Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
National Hospital for Kids in Crisis,	)	DATE: March 5, 1996
	)	
Petitioner,	)	
	)	
- v.-	)	Docket No. C-94-333
	)	Decision No. CR413
Health Care Financing Administration.	)	
	)	

DECISION

In this decision I conclude that, on June 24, 1993, the Health Care Financing Administration (HCFA) properly determined not to certify Petitioner as a participant in the Medicare program based on its finding that Petitioner was not complying with a condition of participation in Medicare. The effect of my decision is to sustain HCFA's later determination that Petitioner first became eligible to participate in Medicare on October 25, 1993.

I. Background

The facts and law which I recite as background to this case are not disputed by the parties. Petitioner is a nonprofit hospital that provides care to children who are hospitalized for treatment of mental disorders. Petitioner applied to participate in the Medicare program as a psychiatric hospital.

An applicant for participation in Medicare may not participate in the program until HCFA certifies that the applicant is complying with all Medicare participation requirements. 42 C.F.R. § 489.13. HCFA directs that an applicant for participation in Medicare be surveyed in order to ascertain whether the applicant is complying with participation requirements. On May 24 - 25, 1993, Petitioner was surveyed by two psychiatric consultants who had been retained by HCFA. The surveyors evaluated

Petitioner's operations pursuant to regulations which govern Medicare participation of psychiatric hospitals.

The regulations that govern Medicare participation of psychiatric hospitals are contained in 42 C.F.R. Part 482. These regulations describe three levels of requirements that a psychiatric hospital must comply with in order to participate in Medicare. These three levels of requirements are known as "conditions," "standards," and "elements" of participation. Conditions of participation are fundamental requirements of participation. For example, 42 C.F.R. § 482.61, which prescribes the medical records that must be maintained by a participating psychiatric hospital, states as a condition of participation that the medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of treatment provided to patients.

A standard of participation is a subpart of a condition of participation. For example, a standard of the medical records condition, contained in 42 C.F.R. § 482.61(a), is that medical records must stress the psychiatric component of the patient's record. An element of participation is a subpart of a standard. Thus, 42 C.F.R. § 482.61(a)(1) provides, as an element of the preceding standard, that identification data in a patient's medical record must include that patient's legal status.[1]

HCFA will not permit an applicant to participate in Medicare until the applicant corrects any deficiency identified during a survey. 42 C.F.R. § 489.13. HCFA furnishes the applicant with a written notice of any deficiency ascertained at a survey. See 42 C.F.R. §§ 488.24, 488.26.[2]

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[1] As I discuss below, at Part III.A, a failure to comply with a standard or an element of participation may be so egregious as to comprise a failure to comply with the condition of participation of which the standard or element is a subpart.

[2] The regulations governing survey, certification, and enforcement procedures were revised, effective July 1995. 59 Fed. Reg. 56116, 56237 (1994). My citations to regulations in this decision are to regulations which were in effect prior to July 1995, inasmuch as the actions at issue occurred prior to that date. However, the revised regulations would not appear to direct a

An applicant who is found not to be in compliance with a standard or element of certification may obtain HCFA's permission to participate if it assures HCFA that it is making the correction. The applicant may submit a plan of correction to HCFA. 42 C.F.R. §488.28(a). HCFA will permit an applicant who submits an acceptable plan of correction to participate, as of the date that the deficiency is corrected, or on the date of the plan of correction, whichever is the earlier date. 42 C.F.R. § 489.13(b).

HCFA does not provide an applicant who fails to comply with a condition of participation the opportunity to submit a plan of correction. See 42 C.F.R. § 488.28(a). An applicant who fails to comply with a condition of participation must submit a new application for participation to HCFA, and HCFA will have the applicant resurveyed. The applicant will be certified only after the resurvey, assuming that the resurvey establishes that the applicant is complying with all conditions of participation and that no additional deficiencies are identified. The necessity for a resurvey to establish compliance with a condition of participation means that, often, substantial time will elapse between identification of a condition-level deficiency at the first survey and the eventual date of certification.

The consultants who surveyed Petitioner on May 24 - 25, 1993 found that Petitioner was not in compliance with a Medicare condition of participation stated in 42 C.F.R. § 482.62, which describes special staffing requirements for psychiatric hospitals. HCFA accepted this finding, and, on June 24, 1993, it informed Petitioner that Petitioner did not meet the special staffing condition of participation in Medicare.

Consistent with HCFA's procedures, Petitioner was not afforded the opportunity to submit a plan of correction to HCFA to show that the condition-level deficiency had been corrected. HCFA advised Petitioner that Petitioner had a right to request reconsideration of HCFA's determination that Petitioner did not meet the special staffing condition. Petitioner requested reconsideration. While this request was pending with HCFA, Petitioner reapplied to HCFA to be certified as a participating provider. On September 24, 1993, Petitioner was resurveyed by consultants working on behalf of HCFA. The surveyors concluded that, as of that date, Petitioner was complying with all Medicare

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different outcome.

conditions of participation. However, they concluded also that Petitioner was not complying with elements of standards of participation contained in 42 C.F.R. § 482.61(a), the regulation which governs medical records maintained by psychiatric hospitals.

HCFA afforded Petitioner the opportunity to submit a plan of correction which addressed the deficiencies in elements of participation that were identified at the September 24, 1993 resurvey of Petitioner. Petitioner submitted a plan of correction, which HCFA received on October 25, 1993. On November 2, 1993, HCFA advised Petitioner that HCFA had accepted the plan of correction. Petitioner was certified to participate in Medicare effective October 25, 1993.

Petitioner continued to request that HCFA reconsider its June 24, 1993 determination that Petitioner did not meet a condition of participation in Medicare. On January 24, 1994, HCFA advised Petitioner that HCFA was sustaining its June 24, 1993 determination that Petitioner failed to meet a condition of participation. HCFA restated that the effective date of Petitioner's participation in Medicare was October 25, 1993.

Petitioner requested a hearing. In its request, Petitioner disputed that the deficiencies that were found at the May 24 - 25, 1993 survey were so severe as to establish that Petitioner was not in compliance with a condition of participation in Medicare. Petitioner asserted that HCFA should have afforded Petitioner the opportunity to submit a plan of correction to HCFA to address the deficiencies that had been identified at the May 24 - 25, 1993 survey of Petitioner.

The case was assigned to me for a hearing and decision. On September 26 - 27, 1995, I conducted a hearing in Philadelphia, Pennsylvania.[3] I base my decision in this

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[3] The parties made prehearing motions for disposition of this case. On February 28, 1995, I denied those motions and ruled that disputed issues of material fact existed which needed to be heard. My ruling is contained in the transcript of oral argument of those motions, which I cite to as "Tr. of oral argument and ruling, February 28, 1995, at (page)."

The transcript of the hearing which I conducted on September 26 - 27, 1995 is a separate document. I cite to that transcript as "Tr. at (page)."

case on the record of that hearing, on the parties' arguments, and on the applicable law.

II. Issue, findings of fact, and conclusions of law

Petitioner concedes that, as of the May 24 - 25, 1993 survey, it was not complying with all requirements of participation. However, Petitioner argues that it was complying with all conditions of participation as of May 24 - 25, 1993. It contends that any deficiencies which existed as of that date were not so severe as to be condition-level deficiencies.

Petitioner asserts that HCFA was required to afford Petitioner the opportunity to submit a plan of correction to address the deficiencies that were identified at the May 24 - 25, 1993 survey.[4] Petitioner argues that, had HCFA permitted Petitioner to submit a plan of correction, Petitioner would have established compliance with HCFA's requirements of participation by no later than June 30, 1993. Much of the evidence that Petitioner introduced at the September 26 - 27, 1995 hearing addressed its efforts prior to June 30, 1993 to correct the deficiencies that were identified by HCFA at the May 24 - 25, 1993 survey of Petitioner.

The issue in this case is whether, based on the May 24 - 25, 1993 survey, HCFA properly determined that Petitioner was ineligible to participate in Medicare due to a failure by Petitioner to comply with a condition of participation in Medicare. If HCFA concluded properly that, as of May 24 - 25, 1993, Petitioner failed to comply with a condition of participation, then HCFA correctly determined that Petitioner could not be certified until Petitioner was resurveyed and found to be in compliance with all participation requirements.

If Petitioner was not complying with a condition of participation on May 24 - 25, 1993, then evidence that it offered to show that it corrected deficiencies prior to June 30, 1993 is irrelevant. On the other hand, if the deficiencies identified by HCFA as a result of the May 24

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[4] Petitioner does not argue that HCFA would have been obligated to afford Petitioner the opportunity to submit a plan of correction to HCFA, if HCFA determined correctly that Petitioner was failing to comply with a condition of participation as of the May 24 - 25, 1993 survey.

- 25, 1993 survey were not so severe as to be condition-level deficiencies, then HCFA would have been required under its regulations to afford Petitioner the opportunity to submit a plan of correction to HCFA. In that event, evidence proving that Petitioner corrected the deficiencies prior to the resurvey conducted on September 24, 1993 becomes relevant.

I make the following findings of fact and conclusions of law (Findings) which support my decision that, based on the May 24 - 25, 1993 survey, HCFA properly determined that Petitioner was not complying with a condition of participation. I discuss these Findings, in detail, below.

1. An applicant for participation in Medicare does not comply with a Medicare condition of participation where its failure to satisfy requirements of participation substantially limits that applicant's capacity to provide care or where that failure adversely affects the health and safety of patients.

2. A condition-level deficiency exists where the deficiency results in a potential for harm to patients.

3. It is a condition of participation in Medicare that a psychiatric hospital have adequate numbers of qualified professional staff, including nurses, to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

4. HCFA's finding of a condition-level deficiency in this case relies on the plain meaning of the regulation which governs the professional staff which must be present at a psychiatric hospital.

5. The facility for which Petitioner sought certification treats children who are suffering from serious mental problems.

6. Nursing services provided by Petitioner include assessment of patients' physical and mental status, secluding and restraining patients when necessary, administering medications to patients, and monitoring the effects of medications.

7. As of May 24 - 25, 1993, some of the nursing services that Petitioner provided to its patients were being provided by child care counselors who did not have the professional training of nurses and who were not supervised by nurses.

8. As of May 24 - 25, 1993, Petitioner did not have an adequate number of nurses on duty at its facility to perform all of the services that should be provided by nurses.

9. As of May 24 - 25, 1993, Petitioner's failure to have an adequate number of nurses to provide the services that should be provided by nurses threatened the health and safety of Petitioner's patients and substantially limited Petitioner's ability to provide adequate care to patients.

10. As of May 24 - 25, 1993, Petitioner was not complying with the condition of participation in Medicare governing staffing in psychiatric hospitals.

III. Discussion

A. Applicable law (Findings 1 - 4)

Under regulations which govern participation in the Medicare program, a provider or supplier fails to meet a condition of participation where it manifests deficiencies that are:

> . . . of such character as to substantially limit the provider's or supplier's capacity to render adequate care or which adversely affect the health and safety of patients; . . .

42 C.F.R. § 488.24(a).[5]

In determining the level of a deficiency, it is necessary to examine the actual or potential impact that the deficiency may have on an entity's capacity to provide care or on the health and safety of patients. An entity's failure to comply with the requirements of a standard or element of a condition of participation also

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[5] In the revised regulations which became effective in July 1995, this identical language is contained at 42 C.F.R. § 488.24(b). 59 Fed. Reg. 56237 (1994).

may be a failure to comply with the overall condition if the failure substantially compromises the entity's ability to provide care or adversely affects the health and safety of patients.

Petitioner argues that, in order to show that an entity is not complying with a condition of participation, HCFA must prove that a deficiency in that entity's operations is not just potentially harming, but is actually harming, patients. Petitioner Reply to HCFA Posthearing Brief at 5 - 6. I do not agree with this argument. It is not supported by either the language of 42 C.F.R. § 488.24(a) or by logical application of that language.

I read the regulation as encompassing not only the circumstance where demonstrable harm results from a deficiency, but also the circumstance where the potential for harm results from a deficiency. The regulation does not state that a condition-level deficiency exists only where that deficiency is causing actual, measurable harm to patients. The regulation explicitly provides that a deficiency will be of a condition level of severity where the deficiency impairs an entity's capacity to provide adequate care. A finding of impairment of an entity's capacity to provide adequate care encompasses both circumstances where the deficiency causes actual harm to patients and where it creates the potential for harm to patients. Also, the regulation specifically defines a condition-level deficiency as being a circumstance that adversely affects the health and safety of patients. A finding of a deficiency that adversely affects the safety of patients plainly would encompass a situation where the deficiency poses a potential for harm to patients.

Furthermore, it would undermine the purpose of Medicare certification to read the regulation as defining a condition-level deficiency to exist only where there is proof of harm to patients. The purpose of certification is to protect the health and safety of program beneficiaries from acts and omissions that either cause them harm or which might cause them harm. It would be contrary to the purpose of certification to require HCFA to wait until there is proof of actual harm to patients before taking action against a deficiency that poses the potential for causing harm.

The condition which HCFA determined Petitioner not to be complying with is in the regulation which governs the staffing of psychiatric hospitals that participate in

Medicare. 42 C.F.R. § 482.62. The regulation states that a psychiatric hospital must have:

> . . . adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

Id. The regulation restates this general requirement as a standard for hospital personnel. 42 C.F.R. § 482.62(a). The regulation contains a standard governing nursing staff, which requires a psychiatric hospital to have adequate numbers of registered nurses, licensed practical nurses, and mental health care workers to provide necessary care to patients. 42 C.F.R. § 482.62(d), (d)(2).

The regulation does not quantify the numbers of professional staff that must be on hand to provide services to patients. It states only that the professional staff must be "adequate" to provide necessary services.

Petitioner asserts that HCFA premises its determination that Petitioner failed to comply with the condition in 42 C.F.R. § 482.62 on an interpretation of the regulation that departs from the regulation's plain meaning. Petitioner Posthearing Brief at 5. I discuss in detail the surveyors' findings which are central to HCFA's determination below, at Parts III.B. and III.C. However, I recite the conclusions on which HCFA premises its determination and the surveyors' findings here so that I may decide Petitioner's argument concerning HCFA's asserted interpretation of the regulation.

HCFA determined that Petitioner failed to comply with the standards contained in 42 C.F.R. §§ 482.62(a) and (d) because Petitioner did not have an adequate number of nurses on hand to provide necessary nursing care to patients. HCFA determined that this failure was so egregious as to substantially limit Petitioner's capacity to provide care to its patients. HCFA found also that the deficiency jeopardized the health and safety of Petitioner's patients.[6]

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[6] In its prehearing motion for disposition, Petitioner argued that HCFA's finding of a condition-level deficiency was insufficient because the notice of

Central to HCFA's determination is the surveyors' finding that, as of May 24 - 25, 1993, Petitioner did not have a sufficient number of nurses on hand to provide all nursing services directly. Also central is the surveyors' finding that some nursing services were in fact being provided by child care counselors, who were not nurses, who were not professionally qualified to provide nursing services, and who were not supervised by nurses. In sum, the surveyors found that Petitioner had an inadequate number of nurses on hand to provide nursing services and that Petitioner was using non-nursing personnel who were not under the supervision and control of nurses to provide those services.

Petitioner contends that HCFA interprets 42 C.F.R. § 482.62 to mean that, where a psychiatric hospital employs child care counselors, the counselors must be supervised by nurses. Petitioner Posthearing Brief at 5. Petitioner asserts that the deficiency identified by HCFA under HCFA's reading of the regulation is that Petitioner did not have its child care counselors supervised by nurses. Petitioner argues that the regulation is silent as to the supervisory controls that a psychiatric hospital must exercise over its child care counselors. Petitioner thus argues that HCFA premises its determination as to the adequacy of Petitioner's professional staff on an interpretation of 42 C.F.R. § 482.62 that departs from the plain meaning of the regulation.

Petitioner argues additionally that, inasmuch as HCFA's interpretation of the regulation is not within the regulation's plain meaning, then HCFA cannot reasonably hold Petitioner accountable to that interpretation. Petitioner Posthearing Brief at 5. Alternatively, Petitioner argues that HCFA cannot reasonably hold Petitioner accountable to HCFA's interpretation without

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that finding which HCFA sent to Petitioner did not specifically recite that Petitioner manifested a deficiency which substantially limited Petitioner's capacity to provide care or which adversely affected the health and safety of patients, as described in 42 C.F.R. § 488.24(a). I did not agree with this argument. I concluded that a finding of a condition-level deficiency by HCFA incorporated the definition of a condition-level deficiency stated in the regulation. Tr. of oral argument and rulings Feb. 28, 1995, at 12. Petitioner has not restated this argument again in its posthearing briefs. I conclude that there is no need for me to address it again in detail.

first providing Petitioner with notice of that interpretation. Id.

Petitioner mischaracterizes HCFA's determination that Petitioner failed to comply with 42 C.F.R. § 482.62. The gravamen of HCFA's determination is that Petitioner failed to employ an adequate number of nurses to provide necessary nursing services. HCFA's determination is based on the plain meaning of 42 C.F.R. § 482.62.

The plain meaning of the regulation is that a psychiatric hospital must have adequate numbers of professionals on hand, including nurses, to perform the duties that are within the province of the professional staff. Contrary to Petitioner's characterization of HCFA's determination, HCFA did not determine that, under 42 C.F.R. § 482.62, child care counselors necessarily must be supervised by nurses. HCFA did not determine that there exists any particular supervisory requirement in the regulation applicable to child care counselors. Where child care counselors perform duties that are not nursing duties, there would be no need for them to be supervised by nurses.

HCFA determined that Petitioner may not make up for a shortfall in nursing personnel by assigning nursing duties to non-nurses who are not under the supervision and control of nurses. Under HCFA's analysis, child care counselors need to be supervised by nurses only if they are being used to assist nurses in the performance of nursing duties. That is entirely consistent with the regulation's requirement that there be adequate professional staff, including nurses, to perform the duties assigned to that staff.

Petitioner corrected its nursing staff deficiency by placing its child care counselors under the direct supervision and control of nurses. The child care counselors became assistants to the nurses and were used to augment nurses providing services. Ultimately, HCFA accepted this arrangement as an adequate way to meet the nursing staff requirements of 42 C.F.R. § 482.62. P. Ex. 19. The fact that HCFA accepted this restructuring of Petitioner's operations as a way to correct a deficiency in those operations does not suggest that HCFA interpreted the staffing regulation to require this arrangement. Petitioner could have corrected the deficiency by hiring additional nurses and by assigning only non-nursing duties to child care counselors.

It is unnecessary for me to decide Petitioner's argument that HCFA failed to provide Petitioner with adequate notice of HCFA's interpretation of 42 C.F.R. § 482.62, given my conclusion that HCFA's determination comports with the plain meaning of the regulation. I would note however, that I am not persuaded that HCFA was obligated in this case to provide Petitioner with advance notice of its interpretation of the regulation, assuming the interpretation to be reasonable.

I have concluded in other cases that HCFA is obliged to give a provider notice of its interpretation of a regulation before using that interpretation as grounds for finding a condition-level deficiency and terminating the provider's participation in Medicare, where the interpretation, albeit reasonable, is not evident from the language of the regulation. Hospicio en el Hogar de Utuado, DAB CR371 (1995). My rationale is that it would not be reasonable for HCFA to terminate a provider who has an ongoing relationship with HCFA, where HCFA's interpretation of a regulation is not apparent from the face of the regulation, without HCFA first giving the provider notice of that interpretation. Here, however, Petitioner did not have an ongoing provider relationship with HCFA. As of May 24 - 25, 1993, it was an applicant for provider status. The regulations provide plainly that an applicant for participation in Medicare may not be certified as a participating provider until it complies with all participation requirements. 42 C.F.R. § 489.13.

B. The facts supporting HCFA's determination (Findings 5 - 9)

I ruled that HCFA had the burden of proving, by a preponderance of the evidence, the facts on which it based its determination that Petitioner was not complying with a Medicare condition of participation. HCFA established the facts on which I base my Findings 5 - 9 by a preponderance of the evidence.

The evidence offered by HCFA consists largely of the testimony of the two surveyors who conducted the May 24 - 25, 1993 survey, Chester A. Woffard, R.N. (Tr. at 67 - 176) and Raymond E. Ackerman, M.D. (Tr. at 177 - 225).[7] Dr. Ackerman testified additionally as a rebuttal witness

[7] The transcript refers to Mr. Woffard, inaccurately, as Mr. "Wofford."

for HCFA (Tr. at 408 - 413). I find these witnesses to be credible and their testimony to be persuasive.

The testimony of Mr. Woffard and Dr. Ackerman includes observations that the surveyors made concerning the way in which Petitioner was providing care to its patients. Their testimony includes also opinions on the questions of whether Petitioner had an adequate number of nurses on its staff to perform all nursing duties, whether duties assigned to child care counselors were, in fact, nursing duties and, whether Petitioner's staffing arrangements potentially harmed patients.

Mr. Woffard is a registered nurse with a master's degree in psychiatric nursing. P. Ex. 12 at 1. He has many years of experience in the field of psychiatric nursing, including extensive supervisory experience. Id. Mr. Woffard has performed certification surveys on behalf of HCFA since 1983, and his experience as a surveyor includes many surveys of psychiatric hospitals for the purpose of determining whether the hospitals are complying with Medicare staffing requirements. Id.

Dr. Ackerman has been board-certified as a psychiatrist since 1969. HCFA Ex. 2 at 1. He has performed surveys on behalf of HCFA or its predecessor since 1977. Tr. at 178. He has surveyed more than 125 hospitals for compliance with Medicare participation requirements, including professional staffing requirements. Id. at 178 - 179.

Mr. Woffard is qualified to testify about the duties that fall within the province of nurses and about the risks that are inherent in assigning nursing duties to non-nurses. Both Mr. Woffard and Dr. Ackerman are qualified to testify as to whether duties that were assigned by Petitioner to child care counselors were in the nature of nursing duties. Both of these witnesses are qualified to opine as to the effect of Petitioner's professional staffing arrangements of the welfare of patients. Petitioner now argues that I should not accept the opinions of Mr. Woffard and Dr. Ackerman as expert opinions. Petitioner Reply to HCFA Posthearing Brief at 2. Petitioner premises this argument on HCFA's failure at the September 26 - 27, 1995 hearing to announce explicitly that it intended to offer the opinions of these two witnesses as experts. I do not find that HCFA's failure at the hearing to announce explicitly that it intended to offer the expert opinions of Mr. Woffard and Dr. Ackerman bars me from considering the expert opinions that were offered by these witnesses and attaching to those opinions the weight that is due to

them. Petitioner cannot claim credibly that it was ambushed by HCFA. It was obvious at the hearing that HCFA intended that these witnesses be considered as experts in the way psychiatric hospitals provide services to their patients. Petitioner had ample opportunity to cross-examine these witnesses on their expertise and their opinions and to impeach their testimony.

Mr. Woffard and Dr. Ackerman are qualified to opine whether Petitioner's staffing arrangements were inadequate or whether they created a potential for harm to patients. The witnesses are not qualified to opine as to whether the inadequacies they attested to prove a failure by Petitioner to comply with the requirements of 42 C.F.R. § 482.62, or whether the potential for harm resulting from those inadequacies meets the definition of a condition-level deficiency contained in 42 C.F.R. § 488.24(a). A finding as to whether facts prove a failure to comply with the terms of a regulation, or whether the facts prove a condition-level deficiency requires an application of law to evidence which the witnesses are not qualified to make.

In many respects, the findings made by Mr. Woffard and Dr. Ackerman as to the way in which Petitioner organized its professional staff are not challenged by Petitioner. As I discuss below, a central finding by the surveyors is that nurses on duty for Petitioner did not have supervisory authority over child care counselors. This central finding is corroborated by Petitioner's own witnesses. See, e.g., P. Ex. 17.

However, Petitioner denies that the effect of its organization of staff was to pose a potential for harming Petitioner's patients. In concluding that the potential for harm existed, I have considered carefully the testimony of Petitioner's witnesses, especially that of Petitioner's expert witness, Christine M. Doleski, R.N. (Tr. at 377 - 404).

Ms. Doleski, like Mr. Woffard, is a registered nurse with a master's degree in psychiatric nursing and substantial experience in the field of psychiatric nursing. P. Ex. 13; Tr. at 379. I find her well qualified to testify as an expert. Furthermore, I find her testimony to be credible. However, I am not persuaded by Ms. Doleski's testimony that Petitioner rebutted the key concern raised by HCFA's surveyors, that the organization of Petitioner's professional staff created a potential for harming patients. I discuss my reasons for this conclusion at Part III.B.4. of this decision.

1. Petitioner's facility and patients (Finding 5)

As of May 24 - 25, 1993, the facility for which Petitioner was applying for certification as a psychiatric hospital consisted of a building wing which was housing approximately 12 patients. P. Ex. 18 at 1. At that time, the facility consisted of a nursing station, eight bedrooms, some of which were occupied by one patient and some of which were occupied by two patients, and two contiguous rooms which were used for patient therapy and activities. Id. Then, and now, Petitioner's facility treats children who range in age from about six to about 18 years. Tr. at 246. The duration of a typical patient stay, then, and now, is about three weeks. Tr. at 249.

Petitioner's patients are seriously ill. Patient diagnoses include major depressive disorders, personality disorders, schizophrenia, or other psychotic disorders, including drug-induced disorders. Tr. at 250. In a majority of cases, the patients pose threats, either to themselves or to others. Tr. at 251. Some patients require continuous, direct observation and supervision. See P. Ex. 17 at 3; Tr. at 137. At times, it is necessary to seclude (isolate) a patient or to physically restrain a patient. See P. Ex. 17 at 3; Tr. at 136. Most of the patients are on medication. Tr. at 187. The medications administered to the patients may have side effects which affect the patients' physical and mental activities. Id. Some of the patients suffer from disorders, including epilepsy, which may produce seizures, and organic brain disorders. Tr. at 187 - 188.

2. Nursing services provided by Petitioner (Finding 6)

Petitioner asserts that HCFA has not offered a definition of what comprises nursing services. Petitioner Reply to HCFA Posthearing Brief at 4. Petitioner argues that HCFA cannot hold Petitioner accountable for failing to comply with the regulation governing a psychiatric hospital's professional staff, because HCFA has never defined what comprises nursing services. Id.

I disagree with this assertion. This case focuses on HCFA's allegation that Petitioner lacked a sufficient number of nurses to perform certain specific nursing services. HCFA identified what nursing services are at issue and proved by a preponderance of the evidence that these services fall within the generally accepted understanding of what comprises nursing services at a

psychiatric hospital. Petitioner did not argue that any of these services are not nursing services, nor did it offer evidence to rebut the evidence that HCFA introduced to prove that the services are nursing services.

It is true that the regulation which governs staffing at psychiatric hospitals does not define nursing services. See 42 C.F.R. § 482.62(d). Nor did HCFA attempt through the presentation of evidence to offer a comprehensive definition of what comprises nursing services. However, Mr. Woffard and Dr. Ackerman persuasively defined the services which I describe in this section to constitute nursing services which a psychiatric hospital should assign to its nurses. Tr. at 88 - 89, 185 - 191. Petitioner cannot now assert credibly that it could not have been expected to know that these services should be provided by nurses. The services fall within the scope of services that nurses are licensed to provide. Tr. at 91. Additionally, they fall within the scope of services that psychiatric hospitals commonly assign to nurses. Id.

The nursing services which Petitioner provides to its patients include the monitoring of patients' conditions, the assessment of patients' mental and physical status, and secluding and restraining patients when necessary. Tr. at 86, 88 - 91, 185 - 191. These services fall within the unique professional training and licensure of nurses.

It is necessary for people who are monitoring the status of psychiatric patients to be trained and qualified to make informed judgments about what they are monitoring. Tr. at 187 - 188. For example, observed behaviors such as restlessness and agitation may be the consequence of an illness or they may be the side effects of medication. Id. It is important to be able to differentiate between possible causes of an observed behavior in order to be able to make an informed judgment and a recommendation about the treatment that should be administered to the patient. Nurses possess the necessary skills and training to make an informed judgment about the cause or causes of observed behavior. Tr. at 186 - 191.

3. The manner in which Petitioner provided nursing services (Findings 7 - 8)

As of May 24 - 25, 1993, Petitioner had a total of four registered nurses providing nursing services to patients. P. Ex. 9 at 43; see Tr. at 102 - 103. Each of the four nurses was assigned to work a specific eight-hour shift. P. Ex. 9 at 43. One nurse was assigned to work the day

shift, one nurse was assigned to work the evening shift, and two nurses were assigned to work the night shift. Id. Thus, on two of the three shifts there was only one nurse on hand to provide nursing services to the approximately 12 patients who were hospitalized at Petitioner's facility.

As of May 24 - 25, 1993, Petitioner did not have an adequate number of nurses on duty to provide all nursing services. Tr. at 102 - 103. It was not possible for the one nurse who was on duty most of the time to directly observe all of Petitioner's patients and to provide nursing services to all of them. Id. Petitioner relied on child care counselors, who are not nurses, who are not qualified to provide nursing services, and who were not supervised by nurses, to provide nursing services.

Petitioner assigned child care counselors to work with the nurse or nurses on duty on each shift. P. Ex. 9 at 51. Child care counselors are individuals who are experienced in dealing with children who suffer from mental illnesses but who lack the training and licensure of nurses. See P. Ex. 20. Generally, three or four child care counselors were assigned to the day shift, four or five child care counselors were assigned to the evening shift, and two child care counselors were assigned to the night shift. Id.; P. Ex. 17 at 1.

As of May 24 - 25, 1993, the nurses who were on duty on a shift had no supervisory authority over the child care counselors who were on duty with them. P. Ex. 17 at 1; see Tr. at 83. There were no articulated lines of reporting between the child care counselors and the nurses. Tr. at 83 - 84. Petitioner organized its nursing staff and its child care counselor staff under two separate lines of authority, with each staff having its own supervisors. Tr. at 83 - 84.

That is not to say that there was an absence of communication between nurses and child care counselors. Individuals on each staff worked with each other as teams. P. Ex. 17 at 1. The teams met frequently to discuss the treatments being given to patients and to develop treatment goals. P. Ex. 17 at 3. Nurses and child care counselors cooperated closely with each other. P. Ex. 20 at 2 - 3; Tr. at 395 - 396.

However, although the child care counselors may have worked closely with nurses, and may even have deferred to them, the child care counselors were not subordinate to nurses, nor were the child care counselors required to obtain the permission of nurses before initiating direct

patient care. Tr. at 95 - 96; see P. Ex. 17 at 2 - 4. Crisis intervention activities were not under the supervision of nurses. Tr. at 95. Child care counselors had authority to initiate decisions to implement seclusion and restraint of patients without first consulting with, or obtaining the permission of, nurses. Tr. at 96.

Furthermore, the fact that on two of three shifts there was only one nurse present meant that Petitioner used child care counselors to provide one-to-one observation of patients without the supervision of nurses. HCFA Ex. 4 at 4. One-to-one observation is used in treating seriously disturbed patients, patients who are aggressive, suicidal, or in danger of injuring themselves, and patients who suffer from organic disturbances such as seizure disorders. Id.

The training and experience possessed by child care counselors did not qualify them to work unsupervised by nurses to assess a patient's mental status, to differentiate between symptoms that might be caused by a patient's conditions or which might be produced by medications, or to initiate seclusion or restraint of a patient. Tr. at 86, 88 - 92, 191 - 192. The fact that Petitioner assigned nursing services, including one-to-one observation of patients, to child care counselors who were not supervised by nurses meant that nursing services were being provided by individuals who were not qualified to provide such services.

4. The consequences of Petitioner's staffing arrangement (Finding 9)

There is no evidence that the manner in which Petitioner provided nursing services to its patients harmed patients. For example, there is no evidence to show that a child care counselor inappropriately secluded or restrained a patient or that a child care counselor misinterpreted the cause of a patient's symptoms, with detrimental effect to the patient. However, the preponderance of the evidence is that a potential for harm to patients existed in the way in which Petitioner provided nursing services as of May 24 - 25, 1993. HCFA Ex. 4; Tr. at 196 - 197.
Petitioner's failure to have an adequate number of nurses to provide nursing services, or to supervise nursing services provided by child care counselors, substantially limited Petitioner's ability to provide adequate care to its patients. Id.

Patients can experience harm from the failure to provide psychiatric nursing services properly. For example, an incorrect decision to seclude or restrain a patient can cause harm to that patient. HCFA Ex. 4 at 3 - 4. Failure to have a nurse perform one-to-one observation of a patient, or to supervise that observation, can also cause harm to a patient. Id. at 5.

Petitioner argues that no potential for harm existed from its delegation of nursing duties to child care counselors who were not supervised by nurses. Petitioner bases this argument on the close cooperation that existed between its nurses and child care counselors as of May 24 - 25, 1993. According to Petitioner, the close working relationship between the nursing and counseling staffs assured that the staffs functioned in an integrated manner and that there was an effective flow of information between child care counselors and nurses.

I am not persuaded that the close cooperation and information flow that existed between child care counselors and nurses eliminated the risk caused by assigning nursing duties to child care counselors who were not supervised by nurses. Close cooperation between child care counselors and nurses is not an acceptable substitute for supervision of child care counselors by nurses, where such supervision is required. The fact is that child care counselors were assigned duties that they were not qualified to perform in the absence of supervision by nurses, and the child care counselors were not supervised by nurses in performing these duties. That arrangement created the potential for harm to patients.

I have carefully considered Ms. Doleski's testimony in reaching my conclusion that the staffing arrangement utilized by Petitioner as of May 24 - 25, 1993 was potentially harmful to patients and substantially limited Petitioner's capacity to provide adequate care to patients. Ms. Doleski attested to the high degree of cooperation and teamwork that existed between the child care counselors and nurses. Tr. at 392 - 393, 395. She asserted that the staffing arrangement at Petitioner's facility did not impede the ability of nurses to direct the providing of care to patients. Tr. at 395.

Ms. Doleski's testimony supports the conclusion that there existed an excellent working relationship at Petitioner's facility between child care counselors and nurses. It reinforces the testimony of members of Petitioner's staff that they cooperated closely with each other. P. Exs. 17, 20. However, it does not overcome

the conclusion that a potential for harm to patients existed in the way Petitioner organized its staff. Despite the cooperation attested to by Ms. Doleski, there remain the facts that child care counselors were assigned duties that were beyond the scope of their education and training, and that they were not supervised by nurses in the performance of those duties. That created the possibility that a child care counselor could make a decision that harmed a patient, even if that possibility may have been ameliorated somewhat by a high level of cooperation among Petitioner's staff.

C. The level of Petitioner's deficiency (Finding 10)

As of May 24 - 25, 1993, Petitioner was not complying with the condition of participation contained in 42 C.F.R. § 482.62. Petitioner did not have an adequate number of nurses on duty to provide nursing services to its patients. That failure created a potential for harm to patients and substantially limited Petitioner's ability to provide adequate care to its patients.

The consequence of this failure to comply with a condition of participation is that HCFA was not obligated to accept a plan of correction from Petitioner, or other assurances from Petitioner that it had corrected the deficiency, prior to conducting a resurvey of Petitioner to assure that the deficiency had been corrected. 42 C.F.R. §§ 488.28, 489.13. Evidence that Petitioner offered to prove that it corrected the staffing deficiency prior to the September 24, 1993 resurvey is thus irrelevant.

As I describe in Part I of this decision, the surveyors found, on September 24, 1993, that Petitioner had corrected its failure to comply with the condition of participation contained in 42 C.F.R. § 482.62. However, the surveyors found that, as of that date, Petitioner was not complying with elements of another condition of participation. Petitioner has not denied that, as of the date of the resurvey, it was not complying with these elements. Therefore, HCFA afforded Petitioner the opportunity to submit to HCFA a plan of correction showing how it would correct the additional deficiency. That plan was submitted on October 25, 1993, and HCFA accepted the plan. Thus, HCFA certified Petitioner to participate in Medicare effective October 25, 1993. That date was appropriate, in light of HCFA's previous finding of a condition-level deficiency and in light of the unchallenged findings made by the surveyors at the September 24, 1993 resurvey of Petitioner.

IV. Conclusion

I conclude that HCFA correctly determined that, as of May 24 - 25, 1993, Petitioner was not complying with a condition of participation in the Medicare program.

/s/

Steven T. Kessel
Administrative Law Judge