Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
T. Bruce Vest, M.D.,	)	DATE: December 1, 1995
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-95-035
	)	Decision No. CR405
The Inspector General.	)	
	)	

DECISION

This case comes before me pursuant to the request for hearing timely filed by Petitioner to contest the Inspector General's (I.G.'s) determination that he should be excluded from participation in the Medicare program and the State health care programs defined in section 1128(h) of the Social Security Act (Act) for a period of five years under section 1128(b)(6)(B) of the Act. By delegation from the Secretary of Health and Human Services (Secretary), the I.G. may impose and direct an exclusion against an individual who has

> furnished or caused to be furnished items or services to patients (whether or not eligible for services under title XVIII [Medicare] . . .) substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care.

Act, section 1128(b)(6)(B); see also 42 C.F.R. § 1001.701(a)(2). For the reasons discussed below, I conclude that the I.G. has failed to prove that Petitioner furnished items or services that were either substantially in excess of his patients' needs or that failed to meet professionally recognized standards of health care. Therefore, there is no basis for Petitioner's exclusion.

PROCEDURAL HISTORY

The I.G. may make exclusion determinations under section 1128(b)(6) of the Act based upon a sanction report from "[f]iscal agents or contractors" or information from "[a]ny other sources deemed appropriate" by the I.G. 42 C.F.R. § 1001.701(b)(3) and (5). The exclusion in this case was requested by the Health Care Service Corporation, which does business as Blue Cross and Blue Shield of Illinois (Illinois Carrier or Carrier), the fiscal agent in the State of Illinois for the Medicare Part B program.[1] I.G. Ex. 11. The sanction request was based on an analysis done by the Illinois Carrier's Medical Director, Douglas Busby, M.D., who concluded that Petitioner had rendered 77 services that were medically unnecessary or of poor quality in treating 10 Medicare patients during visits that occurred between April 9, 1992 and September 6, 1993. I.G. Ex. 11 at 1; I.G. Ex. 12.[2]

On May 25, 1994, the I.G. notified Petitioner of the intent to exclude him based on most, but not all, of the services criticized by Dr. Busby. I.G. Exs. 1, 2, 12.

Petitioner then submitted a written response, arguing, inter alia, that "the review of each visit does not take into account the past records of the patient's visits nor the immediate follow-up examinations, all of which were available to Medicare" as part of Petitioner's prior submissions for Medicare reimbursement. P. Ex. 5 at 2.

---

[1] Section 1842 of the Act specifies the use of carriers for the administration of benefits under the Supplementary Medical Insurance Benefits for the Aged and Disabled program, known as Medicare Part B. As explained by regulation, the term "carrier" means an entity that has a contract with the Health Care Financing Administration (HCFA) of the Department of Health and Human Services (HHS) to determine and make Medicare payments for Part B benefits and to perform other related functions. 42 C.F.R. § 400.202.

[2] In two instances, Dr. Busby's report included several services in a single paragraph. In reporting on the treatment of Patient L.W. on August 5, 1993, Dr. Busby included in one paragraph two services: X-rays of lumbosacral spine and MRI of lumbar spine. I.G. Ex. 12 at 123. Also, in reporting on the treatment of the same patient on August 13, 1993, Dr. Busby included in one paragraph these three services: CT abdomen, CT pelvis, and X-ray abdomen. I.G. Ex. 12 at 148.

He availed himself also of the opportunity to make an in-person presentation to Kenneth Nelson, M.D., of the I.G.'s Office. P. Ex. 4; I.G. Ex. 4.

Subsequently, the I.G. notified Petitioner by letter dated November 18, 1994 that the determination to exclude him had not been altered. However, the I.G., by Mr. James Patton, deleted seven more services, while agreeing with all other "violations" identified in the notice of intent to exclude Petitioner. I.G. Ex. 5.

The Secretary's implementing regulation states that an exclusion pursuant to section 1128(b)(6)(B) will be for a period of three years, unless one or more of the enumerated aggravating or mitigating factors exist and warrant modifying the three-year benchmark period. 42 C.F.R. § 1001.701(d)(1). In the notice of exclusion, the I.G. states that the exclusion of five years is based upon the following two aggravating factors:

> The violations were serious in nature and occurred over a period of one year or more;
>
> The violation resulted in financial loss to Medicare . . . of $1,500 or more.

I.G. Ex. 4 at 2 - 3; 42 C.F.R. § 1001.701(d)(2)(i) and (iv).

During a prehearing conference held on January 13, 1995, the parties agreed that they would endeavor to proceed on the basis of written arguments and documentary evidence alone. Order and Schedule for Filing Briefs and Documentary Evidence 2 (Jan. 17, 1995). Accordingly, Petitioner submitted a Motion to Reverse Denial of Certain Laboratory Tests . . . and to Dismiss Exclusion Decision (P. Prehrg. Br.) along with various exhibits. However, in her response brief (I.G. Prehrg. Br.), the I.G. requested an in-person hearing because there is no regulatory definition for "substantially in excess of such patients' needs" and the exclusion "turn[s] on the consideration of medical records which must be evaluated by medical experts." I.G. Prehrg. Br. at 4, 35.

I granted the I.G.'s motion for an in-person hearing for the reason argued by the I.G. Order and Notice of Hearing (May 18, 1995). My prehearing order also identified the issues as:

> Whether the I.G. had a basis for excluding Petitioner; [and,]

> Whether the exclusion of five years imposed and directed against Petitioner by the I.G. is reasonable.

Order and Notice of Hearing 2. Pursuant to 42 C.F.R. § 1005.15(c), my Order stated also that the I.G. would have the burden of coming forward with evidence proving that there is a basis for the exclusion and that the length of the exclusion is reasonable; Petitioner would have the burden of coming forward with evidence in support of Petitioner's arguments. Id.[3] As specified by regulation, the standard of proof at a hearing is a preponderance of the evidence. 42 C.F.R. § 1001.2007(c).

During the final prehearing conference, held on July 7, 1995, I considered Petitioner's motion to strike various of the I.G.'s proposed exhibits, as well as Petitioner's motion, in the alternative, to subpoena several categories of witnesses (totalling 53 witnesses) in order to refute the truth of those proposed exhibits offered by the I.G. I granted Petitioner's motion to strike the specified proposed exhibits. Ruling Excluding Certain Proposed Exhibits and Summary of Prehearing Conference (July 10, 1995).[4]

The in-person hearing took place July 13 through 15, 1995, in Alton, Illinois.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

For the reasons discussed in the designated sections of this Decision, I make the following findings and conclude that the exclusion imposed and directed by the I.G. under section 1128(b)(6)(B) of the Act must be set aside for lack of a proven basis:

---

[3] In order to permit administrative law judges to continue their practice of allocating the burden of proof as they see fit, the regulations do not specify which party bears the burden of going forward or which party has the burden of persuasion in cases involving exclusions under section 1128(b) of the Act. 57 Fed. Reg. 3326 - 27 (Jan. 29, 1992).

[4] After the hearing, the I.G. reargued the relevancy and weight of certain of the I.G.'s proposed exhibits which I had excluded. I have treated those arguments as the I.G.'s motion for reconsideration, which I deny in a ruling issued concurrently with this decision.

1. The facts of record do not establish the merits of the Carrier's conclusion that Petitioner had a history of "overutilization," which was unchanged despite efforts to educate him. See Section I of Discussion, below.

2. The I.G.'s reliance on the Carrier's inadequately supported conclusion does not establish a basis for Petitioner's exclusion. Finding 1; See Section I, below.

3. The evidence fails to prove that the criteria and instructions Dr. Busby followed in reaching his opinions in support of the Carrier's exclusion recommendation were reasonable or related to the requirements of section 1128(b)(6)(B) of the Act. See Section II.A., below.

4. Dr. Busby did not testify as an independent medical expert concerning the totality of relevant medical evidence in this case; Dr. Busby's role at hearing was limited to explaining his creation of the written report in support of the Carrier's exclusion recommendation. See Section II.B., below.

5. Dr. Busby's opinions fail to prove the I.G.'s contention that the care rendered by Petitioner was substantially in excess of his patients' needs. See Section II.C., below.

6. Dr. Busby's opinions fail to prove the I.G.'s contention that Petitioner rendered care that failed to meet professionally recognized standards. See Section II.D., below.

7. The I.G. did not prove a basis for the exclusion with Dr. Busby's opinions. Findings 3 - 6; see Section II, below.

8. The medical records Petitioner submitted to the Carrier in support of particular claims for Medicare reimbursement are insufficient to prove a basis for the exclusion in this case. See Section III, below.

9. The I.G. did not prove that other evidence or medical opinions support her determination that a basis for the exclusion exists. See Section IV, below.

10. Petitioner is entitled to rely on medical opinions regarding his patients' complete medical records. See Section V.A., below.

11. Based on the experts' professional experiences and the documents they reviewed, the opinions of Petitioner and his expert witness are entitled to greater weight

than the contrary opinions of Dr. Busby. See Section V.B., below.

12. The evidence introduced by Petitioner is more credible than that introduced by the I.G. Findings 1 - 11; see Section V, below.

13. The I.G. lacked a basis for imposing and directing an exclusion against Petitioner pursuant to section 1128(b)(6)(B) of the Act. Findings 1 - 12.

SUMMARY OF THE PARTIES' EVIDENCE AND THEORIES

The I.G. argues that she is authorized to exclude Petitioner pursuant to section 1128(b)(6)(B) of the Act. According to the I.G., Petitioner rendered services that were: 1) substantially in excess of patients' needs, and 2) of a quality which failed to meet professionally recognized standards of care. I.G. Prehrg. Br. 35. According to the I.G., both components are proven by the inadequacies in the medical records Petitioner submitted to the Carrier in order to seek payment for his services under the Medicare program. Tr. 216; I.G. Proposed Findings 84, 85.

The merits of the I.G.'s case rest entirely on the opinions of Douglas Busby, M.D., the Illinois Carrier's current Medical Director. Dr. Busby was the I.G.'s only witness at hearing, and the I.G. has submitted only his written medical report into evidence. Dr. Busby formed his opinions based on a document review process which the I.G. argues was thoughtful and complete. I.G. Prehrg. Br. at 16 ; I.G. Posthearing (Posthrg.) Br. at 2.

However, as discussed herein, Dr. Busby testified only concerning the circumstances under which he prepared a sanction recommendation to the I.G. and the limited documents he reviewed in reaching the opinions expressed in that recommendation. He based his selection and review of documents on instructions given to him by the I.G. during September 1993. The I.G. has not shown that the instructions followed by Dr. Busby relate reasonably to the exclusion criteria. Even though the I.G. had persuaded me to hold an in-person hearing in this case based on her argument that expert medical testimony was critical to the issues in this case (I.G. Prehrg. Br. at 35), the I.G. chose to limit her proof to the opinions of Dr. Busby, who did not review any of the medical records referenced or submitted by Petitioner subsequent to the time that the I.G. issued her notice of intent to impose an exclusion. The I.G. contends that Dr. Busby's

conclusions, based on his review of selected records, conclusively establish a basis for the exclusion. She vigorously objected to my admitting into evidence any information Dr. Busby had failed to review, such as the patients' complete medical files and Medicare reimbursement determinations made by the Carrier based on the same medical records Dr. Busby criticized.

The I.G. did not offer the medical opinions of any other expert or of anyone else who may have reviewed additional medical records and helped form conclusions on the I.G.'s behalf. In addition, the I.G. chose not to offer any rebuttal evidence concerning the merits of the contrary medical opinions given by Petitioner and his expert witness.

At the hearing, Petitioner introduced his own medical opinions, as well as the written report and testimony of Rodolfo U. Beer, M.D., a general surgeon who has been practicing in the Alton area since 1967. E.g., P. Exs. 79, 80; Tr. 517 - 19. Petitioner and Dr. Beer have more experience than Dr. Busby in the diagnosis and treatment of elderly patients. Moreover, both Dr. Beer and Petitioner testified that they had reviewed the complete patient files, which Dr. Busby did not do for the reasons detailed herein. The medical opinions of Petitioner and Dr. Beer contradict the conclusions reached by Dr. Busby on the medical necessity and quality of care issues.

During the hearing, Petitioner made available, on more than one occasion, the complete patient files for the I.G.'s review or use in cross-examination. E.g., Tr. 433 - 35, 506 - 08. The I.G. objected and declined to review them each time. Id.

Petitioner asserted also as part of his defense that approximately 50 of the more than 70 services criticized by Dr. Busby have been approved for Medicare reimbursement, based on a full prepayment review of the same records considered by Dr. Busby. E.g., Tr. 8 - 12; P. Exs. 9, 88. Therefore, Petitioner argues that there exists a difference of professional opinion even within the Carrier, and such a difference of professional opinion does not establish a basis to exclude Petitioner. Tr. 8 - 12.[5] Petitioner believes that approval of his

---

[5] During the hearing, Petitioner requested partial summary judgment based on these arguments. Tr. 8 - 12. I denied the motion. However, Petitioner's arguments established the relevancy of his Medicare

(continued...)

Medicare claims pursuant to a full prepayment review, or pursuant to an on-merits hearing of a claim that was initially denied by the Carrier, must at least create the presumption that Petitioner's diagnosis and procedures were in fact proper under Medicare guidelines. P. Posthrg. Br. at 10.

As I explain in more detail below, I conclude that neither the documentary evidence of record nor Dr. Busby's testimony at hearing establishes a basis for Petitioner's exclusion. Therefore, I do not reach the issue of whether the length of exclusion is reasonable.

DISCUSSION

I. The I.G. did not prove a factual basis for the exclusion by adopting the Carrier's opinion that Petitioner has a history of "overutilization," which did not change despite the Medicare prepayment review process instituted by the Carrier in September of 1989.

The Illinois Carrier requested Petitioner's exclusion because, in the opinion of the Illinois Carrier, more than 70 services "show unchanged pattern of medical management [by Petitioner] over time" and "educational efforts directed at reducing [Petitioner's] overutilization ha[d] no discernable effect." I.G. Ex. 11. The I.G. apparently adopted the Carrier's conclusion, making the same contention in her prehearing brief, in her opening statement at hearing, and through witness testimony. E.g., I.G. Prehrg. Br. at 15; Tr. 29, 55 - 74. The I.G. maintained also after the hearing that the "[C]arrier and OIG struggled to educate Dr. Vest for six years after identifying him as a problem provider." I.G. Posthrg. Reply at 3. The I.G.'s position appears to be that the merits of the I.G.'s exclusion determination, based on the approximately 70 services identified by the I.G., are supported by the Carrier's determination that Petitioner has a history of "overutilizing" services and that the full prepayment review procedures imposed by the Carrier have not changed his practice pattern.

The I.G.'s evidence shows that, in the opinion of the Carrier, Petitioner was significantly "overutilizing" diagnostic procedures and services under the Medicare

---

[5] (...continued)
payment evidence.

program. E.g., I.G. Ex. 11; Tr. 4 - 7. "Overutilization" is a term used by the Carrier to describe a provider who is submitting claims which the Carrier considers to be excessive. Tr. 55. The Carrier concluded that Petitioner's utilization of medical procedure(s) was excessive after several audits conducted between 1987 and September 1988 showed that his utilization exceeded by 95 percent to 96 percent the utilization of the same procedure(s) by his peer group in the locality designated by the Carrier. Tr. 59 - 60.

After Petitioner's name had appeared repeatedly on the Carrier's list of "aberrant" providers and the Carrier had conducted audits for that reason, the Carrier followed the I.G.'s advice and placed all of Petitioner's Medicare claims under a full prepayment review process, beginning in September 1989. Tr. 55 - 56, 91. As noted by the I.G., Medicare Part B payments cannot be authorized "for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." Section 1862(a)(1)(A) of the Act; I.G. Prehrg. Br. at 8. It is the duty of each carrier to "make such audits of the records of providers of services as may be necessary to assure that proper payments are made . . . ." Act, section 1842(a)(1)(C).

I conclude that the I.G. has not introduced evidence sufficient to prove the merits of the Carrier's conclusions that Petitioner was overutilizing services prior to September 1989, that placing and maintaining him under full prepayment review process was appropriate, or that his overall pattern of "overutilization" has remained unchanged despite the prepayment review process. The evidence concerning these conclusions merely explains why the Carrier was interested in having Petitioner excluded from the Medicare program. Such evidence does not establish the correctness of the I.G.'s conclusion that Petitioner should be excluded for having rendered the approximately 70 services to 10 patients during 1992 and 1993.

First of all, the Carrier's determination that Petitioner's practice patterns were aberrant, compared with others in his peer group and locality, is not supported by credible evidence. Dr. Busby, as the Carrier's Medical Director, could not specify the locality or peer group applicable to Petitioner during the time when the "overutilization" determination was made -- except that St. Louis, Missouri, and its practitioners were not considered, despite their

proximity to the Alton area, because the Carrier did not do any work outside of Illinois. Tr. 56 - 59, 80 - 81. Nor did Dr. Busby know whether Petitioner was "aberrant" with respect to one or more procedures, or with respect to which procedures. Tr. 58, 150.

Dr. Busby conceded that it would be very difficult to find a peer group for Petitioner, given his dual specialties (42 years of general practice with Board Certification in Radiology) and the amount of sophisticated diagnostic equipment in his office (e.g., MRI and CAT Scan). Tr. 149. At one point, Dr. Busby even suggested that it might have been appropriate to compare Petitioner's practice patterns to Chicago's Rush Presbyterian Hospital or the State's other large health care centers, which tended to have more sophisticated equipment and more specialists than other locations in Illinois. Tr. 151 - 52. Dr. Busby did not know information such as how many CAT scanners are in the various counties in the vicinity of Alton, or whether a particular county was large, small, or rural. Tr. 152 - 53. However, after Dr. Busby claimed also that no location in the United States is unique, he acknowledged that the Carrier divided the State of Illinois into localities in its evaluations only because the Carrier could not handle the entire population of the State as a whole. Tr. 151 - 52 ("What we try to do is we try to group into large segments of the population").

In addition, one key factor in the Carrier's decision to request Petitioner's exclusion was its concern for the amount of money (estimated by the Carrier to be approximately $200,000 per year[6]) Petitioner's prepayment reviews were taking out of the Carrier's budget. Tr. 86, 91. At the beginning of each year, the Illinois Carrier must negotiate with HCFA for a fee to process all Medicare claims in the State, and the Illinois Carrier

---

[6] Even though the I.G. used the aggravating factor codified at 42 C.F.R. § 1001.701(d)(2)(iv) to allege a financial loss to the Medicare program of $1500 or more due to the prepayment review of Petitioner's claim and Petitioner's exercise of his administrative appeal rights (I.G. Ex. 4 at 3), there is no proof what funds the I.G. considers to be from the "Medicare program," and there is no evidence explaining the source of funds HCFA provides to the Carrier each year to process Medicare claims. The I.G. evidence shows only that the amount of financial loss alleged to support this aggravating factor came from the Carrier's budget. Tr. 91.

believed it must stay competitive with other carriers in its bids. Tr. 89. The Carrier was concerned that the approximately $200,000 it took to conduct prepayment reviews of Petitioner's claims each year was cutting into its operating costs and that it needed a profit margin in order to expand and to be competitive in the marketplace. Tr. 90. In addition, the Carrier was also concerned about whether it could "increase our salaries? Is there enough money to increase salaries from profit?" Tr. 90 - 91.

Based on the Illinois Carrier's concerns for its finances, Dr. Busby suggested to the I.G. that the Carrier pay all of Petitioner's claims out of the Medicare Trust Fund rather than review each claim at the expense of the Carrier's budget. Tr. 90. However, his suggestion was rejected. Tr. 90, 91. Nevertheless, Dr. Busby's testimony leaves no doubt that the Carrier's financial wellbeing was a major factor in the Carrier's decision to recommend Petitioner's exclusion from the Medicare program.

The I.G. has placed into evidence the fact that the Carrier projected a Medicare overpayment to Petitioner of more than $1,700,000 based upon a sampling of claims submitted by Petitioner during the period October 1, 1988 through September 30, 1991. I.G. Ex. 10. However, I cannot adopt this projection, because the merits of the Carrier's determinations are pending adjudication in another forum. E.g., Tr. 4 - 5, 516. In fact, after an objection from Petitioner, the I.G. stipulated that the document containing the projected overpayment (I.G. Ex. 10) was offered to show that Petitioner was placed under full prepayment review and that the Carrier escrowed the funds. Tr. 4 - 7.

Another problem with the I.G.'s use of the Carrier's conclusion that Petitioner failed to change his overall pattern of overutilization, is the fact that the I.G. has not endeavored to show how many claims were filed by Petitioner and the disposition of those claims pursuant to full prepayment reviews. Instead, the I.G. relies upon the implications of her argument that, for six years, the Carrier and the I.G. "struggled" to educate Petitioner after having identified him as a "problem provider." I.G. Posthrg. Reply at 3. The record does not adequately support the I.G.'s argument or the inferences she would have me draw concerning the justification for Petitioner's exclusion.

For example, the fact that the Carrier did not remove Petitioner from the prepayment review plan does not

indicate that the Carrier continued to find problems with the Medicare claims submitted by Petitioner. Dr. Busby testified that the prepayment review for a physician would not end unless the physician promised the Carrier, in writing, to refrain from billing Medicare for a disputed procedure or represented, in writing, that the physician had changed practice patterns. Tr. 77 - 79. (This information is not contained in any of the Carrier's correspondence with Petitioner.) Therefore, even though the Carrier may be approving most of a provider's claims after reviewing a provider's records under the full prepayment review process, the prepayment review process would continue. Tr. 79.

As part of his defense, Petitioner contended that, of those services specifically criticized by Dr. Busby in his exclusion recommendation: 1) approximately 50 were actually reimbursed under the Medicare program during the time that Petitioner was under the full prepayment review process; and 2) payments for the other services denied by the Carrier are pending review and may be subject to on-merits hearings before other administrative law judges. E.g., Tr. 8 - 12, 19; P. Prehrg. Br. at 3, 5; P. Exs. 9, 88. The evidence establishes that, under the prepayment review process, the Illinois Carrier was reviewing each of Petitioner's services and supporting documents before deciding whether to authorize Medicare payments. E.g., Tr. 69 - 73, 76 - 77. The Illinois Carrier had assigned the prepayment review of Petitioner's claims to its most experienced analysts (Tr. 160), to two nurses on staff (Tr. 70), and to physicians contracted by the Carrier when more complicated issues arose (Tr. 76, 163). The instructions issued by the Carrier to its staff stated that, unless Petitioner attached the patient's complete history and physical to each claim, and unless the diagnostic procedures related to a specific diagnosis or symptoms, Medicare payment would be denied. P. Ex. 9 at 87. There were repeated contacts between the Carrier's Medical Director and the reviewing staff to ensure that the staff was functioning appropriately. Tr. 76. Questions concerning the medical necessity of procedures were supposed to have been referred to the Carrier's Medical Director. P. Ex. 9 at 87.

The I.G. objected to Petitioner's use of any Medicare payment information, based on the following arguments: 1) the payment evidence is irrelevant because the I.G. did not base the exclusion on considerations of Medicare payments (I.G. Prehrg. Br. at 15); 2) a payment summary prepared by Petitioner as P. Ex. 88 should not be considered the "authoritative word" due to possible conflicts with copies of actual government issued payment

records contained in P. Ex. 9 (Tr. 18); 3) ascertaining the accuracy of Petitioner's payment summary by comparing it with the copies of government records would be complicated (Tr. 19 - 20); and 4) it would be very time-consuming to retrieve and review the relevant microfiches maintained by the Illinois Carrier (Tr. 19 - 20).

I do not find any of these objections to be meritorious. The I.G. has had ample time to ascertain the accuracy of the payment information. Petitioner first raised the issue in his January 1995 prehearing brief, which included the payment summary and copies of government generated payment records that are now in evidence as P. Ex. 9.[7] In addition, when I admitted Petitioner's Exhibit 88 at the hearing, I informed the I.G. that she was free to develop the accuracy issue through witness testimony and bring inaccuracies in the summary to my attention in her posthearing brief. Tr. 18. Therefore, in the absence of any contrary evidence from the I.G., I consider to be true Petitioner's representations that he was paid under the Medicare program for approximately 50 of the services criticized by Dr. Busby and that the remaining services are under review and may result in decisions favorable to him on the payment issue. Petitioner's evidence concerning the Carrier's payment of the approximately 50 services is relevant at least to refute the I.G.'s contention that efforts to educate him under the prepayment review process have failed.

For the foregoing reasons, I have concluded that the I.G. has failed to prove the merits of the Carrier's determinations that Petitioner was an "aberrant provider" whose Medicare claims needed to be placed and maintained under a full prepayment review process beginning in September of 1989, or that the Carrier's efforts to educate Petitioner failed. Accordingly, these determinations made by the Carrier and adopted by the I.G. do not establish a factual basis for the exclusion in controversy.

---

[7] At the hearing, the I.G. did not object to P. Ex. 9, and I admitted it. Tr. 3.

II. The I.G. did not prove, with the use of Dr. Busby's opinions, that a basis for the exclusion exists.

A. The evidence fails to prove that the criteria and instructions Dr. Busby followed in reaching his opinions in support of the Carrier's exclusion recommendation were reasonable or related to the requirements of section 1128(b)(6)(B) of the Act.

I will discuss in this section the problems with the foundation of Dr. Busby's opinions and their consequences for the I.G.'s case.

The evidence establishes that, in 1992, Charles C. Henderson, M.D., the Carrier's Medical Director at that time, submitted records of 10 cases to the I.G. and recommended that the I.G. exclude Petitioner under section 1128(b)(6)(B) of the Act. Tr. 77; P. Ex. 82. The I.G., by James Patton, rejected the recommendation in a memorandum dated April 27, 1992. P. Ex. 82. Among the problems found by Mr. Patton was the fact that the medical reviewer did not adequately clarify why the care provided was unnecessary, what the proper care should be, and why. P. Ex. 82 at 1. Mr. Patton stated also:

> medical reviewers should, if appropriate, review the medical records of the care provided by the physician to the patient prior to and/or subsequent to the care in question. We have frequently found when the case has reached the administrative review level, the physician has been able to justify his/her treatment as being appropriate based on the treatment prior to or subsequent to the care in question.

P. Ex. 82 at 2.

Thereafter, Dr. Busby assumed the position of the Carrier's Medical Director and began working on the Carrier's second request to exclude Petitioner from participation in the Medicare program. In August of 1993, Dr. Busby went to the I.G.'s office and received training on how the I.G. wished to have the Carrier prepare its submission. Tr. 93. The training was provided because this was the first case in which a carrier had requested an exclusion under section 1128(b)(6)(B) of the Act. Tr. 93, 94. The I.G.'s staff instructed Dr. Busby to focus on three issues: 1) the reason for requesting the exclusion; 2) the selection of cases; and 3) the medical necessity and quality of care. Tr. 93 - 94.

Dr. Busby testified that, under the first issue, the sole reason for requesting the exclusion was "financial to the carrier; that is, how it is costing the carrier out of its budget -- not the Medicare trust fund, but out of its budget -- to operate." Tr. 93 - 94. There was no evidence explaining the relationship between the Carrier's concern for its budget and the exclusion criteria established by statute.

Dr. Busby testified also that, under the second issue the I.G. instructed him to consider, the case selection criterion, was "what the carrier perceives are costing the carrier to review." Tr. 94. There was no explanation of what this selection criterion meant, except that the medical records reviewed by Dr. Busby were not selected randomly, and the I.G. told Dr. Busby to disregard the issue of whether Medicare payments have been made pursuant to a review of those records. Tr. 94 - 95.

With respect to the third criterion (the medical necessity and quality of care issues), Dr. Busby testified that the I.G.'s attorney told him: "Present the records that you have available to you that were submitted by the provider; your comments don't mean anything to us, except we want to see how you are thinking, but we are going to review these entirely independently." Tr. 95. After his training at the I.G.'s office, Dr. Busby found medical records submitted with Petitioner's claims which indicated to him that, between April 9, 1992 and September 16, 1993, Petitioner provided more than 70 services that were either "medically unnecessary" or of "poor quality" to 10 Medicare patients. I.G. Ex. 12.

However, the evidence does not disclose whether the I.G. informed Dr. Busby of the requirement that, to exclude Petitioner, there must be services substantially in excess of the patients' needs or care of a quality which fails to meet professionally recognized standards of care. Act, section 1128(b)(6)(B). The evidence also does not disclose how many other claims and associated records Dr. Busby reviewed before he located those he placed into his report, or what significance, if any, Dr. Busby placed on the size of Petitioner's patient base during the relevant time period. (In 1992, for example, Petitioner had approximately 19,000 registered patients, out of which 30 to 35 percent were Medicare beneficiaries. Tr. 512.)

Nor does the evidence establish the reasonableness of Dr. Busby's failure to heed Mr. Patton's 1992 letter to the

Carrier concerning the evaluation of pre- and post-treatment records. According to Dr. Busby's testimony, even though he disregarded the determination of whether Medicare payment had been authorized for any given claim, he based his opinions on a review of only the records submitted by Petitioner to claim Medicare reimbursement for particular services. See Tr. 153, 178, 245. He said he reviewed only those records because the I.G.'s office had instructed him to render opinions "based on information at hand." Tr. 121. He asked the I.G. if he should get more information and was told "no." Tr. 183. He testified that he did not review the records pertaining to the care rendered prior to or after the services he considered because an attorney from the I.G.'s office and Dr. Nelson, the Medical Advisor or Medical Director on the I.G.'s staff, had directed him not to do so. Tr. 250 - 51.

Dr. Busby said he would have preferred to have had additional records to review in formulating his opinions. Tr. 245. Additional records may have clarified matters, eliminated his concerns, or changed his opinions. E.g., Tr. 109, 126, 182. Dr. Busby thought that having knowledge of whether Petitioner had referred his patients to other physicians, for example, would have helped him form his opinion on a given service. Tr. 182. He did not consider it appropriate to ask Petitioner for the information "when we knew we were going for an exclusion with the Office of Inspector General[.]" Tr. 182. Dr. Busby testified also that he thought asking Petitioner for additional records might have afforded Petitioner the opportunity to create information. Tr. 127.

However, neither did Dr. Busby attempt to retrieve any additional records Petitioner previously had submitted to the Carrier. Dr. Busby indicated that retrieval of records other than those he reviewed for his exclusion recommendation would have added work for the Carrier because, according to Dr. Busby, the records Petitioner submitted were voluminous -- possibly requiring the lease of a separate building and the employment of three individuals to maintain. Tr. 259. When asked if reviewing other records was too heavy a burden for the Carrier to bear, Dr. Busby answered that the Carrier retires records on microfiche and maintains them in archives, and that, even though he had access to hard copies or microfiche of such records, it would have been a sizeable undertaking to retrieve all relevant records, such as those of other doctors who treated the same

patients and all the diagnostic tests undergone by the patients.[8] Tr. 260 - 61.

When Dr. Busby was asked whether he had an opinion as to Petitioner's overall pattern of treatment based upon his review of the records, Dr. Busby responded in the affirmative. Tr. 348. However, he was not asked what that opinion was, and he did not volunteer that opinion. When asked if his overall impression of Petitioner's practice pattern would have been changed if he had reviewed additional evidence, he answered: "My view would not have changed." Id. He provided no explanation of why no evidence could change his overall impression. There is inadequate basis in the record to reconcile his professed intransigence with his earlier testimony that his opinions on individual services could have been changed by additional information.

In sum, the I.G. failed to prove the relationship between the requirements of the statute and the criteria and instructions followed by Dr. Busby in preparing the Carrier's exclusion recommendation. Nor do the methods applied by Dr. Busby in reaching his opinions of record appear to be fair or valid on their face. Dr. Busby lacked conviction in his own opinions due to the limitations imposed by the I.G. and the Carrier's own record-keeping system. In addition, the evidence shows that Dr. Busby formulated his opinions based only on the instructions he received in August 1993, which are not fully consistent with the instructions the I.G. had issued to the Carrier in 1992 concerning the additional medical documents which might need to be reviewed. The existence of these apparently conflicting instructions, and the absence of any evidence to reconcile them, further undermines the validity of Dr. Busby's opinions. For the reasons stated earlier, I give no weight to his assertion that no additional documents would have changed his opinion concerning Petitioner's overall pattern of treatment.

---

[8] I assume this is the reason why Dr. Busby and the I.G. reached certain conclusions, such as that an MRI service provided by Petitioner was medically unnecessary in part because a diagnostic workup done during the patient's prior hospitalization "may have included this study." I.G. Ex. 2 at 17; I.G. Ex. 12 at 194.

B. Dr. Busby did not testify as an independent medical expert concerning the totality of relevant medical evidence in this case; Dr. Busby's role was limited to explaining his creation of the written report supporting the Carrier's exclusion recommendation.

Even though the I.G. persuaded me to hold an in-person hearing due to the importance of having the medical records explained by medical experts (I.G. Prehrg. Br. at 35), the I.G.'s only witness was Dr. Busby, who did not review all of the medical records which were submitted by Petitioner for the I.G.'s review or made available to the I.G. during the course of these proceedings. At the hearing, the I.G. made clear that Dr. Busby was not qualified as an independent medical expert to render opinions on documents he neither created nor reviewed. The I.G. called him to testify only about the circumstances under which he rendered the opinions contained in his report in support of the Carrier's sanction request, which report the I.G. has introduced into evidence. Tr. 239; I.G. Ex. 12. Dr. Busby stated that his purpose in appearing at the hearing was not to present evidence in order to exclude Petitioner, but to testify about what he had presented to the I.G. originally. Tr. 237; see I.G. Ex. 12.

Dr. Busby testified that the I.G.'s office told him during his training in August of 1993 that his opinions on Petitioner's services would not mean anything except to show how he thinks, and that the I.G. would review the matter independently. Tr. 95. Dr. Busby was told by the I.G. that his involvement in the case would be over after he prepared his report to the I.G. based on a review of the records he selected to support the Carrier's exclusion request. Tr. 177 - 78; see I.G. Ex. 11.

Dr. Busby was aware that a "hearing" (i.e., the presentation to and review by Dr. Nelson of the I.G.'s office on the proposal to exclude Petitioner) had occurred on July 26, 1994, but Dr. Busby was given no information concerning it, nor was he invited to attend or provide comments. Tr. 96. Even when he asked about the status of his report and opinions after the "hearing," he was told by the I.G.: "It is none of your concern. We are managing it. We make the decision." Tr. 96. Moreover, Dr. Busby did not read Petitioner's exhibits in his preparation for the hearing. Tr. 270. Dr. Busby believed that his lack of knowledge regarding the remaining evidence in the case was brought about by a directive from the I.G. Tr. 183.

C. Dr. Busby's opinions fail to prove the I.G.'s contention that the care rendered by Petitioner was substantially in excess of his patients' needs.

The I.G. chose to make her case at the hearing based solely on the testimony of Dr. Busby. However, among the many problems with the I.G.'s reliance upon Dr. Busby's testimony is her failure to elicit from him an opinion that Petitioner rendered care substantially in excess of the needs of his patients. In his written report to the I.G., and in his testimony at hearing explaining the contents of that report, Dr. Busby consistently used the term "medically unnecessary." However, he never stated in his written report or during his testimony whether "medically unnecessary" meant the same thing to him as "substantially in excess of the needs of such patients." Nor has he indicated that he was even aware of the latter phrase's place in an exclusion proceeding. See I.G. Ex. 12; Tr. 122.[9] It is true that, under most circumstances, whatever Dr. Busby may have meant by "medically unnecessary" would not be binding on the I.G. under her exclusion authority. However, here, the I.G. chose to rely on his opinion.

Dr. Busby's testimony shows that he has consistently used the same definition of "medically necessary" that the Carrier should have used in determining Medicare payments.[10] See Act, section 1862(a)(1)(A) (Part B

---

[9] I do not imply that Dr. Busby's conclusions on "medical necessity" are immaterial to the issue of whether the I.G. had a basis for imposing the present exclusion under section 1128(b)(6)(B) of the Act. "Unnecessary" could mean not needed at all in ordinary usage, and it is possible to construe several of Dr. Busby's opinions as meaning that the services were not needed at all by the patients (as opposed to being merely non-essential). However, as noted elsewhere in this Decision, there are contrary medical opinions concerning the patients' needs.

[10] In her prehearing brief, the I.G. generally stated that the Carrier's payment was based on a "different standard" than that considered by Dr. Busby. I.G. Prehrg. Br. at 15. However, the different standard appears to relate only to the allegedly more thorough review done by Dr. Busby. For example, when the I.G. opposed Petitioner's use of the Medicare payment evidence, she argued only that the Carrier's prior Medical Director did not personally approve the claims,

(continued...)

payments cannot be authorized "for any expenses incurred for items or services . . . not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member"). For example, in describing the instructions the I.G. gave him, he noted: "[W]e deal, on the side of Medicare Part B, with what is medically reasonable and necessary" (Tr. 95), but he did not testify that the I.G. instructed him to consider the issue of whether the care was "substantially in excess of the needs of such patients." Tr. 93 - 95. When asked during the hearing to describe the problems created for the Medicare program by Petitioner's medical records, Dr. Busby spontaneously identified the difficulties with training the Carrier's analysts and others in the review of such records. Tr. 104. When asked on cross-examination: "[Y]ou don't like the way he practices medicine. Is that correct?" -- Dr. Busby responded: "I don't care for the way he is billing the Medicare program trust fund[,]" and "I believe that it is the responsibility of another organization to determine whether or not his practice is appropriate." Tr. 168.

In the single instance during the hearing when the I.G. used the term "in excess of the patient's needs" in questioning Dr. Busby,[11] Dr. Busby gave an explanation for "medical necessity." Tr. 122. According to Dr. Busby, "[m]edical necessity is based principally on prudence" -- as exemplified by, "Is it necessary to establish a diagnosis, and do we expect that the diagnosis is going to lead to a definitive form of treatment or a modification of the treatment?" Id. His definition of "medical necessity" is essentially the same as the Carrier's explanation of the same matter for payment purposes: "Medicare does not pay for screening tests that have no clinical application in the patient's care." I.G. Ex. 9 at 2.

To justify an exclusion under section 1128(b)(6)(B) of the Act, it is not enough to apply the definition of "medically unnecessary" under section 1862(a)(1)(A) of

---

[10] (...continued)
that the qualifications of those who approved the claims were not of record, and that Dr. Busby conducted a more thorough review for the I.G.'s sanction action. Tr. 12 - 14.

[11] "Q: And how, if at all, does that differ from a finding that the care was medically unnecessary or in excess of the patient's needs?" Tr. 122.

the Act. Even a service that was not needed at all by the patient under section 1862(a)(1)(A) of the Act does not automatically mean that it substantially exceeds the patient's needs within the meaning of section 1128(b)(6)(B) of the Act. This is so because, when Medicare payment is under consideration, the medical necessity determination is limited to whether a particular service was medically reasonable and necessary for "the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Act, section 1862(a)(1)(A). Certain medical services are excluded from Medicare coverage and the concept of medical reasonableness under section 1862(a)(1)(A) of the Act because they do not relate to the diagnosis or treatment of an illness, injury, or a malformed body part.[12] By contrast, the exclusion statute and its implementing regulation relied upon by the I.G. do not limit the issue of patients' needs to the consideration of whether a patient is a Medicare beneficiary or whether the service is covered under the Medicare program. The statute and implementing regulation specify consideration of the needs of patients "whether or not eligible for services under Title XVIII," and "whether or not covered by Medicare," respectively. Act, section 1128(b)(6)(B); 42 C.F.R. § 1001.701(a)(2).

Even though the statute and its implementing regulation do not define those services that are "substantially in excess of the needs of such patients," this fact does not mean that the I.G. should omit expert medical testimony explaining which services were considered by the I.G. to be substantially in excess of the patient's needs and why. See 57 Fed. Reg. 3306 (Jan. 29, 1992) ("This determination is always made on the basis of expert medical opinion").

In her posthearing brief, the I.G. uses the language in the regulation's preamble concerning a "pattern of violations" to argue that Petitioner had furnished services substantially in excess of his patients' needs. I.G. Posthrg. Br. at 8. The preamble referenced by the I.G. states that the I.G. has discretion to impose an exclusion even where there is no pattern of violations.

---

[12] Such services include eye examinations for the purpose of prescribing, fitting, or changing eyeglasses or contact lenses; examinations for prescribing, fitting, or changing hearing aids; immunizations; dental services in connection with the care, treatment, filling, removal, or replacement of teeth, or structures directly supporting the teeth. 42 C.F.R. § 411.15.

However, Congress did not intend that the I.G. automatically exclude an individual where the violation was an isolated or inadvertent instance. 57 Fed. Reg. 3306 (Jan. 29, 1992). The preamble does not state, as alleged by the I.G., that "a 'pattern of violations' may result in a finding that care has been furnished 'substantially in excess of patient's needs' . . . ." I.G. Posthrg. Br. at 8. According to the preamble, there must be at least one service that substantially exceeds the patient's needs to form a "violation" in the first instance; this single violation, or several of these violations (whether or not in a pattern), may then result in an exclusion. The I.G.'s authority to impose an exclusion based on a "pattern of violations" does not establish that any of the services in the alleged pattern substantially exceeded a patient's needs and therefore constitutes a "violation."

D. Dr. Busby's opinions fail to prove the I.G.'s contention that Petitioner rendered care that failed to meet professionally recognized standards.

Just as Dr. Busby's opinions were insufficient to establish that Petitioner furnished services that were excessive within the meaning of the statute, his opinions are similarly unpersuasive on the I.G.'s contention that Petitioner provided services that were not of a quality that meets professionally recognized standards. The I.G. relies upon Dr. Busby's designation of numerous services as being of "poor quality" when the statutory requirement is that the services were of a quality which failed to meet professionally recognized standards of health care. I will discuss separately, below, Dr. Busby's testimony concerning the professionally recognized standard for medical documentation and its relationship to the poor quality of care alleged by the I.G. In this section, I discuss only my conclusion that Dr. Busby's definition of "poor care" for particular services was ambiguous, based on wholly subjective criteria, and not in accord with the statutory requirement for an exclusion.

Dr. Busby concluded that certain services or care rendered by Petitioner were of "poor quality" (e.g., Tr. 119 - 23, 138) without ever having defined "poor quality" and without having ever correlated his opinions with any spectrum of care or standards for the same services that are generally recognized in the medical community. When the I.G.'s counsel provided him with an opportunity to define his terms at hearing, Dr. Busby merely equated "good medical practice" with "good quality of care". Tr. 122. This equation is ambiguous, as is his testimony

that every hospital and school across the U.S. train to the same standard of care (Tr. 82), that the Medicare carriers' Medical Directors have agreed at their meetings that the standard of care is the same throughout the United States (Tr. 84), and that he believes every patient in Illinois deserves the best and most aggressive possible care (Tr. 142).

The standard applied by Dr. Busby for evaluating the quality of care was, basically, "[W]ould I have, on the basis of the information that was available to me, placed this individual on this particular drug, conducted this particular treatment" (Tr. 121 - 22), or "Was it clinically necessary, based on my level of knowledge and understanding of medicine" (Tr. 155). Dr. Busby testified also that, to treat an individual appropriately requires

> an appropriate level of knowledge, an understanding, and in dealing with the individual taking a comprehensive medical history, conducting a thorough medical examination, a judicious or prudent use of diagnostic tests, appropriate interpretation of all information that has been gathered, and the application of any treatment that is necessary or the referral of that individual for appropriate specialist care.

Tr. 225. Petitioner agrees. Tr. 429.

Even though Dr. Busby asserted baldly that the standard he applied meant no reasonable physician would have done what Petitioner did (Tr. 155), I do not find his assertion persuasive, for several reasons. Dr. Busby could not explain why some of his opinions were reversed by Dr. Nelson of the I.G.'s office or whether Dr. Nelson and Petitioner were acting as reasonable or unreasonable physicians in disagreeing with his opinions. Tr. 155 - 56. He cited no medical literature to support his opinions. Tr. 208. Because he did not know why the Carrier paid many of the services he criticized or whether Medicare payments for those services had been approved by other physicians, he conceded the possibility that there might have been a difference of medical opinion on those services. Tr. 164.

In addition, some of Dr. Busby's testimony, such as his criticism of Petitioner's use of the C reactive protein test because it is considered to be antiquated by the medical community at large and is seldom used (Tr. 200; I.G. Posthrg. Reply at 5) simply fails to articulate the

existence of a professionally recognized standard of health care which Petitioner has failed to meet. As shown by the report of Petitioner's expert, Dr. Beer, there is a difference of professional opinion concerning the usefulness of the test. E.g., Tr. 521; P. Ex. 79 at 4.

The I.G. argues that the term "professionally recognized standards of care" is applied subjectively because, as explained in the preamble to the implementing regulation, "[i]t would be very difficult to formulate a wholly objective standard in the area of medical practice, where a certain amount of subjectivity in judgment is inevitable." I.G. Posthrg. Br. at 8, 9 n.4 (citation omitted). However, this does not mean that Dr. Busby, in applying his own level of knowledge and understanding of medicine, thereby applied the "professionally recognized standards of care" to determine the quality of care issue. As stated in the regulation, "professionally recognized standards of health care" are statewide or national standards of care that professional peers of the individual whose provision of care is an issue recognize as applying to those peers practicing or providing care within a state. 42 C.F.R. § 1001.2. This regulatory definition implies the existence of some specific, quantifiable level of quality on which professional peers as a group can agree.

The evidence of record establishes that Dr. Busby has specialties and qualifications which are different than Petitioner's (see section V.B., below). His testimony did not establish the professionally recognized standards of Petitioner's peers, against which each of the services in issue should be measured and deemed deficient. Therefore, I am unable to conclude from Dr. Busby's testimony and written report that Petitioner's treatment failed to meet such a standard.

III. The medical records Petitioner submitted to the Carrier in support of particular claims for Medicare reimbursement are not sufficient to prove a basis for the exclusion in this case.

The I.G. failed to establish a basis for Petitioner's exclusion by relying upon Dr. Busby's opinions. Likewise, the I.G.'s reliance on only the medical records Petitioner submitted to the Carrier seeking payment of particular Medicare claims fails to establish a basis for Petitioner's exclusion.

The I.G. argues that Dr. Busby's testimony establishes that not having enough medical documentation violates

common or acceptable standards of medical practice. Tr. 216. By medical "documentation," Dr. Busby meant the requirement for documenting a comprehensive history and a thorough examination before ordering a diagnostic test or rendering an opinion leading to treatment.[13] Tr. 130 - 31.

The I.G. argues that it was not necessary for Dr. Busby or the I.G. to review the full medical file of each patient, or even any other medical records than those reviewed by Dr. Busby. The I.G. reasons that the "requirements of claims submission under prepayment review in this case and good medical practice in general demands that contemporaneous support for all tests and services be recorded on the date rendered, and a reviewer or tribunal, consequently, need look no further than the contemporaneous record made . . . in order to evaluate the reasonableness of the services rendered" that day. I.G. Posthrg. Reply at 3 (citations omitted). The I.G. has framed the issues thus throughout the hearing:

> [A]s we have stated from the beginning the issue is not whether these tests are useful in diagnosing disease.
>
> The question is whether they are called for based upon the medical records which were submitted by Dr. Vest for the purpose of having his claims paid after being repeatedly instructed as to what was necessary to put into those tests [sic] . . . .

Tr. 214.

---

[13] One of the significant documentation problems alleged by the I.G. is the absence of notation in any of the records reviewed by Dr. Busby concerning whether Petitioner had discussed with the patient why a test was ordered, what the tests results were or what they meant, or why a prescribed course of treatment was needed. See, I.G. Proposed Finding 51 (citing Tr. 106). However, the evidence is unclear as to which records submitted to the Carrier should have contained a physician's discussions of treatment courses and needs with his patient. Moreover, the Carrier's letter to Petitioner specifies that the patient's "initial history and physical" must be submitted, whereas the Carrier's internal memorandum to staff states that the patient's "complete history and physical to each claim" must be submitted. I.G. Ex. 9 at 2; P. Ex. 9 at 87.

> And I believe that that is the ultimate issue in this case: medical necessity as defined by the submission of medical records for the purpose of payment.

Tr. 215.

> And more important to the issue here today, for the purpose of reimbursement, you have to have the documentation.

Tr. 216. The I.G. argues that inadequacies in the documents Petitioner submitted to the Carrier in order to seek Medicare reimbursement prove that he provided services in substantial excess of patients' needs and of a quality which failed to meet professionally recognized standards of care. Tr. 216; I.G. Proposed Findings 84, 85. The I.G. contends that the Carrier's prepayment review process placed obligations upon Petitioner to submit comprehensive documentation with his claims. I.G. Posthrg. Br. at 12; I.G. Proposed Finding 40.

I reject the I.G.'s premise that the prepayment review process imposed documentation submission obligations upon Petitioner, which entitled the I.G. to impose an exclusion based only on those documents Petitioner submitted with his Medicare claims. The testimony before me indicates that the Carrier utilizes professionally recognized standards for documentation in determining whether payment is due under the Medicare program. Tr. 129 - 30, 216. But it does not follow that a physician's failure to satisfy Medicare reimbursement procedures conclusively proves that he has violated the professionally recognized standard for medical documentation.

Physicians participate in Medicare Part B on a voluntary basis. Act, section 1842(h)(1). If physicians do not submit documents which will enable the carrier to make its determinations, the physicians should not receive Medicare payments, whether or not they are under a prepayment review system. The mere failure to send the necessary documents to the carrier in support of a claim, even assuming that the carrier had denied payment for that reason, should not cause the I.G. to conclude that a physician must be excluded under section 1128(b)(6)(B) of the Act. As stated in the preamble to the Secretary's regulations, the I.G. is to determine liability under section 1128(b)(6)(B) of the Act based on "all of the facts available." 57 Fed. Reg. 3306 (Jan. 29, 1992).

I have noted already Dr. Busby's testimony that he was told by the I.G. not to review certain types of records in preparing his exclusion recommendation, that he did not select patient services randomly for his review, and that he reviewed only the medical records associated with particular claims because to do otherwise would have been very time-consuming under the Carrier's record maintenance system. In essence, the I.G. and Dr. Busby limited "all of the facts available" for the determination of Petitioner's liability to only those facts that would support the Carrier's recommendation to exclude Petitioner.

I find relevant and persuasive the testimony of Petitioner's expert witness, Dr. Rodolfo Beer, who stated that no physician would diagnose or treat a patient based on only part of the patient's available records. Tr. 519 - 20. Dr. Beer testified that it was bad practice for any physician to provide an opinion without reading a patient's full chart. Tr. 520. Nowhere in the record is there any testimony that any physician considers it appropriate to evaluate a patient's medical needs or the quality of health care services provided to a patient by using only the documents associated with Medicare claims for services rendered on particular days. As discussed earlier, even Dr. Busby indicated that he did not think the limitation was proper, in that he had repeatedly asked the I.G. if he should consider additional information. E.g., Tr. 183. The memorandum Mr. Patton issued earlier on behalf of the I.G. to the Carrier shows also that an exclusion may not be appropriate based only on an evaluation of a patient's needs on a given day or on the quality of services reviewed in isolation. See P. Ex. 82.The memorandum notes that providers have been able to justify their services at the administrative review level based on pre-service and post-service records. Id.

It is true that the I.G. reasonably could have inferred that certain documents were never created, or certain information was never taken, when Petitioner did not submit them to the Carrier in support of his Medicare claims for reimbursement. However, such inferences have been rebutted by Petitioner in several ways.

First, there is Dr. Beer's testimony, which was based on a full evaluation of each of the 10 patients' complete medical records. Tr. 519. His conclusion was that the information Dr. Busby thought missing was in the patients' files and that the information contained in the patients' files exceeded the standards of the medical community. Tr. 523. I find Dr. Beer's testimony on these matters to be credible for the following reasons:

1) his testimony was based on a review of the entire patient files; 2) he did not have anything to gain if the decision to exclude Petitioner is reversed; 3) he is a practicing physician who actually diagnoses and treats patients; and 4) he Beer is familiar with the standard of practice applicable to the area where Petitioner practices. Tr. 518.

In addition, Petitioner has demonstrated good reasons for having failed to send the Carrier more records in support of each Medicare claim. Petitioner acknowledges that he did not submit cumulative records with each Medicare claim. However, he testified, and his counsel argued, that he had sent the Carrier "everything," including prior and subsequent records for patients, and that the Carrier had patient files in their entirety in its possession. Tr. 247, 386 - 87. Petitioner's testimony is consistent with the I.G.'s stipulation that the patient files in their entirety are in the possession of the program. Tr. 506 - 08.

I find credible Petitioner's explanation that, when he was receiving payments from the Carrier for services claimed pursuant to the full pre-payment review process, such payments led him to believe that the records he submitted to the Carrier were adequate, proper, and satisfactory to the Carrier to show the medical reasonableness and necessity of such services under Medicare payment criteria. See Tr. 162 - 63. His explanation is consistent with his testimony that he thought he was doing things correctly but would have sent in additional records if he had perceived a need to do so. Tr. 386 - 87. Even Dr. Busby acknowledged that it was "possible" for Petitioner to reach a reasonable conclusion that, because the Carrier was authorizing Medicare payments for these claims, Petitioner need not send additional supporting medical records. Tr. 162 - 63.

The totality of the evidence fails to support the I.G.'s contention that a valid basis for this exclusion has been proven by Dr. Busby's evaluation of medical records submitted by Petitioner only for the purpose of claiming Medicare reimbursement.

IV. The I.G. did not prove that other evidence or medical opinions supports her determination that a basis for the exclusion exists.

The I.G. has alleged on at least one occasion that Mr. Patton of the I.G.'s staff made the exclusion determination "upon consultation with OIG's own medical advisors." I.G. Posthrg. Br. at 8. However, the I.G. has never attempted to introduce into evidence the identities and opinions of these medical advisors. I agree with Petitioner that, if the I.G. had resorted to other medical experts' advice in imposing the exclusion, these experts' qualifications and opinions are not of record, and the I.G. cannot rely on the existence of such experts or opinions. See P. Posthrg. Reply at 1.

The I.G. alleged also that Mr. Patton had reviewed all of the evidence alluded to by Petitioner during an earlier administrative proceeding conducted by the I.G.'s office. I.G. Posthrg. Reply at 2. Again, the I.G.'s evidence does not establish the truth of that representation. The I.G.'s evidence establishes only that Dr. Busby did not have knowledge of such evidence. Tr. 96.

As a result of the I.G.'s decision to present only the medical report and testimony of Dr. Busby, the gaps in Dr. Busby's knowledge concerning the I.G.'s reasons for excluding Petitioner reinforce Petitioner's argument that physicians may have legitimate bases for their disagreements and mere differences in their professional opinions cannot suffice as a basis for an exclusion. See, e.g., Tr. 155 - 56.

I note, for example, that Dr. Busby, in recommending that the I.G. exclude Petitioner, provided opinions adverse to Petitioner on 77 services, which were described in 75 paragraphs of his report. I.G. Ex. 12. In the notice of the I.G.'s intent to exclude Petitioner, Mr. Libercci of the I.G.'s staff omitted at least three of those services without explanation. See I.G. Ex. 12 at 123 (X-rays of the cervical spine and X-rays of lumbosacral spine and MRI of lumbar spine for Patient L.W. on August 5, 1993); I.G. Exs. 1, 2 at 12. After Petitioner appeared in person for the submission of documents and oral arguments to Dr. Kenneth Nelson of the I.G.'s office in Baltimore, Maryland (Petitioner had no opportunity to examine or cross-examine witnesses during this presentation (P. Ex. 4)), Mr. Patton of the I.G.'s staff summarily eliminated seven additional findings when he issued the notice of exclusion. I.G. Ex. 5.

The I.G. has not attempted to prove what evidence was considered by anyone other than Dr. Busby. Even though the I.G. points out that Petitioner had the opportunity to submit additional medical records to the I.G.'s medical reviewer, Dr. Nelson (I.G. Posthrg. Br. at 11 n.5), the problem here is that, even though Petitioner appears to have submitted additional medical records, the I.G.'s evidence does not show that the additional records were analyzed.

There is, moreover, no adequate evidence explaining how the I.G. equated Dr. Busby's findings that certain services were medically unnecessary or of poor quality with the requirements for an exclusion under section 1128(b)(6)(B) of the Act: that the care substantially exceeded the patients's needs or was of a quality that failed to meet professionally recognized standards of health care. Act, section 1128(b)(6)(B). The notice of the I.G.'s intent to exclude Petitioner under section 1128(b)(6)(B) of the Act contains the first of many instances in which the services characterized by Dr. Busby as "medically unnecessary" and of "poor quality" were described by the I.G. as "substantially in excess of the needs of such patients" and failed to meet professionally recognized standards of health care. I.G. Ex. 1.

The I.G. argues in her brief that, because the diagnostic tests and medical services furnished to 10 patients were not justified by the medical findings reviewed by Dr. Busby, they were therefore "in excess of the patient's needs," and the I.G. was entitled to conclude that Petitioner provided services "substantially [in the main, in substance] in excess of the patients' needs." I.G. Posthrg. Br. at 8. Elsewhere in the Decision, I discuss in detail the consequences of the I.G.'s failure to analyze additional evidence. I note here, however, that the I.G.'s alleged limitation of her exclusion determination to only those documents reviewed by Dr. Busby does not comport with Petitioner's opportunity to submit additional evidence for the I.G.'s consideration in response to the notice of intent to exclude him, and such a limitation does not comport with the I.G.'s prior representation to Petitioner that everything he submitted would be used in the exclusion determination. 42 C.F.R. § 1001.2001(b); P. Ex. 4.

Based on the record as a whole, there is an inadequate basis to conclude that the I.G.'s exclusion determination had greater factual support or was better reasoned than the opinions provided by Dr. Busby, which also do not establish a basis for the exclusion.

V. The evidence introduced by Petitioner is more credible than that introduced by the I.G.

A. Petitioner is entitled to rely on medical opinions regarding his patients' complete medical records.

In her reply brief, the I.G. argues that the additional medical documents alluded to by Petitioner and Dr. Beer at the hearing are not of record, and, therefore, they are not before me. I.G. Posthrg. Reply at 2. The I.G. argues also that it is illogical for Petitioner to require Dr. Busby, and me -- by extension, to review a patient's entire medical history before rendering an informed opinion. Id. at 3.

I find these arguments to be without merit.

Petitioner is properly arguing the consequences of Dr. Busby's failure to conduct as complete a review of the available medical records as he (Petitioner) and Dr. Beer testified to have done. It may be that, in the example cited by the I.G. (the X-ray of the left foot when there were documented complaints for the right foot), no additional amount of document review could have changed Dr. Busby's opinion that the procedure was unnecessary. Id.; but see P. Ex. 79 at 1 (Dr. Beer's Affidavit with contrary opinion and reasons). However, there are other opinions rendered by Dr. Busby which, on their face, could have benefitted from the review of additional medical records. For example, Dr. Busby criticized the MRI done for Patient G.N. as medically unnecessary, partly because a prior hospitalization with a diagnostic workup "may have included this study." I.G. Ex. 12 at 194 (emphasis added). Other examples include the CBC and differential WBC and 23-test blood chemistry panel performed on August 19, 1993 for Patient J.M., which Dr. Busby found to be medically unnecessary because they had already been done during the patient's July 3, 1993 visit. I.G. Ex. 12 at 113. However, Dr. Busby acknowledged that there are frequently justifications for repeating tests. Tr. 204 - 05. Dr. Beer pointed out that some of the tests were repeated after a few days of treatment in order to track the effectiveness of treatment. Tr. 533. Dr. Busby testified also that having additional records may have clarified matters, eliminated some of his concerns, or altered his opinions. E.g., Tr. 109, 126, 182. I cannot agree with the I.G. that Dr. Busby rendered informed opinions when other physicians who are no less qualified than he is have reached contrary conclusions based on medical records he failed to read.

With respect to the I.G.'s argument that the additional medical documents referenced by Petitioner and Dr. Beer are not of record, I note that Petitioner moved to introduce them at the hearing. Tr. 506 - 08. Petitioner explained his failure to offer the additional medical records prior to hearing by alleging that he was surprised by the I.G's reliance at the hearing on a theory of inadequate documentation. Tr. 214 - 15, 506. I find Petitioner's explanation to be reasonable. As I have noted previously, the I.G. has an obligation to determine the exclusion based on "all of the facts available" (57 Fed. Reg. 3306 (Jan. 29, 1992)), Petitioner had informed the I.G. that she should consider other records he had submitted to the Medicare program (P. Ex. 5 at 2), and the I.G. represented to Petitioner that any additional evidence provided by Petitioner would be considered in the exclusion determination (P. Ex. 4). Nothing in the exclusion notice or the I.G.'s prehearing brief had placed Petitioner on notice that the I.G. would then describe her position thus at hearing:

> [I]t has been the Inspector General's position all along that Dr. Vest had provided care which is medically unnecessary and substantially in excess of the patient's needs, because the treatments and the diagnostic tests which he is administering are not borne out by the medical records which he submitted in support of their payment.

Tr. 507. Moreover, despite the I.G.'s additional contention at hearing that Petitioner should be able to point to information in his medical records that "substantiates [his] follow-up actions" (id.), the I.G. objected to Petitioner's introducing the records favorable to Petitioner at the hearing. Tr. 508.

The additional medical documents considered by Petitioner and Dr. Beer were not admitted into the record only because Petitioner withdrew his motion to have them admitted upon the I.G.'s stipulation that copies of those documents were in fact received by the "Medicare program." Tr. 507 - 08. Implicit in the I.G.'s stipulation is the fact that the Carrier, Dr. Busby, and the I.G. have had the opportunity to evaluate the additional documents and to refute the conclusions of Dr. Beer and Petitioner. Moreover, Petitioner had also made available at the hearing the additional medical records for the I.G.'s review and use during cross-examination. Tr. 434 - 35. At no time did the I.G. review or make use of the additional medical records, or refute the merits

of the medical opinions based on a review of the patient records in their entirety.[14]

For the foregoing reasons, I find it proper to give weight to the opinions of Dr. Beer and Petitioner based on the contents of the complete patient files even though these patient files are not of record.

B. Based on the experts' professional experiences and the documents they reviewed, I have given greater weight to the opinions of Petitioner and his expert witness than the contrary opinions of Dr. Busby.

The I.G. contends that a recurring pattern in the records reviewed by Dr. Busby is that the medical findings in the records submitted by Petitioner in support of his Medicare claims do not correspond to or substantiate the need for the diagnostic tests that were ordered. See I.G. Proposed Finding 49 (citing Tr. 105). Dr. Busby's qualifications bear on the weight to be accorded his observations because, as discussed above, Dr. Busby was applying an evaluation standard based on his personal level of medical knowledge and understanding. He and Petitioner agree that, in order to treat an individual appropriately, there must be an appropriate level of knowledge or understanding of the disease process, which will then permit an appropriate interpretation of all the information gathered from a comprehensive medical history and a thorough medical examination. Tr. 225, 429. I believe the same is true in the situation where a physician is reviewing medical records in order to determine the patient's needs or the appropriateness of the care rendered to that patient. Even the definition of professionally recognized standards of health care refers to the "peers" of the individual whose services

---

[14] In my Ruling Denying the I.G.'s Motion for Reconsideration Concerning the Exclusion of I.G.'s Proposed Exhibits 17 to 24, I discuss and reject the possible inference that the I.G.'s proposed exhibits pertaining to criminal proceedings involving the falsification of different patient records may suggest that Petitioner has fabricated or lied about the medical records in this case. For this Decision, I re-emphasize that the use of such an inference is inappropriate, since the I.G. has had ample opportunity to gather and introduce proof of any alleged fabrication of the records used in this case. There is no proof that Petitioner has fabricated or lied about any medical record used in this case.

are at issue. See 42 C.F.R. § 1001.2. Therefore, I have analyzed the professional experiences of the three physicians whose opinions are of record.

I agree with Petitioner that Dr. Busby lacks experience in diagnosing and evaluating the ailments of elderly patients who may have multisystem disorders that may not be manifested in the same way as in younger patients. Dr. Busby has a subspecialty in aerospace medicine, which is a specialized form of occupational medicine. Tr. 39 - 40. His principal responsibility as the Carrier's Medical Director is interpreting Medicare coverage for purposes such as the reimbursement of services. Tr. 41. He has experience in containing health care costs from his current position with the Carrier as well as from his prior position as the medical director for LTV Steel. Tr. 44, 147 - 48.

Whereas Dr. Beer and Petitioner have been involved in direct patient care for a number of years, there is no evidence that Dr. Busby has maintained a medical practice or has provided direct patient care since assuming his position as the Carrier's Medical Director. In the past, Dr. Busby has covered a general practice intermittently over a period of 25 years, but he could not say how many patients he had actually treated. Tr. 145 - 46. Even though the services in issue were provided to elderly Medicare patients, Dr. Busby has never specialized in geriatric medicine and could not say how many geriatric patients he has treated. Tr. 221. He has never conducted a health examination on patients over 60 years of age. Tr. 147. He has diagnosed and treated patients in their 70's when he worked in an emergency room or covered a general practice; but he has not treated such patients on a regular basis. Tr. 147 - 48. He agreed that geriatric medicine usually involves multi-system diseases; that, as a general rule, certain diseases would present classical signs and symptoms in the young but not in the elderly; and that, in some cases, treating one disorder without treating associated disorders can accelerate complications. Tr. 221, 223, 224. He did not use any medical literature in reaching his conclusions that the 72 services he reviewed were medically unnecessary or of poor quality. Tr. 208.

I find the foregoing evidence to be relevant to the issue of which medical expert's opinions are entitled to greater weight with respect to the services in controversy. I use as examples the multi-panel tests criticized by Dr. Busby, because the I.G. alleged that it was Petitioner's pattern of ordering blood chemistry

panels which caught the attention of the Carrier, and for which Petitioner was excluded. I.G. Prehrg. Br. at 22.

The I.G. cited 13 instances in which Petitioner ordered such tests for 10 Medicare patients he saw during 1992 and 1993. I.G. Prehrg. Br. at 20. Most of Dr. Busby's opinions concerning these tests indicate that he felt them medically unnecessary because either no test within the panel was indicated by the patients' symptoms or complaints in the documents he reviewed, or only a small number of tests within the panel were indicated. I.G. Ex. 12.[15] Petitioner and Dr. Beer disagree with Dr. Busby's conclusions. In addition to discussing information not mentioned by Dr. Busby, Dr. Beer and Petitioner also cited Medicare reimbursement rules concerning the payment of full, automated panel tests on the patient's initial visit when one or more tests is needed. E.g., P. Ex. 79 at 6, 8. Dr. Busby agreed that Medicare payment regulations provide for payment of the initial battery of tests if one of the tests in the battery relates to the patient's complaints. Tr. 186 - 88.

However, Dr. Busby insisted that performing the additional tests in the battery would not be appropriate even though the full panel would be paid under Medicare reimbursement criteria. Tr. 186 - 87, 190 - 91. His reasoning was that he conducted his review under the I.G.'s guidelines, and the I.G. told him not to consider prices in his analysis. Tr. 190 - 91.[16] He testified,

---

[15] Elsewhere in this Decision, I have noted Dr. Busby's conclusion that Petitioner unnecessarily ordered at least two of the same tests for a patient on a subsequent visit. There are contrary medical opinions concerning the necessity of those repeated tests, including the testimony of Dr. Beer, who explained that Petitioner ordered the same tests after a few days of treatment in order to evaluate the success of the treatment. Tr. 533.

[16] There were extensive objections and argument by the I.G., as well as statements by Dr. Busby, concerning why Petitioner should not delve into or rely on Medicare payment rules concerning these laboratory tests. Tr. 189 - 96. To the best of my understanding, Dr. Busby's position is that payment information is not relevant to his opinion because he received the I.G.'s directive not to consider cost or payment information. To the best of my understanding, the I.G.'s objections

(continued...)

however, that if he had a medical practice and were billing for his services, he would consider cost, and that a doctor diagnosing patients in his office would consider the cost of the tests to be used. Tr. 196 - 97.

Petitioner and Dr. Beer testified concerning the atypical presentation of disease symptoms, the likelihood of multi-system ailments in the elderly, and the difficulties in diagnosing the elderly as justifications for some of the multi-panel tests at issue. E.g., Tr. 361 - 64, 521, 531. As noted by Dr. Beer, the youngest of the patients considered in Dr. Busby's report was 69 years old, and the oldest was 84 or 85 years old. Tr. 521. Dr. Beer, who has practiced as a general surgeon in the Alton area since 1967 (Tr. 517 - 18), and who has no interest in the outcome of this case, felt the full panel tests were important because all systems have some sort of derangement at these advanced ages, and the full panel tests provide a good means to obtain quick information and evaluation of practically every system. Tr. 521, 531.

Also according to Petitioner, the full-panel automated test costs approximately $26 under the Medicare program guidelines; it gives valuable information quickly; its results are simpler to obtain than reprogramming the equipment to obtain separate test results; and having the full panel done is less costly in the long run because it avoids the physician's having to guess at some of the results. Tr. 359, 361. Petitioner's cost information is consistent with the information contained in the Medicare Carrier Manual, which acknowledges that the cost of a

---

[16] (...continued)
and arguments are that, because Dr. Busby did not consider Medicare payment codes or outcomes in recommending Petitioner's exclusion, Dr. Busby conducted a review for medical necessity that is distinct from the review done for Medicare payment purposes pursuant to the statutory prohibition against reimbursing for services that are medically unreasonable and unnecessary. See Act, section 1862(a)(1)(A). I do not think either the I.G. or her witness has adequately addressed the inference from the payment rule or regulation cited by Petitioner that there exist administratively noticed facts and determinations favorable to Petitioner with respect to the medical necessity and reasonableness of ordering full panel tests on a patient's initial visit when only one test of the panel is warranted by the patient's condition.

battery of tests is ordinarily low as compared with the cots of tests performed individually. See I.G. Prehrg. Br. at 22.[17]

For these reasons, I did not find Dr. Busby's opinions on the multi-panel tests and other services more credible or persuasive than the contrary medical opinions submitted by Petitioner and his expert witness, Dr. Beer.

CONCLUSION

The totality of the record before me reveals numerous problems with Dr. Busby's opinions and the I.G.'s case. In addition, I found more persuasive the contrary medical opinions submitted by Petitioner and Dr. Beer, who are experienced in the diagnosis and treatment of geriatric patients and have reached their conclusions based on a review of complete patient files. I conclude that the I.G. has failed to prove a basis for the exclusion under review.

Accordingly, I set aside the five year exclusion imposed and directed by the I.G.

/s/

Mimi Hwang Leahy

Administrative Law Judge

---

[17] The I.G. noted also the part of the Medicare Carrier Manual which states that the periodic auditing of bills, reviewing physician service profiles, and analyzing large volumes of continuing batteries of tests for possible repeat tests, creates a financial burden on the Medicare program. I.G. Prehrg. Br. at 22 (citation omitted). However, the cost of auditing providers or analyzing tests does not provide a basis for exclusion under section 1128(b)(6)(B) of the Act.