in many cases, assuming I accepted the I.G.'s interpretation of the new regulations. See The Inspector General's Response to Petitioner's Post-Hearing Reply Brief at 6 - 7.

and administrative law judges have found to be guaranteed by the Act.

The Board and its administrative law judges long have held that section 1128 is a remedial statute. Exclusions imposed under section 1128(b) cannot be imposed for other than remedial reasons. See <u>United States v. Halper</u>, 490 U.S. 435, 448 (1990) (<u>Halper</u>).

The <u>Halper</u> case decided the question of whether a punitive sanction imposed under the False Claims Act in addition to a criminal punishment for the same offense 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 <u>Halper</u> that the aims of retribution and deterrence are not legitimate nonpunitive government objectives. It concluded that:

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, 168-69 (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 <u>remedial</u> purpose for any exclusion imposed pursuant to section 1128(b) of the Act is to protect federally-funded health care programs and their beneficiaries and recipients from parties who are not trustworthy to provide care. <u>Hanlester Network, et al.</u> DAB CR181 at 37-38 (1992) (<u>Hanlester</u>). Section 205(b) of the Act guarantees parties who are excluded pursuant to section 1128(b), 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(b). <u>Bilang</u>,

DAB 1295 at 9; <u>Eric Kranz, M.D.</u>, DAB 1286 at 7-8 (1991) (<u>Kranz</u>); <u>Hanlester</u> at 39-43.

Section 1128(b) does not require the I.G. to impose an exclusion in every case in which he finds that an individual has engaged in conduct that would authorize an exclusion. Bilang at 8; Kranz at 9; Hanlester at 36-37. Whether or not an exclusion should be imposed in a particular case depends on the facts of that case in light of the Act's remedial purpose. Moreover, in circumstances where section 1128(b) authorizes the I.G. to impose an exclusion and where an exclusion is determined remedially to be necessary, section 1128(b) does not set a minimum length of exclusion. As with the question of whether to impose a permissive exclusion at all, the issue of the length of any exclusion that is imposed turns on the remedial basis for the exclusion and the evidence which is unique to each case.

Section 205(b) of the Act guarantees an excluded party the right to a <u>de novo</u> hearing as to the reasonableness of the length of an exclusion imposed under section 1128(b). <u>Bilang</u> at 9; <u>Kranz</u> at 7-8; <u>Hanlester</u> at 39-43. The <u>de novo</u> 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 <u>Bilang</u> and <u>Kranz</u>, 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. <u>Kranz</u> at 8; <u>See Joel Davids</u>, DAB 1283 (1991) at 7; <u>Vincent Baratta</u>, <u>M.D.</u>, DAB 1172 at 11 (1990) (<u>Baratta</u>).

These general considerations have been invoked by the Board's appellate panels and administrative law judges to preclude findings that exclusions are per se reasonable where they are coterminous with State-imposed license suspensions or revocations. In Bilang, an appellate panel held that:

The scheme Congress established in section 1128 permits the Secretary to conserve program resources by relying where possible on other federal or state court or administrative findings. However, Congress did not require imposition of an exclusion [under section 1128(b)(4)] on all providers who surrendered their licenses, nor mandate any particular period of exclusion in such circumstances. This grant of discretion to the Secretary is inconsistent with the I.G.'s apparent position that the surrender of a license creates a

presumption of culpability which cannot be rebutted for any purpose.

Bilang at 8. The appellate panel held further that "(i)f Congress had intended the state action to be determinative for federal purposes, Congress would not have made the exclusion permissive, nor have provided for de novo review." Id. at 9.

If I were to interpret 42 C.F.R. § 1001.501 as advocated by the I.G., I would be establishing a rule that in most cases an exclusion which is coterminous with a State license revocation or suspension is per se reasonable. That would conflict squarely with the appellate panel's decision in Bilang and with the rationale for that decision. In Bilang, the appellate panel held that the I.G. could rely on the decision of a State licensing authority to revoke or suspend a party, both as proof of authority to exclude under section 1128(b)(4) and as evidence of the sanctioned party's culpability. State authority's decision thus serves as evidence to support the I.G.'s determination that an exclusion of a particular length is remedially necessary. However, the appellate panel found that the State authority's decision was not conclusive proof that an exclusion for a given term was justified. Rather, it was evidence from which reasonableness could be inferred, but which could be rebutted by an excluded party, at a hearing before an administrative law judge. Bilang at 7-9, 12; see also Christino Enriquez, M.D., DAB CR119 (1991).

In <u>Kranz</u>, an appellate panel likened an exclusion imposed pursuant to section 1128(b)(4) to an action debarring a contractor from receiving federal contracts. <u>Kranz</u> at 9. The appellate panel affirmed an administrative law judge's decision that, based on the evidence adduced in that case, an exclusion which was coterminous with a State license revocation would be unreasonable. It held:

Like an action debarring a contractor from receiving any federal contracts, an exclusion is generally to be a time-related remedy. The absence of a rational relationship between the indefinite period of exclusion the I.G. proposed here and the remedial purpose of the Act is all the more apparent when one considers that this period might exceed the five-year period mandated for a person convicted of a program-related crime under section 1128(a).

Kranz at 9 (emphasis added).

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 at 18 (1989), aff'd 731 F. Supp. 835 (Greene) at 18.7 If the new regulations are explicit in their instructions to me, I must apply the plain meaning of the regulations, even though they may conflict with the letter of the Act, Congress' intent, or the Board's interpretations of the Act. Therefore, I make no findings here as to whether these regulations are ultra vires the Act.

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

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

Greene at 17 (emphasis added). Therefore, in interpreting the regulations, I must read them consistent with the Act and the Board's decisions interpreting the Act. Furthermore, to the extent that the regulations are unclear or ambiguous, I must look to the Act and case law interpreting the Act as a controlling statement of intent. Kickapoo Tribe of Oklahoma, DAB CR170 at 14 (1991).

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.

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

However, the new regulations do not mandate the interpretation advocated by the I.G. 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. I conclude that the regulations contained in Part 1001 (42 C.F.R. § 1001.501 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 making exclusion determinations, they do not establish criteria for administrative review of the reasonableness of the I.G.'s determinations. The criteria which must be used by administrative law judges to evaluate the reasonableness of exclusions continue to be those criteria established by the Board's appellate panels. In so holding, I agree with Administrative Law Judge Steinman's rationale in Charles J. Barranco, M.D., DAB CR187 (1992), for finding this regulation to be inapplicable at the level of the administrative hearing.8

There is not even a suggestion in these regulations that they are intended to establish criteria for administrative review of the reasonableness of exclusions. The plain meaning of the regulations contained in Part 1001 is to establish criteria for the

In <u>Barranco</u>, 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.

I.G. to use in making exclusion determinations. Neither the regulations nor the interpretive comments to the regulations state that the criteria for I.G. exclusion determinations contained in Part 1001 supersede the Board's decisions as to the meaning of the Act.

The letter of these regulations only establishes criteria to be employed by the I.G in making exclusion determinations. Each subpart of Part 1001 refers only to "the OIG." "OIG" is defined by 42 C.F.R. § 1001.2 to mean "Office of Inspector General of the Department of Health and Human Services." 57 Fed. Reg. 3330. The comments to Part 1001 of the Regulations provide that "[t]he basic structure of the proposed regulations in this part set forth for each type of exclusion the basis or activity that would justify the exclusion, and the considerations the OIG would use in determining the period of exclusion." 57 Fed. Reg. 3299 (emphasis added).

The Part 1001 regulations are part of a broader enactment which includes regulations governing hearings held by administrative law judges to review exclusions imposed pursuant to section 1128 of the Act. These regulations are found at Part 1005. 42 C.F.R. Part 1005; 57 Fed. The Part 1005 regulations neither state Reg. 3350-54. nor suggest that the criteria for determining exclusions in Part 1001 are to be followed by administrative law judges in deciding as to the reasonableness of exclusions. The regulations provide that an administrative law judge shall, based on the evidentiary record of the hearing, affirm, reverse, increase, or reduce an exclusion imposed by the I.G. 42 C.F.R. § 1005.20(a) and (b). Neither this regulation nor the interpretive comments to the regulations provide that the standard for review to be employed by administrative law judges in evaluating exclusions shall be that used by the I.G. to make exclusion determinations.

The I.G. seems to argue that this directive is implicit in 42 C.F.R. § 1005.4(c)(5), which forbids administrative law judges from reviewing the I.G.'s exercise of discretion to exclude a party under section 1128(b) of the Act or to determine the scope or effect of the exclusion. This regulation does not define the term "exercise of discretion." However, it plainly does not vest authority in the I.G. to interpret and apply regulations as "exercises of discretion" which are immune from review by administrative law judges and the Board's appellate panels.

I do not infer from these regulations' silence as to the standard of review to be employed by administrative law judges in section 1128 cases that the Secretary intended that administrative law judges be free to invent a standard to be employed in such cases. As of the date of the regulations' publication, the Secretary had adopted a standard of review. That standard is expressed in Bilang, Kranz, and other Board appellate panel decisions. They are the Secretary's interpretation of the Act. I infer from the regulations' silence as to a standard of review that the Secretary intended that the standard adopted by the Board not be overruled or superseded by the new regulations.

In interpreting the Act, the Board serves as the Secretary's delegate and acts for the Secretary. The Board appellate panel decisions which I have cited here as establishing criteria for evaluating the reasonableness of exclusions all predate the publication date of the new regulations. Had the Secretary intended to overrule his prior interpretations of the Act by publishing the new regulations, he would have explicitly said so. 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.

The I.G. contends that "(p)rior to the promulgation of the new regulations, . . [administrative law judges] arguably had some discretion to apply their own interpretations, to the extent particular issues were not specifically addressed in the statute, and to substitute their judgment for that of the Secretary." The Inspector General's Response to Petitioner's Post-Hearing Reply Brief at 7. This argument suggests that administrative law judge and appellate panel decisions which predate the regulations' publication did not express the Secretary's judgment as to the Act's meaning. Implicit in this argument is the contention that the new regulations constitute the first expression of judgment by the Secretary as to the meaning and application of sections 205(b) and 1128 of the Act.

This assertion betrays a misconception of the roles of administrative law judges and of the Board's appellate panels. Just as the Secretary has delegated authority to the I.G. to make exclusion determinations, he has delegated authority to administrative law judges and the Board's appellate panels to decide the reasonableness of exclusion determinations. The authority vested by the Secretary in the Board includes the authority to act on

behalf of the Secretary in interpreting regulations and the Act. <u>Greene</u> at 17. Administrative law judges and the Board's appellate panels do not "substitute their judgment" for the Secretary's judgment. Rather, they exercise their delegated authority to speak for the Secretary. The fact that the new regulations neither expressly nor impliedly overrule previous administrative law judge and appellate panel decisions is significant in that it demonstrates that the Secretary has opted not to rescind his interpretations of the Act.

Furthermore, the Secretary's decision not to overrule or supersede Board interpretations of the Act establishing the standard for review of section 1128 exclusions stands in contrast to specific instances where he has, through the new regulations, explicitly established standards of review of I.G. determinations which are binding on administrative law judges and the Board's appellate panels. For example, the new regulations containing criteria for determining civil money penalties, assessments, and exclusions apply to "the Department" and not just to the I.G. 42 C.F.R. §§ 1003.106, 1003.107.10

The Part 1005 regulations contain many sections which would be meaningless if the standard for determining exclusions contained in Part 1001 were construed to be a standard for reviewing the reasonableness of exclusion The Part 1001 regulations all but determinations. mandate exclusions of predetermined length in most cases where exclusions are imposed under section 1128(b). contrast, the Part 1005 regulations envision adversary hearings where the review of exclusions is not rigidly bound by the criteria and evidence employed by the I.G. to make exclusion determinations. I am not prepared to conclude that the new regulations create only hollow rights to administrative hearings. The criteria established by the regulations for the conduct of hearings under section 1128 make sense if administrative law judges adhere to the criteria for evaluating the reasonableness of exclusions established by the Board in Bilang and Kranz. The appellate panel decisions in those

<sup>&</sup>lt;sup>10</sup> Arguably, civil money penalty (CMP) hearings under section 1128A of the Act are different from exclusion hearings under section 1128(b), in that in CMP hearings the I.G.'s penalty, assessment, and exclusion determinations do not become effective until reviewed and sustained or modified by an administrative law judge. However, hearings in both CMP and exclusion cases derive from I.G. determinations, and, in both types of cases, the hearings are de novo reviews of those determinations.

cases envision hearings where both the I.G. and petitioners are afforded a full opportunity to present evidence as to the reasonableness of exclusions consistent with the Act's remedial purpose. However, the broad evidentiary standards and comprehensive procedural safeguards which the regulations establish for hearings under section 1128 would be pointless if the criteria for evaluating the reasonableness of exclusions obviated the need for hearings.

For example, the regulations provide that evidence which may be considered by an administrative law judge in reviewing an exclusion determination shall not be limited to that on which the I.G. relies in his notice of exclusion. 57 Fed. Reg. 3353 (to be codified at 42 C.F.R. § 1005.15(f)(1)). This section plainly envisions administrative hearings at which parties are free to offer evidence which relates to the reasonableness of exclusions. 11 However, if the Part 1001 regulations were construed to establish criteria for the review of exclusion determinations, there would be few, if any hearings, where an excluded party could offer relevant evidence. For example, in a case such as the present case, if 42 C.F.R. § 1001.501 were read to establish review criteria, the I.G.'s entire presentation would be limited to showing that the exclusion was coterminous with the State license suspension or revocation. petitioner's presentation would be limited to evidence (assuming any existed) showing that the exclusion was not coterminous. The regulation would make irrelevant all evidence as to the petitioner's trustworthiness. suspect that, as a consequence, most "hearings" under section 1128(b)(4) would be decided on motions for summary disposition, assuming 42 C.F.R. § 1001.501 were to establish the standard for review. And, equally likely, most "hearings" under the other subparts of section 1128(b) would be decided on motions for summary disposition.

The Part 1005 regulations also establish comprehensive procedural safeguards for the conduct of adversary hearings pursuant to section 1128 of the Act, which would become meaningless if the Part 1001 regulations were construed to establish standards for review of exclusion determinations. For example, discovery of documents is provided for by 42 C.F.R. §§ 1005.3, 1005.7. The

The evidence which I admitted in this case concerning Petitioner's trustworthiness would not be relevant to the length of the exclusion under any of the criteria contained in 42 C.F.R. § 1001.501.

regulations mandate prehearing exchanges of lists of witnesses, as well as witness statements and exhibits.
42 C.F.R. § 1005.8. The regulations provide a mechanism to subpoena witnesses to testify at hearings. 42 C.F.R. § 1005.9. They provide for on-the-record hearings which may include the testimony of witnesses and the cross-examination of witnesses. 42 C.F.R. §§ 1005.15, 1005.16. They contain standards governing the admission of evidence at hearings. 42 C.F.R. § 1005.17. They provide for recorded and transcribed hearings. 42 C.F.R. § 1005.18.

None of these regulations would be needed if, in fact, nearly all section 1128(b) cases could be decided on motion for summary disposition. However, as I hold above, that would be the consequence in most cases if Part 1001, and 42 C.F.R. § 1001.501 in particular, were held to establish criteria for the administrative review of exclusions imposed and directed under section 1128(b)(4). 12

As Judge Steinman observed in Barranco, the new regulations codify the I.G.'s own internal policy which he has up to now employed to govern his exclusion determinations. There has never been a particular nexus between the criteria employed by the I.G. to make exclusion determinations and criteria employed by administrative law judges or the Board's appellate panels to evaluate the reasonableness of such determinations. For example, the I.G.'s agents have testified routinely in cases involving section 1128(b)(4) exclusions that the I.G.'s policy is to make exclusions coterminous with license suspensions or revocations imposed by State licensing authorities. However, the Board's appellate panels and administrative law judges have held that the purpose of the administrative hearing is to objectively adjudicate the reasonableness of the I.G.'s exclusion determinations pursuant to the remedial criteria contained in the Act and not to second-quess the I.G. or

Although the other regulations contained in Part 1001 are not at issue here, it is evident from a reading of these regulations that they would also eliminate the need for hearings in most cases as to the reasonableness of exclusions imposed under section 1128(b) of the Act, were they found to establish criteria for administrative review of the reasonableness of exclusions. See Aloysius Murcko, D.M.D., DAB CR189 at 11 (1992).

his agents. <u>Kranz</u> at 7.<sup>13</sup> The I.G.'s internal policies and his adherence to them have not been standards by which the reasonableness of exclusions has been adjudicated.<sup>14</sup>

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

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

If, in fact, the new regulations do establish criteria to be employed at the level of administrative hearings for evaluation of the reasonableness of exclusions imposed under section 1128 of the Act, they are not applicable to cases which were pending as of the date of their publication. To apply these regulations to such cases as is advocated by the I.G. would strip excluded parties of

In decisions issued prior to publication of the new regulations, administrative law judges frequently made note of exclusion criteria contained in regulations which have now been superseded. See 42 C.F.R. § 1001.125 (1989). These regulations were always considered to be relevant, albeit nonbinding, guidelines as to some of the criteria used to judge the reasonableness of exclusions. However, neither administrative law judges nor the Board's appellate panels ever found these regulations to establish binding standards for administrative review of exclusions.

In <u>Hanlester</u>, I noted that the I.G. frequently called his agents to testify at exclusion hearings as to whether they had followed the I.G.'s criteria for making exclusion determinations. I observed there that I often had counseled parties to exclusion cases that this evidence is irrelevant because it has nothing to do with the issue of whether the exclusion, as measured against the evidence and the Act's remedial purpose, is reasonable. Hanlester at 41 n.31.

previously vested rights and operate to create manifest injustice. Such an application would be an unlawful retroactive application of the new regulations which was not intended by the Secretary. Barranco at 23-24; see also Hanlester at 43-48.

The rationale which I gave in <u>Hanlester</u> for concluding that 42 C.F.R. §§ 1005.4(c)(5) and (6) were not applicable there applies equally to the question of whether 42 C.F.R. § 1001.501 is applicable here. Procedurally, this case is in the same posture as was Hanlester as of the date of the regulations' publication. In both this case and Hanlester, the exclusion determination and the hearing predated the regulations' publication date. 15 The only procedural difference between Hanlester and this case is that, in Hanlester, the exclusions determined by the I.G. pursuant to section 1128(b)(7) of the Act did not become effective until my decision. By contrast, the exclusion which the I.G. imposed against Petitioner in this case became effective shortly after transmittal by the I.G. to Petitioner of the notice of exclusion. That is not a meaningful procedural difference, however. As I held in Hanlester, the "decision of the Secretary" which comprises the basis for a petitioner's hearing rights under sections 205(b) and 1128 of the Act is the I.G.'s exclusion determination. Hanlester at 48.

Both <u>Hanlester</u> and the present case involve the question of whether regulations which, as interpreted by the I.G., profoundly alter parties' substantive rights, govern administrative review of exclusion determinations which were made at a date prior to the date of the regulations' publication. At issue in <u>Hanlester</u> were regulations which limit an administrative law judge's authority to reduce an exclusion or to review exercises of discretion by the I.G. 42 C.F.R. §§ 1005.4(c)(5), (c)(6). At issue here are regulations which the I.G. contends establish substantive criteria for review of the reasonableness of the I.G.'s exclusion determinations. I held in <u>Hanlester</u> that the regulations at issue there affected excluded parties' substantive rights to a full review of their

The I.G. contended in <u>Hanlester</u> that the Part 1001 regulations did not govern the administrative review in that case, whereas he asserts that they do apply here. He offers no explanation as to why application of those regulations in <u>Hanlester</u> would have been an unlawful retroactive application there, whereas application of the same regulations in this case allegedly would be a lawful prospective application of the regulations.

exclusions under sections 1128(b) and 205(b) of the Act. That is equally true here, assuming the I.G.'s interpretation of 42 C.F.R. § 1001.501 is correct.

Essentially, the I.G. is contending here, as he did in Hanlester, that the new Part 1001 regulations merely codify law previously in effect. Thus, according to the I.G., the new regulations do not serve to strip parties of previously vested substantive rights, inasmuch as those asserted rights had never inured to excluded parties in the first place. I do not agree with the I.G.'s contention concerning the Part 1001 regulations in general, and 42 C.F.R. § 1001.501 in particular, for the same reason that I disagreed in Hanlester with the I.G.'s assertion that 42 C.F.R. §§ 1005.4(c)(5) and (c)(6) merely codified preexisting law. As I held in Hanlester, sections 1128(b) and 205(b) of the Act confer on excluded parties the right to a full administrative review of the reasonableness of their exclusions. Hanlester at 35-43. Regulations which, if applicable at the level of the administrative hearing, restrict those rights conferred by the Act constitute substantive and not merely procedural changes.

Both <u>Hanlester</u> and the present case involve the question of whether regulations which, as interpreted by the I.G., profoundly alter parties' substantive rights, govern administrative review of exclusion determinations which were made at a date prior to the date of the regulations' publication. At issue in <u>Hanlester</u> were regulations which limit an administrative law judge's authority to reduce an exclusion or to review exercises of discretion by the I.G. 42 C.F.R. §§ 1005.4(c)(5), (c)(6). here are regulations which the I.G. contends establish substantive criteria for review of the reasonableness of the I.G.'s exclusion determinations. As I hold above, 42 C.F.R. § 1001.501 would dramatically affect parties' rights to a full review of exclusions imposed pursuant to section 1128(b)(4) if applied to govern administrative review of such exclusions. Thus, this regulation would constitute a substantive change in parties' rights if given the effect urged by the I.G.

As a general matter, administrative rules should not be applied retroactively unless their language specifically requires retroactive application. Bowen v. Georgetown University Hospital et al., 488 U.S. 204, 208 (1988);

United States v. Murphy, 937 F. 2d 1032 (6th Cir. 1991). Application of a regulation to strip a party of a previously vested right would be an unlawful retroactive application of the regulation. United States v. Murphy; see also Griffon v. United States Department of Health and Human Services, 802 F. 2d 146 (5th Cir. 1986). Absent a specific instruction to me by the Secretary, I would not infer that he had intended that regulations be applied retroactively to strip parties of previously vested rights.

The I.G. attempts to distinguish this case from Bowen v. Georgetown University Hospital by asserting that, in Bowen, the regulations at issue were promulgated with the specific purpose that they apply retroactively, whereas, in this case, the Part 1001 regulations are intended to apply prospectively. Obviously, that contention stands or falls on the I.G.'s characterization of his asserted application of the Part 1001 regulations as "prospective." The accuracy of that characterization in turn depends on whether the new regulations strip parties of previously vested rights. Inasmuch as they would do precisely that, assuming the I.G.'s assertion that the regulations govern administrative review of exclusions to be correct, they cannot legitimately be characterized as "prospective." As I hold above, these regulations do not codify preexisting law, they profoundly alter it, assuming that they govern administrative reviews of exclusion determinations.

Application of 42 C.F.R. § 1001.501 in this case to strip Petitioner of his previously vested right to a full review of the reasonableness the I.G.'s exclusion determination would contravene the standards announced in Bowen v. Georgetown University Hospital and United States v. Murphy. There is nothing in the regulations which can be interpreted as a directive to apply them in a way which would produce such a consequence. Therefore, I conclude that to apply 42 C.F.R. § 1001.501 here as is advocated by the I.G. would constitute an unlawful retroactive application of the regulation. Barranco at 23-24.

Administrative Law Judge Steinman's decision in <u>Barranco</u> provides a thorough analysis of the Supreme Court's decision in <u>Bowen v. Georgetown University</u> <u>Hospital</u> and related cases. <u>Barranco</u> at 22.

3. An indefinite exclusion until Petitioner obtains a valid license to practice medicine in Missouri is not reasonable under the circumstances of this case.

I conclude that the I.G. has failed to show a meaningful remedial basis for an indefinite exclusion until Petitioner regains a valid license to practice medicine in Missouri. Petitioner is currently licensed to practice medicine in Illinois. 17 Petitioner testified that he relinquished his Missouri license because he concluded that he no longer needed it and he has expressed no intent to apply for reinstatement nor to resume practice in Missouri. In light of Petitioner's intention not to resume the practice of medicine in Missouri, there is no rational basis to condition reinstatement on his obtaining a Missouri license. terms of the exclusion imposed by the I.G. would require Petitioner, as a condition for reinstatement, to engage in acts which are wholly unrelated to his practice of medicine. For this reason, an exclusion until Petitioner obtains a valid license to practice Medicine in Missouri could amount to a permanent exclusion. In order for a permanent exclusion to be reasonable, the evidence would have to demonstrate that there is little or no possibility that Petitioner would ever become trustworthy. See Bilang, DAB CR141 at 11 n.6 (1991). The I.G. has presented no such evidence.

On the other hand, an exclusion plainly is warranted by the evidence. Section 1128(b)(4)(B) authorizes the exclusion of providers who surrender their health care licenses during the pendency of disciplinary proceedings before State licensing authorities. The legislative history of section 1128(b)(4)(B) suggests congressional recognition of the probability that providers who resign their licenses in the face of disciplinary charges ordinarily do so to avoid the stigma of an adverse finding. See S. Rep. No 109, 100th Cong., 1st Sess. 3, reprinted in 1987 U.S. Code Cong. & Admin. News 682, 688. This amounts to a legislative finding that an inference of untrustworthiness ought to attach to providers who surrender their licenses in such circumstances.

As I concluded in part 1 of this decision, Petitioner surrendered his Missouri medical license while a

<sup>17</sup> The Illinois licensing authorities have apparently initiated an investigation of the circumstances under which Petitioner surrendered his license to practice medicine in Missouri. Tr. II/226, 249, 252.

disciplinary proceeding was pending before Missouri licensing authorities. As part of the settlement agreement pursuant to which Petitioner surrendered his license, he admitted that he had written prescriptions for controlled substances which contained false or misleading information. Therefore, the circumstances under which Petitioner surrendered his license, without more, justify an inference that Petitioner has engaged in conduct which indicates untrustworthiness.

There is additional evidence in this case which justifies an exclusion. In the course of his hearing before me, Petitioner admitted that he had enabled his wife to abuse controlled substances by prescribing amounts of the substances beyond his wife's legitimate medical needs. Petitioner enabled his wife to abuse controlled substances by prescribing them at more frequent intervals than was medically necessary. He continued to engage in this behavior over a period of at least a year and a half. At some level, Petitioner was aware at the time he wrote the prescriptions that he was doing something wrong. However, due to his personal relationship with his wife and his desire to save his marriage, he rationalized his conduct. Petitioner allowed his medical judgment to be clouded by his personal relationship with his wife. Petitioner's lapses of judgment, first in entering into a doctor-patient relationship with his wife, and second in enabling her to abuse controlled substances, indicate a lack of trustworthiness.

Moreover, to facilitate his wife's drug abuse, Petitioner wrote prescriptions in Missouri listing an address at which he neither practiced nor resided. Petitioner admitted to investigators that this conduct amounted to obtaining controlled substances by fraud, a felony. This conduct demonstrates that Petitioner was willing to resort to dishonesty to obtain controlled substances for his wife. Such dishonesty also indicates a lack of trustworthiness.

Petitioner effectively abetted his wife's abuse of controlled substances. This lapse of judgment by Petitioner could have endangered his wife's health. It demonstrates that Petitioner lacks the capacity to distinguish between what he construes as his obligations to his close family and his duties as a physician. Petitioner's conduct shows a propensity to engage in acts or practices which could endanger the health or safety of program beneficiaries or recipients and also demonstrates a dishonest effort to conceal such acts or practices. Based on this evidence, I find Petitioner to be an untrustworthy provider of care.

However, Petitioner's conduct since he surrendered his license, and his testimony before me, convince me that he understands the wrongfulness of his conduct and has taken steps to ensure that such conduct will not be repeated in the future. Petitioner has now, perhaps somewhat belatedly, come to the realization that his wife has a substance abuse problem. He has encouraged her to seek treatment. He has informed her that he will not again prescribe controlled substances for her, nor treat her for any other medical condition. He himself has sought support through Alanon, a program for family members of persons with substance abuse problems.

Petitioner now recognizes that it is inappropriate for him to treat members of his family. He states credibly that he will not do so again. From the evidence before me, it appears that Petitioner's lapses in medical judgment and acts of dishonesty arose out of his inappropriate physician-patient relationship with his wife. There is no evidence before me that would establish that Petitioner has engaged in untrustworthy behavior in his treatment of patients other than his wife. For these reasons, I conclude that it is unlikely that Petitioner will again prescribe controlled substances for his wife or engage in other dishonest conduct in prescribing controlled substances.

Based on the seriousness of the actions to which Petitioner has admitted, I conclude that an exclusion is warranted. However, I conclude that an indefinite exclusion is not necessary to serve the remedial purposes of section 1128. Based on Petitioner's recognition of his improper conduct and his credible testimony that he will not repeat such conduct in the future, I conclude that an exclusion of two years will be adequate for Petitioner to demonstrate his trustworthiness to provide services to beneficiaries and recipients of the Medicare and Medicaid programs. Alternatively, Petitioner's

The investigative report contains some hearsay statements that could call into question Petitioner's general competence as a physician. However, the Missouri authorities did not pursue disciplinary action against Petitioner based on these allegations, and the I.G. does not contend here that Petitioner should be excluded based on these allegations.

<sup>19</sup> A two-year exclusion will make Petitioner eligible for reinstatement at about the same time that he would be eligible to apply to Missouri for reinstatement of his physician's license.

exclusion could be for less than two years if a State licensing agency reviews all of the factual and legal issues which were before the State of Missouri when Petitioner surrendered his license and, based on the result of that review, either: 1) grants Petitioner a license; or 2) in the case of the Illinois State licensing agency, takes no significant adverse action against Petitioner's license. At the end of two years, or when a State licensing agency takes the actions described above, whichever is sooner, Petitioner will be eligible to apply for readmission to the programs.

The exclusion, as modified by my decision, will provide Petitioner with a reasonable period of time within which to reaffirm his trustworthiness as a program provider. Because Petitioner has indicated no interest in returning to Missouri to practice medicine, it would be unreasonable to insist that Petitioner and the State of Missouri expend their resources to reinstate Petitioner's Missouri license simply to enable Petitioner to treat Medicare and Medicaid beneficiaries in another State. See Barranco at 36. On the present facts, the State of Missouri has no further interest in Petitioner--he does not practice there and does not treat Missouri citizens. Id. at 38. It bears no relationship to Petitioner's trustworthiness to impose an indefinite exclusion based on relicensure in Missouri. Therefore, in the absence of a thorough review of the circumstances of Petitioner's surrender of his Missouri license by another State licensing agency, Petitioner would be excluded for two Alternatively, the exclusion could be shorter if such a review is undertaken by a State which has an interest in whether Petitioner is licensed to treat its citizens and in which Petitioner has an interest in proving his competence and integrity to practice.

#### CONCLUSION

Based on the law and the evidence, I conclude that an indefinite exclusion until Petitioner obtains a valid license to practice medicine in Missouri is extreme and excessive. I therefore modify the period of exclusion imposed and directed by the I.G. to the earlier of: 1) a two year exclusion; or 2) an exclusion until such time as a State licensing agency reviews all of the factual and legal issues that were before the State of Missouri when Petitioner surrendered his license and, based on the result of that review either a) grants Petitioner a license, or b) if the review is by the Illinois licensing agency, takes no significant adverse action against Petitioner's existing license.

/s/

Steven T. Kessel Administrative Law Judge