Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Thelma C. Villanueva, M.D.,	)	DATE: August 21, 1996
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-96-185
	)	Decision No. CR431
The Inspector General.	)	
	)	

DECISION

I find that the two-year exclusion that the Inspector General (I.G.) imposed against Petitioner is unreasonable. I modify the exclusion so that Petitioner will be eligible to apply to the I.G. for reinstatement into the Medicare program on the date that Petitioner is reinstated by the State of New York to participate in the New York Medicaid program.[1]

I. Background

On January 24, 1996, the I.G. excluded Petitioner from participating in Medicare and State health care programs (including Medicaid), for a period of two years.[2] The I.G. advised Petitioner that the exclusion was being imposed pursuant to section 1128(b)(5) of the Social

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[1] This does not mean that Petitioner will be reinstated automatically on the date that she is reinstated to participate in the New York Medicaid program. As I discuss below, my modification of Petitioner's exclusion by the I.G. means that she will be eligible to apply to the I.G. for reinstatement on the date that she is reinstated by the State of New York to participate in the New York Medicaid program.

[2] The notice which the I.G. sent to Petitioner on January 24, 1996 erroneously advised Petitioner that she was being excluded for five years. The I.G. subsequently corrected this error in a notice dated April 12, 1996. I.G. Ex. 4.

Security Act (Act), based on Petitioner's exclusion or suspension from a federal or State health care program for reasons bearing on Petitioner's professional competence, professional performance, or financial integrity.

Petitioner requested a hearing. The case was assigned to me for a hearing and a decision. I held a prehearing conference by telephone, during which time the parties advised me that they believed that the case could be heard and decided without an in-person hearing. I established a schedule for the submission of proposed exhibits, briefs, and reply briefs. The I.G. submitted four exhibits (I.G. Ex. 1 - 4) and a brief.[3] Petitioner submitted a brief and no exhibits. Each party submitted a reply brief. Petitioner did not object to my receiving into evidence the I.G.'s proposed exhibits. I admit into evidence I.G. Ex. 1 - 4.

II. Issues, findings of fact and conclusions of law

The issues in this case are whether the I.G. has authority to exclude Petitioner pursuant to section 1128(b)(5) of the Act and whether the two-year exclusion that the I.G. imposed against Petitioner is reasonable.

I make the following findings of fact and conclusions of law (Findings), which support my decision that the I.G. has the authority to exclude Petitioner, but that the two-year exclusion that the I.G. imposed is unreasonable and must be modified so that Petitioner will be eligible to apply to the I.G. for reinstatement on the date that she is reinstated by the State of New York to participate in the New York Medicaid program. I discuss my Findings in detail, below.

1. On October 25, 1994, the New York Department of Social Services (Department of Social Services) excluded Petitioner from participating in the New York Medicaid program for a period of two years. I.G. Ex. 1, 2.

2. The suspension was for reasons bearing on Petitioner's professional competence, professional performance, or financial integrity. I.G. Ex. 1 - 3, Decision at 5.

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[3] In her brief, the I.G. styled her submission as a motion for summary disposition. In fact, I am deciding this case based on the written evidence that has been submitted. I am not issuing a summary disposition.

3. The I.G. is authorized to exclude Petitioner pursuant to section 1128(b)(5) of the Act. Findings 1, 2; Decision at 5.

4. The I.G. did not prove that the acts for which Petitioner was suspended caused financial damage to the New York Medicaid program, and, thus, failed to prove the presence of an aggravating factor. Decision at 5 - 8.

5. Petitioner proved that she was suspended from participating in the New York Medicaid program for a period of less than three years, and, thus, proved the presence of a mitigating factor. Decision at 6 - 8.

6. A two-year exclusion is not reasonable. Decision at 8 - 11.

7. It is reasonable to modify the exclusion in this case so that Petitioner will be eligible to apply to the I.G. for reinstatement on the date that she is reinstated by the State of New York to participate in the New York Medicaid program. Decision at 11 - 12.

III. Discussion

A. The facts (Finding 1)

The material facts of this case are not disputed. Petitioner is a physician. On October 25, 1994, the Department of Social Services excluded Petitioner from participating in the New York Medicaid program for a period of two years. I.G. Ex. 1. The effective date of the exclusion was 20 days from the date of the notice. Id. at 2. Thus, Petitioner's State exclusion commenced on November 14, 1994, and will end on November 14, 1996. Id. She will be eligible to apply to the State of New York for reinstatement to participate in the New York Medicaid program on that date.

The exclusion was based on a determination that Petitioner had engaged in unacceptable practices, as defined in State regulations. These unacceptable practices consisted of the following:

1. Submitting or causing to be submitted a claim or claims: for unfurnished medical care, services or supplies; and for medical care, services or supplies provided at a frequency or in an amount not medically necessary.

> 2. Unacceptable record keeping, consisting of failure by Petitioner to maintain records necessary to fully disclose: the medical necessity for and the nature and extent of the medical care, services or supplies furnished by Petitioner; or to comply with the requirements of State law.
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> 3. Excessive services, consisting of furnishing or ordering medical care, services or supplies that are substantially in excess of the needs of patients.
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> 4. Failure to meet recognized standards, consisting of furnishing medical care, services or supplies: that failed to meet professionally recognized standards of health care or which were beyond the scope of Petitioner's professional qualifications or license.

I.G. Ex. 1 at 1 - 2.

The Department of Social Services's determination to exclude Petitioner, and its findings of unacceptable practices, were based on an audit of 25 records of care provided or ordered by Petitioner. I.G. Ex. 1 at 6, I.G. Ex. 2 at 5. The major finding of this audit was that Petitioner inappropriately and excessively ordered laboratory tests of patients, without proof that the patients needed such tests or would benefit from them. Id. The audit found, however, that, with two exceptions, Petitioner's clinical work was within acceptable guidelines. Id.

There is no evidence in this case that Petitioner profited unlawfully or wrongfully from the laboratory tests that she ordered which the audit found to be inappropriate. Moreover, although the Department of Social Services concluded that Petitioner had submitted or caused to be submitted inappropriate claims for services, there is no evidence to show the dollar amount of the claims that were made for the laboratory services. Nor is there any evidence to show that the New York Medicaid program made reimbursement payments for these claims.

Petitioner appealed the determination of the Department Social Services to exclude her to a State administrative law judge. I.G. Ex. 2. In November 1995, Petitioner withdrew her hearing request. Id. at 2.

B. The I.G.'s authority to exclude Petitioner (Findings 2 - 3)

Section 1128(b)(5) of the Act authorizes the Secretary, or her delegate, the I.G., to exclude an individual where that individual is suspended or excluded from a federal or State health care program, or is otherwise sanctioned under such programs, for reasons bearing on that individual's professional competence, professional performance, or financial integrity. I find that the Department of Social Services' exclusion of Petitioner from the New York Medicaid program constituted an exclusion of Petitioner for reasons bearing on her professional competence and professional performance. Therefore, the I.G. is authorized to exclude Petitioner.

The reasons for the exclusion are self-evident from the findings made by the Department of Social Services. That agency found that Petitioner had: submitted or caused to be submitted claims for unnecessary services, engaged in improper record keeping, provided excessive services, and failed to comply with professionally recognized standards of health care, each of these findings related to Petitioner's performance as a physician and to her professional competence.

I do not find that the Department of Social Services' findings bear on Petitioner's financial integrity. There was no finding that Petitioner sought to profit wrongfully from her services. However, it is not necessary to find that Petitioner was excluded for reasons bearing on her professional competence, professional performance, and her financial integrity in order to find authority to exclude her under section 1128(b)(5). It is enough, for purposes of establishing the I.G.'s authority to exclude Petitioner, that she was excluded from participating in a State health care program for any of the reasons specified in section 1128(b)(5).

C. The presence or absence of aggravating or mitigating factors (Findings 4 - 5)

An exclusion imposed under one of the subsections of section 1128 of the Act must be remedial and not punitive. The purpose of section 1128 is to protect federally funded health care programs and beneficiaries and recipients of those programs from individuals or entities who are not trustworthy to provide care. Therefore, an exclusion imposed pursuant to any subsection of section 1128, including section 1128(b)(5), should be for a period of time that is necessary to accomplish the Act's remedial purpose.

The criteria for determining the reasonable length of any exclusion imposed pursuant to section 1128 are contained in regulations at 42 C.F.R. Part 1001. The regulation which establishes the criteria for determining the reasonable length of an exclusion imposed pursuant to section 1128(b)(5) is 42 C.F.R. § 1001.601. This regulation prescribes that an exclusion imposed pursuant to section 1128(b)(5) of the Act will be for a period of three years, unless there exist factors that the regulation defines to be either aggravating or mitigating, which may be a basis for an exclusion of more or less than three years. 42 C.F.R. § 1001.601(b).

In this case, the I.G. alleges the presence of an aggravating factor and concedes the presence of a mitigating factor. The aggravating factor which the I.G. alleges to be present is stated at 42 C.F.R. § 1001.601(b)(2)(i):

> The acts that resulted in the exclusion, suspension or other sanction under the Federal or State health care program had, or could have had, a significant adverse impact on Federal or State health care programs or the beneficiaries of those programs or other individuals; . . . .

The mitigating factor which the I.G. concedes to be present is stated at 42 C.F.R. § 1001.601(b)(3)(i):

> The period of exclusion, suspension or other sanction under the Federal or State health care program is less than 3 years; . . . .

There is no question that a mitigating factor exists in this case. Petitioner was excluded from the New York Medicaid program for a period of two years.

I do not find that the I.G. proved the presence of the alleged aggravating factor.[4] The evidence offered by the I.G. does not prove that Petitioner's actions caused, or even could have caused, a significant adverse financial impact on the New York Medicaid program.

According to the I.G., the evidence in this case proves that, by ordering unnecessary tests, Petitioner engaged in conduct that had a significant adverse financial impact on the New York Medicaid program. I.G.'s brief at 8. In effect, the I.G. argues that I should infer that,

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[4] I imposed on the I.G. the burden of proving the existence of any alleged aggravating factors. See 42 C.F.R. § 1005.15(b).

by ordering unnecessary tests, Petitioner caused the New York Medicaid program to make unnecessary reimbursement payments for those tests. The I.G. argues further that it need not prove the amount of payments made by the New York Medicaid program for the unnecessary tests that Petitioner ordered. The I.G. asserts that it is axiomatic that payment by the New York Medicaid program for any claim which is not properly reimbursable results in significant financial damage to that program. The I.G. cites Anthony Accuputo, Jr., DAB CR249 (1992), as support for this assertion.

I would find that the I.G. proved the existence of an aggravating factor if the I.G. had proved that Petitioner's ordering of unnecessary laboratory tests resulted in or could have resulted in substantial payments by the New York Medicaid program for items or services for which reimbursement should not have been made. The Accuputo decision notwithstanding, I do not agree with the I.G.'s argument that proof of payment of any amount of reimbursement by a Medicaid program for an item or service for which reimbursement should not have been made is proof of a "significant" adverse financial impact on the program. To accept that argument would mean that the word "significant" would be interpreted to mean "any." Such an interpretation does not comport with the plain meaning of the word "significant."

It is not necessary, however, for me to decide here what would constitute a significant adverse financial impact on the New York Medicaid program, within the meaning of 42 C.F.R. § 1001.601(b)(2)(I). Here, there is no evidence that Petitioner's ordering of unnecessary laboratory tests either resulted in or even could have resulted in any reimbursement payments -- much less, significant reimbursement payments -- by the New York Medicaid program.

There is no proof that Petitioner's ordering of unnecessary laboratory tests resulted in the payment by the New York Medicaid program of any reimbursement for those tests. The record of this case is simply devoid of any evidence which proves the dollar amount of the claims made for the unnecessary tests that Petitioner ordered, or the amount of reimbursement, if any, paid by the New York Medicaid program for such claims. No finding was made by the Department of Social Services that the New York Medicaid program paid any reimbursement for the tests. The I.G. offered no evidence, separate from the Department of Social Services' findings, which would establish that the New York Medicaid program paid reimbursement for any of the tests.

There is no proof that Petitioner's ordering of unnecessary laboratory tests could have had an adverse financial impact on the New York Medicaid program. Not only did the I.G. not prove that the program paid reimbursement for the tests, but the I.G. did not prove that the New York Medicaid program might have made significant reimbursement payments on any of the claims made for those tests.

In order to prove the possibility of significant adverse financial impact on the New York Medicaid program resulting from reimbursement claims for unnecessary tests, the I.G. would have to prove that the tests ordered by Petitioner were for items or services that were covered by the New York Medicaid program, and for which the program would have paid reimbursement if reimbursement claims were made. The I.G. did not offer any evidence that the types of tests ordered by Petitioner were covered services for which the New York Medicaid program might have paid reimbursement. Accordingly, the I.G. did not meet its burden of proof because it failed to offer any evidence from which I could conclude that Petitioner's ordering of unnecessary laboratory tests either did have or could have had an adverse financial impact, within the meaning of 42 C.F.R. § 1001.501(b)(2)(i).

D. Whether a two-year exclusion is reasonable (Finding 6)

The existence of aggravating or mitigating factors in a case does not mean that an exclusion of any particular length is necessarily reasonable or unreasonable. The regulation which governs exclusions imposed pursuant to section 1128(b)(5) does not prescribe any formula for determining what is reasonable, aside from establishing a benchmark exclusion of three years where no aggravating or mitigating factors are present. 42 C.F.R. § 1001.601(b)(1) - (3). In order to decide whether an exclusion of more or less than three years is reasonable, I must look at the evidence which relates to any aggravating or mitigating factors, and decide what that evidence shows about an excluded individual's trustworthiness to provide care.

The I.G. seems to argue that I am without authority to modify an exclusion that I find to be unreasonable. According to the I.G., the length of an exclusion has been left to the I.G.'s discretion. I.G.'s brief at 3. And, according to the I.G., an administrative law judge has no authority to review the I.G.'s exercise of discretion in imposing an exclusion. Id.; See 42 C.F.R. § 1005.4(c)(5).

Although the I.G.'s argument is not entirely clear, the I.G. appears to be asserting that her choice of the length of an exclusion is immune from review because such a determination is an act of discretion. If that is what the I.G. is arguing, I find such argument to be without merit.

The regulation relied on by the I.G. states that an administrative law judge may not:

> Review the exercise of discretion by the OIG to exclude an individual or entity under section 1128(b) of the Act, or determine the scope or effect of the exclusion, ...

42 C.F.R. § 1005.4(c)(5).

I do not read this regulation as precluding my review of the issue of whether the length of an exclusion is reasonable. The regulation plainly exempts from review the I.G.'s discretion to impose, or not to impose, an exclusion in a case involving section 1128(b) of the Act. The regulation also exempts from review the I.G.'s determination as to what would constitute a violation of the terms of an exclusion. But the regulation says nothing that would suggest that it exempts from review the I.G.'s determination of the length of an exclusion.

Furthermore, the I.G.'s apparent interpretation of 42 C.F.R. § 1005.4(c)(5) would render meaningless 42 C.F.R. § 1005.20(b). This regulation states in relevant part, that, in deciding a case, including a case brought pursuant to section 1128 of the Act, the administrative law judge may:

> affirm, increase or reduce the penalties, assessment or exclusion proposed or imposed by the IG, or reverse the imposition of the exclusion.

Although I have authority to review the length of the exclusion imposed by the I.G., I do not have the authority to simply substitute my judgment for that which has been exercised by the I.G. The test that I apply in reviewing the length of an exclusion is that of reasonableness. I must sustain an exclusion if it comports reasonably with the Act's purpose of protecting federally funded health care programs and program beneficiaries and recipients from providers who are not trustworthy. However, if the exclusion does not comport reasonably with the Act's remedial purpose, then I must modify it so that it does comport with that purpose.

The presence of a mitigating factor in this case, not offset by any aggravating factor, suggests that an exclusion of less than the three-year benchmark stated in 42 C.F.R. § 1001.601(b) may be reasonable. However, that does not mean that an exclusion of any particular duration is reasonable. And, where a mitigating factor is established, an exclusion is not per se reasonable because it is for a period of less than the benchmark period. See 42 C.F.R. § 1001.601(b).

The two-year exclusion which the I.G. imposed against Petitioner is not reasonable. There is no evidence that it comports with the Act's remedial purpose.

The only evidence in this case which addresses Petitioner's trustworthiness to provide care is the record created by the Department of Social Services in the State exclusion proceedings against Petitioner. It shows that Petitioner ordered unnecessary tests and that, in two instances, Petitioner's treatment records failed to comply with recognized standards of care. However, the dates of this misconduct are not specified in the findings of the Department of Social Services, nor are they specified in the audit report that accompanies those findings. I.G. Ex. 1. Therefore, upon the record before me, the I.G. has not included any documentation regarding whether the episodes upon which the Department of Social Services premised its findings constitute a protracted pattern of misconduct by Petitioner, or are relatively isolated episodes of misconduct.

The Department of Social Services' findings regarding Petitioner's lack of trustworthiness assume a great importance in light of the paucity of evidence of Petitioner's misconduct. The Department of Social Services found that Petitioner would be eligible to apply for reinstatement to the New York Medicaid program on November 14, 1996. That is a finding that Petitioner will be untrustworthy to provide care at least until November 14, 1996. It is also a finding that Petitioner may be able to demonstrate that she is trustworthy on or after that date.

The effect of the I.G.'s exclusion of Petitioner is that she will not become eligible to apply to the I.G. for reinstatement until late February of 1998. That is a date nearly 15 months later than the date when Petitioner will be eligible to apply to the State of New York for reinstatement to the New York Medicaid program. I find this exclusion to be unreasonable, given that the only evidence of record relating to Petitioner's trustworthiness shows that she may become trustworthy to provide care as early as November 14, 1996. The I.G. has

simply not established any rational or logical basis for me to conclude that Petitioner must be considered to be untrustworthy beyond November 14, 1996.

E. Modification of the exclusion (Finding 7)

I modify the exclusion that the I.G. imposed against Petitioner so that she will be eligible to apply to the I.G. for reinstatement on the date that the State of New York reinstates her to participate in the New York Medicaid program. This date will be no earlier than November 14, 1996. The modification which I am directing thus conforms the exclusion to the only credible evidence of record relevant to when Petitioner will become trustworthy to provide care. In effect, it makes the exclusion imposed by the I.G. coterminous with that which was imposed by the Department of Social Services.

My conclusion that the exclusion ought to be modified to make it coterminous with that which was imposed by the Department of Social Services should not be taken to mean that such a result would be appropriate in every case of an exclusion imposed pursuant to section 1128(b)(5). The regulation which implements this section makes it clear that the Secretary has concluded that a coterminous federal exclusion is not necessarily appropriate in such a case. 42 C.F.R. § 1001.601. The fact that the Department of Social Services imposed an exclusion against Petitioner which may end as early as November 14, 1996 did not necessarily obligate the I.G. to impose a coterminous exclusion.

However, in this case, the only evidence of Petitioner's trustworthiness is that she may become trustworthy as early as November 14, 1996. In light of that, the I.G. should have developed additional evidence of Petitioner's lack of trustworthiness to support an exclusion that would have not made Petitioner eligible to apply to the I.G. for reinstatement until February 1998.

Also, I wish to make it clear that I am not modifying the I.G.'s exclusion to end on November 14, 1996, because Petitioner may not satisfy the State of New York that she has become trustworthy to provide care as of that date. November 14, 1996 is merely the date upon which Petitioner will become eligible to apply to the State of New York for reinstatement to the New York Medicaid program. The State of New York appears to have discretion not to reinstate Petitioner if she does not prove herself to be trustworthy as of that date. The I.G. is under no obligation to consider Petitioner's application for reinstatement if she has not satisfied

the State of New York that she is trustworthy to provide care.

IV. Conclusion

I conclude that the two-year exclusion imposed by the I.G. against Petitioner is unreasonable. I modify it so that Petitioner's exclusion will be in effect until she is reinstated by the State of New York to participate in the New York Medicaid program.

/s/

Steven T. Kessel
Administrative Law Judge