

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

|                       |   |                    |
|-----------------------|---|--------------------|
| In the Case of:       | ) |                    |
|                       | ) |                    |
| The Inspector General | ) | DATE: May 31, 1990 |
|                       | ) |                    |
| - v. -                | ) |                    |
|                       | ) | Docket No. C-127   |
| Tommy G. Frazier and  | ) |                    |
| Prater Drugs, Inc.,   | ) | DECISION CR 79     |
| Respondents.          | ) |                    |

DECISION

Respondents requested a hearing to contest the Inspector General's (the I.G.) proposed imposition against them, jointly and severally, of civil monetary penalties, assessments, and an exclusion from participation in Medicare and State health care programs.<sup>1/</sup> The I.G. alleged that Respondents violated section 1128A of the Social Security Act (the Act), as implemented by 42 C.F.R. 1003.100 et seq.

I held a hearing in Lexington, Kentucky, on November 14-16, 1989. Based on the law, regulations, and evidence adduced at the hearing of this case, I conclude that Respondents unlawfully presented or caused to be presented 20 claims for items or services that they knew, had reason to know, or should have known were not

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<sup>1/</sup> "State health care program is defined by subsection 1128(h) of the Social Security Act to include any state plan approved under Title XIX of the Act (such as Medicaid). The definition also encompasses programs receiving funds under Title V of the Act (Maternal and Child Health Services Block Grant), and Title XX of the Act (Social Services Block Grant). I use the term "Medicaid," hereafter, to represent all State health care programs encompassed by the exclusions I impose in this case.

provided as claimed. I impose penalties of \$24,000 and assessments of \$288.92 against Respondents, jointly and severally. Also, I exclude Respondents from participating in the Medicare and Medicaid programs for five years.

#### ISSUES

The issues in this case are whether:

1. As required by section 1128A(c) of the Act, the I.G. initiated a proceeding against Respondents not later than six years after the claims at issue were presented.

2. In violation of section 1128A of the Act, Respondents presented or caused to be presented claims for items or services which they knew, had reason to know, or should have known were not provided as claimed; and

3. Penalties, assessments, and an exclusion should be imposed against Respondents, and if so, in what amount and for what period of time. 2/

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2/ At the hearing of this case, Respondents' counsel asserted that the Secretary's delegation of authority to the I.G. to initiate proceedings pursuant to the Act had expired at the completion of the term of President Reagan and had not been renewed. Therefore, according to counsel, the I.G. lacked authority to initiate the present case against Respondents. I invited the parties to argue this issue in posthearing briefs. Respondents did not raise the issue in their posthearing brief and, therefore, I conclude that they no longer wish to argue it.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Respondent Tommy G. Frazier (Respondent Frazier) is a registered pharmacist. Tr. at 8.3/
2. Respondent Prater Drugs, Inc. (Respondent Prater), was incorporated in June 1969. Tr. at 7.
3. Respondent Frazier has owned 100% of the stock in Respondent Prater since 1973. Tr. at 7.
4. In November 1972, Respondent Frazier and Thomas Utter incorporated Parkway Drugs, Inc. (Parkway). Tr. at 7.
5. In September 1975, the partnership was dissolved and Respondent Frazier assumed complete control of Parkway. Tr. at 7.
6. Parkway remained open and operating until 1986. Tr. at 7-8.
7. The Kentucky Medical Assistance Program (KMAP) is the state Medicaid agency for Kentucky, and is designated pursuant to Title XIX of the Social Security Act to administer that state's Medicaid plan. Tr. at 8.
8. KMAP reimburses participating pharmacists for covered prescription drugs provided to Medicaid recipients. Tr. at 50-51; I.G. Ex. 42.1.
9. Any pharmacy holding an operation permit from the Kentucky Board of Pharmacy may participate in KMAP. I.G. Ex. 42.1
10. All pharmacies that participate in KMAP must sign an "Agreement of Participating Pharmacies" which requires them to abide by the policies and procedures of KMAP. Tr. at 33; I.G. Ex. 42.1

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3/ The parties' exhibits and the transcript of the hearing will be cited as follow:

|                    |                   |
|--------------------|-------------------|
| I.G. Exhibit       | I.G. Ex. (number) |
| Respondent Exhibit | R. Ex. (number)   |
| Transcript         | Tr. at (page)     |

11. From September 1966 through the present, Respondent Prater has continuously participated in KMAP using provider number 54005780. Tr. at 8.

12. On May 25, 1989, the Inspector General (I.G.) informed Respondents that he sought to impose against them, jointly and severally, penalties of \$24,000, assessments of \$288.92, and a five year exclusion from participation in the Medicare and Medicaid programs.

13. The I.G. alleged that, in violation of section 1128A of the Social Security Act, Respondents presented or caused to be presented to KMAP 20 claims which they knew, had reason to know, or should have known, were not provided as claimed.

14. The I.G. alleged that Respondents presented or caused to be presented to KMAP reimbursement claims for brand name drug products when, in actuality, Respondents dispensed generic drug products.

15. In order to obtain reimbursement for drugs dispensed to Medicaid recipients, Respondents were required to present reimbursement claims to KMAP. Tr. at 103

16. Appalachian Computer Services (ACS) is a data entry company located in London, Kentucky. I.G. Ex. 46.

17. ACS does not act as an agent of KMAP, nor is it affiliated with the United States Government. I.G. Ex. 46.1

18. From October 1981 through June 1983, Respondents contracted with ACS to prepare Medicaid reimbursement claims on their behalf. Tr. at 8, 520.

19. ACS supplied Respondents with "Title XIX Claim Information Sheets" which Respondents used to record information from which ACS prepared Medicaid reimbursement claims. I.G. Ex. 46.1

20. Title XIX Claim Information Sheets requested the following information from Respondents for each claim submitted to ACS: (1) provider name and address; (2) prescription number; (3) date of dispensing; (4) recipient beneficiary identification number; (5) National Drug Code (NDC) of drug; (6) price of drug. I.G. Ex. 46.1.

21. All reimbursement claims which ACS prepared on Respondents' behalf were created from information which Respondents placed on Title XIX Claim Information Sheets. Findings 19, 20.

22. Respondent Frazier employed billing clerks at both Respondent Prater and Parkway to perform duties associated with billing, including completion of Title XIX Claim Information Sheets. Tr. at 217, 374, 529; I.G. Ex. 58.1

23. From 1978 through 1982, Connie Brewer, formerly known as Connie Hurst, was employed by Respondent Frazier at Parkway. Tr. at 374.

24. Respondent Frazier taught Connie Brewer how to do KMAP billing. Tr. at 384; I.G. Ex. 50.1

25. Respondent Frazier instructed Connie Brewer to record information to be used in billing KMAP for drugs sold at Parkway by making a "cross" on prescription forms of KMAP recipients and writing the NDC of the drug to be billed to KMAP across the top of the cross. Tr. at 383, 391-392.

26. The NDC is a unique and universally known number which identifies a particular drug product. Tr. at 50.

27. Although generic drugs were being used to fill prescriptions, Respondent Frazier instructed Connie Brewer to record the NDC of a brand name drug and to bill KMAP for brand name drugs. Tr. at 379, 381, 383-384, 409, I.G. Ex. 50.1.

28. Connie Brewer was instructed by Respondent Frazier to write in the amount of the drug product dispensed on the bottom left-hand side of the cross. Tr. at 382.

29. Connie Brewer was instructed by Respondent Frazier to write in the number of days for which the drug product was supplied on the bottom right-hand side of the cross. Id.

30. From 1973 through January 1982, Janice Lemaster was employed as a billing clerk at Respondent Prater. I.G. Ex. 49.1.

31. During her period of employment at Respondent Prater, Janice Lemaster used the same cross system to

record billing information for KMAP claims that was used by Connie Brewer at Parkway. Tr. at 232.

32. Prior to her employment at Prater, Janice Lemaster had never performed KMAP billing work. Tr. at 216.

33. Janice Lemaster did KMAP billing pursuant to Respondent Frazier's instructions. I.G. Ex. 49.1; Findings 22-31.

34. Eula Slone was employed at Respondent Prater from September 1982 through November 1988. I.G. Ex. 58.1

35. The 20 claims at issue were presented during the period of time when Eula Slone was employed at Respondent Prater. I.G. Ex. 58.1.

36. Eula Slone used the same "cross" system utilized by Connie Brewer and Janice Lemaster to record claims data for Medicaid prescription drug sales. I.G. Ex. 58.1.

37. Eula Slone did KMAP billing pursuant to Respondent Frazier's instructions. Findings 35, 36.

38. Respondents submitted Title XIX Claim Information Sheets to ACS. Tr. at 531; I.G. Ex. 1.5-20.5.

39. ACS transferred the information from the Title XIX Claim Information Sheets which it received from Respondents onto computer disks and sent the computer disks to KMAP for processing and reimbursement. I.G. Ex. 46.1.

40. Based on information submitted to it by the provider who presented the claim or caused it to be presented, KMAP creates a remittance statement for each claim it receives and reimburses. Tr. at 95-96.

41. Each of the 20 claims in issue are detailed on a KMAP remittance statement. I.G. Ex. 1.1-20.1.

42. Each KMAP remittance statement contains the following information: (1) provider name; (2) provider number; (3) recipient name; (4) recipient identification number; (5) transaction control number; (6) date on which drug product was dispensed; (7) Rx number (8) drug code; (9) quantity dispensed; (10) whether prescription represented a refill; (11) amount billed by provider; (12) amount of charges not covered by KMAP; (13) claim amount paid by KMAP. Tr. at 76.

43. Respondents presented or caused to be presented to KMAP each of the 20 claims in issue. Tr. at 8; I.G. Ex. 1.1-20.1, 1.5, 5.5, 6.5, 9.5, 12.5-14.5, 16.5, 18.5, 20.5; Findings 38-41.

44. The date KMAP received each of the 20 claims at issue is documented in a transaction control number on a remittance statement. Tr. at 80, 82-86; I.G. Ex. 1.1-20.1, 47.1.

45. The I.G. may initiate an action under section 1128A of the Social Security Act within six years of the date that a claim at issue was presented. Social Security Act, section 1128A(c).

46. For purposes of determining whether an action was initiated within the six-year statute of limitations, the term "presented" refers to the date on which a claim was received by an agent acting on behalf of the United States or a state. Social Security Act, section 1128A(c).

47. Each of the 20 claims at issue was presented to KMAP within six years of the date that the I.G. initiated his action in this case. Findings 12, 44.

48. For each of the 20 claims in issue, the I.G. initiated his action against Respondents within the six-year statute of limitations. Findings 44, 45.

49. Each pharmacy which claims reimbursement for a drug provided to a KMAP recipient must provide KMAP with the NDC of the drug for which reimbursement is claimed. Tr. at 42-43.

50. The NDC is a number containing up to ten digits that identifies each drug by either a generic name, brand name, or manufacturer. Tr. at 42.

51. The NDC is a code that is universally used, and it is used by KMAP to identify the specific drug for which a pharmacy is claiming reimbursement. Tr. at 42-43.

52. By referring to the NDC provided by the pharmacy on its claim, KMAP determines the drug which the pharmacy claims to have dispensed. Tr. at 76.

53. KMAP determines the amount of reimbursement owed to a pharmacy for a claim based in part on the pharmacy's identification of the drug dispensed. Tr. at 76.

54. Based on a formula, KMAP reimburses participating pharmacies for covered drugs provided to Medicaid recipients. Tr. at 44-48.

55. The purpose of KMAP's drug reimbursement formula is to protect the Medicaid program from excessive charges or excessive payments, and to establish a uniform, fair and equitable means of reimbursing pharmacies for medications that are provided to Medicaid recipients. Tr. at 48.

56. KMAP's reimbursement formula operates to reimburse a participating pharmacy for each prescription for a covered drug, by paying the pharmacy the lower of:  
(1) lower of the pharmacy's usual and customary charge;  
or (2) a dispensing fee for each prescription, plus the lower of:

- a. the drug's Estimated Acquisition Cost (EAC) per unit of drug dispensed;

- b. the drug's Maximum Allowable Cost (MAC) per unit of drug dispensed,

multiplied times the number of units of the drug dispensed. Tr. at 44-48; I.G. Ex. 42.1.

57. The dispensing fee is analogous to a labor charge. Tr. at 46 -47.

58. At all times relevant to this case, the dispensing fee paid to participating pharmacies was \$2.35 per prescription. I.G. Ex. 42.3; Tr. at 46-47.

59. In calculating the payment per unit of drug dispensed, KMAP will determine the following, based on the NDC of the drug for which reimbursement is claimed, and data maintained by KMAP:

- a. the drug's EAC;

- b. the drug's MAC;

Tr. at 44-48.



60. The EAC is KMAP's determination of the wholesale cost for which a pharmacy could purchase a manufacturer's version of a particular drug. Tr. 44-46.

61. KMAP has assigned an EAC to every version of a drug for which it reimburses. Id.

62. The MAC is KMAP's determination of the median wholesale cost of all manufacturers' versions of a particular drug. Tr. at 44-46.

63. KMAP has not determined a MAC for every covered drug because some drugs are not manufactured by enough manufacturers to provide KMAP with data from which a MAC may be determined. Tr. 43-44, 72; I.G. Ex. 42.1.

64. A pharmacy's usual and customary charge for a drug is the amount a pharmacist would charge the general public to fill a prescription for that drug. Tr. at 49-50.

65. A brand name is used by a manufacturer in marketing a drug that it has developed. Once established, a brand name is only used by one manufacturer. Tr. at 61.

66. A generic brand of a drug is manufactured and marketed under the same name by several different manufacturers. Tr. at 60.

67. A generic drug is equivalent in product, ingredient, composition and effectiveness to the brand name version of the same drug. Tr. at 61.

68. Generally, a brand name drug is more expensive than its generic equivalent, and thus, will have a higher EAC than its generic equivalents. Tr. at 64-65.

69. At all times relevant to this case, Kentucky law required pharmacies to dispense generic versions of prescription drugs to Medicaid recipients except in those cases where the prescribing physicians specified that brand name drugs must be provided to the recipients or a generic equivalent for the brand name drug product was not available. Tr. at 7, 133.

70. Respondents were aware of this law. Tr. 553; Findings 1-5.

71. Each of the 20 claims at issue are for prescriptions to KMAP recipients which Respondents filled with generic

drugs. Tr. at 25-26, 143, 149, 183, 343, 466, 605-606; I.G. Ex. 1.6-20.6, 59.1.

72. Each of the 20 claims at issue claim reimbursement for brand name drugs. I.G. Ex. 1.1-20.1, 1.5, 5.5, 6.5, 9.5, 12.5-14.5, 16.5, 18.5, 20.5.

73. The 20 claims at issue are claims for reimbursement for items which Respondents presented or caused to be presented to KMAP that were not provided as claimed. Findings 71, 72; Social Security Act, 1128A(a).

74. Although prescriptions for KMAP recipients were being filled with generic drugs, Respondent Frazier instructed his employees to always bill KMAP for brand name drugs. Tr. at 379, 381, 383-384, 409; I.G. Ex. 49.1, 50.1, 58.1; Findings 22-37.

75. Respondents knew that the 20 claims at issue in this case were not provided as claimed. Finding 74.

76. Respondent Prater signed a provider participation agreement with KMAP and agreed to abide by KMAP's rules and procedures. Tr. at 33.

77. Respondents had a pre-existing duty to verify the truth and accuracy of the claims which were presented to KMAP on their behalf. Findings 3, 76.

78. Respondents received remittance statements from KMAP which identified the drugs for which Respondents were reimbursed. Tr. at 76; Findings 40-42.

79. Respondents had information to place them, as reasonable providers, on notice that the 20 claims at issue were not provided as claimed. Findings 38-42, 78.

80. Respondents had reason to know that the 20 claims at issue were not provided as claimed. Findings 76-79.

81. Respondents were indifferent to whether the 20 claims at issue truthfully claimed reimbursement for the items claimed. Findings 74, 75, 78, 79.

82. Respondents should have known that the 20 claims at issue were not provided as claimed. Finding 81.

83. The I.G. did not establish by a preponderance of the evidence which generic drugs were supplied by Respondents to fill each of the prescriptions for which reimbursement

was claimed with respect to the 20 claims at issue, See Tr. at 140-152; I.G. Ex. 2.2-20.4.

84. For the 20 claims at issue, the EACs for the brand name drugs billed to KMAP by Respondents were greater than EACs for all generic equivalents of those drugs. Tr. at 60; I.G. Ex. 41.1 through 41.6.

85. For each of the 20 claims at issue, the reimbursement KMAP paid to Respondents for the brand name drugs for which reimbursement was falsely claimed was at least as much as would have been reimbursed had Respondents truthfully claimed reimbursement for the drugs they dispensed. Findings 56, 59-63, 84.

86. The brand name drugs for which Respondents falsely claimed reimbursement in claims 2, 4-7, 11, 12, 16 and 20, are drugs for which KMAP established no MAC. I.G. Ex. 41.1 through 41.6.

87. Respondents received an overpayment for claims 2, 4-7, 11, 12, 16 and 20 because the EACs for the brand name drug products Respondents billed to KMAP were greater than the EACs for any generic drug products which Respondents would have actually dispensed. Findings 56, 59-63, 84, 86.

88. The I.G. did not prove the amount of overpayment Respondents received for claims 2, 4-7, 11, 12, 16 and 20. See Finding 83.

89. Claims 1, 3, 8-10, 13-15, and 17-19 are for drugs which were assigned a MAC by KMAP. I.G. Ex. 41.1 through 41.6.

90. The I.G. did not prove that Respondents received an overpayment for claims 1, 3, 8-10, 13-15, and 17-19, because the I.G. did not prove that the prescriptions for which these claims sought reimbursement were filled with generic drugs which had EACs that were less than the MACs for those drugs. See Findings 83, 89.

91. The Act provides for the imposition of a penalty of up to \$2,000.00 for each item or service which is not provided as claimed, and assessments of up to twice the amount claimed. Social Security Act section 1128A(a).

92. In determining the appropriate amount of penalty, assessment, and exclusion to be imposed against Respondents, the Act and regulations direct that both

aggravating and mitigating factors be considered. Social Security Act, section 1128A; 42 C.F.R. 1003.106.

93. The factors which may be considered as aggravating or mitigating include: (1) nature of the claim or request for repayment; (2) degree of culpability; (3) history of prior offenses; (4) financial condition; (5) such other matters as justice may require. 42 C.F.R. 1003.106.

94. If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close to, or at, the maximum permitted by law. 42 C.F.R. 1003.106(c).

95. In proceedings brought pursuant to the Act, a respondent has the burden of proving the existence of any mitigating factors. 42 C.F.R. 1003.114(d).

96. The claims at issue are a small part of a pattern of false claims by Respondents, extending over a period of years. Findings 22-37, 74, 75; 42 C.F.R. 1003.106(b)(1).

97. The claims at issue were part of a scheme by Respondents to systematically extract reimbursement from KMAP to which Respondents were not entitled. Findings 22-37, 74, 76, 96; 42 C.F.R. 1003.106(b)(2).

98. The scheme was in deliberate contravention of KMAP's provider reimbursement guidelines and the promises Respondents made when Respondent Prater executed a provider participation agreement with KMAP. Findings 76, 97; 42 C.F.R. 1003.106(b)(2).

99. Respondents' pattern of unlawful conduct jeopardized the integrity of the Medicaid program in Kentucky and frustrated the objective of the program to provide needed medications to recipients at the lowest possible cost. Finding 55; 42 C.F.R. 1003.106(b)(5).

100. Respondent Frazier's intentional conduct establishes a high degree of culpability. 42 C.F.R. 1003.106(b)(2).

101. Because the claims at issue were but a small part of a much larger pattern of false claims presented by Respondents over a period of several years, it is not a mitigating factor that the 20 claims at issue were of the same type, occurred within a short period of time, and

the total amount claimed was less than \$1,000.00. See 42 C.F.R. 1003.106(b)(1).

102. Respondents have not proved by a preponderance of the evidence that the imposition of penalties of \$24,000.00 and assessments of \$288.92 would jeopardize their ability to continue as health care providers. 42 C.F.R. 1003.106(b)(4).

103. Penalties of \$24,000.00 and assessments of \$288.92 imposed against Respondents, jointly and severally, are appropriate in this case.

104. An exclusion against Respondents from participating in the Medicare and Medicaid programs for a period of five years is appropriate in this case.

#### ANALYSIS

1. As is required by section 1128A(c) of the Act, the I.G. initiated a proceeding against Respondents not later than six years after the claims at issue were presented.

Respondents contend that the I.G. is barred from pursuing his case against them with respect to 12 of the claims in issue (counts 2, 6-9, 11, 13-16, 19, and 20) because, as to these claims, the I.G. failed to initiate a proceeding against Respondents within six years after the claims had been presented. The I.G. disputes this contention and asserts that the evidence establishes that the I.G. initiated the proceeding within six years of the dates when all of the claims at issue were presented. I conclude that the I.G. timely initiated his case with respect to all 20 of the claims.

The statute of limitations for commencement of a proceeding under the Act is contained in section 1128(c)(1).<sup>4/</sup> This section states in relevant part:

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<sup>4/</sup> The six-year statute of limitations was added to the Act effective September 1, 1987, and is not applicable to administrative proceedings commenced prior to that date. P.L. 100-93 (1987). Proceedings commenced prior to September 1, 1987 are subject to a five-year limitations period established by regulation. 42 C.F.R. 1003.132. Respondents moved to dismiss this proceeding on the

(continued...)

The Secretary may not initiate an action under this section with respect to any claim, request for payment, or other occurrence described in this section later than six years after the date the claim was presented, the request for payment was made, or the occurrence took place.

At issue here is whether the claims were "presented" within six years of the date the I.G. initiated the proceeding, May 25, 1989.

The evidence establishes that Respondents furnished claims information to a computer service company which recorded that information on computer disks. Findings 16-21. These disks were then provided to KMAP, the Kentucky Medicaid program, which processed claims based on the information contained in them. Finding 39. KMAP recorded the dates when all claims were received for processing on remittance statements. Finding 44. Remittance statements in evidence establish that all 20 claims in issue were received by KMAP within six years of May 25, 1989. Finding 47.

These facts are not disputed by the parties. However, Respondents contend that the term "presented" in section 1128(c)(1) means the date that a party transmits claims for processing, rather than the date that the recipient of the claims receives them. Respondents contend that the transmittal date should be the date that Respondents sent claims data for the claims at issue to the computer service company. Respondents argue that, with respect to 12 of the 20 claims, that date was outside the six-year period.

I disagree with Respondents' characterization of the meaning of the term "presented." I conclude that the term should be construed to mean the date that claims were received for processing by KMAP.

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4/ (...continued)  
ground that it is governed by the five-year regulatory limitation period and not by the statute of limitations. I denied this motion, ruling that the proceeding in this case commenced after September 1, 1987. Respondents did not raise this issue again in their post-hearing submission.

The term "presented" is not defined in section 1128A(c) or elsewhere in section 1128A. In the absence of a specific statutory definition, the term should be given its common and ordinary meaning. The verb "present" is defined in Webster's Third New International Dictionary 1969 Edition as:

1a: to bring about or introduce into the presence of someone . . . 3a: to lay or put before a person for acceptance.

The definition encompasses not just the transmission of something, but its receipt as well. It is entirely consistent with this definition to conclude that "presented," as used in section 1128A(c), means the receipt of claims for processing.

This definition is consistent with the purpose of statutes of limitations. Statutes of limitations, including section 1128A(c), are intended to prevent parties from sleeping on their rights beyond a point in time which the legislature has determined to be the reasonable limit for initiation of a proceeding. A party should not be held responsible for failure to exercise a right unless that party knows or has reason to know that the right has accrued. See Gibson v. United States, 781 F.2d 1334 (9th Cir. 1986), cert. denied 479 U.S. 822 (1987); King v. New York Telephone Co., 785 F.2d 31 (2d Cir. 1986).

The I.G.'s right to charge a party with presenting a false claim or causing a false claim to be presented does not accrue until the claim is received for processing. The I.G. could not possibly know or have reason to know that a false claim had been presented until that claim had been received by the program agent responsible for processing that claim. In this case, that occurred when KMAP received from the computer service company the computer disks containing the claims at issue.

2. Respondents presented or caused to be presented claims for items or services which they knew, had reason to know, or should have known were not provided as claimed, in violation of section 1128A of the Act.

The issue of liability in this case subsumes two questions. First, did Respondents present or cause to be presented false claims for Medicaid reimbursement? Second, should Respondents have known, or did Respondents

know or have reason to know, that the claims were false?<sup>5/</sup> I conclude from the evidence that Respondents presented or caused to be presented all 20 of the claims at issue and that these claims were false. I conclude further that these false claims were a small manifestation of a longstanding scheme by Respondents to defraud the Kentucky Medicaid plan, by claiming reimbursement for brand name prescription drugs that Respondents had not dispensed to Medicaid recipients. Therefore, I conclude that Respondents knew that the items at issue were not provided as claimed. Alternatively, I conclude that Respondents had reason to know or should have known that the items were not provided as claimed.

The 20 claims consist of claims for prescription drugs which Respondents dispensed to Medicaid recipients. Respondents filled all of these prescriptions with generic drugs, as indeed they were required to do by Kentucky law. However, Respondents then caused reimbursement claims to be submitted to KMAP for brand name drugs. These false claims were part of a longstanding pattern of fraudulent submissions by Respondents which were intended to deceive KMAP into paying higher reimbursement for Respondents' Medicaid claims than Respondents were entitled to receive.

a. Respondents caused false claims to be presented.

There is no dispute that Respondents caused the claims to be presented. The uncontroverted evidence establishes that Respondents retained a computer service company to prepare Medicaid claims for them. These claims were prepared entirely from the data which Respondents provided to the computer service company. Finding 21.

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<sup>5/</sup> Prior to December 22, 1987, the Act's standard of liability for a party who filed a false claim was couched in terms of whether the party knew or had reason to know the item or service was not provided as claimed. On December 22, 1987, Congress retroactively substituted the "should know" standard for the "reason to know" standard. No court has decided the validity of Congress' retroactive application of the "should know" standard to claims for items or services presented prior to December 22, 1987. In light of this unresolved issue, I use the "knows" and "should know" standard of the 1987 revision, as well as the pre-revision "has reason to know" standard, to decide Respondent's liability.



The computer service company then transmitted the claims to KMAP.

There is also no dispute that the prescriptions at issue were filled with generic drugs, or that the claims which Respondents presented or caused to be presented to KMAP for these drugs sought reimbursement for brand name drugs. Findings 71, 72. Indeed, Respondents have admitted filling the prescriptions with generic drugs and claiming reimbursement from KMAP for brand name drugs. This evidence is corroborated by evidence establishing that, when the actual prescriptions for the 20 claims were examined by an investigator, none of the prescriptions contained brand name drugs. Finding 71; Tr. at 143, 149, 183, 343.6/ Therefore, the evidence establishes that the items or services represented by the 20 claims at issue were not provided as claimed, within the meaning of section 1128A(a)(1) of the Act.

There is substantial dispute that the Respondents are culpable as defined by the Act. Respondents deny that they ever intended to defraud Medicaid. They assert that, to the extent false claims were presented, they resulted from the misfeasance of Respondents' employees.

I disagree with these contentions. There is strong and persuasive evidence in this case that Respondent Frazier instructed his employees to systematically defraud

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6/ Although I rely on the evidence obtained by the I.G.'s investigator to corroborate Respondents' admissions that the prescriptions at issue were filled with generic drugs, I do not rely on this evidence to conclude that a specific manufacturer's generic version of a particular drug was used by Respondents to fill any given prescription. The investigator testified that he visited Medicaid recipients and examined the pills they produced for each of the prescriptions. All were eventually established to be generic drugs. However, these visits took place days or weeks after Respondents had filled the prescriptions. It is within the realm of reasonable possibility that during the intervening period, recipients commingled the pills they received from Respondents with generic drugs they received from other sources. On the other hand, the fact that none of the pills examined by the investigator were brand name drugs is strong evidence that none of the prescriptions were filled with brand name drugs.

Medicaid by claiming reimbursement for brand name drugs when generic drugs had in fact been supplied.

b. Respondents knew that the claims were false.

A party "knows" that an item or service is not provided as claimed when he or she knows that the information that he or she is placing or causing to be placed on a claim is untrue. Anesthesiologists Affiliated et al. and James E. Sykes, D.O. et al., DAB Civ. Rem. C-99, C-100 (1990); Thuong Vo, M.D. and Nga Thieu Du, DAB Civ. Rem. C-45 (1989). It is not necessary for a respondent to personally make a false claim in order to satisfy the "knows" test. All that is necessary to satisfy the test is that a respondent issue instructions concerning the preparation of claims which he or she knows will result in the inclusion of false information in the claims.

The evidence establishes that Respondents instructed their employees to systematically generate false Medicaid claims, including the claims at issue. One witness, Connie Brewer, credibly testified that she was instructed by Respondent Frazier to record as claims information for all Medicaid sales the product identification numbers of brand name drugs, irrespective of whether generic drugs had actually been dispensed. Finding 27. No evidence was offered to show that this witness' testimony was anything but truthful.

Respondents object to inferences being drawn from Ms. Brewer's testimony concerning the 20 claims at issue, arguing that the witness was employed at a pharmacy other than Respondent Prater during a time period previous to the dates when the prescriptions which underlie the claims at issue were filled. However, for several reasons, I find that the testimony persuasively explains the circumstances under which the claims at issue were generated.

First, the system which Ms. Brewer testified she was instructed by Respondent Frazier to use for recording Medicaid claims data was used verbatim by other billing clerks employed at pharmacies owned or controlled by him, including a clerk who was employed at Respondent Prater during the time when the claims at issue were generated. Findings 31, 37. This system consisted of inscribing a cross on the face of the prescription and writing certain information on the segments created by the cross. This information included the product identification number (the NDC) of the drug to be billed to KMAP. The fact

that the same billing system was used for years by employees at both pharmacies operated by Respondent Frazier strongly suggests that it was used at all times to accomplish the identical objective of defrauding KMAP.

Second, Ms. Brewer's testimony concerning the instructions given to her by Respondent Frazier to claim reimbursement for brand name drugs was corroborated by an affidavit executed by a former employee who worked at Respondent Prater, Janice Lemaster. I.G. Ex. 49.1. Ms. Lemaster testified at the hearing that she could no longer remember as true many of the assertions contained in her affidavit. I conclude that the affidavit, despite Ms. Lemaster's testimony, is a truthful account of what Ms. Lemaster knew as of the date of the affidavit's execution, February 16, 1984. It is far closer in point of time to the events which are the subject of the affidavit than is Ms. Lemaster's testimony at the hearing.<sup>7/</sup>

Third, the account of Respondent Frazier's instructions given by Ms. Brewer and corroborated by Ms. Lemaster consists of the only plausible explanation in evidence to account for the claims at issue. Respondents gave no plausible explanation for how such admittedly false claims were generated.

Respondent Frazier testified that he was unaware how Medicaid claims were billed at pharmacies he operated, prior to the initiation of the investigation which led to this proceeding. Tr. at 535, 543. He asserted, however, that the reason his employees recorded the identification numbers of brand name drugs as claims information for Medicaid claims was that it was easier for the employees to remember brand name identification numbers than the identification numbers for generic drugs. This was so, according to Respondent Frazier, because brand name identification numbers generally contained fewer digits than generic product identification numbers. Tr. at 542.

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<sup>7/</sup> I closely observed Ms. Lemaster's demeanor during her testimony. It was apparent to me that she was a reluctant witness, and that she was trying to minimize the effect of testimony that might be construed as damaging to Respondents. Nonetheless, her testimony, and in particular, her affidavit, largely corroborated Ms. Brewer's testimony.

I conclude that Respondent Frazier's testimony, that he was unaware of billing practices at Respondent Prater, is not credible. Respondent Frazier's testimony was not supported by the testimony of any of his former employees and, in many respects, was contradicted by his former employees. Tr. at 384; I.G. Exs. 49.1; 50.1. Even if it had not been contradicted, Respondent Frazier's assertion that he was ignorant of the manner in which Medicaid claims were generated by the pharmacies he operated would have strained credulity. I cannot accept that this proprietor and sole owner of a small business was ignorant of the manner in which he claimed reimbursement for sales which, by his admission, accounted for up to 50 percent of his business. Furthermore, his professions of ignorance were belied by other testimony he gave which showed that he was keenly aware of his business' profit margin and markup on sales of drugs to Medicaid recipients. See Tr. at 547-548. They were also belied by Ms. Brewer's testimony that Respondent Frazier studied cost data for drugs and complained about his low margin of profit on Medicaid prescriptions. Tr. at 390-391.

Moreover, the explanation Respondent Frazier offered for the false claims makes no sense. It is certainly within the realm of possibility that occasionally an employee of a pharmacy might record an incorrect product identification number on a claims document. It is also possible that one employee might, for a time, systematically misrecord identification numbers. But Respondent Frazier offered his testimony as a blanket explanation for all of the Medicaid claims generated at pharmacies he owned or controlled, including the claims at issue, and I conclude that this explanation is outside the realm of reasonable possibility.

Furthermore, Respondent Frazier would be in no position to know whether his explanation is correct, if, as he claimed, he knew nothing about his pharmacies' Medicaid billing procedures at the time the claims at issue were generated. He did not testify that he had interviewed his former employees, and he offered no reason why former employees would contradict his testimony.

Respondent Frazier attempted to buttress his testimony by asserting that there would have been no motive to systematically claim reimbursement for brand name drugs. He asserted that, unless the Medicaid claim specified that the treating physician requested the recipient be supplied with a brand name drug, a pharmacy would be paid no more than the drug's Maximum Allowable Cost (the

"MAC") as per unit reimbursement. Tr. at 542. According to Respondent Frazier, because none of the claims at issue specified that a physician had requested a brand name drug, KMAP would not have reimbursed Respondents higher than the MAC, which Respondents would have received irrespective of whether they claimed reimbursement for brand name or generic drugs.

This assertion is untrue. As I discuss infra, there is a potential for an unlawful return to be made on fraudulent Medicaid claims, irrespective whether the provider claims that the prescribing physician specified that the prescriptions be filled with brand name drugs.

c. Respondents had reason to know that the claims were false.

The "reason to know" standard contained in the Act prior to December 22, 1987 created a duty on the part of a provider to prevent the submission of false or improper claims where: (1) the provider had sufficient information to place him, as a reasonable medical provider, on notice that the claims presented were for items or services not provided as claimed, or (2) there were pre-existing duties which would require a provider to verify the truth, accuracy, and completeness of claims. Anesthesiologists Affiliated, supra; Vo, supra; George A Kern, M.D., DAB Civ. Rem. C-25 (1987). Although I have concluded that Respondents knew that the items or services in the 20 claims as issue were not provided as claimed, the evidence also establishes, alternatively, that Respondents had reason to know that the items or services were not provided as claimed.

Respondents knew that instructions that they had given to their billing clerks concerning the preparation of data to be used in claims would result in the presentation of false claims. Therefore, Respondents had information to place them, as medical providers, on notice that their claims were for items or services not provided as claimed.

Furthermore, Respondent Prater executed a provider agreement with KMAP which obligated it to adhere to the policies and criteria of KMAP for claiming reimbursement for prescriptions filled for Medicaid recipients. I conclude that this agreement and the policies incorporated therein imposed a duty on Respondents to verify the truthfulness and accuracy of their Medicaid claims, a duty which they ignored.

d. Respondents should have known that their claims were false.

The broadest standard of liability under the Act is "should know." This standard subsumes reckless disregard for the consequence of a person's acts. It subsumes those situations where a respondent has reason to know that items or services were not provided as claimed. "Should know" also subsumes negligence in preparing and submitting, or in directing the preparing and submitting of, claims. Mayers v. U.S. Dept. of Health and Human Services, 806 F.2d 995 (11th Cir. 1986), cert. denied, 484 U.S. 822 (1987); Anesthesiologists Affiliated, supra, at 56; Vo, supra, at 20.

Inasmuch as Respondents had reason to know that their claims were false, they also should have known that their claims were false. The evidence in this case establishes that, at the least, Respondents were indifferent to the activities of their employees. Respondent Frazier's testimony that, prior to the initiation of the investigation which led to this proceeding, he was unaware of the manner in which his pharmacies' Medicaid claims were prepared and billed is, although not a credible explanation of how the false claims were presented, an admission of indifference. His indifference is especially apparent in light of his assertion that Medicaid business accounts for between 25 and 50 percent of Respondents' total business. I conclude that such indifference amounts to a reckless disregard for the consequences of Respondents' claims activities.

I am not concluding, however, that the record of this case establishes that Respondents' employees were negligent, or that Respondents should be held liable for the negligent acts of their employees. The evidence establishes that the employees merely carried out Respondents' instructions to them. To the extent that the claims at issue resulted from misfeasance, it is the misfeasance of Respondents, and not their employees, which would be the cause of the false claims.

3. Penalties, assessments, and an exclusion are appropriate in this case.

The remedial purpose of the Act is to protect government financed health care programs from fraud and abuse by

providers. Mayers, supra, 806 F.2d at 997; Anesthesiologists Affiliated, supra, at 58; Vo, supra, at 22. The assessment and penalty provisions of the Act are designed to implement this remedial purpose in two ways. One is to enable the government to recoup the cost of bringing a respondent to justice and the financial loss to the government resulting from the false claims presented by that respondent. The other is to deter other providers from engaging in the false claims practices engaged in by a particular respondent. Mayers, supra, at 999; Anesthesiologists Affiliated, supra, at 58; Vo, supra, at 22.

The exclusion remedy is designed to protect the Medicare and Medicaid programs from future misconduct. Anesthesiologists Affiliated, supra, at 58. It is thus distinguishable from assessments, which compensate the government for wrongs already committed. Medicare and Medicaid programs have a contractual relationship with those providers who treat beneficiaries and recipients and present claims for reimbursement. Federally funded health care programs are no more obligated to continue to deal with dishonest or untrustworthy providers than any purchaser of goods or services would be obligated to deal with a dishonest or untrustworthy supplier. The exclusion remedy allows the Secretary to suspend his contractual relationship with those providers of items or services who are dishonest or untrustworthy. One purpose of any exclusion, therefore, is to protect the integrity of the Medicare and Medicaid programs for a sufficient period of time to assure that these programs will not continue to be harmed by dishonest or untrustworthy providers of items or services.

Exclusion serves an ancillary purpose of deterring providers of items or services, including those providers against whom the remedy is imposed, from engaging in the same or similar misconduct as that engaged in by the excluded providers. In that respect, it is an exemplary remedy because it reinforces the penalties which may be imposed pursuant to the Act. Anesthesiologists Affiliated, supra, at 58.

The Act and implementing regulations provide that a penalty of up to \$2,000.00 and an assessment of not more than twice the amount claimed may be imposed on a respondent for each item or service which is established as not having been provided as claimed. Social Security Act, section 1128A(a); 42 C.F.R. 1003.103, 1003.104. The maximum penalties which I may impose against Respondents

in this case are \$40,000.00, based on their causing 20 false claims to be presented for payment. The maximum assessments which I may impose are \$288.92, twice the dollar amount claimed in the 20 false claims.

Neither the law nor regulations provide for a maximum exclusion which I may impose. However, the regulations provide that the length of the exclusion should be determined by the same criteria that I employ to determine the appropriate amount of the penalty and assessment. 42 C.F.R. 1003.107.

Regulations prescribe that, in determining the amount of a penalty and assessment, I must consider, as guidelines, factors which may either be mitigating or aggravating. 42 C.F.R. 1003.106. These include: (1) the nature of the claim or request for payment and the circumstances under which it was presented, (2) the degree of culpability of the person submitting the claim or request for payment, (3) the history of prior offenses of the person submitting the claim or request for payment, (4) the financial condition of the person presenting the claim or request for payment, and (5) such other matters as justice may require. 42 C.F.R. 1003.106(a).

A respondent has the burden of proving the presence of mitigating factors, including financial hardship. 42 C.F.R. 1003.114(c). The regulations provide that, in cases where mitigating factors are preponderant, the penalty and assessment should be set correspondingly below the maximum permitted by law. 42 C.F.R. 1003.106(c)(1). The regulations also provide that, in cases where aggravating factors are preponderant, the penalty and assessment should be set close to the maximum permitted by law. 42 C.F.R. 1003.106(c)(2).

The Act has been interpreted to permit the imposition of a penalty and assessment which exceeds the amount actually reimbursed to a respondent for items or services not provided as claimed. Chapman v. U.S. Dept. of Health & Human Services, 821 F.2d 523 (10th Cir. 1987); Mayers, supra, 806 F.2d at 99. This reflects the legislative determination that activities in violation of the Act "result in damages in excess of the actual amount disbursed by the government to the fraudulent claimant." Mayers, supra, 806 F.2d at 999.

I find that assessments of \$288.92 and penalties of \$24,000.00 should be imposed against Respondents, jointly and severally. I also find that Respondents should be



excluded from participation in Medicare and Medicaid for five years. My findings result in part from my conclusion that there exist significant aggravating factors in these cases, and no mitigating factors.

The violations established in this case were deliberate and fraudulent. The false claims resulted from instructions Respondents gave their employees to claim Medicaid reimbursement for brand name drugs, even where generic drugs were supplied to recipients. These fraudulent claims were part of a pattern of such claims that Respondents had engaged in for years. The testimony of former employees establishes to my satisfaction that such deliberately false claims were being made at least several years prior to the claims at issue in this case. Furthermore, the testimony of these employees proves a consistent pattern of false claims.

Contrary to Respondents' assertions, their false claims fraudulently obtained Medicaid reimbursement greater than that which Respondents would have obtained had the claims been honestly stated. Respondents' false claims manipulated the KMAP drug reimbursement formula to produce illegal overpayments.

KMAP employed a formula which had as an element a payment per unit of drug dispensed by a pharmacy. That formula was designed to pay the pharmacy the lowest of either the pharmacy's usual and customary charge for the drug, a dispensing fee plus the drug's Estimated Acquisition Cost (EAC), or a dispensing fee plus the drug's Maximum Allowable Cost (MAC). Findings 56-64. Different versions of a particular drug usually had different EACs, with the brand name version of the drug almost always having the highest EAC. The MAC was the median of all EACs for a particular drug. In many cases, KMAP did not establish a MAC for a drug.

The motivation for falsely claiming reimbursement for a brand name drug lay in the fact that a brand name drug's EAC was almost always higher than the EACs of the drug's generic equivalents. In cases where there was no MAC for the product, Respondents would receive, as a per unit cost from KMAP, the EAC of the brand name drug for which

they claimed reimbursement.<sup>8/</sup> Because that EAC was higher than the EACs of generic drugs, Respondents would receive an overpayment for the false claim.<sup>9/</sup>

There also existed motivation to falsely claim that brand name drugs had been supplied in those cases where KMAP had established a MAC for a class of drugs. Respondents argue that, in such cases, KMAP would generally not pay more than the MAC as per unit reimbursement.<sup>10/</sup> That does not mean that an unlawful overpayment could not have been obtained by falsely claiming reimbursement for a brand name drug. Such overpayment would occur in any case where the EAC of the brand name version of a drug equalled or exceeded all versions of that drug's MAC, and the EAC of the generic drug actually supplied was less than the MAC.

Although the evidence establishes that many of the claims at issue resulted in unlawful overpayments to Respondents, I have not found a specific dollar amount of the overpayments. In order to do so, I would have had to decide which generic drugs were used by Respondents to fill prescriptions, because each generic drug has its own EAC. As noted supra, while the evidence unequivocally proves that Respondents filled all 20 prescriptions in question with generic drugs, the evidence does not prove which manufacturer's generic drugs were used by Respondents to fill particular prescriptions. See n.6,

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<sup>8/</sup> Respondents did not claim a usual and customary charge for the drugs on any of the claims at issue. See I.G. Ex. 1.1-20.1.

<sup>9/</sup> See, for example, the claims identified by the I.G. as claims 2, 4-7, 11, 12, 16, and 20. There existed no MAC for the class of drugs dispensed for each of these claims. The EAC for the brand name version of the drug dispensed in each of these cases was higher than the EAC of any generic equivalent of that drug. Therefore, by falsely claiming that they had dispensed brand name drugs, Respondents assured themselves of an illegal overpayment on each of these claims. Findings 86-88.

<sup>10/</sup> The exception would have occurred had the party claiming reimbursement asserted that the Medicaid recipient's physician had specified that a brand name drug be supplied to the recipient. Such a "physician override" was not claimed in any of the 20 claims at issue in this case.

supra. The Act does not require the I.G. to prove a specific overpayment as a prerequisite to establishing a violation. Social Security Act, section 1128A(a).

Respondents' scheme to systematically falsely claim reimbursement for brand name drugs would not produce large overpayments on individual claims. The difference between the EACs of brand name drugs and the EACs of generic drugs often amounted to only a few cents. Actual overpayments could range between pennies and a few dollars per false claim.

However, over time, such a scheme would inevitably produce substantial illegal returns. I have concluded that the 20 claims at issue in this case were a manifestation of a longstanding fraud. The small overpayments that these claims generated are only a symptom of a pattern of fraudulent claims.

The most serious aggravating factor in these cases is the damage that Respondents' pattern of fraudulent claims did to the integrity of the Kentucky Medicaid program. The State of Kentucky decided as a matter of legislative policy that Medicaid prescriptions should ordinarily be filled with generic drugs. This policy was incorporated into KMAP's drug reimbursement formula. The formula was specifically designed to protect the Medicaid program from excessive charges or excessive payments, and to establish a uniform, fair, and equitable means of reimbursing pharmacies for medications that are provided to Medicaid recipients. Finding 55. Respondents' circumvention of this policy rendered it meaningless as it applied to them.

Normally, I would consider a small number of false claims perpetrated over a short period of time, and involving only a small sum, to be a mitigating factor. See 42 C.F.R. 1003.106(b)(5). I do not find that such evidence establishes mitigation in this case, because these claims are only a small sample of a longstanding pattern of unlawful conduct.

I do not find credible Respondents' assertions that they are financially incapable of paying the penalties and assessments. They offered only anecdotal evidence of their financial status. No business or personal records, such as corporate statements, business or personal income tax returns, or financial statements, were offered by Respondents to substantiate their assertions. Moreover, Respondent Frazier's lack of credibility on other issues

impugns his credibility as to his assertions of financial hardship.

Both the assessments and the penalties are amply justified by the evidence in this case, and by the factors which I have enumerated. The assessments cannot begin to recoup the cost which the government incurred in connection with this case. The hearing was the culmination of an investigation into Respondents' Medicaid claims practices which lasted for many years. The hearing lasted three days, and required the compensation, travel, and lodging of a number of federal employees at government expense, plus the cost of the transcript.

The penalties are only slightly more than one half of the amount which the law permits me to impose in this case. I conclude that they are justified by the egregious conduct which the record establishes. Furthermore, I conclude that the penalties are a necessary deterrent against others engaging in the conduct engaged in by Respondents. The drug reimbursement requirements established by the Kentucky legislature and KMAP are meaningless if pharmacists systematically contravene them. The penalties, therefore, serves as a reminder to others that there are serious consequences for willfully damaging the integrity of the Medicaid program.

I conclude that the five year exclusion from participation in Medicare and Medicaid which I have imposed on Respondents is a necessary remedy in two respects. First, the exclusion will assure that these Respondents will not be in a position to do further damage to the integrity of federally funded health care programs. Second, they will warn Respondents and other providers of health care that they cannot ignore their legal obligations to these programs.

I base my conclusion that these Respondents should be excluded for five years, as opposed to a shorter or longer period, on the aggravating factors and the remedial considerations which I have cited in this Decision. Respondents' manifest untrustworthiness and the damage they caused to the integrity of the Kentucky Medicaid program provides ample basis to conclude that federally funded health care programs need not do business with them for five years.

I also base the length of the exclusion on my conclusion that the unlawful conduct engaged in by Respondents is

indistinguishable from the type of conduct for which Congress prescribed a minimum mandatory five year exclusion under section 1128(a)(1) of the Social Security Act. That section mandates five year exclusions for parties convicted of criminal offenses related to the delivery of an item or service under the Medicare or Medicaid programs. Congress' intent was not to prescribe additional punishment for such offenders. Rather, Congress concluded that parties who engage in theft, fraud, and other criminal offenses of a financial nature against Medicare or Medicaid have demonstrated by their conduct that they should not be trusted to do business with these programs for at least five years. See Jack W. Greene, DAB App. 1078 (1989), aff'd sub nom Greene v. Sullivan, Civil No. 3-89-758 (E.D. Tenn. February 8, 1990).

I am not concluding that the evidence in this case establishes that Respondents are guilty of a crime. However, I do conclude that Respondents have engaged in fraud, as that term is commonly and ordinarily used. Furthermore, the misconduct engaged in by Respondents -- fraudulently claiming reimbursement from a Medicaid program for brand name drugs -- is the same type of misconduct which has resulted in five year exclusions under section 1128(a)(1). Greene, supra. Given that, the identical policy considerations which Congress decided required five year minimum exclusions pursuant to section 1128(a)(1) also apply here.

Respondents contend that an exclusion will force the demise of Respondent Prater as a health care provider. They assert that, inasmuch as half of Respondent Prater's business consists of Medicaid, the business would no longer be viable if it were deprived of Medicaid reimbursement.

An exclusion imposed pursuant to the Act will have an adverse financial impact on the person against whom the exclusion is imposed. The law places the integrity of the Medicare and Medicaid programs ahead of the pecuniary interests of providers. In determining to impose an exclusion, the primary consideration must be the degree to which the exclusion serves the law's remedial objectives. An exclusion is remedial if it does reasonably serve these objectives, even if it has a severe adverse impact on the person against whom it is imposed.

Respondents' argument could be made by any provider of health care who depends on federally funded programs as a principal revenue source. If I were to accept Respondents' argument, then I would be forced to conclude that, in any case where a provider's livelihood depends on federally funded reimbursement, the remedies contemplated by law could not be imposed. The Act would then become meaningless.

I conclude that, in this case, the need to impose a meaningful remedy to protect the integrity of the Medicare and Medicaid programs supersedes the damage that such remedy may cause Respondents' business. There may be cases where the remedy can be tempered in a way to preserve a provider's business and still protect program integrity. In this case, however, that is not possible.

#### CONCLUSION

For the reasons set forth in this Decision, I impose assessments of \$288.92, and penalties of \$24,000.00 against Respondents, jointly and severally. I also impose an exclusion of five years against Respondents from participating in the Medicare and Medicaid programs.

/s/

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Steven T. Kessel  
Administrative Law Judge