Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	DATE: June 18, 1993
Domingos R. Freitas,	)	
	)	
Petitioner,	)	Docket No. C-92-006
	)	Decision No. CR272
- v. -	)	
	)	
The Inspector General.	)	
	)	

DECISION

On July 22, 1991, the Inspector General (I.G.) notified Petitioner, Domingos R. Freitas, that he was being excluded from participation in the Medicare program and any State health care program[1] for a period of ten years. The I.G. advised Petitioner that: 1) his exclusion was based on his conviction for criminal offenses "relating to the delivery of a health care item or service," within the meaning of section 1128(a)(1) of the Social Security Act; and 2) section 1128(c)(3)(B) of the Act provides that such exclusions be for a period of not less than five years. Further, the I.G. informed Petitioner that he was being excluded for a period of ten years based on the aggravating circumstances of the case.

Petitioner requested a hearing, and the case was assigned to me. At the November 18, 1991 prehearing conference, the I.G. contended that Petitioner's request for a hearing was not timely filed and moved to dismiss the case. In my Prehearing Order dated November 22, 1991, a briefing schedule was established. Subsequent to the filing of his brief, the I.G. withdrew the motion to dismiss.

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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. I use the term "Medicaid" hereafter to represent all State health care programs from which Petitioner was excluded.

At the November 18, 1991 prehearing conference, the parties agreed that, in the event I denied the I.G.'s motion to dismiss, they would proceed by motions for summary disposition. The parties agreed that the issue for summary disposition would be whether the I.G. had the authority to exclude Petitioner pursuant to section 1128(a)(1) of the Act. The parties also agreed that, if necessary, there would be a subsequent in-person hearing on whether the additional five-year period of exclusion was reasonable.

On April 29, 1992, after the submission of briefs and considering the arguments contained therein, I issued a Ruling in which I denied the I.G.'s motion for summary disposition. The basis for my Ruling was that there was insufficient undisputed evidence from which I could conclude that Petitioner's criminal offenses were program related within the meaning of section 1128(a)(1). The evidence presented by the I.G. failed to establish that the pharmaceuticals that formed the basis for Petitioner's criminal convictions were actually billed to the Medi-Cal program.[2] Accordingly, I was unable to conclude, at that time, that the I.G. had the authority to exclude Petitioner.

On May 27, 1992, I issued an Order and Notice of Hearing that established the schedule through which this case would proceed to an in-person hearing. On September 15, 1992, I conducted an in-person hearing in this case in San Francisco, California. The parties have submitted posthearing briefs.

I have considered the arguments, the evidence, and the applicable law. I conclude that the I.G. has the authority to exclude Petitioner pursuant to sections 1128(a)(1) and 1128(c)(3)(B) of the Act. I further conclude that the ten-year exclusion imposed and directed by the I.G. is supported by the record in this case and thus reasonable.

ISSUES

The issues in this case are whether:

1. Petitioner was convicted of a criminal offense related to the delivery of a health care item or service within the meaning of section 1128(a)(1) of the Act;

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[2] Medi-Cal is the California Medicaid program.

2. Petitioner's exclusion of ten years is reasonable.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. At all times relevant to this case, Petitioner was a pharmacist licensed by the California State Board of Pharmacy (Board of Pharmacy). I.G. Ex. 3 at 1 - 2; 10.[3]

2. At all times relevant to this case, Petitioner was licensed by the Board of Pharmacy to do business as Plaza Pharmacy. I.G. Ex. 3 at 1 - 2; 10.

3. On April 20, 1989, the Board of Pharmacy filed an Accusation against Petitioner and Plaza Pharmacy, accusing Petitioner of dispensing drugs without valid prescriptions and refilling prescriptions without authorization. I.G. Ex. 4 at 3 - 26.

4. Included in the Accusation was the charge that, commencing in November 1983 Petitioner dispensed drugs

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[3] The parties' exhibits and briefs, the transcript of the hearing and my findings of fact and conclusions of law will be cited as follows:

I.G.'s Exhibit	I.G. Ex. (number at page)
Petitioner's Exhibit	P. Ex. (number at page)
Transcript of Hearing	Tr. (page)
I.G's Posthearing Brief	I.G. Br. (page)
Petitioner's Posthearing Brief	P. Br. (page)
I.G's Reply Brief	I.G. R. Br. (page)
Petitioner's Reply Brief	P. R. Br. (page)
I.G's Brief on New Regulations	I.G. Reg. Br. (page)
Petitioner's Supplemental Brief	P. S. Br. (page)
My Findings and Conclusions	FFCL

"pursuant to allegedly issued or authorized prescriptions by a Dr. Thomas Daglish." I.G. Ex. 4 at 3.

5. One of the persons for whom Petitioner filled and refilled prescriptions without authorization by Dr. Daglish was patient SV. I.G. Ex. 4 at 5 - 6.[4]

6. Included in the Accusation was the charge that, commencing in September 1984, Petitioner refilled prescriptions issued by a Dr. C.H. Kleyn for patient GW. The charge alleges that Dr. Kleyn did not authorize the refills. I.G. Ex. 4 at 11 - 15.

7. On December 14, 1989, Petitioner signed a Stipulation, Decision, and Order of the Board of Pharmacy (Board of Pharmacy Stipulation) in which he admitted that from October 20, 1983 through October 16, 1987, he had, on over 800 occasions, dispensed drugs without valid prescriptions or refilled prescriptions without authorization for customers at Plaza Pharmacy. I.G. Ex. 3; FFCL 2.

8. In the December 14, 1989, Board of Pharmacy Stipulation, Petitioner admitted, among other things, that he had refilled prescriptions for patients SV and GW without proper authorization. I.G. Ex. 3 at 2, 4, 5, and 10 - 14.

9. Among the prescriptions Petitioner admitted refilling without authorization was one for the drug Inderal for SV on June 9, 1987 (Prescription # 95212). I.G. Ex. 3 at 5; 7 at 1, 2.

10. Among the prescriptions Petitioner admitted refilling without authorization was one for the drug Dyazide for GW on September 14, 1987 (Prescription # 84141). I.G. Ex. 3 at 12; 7 at 6.

11. As a result of Petitioner's admissions, the Board of Pharmacy took disciplinary action against him, including revoking his pharmacy license (PU 24514, which was issued to him individually) and his permit (AB16487, which was issued to him to do business as Plaza Pharmacy). I.G. Ex. 3 at 24 - 30.

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[4] Wherever possible, I refer to the persons who received unauthorized prescriptions or refills from Petitioner by their first and last initials. In one instance where the record indicates only the patient's last name and gender, I refer to her as Cl.

12. The Board of Pharmacy stayed the revocation of Petitioner's pharmacy license and permit, Petitioner was suspended from the practice of pharmacy for a period of 45 days, and placed Petitioner on probation for three years. I.G. Ex. 3 at 26 - 30.
Petitioner's conviction is program-related.[5]

13. SV and GW were Medi-Cal recipients at all times relevant and material to this case, specifically during the period of time from October 10, 1985 through September 30, 1988. I.G. Ex. 1 at 14 - 18; 5 at 1 - 5; 7 at 1 - 8.

14. SV and GW were regular customers of Plaza Pharmacy and routinely had their Medi-Cal prescriptions filled and refilled there. I.G. Ex. 5.

15. On January 9, 1990, Petitioner was indicted on 15 felony counts, all involving either improper dispensation and prescription of controlled substances or submission of false or fraudulent Medicaid claims. I.G. Ex. 1 at 2 - 8.

16. Included in the felony complaint was the charge (Count XIII) that Petitioner did willfully and unlawfully, with intent to defraud, present and cause to be presented to the State of California for allowance or payment a false and fraudulent Medi-Cal claim, to wit number 7168634255101, for services rendered to recipient SV on June 9 and June 22, 1987, in violation of section 14107 of the (California) Welfare and Institutions Code. I.G. Ex. 1.

17. Count XIII of the felony complaint described one single and continuing transaction, which began on June 9, 1987, when Petitioner wrongfully refilled a prescription for Medi-Cal recipient SV, and which culminated on June 25, 1987, the date that Medi-Cal issued a check for reimbursement for the wrongfully refilled prescription. I.G. Ex. 1, 8 at 2.[6]

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[5] I have included headings in my Findings of Fact and Conclusions of Law (FFCL) solely for the benefit of the reader. These headings are not FFCL, nor do they alter the meaning of any of my FFCL.

[6] For the sake of simplicity, I use the June 25, 1987 date as the culminating date of the transaction. One part of Mr. Temmerman's affidavit (I.G. Ex. 8 at 3) states that June 22, 1987 was the date on which the unauthorized refill was presented to Medi-Cal for

18. Included in the felony complaint was the charge (Count XV) that Petitioner did willfully and unlawfully, with intent to defraud, present and cause to be presented to the State of California for allowance or payment a false and fraudulent Medi-Cal claim, to wit number 7266630595001, for services rendered to recipient GW on September 14 and 28, 1987, in violation of section 14107 of the (California) Welfare and Institutions Code. I.G. Ex. 1, 8 at 2, 3.

19. Count XV of the felony complaint described a single and continuing transaction, which began on September 14, 1987, when Petitioner wrongfully refilled a prescription for Medi-Cal recipient GW, and which culminated on October 2, 1987, the date Medi-Cal issued a check for reimbursement for the wrongfully refilled prescription. I.G. Ex. 1, 8 at 3.[7]

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reimbursement. However, it is apparent, from the affidavit as a whole and from the supporting documentation, that the final date in the transaction that began with Petitioner's unauthorized refill for SV on June 9, 1987 can be characterized as either June 25, 1987, the date Medi-Cal wrote the check to reimburse Petitioner for the unauthorized refill, or June 30, 1987, the date on which Petitioner, as Plaza Pharmacy, cashed the Medi-Cal check. I.G. Ex. 7 at 1 - 4, 8. Since there is no specific documentation in the record to support Mr. Temmerman's assertion that June 22 was the date on which the claim for was presented to Medi-Cal for reimbursement, for my purposes in this Decision I view this transaction as culminating on June 25, 1987, the date Medi-Cal wrote the check to reimburse Petitioner for the unauthorized refill. I.G. Ex. 7 at 1 - 4, 8.

[7] For the sake of simplicity, I use the October 2, 1987 date as the culminating date of the transaction. One part of Mr. Temmerman's affidavit (I.G. Ex. 8/3) contains the September 28, 1987 date as the date on which the unauthorized refill was presented to Medi-Cal for reimbursement. However, it is apparent from the affidavit as a whole and the supporting documentation, that the final date in the transaction that began with Petitioner's unauthorized refill for GW on September 14, 1987 can be characterized as either October 2, 1987, the date Medi-Cal wrote the check to reimburse Petitioner for the unauthorized refill, or October 7, 1987, the date on which Petitioner (Plaza Pharmacy) cashed the Medi-Cal check. I.G. Ex. 7 at 5 - 8; I.G. Ex. 8. Since there is no specific documentation in the record as to when this particular claim was actually presented to Medi-Cal for

20. On March 21, 1990, pursuant to a negotiated plea agreement, a superseding Information, No. 28598 (Information), was filed in which the charges against Petitioner were revised and reduced to three counts. I.G. Ex. 1, 8.

21. Count I of the Information charged Petitioner with willfully and unlawfully prescribing, administering, and dispensing Codeine to an habitual user, a felony. There is no evidence, nor has the I.G. contended, that Count I is program-related. I.G. Ex. 1 at 9, 10, and 14 - 18; 8.

22. Count II of the Information charged that on or about

June 22, 1987, Petitioner unlawfully refilled a prescription for a dangerous drug for SV without authorization as required under California law, a misdemeanor. I.G. Ex. 1 at 9, 10, and 14 - 18; 8.

23. Count III of the Information charged that on or about September 28, 1991, Petitioner unlawfully refilled a prescription for a dangerous drug for GW without authorization as required under California law, a misdemeanor. I.G. Ex. 1 at 9, 10, and 14 - 18; 8.

24. Count II of the Information described exactly the same transaction as had been described in Count XIII of the felony complaint. However, instead of charging Petitioner with a felony, the Information charged him with the misdemeanor offense of refilling a prescription for a dangerous drug without authorization. I.G. Ex. 1, 8, 9; Tr. 180 - 201; 210 - 17; FFCL 15 - 16.

25. Count III of the Information described exactly the same transaction as had been described in Count XV of the felony complaint. However, instead of charging Petitioner with a felony, the Information charged him with the misdemeanor offense of refilling a prescription for a dangerous drug without authorization. I.G. Ex. 1, 8, 9; Tr. 210 - 17; FFCL 17 - 18.

26. Counts II and III of the Information do not contain a specific reference to the Medi-Cal program, at least in part, because Petitioner's criminal attorney was aware of the possibility of a subsequent administrative sanction

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payment, I view this transaction as culminating on October 2, 1987, the date Medi-Cal wrote the check to reimburse Petitioner for the unauthorized refill. I.G. Ex. 7 at 5 - 8, 8.

and did not want Petitioner to plead to charges that were, on their face, program-related. Tr. 208, 220 - 22.

27. On April 20, 1990, in a California State court, Petitioner entered a plea of nolo contendere to the three counts contained in the Information. The court accepted Petitioner's plea and judgment was entered on all three counts. I.G. Ex. 1 at 9 - 13; FFCL 19 - 24.

28. Petitioner was given a suspended sentence of one year in jail for willfully and unlawfully prescribing, administering, and dispensing Codeine to an habitual user (Count I of the Information) and a suspended sentence of 90 days in jail for each of the two counts of refilling a prescription for a dangerous drug without authorization (Counts II and III of the Information). I.G. Ex. 1 at 11, 12.

29. Petitioner was sentenced to pay $2246.27 in restitution to the Medi-Cal program, a "restitution fine" of $500, a fine of $5000, and a period of probation for five years. I.G. Ex. 1 at 11, 12, and 15.

30. Only Petitioner's pleas to the two misdemeanor offenses (Counts II and III of the Information) are relevant to my determination as to whether the I.G. had the authority to exclude Petitioner under section 1128(a)(1) of the Act. FFCL 20 - 25.

31. Petitioner's plea to the felony charge (Count I of the Information) is relevant only to the issue of Petitioner's trustworthiness and not to the authority of the I.G. to exclude Petitioner. Section 1128(a)(1) of the Act; I.G. Ex. 2; FFCL 20 - 21.

32. The June 22, 1987 date contained in Count II of the Information is a date that falls between the date Petitioner refilled prescription number 095212 for Medi-Cal recipient SV without authorization (June 9, 1987) and the date on which Medi-Cal issued a check to reimburse Petitioner for the unauthorized refill (June 25, 1987). Tr. 190 - 92, 210 - 17; I.G. Ex. 6, 7 at 1 - 4, 8.

33. The September 28, 1987 date contained in Count III of the Information is a date that falls between the date Petitioner refilled prescription number 084141 for Medi-Cal recipient GW without authorization (September 14, 1987) and the date on which Medi-Cal issued a check to reimburse Petitioner for the unauthorized refill (October 2, 1987). Tr. 190 - 92, 210 - 17; I.G. Ex. 6, 7 at 5 - 8, 8.

34. Medi-Cal paid for the drugs that Petitioner admitted, and was convicted of, refilling without authorization for SV and GW. Tr. 214 - 17; I.G. Ex. 1, 3, and 6 - 8; FFCL 13, 14, 16 - 20, 22 - 27.

35. Medi-Cal (Medicaid) is a State health care program as defined by the Social Security Act (Act). 42 U.S.C. § 1320a-7(h).

36. Petitioner was convicted of three criminal offenses, within the meaning of section 1128(i) of the Act. FFCL 27.

37. Petitioner was convicted of two criminal offenses related to the delivery of an item or service under the Medicaid program, within the meaning of section 1128(a)(1) of the Act. FFCL 13 - 36.

38. Sections 1128(a)(1) and 1128(c)(3)(B) of the Act provide for a minimum mandatory exclusion of five years.

Petitioner's exclusion for ten years is reasonable.

39. Petitioner admitted that he dispensed without a valid prescription or refilled prescriptions without authorization for the following drugs: Dyazide, Inderal, Naproxen, Kenalog Lotion, Hydrochlorothiazide, Hydralazine, Acetaminophen with Codeine, Phenergan with Codeine, Tenormin, Apresoline, Persantine, Dipyridamole, Talwin, Potassium HCL, Feldene, Butisol Sodium, Aldactazide, Anusol HC, Wyanoids HC, Meprobamate, Tagamet, Septra DS, and Mycostatin suspension. I.G. Ex. 3; Tr. 109 - 59.

40. The drug Dyazide is a diuretic (a drug that eliminates excess water in the body) that is used in the treatment of high blood pressure. The possible deleterious side effects from Dyazide include dizziness, mental confusion, and the altering of a patient's electrolytes (in this case potassium), which can lead to irregular heartbeat. Tr. 109 - 11.

41. Standard practice for the treatment of patients with Dyazide includes laboratory tests to check the patient's potassium levels. The laboratory tests should be performed twice weekly for the first month the patient is being treated with Dyazide, and then twice a year after that time. Tr. 110 - 11.

42. The drug Inderal is a medication that causes the heart to beat less rapidly and less forcefully, thus

causing a reduction in the patient's blood pressure. Inderal is used in the treatment of high blood pressure. The possible deleterious side effects from the use of Inderal include fainting, asthma, cardiac arrest, and irregular heartbeat. Tr. 111 - 15.

43. Standard practice for the treatment of patients with Inderal includes periodic monitoring of potassium levels and kidney function. Tr. 113 - 15.

44. Tenormin is the same type of drug as Inderal, i.e., it acts to decrease the heart rate and the force of the contraction of the heart muscle. The possible deleterious side effects from Tenormin are the same as Inderal. Tr. 125.

45. Standard practice for the treatment of patients with Tenormin is the same as that for Inderal. Tr. 125.

46. Hydrochlorothiazide is a diuretic that is used to treat high blood pressure. The possible deleterious side effects from Hydrochlorothiazide are the same as those from Dyazide. Tr. 119 - 20, 127.

47. Standard practice for patients undergoing treatment with Hydrochlorothiazide is the same as with Dyazide. Tr. 120, 127.

48. The combination of Hydrochlorothiazide and Dyazide being simultaneously administered to one patient is medically contradictory and potentially dangerous if the patient is not being medically monitored. Tr. 129 - 30.

49. Hydralazine is a drug that is used to treat high blood pressure. Hydralazine lowers a patient's blood pressure by relaxing the muscles around the veins. The possible deleterious side effects from Hydralazine include fainting and increased heart rate (tachycardia). Tr. 120 - 21.

50. Apresoline is the brand name for Hydralazine and has the same pharmacological effects and side effects as Hydralazine. Tr. 125 - 26.

51. Standard practice for treating patients with Hydralazine is periodic monitoring of the patient's blood pressure and heart rate. Tr. 121.

52. The standard practice for treating patients with Apresoline is the same as for treating patients with Hydralazine. FFCL 50 - 51.

53. Aldactazide is a diuretic drug similar to Dyazide, and is used in the treatment of high blood pressure. The possible deleterious side effects from Aldactazide are similar to Dyazide. Tr. 132; see Tr. 109 - 11.

54. Standard practice for the treatment of patients with Aldactazide is similar to the standard practice for treating patients with Dyazide. Tr. 132; see Tr. 110 - 11; FFCL 40 - 41, 53.

55. Potassium HCL is a drug which replaces potassium in the body. Tr. 128.

56. A patient receiving Potassium HCL also should receive laboratory blood testing to establish and maintain the proper potassium level. Tr. 128.

57. Improper potassium levels in the body can lead to irregular heartbeat. Tr. 119 - 20, 127, 132.

58. Feldene is a drug that is an anti-inflammatory agent and is used primarily to alleviate the symptoms of arthritis. The potential deleterious side effects of Feldene are ulceration of the stomach lining, gastrointestinal bleeding, and the loss of potassium from the body resulting from that bleeding. Tr. 130.

59. The drug Naproxen is a non-steroidal anti-inflammatory used primarily in the treatment of arthritis. The possible deleterious side effect from the use of Naproxen is the erosion of the stomach lining leading to gastrointestinal bleeding. Tr. 117 - 18.

60. Standard practice for treating patients with Naproxen is to alert the patient to the possibility of having black stools or other signs indicative of gastrointestinal bleeding, and, if a patient complained of these symptoms, to order laboratory testing to monitor the levels of iron and red blood cells present in the patient's blood. Tr. 117 - 18.

61. Petitioner dispensed Naproxen to a customer. There is insufficient evidence in the record to establish that the customer to whom Petitioner dispensed Naproxen without authorization was alerted to the signs indicative of gastrointestinal bleeding or received medical testing, in accordance with standard practice for persons being treated with Naproxen. I.G. Ex. 3; FFCL 60.

62. There are five schedules of controlled substances. Schedule I drugs are totally illegal and have no medical use. Schedule II drugs have a high abuse potential but

have some medical use. Schedule II includes morphine and demerol. Schedule III drugs have a medical use and have less potential for abuse than drugs classified as Schedule II. Codeine is classified as a Schedule III drug. Schedule IV drugs have a medical use and have less abuse potential than Schedule III drugs. Schedule V drugs have a medical use and have less abuse potential than Schedule IV drugs. Tr. 122 - 23.

63. Acetaminophen with Codeine is a combination of two drugs, Acetaminophen and Codeine. Acetaminophen is the generic name for Tylenol. Codeine is a Schedule III narcotic. The possible deleterious side effects of Codeine are nausea, vomiting, drowsiness, dizziness, and addiction. Tr. 120 - 24.

64. Talwin is a Schedule IV synthetic narcotic (opiate-related drug) that is used as a painkiller. The possible deleterious side effects from Talwin are drowsiness, addiction, and hallucinations. Tr. 133.

65. Talwin is a drug that is so widely abused that physicians are reluctant to prescribe it. Tr. 134.

66. Butisol Sodium is a Schedule III drug that is used to induce sleep or reduce anxiety symptoms. Butisol Sodium is a depressant that can cause drowsiness and has a relatively high risk of addiction. Tr. 131.

67. The medically approved use of Butisol Sodium is limited to two weeks. After two weeks of use, Butisol Sodium loses its effectiveness in treating the symptoms that it is supposed to alleviate and the patient is at risk of becoming addicted to the drug. Tr. 131 - 32.

68. A person who takes Butisol Sodium for more than two weeks may, upon the cessation of the use of the drug, experience withdrawal symptoms for up to two weeks. Tr. 132.

69. Petitioner refilled several prescriptions for Butisol Sodium without authorization for a customer over periods of time exceeding two months and in some instances lasting over five months. I.G. Ex. 3 at 10 - 14.

70. Petitioner refilled prescriptions for a customer without authorization for the drug Butisol Sodium over an extended period of time, in contradiction of the approved medical usage of the drug. I.G. Ex. 3 at 10 - 14; FFCL 66 - 69.

71. Meprobamate is a drug that is a Schedule IV sedative hypnotic, similar to valium. Meprobamate is used for the short term alleviation of the symptoms of anxiety disorders. Tr. 141.

72. Petitioner dispensed prescriptions for the drug Meprobamate for a customer without authorization over an extended period of time, in contradiction of the drug's medically indicated usage. Tr. 141; I.G. Ex. 3; FFCL 62, 71.

73. Petitioner filled and refilled prescriptions without authorization for the drug Talwin for customer LC from August 28, 1984 through February 13, 1987. I.G. Ex. 1, 3 at 17 - 19.

74. Petitioner filled and refilled prescriptions without authorization for the drug Meprobamate for LC from July 31, 1984 through January 26, 1987. I.G. Ex. 1; 3 at 19 - 20.

75. Petitioner filled and refilled prescriptions without authorization for the drug Acetaminophen with Codeine for LC from January 2, 1985 through October 16, 1987. I.G. Ex. 1; 3 at 20 - 22.

76. For over one year, Petitioner simultaneously filled and refilled prescriptions for Talwin, Meprobamate, and Acetaminophen with Codeine for LC. Tr. 138 - 144; I.G. Ex. 3 at 17 - 22; FFCL 73 - 75.

77. With the exception of the treatment of the pain caused by cancer, there is no legitimate medical purpose for a person to be receiving the drugs Talwin, Meprobamate, and Acetaminophen with Codeine simultaneously. Tr. 143.

78. There is no evidence in the record that LC, the person for whom Petitioner simultaneously and without authorization refilled prescriptions for Talwin, Meprobamate, and Acetaminophen with Codeine, had cancer.

79. From December 14, 1984 through September 3, 1987, Petitioner dispensed, without a valid prescription, and refilled without authorization, 24 prescriptions (120 refills) of Phenergan with Codeine for customer M. I.G. Ex. 3 at 22.

80. Phenergan with Codeine is a Schedule V narcotic that is typically prescribed for a two week period to treat the symptoms of a cold. Tr. 174.

81. There is no evidence in the record showing that there was a legitimate medical purpose for Petitioner to dispense without a valid prescription and refill without authorization 24 prescriptions (120 refills) for Phenergan with Codeine for M from December 14, 1984 through September 3, 1987. Tr. 144 - 145; FFCL 62, 79 - 80.

82. From October 20, 1983 through October 16, 1987, Petitioner provided 111 unauthorized refills of the drug Talwin to customer Cl. I.G. Ex. 3 at 16.

83. There is no evidence in the record from which I can conclude that there was a legitimate medical purpose for Petitioner to provide 111 refills of Talwin to Cl. Tr. 137 - 38; FFCL 82.

84. Petitioner was accommodating Cl's addiction to the drug Talwin. Tr. 137 - 38; FFCL 82 - 83.

85. Withdrawal symptoms for someone who is addicted to one type of drug manifest themselves as painful effects that are the opposite of the effect of the drug to which the person is addicted. For example, upon withdrawal a person who is addicted to depressants would experience hyperactivity, nervousness, insomnia, salivation and increased nerve activity. Tr. 132.

86. A pharmacist has a duty to inform a physician when he sees irregularities or any potential problems in the manner in which the physician is prescribing drugs. Tr. 154, 156.

87. A pharmacist has a duty to question a physician regarding any medically inappropriate medications prescribed by the physician. Tr. 156.

88. A pharmacist has a duty to warn patients about the risks involved in driving and similar tasks when he fills their prescriptions for medication that causes drowsiness or dizziness. Tr. 124.

89. There is insufficient evidence in the record to establish that Petitioner warned the persons to whom he provided, without authorization, prescriptions or refills that caused drowsiness, about the risks involved in driving and similar tasks. FFCL 62 - 64, 66, 71 - 76, 79 - 82.

90. A pharmacist may suggest alternative medications for a physician to prescribe, but the physician has the

authority to reject the pharmacist's suggestions. Tr. 156.

91. A pharmacist has a right not to fill a prescription if he does not think it is medically appropriate. Tr. 154.

92. A pharmacist may not prescribe medications for or treat patients. Tr. 155.

93. A pharmacist has no right to function as a doctor and prescribe medication, even if he believes that a doctor is not adequately treating the patient. Tr. 154 - 55.

94. If a physician does not authorize a prescription medication, that medication cannot be dispensed by anyone, including a pharmacist. Tr. 155, 248 - 49.

95. A pharmacist has no authority to order laboratory tests. Tr. 159.

96. Petitioner admitted that he dispensed without a valid prescription, or refilled prescriptions without authorization, over 800 prescription medications. I.G. Ex. 3.

97. Petitioner violated his duties as a pharmacist by dispensing more than 800 prescription medications without authorization from a physician. I.G. Ex. 1, 3; FFCL 39, 92 - 94, 96.[8]

98. Petitioner dispensed without authorization the drugs Hydrochlorothiazide and Dyazide simultaneously for the same person. I.G. Ex. 3 at 10 - 12; FFCL 39.

99. There is insufficient evidence in the record to establish that the person to whom Petitioner dispensed a combination of Hydrochlorothiazide and Dyazide was being

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[8] I use the terms "dispensed without authorization" or "dispensing without authorization" as a shorthand method throughout this Decision to refer to any incidents where Petitioner improperly dispensed a prescription drug without a valid prescription or refilled a prescription without authorization. Petitioner has not disputed that, at any time he dispensed a prescription medication without authorization, the customer to whom it was nominally dispensed actually received it.

medically monitored or was receiving any form of laboratory testing.

100. Petitioner's dispensing the drugs Hydrochlorothiazide and Dyazide simultaneously for a customer was a medically contradictory combination of drugs that could have been harmful to the customer. Tr. 129 - 45; FFCL 39 - 41, and 46 - 48.

101. Petitioner dispensed without authorization medications for customers over periods of time that were in excess of the medical usefulness of the drugs. Tr. 131 - 45; I.G. Ex. 3; FFCL 62, 66 - 72.

102. There is no evidence in the record establishing that any of the customers to whom Petitioner dispensed without authorization the drugs Dyazide, Inderal, Hydrochlorothiazide, Hydralazine (Apresoline), Tenormin, Potassium HCL, Naproxen and Aldactazide received any medical or laboratory testing prior to, or in the period following, the time Petitioner dispensed the drugs. FFCL 39.

103. Petitioner subjected a number of his customers to deleterious side effects and dangers to their health by dispensing without authorization the drugs Dyazide, Inderal, Hydrochlorothiazide, Hydralazine (Apresoline), Tenormin, Potassium HCL, Naproxen, and Aldactazide, although these customers were not receiving follow-up testing or medical monitoring, in accordance with standard practice for persons undergoing treatment with these drugs. Tr. 108 - 42, 247 - 48; I.G. Ex. 3; FFCL 39 - 61.

104. Petitioner subjected a number of his customers to the risk of drug addiction by dispensing without authorization the addictive drugs Talwin, Butisol Sodium, Meprobamate, Phenergan with Codeine, and Acetaminophen with Codeine. Tr. 108 - 42; I.G. Ex. 3; FFCL 62 - 85.

105. Petitioner violated his duty of care as a pharmacist by dispensing without authorization addictive drugs in quantities or intervals that allowed the persons who were receiving the drugs to abuse the drugs, become addicted to the drugs, or use the drugs in a manner inconsistent with their valid medical usage. Tr. 131 - 37, 141 - 50; I.G. Ex. 3; FFCL 39, and 62 - 95.

106. Persantine (Dipyridamole) is an anti-platelet (blood thinning) drug used to treat angina and prevent myocardial infarctions. The possible deleterious side effects from the use of Persantine are an increased risk

of bleeding or bruising, and low blood pressure. Tr. 125 - 27.

107. Persantine and Dipyridamole are the same drug. Persantine is the brand name and Dipyridamole is the generic name. Tr. 126.

108. Petitioner dispensed without authorization to customer H Persantine (Dipyridamole) from August 17, 1984 through October 13, 1987. FFCL 39; I.G. Ex. 3 at 6 - 9.

109. Petitioner subjected customer H to the risk of deleterious side effects by dispensing without authorization Persantine (Dipyridamole). FFCL 107 - 08.

110. Tagamet is a stomach medication that reduces the amount of acid released by the stomach and that is used for the treatment of ulcers. The possible deleterious side effect from the use of Tagamet is dizziness. Tr. 145 - 46.

111. Petitioner dispensed the drug Tagamet 45 times without authorization. I.G. Ex. 3 at 23 - 24.

112. By dispensing Tagamet without authorization 45 times for a customer, Petitioner subjected that customer to the detrimental side effect of dizziness from the use of this drug. FFCL 39 and 110 - 11; Tr. 146.

113. Kenalog lotion is a cortisone-type drug that is applied to the surface of the skin to treat inflammatory disorders of the skin like eczema and psoriasis. The possible deleterious side effects from the long term use of Kenalog lotion are thinning of the skin and a reduction in the body's ability to fight infection. Tr. 118 - 19.

114. There is insufficient evidence in the record to establish that the customer to whom Petitioner dispensed without authorization Kenalog lotion used this drug over a long period of time. I.G. Ex. 3; Tr. 118 - 19.

115. There is insufficient evidence in the record to establish that Petitioner, by dispensing without authorization Kenalog lotion, caused the person to whom the drug was dispensed to be subjected to any of the drug's potential detrimental side effects. I.G. Ex. 3, FFCL 113 - 14.

116. Anusol HC and Wyanoids HC are drugs that are used in the treatment of hemorrhoids. Tr. 133.

117. There is insufficient evidence in the record to establish that there are any potential detrimental side effects from the drugs Anusol HC and Wyanoids HC.

118. There is insufficient evidence in the record that Petitioner, by dispensing without authorization Anusol HC and Wyanoids HC, caused any of his customers to be subjected to detrimental side effects from these drugs. FFCL 116 - 17.

119. Septra DS is an antibiotic that is used in the treatment of urinary tract infections. Tr. 146.

120. There is insufficient evidence in the record to establish that Petitioner, by dispensing without authorization Septra DS, caused his customers to be subjected to any detrimental side effects. FFCL 39; Tr. 146.

121. Mycostatin suspension is a medication that is used to treat fungal infections within the mouth. Tr. 146.

122. There is insufficient evidence in the record to establish that Petitioner, by dispensing without authorization Mycostatin suspension, caused any of his customers to be subjected to any detrimental side effects. FFCL 39; Tr. 146.

123. Petitioner received and read the I.G.'s July 22, 1991 letter informing him that: 1) he was excluded from Medicare and any State health care program; 2) such exclusion would commence as of August 11, 1991; 3) payment would not be made to any entity Petitioner was serving as an employee or in any capacity for any services he provided after the effective date of the exclusion; and 4) if Petitioner submitted or caused to be submitted claims for items or services after the effective date of his exclusion, he could be subject to a civil monetary penalty. Tr. 259 - 62; I. G. Ex. 2 at 3 - 5.

124. Petitioner continued to fill or refill prescriptions for Medi-Cal recipients after he received and read the I.G.'s letter informing him of his exclusion and notifying him of the terms of his exclusion. Tr. 262 - 69.

125. Subsequent to August 11, 1991, Petitioner filled or refilled prescriptions for Medi-Cal recipients without ensuring that the programs would not be billed. He acknowledged that it was possible that the Medi-Cal program did receive claims for reimbursement for

prescription medications he dispensed after August 11, 1991. Tr. 250 - 51, 262 - 69.

126. Petitioner's assertions that he did not know or think he was excluded as of August 11, 1991 and that he did not know what it means to be excluded are not credible. Tr. 259 - 69; I.G. Ex. 2.

127. Petitioner has not made a meaningful effort to comply with the terms of his exclusion. FFCL 123 - 26.

128. That Petitioner has not made a meaningful effort to comply with the terms of his exclusion is evidence of his lack of trustworthiness to be a program provider. FFCL 127.

129. The California Department of Health Services suspended Petitioner from participation in the Medi-Cal program effective December 4, 1990. I.G. Ex. 2 at 16.

130. I find not credible Petitioner's assertions that he dispensed without authorization a large quantity of addictive drugs to LC, an habitual user, because of her chronic back problem and because he thought she was allowing her husband to use the drugs for his kidney stones. Tr. 241 - 45; FFCL 39, 62 - 65, and 73 - 77.

131. There is no evidence in the record that LC's husband had a valid prescription for any type of painkilling medication during the time Petitioner was dispensing without authorization painkilling medication for LC.

132. I find not credible Petitioner's assertion that LC's husband had a valid prescription for painkilling medication at the time that Petitioner was dispensing without authorization painkilling drugs for LC. Tr. 240 - 43; FFCL 130 - 31.

133. Petitioner's unsubstantiated assertion, even if true, that LC's husband had a valid prescription for painkilling medication at the time Petitioner was, without authorization, dispensing addictive painkilling medications for LC is an attempt to minimize responsibility for his actions, and is indicative of his lack of trustworthiness. FFCL 130 - 32.

134. Petitioner's assertion that he dispensed addictive drugs without authorization for LC because she and her husband could not always get to a doctor is not credible. FFCL 73 - 77; Tr. 241 - 43.

135. Petitioner's unsubstantiated assertion, even if true, that he dispensed drugs without authorization for LC because she and her husband could not always get to a doctor is an attempt to minimize responsibility for his actions and is indicative of his lack of trustworthiness. FFCL 134.

136. Petitioner violated his duty as a pharmacist when he dispensed prescription medication to LC although he knew that she was giving some of the drugs to her husband. Tr. 241 - 43; FFCL 76, 88, 92 - 94, 130 - 32, and 134.

137. Petitioner has demonstrated a consistent pattern of committing unprofessional acts which are in derogation of his duties as a pharmacist. FFCL 39, 97 - 105, and 136.

138. Petitioner has demonstrated a consistent pattern of committing acts that place program recipients and others at risk of drug addiction. FFCL 39, 62 - 85, 104, and 105.

139. Petitioner has demonstrated a consistent pattern of committing acts that place program recipients and others at risk from the detrimental side effects of unauthorized prescription drugs and from a lack of appropriate medical monitoring and follow-up care. FFCL 39 - 61.

140. Petitioner has demonstrated a willingness to commit criminal acts which are harmful to the Medicare and Medicaid programs. FFCL 13 - 20, 22, 29, 32 - 37.

141. Petitioner's sworn testimony at the administrative hearing is in direct conflict with an earlier sworn declaration he made during an investigation by the California Board of Pharmacy. I.G. Ex. 11 at 24; Tr. 255 - 56.

142. Petitioner's assertion that he dispensed prescription drugs without authorization because he was being mindful of the convenience of his customers is an attempt to minimize the seriousness of his actions and shows a reluctance to admit wrongdoing. Tr. 238.

143. Petitioner's assertion that his customers would have told him if he was placing any of them at risk is an attempt to minimize the seriousness of his actions, and shows a reluctance to admit wrongdoing. Tr. 247 - 48.

144. Petitioner's demeanor and testimony while under oath on the witness stand indicates a reluctance for him

to take full responsibility for his actions and a reluctance to admit wrongdoing. Tr. 237 - 69.

145. Petitioner believes that he helped some of his customers by dispensing prescription medication without authorization. I.G. Ex. 12.

146. Petitioner has dispensed prescription medication without authorization on more occasions than have been documented by the I.G.'s investigation. Tr. 253 - 54.

147. Petitioner does not fully comprehend or appreciate the seriousness of his dispensing prescription medication without authorization. FFCL 123 - 46.

148. The remedial purpose of section 1128 of the Act is to protect federally-funded health care programs and their beneficiaries and recipients from providers who have demonstrated by their conduct that they cannot be trusted to handle program funds or treat beneficiaries and recipients.

149. Petitioner has demonstrated a consistent pattern over almost four years of dispensing prescription medication without authorization. FFCL 39, 96, and 97; I.G. Ex. 3.

150. The financial loss to the Medi-Cal program resulting from Petitioner's criminal misconduct amounted to over $2246.27, a significant amount of money. Tr. 215 - 17; I.G. Ex. 1, 3.

151. The serious nature of Petitioner's conviction in State court is reflected in the fact that he was placed on probation for five years and ordered to pay fines totaling $5500. FFCL 29.

152. The serious nature of Petitioner's conduct is reflected by the State of California placing his pharmacy license on probationary status for a term of three years. FFCL 11 - 12.

153. Petitioner is not a trustworthy health care provider. FFCL 1 - 152.

154. A lengthy exclusion is needed in this case to satisfy the remedial purposes of the Act. FFCL 1 - 153.

155. The Secretary of the Department of Health and Human Services (the Secretary) delegated to the I.G. the authority to determine, impose and direct exclusions

pursuant to section 1128 of the Act. 48 Fed. Reg. 21662 (1983).

156. The ten-year exclusion imposed and directed against Petitioner by the I.G. is reasonable. FFCL 1 - 155.

The regulations published on January 29, 1992 do not apply to this case.

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

158. 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(a)(1) of the Act. 42 C.F.R. § 1001.102.

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

160. The regulations published on January 29, 1992 at 57 Fed. Reg. 3298 et seq. (42 C.F.R. § 1001 et seq.) and January 22, 1993 at 58 Fed. Reg. 5617 - 5618 are not applicable to this pending case (the I.G.'s determination to exclude was dated July 22, 1991), since such application would strip Petitioner retroactively of rights vested prior to January 29, 1992. Tajammul H. Bhatti, DAB 1415, at 12 (1993); Behrooz Bassim, M.D., DAB 1333, at 5 - 9 (1992); Narinder Saini, M.D., DAB CR217 (1992), aff'd, DAB 1371 (1992); Charles J. Barranco, M.D., DAB CR187 (1992); Bruce G. Livingston, M.D., DAB CR202 (1992); Syed Hussaini, DAB CR193 (1992).

161. My adjudication of the length of the exclusion in this case is not governed by the criteria contained in 42 C.F.R. § 1001.102. FFCL 157 - 60.

RATIONALE

1. Petitioner was "convicted" within the meaning of section 1128(i) of the Act.

Section 1128(i) provides: "For purposes of subsections (a) and (b) (of section 1128 the Act), an individual or entity is considered to have been "convicted" of a criminal offense ... when a plea of nolo contendere by the individual or entity has been accepted by a Federal, State or local court... ." The record indicates, and Petitioner does not dispute that, on April 20, 1990, Petitioner pled nolo contendere to all three counts contained in Information No. 28598, specifically, two misdemeanor counts of unlawfully refilling a prescription for a dangerous drug without authorization, and one felony count of willfully and unlawfully prescribing, administering, and dispensing Codeine to an habitual user. The court accepted Petitioner's plea. FFCL 27. Petitioner was therefore "convicted" of a criminal offense as that term is defined in the Act.

2. Petitioner was convicted of a criminal offense related to the Medicare or Medicaid programs.

Section 1128(a)(1) of the Act mandates the exclusion of individuals who have been convicted of a criminal offense related to the delivery of an item or service under the Medicare or Medicaid programs.

Petitioner contends that the offenses to which he pled nolo contendere were not related to the delivery of an item or service under Medicare. On that basis, Petitioner contends that this case should be governed by the permissive exclusion provisions of section 1128(b)(3), not the mandatory exclusion provisions of section 1128(a)(1) of the Act.[9] Petitioner's argument is that while some of the unauthorized prescription refills were paid for by the Medi-Cal program, his conviction on the two misdemeanor counts was related only to those prescriptions he refilled on June 22, 1987 and September 28, 1987, and the I.G. has not been able to show that Medi-Cal paid for the prescriptions referenced in his

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[9] Section 1128(b)(3) of the Act provides for a permissive exclusion for "[A]ny individual or entity that is convicted, under Federal or State law, of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." Under section 1128(b)(3), there is no requirement that the conviction be program-related.

conviction. Petitioner alleges that the patients themselves, and not the Medi-Cal program, paid for the specific prescriptions at issue. P. Br. 9 - 15.

Petitioner contends that there is no evidence that establishes that the three offenses for which he was convicted relates to the delivery of a Medi-Cal item or service. With respect to Count I of the Information, he is correct. There is no evidence in the record from which I can conclude that Petitioner's plea to the felony charge of prescribing Codeine to an habitual user is program-related. However, the I.G. has not based Petitioner's exclusion on his conviction for prescribing Codeine to an habitual user. Accordingly, I can consider Petitioner's conviction for prescribing Codeine to an habitual user only as it relates to Petitioner's trustworthiness.

In analyzing whether Counts II and III are program-related, my analysis begins with the court documents. The court documents, on their face, do not establish that Petitioner's conviction is program-related. Where a conviction is not, on its face, program-related, my determination as to whether a conviction is program-related involves consideration of extrinsic evidence of all of the relevant facts and circumstances surrounding the conviction. Francis Craven, DAB CR143 (1991); DeWayne Franzen, DAB 1165 (1990); Carolyn Westin, DAB 1381, at 11 - 12 (1993).

Accordingly, I must look at all of the facts and circumstances surrounding Petitioner's conviction to determine whether it is program-related.

Petitioner's contention that his conviction for Counts II and III of the Information is not program related is without merit. Petitioner has not disputed that Medi-Cal recipients SV and GW received unauthorized refills from Petitioner on June 9, 1987 and September 14, 1987, respectively. However, Petitioner has contended that there is no evidence from which I can conclude that Petitioner actually refilled prescriptions on June 22 and September 28, 1987, or that he billed to, or was paid by, the Medi-Cal program for those prescriptions.

While the Information specifically mentions the dates of June 22 and September 28, it does so with the qualifying phrase "on or about." Mr. Temmerman's testimony and the record as a whole establish that the actual refills on which the charges in Counts II and III of the Information were based, and to which Petitioner pled nolo contendere, occurred not on June 22 and September 28, 1987, but

rather on June 9 and September 14, 1987.[10] The June 22 and September 28, 1987 dates appearing in the Information were selected because they fall between the date Petitioner unlawfully refilled the prescription and the date Medi-Cal program paid the improper claims. These dates could conceivably be the dates that Medi-Cal authorized the payment for the unlawful prescriptions; however, there is no information in the record that ties either June 22 or September 28, 1987 to a specific event in the chain of events which culminated with the payment by Medi-Cal for the unauthorized refills referenced in the Information.

Mr Temmerman testified that when these types of charges are made against a criminal defendant, the prosecutor does not always know the date that the defendant submitted the claim for reimbursement to the Medi-Cal program. The prosecutor likely knows the date the claim was paid and the date the pharmacist dispensed the medication without authorization. Also, as Mr. Temmerman testified, the prosecutor does not always know the date that the Medi-Cal program relied on the defendant's billing or the date that the Medi-Cal program authorized payment of the claim submitted by the defendant. Therefore, the prosecutor customarily uses dates that may fall somewhere between the date the medication was dispensed and the date actual payment was made to the defendant by the Medi-Cal program. Tr. 214 - 17.

a. Count XIII of the Felony Complaint became Count II of the Information.

Count XIII of the original felony complaint charged that Petitioner did "willfully and unlawfully and with intent to defraud, present and cause to be presented to the State of California for allowance or payment a false and fraudulent Medi-Cal claim, to wit, number 716863255101 for services rendered to beneficiary SV on June 9 and June 22, 1987." I.G. Ex. 1. As Mr. Temmerman testified, pursuant to a plea bargain arrangement with Petitioner and his counsel, Count XIII of the felony complaint was reduced to a misdemeanor. I.G. Ex. 8; Tr. 211. As a result, Count XIII of the felony was re-charged in Count II of the Information. I.G. Ex. 8; Tr. 211. Count II of the Information states that "on or about June 22, 1987, [Petitioner] did refill a prescription for a dangerous drug for SV without authorization from the original

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[10] Mr. Temmerman is the prosecuting attorney who handled Petitioner's criminal case and subsequent plea to Counts I - III of the Information.

prescriber." As Mr. Temmerman admitted, it would have been more appropriate to have the Information reflect the date that Petitioner actually refilled the prescription without authorization. I.G. Ex. 8; Tr. 210 - 12. Instead, the person who drafted the Information chose a date that fell somewhere between the time Petitioner refilled the prescription without authorization and the time Medi-Cal paid for the unauthorized refill. I.G. Ex. 8; Tr. 210 - 14.

b. Count XV of the Felony Complaint became Count III of the Information.

Count XV of the original felony complaint charged that Petitioner did "willfully and unlawfully with intent to defraud, present and cause to be presented to the State of California for allowance or payment a false and fraudulent Medi-Cal claim, to wit, number 726630595001." I.G. Ex. 1. Again, pursuant to a plea bargain arrangement with Petitioner and his counsel, Count XV of the felony complaint was reduced to a misdemeanor and recharged as Count III in the Information. I.G. Ex. 8. Count III of the Information states that on or about September 28, 1987, Petitioner did refill a prescription for a dangerous drug for GW, without authorization from the original prescriber. Here again, Mr. Temmerman admitted that it would have been more appropriate had the Information reflected the date that Petitioner actually refilled the prescription without authorization. I.G. Ex. 8; Tr. 213 - 14. Again, the person who drafted the Information chose a date (September 28, 1987) that fell somewhere between the time Petitioner refilled the prescription without authorization and the time Medi-Cal paid for the unauthorized refill. I.G. Ex. 8; Tr. 213 - 14.

In both instances, Petitioner was charged with a felony offense and subsequently pled to a misdemeanor charge based on the same set of underlying facts. However, on their face, the documents of conviction do not provide enough information to allow me to decide that Petitioner's convictions for the two misdemeanors are program-related. This is due, at least in part, to the fact that Petitioner's attorney at the criminal proceedings did not want his client to plead to a charge that, on its face, was related to the Medi-Cal program. Tr. 208, 220 - 22. Apparently, to that end, the charges in the Information do not contain specific references to the Medi-Cal program, whereas the charges in the Felony Complaint do make reference to the Medi-Cal program. I.G. Ex. 1. It is apparent from Mr. Temmerman's testimony that Petitioner's criminal attorney at the time

of the plea bargain was well aware of the possibility of a subsequent administrative sanction and wanted to give his client a chance to prevail. Tr. 220 - 22.[11]

c. Counts II and III of the Information are program-related.

My examination of the evidence submitted by the I.G. reveals that Petitioner refilled two prescriptions for SV on June 9, 1987.[12] Petitioner was charged in Count XIII of the felony complaint with submitting a false claim number 7168634255101 for services rendered to recipient SV. Count II of the Information mentions SV, but does not contain any claim number. Mr. Temmerman testified that he based the charges contained in Count II in the Information on the same transaction that was documented in Count XIII of the felony complaint, namely the submission by Petitioner of Medi-Cal claim number 7168634255101. This number, minus the last two digits, is the Medi-Cal claim control number that appears in the pharmacy services statement (claim for services) that was submitted by Petitioner to the Medi-Cal program for reimbursement, and for which Petitioner was ultimately reimbursed.[13] I.G. Ex. 7 at 1 - 4; Tr. 214 - 17.

Tracking the Medi-Cal claim number mentioned in Count XIII of the felony complaint, the unrefuted documentary

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[11] Mr. Temmerman informed Petitioner's criminal attorney that he was indifferent as to whether Petitioner pled to Medi-Cal fraud, as long as the charges were representative of the offenses committed by Petitioner. Tr. 208. Mr. Temmerman further informed Petitioner's criminal attorney that Petitioner would still be subject to an administrative sanction because he was pleading to dispensing drugs for which the Medi-Cal program paid. Tr. 221.

[12] The evidence indicates that Petitioner refilled two separate prescriptions for SV on June 9, 1987. I.G. Ex. 7 at 2. However, only one of these refills has the claim control number of 7168634255101, which matches the claim control number stated in Count XIII of the felony complaint.

[13] The claim for services submitted by Petitioner reveals that, on June 9, 1987, Petitioner refilled prescription number 095212 for Medi-Cal recipient 54300086308002. As stated earlier, Medi-Cal recipient 54300086308002 is SV. I.G. Ex. 7 at 1.

evidence submitted by the I.G. shows that Petitioner provided a prescription refill, number 095212, to SV on June 9, 1987. I.G. Ex. 7; Tr. 215. It establishes also that, on June 16, 1987, Petitioner submitted a claim for reimbursement to Medi-Cal for that same refill. I.G. Ex. 7 at 1; Tr. 215. Lastly, it shows that on June 25, 1987, Medi-Cal authorized a check to be sent to Petitioner for that same unauthorized prescription refill and that Petitioner received reimbursement for the refill of prescription number 095212. I.G. Ex. 7 at 3 - 4; Tr. 216.[14] Both at the hearing and in an affidavit, Mr. Temmerman specifically identified this documentation as that which he used to charge Petitioner in Count II of the Information. I.G. Ex. 8; Tr. 214 - 17.

The Medi-Cal claim control number listed in Count XV of the felony complaint is 726630595001. Mr. Temmerman testified that he based the charges contained in Count III in the Information on the same transaction that was documented in Count XV of the felony complaint, namely the submission by Petitioner of Medi-Cal claim number 726630595001, for the refill of GW's prescription. This same claim number (minus the last two digits), in conjunction with this particular Medi-Cal recipient's name and Medi-Cal number, appear in the pharmacy services statement (claim for services) that was submitted by Petitioner to the Medi-Cal program for reimbursement.[15] I.G. Ex. 7 at 5; Tr. 214 - 17.

The unrefuted documentary evidence establishes that, on September 14, 1987, Petitioner provided Medi-Cal recipient GW with an unauthorized refill of her prescription. I.G. Ex. 1, 7 at 5 - 6. Petitioner submitted a claim to Medi-Cal for reimbursement for that refill. I.G. Ex. 7 at 5 - 6. Mr. Temmerman testified that Petitioner's September 14, 1987 unauthorized refill of GW's prescription (contained in Count XV of the felony complaint) was the specific transaction for which Petitioner was charged in Count III of the Information. I.G. Ex. 8; Tr. 216 - 17. Lastly, the documentary

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[14] The reimbursement check that Petitioner received in the amount of $623.62 includes payment of $35.12 for prescription number 095212. I.G. Ex. 7 at 2 - 4.

[15] The claim for services submitted by Petitioner reveals that, on June 9, 1987, Petitioner refilled prescription number 095212 for Medi-Cal recipient 54300086308002. As stated earlier, Medi-Cal recipient 54300086308002 is SV. I.G. Ex. 7 at 1.

evidence establishes that, on October 2, 1987, Medi-Cal issued a check to Plaza Pharmacy for the unauthorized refill.[16] I.G. Ex. 7 at 6 - 8; Tr. 216 - 17.

Petitioner provided unauthorized refills of prescriptions to SV and GW on June 9 and September 14, 1987, respectively. The I.G. has shown that both SV and GW were Medi-Cal recipients on June 9, 1987 and September 14, 1987, respectively.[17] The I.G. has shown also that both SV and GW were customers of Plaza Pharmacy, where they both routinely had their Medi-Cal prescriptions refilled. I.G. Ex. 5. The I.G. has established that the Medi-Cal program reimbursed Petitioner for those same refills by issuing checks to Plaza Pharmacy. Petitioner has not disputed that he was the owner and operator of Plaza Pharmacy.[18] Additionally, the I.G. provided concise and pertinent testimony from the prosecuting attorney in Petitioner's criminal case. Moreover, Petitioner was ordered by the sentencing court to pay restitution to the Medi-Cal program in the amount of $2246.27. I.G. Ex. 1. This fact lends additional support to Mr. Temmerman's testimony that Counts II and III of the Information are program-related. The record as a whole provides the necessary link between the charges in Counts II and III of the Information and the unauthorized refills documented in I.G. Ex. 7 to establish that the transactions in Counts II and III for which Petitioner was convicted were program related.

An appellate panel of the Departmental Appeals Board (DAB) has held that an offense is related to the delivery

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[16] The evidence establishes that the Medi-Cal program issued a check to Petitioner on October 2, 1987, that was for payment of a number of his claims for reimbursement for services, including the specific refill at issue here. I.G. Ex. 7 at 5 - 8. Plaza Pharmacy cashed this check on October 7, 1987. I.G. Ex. 7 at 7 - 8.

[17] During all times relevant to this case, SV's Medi-Cal recipient number was 54300086308002. I.G. Ex. 5 at 3; 7 at 1 - 2. GW's Medi-Cal recipient number, during all times relevant to this case, was 54109568487459. I.G. Ex. 7 at 5.

[18] Petitioner has not disputed that, during the relevant time period, he was the owner and operator of Plaza Pharmacy. Pharmacy permit number AB16487 was issued to Petitioner to do business as Plaza Pharmacy. I.G. Ex. 4 at 27; FFCL 1 - 2.

of an item or service where there is a common sense connection between an offense and the delivery of an item or service under Medicare and Medicaid. Thelma Walley, DAB 1367, at 9 (1993), citing Boris Lipovsky, M.D., DAB 1363 (1992). The evidence in this case, like that in Walley, establishes a common sense connection between Petitioner's criminal conviction and the delivery of a Medicare item or service. Petitioner was convicted of two counts of refilling a prescription without authorization. The persons for whom Petitioner refilled the prescriptions were Medi-Cal recipients at the time. Petitioner submitted the claims to, and was reimbursed by, the Medi-Cal program for those same prescriptions. Under the criteria enunciated in Walley, Petitioner's conviction is program-related.

It has been held also that "the submission of a bill or claim for Medicaid reimbursement is the necessary step, following the delivery of the item or service to bring the 'item' within the purview of the program." Jack W. Greene, DAB 1078 (1989), aff'd sub nom. Greene v. Sullivan, 731 F. Supp. 835 and 838 (E.D. Tenn. 1990). In this case, Petitioner was convicted of two counts of refilling a prescription without authorization. The evidence establishes that Petitioner refilled prescriptions for two Medi-Cal recipients without authorization. Petitioner then submitted claims for reimbursement to the Medi-Cal program for the unauthorized refills. Accordingly, under the Greene analysis, Petitioner's criminal conviction is program-related.

Lastly, a criminal offense has been found to meet the statutory test where either the Medicare or the Medicaid program is the victim of the crime. Napoleon S. Maminta, M.D., DAB 1135 (1990). In this case, the Medicaid program is one of the victims of Petitioner's crime. Through Petitioner's criminal actions, Medicaid (via Medi-Cal) reimbursed for unauthorized refills and Petitioner received reimbursement to which he was not entitled. Petitioner's refilling of the two prescriptions in question therefore victimized the Medi-Cal program by inducing it to pay for refills that were unauthorized and illegal.

The evidence taken in its entirety establishes that the offenses to which Petitioner pled were related to the Medi-Cal program. The record establishes that Petitioner submitted two bills to Medi-Cal for two unauthorized refills he provided to two Medi-Cal recipients. The two refills that formed the basis for the charges to which Petitioner pled guilty have been specifically identified

by the I.G. by reference numbers on the Medi-Cal billing documentation. The record establishes also that Petitioner received reimbursement from the Medi-Cal program for the two unauthorized refills. As shown above, the record supports that Petitioner's criminal offense was program-related under any of three relevant tests. Petitioner was therefore convicted of a criminal offense within the meaning of section 1128(a)(1) of the Act.

3. The parol evidence rule is not a bar to Mr. Temmerman's testimony.

Petitioner argues that Mr. Temmerman's testimony is not admissible because of the parol evidence rule. According to Petitioner, the parol evidence rule mandates that

> extrinsic evidence is not admissible for the purpose of varying or contradicting judicial or official records or written instruments that dispose of property or that are contractual in nature, and that are valid, complete, unambiguous and unaffected by accident or mistake.

P. Br. at 13.

Petitioner contends that, as parol evidence, the testimony of Mr. Temmerman is not admissible to explain or elaborate upon Counts II and III of the Information. Petitioner's analysis is not correct. First, in order for the parol evidence rule to apply, the extrinsic evidence must be introduced for the purpose of varying or contradicting judicial records that are valid, complete, unambiguous, and unaffected by accident or mistake. However, Mr. Temmerman's testimony did not serve to contradict the documents of conviction, it merely elaborated upon them. The documents of conviction were, on their face, somewhat ambiguous because they contained the phrase "on or about."

Moreover, the conviction documents were "affected by accident or mistake" because the specific dates contained in them were not the dates Petitioner actually refilled the prescriptions. Instead, the date appearing in the Information were dates chosen that were somewhere between the date the unauthorized refill occurred and the date Medi-Cal paid for the drugs. Although the charges in the Information contain the phrase "on or about", the relatedness between Petitioner's misconduct and Medi-Cal would be more clearly seen if the dates on which Petitioner refilled the prescriptions had appeared in the two misdemeanor counts.

Mr. Temmerman's testimony established that the initial felony counts that were filed against Petitioner (Counts XIII and XV) contained both the refill and payment dates. When the plea bargain arrangement was reached with Petitioner, the refill date was not kept in the document, although, according to Mr. Temmerman, it should have been. To the extent that the refill dates should have been included, the charges against Petitioner were "affected by accident or mistake." Therefore, by Petitioner's own definition, Mr. Temmerman's testimony is not parol evidence because the documents were affected by the accident or mistake of inadvertently omitting the refill dates.

Second, Petitioner's objection to Mr. Temmerman's testimony assumes that my authority in hearing and deciding exclusion cases is limited solely to a review of the conviction documents. This assumption is not correct. Section 205(b) of the Act provides for a de novo hearing, under which I can consider all relevant evidence to determine whether a Petitioner should be excluded. In several decisions, administrative law judges and appellate panels reviewing those decisions have held that we are not confined to a mere review of the conviction documents in determining whether a petitioner's conviction is program-related. Where a conviction is not, on its face, program-related, my determination as to whether a conviction is program-related involves consideration of extrinsic evidence of all of the relevant facts and circumstances surrounding the conviction. Francis Craven, DAB CR143 (1991); DeWayne Franzen, DAB 1165 (1990); H. Gene Blankenship, DAB CR42 (1989); Carolyn Westin, DAB 1381, at 11 - 12 (1993).

Petitioner did not object to this evidence when it was offered at the hearing. From the time he received the I.G.'s witness list, approximately one month prior to the hearing, Petitioner was on notice that the I.G. would call Mr. Temmerman to testify. Petitioner also was on notice of the general substance and nature of the testimony the I.G. intended to elicit from Mr. Temmerman.

Third, Petitioner voiced no objection to the proposed testimony of Mr. Temmerman at any time during the prehearing process. Nor did Petitioner voice any objection to Mr. Temmerman's testimony on the basis of parol evidence at the hearing on September 15 and 16, 1992. Petitioner did not mention this parol evidence argument until he filed his post-hearing brief on December 3, 1992. Therefore, Petitioner's objection to Mr. Temmerman's testimony on the basis of parol evidence

is untimely. To permit Petitioner to raise such an eleventh hour objection, where he had ample opportunity to raise it earlier, would be unfair and prejudicial to the I.G. in that there would be no opportunity to offer other evidence in lieu of Mr. Temmerman's testimony.

Accordingly, I conclude that Petitioner's objection to Mr. Temmerman's testimony on the basis of parol evidence is without merit and untimely.

4. The I.G. was required to exclude Petitioner for a minimum period of five years.

Petitioner argues that even if it is determined that he was convicted of a program related offense, he is subject to the permissive exclusion provisions of section 1128(b), not to the mandatory exclusion provisions of section 1128(a) of the Act. P. Br. 8 - 15. It is arguable that Petitioner was convicted of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance, within the meaning of section 1128(b)(3) of the Act. However, it is well settled that if an individual or entity is convicted of a program-related offense under section 1128(a), the Secretary must impose an exclusion under that section. Maminta at 14; Greene, DAB 1078, at 9 - 11 (1989); Charles K. Wheeler and Joan K. Todd, DAB 1123, at 6 - 7 (1990).

In Greene and Wheeler, an appellate panel of the DAB specifically found that the I.G. has no discretion but to impose an exclusion under the mandatory provisions of section 1128(a), even where the petitioner's offense arguably could be classified as a permissive exclusion. Greene at 9 - 11; Wheeler at 6 - 7. The ALJ in Greene conceded that if the permissive exclusion provisions are read in isolation, there are instances in which they would literally encompass the offense for which a petitioner was convicted. Jack W. Greene, DAB CR56, at 13 (1989). However, both the ALJ and the appellate panel interpreted the presence of the mandatory exclusion provisions of section 1128(a) to mean that the permissive exclusion provisions apply only to instances where an individual has not been convicted of a criminal offense related to the delivery of a health care item or service under Medicare or Medicaid. Greene DAB CR56, at 13 (1989); DAB 1078, at 9 - 10 (1989).

As I have determined that Petitioner's conviction is for an offense related to the delivery of an item or service under Medicaid, Maminta, Greene, and Wheeler support my holding that the I.G. had no discretion but to impose an

exclusion of no less than five years upon Petitioner, pursuant to sections 1128(a)(1) and 1128(c)(3)(B) of the Act.

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

On January 29, 1992, the Secretary published regulations (Parts 1001 - 1007) (hereafter new regulations) pertaining to his authority under the Medicare and Medicaid Patient and Program Protection Act (MMPPPA), Public Law 100-93, to exclude individuals and entities from reimbursement for services rendered in connection with the Medicare and Medicaid programs.[19] These new regulations also included amendments to the civil money penalty authority of the Secretary under the MMPPPA. For purposes of this proceeding, the specific regulatory provisions relating to mandatory exclusions under section 1128(a)(1) of the Act (section 1001.102) and appeals of such exclusions (Part 1005) must be considered in terms of their applicability to this case.
The I.G. argues that the new regulations became effective upon publication on January 29, 1992. Petitioner argues that the new regulations should not be applied to this case because his hearing request was made prior to the publication of the new regulations. Tr. 143. Prior to the new regulations, when determining whether the length of an exclusion imposed and directed against the party by the I.G. was reasonable, administrative law judges usually evaluated an excluded party's "trustworthiness" in order to gauge the risk that party might pose in terms of the harm Congress sought to prevent. Appellate panels of the DAB have approved the use of the term "trustworthiness" as a shorthand term for those cumulative factors which govern the assessment of whether a period of exclusion imposed by the I.G. is reasonable. See, Hanlester Network, et al., DAB 1347, at 45 - 46 (1992); Bassim at 13.

The new regulations affect procedural and substantive changes with respect to the imposition of exclusions. 42 C.F.R. Parts 1001 - 1007; 57 Fed. Reg. 3298 - 3358 (1992). For example, the new regulations mandate that, with regard to exclusions directed and imposed by the I.G. in accordance with section 1128(a)(1) in excess of the mandatory minimum five year period, only the specific factors enumerated in section 1001.102(b) are to be considered a basis for lengthening the period of

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[19] These regulations can be found at 42 C.F.R. § 1001 et seq., 57 Fed. Reg. 3298 - 3358 (1992).

exclusion. 42 C.F.R. § 1001.102. Only if one or more of the aggravating factors listed in section 1001.102(b) justifies an exclusion longer than five years can the specific mitigating factors listed in section 1001.102(c) be considered. 42 C.F.R. § 1001.102(b). It is undisputed that the new 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 his trustworthiness to provide care.[20] Such regulations also affect the procedural rights of Petitioners in light of the limitations on the authority of the ALJ to reduce to zero an exclusion mandated by the I.G. See 42 C.F.R. § 1005.4(c)(6).

I conclude that my review of the reasonableness of the exclusion imposed and directed against Petitioner is not governed by the criteria enumerated in the new regulations. The new regulations substantially alter the due process rights of Petitioners to have a full de novo review of the I.G.'s determination to exclude them. Bruce G. Livingston, D.O., DAB CR202 (1992) (Livingston); Charles J. Barranco, M.D., DAB CR187 (1992) (Barranco); Syed Hussaini, DAB CR193 (1992); Steven Herlich, DAB CR197 (1992); Stephen J. Willig, DAB CR192 (1992); Sukumar Roy, M.D., DAB CR205 (1992); Aloysius Murcko, M.D., DAB CR189 (1992); Narinder Saini, M.D., DAB CR217 (1992) (Saini); Tajammul H. Bhatti, M.D., DAB CR245 (1992); Anthony Accaputo, Jr., DAB CR249 (1993). An appellate panel of the Departmental Appeals Board (DAB) held they do not apply in cases involving exclusion determinations made prior to the regulations' publication date. Behrooz Bassim, M.D., DAB 1333, at 5 - 9 (1992). This view was recently reaffirmed by an appellate panel of the DAB in the case of Tajammul H. Bhatti, M.D., DAB 1415, at 12 (1993).

In holding that the new regulations were inconsistent with prior DAB decisions on the scope of review and the length of an exclusion and in holding that the new regulations represent substantive changes in the law, the appellate panel in Bassim noted the distinction between the effective date of a new regulation and the permissible effect of a regulation. Bassim at 6. The

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[20] Moreover, 42 C.F.R. § 1001.102 limits my consideration of aggravating factors to those specifically mentioned therein, and could, under the appropriate scenario, impair the I.G.'s ability to demonstrate a petitioner is deserving of a lengthy exclusion.

panel held that the new regulations were inconsistent with prior DAB decisions on the scope of review and the length of an exclusion and that the new regulations represent substantive changes in the law. Bassim at 6 - 7. The panel determined that the Secretary did not intend to retroactively alter the substantive rights of petitioners with the new regulations. Bassim at 8 - 9.

The panel cited several rationales to support its determination that the new regulations were not to be applied retroactively to cases where the petitioner had been excluded prior to January 29, 1992. The panel noted that the concept of retroactivity is not favored in law and that the agency's authority to promulgate rules having a retroactive effect must be granted expressly by Congress. Bassim at 6. Moreover, the panel noted also that even with such a statutory grant of authority, the agency's rules will not be applied retroactively unless their language clearly requires this result. Bassim at 6.

Congress did not authorize the Secretary to promulgate rules having a retroactive effect, and there was no statement by the Secretary that the new regulations were intended to apply retroactively to achieve substantive changes. In the panel's view, if the Secretary had intended to effect substantive changes in pending cases, this intent would have been expressly stated given the resultant administrative complications in the appeals process as well as the potential prejudice to petitioners. Bassim at 7. The panel held that parts of the new regulations which affect substantive changes may be applied only to cases in which the I.G.'s Notice of Intent to Exclude, Notice of Exclusion, or Notice of Proposal to Exclude is dated on or after January 29, 1992. Bassim at 9.

I further conclude that it was not the Secretary's intent to retroactively apply the new regulations to unlawfully strip parties, including Petitioner, of previously vested rights. Therefore, the new Part 1001 regulations were not intended to apply to cases pending as of the date of their publication (assuming they establish criteria for administrative review of exclusions). I have previously addressed this issue in depth in my decisions in Barranco at 16 - 27 and Livingston at 8 - 10. ALJ Steven T. Kessel has addressed this issue in depth in his decision in Saini at 11 - 19. For purposes of this case, I incorporate the rationale in Barranco, Livingston, and Saini that Petitioner's de novo hearing rights would be substantially adversely affected and it would be

manifestly unjust to retroactively apply the January 29, 1992 regulations.

6. A clarification of the new regulations is not applicable to my determination in this case.

On January 22, 1993, the Secretary published a clarification of the January 29, 1992 regulations (hereafter referred to as clarification) that purported to make the regulations of Part 1001:

> applicable and binding on the Office of Inspector General (OIG) in imposing and proposing exclusions, as well as Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG (and, where applicable, in imposing exclusions proposed by the OIG).

42 C.F.R. § 1001.1; 58 Fed. Reg. 5618 (1993).

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

At the time he signed the clarification on December 18, 1992, Secretary Sullivan, or those to whom he entrusted the drafting of the clarification, must be assumed to have been aware of the DAB appellate panel's decision in Bassim, which was issued on May 28, 1992. More importantly, the DAB is delegated authority to make final interpretations of law on behalf of the Secretary upon review of ALJ decisions. Gideon M. Kioko, M.D., DAB CR256 (1993). Thus, in effect the DAB appellate panel was speaking for the Secretary when it concluded that the new regulations were not to apply retroactively to cases pending prior to promulgation of the new regulations. It gave its rationale as follows:

> In our view, if the Secretary had intended to effect substantive changes in pending cases, this intent would have been expressly stated since this effect would create administrative complications in the

> appeals process, as well as potential prejudice for petitioners.
>
> * * * * *
>
> In sum, absent specific instructions in the Act or the preamble to the 1992 Regulations directing that they apply to pending cases, we conclude that the Secretary did not intend to alter a petitioner's substantive rights in such fundamental ways as suggested by the I.G. We also conclude that portions of the 1992 Regulations which change substantive law may permissibly be applied only to cases in which the I.G.'s Notice of Intent to Exclude, Notice of Exclusion, or Notice of Proposal to Exclude is dated on or after January 29, 1992.

Bassim at 7 - 9.

Contrary to expressly stating his intent or providing specific instructions directing that the new regulations apply retroactively to cases pending prior to January 29, 1992, the Secretary emphasized that such regulation did not make "any substantive changes" to the "scope" of the new regulations. 58 Fed. Reg. 5618. No other conclusion can be reached but that in the clarification the Secretary did not modify the appellate panel decision in Bassim, which held that the new regulations do not apply to cases pending prior to January 29, 1992. This case was pending as of that date.

At my request, the parties filed supplemental briefs to address the applicability and impact of the new regulations on this case. I deemed this especially necessary since the parties had prepared for this hearing under the assumption that the case would be heard and decided under the trustworthiness standard. It was not until several months after the September 15, 1992 hearing, on January 22, 1993, that the clarification was published.

The parties were specifically asked whether they wished to submit additional evidence in light of the clarification. Both parties declined, but requested that they be given an opportunity to brief the issue of the applicability and effect of the new regulations and the clarification on this case.

Petitioner contends that if I decide this case under the framework enunciated in the clarification, it would constitute an unlawful retroactive application of the

regulations against him. Petitioner contends that it would violate his rights to a de novo hearing, because my determination would be reduced to little more than a review of whether the I.G. properly exercised his discretion in deciding to exclude him. Petitioner contends also that the clarification is void because it was issued without proper Secretarial authority. Petitioner notes that Secretary Louis Sullivan is listed as the approving authority of the clarification. Petitioner avers that on January 22, 1993, Dr. Sullivan no longer had the authority to make and publish rules and regulations pursuant to 42 U.S.C. § 1302.

Petitioner argues also that the I.G. does not have the authority to issue regulations, because an April 18, 1983 delegation of authority to the I.G. from the Secretary specifically denies the I.G. the authority to issue regulations. Petitioner asserts that, although the I.G. contends that the clarification is merely an interpretive rule and therefore not subject to the notice and comment provisions of the Administrative Procedure Act (5 U.S.C. § 552(a)), the clarification alters substantive rights and as such is not an interpretive rule. Petitioner contends that interpretive rules cannot substantively alter rights and obligations. Lastly, Petitioner contends that the clarification was issued in direct violation of (Director of the Office of Management and Budget) Leon Panetta's January 22, 1993 Memorandum (58 Fed. Reg. 6074-01, January 25, 1993). According to Petitioner, Mr. Panetta's Memorandum mandated a temporary moratorium on new regulations. For all the above stated reasons, Petitioner moves that I strike the clarification as illegal and invalid. P. S. Br. 2 - 3.

The I.G. contends that I am bound to apply the clarification in my determination because it specifically states in the clarification that it applies to all pending cases. The I.G. contends that this is a pending case within the plain meaning of the word and accordingly takes the position that the clarification is controlling in my determination in this case. The I.G. contends also that the clarification was properly issued under the authority of the Secretary because on December 18, 1992, then Secretary Louis Sullivan approved the clarification that was subsequently published on January 22, 1993. The I.G. avers that the clarification was not in conflict with Director Panetta's January 22, 1993 Memorandum, because the clarification was filed for publication in the Federal Register at 8:45 a.m. on January 21, 1993, although it was not actually published until January 22, 1993. The Panetta Memorandum was filed for publication on January 22, 1993, at 12:05 p.m., although it was not

actually published until January 25, 1993. Moreover, the I.G. contends that the Panetta Memorandum creates no right or standing of private parties to avoid the application of regulations.

In response to Petitioner's arguments that the clarification was an improper exercise of authority by the I.G., the I.G. maintains that I cannot address this issue because I do not have the authority to invalidate statutes or regulations.

Petitioner's arguments with regard to the validity and legality of the clarification in effect are arguments that, if successful, would require me to find that the clarification is ultra vires the Act. It is well settled that I do not have the authority to make such a determination. David S. Muransky, DAB CR95 (1990), aff'd DAB 1227 (1991); Hanlester Network, et al., DAB CR181 (1992); Charles J. Barranco, DAB CR187 (1992).

Accordingly, because I do not have the authority to hold the clarification ultra vires the Act, I do not admit the three exhibits that Petitioner submitted in conjunction with his March 23, 1993 supplemental brief, because these exhibits, if at all relevant, would be relevant only as to the issue of whether the clarification was ultra vires.

Since the January 29, 1992 regulations lacked retroactive effect for the reasons stated in Bassim, they could not have acquired such effect with subsequent textual clarifications that do not purport to modify the scope of the January 29, 1992 regulations and have been published without satisfying the procedures necessary under the Administrative Procedure Act for effecting substantive changes. Accordingly, neither the January 29, 1992 regulations or the subsequent January 22, 1993 clarification is controlling upon my determination in this case, where the notice of exclusion issued on July 22, 1991, well in advance of the publication of the new regulations on January 29, 1992 or the clarification on January 22, 1993.

7. A ten year exclusion is appropriate and reasonable.

Since the minimum mandatory exclusion of five years is applicable to Petitioner, the issue before me is whether the I.G. is justified in excluding Petitioner for ten years. Resolution of this issue depends on analysis of the evidence of record in light of the remedial purposes of the Act. Lakshmi N. Murty Achalla, M.D., DAB 1231

(1991); Joel Davids, DAB 1283 (1991); Robert Matesic, R.Ph., d/b/a Northway Pharmacy, DAB 1327 (1992).[21]

Congress enacted the exclusion law to protect the integrity of federally funded health care programs. Among other things, the law is designed to protect program beneficiaries and recipients from individuals who have demonstrated by their behavior that they threaten the integrity of federally funded health care programs or that they could not be entrusted with the well-being and safety of beneficiaries and recipients. S. Rep. No. 109, 100th Cong., 1st Sess. 1 (1987), reprinted in 1987 U.S.C.C.A.N. 682, 682.

An exclusion imposed and directed pursuant to section 1128 of the Act advances this remedial purpose. The principal purpose is to protect programs and their beneficiaries and recipients from untrustworthy providers until the providers demonstrate that they can be trusted to deal with program funds and to properly serve beneficiaries and recipients. As an ancillary benefit, the exclusion deters other providers of items or services from engaging in conduct which threatens the integrity of the programs or the well-being and safety of beneficiaries and recipients. H. R. Rep. No. 393, Part II, 95th Cong., 1st Sess. 69 (1977), reprinted in 1977 U.S.C.C.A.N. 3039, 3072.

My purpose in hearing and deciding the issue of whether an exclusion is reasonable is not to substitute my judgment for that of the I.G., but to decide whether the length of the exclusion imposed by the I.G. was extreme or excessive. 48 Fed. Reg. 3744 (1983); Abelard A. Pelaez, M.D., DAB CR157, at 14 - 15 (1991); Barranco at 29 - 30.

An exclusion is extreme or excessive to the extent it does not protect the programs and their beneficiaries and recipients from untrustworthy providers. An exclusion is

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[21] In making my analysis of the reasonableness of the I.G.'s ten-year exclusion, I am guided also by the federal regulations at 42 C.F.R. § 1001.125(b). These regulations require the I.G. to consider factors related to the serious and program impact of the offense and to balance those factors against any factors that demonstrate trustworthiness. Leonard N. Schwartz, DAB CR36 (1989). Appellate panels of the DAB have incorporated such an analysis in decisions evaluating the reasonableness of the length of mandatory exclusions in excess of five years.

also extreme or excessive when it does not serve to deter other providers from engaging in conduct that threatens the programs or the well-being and safety of program beneficiaries and recipients.

An appellate panel in The Hanlester Network, et al., DAB 1347 (1992) restated the Departmental Appeals Board's view of considerations used in evaluating trustworthiness:

> - the circumstances of the misconduct and the seriousness of the offense, in particular the commission of misconduct in the nature of a program-related crime, see [The Hanlester Network, et al,] DAB 1275, at 52 [(1991)];
>
> - 'the degree to which a [Petitioner] is willing to place the programs in jeopardy,' even if no actual harm is accomplished, id. at 52; [footnote omitted]
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> - the failure to admit misconduct, or express remorse, or evidence rehabilitation, see e.g., Olufemi Okonuren, M.D., DAB 1319, at 13 (1992); Robert Matesic R.Ph. d/b/a Northway Pharmacy, DAB 1327, at 12 (1992); and
>
> - the 'likelihood that the offense or some similar abuse will occur again,' see e.g., Matesic, at 8.

Hanlester DAB 1347, at 46 - 7.

In applying these factors to determine when a provider should be trusted and allowed to reapply for participation in the federally-funded health care programs, the totality of the circumstances of each case must be evaluated in order to reach a determination regarding the appropriate length of an exclusion. My authority as an ALJ in these proceedings includes the authority to review all of the evidence on the reasonableness of an exclusion. Robert Matesic, R.Ph., d/b/a/ Northway Pharmacy, DAB 1327 (1992). Specifically, since the reasonableness of an exclusion turns on the length of time necessary to establish that a provider is not likely to repeat the type of conduct which precipitated the exclusion, I must evaluate all factors relevant to that issue. Matesic at 12. These include the following:

> the nature of offenses committed by Petitioner, the circumstances surrounding the offense, whether and

> when Petitioner sought help to correct the behavior which led to the offense, how far the provider has come toward rehabilitation, and any other factors relating to the provider's character and trustworthiness.

Matesic at 12. I have done this with respect to Petitioner and I have reached the following conclusions regarding his trustworthiness to be a program provider.

Petitioner's criminal misconduct was serious. He pled nolo contendere to three separate criminal charges, two involving the unauthorized refill of prescriptions and one involving dispensing Codeine to an habitual user. Petitioner's conviction for the two counts of refilling prescriptions without authorization are misdemeanors and Petitioner's conviction for unlawfully dispensing codeine to an habitual user is a felony.[22] Petitioner was given a suspended sentence of incarceration for 90 days on each of the misdemeanor counts and one year on the felony count. Petitioner was fined a total of $5500 and required to pay $2246.27 in restitution to the Medi-Cal program. FFCL 29. Although Petitioner's terms of incarceration were suspended by the sentencing court, the fact that he was sentenced to incarceration, even on the misdemeanor offenses, supports the notion that the sentencing court believed the offenses for which Petitioner was convicted were serious. Moreover, Petitioner was required to pay $7746.27 in fines and restitution, a significant amount by any standard, and further evidence that the sentencing court viewed Petitioner's convictions as serious offenses.

Petitioner admitted to the California Board of Pharmacy that, on more than 800 occasions over a period of approximately four years, he had dispensed prescription medication without authorization. FFCL 7. Such conduct was improper and a violation of Petitioner's professional duties as a pharmacist. FFCL 92 - 94, 97. The seriousness of Petitioner's conduct is manifested by the fact that the California Board of Pharmacy revoked Petitioner's pharmacy license and permit. FFCL 13. The revocation of Petitioner's pharmacy license and permit was suspended, Petitioner was suspended from the practice of pharmacy for 45 days, and he was placed on probation

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[22] I did not consider Petitioner's felony conviction for purposes of whether he was convicted of a program-related offense, but I find it appropriate and relevant to consider it as it relates to Petitioner's trustworthiness.

for three years. FFCL 12. Under the standards enunciated in both Hanlester and Matesic, Petitioner's misconduct is indicative of a lack of trustworthiness.

8. Petitioner, without authorization, dispensed addictive drugs to his customers.

Petitioner's conduct in dispensing addictive prescription medication without authorization subjected his customers to numerous serious medical and physiological risks. Petitioner was convicted of the felony of dispensing Codeine to an habitual user. This activity, while not related to the delivery of a Medicare or Medicaid item or service, was a violation of his duties as a pharmacist and subjected the customer to the risks associated with drug addiction. FFCL 21, 27, 31, 62 - 63, 85 - 88, 91 - 94, and 105.

Petitioner, without the appropriate or required authorization, provided drugs to or refilled prescriptions for LC for the drug Meprobamate, a Schedule IV sedative, from July 31, 1984 through January 26, 1987. FFCL 62, 71, and 74. As a direct result of Petitioner's actions, LC received the drug Meprobamate, which is used for the short term alleviation of the symptoms of anxiety disorders, for a period of almost two and one-half years. In doing so, he subjected LC unnecessarily to risks of addiction and deleterious side effects. FFCL 62, 71 - 72, and 74.

For a period of over one year, Petitioner, without authorization, simultaneously filled and refilled prescriptions for the drugs Talwin, Meprobamate and Acetaminophen with Codeine for LC. FFCL 76. As the I.G.'s expert testified, there is no legitimate medical reason for a person to simultaneously to be receiving these drugs in conjunction with one another, unless the person has cancer. FFCL 77. There was no evidence in the record from which I could conclude that LC had or has cancer. FFCL 78.

In providing (Acetaminophen with) Codeine, Meprobamate, and Talwin to LC, Petitioner subjected her to risks from the serious additive depressant effect this combination of drugs has on the central nervous system. Tr. 139 - 42.[23] The testimony of Supervising Inspector Raymond

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[23] There is no evidence in this case from which I can conclude that the drug Acetaminophen has any deleterious side effects. However, when Acetaminophen is provided in conjunction with Codeine, the patient is

Tom, who possesses a doctorate of pharmacy, appearing on behalf of the I.G., indicates that, in providing three addictive and potentially dangerous drugs simultaneously to LC, Petitioner was supplying a person he knew or should have known was an addict. Tr. 139 - 42.

Also, Dr. Tom testified regarding Petitioner's dispensing the drug Talwin to LC from August 28, 1984 through February 13, 1987. Dr. Tom's testimony demonstrates that the duration and manner in which Petitioner provided Talwin to LC subjected her to risks from addiction. Tr. 139 - 42. Dr. Tom testified that, based solely on the duration of time over which LC was receiving Talwin and Meprobamate from Petitioner, Petitioner should have known that his actions were serving to maintain her addiction to these drugs. Tr. 139 - 42. Moreover, Petitioner violated his duties as a pharmacist by dispensing Codeine, Meprobamate, and Talwin to LC without authorization. FFCL 76, 92 - 94.

Petitioner subjected Cl to risks also by providing her with 111 unauthorized refills of the drug Talwin. I.G. Ex. 3 at 16 - 17. According to Dr. Tom, by providing these unauthorized refills to Cl, Petitioner was accommodating a person who was developing an addiction to the drug. Tr. 137 - 38. This interpretation is further supported by the fact that Talwin is such a widely abused drug that doctors are reluctant to prescribe it. Again, this conduct was a violation of Petitioner's duties as a pharmacist and subjected Cl to the risks of drug addiction and deleterious side effects from the drug Talwin. FFCL 62, 64 - 65, 82 - 85, 89, and 92 - 94.

In another instance, Petitioner dispensed the drug Butisol Sodium without authorization. Again, Petitioner did so for periods of time that far exceeded the medically approved usage of the drug. FFCL 66 - 70. In doing so, he subjected the customer to the risks of addiction and the accompanying painful withdrawal symptoms. FFCL 62, 66 - 71, and 85. Also, in dispensing Butisol Sodium without authorization, he did so in direct contradiction of his professional duties as a pharmacist. FFCL 89, 92 - 94.

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subjected to the risks of addiction and deleterious side effects as described in FFCL 62 - 63, and 85. Therefore, to the extent that I find any adverse consequences to Petitioner's dispensing Acetaminophen with Codeine without authorization, it is due solely to the presence of the drug Codeine in conjunction with the Acetaminophen.

Lastly, Petitioner subjected customer M to the risk of deleterious side effects and addiction from the drug Phenergan with Codeine. Tr. 144. According to Dr. Tom, Phenergan with Codeine is used primarily to alleviate the symptoms of a cold and is typically prescribed for a two week period. FFCL 80; Tr. 144 - 45. The evidence shows that Petitioner provided 120 unauthorized refills of Phenergan with Codeine to M. Tr. 144 - 145. Phenergan with Codeine is a Schedule V narcotic.[24] Dr. Tom's testimony indicated that this number of refills is an excessive amount and that the excessive number was evidence that M was abusing the medication. Dr. Tom testified further that there was no legitimate medical purpose for Petitioner to have provided Phenergan with Codeine to this customer in these amounts and over this length of time.

Petitioner's counsel attempted to get Dr. Tom to admit that a physician would prescribe Phenergan with Codeine for an extended period of time for anyone with a chronic cough. However, while Dr. Tom acknowledged it was possible this could happen, he stated that it was unlikely, because anyone prescribing this medication would take into account the adverse side effects and risk of addiction associated with the use of this drug over a long period of time. As a pharmacist, it was Petitioner's obligation to know and inform his customers of the adverse side effects of medications. FFCL 86 - 88.

In this instance, the record indicates that Petitioner violated his duties as a pharmacist by providing 120 unauthorized refills of Phenergan with Codeine to M.[25] FFCL 79. There is no evidence from which I can conclude that Petitioner warned M about the dangers of driving and operating heavy machinery associated with the use of Phenergan with Codeine, nor is there any evidence in the record that there was a legitimate medical purpose for

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[24] The deleterious side effects of the drug Codeine are contained in FFCL 63. Codeine by itself is a Schedule III controlled substance. FFCL 63. When Codeine is combined with Phenergan, it is classified as a Schedule V controlled substance. FFCL 80. Thus, Phenergan with Codeine has less potential for abuse than Codeine alone. FFCL 62.

[25] Phenergan with Codeine is classified as a Schedule V narcotic. FFCL 78. As such, the use of this drug can cause adverse side effects, including addiction. FFCL 60, 61, 78, 83.

Petitioner to have provided M with this medication. FFCL 79 - 81. This is especially true given the length of time that Petitioner provided this medication to M. All of these factors are indicative that, with respect to M, Petitioner violated his duties as a pharmacist. Additionally, Petitioner's conduct subjected M to the risks of addiction and adverse side effects associated with the long term use of Codeine. FFCL 62, 63, 79 - 81, and 85.

Under both the Hanlester and Matesic analyses, Petitioner's providing addictive drugs in the manner described above is indicative of his lack of trustworthiness. Petitioner has demonstrated that he is more than willing to place the programs in jeopardy. Petitioner has demonstrated also that, although he was not criminally convicted in all of the instances in which he provided addictive drugs to customers, his conduct was clearly serious, jeopardized the health of his customers, and subjected them to the risks of drug addiction and the accompanying painful withdrawal symptoms.

9. Petitioner, without authorization, dispensed non-addictive drugs to customers.

Petitioner subjected some of his customers to serious risks by dispensing non-addictive drugs without authorization. It would be improper and a serious violation of his duty as a pharmacist for Petitioner to dispense any prescription medication without a doctor's order. It was an even more serious violation of that duty here because Petitioner improperly dispensed medication that exposed his customers to potentially harmful side effects.

In one instance, Petitioner dispensed without authorization the contradictory and the potentially harmful combination of the drugs Hydrochlorothiazide and Dyazide for the same customer. FFCL 48, 98 - 100. As Dr. Tom testified, the drugs Hydrochlorothiazide and Dyazide are both diuretics that are used in the treatment of high blood pressure. Using these two drugs in combination is not logical because Dyazide contains an ingredient that is supposed to counteract Hydrochlorothiazide. Tr. 129 - 30. Both drugs can cause the same deleterious side effects of dizziness and mental confusion. These two drugs also cause the alteration of potassium levels in the body, which can lead to irregular heartbeat. FFCL 40, 46. Therefore, by dispensing Hydrochlorothiazide and Dyazide without authorization simultaneously to the same customer, Petitioner did

something that was not only medically illogical but subjected the customer to dangerous side effects.

In other instances, Petitioner dispensed prescription medication without authorization in such a manner that the customers were subjected to danger because they were not receiving appropriate and necessary medical monitoring. Petitioner violated standard medical practices and subjected his customers to potential danger by providing them with medications that altered their blood chemistry and electrolytes, knowing that they were not receiving lab tests that would have established and maintained the appropriate dosage. FFCL 39 - 57, and 102 - 03.

Moreover, the record indicates that Petitioner subjected his customers to deleterious side effects by dispensing non-addictive drugs without authorization. These side effects include fainting, dizziness, cardiac arrest, irregular heartbeat, increased heartbeat, mental confusion, asthma, gastrointestinal bleeding, low blood pressure, and increased likelihood of bleeding. FFCL 39, 40, 42, 44, 46, 49, 50, 53, 54 - 57. By dispensing these medications without authorization, Petitioner not only subjected his customers to these unpleasant and potentially dangerous side effects, he violated his duties as a pharmacist. FFCL 39 - 57, 92 - 96.

Dr. Tom testified that, in cases where a patient is receiving Dyazide, Inderal, Hydrochlorothiazide, Hydralazine (Apresoline), Tenormin, Potassium HCL, or Aldactazide, standard practice dictates that the patient receive periodic laboratory testing to determine, monitor, and maintain appropriate levels of essential blood chemicals. FFCL 41, 43, 45, 47, 51, 52, 54, 56. Had these medications been dispensed with proper authorization, the standard practices which accompany such authorization could have afforded the required protection for Petitioner's customers.

Standard practice with regard to the administration of the drug Dyazide includes testing of the person's blood in a laboratory to check the patient's potassium levels. The testing should be performed twice weekly for the first month the patient is undergoing treatment with Dyazide, then twice yearly after that time. FFCL 41. The same practices apply to patients receiving the drug Hydrochlorothiazide. FFCL 47. A patient undergoing treatment with Aldactazide should receive laboratory tests to check potassium levels. These tests should be administered twice weekly for the first month, and twice annually after that. FFCL 41 and 54.

Standard practice for treating patients with Hydralazine (Apresoline) involves periodic monitoring of the patient's blood pressure and heart rate. FFCL 50 - 52. For the treatment of patients with the drugs Inderal and Tenormin, standard practice includes monitoring of potassium levels and kidney function. FFCL 43, 45. Patients receiving Hydralazine should receive periodic monitoring of blood pressure and heart rate. FFCL 51. Patients receiving Potassium HCL should receive laboratory blood testing to establish and maintain the correct potassium level. FFCL 56.

Petitioner, without authorization, dispensed Dyazide, Inderal, Hydrochlorothiazide, Hydralazine (Apresoline), Tenormin, Potassium HCL, and Aldactazide. FFCL 39. The appropriate care for patients undergoing treatment with these seven drugs involves follow-up medical monitoring and blood testing. Petitioner does not challenge Dr. Tom's testimony that only a physician can order laboratory tests. Petitioner is not a physician and therefore could not authorize laboratory testing for any of his customers. Petitioner took it upon himself to provide customers with these seven drugs without authorization. Since no physician authorized Petitioner to fill or refill a prescription for these seven drugs in the instances documented, there was no physician to authorize medical follow-up and laboratory testing for patients receiving these medications.

Standard practice for patients being treated with Dyazide, Inderal, Hydrochlorothiazide, Hydralazine (Apresoline), Tenormin, Potassium HCL, and Aldactazide requires follow-up medical monitoring and blood testing. By dispensing these medications without authorization, Petitioner denied his customers the protection afforded by the standard practice and subjected them to such risks as irregular heartbeat, dizziness, mental confusion, fainting, asthma, cardiac arrest, and tachycardia (rapid heart rate). FFCL 40, 42, 44, 46, 49, 50, 53, 55, 57. Without laboratory testing, Petitioner had no way of knowing or establishing appropriate dosages or appropriate levels of vital chemicals, such as potassium, in his customers. The result is that Petitioner's practices not only violated his duties as a pharmacist, but subjected his customers to serious risks from deleterious side effects. Additionally, because Petitioner provided these seven medications without authorization, he removed any input, advice, or experience that a physician may have been able to bring to the treatment of the person receiving the medication.

Also, Petitioner denied his customer the benefit of the standard practice by dispensing the drug Naproxen without authorization. As Dr. Tom testified, it is well documented that Naproxen carries with it a substantial risk of gastrointestinal bleeding. Standard practice for the treatment of any patient with Naproxen includes either instructing the patient to be alert to signs indicative of gastrointestinal bleeding or conducting follow-up medical testing to monitor the levels of iron and red blood cells present in the patient's blood. FFCL 59 - 60. The record is devoid of evidence that Petitioner instructed the customer to be alert to signs indicative of gastrointestinal bleeding. Since Petitioner, as a pharmacist, does not have the authority to order medical testing, the customer did not receive any follow-up testing.

Petitioner subjected his customers also to other risks. For example, in refilling a prescription for the ulcer medication Tagamet 45 times without authorization, Petitioner subjected a customer to the risk of loss of balance and spatial confusion. FFCL 110 - 11. Lastly, Petitioner subjected a customer to an increased risk of bleeding and low blood-pressure by unauthorizedly providing the drug Persantine (Dipyridamole) for over three years. FFCL 106.

Petitioner jeopardized the health and safety of his customers by providing them with non-addictive medications without authorization. These actions were also a violation of Petitioner's duties as a pharmacist. Under Hanlester and Matesic, this conduct is indicative of Petitioner's lack of trustworthiness and supports the ten-year exclusion.

10. Petitioner's improper conduct was serious.

Under the Hanlester and Matesic guidelines cited above, Petitioner's criminal conduct in refilling prescriptions without authorization was serious and involved a significant amount of money. The seriousness of Petitioner's offense is reflected in that Petitioner was compelled to pay $2246.27 in program restitution, $5500 in fines, and was sentenced to suspended terms of incarceration, for 90 days and one year. Further evidence of the seriousness of Petitioner's criminal conduct is that one of the offenses for which he was convicted, i.e. willfully and unlawfully prescribing, administering, and dispensing Codeine to an habitual user, was a felony. More importantly, the evidence shows Petitioner's criminal offenses to be serious because, in committing these offenses, Petitioner subjected GW and SV

to risks by refilling prescriptions without the consent and authorization of a physician. Also, Petitioner subjected LC to the health risks associated with drug addiction. All three of Petitioner's criminal convictions involved violations of his professional duties as a pharmacist.

The California State Board of Pharmacy deemed Petitioner's pattern of conduct serious enough to suspend Petitioner from the practice of pharmacy for 45 days and place him on probation for three years. FFCL 11, 12. Under the Hanlester criteria, these factors are relevant to show both the circumstances of Petitioner's misconduct and the degree to which Petitioner is willing to place the programs in jeopardy. Under Matesic, Petitioner's pattern of conduct is relevant as part of the circumstances surrounding the offense and is a factor relating to Petitioner's overall trustworthiness.

While Petitioner was criminally prosecuted and convicted for only three offenses, his pattern of conduct indicates a willingness to place the programs and the health of his customers in jeopardy. Petitioner dispensed medication without authorization or refilled a prescription without authorization over 800 times for almost a four year period. The record contains insufficient evidence for me to conclude whether, at the time of these activities, all of the customers receiving the unauthorized drugs were program recipients. However, in at least two instances, the record shows that Petitioner was convicted of offenses related to the delivery of an item or service under Medicaid. Thus, I conclude that Petitioner was indifferent to the damage to the program caused by his actions. Not all of Petitioner's unauthorized activities were purposely directed at the program. However, Petitioner has shown a propensity to commit serious offenses with little regard for the safety of his customers or the integrity of the programs. This is demonstrated by the fact that in dispensing seven non-addictive drugs without authorization, Petitioner subjected his customers to serious risks from the lack of follow-up laboratory testing and medical monitoring. In one instance, Petitioner dispensed an irrational combination of drugs. In the other six instances, Petitioner's actions deprived his customers of the standard care practices for persons undergoing treatment with these drugs and he did not warn them of potential side effects. In each of these seven instances, Petitioner violated his duties as a pharmacist.

11. Petitioner failed to admit misconduct, express remorse, evidence rehabilitation, or seek help to correct the behavior which led to the offense.

Under the Board's Hanlester analysis, an additional criterion for assessing Petitioner's trustworthiness is the failure to admit misconduct, express remorse, or evidence rehabilitation. Under Matesic, the relevant facts center on whether and when Petitioner sought help to correct the behavior which led to the offense. There is no evidence in the record from which I can conclude that Petitioner received or sought to obtain rehabilitation for the conduct that resulted in his misdeeds. Petitioner contends that the fact he continues to make restitution payments in accordance with the trial court's sentencing should be considered in his favor. However, the fact that Petitioner is complying with the court's order after he pled no contest to criminal charges is not evidence that Petitioner has been rehabilitated. In fact, Petitioner would risk incarceration if he did not completely satisfy the terms of the restitution that the court imposed on him.

More relevant to the issue of Petitioner's rehabilitation is that Petitioner has consistently manifested an unwillingness to take responsibility for his actions and fully admit wrongdoing. This is illustrated by the fact that Petitioner's testimony at the hearing was tinged with reluctance to admit wrongdoing, even when he was asked pointed questions by his own counsel. For example, when questioned by his own counsel as to why he did not call the doctor's office to confirm a prescription (instead of filling or refilling it without authorization), Petitioner stated that a lack of time prevented him from doing so. Tr. 239.

Additionally, Petitioner attempted to justify his dispensing Codeine without authorization to an habitual user by claiming that she had a chronic back problem. Tr. 241 - 42; FFCL 130 - 31. Petitioner stated also that the large number of Codeine refills he provided to the habitual user was justified because she in turn gave some of the medication to her husband for the relief of his kidney stones. Tr. 242 - 43; FFCL 130. Lastly, Petitioner refused to admit that dispensing a combination of Dyazide and Hydrochlorothiazide was medically irrational and potentially very harmful, despite persuasive and credible testimony to the contrary. Tr. 258 - 59.

Petitioner's testimony on this issue is representative of the type of action that led to his exclusion. Petitioner

attempts to justify his actions with after-the-fact rationalizations. Both the evidence and Petitioner's testimony on this issue show that he violated his duties as a pharmacist by providing medication to an habitual user without authorization and subjecting that person to the deleterious side effects from the extended and unauthorized use of Codeine. It also indicates that Petitioner was providing a drug to an habitual user, with full knowledge that she was giving some of the drug to her husband. Petitioner's admission that he knew the habitual user was giving some of the drug to her husband is an additional instance, not alleged by the I.G., of Petitioner dispensing prescription medication to an individual without a physician's authorization, in violation of his duties as a pharmacist. It is also further evidence of Petitioner's untrustworthiness.

Petitioner's lack of rehabilitation and his unwillingness to take responsibility for his actions is further demonstrated by his refusal to admit that he placed his customers at risk. When asked by counsel at the hearing if he placed some customers at risk by filling and refilling prescriptions without authorization, Petitioner responded that his customers would have told him if he were placing them at risk. In making this statement, Petitioner shows that he fails to grasp the seriousness of his conduct. As Dr. Tom stated, it is the pharmacist's obligation, not the obligation of the person receiving the medication, to identify potential problems and inform and question the physician when the physician is prescribing medication that is irregular or medically inappropriate.

Petitioner saw fit to provide prescription medication without a physician's authorization, in effect depriving customers of a physician's medical diagnosis and advice. Petitioner's testimony shows that after he took it upon himself to provide medication without appropriate authorization, he inappropriately believed it was his customers and not himself that should have been aware of and acted to avoid potential risks. It was Petitioner's duty as a pharmacist to warn customers about potential risks. There is no evidence in the record from which I can conclude that Petitioner warned any of his customers about possible side effects from their prescriptions. Petitioner's attempt to place the burden of knowing the risks from various medications on his customers is indicative of his failure to take responsibility for his actions and of his lack of trustworthiness.

Petitioner's sworn testimony before me at the hearing is in direct conflict with an earlier sworn statement he

made to a California Board of Pharmacy inspector and is convincing evidence of his lack of trustworthiness. FFCL 141; I.G. Ex. 11; Tr. 255 - 56. In his sworn statement to the Board of Pharmacy investigator, Petitioner denied that he had overstepped his authority in dispensing prescription medication without authorization. In his sworn statement, Petitioner did not admit to any wrongdoing, and instead stated that he did not realize that what he did would be "construed" as going beyond the limits of his professional judgment. I.G. Ex. 11 at 24. However, when he signed the Board of Pharmacy's Stipulation, Petitioner admitted that, on over 800 occasions, he did dispense medication without authorization. I.G. Ex. 3.

In his sworn statement to the investigator, Petitioner stated he did what was best for his customers. I.G. Ex. 11 at 24. However, in his testimony at the hearing, Petitioner reluctantly, and with vigorous prompting from his counsel, admitted that he did not have the authority to prescribe drugs for his customers. Petitioner attempted to justify his actions by stating that some of the pharmaceuticals he provided to his customers without authorization were not modified upon their subsequent visit to a physician. Tr. 248 - 49. From this testimony, Petitioner demonstrates that he believes that it was harmless for him to provide drugs without authorization if the customer later visited a physician and that physician did not discontinue the customer's use of the drug or substitute other medication.

Petitioner's lack of rehabilitation and his failure to admit misconduct is shown by his failure to recognize that such conduct is a violation of his duties as a pharmacist, even if a physician did not make a change in the medication. Petitioner's testimony demonstrates Petitioner's lack of rehabilitation also by his failure to recognize that his conduct endangered customers by subjecting them to potentially dangerous side effects both from the drugs themselves and from the lack of follow-up laboratory testing and medical monitoring.

12. Petitioner has not made a meaningful effort to comply with the terms of his exclusion.

Under Matesic, I may consider any other factors relating to Petitioner's character in assessing his trustworthiness. Relevant to this criterion is the fact that Petitioner has not made a meaningful effort to comply with the terms of his exclusion.

On July 22, 1991, the I.G. informed Petitioner that, effective August 11, 1991, he would be excluded from Medicare and related State health care programs. The I.G.'s letter further informed Petitioner that the effect of the exclusion was that no payment would be made to him for any items or services provided by him under Medicare and Medicaid, except for emergency items or services. Petitioner was informed also that if he submitted or caused to be submitted claims for items or services furnished after the effective date of the exclusion, he could be subject to civil monetary penalties.

At the hearing, Petitioner acknowledged that he had received and read the I.G.'s July 22 letter. Petitioner stated that he had worked at a pharmacy in November of 1991, after the effective date of the exclusion, and that he had filled or refilled prescriptions for Medi-Cal recipients. Tr. 250 - 51; FFCL 123 - 25. Petitioner admitted that did not tell his employer that he had been excluded.[26] Id. When pressed on this issue by the I.G.'s counsel, Petitioner intimated that he did not know what it means to be excluded and that, because he was in the process of contesting his exclusion, he did not think he was forbidden to submit claims to the Medicaid program. Tr. 260.

I find that Petitioner, with his level of education and experience, would have no difficulty understanding that he was being excluded from seeking reimbursement for items or services rendered to program beneficiaries or recipients. When pressed by the I.G.'s counsel, Petitioner conceded that the meaning of the letter was clear, but contended that, despite the letter's statement that he was excluded effective 20 days from the date of

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[26] Petitioner did not violate the terms of his exclusion by not telling his employer that he was excluded. However, the fact that he did not tell his employer is relevant to Petitioner's lack of trustworthiness. Petitioner's failure to tell his employer he was excluded prevented the employer from making arrangements so that Petitioner would not cause to be submitted claims for reimbursement to the Medi-cal programs, in violation of the terms of his exclusion. Additionally, since, after August 11, 1991, payment could not be authorized to an entity in reimbursement for any Medicare or Medicaid prescription filled or refilled by Petitioner, Petitioner's employer would have been interested to know that Petitioner was excluded.

the letter (August 11, 1991), he assumed that he was not excluded because he had requested a hearing to contest his exclusion.[27] Tr. 260 - 62.

Petitioner contended also that he had never had the letter explained to him until the night before this administrative hearing. Such an assertion is suspect since he has had legal counsel throughout the criminal and administrative proceedings. Moreover, there is some evidence to suggest that the plea agreement in the criminal proceeding was based, in part, on an attempt to avoid the resulting administrative sanctions associated with conviction of a program-related criminal offense. Mr. Temmerman testified that Mr. Wilson, Petitioner's attorney at the criminal proceedings, stated that he did not want Petitioner to plead to charges which, on their face, involved Medi-Cal fraud, because he thought that might impair Petitioner's argument against a subsequent administrative sanction. Tr. 208 - 09, 220 - 21. Lastly, Petitioner contradicted himself when he stated that he understood that filling prescriptions for Medi-Cal recipients after the effective date of the exclusion "is a problem." Tr. 259 - 62.

I do not find Petitioner's testimony on this issue to be credible. He admits receiving and reading the I.G.'s letter, even though he denies that he knew what it meant or that any of his attorneys explained it to him prior to the night before this hearing. I do not find that the I.G.'s July 22 letter is unclear so as to require any explanation. However, if Petitioner had any doubts as to the meaning of the I.G.'s letter, he certainly could have availed himself of the opportunity to inquire of his counsel well before the night before the hearing. A person of reasonable prudence who had such doubts would have at least inquired before placing himself in a situation in which he could be subject to further penalties.

The suspect credibility of Petitioner's testimony on this issue is further demonstrated by his admission that he received another letter informing him that he was excluded by the State of California from participation in the Medi-Cal program. Petitioner admitted that he knew it was a problem when he filled or refilled a prescription for someone and he did not know whether or

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[27] The letter states that Petitioner's exclusion was effective 20 days from the date of the letter. Since the date of the letter was July 22, 1992, the effective date of Petitioner's exclusion was August 11, 1992.

not that person was a Medi-Cal recipient. Tr. 265. This statement indicates that Petitioner has a clear understanding of what it means to be excluded, because Petitioner specifically attempted to avoid violating the terms of the exclusion imposed by the State of California. Petitioner's testimony indicates he had full comprehension of his exclusion by the State because he specifically stated that he tries not to fill prescriptions for Medi-Cal recipients. Tr. 265. If Petitioner can understand his exclusion by the State of California, he is capable also of understanding that the I.G. excluded him. This is especially true in view of the fact that Petitioner admitted that he received and read the I.G.'s July 22, 1991 letter.

Under Matesic, Petitioner's failure to make meaningful efforts to comply with the terms of his exclusion is indicative of his lack of trustworthiness. Petitioner's failure to inform his employer of his exclusion is in keeping with his unwillingness to accept the consequences of his actions. Petitioner's attempt to assert that he did not know what it meant to be excluded is a dubious attempt to extricate himself from culpability for violating the terms of his exclusion.

13. Petitioner's conduct will likely recur.

Under the Hanlester criteria for assessing trustworthiness, I may consider the likelihood that the offense or some similar abuse will occur again. Based on Petitioner's reluctance to admit wrongdoing, his lack of rehabilitation and remorse, and the number and duration of his offenses, I conclude that there is a likelihood that Petitioner will continue on a course of conduct that will eventually lead him to commit these types of offenses again. This position is supported not only by the evidence in the record, but by Petitioner's testimony that establishes that he violated the terms of his exclusion and his indifference in doing so. I conclude that Petitioner is likely to provide prescription medication without authorization in the future because he does not demonstrate an understanding of either the seriousness or extent of his conduct in providing prescription medication without authorization. Petitioner's testimony at the hearing and the record as a whole demonstrate that he has not changed his behavior as a result of the conduct that led to his exclusion.

14. There is an absence of mitigating factors.

Petitioner argues that there are many factors that weigh in favor of my reducing the term of the exclusion. I

will address each of them in turn here. The first factor cited by Petitioner is that he was convicted of only three counts. While this is true, it ignores the nature of the offenses and the potential harm to the persons who received the unauthorized medications. The criminal court recognized the significance of the offenses in the sentence that was imposed. It included a term of incarceration, (which was suspended), a substantial fine in addition to restitution, and a lengthy probationary period.

Petitioner states that his conduct has not had an adverse impact on the beneficiaries of the Medi-Cal program and therefore supports lessening the ten-year exclusion imposed and directed by the I.G. This assertion is simply incorrect. As already set forth, Petitioner's conduct placed the two Medi-Cal recipients cited in the criminal Information at great medical risk. FFCL 9, 10, 13, 14, 16 - 20, 22 - 25, 40 - 43. Of equal significance is the State Board of Pharmacy and the Bureau of Medi-Cal Fraud investigation, which led to the original criminal felony complaint. That investigation disclosed program financial loss for unauthorized prescriptions by Petitioner in the amount of $2246.27. I.G. Ex. 3. The adverse impact in health consequences that such improper and unprofessional conduct had on Petitioner's customers does not need to be restated. FFCL 39 - 112. Moreover, Petitioner admitted at the hearing that he engaged in additional acts of refilling prescriptions without authorization that were not documented in the investigation. Tr. 253 - 54.

Petitioner contends that the amount of financial damage to the Medicaid program from his misconduct should be taken into account in lessening his exclusion. Petitioner contends also that he is in the process of paying the full restitution amount imposed by the sentencing court and that this should be weighed in his favor. It is arguable that the amount of monetary damage which Petitioner's actions cost the program (2246.27) is not excessive. However, it is a significant amount. That Petitioner is paying restitution is commendable, but is not mitigating because his criminal sentence mandates that he do so. Thus, neither of these factors is a basis for finding the ten-year exclusion to be unreasonable.

Petitioner contends that he fell into his misdeeds because of a desire to help others and not because of bad character. Petitioner contends also that, as a doctor of pharmacy, he felt he was the person best able to know what drugs to prescribe for his customers. However, these arguments fail to take into account that

Petitioner's actions were both potentially very harmful to his customers and a violation of his duties as a pharmacist. I do not take issue with Petitioner's contention that he wished to help others. However, in this case, the help he was offering was in the form of providing medications without authorization, and was therefore inappropriate and harmful.

Petitioner contends that the fact he received a suspended sentence of incarceration should be viewed as a factor to lessen the term of his exclusion. Petitioner argues that the fact that both the Pharmacy Board and the court gave him probation should be viewed also as a factor to lessen his term of exclusion. Again, I have considered Petitioner's conduct in its entirety, under the standards in Hanlester and Matesic, and have concluded that Petitioner's conduct merits a ten-year exclusion.

Petitioner states that, for the most part, he did not dispense controlled substances to his customers, and that this should weigh in his favor. However, there are risks inherent in any type of drug, even one that is not a controlled substance. While a particular controlled substance may be considered more dangerous than a drug that is not so classified, there are some serious dangers present in providing non-controlled drugs without authorization to customers. I have gone into these dangerous side effects in great detail and will not repeat them here. Moreover, Petitioner did, on many occasions, provide controlled substances to customers without authorization. FFCL 62 - 85. He admitted dispensing without authorization Talwin, Phenergan, Meprobamate, Butisol Sodium, and Codeine. Such drugs were often dispensed in substantial numbers to the same customer and may have led to an addiction or supplied an existing addiction. FFCL 62 - 85.

Petitioner asserts that the fact he did not forge any prescriptions should weigh in his favor. Although Petitioner was never criminally charged or convicted of forging prescriptions, the State Board of Pharmacy's records contain allegations that Petitioner did forge prescriptions. Petitioner disputes this. I.G. Ex. 11. However, even accepting Petitioner's protestations of innocence, I am not persuaded that his exclusion should be reduced because he was not convicted of forgery. The factors which support a ten-year exclusion have been dealt with in detail and are not offset by Petitioner's alleged innocence of other wrongdoing.

Petitioner contends that his lack of prior program offenses should be considered favorably. However, the

offenses he committed in this case are serious and were committed over a lengthy period of time. The fact that Petitioner has no previous record of Medicare sanctions is more than outweighed by the nature and duration of the offenses he committed here.

Lastly, Petitioner offers that the inspector for the California Board of Pharmacy, who originally investigated Petitioner's case (Mr. Doumit), testified that Petitioner has been excellent in rehabilitation. Tr. 95. Petitioner asserts that this evidences that his past conduct is behind him and will not be repeated. However, as stated earlier, Petitioner has shown a reluctance to acknowledge that he has subjected customers to risks or to admit that he has engaged in improper conduct. Also, Petitioner has offered hollow excuses for his conduct, as in the case where he asserted that he was providing excessive amounts of the drug Codeine to LC because she had a chronic back problem and because she was giving some of the medication to her husband.

Additionally, Petitioner has admitted that he has not made meaningful efforts to comply with the terms of his exclusion. FFCL 125. Therefore, while the inspector's testimony regarding Petitioner's rehabilitation may be valid as it applies to his awareness of Petitioner's conduct, it is not in accord with the total picture that emerged from the evidence at this hearing.

15. Petitioner's character statements do not alter my determination that his exclusion is reasonable.

Petitioner has submitted nine exhibits (P. Ex. 2 - 10) that are essentially character statements that were offered in connection with Petitioner's criminal trial. The I.G. objected to the admission of these exhibits both before and during the hearing. The I.G. argues that since copies of these same documents were submitted in conjunction with Petitioner's criminal trial, the statements cannot be used now for a different purpose than for that which they were intended. The I.G. contends that different considerations exist in a criminal sentencing proceeding than exist in this hearing. Therefore, statements prepared in conjunction with the criminal proceeding are not relevant here because they address different issues and concerns than those that are before me. Additionally, the I.G. objects to the statements on the grounds that the persons making them do not have full knowledge of the extent and nature of Petitioner's wrongdoing. Petitioner argues that the I.G.'s objections go to the weight and not the admissibility of the statements.

I have admitted these nine exhibits, but consider them only to the extent that they indicate full knowledge of Petitioner's conduct. Since these exhibits are all dated either March or April of 1990 (one is undated), I find that these exhibits do not indicate full knowledge of Petitioner's activities. The statements are therefore of very limited value in my determination regarding Petitioner's trustworthiness. These statements (P. Ex. 1 - 9) were drafted over two years before this proceeding and do not reflect any knowledge of Petitioner's conduct after 1990.[28] More importantly, the statements do not reflect that any of the persons making them knew the extent of Petitioner's misdeeds. The statements do reflect the experiences of persons who have had positive experiences with Petitioner on a personal level. However, the statements do not reflect that the people making them had any knowledge that Petitioner had been convicted of three criminal offenses or that Petitioner had been sanctioned by the Board of Pharmacy. Moreover, the statements collectively do not reflect any knowledge of these proceedings. Lastly, the statements were not made under oath or pursuant to affidavit and therefore must be weighed accordingly. Therefore, the exhibits submitted by Petitioner are insufficient to alter my determination of the reasonableness of the exclusion in the face of persuasive evidence to the contrary.

The I.G. objects also to Petitioner's exhibit 11 (a report of a California Pharmacy Board inspection of Petitioner's place of work on November 5, 1991). The I.G. contends that this exhibit is not relevant or even comprehensible, and Petitioner has offered no explanation as to its relevance. Regarding the I.G.'s objections as to P. Ex. 11, I have admitted this exhibit but will accord it minimal weight. Petitioner states that P. Ex. 11 is a copy of a November 5, 1991 Board of Pharmacy report that reflects that no "corrections" were ordered. Since the exhibit is somewhat illegible, I take Petitioner's statement about its content to be true. Petitioner has not offered any testimony as to what a "correction" is as that term is used in P. Ex. 11. No evidence was offered by Petitioner regarding the type of inspection the Pharmacy Board performed. Even assuming

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[28] No date appears on P. Ex. 3. However, because Petitioner's exhibits 2 - 10 are copies of statements that were submitted in conjunction with Petitioner's criminal sentencing in 1990, I infer that P. Ex. 3 has approximately the same date as the other exhibits that were submitted by Petitioner at the sentencing of his criminal trial.

that such document suggests that at the time of the inspection he was complying with the standards or practices of the Pharmacy Board and is evidence of rehabilitation, such a conclusion is contradicted by more probative evidence on that issue, including Petitioner's own testimony demonstrating a lack of understanding of the significance of the unlawfulness of his conduct.

16. The ten year exclusion is reasonable.

A lengthy exclusion is needed to provide Petitioner with an opportunity to demonstrate that he once again can be trusted to be a program provider. Petitioner has demonstrated a propensity to commit willful acts over long periods of time which place program beneficiaries and others at risk. Petitioner has demonstrated his unwillingness also to take responsibility for his past actions. In light of the record of his criminal behavior, his admission to over 800 instances of dispensing prescription medication without authorization, the sanctions imposed by the Board of Pharmacy and the criminal court, the evidence of his untrustworthiness, and the paucity of evidence minimizing his current risk to the program, I conclude that the ten year exclusion imposed and directed against Petitioner is not "extreme or excessive."

17. A ten-year exclusion is reasonable under the new regulations.

I find the ten-year exclusion reasonable even after an alternative evaluation of the exclusion under the new regulations. Even though I do not find that the new regulations apply to this or other cases in which the I.G. had imposed and directed an exclusion prior to January 29, 1992, I have analyzed the evidence along the lines suggested by the I.G. in order to help expedite a final resolution of all potential issues in this case.[29] Even if I had concluded that the new regulations apply to

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[29] I am taking this extraordinary action in this case due to the length of time that this case has been pending at the ALJ hearing level. The notice of exclusion was issued in July 1991 and Petitioner requested a hearing in October 1991. The case has been pending well over 18 months, having been delayed twice due to new regulations and the clarification. Petitioner deserves a final resolution of the reasonableness of his exclusion. Should my decision be reversed, this alternative holding may make it possible to avoid a time-consuming remand.

my adjudication of this case, I would have found reasonable the ten-year exclusion, pursuant to the criteria specified in 42 C.F.R. § 1001.101 and § 1001.102.

As I have indicated, the minimum mandatory provisions of the Act require the imposition of at least a five-year exclusion in this case. Section 1001.102(a) imposes the same result. The ten year exclusion is supported applying the aggravating and mitigating factors set forth in the new regulations. 42 C.F.R. § 1001.102(b) and (c). Below, I will briefly analyze the record in this case applying these factors.

The first aggravating factor involves acts resulting in the conviction, or similar acts, that caused financial loss to the programs of $1500 or more. 42 C.F.R. § 1001.102(b)(1). The conviction documents adequately support a finding that the loss to the Medi-Cal program amounted to $2246.27, an amount exceeding $1500. FFCL 27, 29. This figure was derived by the Board of Pharmacy investigator for program payments for the drugs wrongfully dispensed to five Medi-Cal recipients, documented in the Stipulation between Petitioner and the Board. I.G. Ex. 3. Moreover, the records from the investigation done by the Board of Pharmacy and the Bureau of Medi-Cal Fraud was limited in scope. At the hearing, Petitioner admitted to further unauthorized refilling of prescriptions that were not subject of the investigation. Tr. 253 - 54.

Second, the acts that resulted in the conviction, or similar acts, were committed over a period of one year or more. 42 C.F.R. § 1001.102(b)(2). The record amply supports that, from 1983 to 1987, Petitioner engaged in dispensing prescription medications without authorization. FFCL 39, 92 - 94, 96, 97.

Third, the acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental, or financial impact on one or more program beneficiaries or other individuals. 42 C.F.R. § 1001.102(b)(3). The record is replete with incidents of the type of harm envisioned by this factor and has been set out in detail previously in this decision. FFCL 13 - 20, 22 - 30, 32 - 34, 39 - 112; and discussion at pages 38 - 48.

Fourth, the sentence imposed by the court included incarceration. 42 C.F.R. § 1001.125(b)(4). The sentence imposed included one year for Count I and 90 days each for Counts II and III. Incarceration was subsequently

suspended in favor of a five-year probationary period. FFCL 20 - 23, and 27 - 29.

Fifth, Petitioner has a prior criminal, civil or administrative sanction record. 42 C.F.R. § 1001.125(b)(5). Petitioner's license to practice pharmacy was suspended and Petitioner was placed on probation by the Board of Pharmacy. FFCL 11, 12.

Sixth, Petitioner has been overpaid more than $1500 by the programs as a result of improper billings. 42 C.F.R. § 1001.125(b)(6). Petitioner was paid $2246 for unauthorized prescriptions that were improperly billed to the Medi-Cal program. FFCL 1 - 35.

The first mitigating factor pertains to convictions of three or fewer misdemeanor offenses and the loss to the programs from the criminal activities that resulted in the conviction, or similar acts, of less than $1500. 42 C.F.R. § 1001.125(c)(1). This factor does not apply. For purposes of this factor, Petitioner was convicted of two misdemeanor offenses (Counts II and III of the Information).[30] FFCL 13 - 38. However, the program related financial loss was $2246.27, an amount in excess of $1500. FFCL 29 - 34.

The second mitigating factor pertains to a determination by the court of the existence of a mental, emotional or physical condition before or during the commission of the offense that reduced the convicted person's culpability. 42 C.F.R. § 1001.125(c)(2). The documentation in the record pertaining to Petitioner's conviction fails to disclose that the court determined that any such condition existed in Petitioner's case. I.G. Ex. 1.

The third mitigating factor relates to cooperation with federal or State officials that led to action against others. 42 C.F.R. § 1001.125(c)(3). There is nothing in the record to support the existence of this factor.

Petitioner addressed the above aggravating factors in his brief on the new regulations. P. S. Br. 1 - 13. His analysis was limited to the factors set forth in 42 C.F.R. § 1001.401. This section of the regulations addresses permissive exclusions under section 1128(b)(3)

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[30] This mitigating factor does not specifically indicate that the misdemeanor offenses must be program-related. Nor does it indicate how a non-program-related felony, as is present in this case, should be construed in determining the applicability of this factor.

of the Act pertaining to convictions related to controlled substances. As I previously stated, the I.G. in this case was required to proceed with a mandatory exclusion under section 1128(a)(1) of the Act, based on the program relatedness of Petitioner's conviction. I have previously discussed Petitioner's position on the general issue of mitigation, which included consideration of a number of the same aggravating factors listed above. See discussion at 39 - 55. I will address his specific arguments as to factors raised by the new regulations here. However, for the most part, Petitioner's arguments do not pertain to the specific factors raised by the new regulations and are, therefore, not relevant under the new regulations.

Petitioner attempts to reduce the impact of the extended period of time of his misconduct and the dollar amount involved by applying a mathematical analysis that breaks down the incidents and financial damage to yearly (43 acts, $748) and monthly (3.5 acts, $62) increments. Such an effort is unpersuasive and does not reduce the overall harmful impact of his conduct. The consequences of his dispensing prescription medications without authorization and its impact on his customers have been described in detail elsewhere and need not be repeated. See discussion at 44 - 50. Equally unpersuasive is Petitioner's attempt to minimize the aggravating factors by suggesting that he was motivated by "his desire to help patients" and stating that the record does not show that he "forged any prescriptions". P. S. Br. at 11. It is illogical to suggest that a desire to assist customers negates the harmful effect of his misconduct.

The records of the State Board of Pharmacy contains allegations, disputed by Petitioner, that he did forge prescriptions. The statements by physicians that in many instances they never authorized the initial prescription or the refill supports the conclusion that the prescriptions were essentially forged. It is irrelevant whether Petitioner actually wrote the name of the physician on a prescription. The effect is the same, a prescription was issued and medication was provided to a customer, without the permission or authorization of a physician, and without a medically licensed individual determining the need for such medication based on the condition of the patient. Also, the physicians had no motivation to misrepresent their practices, while the contrary is true for Petitioner. Moreover, Petitioner concedes that his actions were motivated by his "ambitious ego telling him he could act as a physician in the field of pharmacology." P. S. Br. 11. If anything, such an admission supports a ten-year exclusion rather

than, as Petitioner argues, an exclusion of shorter duration. The practice of medicine without a license is in most jurisdictions a criminal act.

Again, Petitioner fails to recognize the significance of his conduct. Petitioner's assertion that a physician was grateful that a patient took medication that was not prescribed strains credulity and is further evidence of his attempt to rationalize his conduct. There is nothing in the record to support Petitioner's assertion that physicians were aware of the nature or extent of his unauthorized activities or that the mental health of his customers was enhanced due to the absence of anxiety about approval of their prescriptions. Lastly, there is no support for Petitioner's assertion that physicians would have authorized the refills since they ordered the original prescriptions. Such an assertion is inapposite to the findings of the State Board of Pharmacy investigation. I.G. Ex. 11.

Thus, in applying the new regulations, I find that all of the six aggravating factors are present, with no mitigating factors applicable to this case. There is no precise guidance in the regulations on how the factors should be weighed in assessing the length of the exclusion. In the preamble to the new regulations, the comments provide the following:

> We do not intend for the aggravating and mitigating factor 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 (1992).

In applying the factors of the new regulations in determining the reasonableness of the ten-year exclusion mandated against Petitioner, I am still guided by the principles of: 1) whether the length of the exclusion is extreme or excessive; and 2) based on the consideration of the aggravating factors described above, when in the future Petitioner will no longer pose a threat to program beneficiaries and recipients.

This record amply demonstrates that, over an extended period of time, Petitioner engaged in providing both controlled and non-controlled pharmaceuticals to customers without authorization. The record also demonstrates that Petitioner's conduct imposed significant medical risk to his customers, especially where Petitioner violated his duties as a pharmacist by supplying controlled substances to persons who were addicted to the drugs. Moreover, the stipulated cost to the program ($2246.27) for his improper billings is a significant amount of money.

The record as a whole establishes the existence of all the aggravating factors demonstrating that Petitioner poses a significant threat to the program. Further, the record is devoid of any mitigating factors that would support a finding that the ten-year exclusion is unreasonable. Considering the applicable aggravating factors, and the absence of any mitigating factors, Petitioner's ten-year exclusion is neither extreme nor excessive, but is reasonable.

CONCLUSION

Based on the law and the evidence, I conclude that the ten-year exclusion imposed and directed against Petitioner is reasonable.

/s/

Edward D. Steinman
Administrative Law Judge