Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
	DATE: February 14, 1994
Joseph Weintraub, M.D.	
Petitioner,	Docket No. C-93-029
	Decision No. CR303
- v. -	
The Inspector General.	

DECISION

On October 15, 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. I conducted a prehearing conference by telephone on January 12, 1993. During that conference, I established a schedule for discovery and prehearing exchanges and scheduled an in-person hearing to begin on March 11, 1993.

On Janurary 22,1993, during the prehearing phase of the proceedings, the Secretary published regulations containing provisions described as a clarification of the exclusion regulations published January 29, 1992. By

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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.

letter dated February 3, 1993, I invited the parties to file prehearing briefs on the question of the impact of these clarifying regulations on this case.

Petitioner's counsel subsequently requested that the March 11, 1993 hearing be rescheduled in order to provide additional time for him to prepare Petitioner's case. In the absence of objection from the I.G., I canceled the March 11, 1993 hearing.

I held a hearing in this matter in San Francisco, California on August 31, 1993 and in Santa Cruz, California on September 1, 1993. Prior to the hearing, Petitioner's counsel informed me that he was withdrawing from this case, and Petitioner appeared at the hearing pro se. The parties subsequently filed posthearing briefs and reply briefs.

I have considered the evidence of record, the parties' arguments, and the applicable law and regulations. I conclude that the I.G.'s determination to exclude Petitioner for three years is excessive, and that Petitioner's period of exclusion should end upon the effective date of this decision.[2] Such period of exclusion is reasonable under the circumstances of this case.

ADMISSION

Petitioner does not dispute that he was convicted of a criminal offense within the meaning of section 1128(b)(3) of the Act. He admits that the I.G. has the authority to exclude him from participating in the Medicare and Medicaid programs pursuant to section 1128(b)(3) of the Act. May 13, 1993 Order and Notice of Hearing at 2; Tr. 6 - 7.[3]

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[2] I define the effective date of the decision to be the date the decision becomes "final and binding on the parties" pursuant to 42 C.F.R. § 1005.20.

[3] The transcript of the hearing and the exhibits admitted into evidence at the hearing will be referred to as follows:

Hearing Transcript	Tr. (page)
Petitioner Exhibits	P. Ex. (number) at (page)
I.G. Exhibits	I.G. Ex. (number) at (page)

ISSUE

The issue in this case is whether it is reasonable to exclude Petitioner for a period of three years.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Petitioner is a physician who specializes in psychiatry. Tr. 235 - 236.

2. On June 15, 1987, a pharmacy manager told an investigator with the California Attorney General's Office that she knew of six of Petitioner's patients who brought in prescriptions for medications to be filled on a regular basis and that these six individuals appeared to be substance abusers. I.G. Ex. 1 at 1.

3. Three of the six individuals mentioned by the pharmacy manager had a history of drug or narcotics violations. I.G. Ex. 1 at 2.

4. The California Attorney General's Office commenced an undercover investigation of Petitioner's prescribing practices on November 13, 1987. I.G. Ex. 1 at 2 - 3.

5. Petitioner issued prescriptions for codeine or vicodin to five different undercover operators, who posed as patients, on eleven different occasions during the period from February 16, 1988 through April 19, 1990. In some of these instances, the codeine was combined with tylenol. In some of these instances, the operator posed as a Medicaid patient. I.G. Ex. 1.

6. Codeine and vicodin are controlled substances. I.G. Ex. 3.

7. Codeine and vicodin are analgesic narcotics which are used for the treatment of pain. Tr. 50, 55.

8. The undercover operators did not complain of pain or give any physical symptoms in any of their visits with Petitioner for medical treatment. I.G. Ex. 1.

9. Some of the undercover operators advised Petitioner that the drugs he prescribed were used or would be used by other individuals for non-medical purposes. I.G. Ex. 1.

10. On July 18, 1990, a felony complaint was filed in the Santa Cruz County Municipal Court by the California

Attorney General's Office against Petitioner. I.G. Ex. 2.

11. The complaint charged Petitioner with six counts of knowingly, willfully and unlawfully prescribing a controlled substance, codeine or vicodin, to an undercover operator, who was not under his treatment for a pathology or condition other than addiction to a controlled substance, in violation of section 11154 of the California Health and Safety Code. I.G. Ex. 2.

12. On July 19, 1990, Petitioner was arrested for prescribing controlled substances without medical necessity. I.G. Ex. 1 at 30.

13. Petitioner was bound over as charged in the Superior Court for the County of Santa Cruz. On October 3, 1990, the California Attorney General's Office filed an Information in the Santa Cruz County Superior Court containing the same charges as the felony complaint. Tr. 204; I.G. Ex. 4.

14. On August 27, 1991, pursuant to a plea bargain, Petitioner pled nolo contendere to count two of the Information. As part of the plea bargain, this count was reduced to a misdemeanor and the remaining five counts were dismissed. I.G. Ex. 5; Tr. 204 - 205.

15. The court accepted the plea, and sentenced Petitioner to two years of unsupervised probation and ordered Petitioner to pay a fine of $1000 and costs of $1330. I.G. Ex. 5.

16. Petitioner was convicted of a criminal offense related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance within the meaning of section 1128(b)(3) of the Act. Findings 10 - 15; May 13, 1993 Order and Notice of Hearing at 2; Tr. 6 - 7.

17. 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).

18. By letter dated October 15, 1992, the I.G. excluded Petitioner pursuant to section 1128(b)(3) of the Act for a period of three years.

19. The I.G. has authority to impose and direct an exclusion against Petitioner pursuant to section 1128(b)(3) of the Act. Findings 16 - 17.

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

21. 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.

22. 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 (DAB), and federal courts in reviewing the imposition of exclusions by the I.G.. 42 C.F.R. § 1001.1(b); 58 Fed. Reg. 5617, 5618 (1993).

23. My adjudication of the length of the exclusion in this case is governed by the criteria contained in 42 C.F.R. § 1001.401. Findings 20 - 22.

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

25. 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 benchmark established by regulation. 42 C.F.R. § 1001.401(c)(2)(i) - (iv); 42 C.F.R. § 1005.15(c).

26. The I.G. did not allege that aggravating factors are present in this case which justify increasing the exclusion imposed pursuant to section 1128(b)(3) of the Act beyond the three year benchmark established by regulation.

27. Petitioner has the burden of proving that mitigating factors exist which justify reducing an exclusion below the three year benchmark established by regulation. 42 C.F.R. § 1001.401(c)(3)(i) - (ii); 42 C.F.R. § 1005.15(c).

28. Petitioner alleged that, as a result of his exclusion, alternative sources of the type of health care

items or service that he furnishes are not available within the meaning of 42 C.F.R. § 1001.401(c)(3)(ii).

29. In order to qualify as an alternative source within the meaning of the regulations, the alternative source must be able to substitute for the items or services furnished by the excluded provider without jeopardizing the health of the recipients of those items or services. James H. Holmes, M.D., DAB CR270 (1993); Sam Williams, Jr., M.D., DAB CR287 (1993).

30. An alternative source of health care is not available within the meaning of the regulations in circumstances where Medicare and Medicaid beneficiaries and recipients are not able to reasonably obtain the type of health care items or services furnished by the excluded provider in a practicable manner consistent with the Secretary's objective to protect beneficiaries and recipients from being deprived of needed health care as a result of the provider's exclusion. James H. Holmes, M.D., DAB CR270 (1993); Sam Williams, Jr., M.D., DAB CR287 (1993).

31. Health care items or services furnished by a provider are not available to Medicare and Medicaid beneficiaries and recipients if the provider is not actively accepting Medicare and Medicaid beneficiaries and recipients as patients. 57 Fed. Reg. 3316 (1992).

32. Petitioner has been engaged in the private practice of psychiatry in downtown Santa Cruz, California, since 1974. Tr. 236, 272 - 273.

33. The parties agree that the geographical area within which the availability of alternative sources should be considered is Santa Cruz County. Tr. 9 - 10.

34. Petitioner provides outpatient psychiatric services, including individual psychotherapy counseling and prescribing medications Tr. 13 - 14, 237, 419.

35. Petitioner treats a variety of psychiatric conditions, including panic disorders, anxiety disorders, depression, personality disorders, and schizophrenia. Tr. 237 - 238.

36. Within the context of providing psychiatric care to patients, Petitioner has treated common physical complaints such as colds, coughs, cramps, and diarrhea. Tr. 273, 292.

37. The types of psychiatric conditions treated by the Santa Cruz County Community Mental Health Program (County Mental Health Program) are limited to serious psychiatric conditions, including schizophrenia, manic depressive illness, severe depression, recurrent suicide attempts, and other conditions which cause an individual to be dangerous, non-functional, or at risk for psychiatric hospitalization. Tr. 319 - 320, 322, 338 - 339, 345 - 346.

38. The types of psychiatric conditions which meet the strict criteria for treatment by the County Mental Health Program are a small percentage of all psychiatric conditions. Tr. 360 - 361.

39. The County Mental Health Program does not provide alternative health care services for treatment of the more common, less serious psychiatric conditions which Petitioner treats such as panic disorders, anxiety disorders, most depressions, and personality disorders. Findings 35, 37 - 38.

40. The County Mental Health Program has almost eliminated individual psychotherapy services, a type of health care service which is routinely provided by Petitioner. Tr. 324 - 325, 328; Finding 34.

41. Inpatient psychiatric care is available to patients admitted to hospitals and institutions in Santa Cruz County, including Dominican Santa Cruz Hospital (Dominican Hospital), Watsonville Community Hospital, and Harbor Hills Institute for Mental Diseases (Harbor Hills). Harbor Hills is a locked psychiatric skilled nursing facility. Tr. 353 - 356, 366, 368.

42. Inpatient psychiatric services furnished at hospitals and institutions in Santa Cruz County are not available to the outpatient population served by Findings 34, 41.

43. Fifteen psychiatrists are enrolled in the Medicare program or the Medicaid program or both programs in Santa Cruz County, Dr. Berman, Dr. Luther, Dr. Anderson, Dr. Koenig, Dr. Gillette, Dr. Aron, Dr. Crockett, Dr. Chagi, Dr. O'Connor, Dr. Nash, Dr. Vanderveer, Dr. Corby, Dr. Davies, Dr. Holland, and Dr. Cramer. I.G. Ex. 12, I.G. Ex. 13.

44. While Dr. Berman has a few Medicaid patients in his outpatient private practice whom he has treated for a number of years, he does not accept new Medicaid patients. Tr. 417 - 418, 430.

45. Dr. Luther treats Medicare and Medicaid patients only in the context of providing inpatient treatment at Dominican Hospital and at Harbor Hills. Tr. 366, 430.

46. Dr. Anderson is unavailable to provide psychiatric care to Medicare and Medicaid patients because he is retired. Tr. 366, 410, 430.

47. Dr. Koenig does not accept Medicaid patients in the context of an outpatient private practice. Tr. 366 - 367, 410, 431.

48. Dr. Gillette has two Medicaid patients and four Medicare and Medicaid crossover patients in his outpatient private practice. One of the two Medicaid patients had been Petitioner's patient prior to Petitioner's exclusion. Tr. 326.

49. Dr. Gillette is willing to accept new Medicare patients, but he is not willing to accept new Medicaid patients. Tr. 346.

50. Dr. Aron does not accept Medicaid patients in the context of an outpatient private practice. Tr. 367, 411, 431.

51. Dr. Crockett has three or four Medicaid patients whom he has treated for 10 to 15 years, but he does not accept new Medicaid patients. Tr. 367, 432.

52. Dr. Chagi does not accept Medicaid patients in the context of an outpatient private practice. Tr. 367 - 368, 411, 432, 476. He is willing to accept Medicare patients on a limited basis. Tr. 367 - 368, 411, 432, 476.

53. Dr. O'Connor is a former employee of Harbor Hills and now he is a State employee in the California penal system. He does not treat Medicare and Medicaid patients in an outpatient, private setting. Tr. 368 - 369, 488.

54. Dr. Nash may have some old Medicaid patients in his private practice, but he does not accept any new Medicaid patients. Dr. Nash is willing to accept new Medicare patients. Tr. 369, 411, 431 - 432, 476.

55. Dr. Vanderveer is employed three-quarters time by the children's program within the County Mental Health Program. He does not accept Medicaid patients in an outpatient, private practice. Tr. 369.

56. Dr. Corby will on occasion accept a Medicaid patient, but he refuses to have more than five percent of his practice consist of Medicaid patients. Tr. 369, 411.

57. Dr. Davies does not accept Medicaid patients in the context of an outpatient, private setting. Tr. 370, 411, 432.

58. Dr. Holland works at Harbor Hills and at a university. He does not accept Medicaid patients in his small, private practice. Tr. 370, 432.

59. Dr. Cramer is unavailable to provide psychiatric care to Medicare and Medicaid patients in the Santa Cruz area because he has moved away. Tr. 370 - 371.

60. There is evidence that three psychiatrists in Santa Cruz County are available to provide outpatient psychiatric care to Medicare patients in Santa Cruz County: Dr. Gillette, Dr. Nash, and Dr. Chagi. Findings 49, 52, 54.

61. As a result of Petitioner being excluded, there are no psychiatrists, except on rare occasions, available to provide outpatient psychiatric care to Medicaid patients in Santa Cruz County who suffer from common, non-severe psychiatric disorders. Tr. 326, 332, 394 - 395, 404 - 405, 417 - 418, 425 - 426, 433.

62. Psychiatrists engaged in the private, outpatient practice of psychiatry are reluctant to accept Medicaid patients because the reimbursement rate for Medicaid patients is low, the Medicaid forms are time-consuming to complete, and Medicaid patients are unreliable in keeping their appointments. Tr. 329 - 330.

63. Approximately five psychologists are available to treat Medicaid patients in Santa Cruz County. Tr. 342.

64. Psychologists are not qualified to prescribe medications and they do not have the background to distinguish when a condition should properly be diagnosed as a physical condition or as a psychiatric condition. Tr. 361, 399, 427.

65. The level of care offered by psychologists to psychiatrically disturbed individuals is not equivalent to the level of care offered by psychiatrists. Finding 64.

66. Health care for psychiatric conditions furnished by psychologists is not an alternative source of the type of health care furnished by Petitioner. Findings 64 - 65.

67. Three physicians in a primary medical group are available to treat Medicaid patients in Santa Cruz County who need medication to treat their psychiatric conditions. Tr. 340 - 341.

68. Primary care physicians are legally qualified to prescribe medications for psychiatric conditions. Tr. 361.

69. Primary care physicians are more likely than psychiatrists to misdiagnose psychiatric conditions and to use the wrong medications in the wrong amounts to treat psychiatric conditions. Tr. 361 - 362.

70. It is possible for a primary care physician to provide psychiatric health care which is comparable in quality to that provided by psychiatrists in limited circumstances, such as where a psychiatric disorder is very mild or where a patient has an established medication profile and his condition remains stable. Tr. 395, 403, 408.

71. In most instances, a psychiatrist, by virtue of his specialized training, is better equipped than a primary care physician to diagnose psychiatric conditions correctly and to treat psychiatric conditions effectively. Tr. 361 - 362.

72. In most instances, health care for psychiatric conditions furnished by primary care physicians who are not psychiatrists is not an alternative source of the type of health care furnished by Petitioner. Findings 69, 71.

73. In most instances, health care for psychiatric conditions furnished by both primary care physicians and psychologists in combination is not an alternative source of the type of health care furnished by Petitioner. Finding 66 72.

74. Other mental health care providers, such as licensed clinical social workers and marriage and family counselors, are not permitted to prescribe medication. Tr. 399.

75. The level of care offered by licensed clinical social workers and marriage and family counselors to psychiatrically disturbed individuals is not equivalent

to the level of care offered by psychiatrists. Finding 74.

76. Health care for psychiatric conditions furnished by licensed clinical social workers and marriage and family counselors is not an alternative source of the type of health care furnished by Petitioner. Findings 74 - 75.

77. Petitioner has met his burden of proving that the mitigating factor specified at 42 C.F.R. § 1001.401(c)(3)(ii), alternative sources of the type of health care items or services furnished by him are not available, is present in this case. Findings 29 - 76.

78. The regulations do not mandate a reduction in the three year benchmark period solely on the basis of the presence of any single mitigating factor. 42 C.F.R. § 1001.401(c)(3).

79. In evaluating the reasonableness of the three year exclusion, it is necessary to weigh the evidence relevant to the aggravating and mitigating factors enumerated in the regulations in a manner that is consistent with the goals of the Act. Act, section 1102.

80. A remedial purpose of section 1128 of the Act is to protect the integrity of federally-funded health care programs and the welfare of beneficiaries and recipients of such programs from individuals and entities who have been shown to be untrustworthy.

81. Pursuant to 42 C.F.R. § 1001.401(c)(3)(ii), it is necessary to consider the need to protect program beneficiaries and recipients from being deprived of needed health care as a result of a provider's exclusion.

82. In evaluating the reasonableness of the three year exclusion, it is necessary to balance the government interest in ensuring that Medicare and Medicaid programs and their beneficiaries and recipients will be protected against untrustworthy providers against the competing government interest in ensuring that Medicare and Medicaid beneficiaries and recipients will not be deprived of needed health care as a result of a provider's exclusion. Findings 80 - 81.

83. The evidence relevant to the mitigating factor specified at 42 C.F.R. § 1001.401(c)(3)(ii) establishes that Medicaid recipients will be deprived of needed health care as a result of Petitioner's exclusion. Finding 77.

84. When Petitioner has met his burden of establishing the mitigating factor at 42 C.F.R. § 1001.401(c)(3)(ii), the I.G. may offset or diminish the impact of such factor on the three year benchmark exclusion by relying on any of the aggravating factors set forth in 42 C.F.R. § 1001.401(c)(2).

85. The I.G. has the burden of proving that there are aggravating factors which offset or diminish the weight of any mitigating factors which are present. 42 C.F.R. § 1001.401(c)(2)(i) - (iv); 42 C.F.R. § 1005.15(c).

86. The aggravating factors at 42 C.F.R. § 1001.401(c)(2)(i) and 42 C.F.R. § 1001.401(c)(2)(ii) are, respectively:

> 1) the acts that resulted in Petitioner's conviction or similar acts were committed over a period of one year or more; [and]
>
> 2) the acts that resulted in the conviction or similar acts had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals or the Medicare or State health care programs.

87. Petitioner improperly issued prescriptions for controlled substances to undercover operators on eleven different occasions occurring over a 26 month period from February 16, 1988 through April 19, 1990, a period of more than one year. Findings 5 - 9.

88. The aggravating factor specified at 42 C.F.R. § 1001.401(c)(2)(i) is present in this case. Finding 87.

89. Petitioner treated hundreds of patients during the 26 month period from February 16, 1988 through April 19, 1990. Tr. 290.

90. The record is devoid of evidence establishing that Petitioner unlawfully prescribed controlled substances to his hundreds of patients who were not undercover agents during the 26 month period from February 16, 1988 through April 19, 1990.

91. Prior to the commencement of the undercover operation, Petitioner prescribed codeine to three patients who had a history of narcotics violations. I.G. Ex. 1 at 1 - 2.

92. There is no evidence showing that the prescriptions for codeine to the three individuals who had a history of narcotics violations were medically inappropriate.

93. The evidence is insufficient to establish that Petitioner engaged in improper prescribing practices prior to February 16, 1988. Finding 92.

94. There is no evidence that Petitioner engaged in improper prescribing practices after April 19, 1990.

95. Codeine and vicodin are physically and psychologically addictive. Tr. 57 - 63.

96. Providing codeine and vicodin to patients for no legitimate medical purpose endangers the health and safety of those patients. Tr. 50, 54 - 63.

97. The aggravating factor specified at 42 C.F.R. § 1001.401(c)(2)(ii) is present in this case. Findings 95 - 96.

98. Petitioner prescribed controlled substances to the undercover operators in an effort to induce them to enter into psychotherapy. Tr. 267 - 268, 287 - 289, 295, 297; I.G. Ex. 1; P. Ex. 1.

99. The practice of prescribing controlled substances to persons who may be substance abusers for the purpose of inducing them into medical treatment is not in accordance with recognized standards of care. Tr. 374 - 375.

100. During the period of time that Petitioner prescribed controlled substances to the undercover operators, he had become disconnected and isolated from the mainstream of psychiatrists located in his local community. Tr. 299 - 300; P. Ex. 1.

101. Petitioner's inappropriate prescribing practices were motivated by humanitarian concerns. Finding 98.

102. There is no evidence that Petitioner engaged in the unlawful prescribing practices for pecuniary gain or to engage in substance abuse.

103. Petitioner took steps to limit the exposure of the undercover operators to the dangers of controlled substances. Tr. 276 - 277, 285, 287, 295; I.G. Ex. 1 at 6, 10, 25.

104. Since his conviction, Petitioner has taken continuing education courses related to chemical

dependency and drug use and he has passed the written portion of the American Board of Psychiatry exam. Tr. 259 - 260.

105. Since his conviction, Petitioner has become more integrated into the medical community. Tr. 253, 300.

106. Petitioner now realizes that it is inappropriate to induce patients to enter into psychotherapy by prescribing controlled substances and he is cautious in his prescribing practices. P. Ex. 3, P. Ex. 4; Tr. 266, 298; Findings 104 - 105.

107. There is little likelihood that Petitioner will again engage in inappropriate prescribing practices in the future.

108. In weighing Petitioner's threat to program beneficiaries and recipients arising from the two aggravating factors specified at 42 C.F.R. § 1001.401(c)(2)(i) - (ii) and the impact of the mitigating factor at 42 C.F.R. § 1001.401(c)(3)(ii), the weight of the evidence demonstrates that the three year benchmark exclusion set forth in 42 C.F.R. § 1001.401(c)(1) imposed and directed against Petitioner is excessive.

109. The remedial considerations of the Act will be served in this case by modifying the exclusion to end upon the effective date of this decision.

RATIONALE

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 it is reasonable to exclude Petitioner for a period of three years, the benchmark period of exclusion mandated by the regulations.

I. This case is governed by regulations published on January 29, 1992 and January 22, 1993.

During an April 26, 1993 prehearing conference, I expressed the view that the factors which I may consider in determining the appropriate length of the exclusion are limited to the factors set forth in the Secretary's implementing regulations that were initially published on January 29, 1992 and subsequently clarified on January 22, 1993. May 13, 1993 Order and Notice of Hearing at 2

- 3. The parties have not argued that this interpretation is in error.

The I.G. contends that a three year exclusion is reasonable pursuant to the criteria for determining the length of exclusions contained in regulations adopted by the Secretary on January 29, 1992 and clarified on January 22, 1993. Petitioner contends the three year exclusion which the I.G. imposed is excessive under the regulations relied on by the I.G.. In resolving this issue, I find it instructive to discuss the history of the applicable regulations and the standards for adjudication which they contain.

The standard of adjudication concerning the reasonableness of an exclusion in effect prior to the adoption of the January 29, 1992 regulations allowed parties to address fully the excluded party's trustworthiness to provide care. Appellate panels of the DAB and administrative law judges delegated to hear cases under section 1128 of the Act have held consistently that section 1128 is a remedial statute. Exclusions imposed pursuant to section 1128 have been found to be reasonable only insofar as they are consistent with the Act's remedial purpose, which is to protect federally-financed health care programs and their 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).

In Matesic, an appellate panel of the DAB discussed the kinds of evidence which should be considered by administrative law judges in hearings as to the reasonableness of the length of exclusions. The appellate panel concluded that any evidence which related to an excluded party's trustworthiness to provide care was relevant to the issue of reasonableness. Matesic, DAB 1327, at 12.

On January 29, 1992, the Secretary published regulations which, at 42 C.F.R. Part 1001, create substantive changes in the law with respect to the imposition of exclusions. For example, the January 29, 1992 regulations establish 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). In addition, the regulations specifically preclude consideration of factors for either lengthening or shortening an exclusion imposed pursuant to section 1128(b)(3) which are not identified by the regulation as either "mitigating" or "aggravating". 42 C.F.R. § 1001.401(c)(2), (c)(3). It is undisputed that the January 29, 1992 regulations alter the substantive

rights of Petitioner because they limit the mitigating factors that can be considered in Petitioner's favor and would bar Petitioner from presenting evidence which is relevant to trustworthiness to provide care.[4]

Subsequent to the publication of the January 29, 1992 regulations, administrative law judges issued a series of decisions, all of which held that the Secretary did not intend these regulations to govern administrative law judge decisions as to the reasonableness of exclusion determinations. Bertha K. Krickenbarger, R.Ph., DAB CR250 (1993); Charles J. Barranco, M.D., DAB CR187 (1992); Narinder Saini, M.D., DAB CR217 (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.[5]

The reasons for finding that the Secretary did not intend the Part 1001 regulations to establish criteria for administrative hearings as to the length of exclusions are stated in detail in the decisions cited above. It is unnecessary to restate those reasons here, except to note that, among other things, the decisions concluded that the Part 1001 regulations, if applied as standards for adjudication at the administrative hearing level, would serve to bar parties from presenting evidence which addresses fully the excluded party's trustworthiness to provide care.

During the first prehearing conference held in this case on January 12, 1993, I ruled that the factors which I may

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[4] Moreover, 42 C.F.R. § 1001.401 limits my consideration of aggravating factors to those specifically mentioned therein, and so could, under the appropriate scenario, impair the I.G.'s ability to demonstrate that a petitioner is deserving of a lengthy exclusion.

[5] In addition, an appellate panel of the DAB held that the January 29, 1992 regulations do not retroactively apply in cases involving exclusion determinations made prior to the regulations' publication date. Behrooz Bassim, M.D., DAB 1333 (1992). The present case does not involve an issue of retroactive application of regulations because the exclusion determination is dated October 15, 1992, which is subsequent to the publication of the January 29, 1992 regulations.

consider in a de novo hearing with regard to the issue of the reasonableness of the length of the exclusion are not limited to the factors set forth in the regulations. January 15, 1993 Order and Notice of Hearing at 2. This ruling was based on the body of decisions of administrative law judges which interpreted the regulations. As of the time that I held the January 12, 1993 prehearing conference, these decisions holding that the regulations did not apply as criteria for review of exclusions at the administrative hearing level constituted the Secretary's final interpretation of the regulations.

On January 22, 1993, ten days after I held the first prehearing conference in this case, the Secretary published regulations containing provisions which are described as a clarification of the scope and purpose of the exclusion regulations published January 29, 1992. These regulations state unequivocally that the exclusion determination criteria contained in 42 C.F.R. Part 1001 must be applied by administrative law judges in evaluating the length of exclusions imposed by the I.G.. 58 Fed. Reg. 5617, 5618 (1993).

The clarification was made applicable to cases which were pending on January 22, 1993, the clarification's publication date. It is undisputed that the present case was pending on January 22, 1993.

I must now apply to this case the criteria for determining the length of exclusions set forth in 42 C.F.R. § 1001.401. The controlling regulations at 42 C.F.R. § 1001.401 mandate that, in cases of exclusions imposed pursuant to section 1128(b)(3) of the Act, the exclusion imposed will be for three years unless specified aggravating or mitigating factors form a basis for lengthening or shortening the exclusion. The standard for adjudication contained in 42 C.F.R. 1001.401 provides that, in appropriate cases, exclusions imposed pursuant to section 1128(b)(3) may be for more than three years where there exist aggravating factors (identified by 42 C.F.R. § 1001.401(c)(2)) that support a lengthening of the exclusion despite the existence of any mitigating factors (identified by 42 C.F.R. § 1001.401(c)(3)). Similarly, an exclusion imposed pursuant to section 1128(b)(3) may be for a period for less than three years where there exist mitigating factors which warrant a reduction in the length of the exclusion even with consideration of any of the aggravating factors.

The regulation specifically states those factors which may be classified as aggravating and those factors which

may be classified as mitigating. Under the regulatory scheme, evidence which relates to factors which are not among those specified as aggravating and mitigating is not relevant to adjudicating the length of an exclusion and cannot be considered.

In this case, the I.G. imposed the three year benchmark exclusion. The I.G. does not contend that there are aggravating factors present in this case which are sufficiently serious to justify lengthening the exclusion beyond the three year benchmark period. Thus, the only disputed issue before me is whether the length of Petitioner's exclusion should be shortened below the three year benchmark period pursuant to the criteria established by the applicable regulations.

The regulations specifically preclude consideration of any factors to shorten the benchmark period if they are not listed as mitigating at 42 C.F.R. § 1001.401(c)(3). The possible mitigating factors which can be considered as a basis for shortening the three year benchmark exclusion are very limited. The applicable regulation provides that only the following factors may be considered as mitigating:

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

42 C.F.R. § 1001.401(c)(3)(i) - (ii).

Citing the mitigating circumstance identified at 42 C.F.R. § 1001.401(c)(3)(ii), Petitioner asserts that the exclusion is unreasonable because alternative sources of the type of health care items or services he furnishes are not available. The I.G. contends that the evidence fails to establish that this mitigating factor is present. The I.G. contends also that even if I were to find that this factor is present, the evidence of record shows that there are aggravating factors which offset any mitigation arising from the presence of this factor and therefore, the three year benchmark exclusion should be upheld.

In analyzing the evidence in this case, my task is to first determine whether the mitigating factor cited by Petitioner is present. If I determine that this factor is not present, then my inquiry ends. Under these circumstances, there would not be any basis to shorten the three year exclusion pursuant to the criteria established by the regulations. If I determine that this factor is present, my task is to evaluate the reasonableness of the three year exclusion by determining the relative weight of this mitigating factor in the context of the aggravating factors which the I.G. asserts are present. Accordingly, I will now consider the threshold question of whether the mitigating factor cited by Petitioner, that alternative sources of the type of health care items or services he furnishes are not available, is present in this case.

II. The evidence establishes that the mitigating factor identified at 42 C.F.R. § 1001.401(c)(3)(ii) is present.

A. Petitioner has the burden of proving mitigating circumstances, including the burden of proving that alternative sources of health care items or service of the type he provides are not available.

The regulations at 42 C.F.R. § 1001.401 do not allocate specifically the parties' respective burdens of proof in establishing the existence of aggravating and mitigating factors. Instead, section 1005.15(c) of the regulations expressly reserves the duty of allocating the burden of proof in certain exclusion cases, such as those governed by 42 C.F.R. § 1001.401, to administrative law judges. I conclude that it is logical and consistent with the language and structure of the regulations to place the burden of proving mitigating circumstances on Petitioner, including the burden of proving alternative sources of the type of health care he furnishes are not available.

It is plain from the language and structure of 42 C.F.R. § 1001.401(c) that the Secretary intended the mitigating circumstances identified in those regulations to be in the nature of affirmative defenses to the imposition of a three year exclusion that would otherwise be mandated by the regulations. 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 the I.G. 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 exclusions imposed under section 1128 of the Act prior to the promulgation of the regulations. An appellate panel of the DAB held in such a case that there is a "general principle that a petitioner has the burden of proving factors which would tend to reduce the exclusion period." Bernardo G. Bilang, M.D., DAB 1295, at 10 (1992). In addition, placing the burden on Petitioner to establish the presence of mitigating circumstances is consistent with the burdens that have been established in other kinds of cases in which exclusion is the remedy. For example, in certain other kinds of cases brought under the Act, the non-federal party has the burden of proving the presence of mitigating circumstances which would justify reduction of a penalty, an assessment, or an exclusion. 42 C.F.R. § 1005.15(b).

B. For the mitigating factor at 42 C.F.R. § 1001.401(c)(3)(ii) to apply, Petitioner must prove that his exclusion will result in a reduction in health care services to the point that obtaining comparable sources of health care imposes an unreasonable hardship on Medicare and Medicaid beneficiaries and recipients.

The mitigating factor identified at 42 C.F.R. § 1001.401(c)(3)(ii), that alternative sources of the type of health care items or services furnished by the individual or entity are not available, is not defined by statute. In the absence of a regulatory definition of this factor, the words describing this mitigating factor should be given their common and ordinary meaning. The word "alternative" is defined in the Random House Dictionary of the English Language, 2d Edition (1987), as "affording a choice of two or more things, propositions, or courses of action." "Available" is defined as "suitable or ready for use or service; at hand." I conclude from these common definitions that, in order for the mitigating circumstance in 42 C.F.R. § 1001.401(c)(3)(ii) to apply, the evidence must show that alternative sources (sources that can be chosen instead) of the type of health care furnished by an excluded provider are not available (suitable or ready for use or service). James H. Holmes, M.D., DAB CR270, at 13 (1993).[6]

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[6] In Holmes, I set forth the legal standard which I am following in this case. Both Dr. Holmes and the Petitioner here were excluded for three years pursuant to

Looking at the phrase "alternative sources" in this context, it is evident that the Secretary contemplated that the alternative sources would take the place or be a substitute for the type of health care provided by the excluded provider. In Holmes, I concluded from this that in order to qualify as an "alternative source" within the meaning of the regulations, the alternative source must provide health care items or services that are comparable or equivalent in quality to the type of items or services provided by the excluded provider. The alternative source must be able to substitute for the items or services furnished by the excluded provider without jeopardizing the health of the recipients of those items or services. Holmes, DAB CR270, at 13.

The alternative source must also be "available." In Holmes, I found that alternative sources are not available within the meaning of the regulation if such sources are not reasonably available. This standard contemplates that an alternative source is not available in circumstances where Medicare and Medicaid patients are not able to reasonably obtain the type of medical services provided by the excluded provider in a practicable manner consistent with the Secretary's objective to protect program beneficiaries and recipients from being deprived of needed health care as a result of the provider's exclusion. For example, an alternative source of health care might be identified as being present to provide the type of health care provided by the excluded provider. However, that alternative source would not be "available" within the meaning of the regulations if it is located at such a great distance in miles from an excluded provider's former Medicare and Medicaid patients that obtaining the alternative health care would result in an unreasonable hardship to those patients.

On the other hand, as I observed in Holmes, merely showing that the consequence of an exclusion is a reduction in the availability of health care services is not tantamount to showing that those services are not available. Certainly, any provider could show that health care services to program beneficiaries and recipients are less available because the provider is excluded. However, in order for the mitigating factor at

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section 1128(b)(3) of the Act. Both Dr. Holmes and the Petitioner here were excluded after January 29, 1992 and both argued that the mitigating factor at 42 C.F.R. § 1001.401(c)(3)(ii) is a basis for reducing their three year exclusions.

42 C.F.R. § 1001.401(c)(3)(ii) to apply, there must be a showing that a consequence of an exclusion is a reduction in health care services to the point that obtaining alternative sources of health care is so impractical that it imposes an unreasonable hardship on Medicare and Medicaid beneficiaries and recipients. This is a far more stringent test to meet than showing merely a reduction in the availability of health care. Holmes, DAB CR270, at 14.

In addition, language in the preamble to the January 29, 1992 regulations indicates that reasonable availability of alternative sources of health care must be viewed in the context of the Medicare and Medicaid programs. The preamble to the regulations states that, in evaluating the availability of alternative sources of health care pursuant to 42 C.F.R. § 1001.401(c)(3)(ii), the Secretary contemplates that the factfinder "will look to whether there are service providers who accept Medicare and Medicaid patients, rather than merely whether services are available generally." 57 Fed. Reg. 3316. This language is consistent with the Secretary's interest in protecting program beneficiaries and recipients from being deprived of needed health care as a result of a provider's exclusion. Under this standard, alternative sources of health care of the type furnished by an excluded provider are not reasonably available within the meaning of the regulations if program beneficiaries and recipients cannot use that source, such as in the situation where the alternative health care provider does not participate in the Medicare or Medicaid programs.

C. Petitioner has met his burden of proving that, by virtue of his exclusion, alternative sources of the type of health care items or services that he furnishes are not available.

Based on my review of the evidence of record, I conclude that Petitioner has sustained his burden of proving that as a result of his exclusion, alternative sources of the type of health care he provides are not available, within the meaning of 42 C.F.R. § 1001.401(c)(3)(ii).

1. As a result of Petitioner being excluded, there are no psychiatrists in Santa Cruz County, except on rare occasions, available to provide outpatient psychiatric care to Medicaid patients who are not severely impaired.

Petitioner is a psychiatrist who provides outpatient psychiatric services. Tr. 235 - 237, 419. The psychiatric services furnished by Petitioner include

individual psychotherapy counseling and prescribing medications. Tr. 13 - 14. Petitioner treats a variety of psychiatric conditions, including panic disorders, anxiety disorders, depression, personality disorders, and schizophrenia. Tr. 237 - 238. Within the context of providing psychiatric care to patients, Petitioner also has treated common physical complaints such as colds, coughs, cramps, and diarrhea. Tr. 273, 292. Petitioner has been engaged in the private practice of psychiatry in downtown Santa Cruz, California, since 1974. Tr. 236, 272 - 273. Petitioner has included among his patients individuals with very limited financial resources and has accepted patients who are Medicaid recipients. Tr. 237, 250, 264; P. Ex. 5 - 6. Petitioner is only one of two psychiatrists practicing in Santa Cruz County who is able to speak Spanish. Tr. 237.[7]

The parties agree that the type of health care services provided by Petitioner are psychiatric services. Tr. 8 - 9. The parties agree also that the geographical area within which I should consider whether alternative health care services are available is Santa Cruz County, California, the location of Petitioner's practice. Tr. 10. In addition, it is not disputed that the regulations contemplate that the availability of alternative sources of health care must be viewed in the context of availability to Medicare and Medicaid beneficiaries and recipients.

Throughout this proceeding, Petitioner has consistently asserted that, as a result of his exclusion, alternative sources of the type of psychiatric services furnished by him are no longer available in Santa Cruz County, California. The I.G. has attempted to rebut this assertion by submitting computer printouts, obtained from the California Department of Health Services (CDHS), which identifies physicians who are "Medicare/Medi-Cal

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[7] A substantial portion of the population of Santa Cruz County consists of Hispanic farm laborers. Tr. 237. Although Petitioner indicated there were only two Spanish speaking psychiatrists in Santa Cruz County, the record does not permit me to make a finding on the issue of whether speaking Spanish to Hispanic patients is an essential element of the treatment which cannot be provided by a monolingual English speaking psychiatrist. Such evidence could be relevant to the determination whether alternative sources of medical care equivalent to that provided by Petitioner currently exist in Santa Cruz County.

Providers" in Santa Cruz County. I.G. Ex. 12.[8] In addition to other information contained in the printouts, such as their addresses and phone numbers, the providers are identified on the printout by physician specialty codes which are listed in another I.G. exhibit. I.G. Ex. 13. The I.G. asserts that this evidence shows that there are "at least 15 Medicare/Medi-Cal providers currently listed with [CDHS] who have identified themselves as practicing psychiatry in Santa Cruz County." I.G. posthearing brief at 37. The I.G. contends that this is conclusive affirmative evidence showing that there are many alternative sources of psychiatric health care available to Medicare and Medicaid patients in Santa Cruz County. According to the I.G., this evidence is sufficient to rebut Petitioner's assertion that alternative psychiatric health care is not available to program beneficiaries and recipients in Santa Cruz County. I.G. posthearing brief at 32.

Petitioner contends that the Medicare and Medicaid enrollment statistics produced by the I.G. have limited significance because enrollment statistics show only that a provider is eligible to treat Medicare or Medicaid patients. Such statistics do not show whether a provider is actively treating Medicare or Medicaid patients or whether he is willing to accept new Medicare or Medicaid patients. Petitioner posthearing reply brief at 1.

I agree with Petitioner that Medicare and Medicaid provider enrollment statistics alone do not conclusively establish that the enrolled providers are "available" to Medicare and Medicaid patients, within the meaning of the regulations. It is undisputed that a provider must be enrolled in the Medicare or Medicaid programs as a necessary prerequisite to making the enrolled provider's health care services available to Medicare beneficiaries or Medicaid recipients. While enrollment in the Medicare or Medicaid programs is a necessary precondition to

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[8] The computer printout referred to "Medicare/Medi-Cal Providers." I read this to mean that the computer printout listed providers who are enrolled in the Medicare program or the California State Medicaid program or both programs. In addition, the computer program contained provider enrollment information in the counties of Monterey, Santa Clara, and Santa Cruz. Since the parties agreed that Santa Cruz County is the relevant geographical area for determining the availability of alternative health care for the purposes of this case, I did not consider provider enrollment information in the counties of Monterey and Santa Clara.

making health care services available to beneficiaries or recipients, it is not sufficient to show that such services will, in fact, be available to beneficiaries and recipients or in what setting such services will be provided.

In order for health care services to be available to Medicare beneficiaries or Medicaid recipients, a health care provider must not only be enrolled as a participant in the Medicare or Medicaid programs, but the provider also must be actively accepting Medicare beneficiaries or Medicaid recipients as patients. Alternative sources of health care are not available if Medicare beneficiaries or Medicaid recipients cannot avail themselves of the alternative sources of health care. It does little good for persons to go to a health care provider who is enrolled in the Medicare or Medicaid programs if the provider refuses to accept new Medicare or Medicaid patients.

At most, the enrollment statistics provided by the I.G. establish that there are 15 psychiatrists in Santa Cruz County who are eligible to treat patients under the Medicare program or under the Medicaid program or under both programs. The statistics do not establish that such physicians were willing to actually treat these patients. If Petitioner is able to show that a provider identified by the I.G. as being enrolled in the Medicare or Medicaid programs is not willing to accept new Medicare or Medicaid patients, then, as a practical matter, the services of that provider are not available to Medicare or Medicaid patients. Moreover, the enrollment statistics do not distinguish between those physicians who provide medical care to Medicare beneficiaries only and those who serve Medicaid recipients.[9]

Petitioner argues that the enrollment statistics produced by the I.G. have limited significance for the additional reason that the enrollment statistics list the eligible Medicare or Medicaid providers of psychiatric services in Santa Cruz County without describing the type of

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[9] Evidence was adduced at the hearing as to whether the physicians practicing in Santa Cruz County named in the printout were willing to accept new Medicare or Medicaid patients. As will be discussed later in this decision, only on rare occasions do psychiatrists in Santa Cruz County provide outpatient care to Medicaid recipients. This reluctance is based on the reimbursement rates and paperwork requirements imposed by Medicaid. Tr. 329, 417 -418.

psychiatric services furnished by these providers. Of particular importance is whether the psychiatric service is provided in an outpatient or inpatient setting. Petitioner contends that the treatment rendered by some of the psychiatrists on the list provided by the I.G. is not comparable to the type of psychiatric services he provides to his patients, which are primarily outpatient services. Petitioner posthearing reply brief at 1 - 2. Petitioner points out also that mental health services provided by Santa Cruz County are available to treat only the most severe mental conditions, and that treatment provided by the County is not an available alternative for the more common, less severe mental conditions which he treats. Petitioner posthearing brief at 1.

The regulations contemplate that alternative sources would take the place of or be a substitute for the type of health care provided by the excluded provider. If Petitioner is able to show that a psychiatrist identified by the I.G. as being enrolled in the Medicare or Medicaid programs does not furnish psychiatric services which are comparable to the psychiatric services furnished by Petitioner, then the services of that psychiatrist are not an alternative source of health care.

Framing this inquiry in the manner urged by Petitioner, I received evidence at the hearing pertaining to the issues of whether the psychiatrists in Santa Cruz County who are enrolled in the Medicare or Medicaid programs are willing to accept Medicare or Medicaid patients and whether those psychiatrists furnish psychiatric services which are comparable to the outpatient psychiatric services furnished by Petitioner. John R. Gillette, M.D., a psychiatrist who is board-certified by the American Board of Psychiatry and Neurology, provided extensive testimony regarding these issues at the hearing. Tr. 320.

Dr. Gillette has been the Director of Psychiatric Services for the County Mental Health Program for 14 to 15 years. He is also chairman of the Mental Health Committee of the Santa Cruz County Medical Society. In addition, he is engaged in the private practice of psychiatry approximately 10 to 12 hours a week. Tr. 320, 330, 335, 348. Dr. Gillette testified that, during the past 15 years, and in the past five years in particular, the County Mental Health Program has been decreasing its services. Such services are limited to treating only those individuals who suffer from serious mental illness. The serious mental illnesses treated by the County include schizophrenia, manic depressive illness, severe depression, recurrent suicide attempts, and other conditions which causes an individual to be dangerous,

non-functional, or at risk for psychiatric hospitalization. Tr. 322, 338 - 339, 345 - 346.

Even for individuals who meet the strict criteria for obtaining treatment from the County Mental Health Program, there are limited opportunities for obtaining outpatient psychotherapy services. Dr. Gillette testified that the County Mental Health Program has almost eliminated individual psychotherapy services. The only individual psychotherapy services furnished by the County Mental Health Program include a limited number of psychotherapy sessions for a select few patients who are in crisis. Tr. 324 - 325, 328.

Dr. Gillette testified that the types of psychiatric conditions which meet the strict criteria for treatment by the County Mental Health Program are a small percentage of all psychiatric conditions. Tr. 360 - 361. The more common, less severe psychiatric conditions, such as panic disorders, anxiety disorders, most depressions, personality disorders, and organic brain disorders, are not treated by the County Mental Health Program. Tr. 327, 338 - 340. Dr. Gillette testified that patients with less severe psychiatric conditions such as these must seek treatment in the private sector. Tr. 340 - 341.

Unfortunately, according to Dr. Gillette, at the same time that the County Mental Health Program has been decreasing its services in recent years, fewer and fewer psychiatrists in private practice have been willing to accept new Medicaid patients. Dr. Gillette testified that, at present, he does not know of any psychiatrist engaged in private practice in Santa Cruz County who has openly expressed a willingness to routinely accept new Medicaid patients. Dr. Gillette noted that while some psychiatrists might have a few Medicaid patients whom they have been seeing for a long period of time, none of these psychiatrists has expressed a willingness to accept new Medicaid patients. Tr. 323, 325, 328. Dr. Gillette stated that, as a result of this situation, there are a large number of individuals who do not have access to psychiatric services in Santa Cruz County. Tr. 325.

Dr. Gillette testified that there are several reasons that private psychiatrists refuse to accept new Medicaid patients. According to Dr. Gillette, the reimbursement rates for Medicaid patients are low, the Medicaid forms are difficult and time-consuming to complete, and Medicaid patients tend to be unreliable in keeping their appointments. If a provider does not bill patients for missed appointments, he will have up to one hour during

which he is not generating any income. Tr. 329 - 330. Dr. Gillette stated that the Mental Health Committee of the Santa Cruz Medical Society, which he chairs, has not been able to do anything to solve the problem of the lack of availability of psychiatric care for Medicaid patients who do not meet the criteria for receiving care through the County Mental Health Program. Tr. 348. He expressed the view that "nothing will change unless the reimbursement rates go [up] or several new psychiatrists . . . come into town and they're hungry." Tr. 350.

Dr. Gillette testified that, prior to his exclusion, Petitioner was the only psychiatrist engaged in private practice to whom the County Mental Health Program could refer Medicaid patients. The only other private psychiatrist who accepted Medicaid patients was an individual who "got into [Medicaid] fraud issues 12 years ago," and stopped treating Medicaid patients. Tr. 332. Dr. Gillette stated also that Petitioner primarily provided psychotherapy services, and that he generally saw patients for hour long appointments, rather than half-hour appointments. Tr. 331 - 332. Dr. Gillette described Petitioner as a psychiatrist who "was able and willing to see people, and to work with many that others didn't want to." Tr. 333.

During his testimony, Dr. Gillette discussed specifically the availability of alternative psychiatric care from each of the 15 psychiatrists identified by the I.G. as "Medicare/Medi-Cal Providers" in Santa Cruz County. He indicated that while he had not necessarily communicated with each and every one of these providers as recently as the last year, he is familiar with their medical practices and believes that he is able to provide accurate information about them. Tr. 375 -376. Dr. Gillette testified that only one of the 15 psychiatrists identified as Medicare/Medi-Cal providers, Dr. Corby, would, on occasion, accept new Medicaid patients on an outpatient basis.[10] However, Dr. Gillette testified that Dr. Corby refuses to have more than five percent of his practice consist of Medicaid patients. Findings 43 - 60.

Dr. Gillette's testimony regarding the availability of alternative psychiatric care to Medicare and Medicaid patients is corroborated the testimony of Dr. Berman, a Board-certified psychiatrist who has engaged in the

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[10] Dr. Gillette indicated that he believed Dr. Berman also might accept Medicaid patients on rare occasions. However, Dr. Berman himself testified that he does not accept new Medicaid patients.

private practice of psychiatry in Santa Cruz since 1972. Tr. 416, 423. Dr. Berman stated that he has mostly an office-based outpatient practice. He provides outpatient psychotherapy with the use of medication. In addition, he is on the staff of Dominican Hospital and is called upon to be a consulting psychiatrist for inpatients at that hospital. Dr. Berman stated that, although he is on the list of Medicare or Medicaid providers produced by the I.G., he does not accept new Medicaid patients. He indicated that he has a few Medicaid patients in his practice with whom he has had a relationship for 15 years. However, he feels that accepting new Medicaid patients is a "great burden" because the Medicaid payment bureaucracy is so slow and cumbersome. Tr. 417 - 418, 430.

Dr. Berman stated that, prior to Petitioner's exclusion, Petitioner had a reputation for accepting Medicaid patients in his private, outpatient psychiatric practice. Tr. 419. Dr. Berman testified that he does not now know of any psychiatrist in Santa Cruz County who is willing to accept Medicaid patients for treatment. He indicated that, although individuals who are severely psychiatrically impaired can be referred to the County supported crisis team, he does not know of any psychiatrist to whom he can refer Medicaid patients with less serious conditions. Tr. 417 - 418, 425 - 426, 433. Dr. Berman indicated that he based his testimony regarding the unavailability of psychiatric services on the knowledge he gained from working in the community over the years and on the fact that his efforts to refer Medicaid patients to other psychiatrists have been unsuccessful.

The testimony of Dr. Halpern, a family practitioner who has practiced in Santa Cruz County for 14 years, further corroborates Dr. Gillette's and Dr. Berman's testimony. Tr. 392 - 393. Dr. Halpern stated that he and his partner are the only family doctors in Santa Cruz who accept Medicaid and Medicare patients on a regular basis. Tr. 393. Dr. Halpern indicated that, in the course of his practice, he has attempted to refer his patients to private psychiatrists for treatment. While psychiatric care is available from the County Mental Health Program in a limited manner to patients in crisis, there are no private psychiatrists to whom Dr. Halpern can refer patients in need of ongoing outpatient psychiatric care. Tr.394 - 395, 404 - 405. He stated also that, prior to Petitioner's exclusion, Petitioner was the only psychiatrist in Santa Cruz County who would see Medicaid patients on a regular basis. Tr. 394. Dr. Halpern testified regarding the availability of the psychiatrists

on the list of enrolled providers supplied by the I.G., and this testimony was consistent with that provided by Dr. Gillette and Dr. Berman. Tr. 409 - 413.

The testimony of Dr. Gillette, Dr. Berman, and Dr. Halpern regarding the availability of psychiatrists in Santa Cruz County was borne out by the testimony provided three former Medicaid patients. All three patients testified that, after Petitioner was excluded, they made serious efforts to find another psychiatrist who would provide them with outpatient psychiatric care. All three of these individuals testified that they personally called some psychiatrists in an effort to make an appointment. In addition, they tried to obtain referrals from either other physicians or the County Mental Health Program. In spite of their best efforts to find a psychiatrist to replace Petitioner, these individuals were unable to do so. Tr. 436 - 437, 440, 445 - 446, 449, 456.

The I.G. attempted to rebut Petitioner's evidence with the testimony of John Ponta, an investigator with the California Attorney General's Office. Tr. 155 - 156. Investigator Ponta testified that he called some of the offices of the 15 psychiatrists (identified by the I.G. as being enrolled as "Medicare/Medi-Cal Providers" in Santa Cruz County) to determine if they accepted new Medicare or Medicaid patients. Investigator Ponta indicated that, in the course of making these telephone calls, he identified himself as a Medicaid recipient or he used an alias. Tr. 469, 476. As a result of his telephone survey, Investigator Ponta stated that he was told that Dr. O'Connor, who is listed as a psychiatrist with an address of 1171 7th Street in Santa Cruz, took new Medicare and Medicaid patients. Tr. 470. Investigator Ponta testified also that he was told that Dr. Nash and Dr. Chagi accepted new Medicare patients, but not new Medicaid patients. Tr. 471, 476.

In addition, Investigator Ponta testified that he determined again through telephoning, that the County of Santa Cruz Health Center at 1060 Emeline Avenue[11] took new Medicare and Medicaid patients. According to Investigator Ponta, the clinic informed him that they had four psychiatrists on staff. The clinic did not mention that there were any restrictions on new Medicare or

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[11] The County of Santa Cruz Health Center at 1060 Emeline Avenue is known also as Santa Cruz County Community Mental Health Services and it is part of the County Mental Health Program. Tr. 319, 471 -472.

Medicaid patients seeing psychiatrists on the staff of the clinic, such as having to have life threatening or severe mental disorders. Tr. 471 - 474.

The I.G. contends that the evidence relating to the availability of psychiatric health care services in Santa Cruz County establishes that "psychiatric care is indeed available in the Santa Cruz County area from a substantial number of individual psychiatrists and institutional providers." I.G. posthearing brief at 42.

I agree with the I.G. that psychiatric care is available to Medicare and Medicaid patients in Santa Cruz County in a variety of institutional settings. However, I find that the psychiatric care provided in these institutional settings is not available to the outpatient population served by Petitioner who do not suffer from severe psychiatric conditions.

The County Mental Health Program provides psychiatric care to patients with serious or life-threatening psychiatric disorders in various settings, including clinics and a halfway house with a sub-acute residential day treatment program. Tr. 319, 324, 336, 471 - 472. The County rarely provides individual psychotherapy services on an outpatient basis. On the other hand, Petitioner primarily provides psychotherapy services, and he often sees patients for up to an hour for psychotherapy sessions. Thus, a type of health care service which is routinely provided by Petitioner, outpatient psychotherapy, is not reasonably available through the County.

As pointed out by the I.G., psychiatric care is available to Medicare and Medicaid patients in hospital facilities in Santa Cruz County. The record shows that Dominican Hospital has a Psychiatric Department staffed by inpatient staff psychiatrists who treat inpatients. In addition, psychiatrists provide consultation on a rotation basis to other patients in the hospital. Watsonville Community Hospital accepts Medicaid patients, and it has three psychiatrists on its staff. Tr. 353 - 356. In addition to these two hospitals, psychiatrists treat Medicaid patients at a psychiatric skilled nursing facility known as Harbor Hills. Tr. 368. Petitioner's practice of psychiatry is not hospital-based. It is office-based. He provides outpatient psychiatric services to patients who are not admitted to a hospital or other psychiatric facility. Since the psychiatric care provided at the hospitals and the psychiatric skilled nursing facility is inpatient care, this type of

psychiatric care is not an available alternative for the outpatient population served by Petitioner.

The I.G. contends that there are "at least five individual psychiatrists" who are willing to "accept new Medicare and/or Medi-Cal patients" in a non-institutional setting. I.G. posthearing brief at 42. The five psychiatrists cited by the I.G. are Dr. Gillette, Dr. Nash, Dr. Chagi, Dr. Corby, and Dr. O'Connor.

The I.G. points to evidence to show that three of these psychiatrists are willing to accept new Medicare patients. Dr. Gillette testified that he would accept new Medicare patients in his private, outpatient practice. Investigator Ponta testified that his telephone survey revealed that Dr. Nash and Dr. Chagi accept new Medicare patients. At best, this evidence supports the conclusion that these three psychiatrists are available to treat Medicare patients. However, even if I were to find that these psychiatrists are available to provide outpatient psychiatric treatment to Medicare patients, none of them are available to provide such care to Medicaid patients. While Dr. Gillette acknowledged that he accepted one of Petitioner's former patients as a new Medicaid patient, he stated unequivocally that he is not willing to treat any additional Medicaid patients. Similarly, Investigator Ponta testified unequivocally that his telephone survey revealed that Dr. Nash and Dr. Corby are not willing to treat Medicaid patients.

The I.G. notes also Dr. Gillette's testimony that Dr. Corby will on occasion accept a Medicaid patient. I note that Dr. Gillette stated also that Dr. Corby refuses to have more than five percent of his practice be Medicaid patients. It appears from this evidence that while Dr. Corby might be available to treat Medicaid patients on occasion, he would be available to absorb only a small percentage of Petitioner's former Medicaid practice.

In addition, the I.G. points to Investigator Ponta's testimony that he determined through a telephone survey that Dr. O'Connor takes new Medicare and Medicaid patients. I assign little probative value to Investigator Ponta's testimony regarding Dr. O'Connor's availability to treat Medicare and Medicaid patients because the source of this information cannot be discerned from the record. Investigator Ponta testified that he did not speak to Dr. O'Connor personally, but that he spoke with someone whom he did not identify in Dr. O'Connor's office. Tr. 475 - 476. It is not even clear from the record what telephone number Investigator Ponta called to get this information. Investigator Ponta

stated that, in the course of conducting his telephone survey, he initially used the telephone numbers found on the enrollment statistics supplied by the I.G.. However, in some instances, the numbers listed were incorrect and he ended up calling a different number. Investigator Ponta stated that he is not sure whether he obtained this information from an individual at Dr. O'Connor's listed number or another number. Tr. 469, 474 - 475.

The record shows that the address and telephone number listed for Dr. O'Connor on I.G. Ex. 12 are the address and telephone number for Harbor Hills, the locked psychiatric nursing facility. Tr. 368, 480 - 481, 487 - 488. Thus, it is possible that Investigator Ponta received this information from an individual employed by Harbor Hills. While an employee at Harbor Hills might provide reliable information about Dr. O'Connor's professional activities at Harbor Hills, information provided from an employee at Harbor Hills regarding Dr. O'Connor's professional activities outside of his work at Harbor Hills would be significantly less reliable.

In fact, the other evidence of record suggests that Dr. O'Connor does not even have a private, outpatient practice. Dr. Gillette testified that, to the best of his knowledge, Dr. O'Connor used to be employed by Harbor Hills, but that he is now employed by the State prison system. This testimony was corroborated by Petitioner. Petitioner indicated that an individual at Harbor Hills told him that Dr. O'Connor no longer works there. Petitioner stated also that he had the opportunity to speak with Dr. O'Connor in the course of his work, and that Dr. O'Connor works for the Probation Department of the penal system. Tr. 488.

It is significant that none of the psychiatrists who appeared as witnesses in this proceeding had any information to suggest that Dr. O'Connor is accepting Medicare or Medicaid patients in a private, outpatient practice. Dr. Gillette affirmatively stated that Dr. O'Connor did not treat Medicaid or Medicare patients in the context of a private, outpatient practice. While Petitioner was aware of Dr. O'Connor's employment by the penal system, he knew nothing to suggest that Dr. O'Connor was engaged in private practice in Santa Cruz County. Dr. Berman and Dr. Halpern both testified that they did not even know Dr. O'Connor. Dr. Gillette, Dr. Berman, Dr. Halpern, and Petitioner have each practiced medicine in Santa Cruz County for at least 14 years, and all four physicians have firsthand knowledge of the mental health delivery system in Santa Cruz County. I

find the testimony of these individuals to be credible and reliable.

On the other hand, the information regarding Dr. O'Connor's availability to Medicare or Medicaid patients from Investigator Ponta's telephone survey is unreliable because the source of this information is unknown. Thus, I find that the evidence showing that Dr. O'Connor does not treat Medicare or Medicaid patients in a private, outpatient setting far outweighs the evidence showing that he is available to provide this type of health care.

The evidence shows that psychiatrists are available in Santa Cruz County to provide psychiatric health care services to severely psychiatrically impaired Medicare or Medicaid patients in the context of the County Mental Health Program. In addition, psychiatrists are available in Santa Cruz County to provide inpatient psychiatric services to Medicare or Medicaid patients who are admitted to hospitals and a locked psychiatric nursing facility. A few psychiatrists are available in Santa Cruz County to provide outpatient psychiatric care to Medicare patients who are not severely psychiatrically impaired. However, since Petitioner was excluded, there are no psychiatrists in Santa Cruz County, except on rare occasions, available to provide outpatient psychiatric care to Medicaid patients who are not severely impaired.

2. Health care providers other than psychiatrists in Santa Cruz County do not have the expertise and qualifications to provide psychiatric care which is equivalent to the level of care provided by Petitioner.

The I.G. contends that the record shows that there are providers other than psychiatrists in Santa Cruz County who provide mental health services to Medicare and Medicaid patients which are comparable to the services provided by Petitioner. Petitioner contends that the level of mental health care furnished by providers who are not psychiatrists is not comparable to the level of care furnished by psychiatrists.

The I.G. points out that Dr. Gillette testified that the County Mental Health Program refers patients who do not meet its criteria for care to other Medicare and Medicaid providers, including psychologists, primary care physicians, clinical social workers, and family counselors. The I.G. contends that the mental health care furnished by these providers is comparable to the care furnished by Petitioner. I.G. posthearing brief at 39 - 41. I.G. posthearing reply brief at 5. I disagree.

While Dr. Gillette testified that the County Mental Health Program refers patients who are not severely psychiatrically impaired to other providers, he made it abundantly clear that this course was taken only because there are not a sufficient number of private psychiatrists available to treat Medicaid and Medicare patients.

Dr. Gillette testified that the County Mental Health Program has a list of four to five psychologists who accept Medicaid patients, and from that list the County Mental Health Program makes referrals to Medicaid patients whom it turns away. Tr. 342. The record shows that the level of care offered by psychologists is not equivalent to the level of care offered by psychiatrists. Dr. Berman, Dr. Halpern and Dr. Gillette testified regarding these differences. Dr. Berman stated that psychologists are qualified to administer psychological tests. They are not qualified to prescribe medications. In addition, psychologists do not have the background to distinguish between physical and psychiatric conditions. Tr. 427. Dr. Halpern noted also that psychologists cannot prescribe medicines. He testified that psychologists cannot handle patients who are truly psychiatrically disturbed. Tr. 399. Dr. Gillette testified that, in psychiatric conditions such as depression, most studies suggest that the best treatment is a combination of medications and psychotherapy. Tr. 342. He stated also that a psychologist cannot prescribe medication. Tr. 361.

The psychiatric services furnished by Petitioner include individual psychotherapeutic counseling and prescribing medications. Given that the use of psychotherapy and medications together is the most effective treatment for some psychiatric conditions, then a psychologist is handicapped in providing the best possible care for those psychiatric conditions because he is unable to prescribe medication. This handicap would jeopardize the health of a patient who is in need of medications for his psychiatric condition. In addition, a psychologist is not trained to diagnose certain medical conditions. The health of a patient in need of treatment for a medical condition would be jeopardized if the condition is undiagnosed or misdiagnosed because the patient is under the care of a psychologist who is not trained to make an appropriate medical diagnosis. In view of the substantial differences in the qualifications of psychiatrists and psychologists, I find that the health care treatment rendered by psychologists to psychiatrically disturbed patients is not equivalent to the treatment rendered by psychiatrists. I conclude that

health care for psychiatric conditions furnished by psychologists is not an alternative source of the type of health care furnished by Petitioner, within the meaning of the regulations.

I conclude also that health care for psychiatric conditions furnished by medical doctors who are not psychiatrists and who specialize in providing primary care is not an alternative source of the type of health care furnished by Petitioner. Dr. Gillette testified that, in addition to making referrals to psychologists for Medicaid patients that the County Mental Health Program turns away, the County Mental Health Program might also tell these patients about the primary medical group in Santa Cruz that does see new Medicaid patients, i.e., Drs. Halpern, Kazel, and Robsen. When asked whether this group of doctors provides psychiatric treatment, Dr. Gillette stated that this practice prescribes medication for disorders such as depression and anxiety. Tr. 340 - 341.

Dr. Gillette testified regarding the differences between a psychiatrist who prescribes psychiatric medication and a medical doctor who is not a psychiatrist who prescribes psychiatric medication. Dr. Gillette stated that while both kinds of practitioners are legally qualified to prescribe psychiatric medications, a psychiatrist is better equipped to prescribe these medications effectively. Dr. Gillette stated that primary care physicians are more likely than psychiatrists to misdiagnose psychiatric conditions and to use the wrong medications in the wrong amounts to treat psychiatric conditions. For example, he stated that studies show that depression is "heavily underrecognized" by primary care physicians and that, when it is recognized, it is rarely treated adequately. He stated that he knows of instances where patients have suffered from strokes or other toxic side effects from psychiatric medications which were incorrectly prescribed by a primary care physician. Tr. 361 - 362.

Dr. Halpern, one of the primary care physicians who treats Medicaid patients in Santa Cruz County, gave testimony which was consistent with Dr. Gillette's testimony. Dr. Halpern testified that, in the context of his primary care practice, he treats patients with depression, panic disorders, and personality disorders. Tr. 403. He stated that he has treated some of Petitioner's former patients and that he is willing to prescribe psychiatric medications if the patients come to him with an established psychiatric medication profile. Dr. Halpern indicated that he does not feel qualified to

begin a patient on psychiatric medications very often, but that he can continue a patient on psychiatric medications once that profile has been established by a psychiatrist. Tr. 395. There is no indication in the record that this group of doctors provides psychotherapy services. Tr. 341, 395.

Dr. Halpern stated that the only situation in which he is comfortable being the primary prescriber of psychiatric medications is when a patient has a mild illness, such as a mild depression. He indicated that, for more serious conditions, he is increasingly uncomfortable prescribing psychiatric medications and that he is very uncomfortable when a patient is deeply disturbed. He stated that:

> What I'm having to do nowadays, unfortunately, is I'm having to move into my discomfort zone more often than I like, in that I can't get psychiatric consultation done as I would like to on these patients.

Tr. 408.

This evidence shows that while technically both psychiatrists and primary care physicians are allowed to prescribe psychiatric medications, a psychiatrist, by virtue of his specialized knowledge, has greater expertise than a primary care physician in the area of diagnosing and treating psychiatric disorders. This evidence suggests that it might be possible for a primary care physician to provide comparable psychiatric care in very limited circumstances, such as where a psychiatric disorder is very mild or where a patient has an established medication profile and his condition remains stable. However, this evidence shows that, in most instances, treatment of psychiatric conditions by a primary care physician is less than optimal care and that such treatment might jeopardize the health of the patient. Since primary care physicians do not have the same level of expertise in treating psychiatric conditions as psychiatrists, I find that primary care physicians do not provide psychiatric health care which is equivalent to the level of care provided by psychiatrists. Therefore, I conclude that psychiatric health care provided by primary care physicians is not an alternative source of psychiatric health care contemplated by the regulations.[12]

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[12] The I.G. points out that Petitioner testified that he provided primary care in the course of his psychiatric practice. Based on this, the I.G. argues

Due to the lack of availability of outpatient psychiatric services in Santa Cruz County, primary care physicians are essentially being required to provide a greater amount of care to such patients than they feel they are capable of providing. The record supports the conclusion that such care is far from optimal and at times may compromise the health of the patient. Similarly, combining the psychotherapy provided by psychologists with the medical care provided by primary care physicians, while an improvement in the level of care, cannot be substituted for the greater expertise and experience possessed by practicing psychiatrists. The deficiencies in care afforded by psychologists and primary care physicians still exist when they combine their care. As patients' conditions change over time, warranting modification in medications, neither of these providers is equipped by training or experience to properly recognize and treat such conditions. While the record suggests that they may be forced to treat such situations, this "make do" care which is caused by the absence of outpatient psychiatric services cannot be considered alternative care, since it is not equivalent or comparable to the level of care provided by Petitioner.

Dr. Gillette testified that, in some instances, the County Mental Health Program refers psychiatric patients to other mental health care providers, such as licensed clinical social workers, or to marriage and family counselors. Tr. 343 - 344. The record shows, however, that these mental health care providers, like psychologists, are not allowed to prescribe medication. Tr. 399. Therefore, these mental health care providers do not provide psychiatric health care which is equivalent in quality to that provided by psychiatrists and these providers are not an alternative source of psychiatric health care contemplated by the regulations. The record shows also that, even if these providers were

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that primary care physicians should be considered an alternative source of the type of health care provided by Petitioner. I accept that, in the context of providing psychiatric care to patients, Petitioner may have treated some common physical complaints. However, the record is clear that the focus of Petitioner's practice is the provision of psychiatric health care. Therefore, the focus of this inquiry is whether other sources of health care are an available alternative to the psychiatric care, rather than to the primary care, provided by Petitioner.

an alternative source of health care, they are not permitted to be Medicaid providers. Tr. 426.[13]

In view of the foregoing, I find that, in most instances, the level of health care provided by health care providers who are not psychiatrists to individuals with psychiatric disorders is not equivalent to the level of care provided by Petitioner, and such care is not an alternative source of health care within the meaning of the regulations. I conclude that the evidence establishes that the mitigating factor specified at 42 C.F.R. § 1001.401(c)(3)(ii) is present in this case.

III. In evaluating the reasonableness of the three year exclusion, I must weigh the evidence relevant to the aggravating and mitigating factors enumerated in the regulations in light of the goals of the Act.

Under the regulatory scheme set forth in 42 C.F.R. § 1001.401, the three year benchmark exclusion imposed by the I.G. cannot be shortened below three years unless Petitioner shows that one or more of the mitigating factors specified in the regulations exists. In this case, Petitioner has met his burden of proving that one of the specified mitigating factors is present. Petitioner has shown that, by virtue of his exclusion, alternative sources of the type of health care items or services furnished by him are not available, within the meaning of 42 C.F.R. § 1001.401(c)(3)(ii).

Since Petitioner has proven that this mitigating factor is present, it is possible to shorten the three year benchmark period of exclusion in this case. While the presence of this factor makes it possible to shorten the three year exclusion, it does not entitle Petitioner to an automatic reduction of the three year exclusion period. The regulation uses the word "may" to indicate the permissive, discretionary use of this mitigating factor as a basis for shortening the exclusion period. 42 C.F.R. § 1001.401(c)(3). The regulations do not madate a reduction in the exclusion period solely on the basis of any single mitigating factor. Rather, what controls the exclusion period is the relative weight of the material evidence of such factor in the context of the total record.

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[13] Dr. Gillette testified that licensed clinical social workers are permitted to be Medicare providers. Tr. 343.

The regulations which govern this case contain no formula for assigning weight to mitigating and aggravating factors once such factors are established by the parties. 42 C.F.R. § 1001.401. In the preamble to the regulations, the comments include the following:

> We do not intend for the aggravating and mitigating factors to have specific values; rather, these factors must be evaluated based on the circumstances of a particular case.
>
> * * * * *
>
> The weight accorded to each mitigating and aggravating factor cannot be established according to a rigid formula, but must be determined in the context of the particular case at issue.

57 Fed. Reg. 3314, 3315.

Thus, in evaluating the reasonableness of an exclusion, I am required to explore in detail, and assign appropriate weight to, those regulatory factors which are aggravating or mitigating. While the regulations limit the specific factors which I may consider in evaluating the reasonableness of an exclusion, I am still guided by the goals of the Act in assigning weight to the factors which are specified in the regulations. The regulations promulgated by the Secretary cannot do more than interpret and implement the Act itself. Section 1102 of the Act authorizes the Secretary to publish only those rules and regulations "not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [she] is charged under this Act." Thus, the regulations should be applied to produce a result which is consistent with that required by the underlying statute. In evaluating the reasonableness of an exclusion, I must weigh those factors which the regulation directs me to consider in a manner that is consistent with the purposes of the Act.

Section 1128 of the Act is a civil statute and Congress intended it to be remedial in application. The remedial purpose of the exclusion law is to protect the integrity of federally-financed health care programs and the welfare of the programs' beneficiaries and recipients. The exclusion law is intended to protect program funds and beneficiaries and recipients from providers who have demonstrated by their conduct that they pose a threat to the integrity of such funds, or to the well-being and safety of beneficiaries and recipients. See S. Rep. No.

109, 100th Cong., 1st Sess. 1 (1987), reprinted in 1987 U.S.C.C.A.N. 682.

The legislative history of the Act shows that, in setting the period of exclusion, Congress intends that the factfinder will consider such factors as the seriousness of the offense, the impact of both the offense and exclusion on beneficiaries, and the availability of alternative providers of needed health care services. S. Rep. No. 109, 100th Cong., 1st Sess. 12 (1987), reprinted in 1987 U.S.C.C.A.N. 693. Congress' intention that the availability of alternate providers be considered in setting the duration of the length of exclusions is embodied in the regulations at 42 C.F.R. § 1001.401(c)(3)(ii). Thus, this regulation implements Congress' intent that the factfinder consider the need to protect program beneficiaries and recipients from being deprived of needed health care as a result of a provider's exclusion.

In view of the fact that the purpose of the exclusion law is to protect federally-financed health care programs and the beneficiaries and recipients of those programs from health care providers who pose a threat to the integrity of those programs and to the welfare of the programs' beneficiaries and recipients, the regulations at 42 C.F.R. § 1001.401 contemplate that the factfinder, in determining the appropriate duration of an exclusion, will balance two competing government interests. Under the regulations, I must balance the government interest in ensuring that Medicare and Medicaid programs and their beneficiaries and recipients will be protected against untrustworthy providers against the competing government interest in ensuring that Medicare and Medicaid beneficiaries and recipients will not be deprived of needed health care as a result of a provider's exclusion.

My authority in hearing and deciding cases pursuant to section 1128 of the Act remains de novo authority. See section 205(b) of the Act as incorporated by section 1128(f) of the Act; 42 C.F.R. § 1005.20. I am not charged with an appellate review of the I.G.'s actions, nor am I directed to conduct an inquiry as to whether the I.G.'s agent has discharged his or her duty competently in a particular case. The purpose of my inquiry is not to determine how accurately the I.G. applied the law to the evidence which was before the I.G.. Instead, the purpose of my inquiry is to evaluate the reasonableness of the exclusion de novo.

A de novo evaluation does not mean that I have unbridled discretion to modify an exclusion. I must sustain the

exclusion if, based on an independent review, I conclude it comports with the regulations' criteria and the remedial purpose of the Act. I must modify the exclusion if, based on an independent review, I conclude that it does not comport with the criteria contained in the regulations and with the remedial purpose of the Act.

Consistent with the requirement to evaluate the reasonableness of an exclusion de novo, I may consider evidence which explains and develops an aggravating or mitigating factor. The presence of an aggravating or mitigating factor in a case may permit inferences about the reasonableness of an exclusion. But far more may be revealed by evidence which explains and develops an aggravating or mitigating factor. Thus, I am not limited to considering evidence which was before the I.G. at the time the I.G. made the exclusion determination. Nor am I limited to considering evidence which relates to conduct which triggered the statutory authority to exclude a provider. As long as evidence is relevant to a regulatory factor, I must evaluate that evidence to determine whether an exclusion is in accord with the goals of the Act. Depending on the circumstances of the case, such an analysis can work to the benefit of the I.G. or Petitioner.

I will not construe the regulations in a manner which will prevent me from evaluating fully the impact of an aggravating or mitigating factor, either individually or collectively, on a provider's fitness to participate in the programs or to treat program beneficiaries and recipients. Applying the clarifying regulations of January 22, 1993 may reduce the scope of my inquiry somewhat from that set forth Matesic, DAB 1327. However, I construe the regulations to require that, once either the I.G. or Petitioner proves the existence of an aggravating or mitigating factor enumerated in 42 C.F.R. § 1001.401(c)(2) or (3), I must evaluate fully the significance of that factor as it relates to the reasonableness of the Petitioner's exclusion. This inquiry is limited to the factors set forth in the regulations.

The decision in John M. Thomas, Jr., M.D., et al., DAB CR281 (1993), provides support for my conclusion that the regulations permit me to admit evidence which develops an aggravating or mitigating factor as long as the evidence relates to the factor under consideration and it sheds light on the ultimate issue of whether an exclusion is reasonably necessary to meet the Act's remedial goals. In Thomas, which involved an exclusion of more than five years imposed pursuant to section 1128(a)(1) of the Act

and 42 C.F.R. § 1001.102, the administrative law judge held that parties should be permitted to develop evidence which explains and develops aggravating and mitigating factors.

The specific mitigating factor under consideration in Thomas was:

> The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition before or during the commission of the offense that reduced the individual's culpability; . . .

42 C.F.R. § 1001.102(c)(2). The administrative law judge in Thomas found support for his conclusion in the preamble to the regulations, which states:

> this factor will not be considered as mitigating if there is an ongoing problem that has not been resolved, such that the program(s) and their beneficiaries continue to be at risk.

57 Fed. Reg. 3315. The comment shows that the adjudicator is not limited to considering evidence which shows only that the sentencing judge found that the provider's culpability was diminished by his mental condition. Instead, assuming that the evidence shows that the threshold conditions identified by this regulation are present, the regulations contemplate a full explication of evidence concerning an excluded provider's mental condition in order to determine whether the provider's mental condition affects his or her trustworthiness to provide care. No part of 42 C.F.R. § 1001.102 expressly authorizes an administrative law judge to consider a provider's recovery from a mental condition described in subpart (c)(2) of the regulation; nor does it expressly authorize an administrative law judge to analyse the related issue of whether a provider is likely to commit the same or similar offenses in the future. Nevertheless, the comments to this regulation indicate that these matters are logical corollaries to the question of how much weight this factor should be given in determining an appropriate exclusion.

In contrast to Thomas, the present case does not involve 42 C.F.R. § 1001.102. However, a similar analysis can be applied to the factors enumerated in 42 C.F.R. § 1001.401. For example, in the present case, Petitioner contends that one of the enumerated mitigating factors justifies shortening the exclusion below the three year

benchmark period; the I.G. relies on aggravating factors to offset or reduce the impact of such mitigation. In such circumstances, Petitioner may offer any evidence which is relevant to the aggravating factors to rebut the implications of untrustworthiness arising from the I.G.'s evidence of aggravation. Evidence as to Petitioner's state of mind and rehabilitation, which would not otherwise be admissible, would be relevant to rebut the implications of untrustworthiness arising from a specified aggravating factor.[14] However, general character evidence disigned to show that Petitioner is "honest" or a "good person" which is offered without regard to a specific aggravating factor cannot be considered under the regulations.

IV. The three year exclusion which the I.G. imposed against Petitioner is excessive.

Since Petitioner was excluded, there are no psychiatrists, except on rare occasions, available to provide outpatient psychiatric care to Medicaid patients who are not severely psychiatrically impaired. Petitioner's exclusion has created a substantial void in the mental health care delivery system in Santa Cruz County, and other health care providers such as psychologists, primary care physicians, licensed clinical social workers, and marriage counselors do not have the expertise or qualifications to fill this void by providing comparable services. I am obligated, pursuant to 42 C.F.R. § 1001.401(c)(3)(ii), to consider the government interest in protecting Medicare and Medicaid patients from being deprived of necessary health care services. I find that this mitigating factor -- alternative sources of the type of health care provided by Petitioner are not available -- has substantial weight. In the absence of any offsetting aggravating factor, this mitigating factor has sufficient independent weight to warrant decreasing the three-year exclusion already imposed.

The I.G. argues that there are two aggravating factors present in this case which have sufficient weight to

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[14] Evidence of remorse or rehabilitation relating to an aggravating factor also could be admitted to prove the unreasonableness of an exclusion in a case where the I.G. has relied on that aggravating factor to impose an exclusion in excess of three years. However, in such a case, the exclusion could not be reduced below the three year benchmark absent proof of a mitigating factor specified in 42 C.F.R. § 1001.401(c)(3).

offset this mitigating factor. The I.G. contends that: 1) the acts that resulted in Petitioner's conviction, or similar acts, were committed over a period of one year or more; and 2) the acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental, or financial impact on program beneficiaries or other individuals. I must now determine if these aggravating factors are present in this case and, if so, I must assign weight to them in accordance with the government interest in protecting the Medicare and Medicaid programs and their beneficiaries and recipients from being exposed to untrustworthy providers. I must then determine the appropriate duration of the exclusion by balancing the government interest in ensuring that program beneficiaries and recipients are not deprived of needed health care against the competing government interest in ensuring that they are protected from untrustworthy providers.

A. The acts that resulted in Petitioner's conviction or similar acts were committed over a period of one year or more.

The I.G. contends that there are two aggravating factors present in this case which offset the mitigating factor that alternative sources of health care are not available. The first aggravating factor cited by the I.G. is that the acts that resulted in Petitioner's conviction or similar acts were committed over a period of one year or more. 42 C.F.R. § 1001.401(c)(2)(i). I conclude that the I.G. has established this aggravating factor.

The record shows that, on June 15, 1987, Mr. Earl Door, an investigator with the California Attorney General's Office, asked the manager of a pharmacy if she knew any doctors in the area who stood out as high prescribers of drugs or narcotics in relation to other doctors in the community. The pharmacy manager told Investigator Door that she knew of six of Petitioner's patients who brought in prescriptions to be filled on a regular basis and that these six individuals appeared to be addicts. Upon further investigation, Investigator Door discovered that all six of these patients were Medicaid recipients and that three of them had drug or narcotic violations which ranged from being under the influence of a drug or narcotic to sales of narcotics. As a result of this information, Investigator Door commenced an undercover criminal investigation of Petitioner. I.G. Ex. 1 at 1 - 2.

The first undercover operation involving Petitioner occurred on November 13, 1987. The undercover operator visited Petitioner's office posing as a potential patient. He told Petitioner that he was under stress and that he wanted some codeine. Petitioner did not give the operator a prescription on that occasion. I.G. Ex. 1 at 2 - 3.

Five additional undercover operations were conducted on February 16, 1988, July 13, 1988, August 4, 1988, August 23, 1988, and October 11, 1988 by three different operators posing as patients. In each instance, Petitioner issued prescriptions for codeine. Codeine is a controlled substance. Codeine is an analgesic narcotic which is used to treat pain. The undercover operators did not complain of pain or give any physical symptoms in any of these operations. I.G. Ex. 1 at 5 - 18, I.G. Ex. 3; Tr. 50.

Dr. David H. Schneider, an employee of CDHS, reviewed the reports of the five 1988 undercover operations to provide an independent professional opinion regarding the appropriateness of Petitioner's prescriptions for codeine during the course of these undercover operations. Dr. Schneider concluded that there was no medical justification for prescribing codeine in all of these operations. I.G. Ex. 1 at 19.

After a lull of approximately 14 months, the undercover operations were resumed. Six additional undercover operations were conducted on December 15, 1989, March 13, 1990, March 29, 1990, April 3, 1990, April 13, 1990, and April 19, 1990 by three operators posing as patients. One of these operators had posed as a patient in one of the previous five operations. For each operation, the operator was instructed to ask Petitioner for a prescription without presenting any psychiatric or medical complaints. Petitioner issued prescriptions for codeine in five of the operations and a prescription for vicodin in one of the operations. Vicodin is a controlled substance. It is also an analgesic narcotic which is used for the treatment of pain. I.G. Ex. 1 at 20 - 29, I.G. Ex. 3; Tr. 55.

Dr. Anthony Atwell, a psychiatrist, reviewed the reports of the six 1990 operations. He concluded that the prescriptions issued by Petitioner in the course of these six operations had "no psychiatric or psychopharmacologic basis" and that they were issued without evidence of "any medical or psychiatric pathology or legitimate medical purpose." I.G. Ex. 3.

Based on the foregoing, on July 18, 1990, a felony complaint was filed in Santa Cruz County Municipal Court by the California Attorney General's Office, charging Petitioner with six felony counts of knowingly, willfully and unlawfully prescribing a controlled substance without medical necessity, to wit: vicodin or codeine, to an undercover operator, who was not under Petitioner's treatment for a pathology or condition other than addiction to a controlled substance, in violation of section 11154 of the California Health and Safety Code. I.G. Ex. 2. On July 19, 1990, Investigator Ponta executed an arrest warrant on Petitioner "for prescribing controlled substances without medical necessity." I.G. Ex. 1 at 30. Petitioner was bound over as charged in the Superior Court for the County of Santa Cruz. On October 3, 1990, the California Attorney General's Office filed an Information in the Santa Cruz County Superior Court containing the same charges as the Felony Complaint. Tr. 204; I.G. Ex. 4.

Pursuant to a plea bargain, on August 27, 1991, Petitioner pled nolo contendere to count two of the Information. As part of the plea bargain, this count was reduced to a misdemeanor and the remaining five felony counts were dismissed. The court accepted the plea, and sentenced Petitioner to two years of unsupervised probation and ordered Petitioner to pay a fine of $1000 and costs of $1330. I.G. Ex. 5; Tr. 204 - 205.

The uncontroverted evidence of record shows that the aggravating circumstance at 42 C.F.R. § 1001.401(c)(2)(i), the acts that resulted in the conviction or similar acts were committed over a period of one year or more, is present in this case. Petitioner was convicted of knowingly and willfully prescribing a controlled substance for no legitimate medical purpose during the course of an undercover operation which took place on March 13, 1990. The record shows that this was not an isolated instance of this type of misconduct. The evidence adduced by the I.G., and not controverted by Petitioner establishes that Petitioner engaged in inappropriate and illegal drug prescribing practices on ten other occasions. These undercover operations occurred over a period of more than one year, spanning a 26 month period from February 16, 1988 to April 19, 1990.

This evidence shows that Petitioner demonstrated a pattern of engaging in inappropriate and illegal drug prescribing practices. I infer from this evidence that, at least at the time of Petitioner's arrest in 1990, Petitioner demonstrated a propensity to engage in illegal drug prescribing practices in the future.

In weighing this factor I observe that the record is devoid of evidence establishing that Petitioner unlawfully prescribed controlled substances to patients who were not undercover agents.[15] Petitioner testified that he treated hundreds of patients during the 26 month period in question. Tr. 290. There is no evidence of record establishing that Petitioner illegally prescribed controlled substances to any of these hundreds of other patients. When viewed in this broader context, the significance of this factor is diminished. I would have assigned more weight to this factor if the I.G. had shown that Petitioner routinely engaged in improper prescribing practices with his other patients over the 26 month period. The I.G. made no such showing. On the contrary, there is affirmative evidence showing that Petitioner did not have the reputation among his professional colleagues as being an individual who was operating a "drug mill." P. Ex. 1 at 2.

The I.G. contends that the evidence "strongly suggests" that Petitioner misprescribed medication to several patients who were not undercover agents prior to the commencement of the investigation. I.G. posthearing reply brief at 13. Petitioner contends that there is insufficient evidence to establish that he engaged in misprescribing practices prior to the investigation. Petitioner posthearing brief at 3.

The record shows that the undercover investigation into Petitioner's prescribing practices was initiated after the manager of a pharmacy told him that six of

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[15] Since the I.G. relies only on incidents involving undercover operators in establishing the presence of the aggravating factor at 42 C.F.R. § 1001.401(c)(2(i), then the length of the period over which the misconduct occurred is directly related to the length of the undercover investigation. The I.G. asserts that there is no indication that Petitioner's unlawful prescriptions for controlled substances would have stopped when they did, were it not for the fact that Petitioner was arrested on July 19, 1990. While this may be true, the converse to this statement is also true. Had the investigation stopped sooner, the length of the period of time in which Petitioner engaged in illegal activities would have been shorter. In this regard, I note that there was a 14 month hiatus in the undercover investigation during the period from October 11, 1988 to December 15, 1989. There is no evidence that Petitioner illegally prescribed controlled substances during this 14 month period.

Petitioner's patients who appeared to be addicts had been coming in with prescriptions from Petitioner on a regular basis. Petitioner produced the prescription profiles of these six patients, and he indicated that he obtained them from the California Attorney General's office. Tr. 85, 90; P. Ex. 11; I.G. Ex. 1 at 1 - 2. Petitioner testified that he had never even met two of the six individuals identified by the pharmacy manager. Tr. 91, 239. The prescription profiles of these two patients do not list Petitioner as a prescribing physician. The prescription profiles of the remaining four individuals show that Petitioner prescribed drugs to them. P. Ex. 11. Three of these four individuals had a history of narcotics violations. I.G. Ex. 1 at 1 - 2.

This evidence shows that, with respect to at least three of Petitioner's patients, Petitioner prescribed drugs to individuals who had a history of narcotic violations. While this evidence was sufficient for the purpose of commencing a criminal investigation, it is not sufficient to establish that the medications prescribed by Petitioner to these individuals was, in fact, illegal.[16] Petitioner testified that he provided primary care in the context of providing psychiatric care, and that, as a result, he prescribed medicine for physical conditions. While Petitioner did not state the specific physical conditions for which he prescribed drugs in each of the instances shown on the prescribing profiles, he indicated that he prescribed codeine to one of the patients for migraine headaches and that he prescribed codeine to another patient for alcoholic peripheral neuropathy, a painful condition. Tr. 239. In the absence of definitive evidence establishing that the prescriptions appearing on the prescription profiles were medically inappropriate, I do not conclude that Petitioner engaged in improper prescribing practices to patients prior to February 16, 1988.

B. The acts that resulted in the conviction or similar acts had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals or the Medicare or State health care programs.

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[16] Even Investigator Door testified that the prescription profiles of the individuals mentioned by the pharmacy manager "were just an indicator that there was a problem" and that his office "didn't focus on these profiles for the prosecution." Tr. 100.

The second aggravating factor cited by the I.G. is that the acts that resulted in the conviction or similar acts had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals or the Medicare or State health care programs. 42 C.F.R. § 1001.401(c)(2)(ii). I conclude that the I.G. has established this aggravating factor.

Petitioner was convicted of violating section 11154 of the California Health and Safety Code, which prohibits physicians from knowingly prescribing a controlled substance to individuals unless there is a legitimate medical need to do so. I.G. Ex. 9. This State law regulating the prescription of controlled substances reflects a legislative conclusion that these substances are potentially dangerous to the health and safety of consumers. Abelard A. Pelaez, M.D., DAB CR157 (1991). Because of the potential for harm and abuse, the California State government has determined that these substances must be strictly regulated for the public good.

The record contains ample evidence of the dangers of the inappropriate use of codeine and vicodin, the controlled substances Petitioner improperly prescribed in the course of the undercover investigation. Based on his extensive training in drugs and narcotics, Investigator Door testified that codeine and vicodin are analgesic narcotics used to treat pain, and that they should not be prescribed unless a physician performs a medical examination. Investigator Door testified that if a physician prescribes these narcotics without performing a medical examination and the patient has a serious illness, the narcotic can mask the patient's pain symptoms and he may not seek the medical attention he needs. Tr. 39, 50, 54 - 57.

In addition, Investigator Door testified that if narcotic alalgesics are used inappropriately they can be both physically and psychologically addictive. He indicated that if an individual takes one prescription of codeine consisting of 30 tablets, that individual will experience some withdrawal symptoms, such as a simple headache, when he finishes taking all 30 tablets. If an individual continues to use this narcotic over a period of weeks or months, he will become addicted to it. Investigator Door stated also that codeine is often abused by mixing it with other drugs or alcohol to give a euphoric effect. Tr. 57 - 61. According to Investigator Door, addicted individuals may become "doctor shoppers" and go to many different doctors to get their prescriptions because they have built up a tolerance to the drug. Tr. 62 - 63. In

addition, heroin addicts might use codeine when heroin is unavailable, to minimize their withdrawal symptoms. Tr. 55.

I find that the credible evidence of record shows that the aggravating circumstance at 42 C.F.R. § 1001.401(c)(2)(ii), the acts that resulted in the conviction or similar acts had a significant adverse physical, mental, or financial impact on program beneficiaries or other individuals or the Medicare or State health care program, is present in this case. The evidence establishes that providing patients with controlled substances for no legitimate medical purpose endangers the health and well-being of those patients. Petitioner, through his position as a medical doctor, was allowed access to these controlled substances and was entrusted with the responsibility to prescribe these controlled substances in an appropriate, safe manner. Petitioner abused that trust, and his misconduct shows that he is capable of engaging in illegal prescribing practices which have potentially serious consequences for his patients. The fact that Petitioner's improper prescribing practices involved undercover operators who posed as patients does not derogate from my conclusion that this factor is present in this case. Had Petitioner engaged in similar inappropriate prescribing practices with patients who were not impostors, the evidence shows that the health and safety of those patients would be threatened.

The I.G. contends that this factor, coupled with the other aggravating factor at 42 C.F.R. § 1001.401(c)(2)(i), has sufficient weight to offset any mitigation resulting from the lack of availability of alternative sources of health care. Petitioner offered evidence at the hearing in an effort to rebut the I.G.'s contention.

C. Petitioner demonstrated that he does not continue to pose a threat to the Medicare and Medicaid programs or to their beneficiaries and recipients.

Petitioner testified that his inappropriate prescribing practices were not motivated by self-interest, but rather by a humanitarian concern for the well-being of his patients. Petitioner testified that the reason he prescribed the controlled substances to the undercover operators is that he was trying to induce them to enter into a "therapeutic alliance" with him. Petitioner indicated that he was willing to prescribe small amounts of medication for a limited period of time to these individuals in an effort "to link with them and to get

them to come in to engage in psychotherapy." Tr. 267 - 268, 287 - 289, 295, 297; Petitioner's posthearing brief at 3.

Petitioner explained that, because he was the only psychiatrist who routinely treated indigent patients in the context of a private outpatient practice, he became over-involved with his patients and he lost contact with other members of the medical community. As a result, he was out of touch with acceptable standards of medical care. According to Petitioner, his isolation in the medical community was compounded by the fact that he had voluntarily resigned from serving on the staff at Dominican Hospital several years earlier and the fact that he was not a member of any psychiatric societies. Petitioner indicated that, due to his professional isolation and his lack of communication with other psychiatrists, he was more likely to engage in inappropriate medical practices. Petitioner stated also that his treatment practices were outmoded because he had been lax in taking continuing education courses related to controlled substances. Tr. 258, 277, 279, 297 - 300. The I.G. characterized Petitioner's testimony explaining his reasons for engaging in the illegal prescribing activity as "extraordinary" and contended that it was totally unsupported by any corroborating evidence. I.G. posthearing brief at 51. I disagree.

Petitioner's testimony is supported by other evidence of record. The reports of the undercover operations are replete with statements showing that Petitioner repeatedly invited the undercover operators to enter into psychotherapy. In fact, Petitioner did not provide codeine to the undercover operator who requested it to treat stress during the first operation which occurred on November 13, 1987. Instead, he indicated that codeine was a "band-aid approach" and he invited the operator to work with him to achieve a more permanent solution to his problems I.G. Ex. 1 at 2. In a subsequent contact with the same operator on February 16, 1988, Petitioner did prescribe some codeine, but he warned the operator that he could not be relied upon to continue to provide prescriptions for stress because of his belief that there are better ways to handle stress. Petitioner again invited the operator to come back if the operator wished to explore other ways to handle stress. I.G. Ex. 1 at 6. Petitioner repeatedly made similar statements in other operations. I.G. Ex. 1 at 13, 15, 27.

In addition, Petitioner's medical colleagues agreed with Petitioner's assessment of the reasons why he engaged in the inappropriate prescribing practices. In a letter

dated December 31, 1990, they noted Petitioner's professional isolation and stated that this isolation "resulted in [Petitioner's] increasing reliance on his own judgment and methods with decreasing reference to the standards of his peers in our community." P. Ex. 1 at 3. Petitioner's colleagues expressed the view that Petitioner did not suffer from chemical dependency or mental illness and that he was not motivated to inappropriately prescribe medication by personal financial gain. Instead, they stated that Petitioner could be faulted for "clinical naivete and perhaps an over-involvement in sense of mission toward those in various states of need and psychological pain." P. Ex. 1 at 3.

The I.G. asserts that, even if it is true that Petitioner was motivated by humanitarian concern for his patients, this would not minimize the seriousness of his misconduct. The I.G. points out that testimony by Petitioner's own witness, Dr. Gillette, establishes that prescribing controlled substances in order to entice an individual into psychotherapy is not within the standard of care. I.G. posthearing brief at 51.

I agree with the I.G. that Petitioner was convicted of a serious criminal offense. Petitioner's inappropriate prescribing practices demonstrate that he has displayed exceedingly poor judgment. Prescribing controlled substances without a legitimate medical need is dangerous, and such misconduct, were it to continue, would pose a grave threat to the integrity of the federally-financed health care programs served by Petitioner and to the welfare of program beneficiaries and recipients. Nevertheless, Petitioner's motivation for his misconduct sheds light on the degree of potential harm resulting from his misconduct. In addition, Petitioner's motivation sheds light on the likelihood that Petitioner will continue to engage in the same misconduct in the future.

The record shows that Petitioner's prescribing practices were motivated by a concern for his patients and that he actively took precautions to limit the potential for harming his patients. Petitioner testified that he made every effort not to give narcotics to individuals who were acutely addicted. Tr. 276 - 277, 287. The investigative reports support this claim. They show that Petitioner repeatedly tried to determine if the operators were acutely dependent on drugs before he prescribed medications to them. In some instances, he attempted to determine this by interviewing the operators, and, in other instances, he inspected the operators' arms to

determine if they had telltale needle marks. I.G. Ex. 1 at 6, 10, 25. Petitioner stated that he was aware that controlled substances are potentially addictive, and he expressed the view that the relatively small amounts he prescribed to the undercover operators would have had a minimal adverse impact. Tr. 285. Petitioner stated also that he was willing to continue to prescribe controlled substances for only a limited period of time. Tr. 295. This evidence suggests that Petitioner was aware of the dangers of controlled substances and that he took steps to limit the exposure of his patients to these dangers.

I accept Petitioner's explanations that his misconduct was motivated by good intentions. Petitioner's benign intentions do not excuse his criminal misconduct. However, the fact that Petitioner has shown that he was not motivated by venality suggests that he will not, in the future, be likely to engage in illegal drug transactions based solely on greed or a malevolent intent. Moreover, there is credible evidence showing that the circumstances which led to Petitioner's wrongdoing no longer are present. Based on this evidence, I am persuaded that there is little likelihood that Petitioner will again engage in inappropriate prescribing practices in the future.

Petitioner has satisfied me by his testimony and his demeanor that he now realizes that it is inappropriate to induce patients to begin psychotherapy by prescribing controlled substances. Petitioner testified that he was "traumatized" by his criminal conviction, and that this caused him to take steps to correct the circumstances that led to his misconduct. Tr. 253. Petitioner stated that since his conviction he has had 123 hours of continuing medical education and that 23 of these hours have been on the subject of chemical dependency and drug use. In addition, he has passed the written part of the American Board of Psychiatry exam. Tr. 259 - 260. Petitioner stated that as a result of his continuing education courses, he realizes that he made a mistake and that he is now more cautious in his prescribing practices. Tr. 266, 298. Petitioner stated that since his conviction, he has become less isolated professionally. He joined the staff of Natividad Medical Center in an attempt to integrate himself into the medical community. Tr. 253, 300.

The record contains letters from Petitioner's professional colleagues which support his claim that he can now be trusted to prescribe controlled substances appropriately. In a letter dated September 14, 1991, Walter J. Wilcox, M.D., Petitioner's immediate supervisor

at Natividad Medical Center, stated that Petitioner's "use of medications can best be described, I believe, as conservative and cautious." P. Ex. 4 at 2. Anthony Sforza, M.D., Medical Director at Natividad Medical Center, stated in an August 1, 1991 letter that he has closely monitored Petitioner's work and that his "prescribing practices are excellent." P. Ex. 3.

D. The interest in providing access to outpatient psychiatric care outweighs the interest in program protection in this case, and justifies shortening the exclusion.

Both of the aggravating factors cited by the I.G. are present in this case. However, when I consider the evidence relevant to these factors in light of the remedial purpose of the Act to protect program beneficiaries and recipients from untrustworthy providers, I find that these factors do not have sufficient weight to justify a lengthy exclusion in this case and they do not completely offset the impact of the mitigating factor specified at 42 C.F.R. § 1001.401(c)(3)(ii). Balancing the need to protect program beneficiaries and recipients from being deprived of needed health care against the need to protect them from untrustworthy providers, I find that the three year benchmark exclusion is excessive in this case.

The evidence demonstrates that the absence of psychiatric services provided by Petitioner and the lack of available alternative sources of psychiatric care deprive Medicaid patients in Santa Cruz of needed health care. This mitigating factor justifies shortening the exclusion significantly below the three year benchmark period. On the other hand, the existence of the criminal conviction and the two aggravating factors specified at 42 C.F.R. § 1001.401(c)(2)(i) - (ii) support an exclusion of some length in this case. Petitioner improperly prescribed controlled substances to undercover operators on eleven different occasions over a 26 month period, a period of more than a year. Moreover, Petitioner's improper prescribing practices could have endangered the health and well-being of his patients. Therefore, at least at the time of his arrest in 1990, Petitioner had demonstrated that he was untrustworthy to provide care to Medicare and Medicaid and their beneficiaries and recipients.

In balancing the competing interests in access to health care and program protection, I assign some weight to the fact that Petitioner improperly prescribed controlled substances to undercover operators over a period of more

than one year. However, the impact of this factor is diminished by the fact that the record is devoid of evidence establishing that Petitioner improperly prescribed controlled substances to his hundreds of patients who were not undercover operators during the 26 month period in question. The weight to be accorded the duration of Petitioner's conduct is also diminished because there was a 14 month hiatus in the undercover investigation, and there is no evidence that Petitioner illegally prescribed controlled substances during this 14 month period.

Similarly, I assign some weight to the fact that Petitioner's conduct had the potential to cause harm to his patients. The impact of this factor is diminished by the evidence showing that Petitioner's inappropriate prescribing practices were motivated by a humanitarian concern for his patients and that he consciously took steps to limit the potential harm to his patients. The evidence shows that at the time he engaged in his improper prescribing practices, Petitioner was isolated from the professional community and that as a result, he was out of touch with acceptable standards of care regarding prescribing medications.

The weight of both aggravating factors is diminished by the evidence showing that the circumstances which led to Petitioner's wrongdoing have been sufficiently altered so that Petitioner no longer poses a threat to program beneficiaries and recipients. There is no evidence that Petitioner continued to engage in improper prescribing practices after his arrest in 1990. To the contrary, the evidence shows that Petitioner has actively taken steps to educate himself about proper drug prescribing practices and that he has integrated himself into the professional psychiatric community. Since his conviction, Petitioner has worked in Natividad Medical Center, and his prescribing practices have conformed with acceptable standards of care. Based on the totality of the evidence, I conclude that modifying the exclusion to end upon the effective date of this decision comports with the remedial objectives of the Act.

CONCLUSION

I conclude that the three year exclusion which the I.G. imposed against Petitioner is excessive. The exclusion is modified to end upon the effective date of this decision.

/s/

Edward D. Steinman
Administrative Law Judge