Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	Date: March 19, 2009
Broughton Hospital, (CCN: 34-4002)	)	
	)	Docket No. C-08-34
Petitioner,	)	Decision No. CR1928
v.	)	
Centers for Medicare & Medicaid Services.	)	

DECISION

Petitioner, Broughton Hospital, established by a preponderance of the evidence that it was in compliance with all applicable conditions of participation from February 1, 2007 through August 25, 2007, contrary to the findings and conclusions of surveys of Petitioner completed on August 2, 2007 and August 25, 2007. Accordingly, the Centers for Medicare & Medicaid Services (CMS) did not have a basis to terminate Petitioner's provider agreement and participation in Medicare on August 25, 2007.

I. Background

Petitioner, located in Morganton, North Carolina, is a psychiatric hospital operated by the State of North Carolina, that was authorized to participate in the Medicare program as a psychiatric hospital, i.e., a provider of in-patient psychiatric services. Petitioner was subject to surveys by the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Acute and Home Care Licensure and Certification Section (the state agency) completed on August 2, 2007, and August 25, 2007, that resulted in findings that Petitioner was not in compliance with program participation requirements and that its deficiencies posed immediate jeopardy to its patients.

CMS notified Petitioner by an undated letter received by Petitioner on August 15, 2007 that, based on the survey completed on August 2, 2007, Petitioner failed to meet three conditions of participation, 42 C.F.R. §§ 482.12, 482.13, and 482.23, and the deficiencies posed an immediate and serious threat to the health and safety of Petitioner's patients. CMS further advised Petitioner that it determined that Petitioner no longer met the requirements for participation in Medicare and its provider agreement would be terminated August 25, 2007, unless the cited deficiencies were corrected before that date. Request for Hearing exhibit (RFH Ex.) 3; Joint Stipulation (Jt. Stip.) ¶ 4.

The state agency conducted a full survey from August 22 through August 25, 2007. By letter dated August 28, 2007, the state agency informed Petitioner that the surveyors found Petitioner was in violation of four conditions of participation, 42 C.F.R. §§ 482.12, 482.13, 482.22, and 482.23; that immediate jeopardy existed based upon an incident that occurred on August 19, 2007; and that the immediate jeopardy identified by the survey completed on August 2, 2007, was not abated.[1] CMS notified Petitioner by letter dated August 30, 2007, that termination occurred effective August 25, 2007. RFH Exs. 6, 7; Jt. Stip. ¶ 8.

Petitioner requested a hearing by letter dated October 12, 2007. The request for hearing was docketed as C-08-34 and assigned to me for hearing and decision on October 22, 2007. A hearing was convened on December 13 and 14, 2007 in Raleigh, North Carolina. Petitioner presented the testimony of Michael Lancaster, M.D.; registered nurses (R.N.) Josh Tipton, Thomas Jones, and Shirley McNeely; certified nurses assistants' (C.N.A.) Terry Milton and Kelly Cline. CMS presented the testimony of Mary E. Johnson, Ph.D.,

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[1] The CMS evidence is inconsistent on whether or not the immediate jeopardy based upon the deficiencies cited by survey that ended on August 2, 2007, was abated. The August 28 notice from the state agency indicates that the immediate jeopardy identified by the August 2 survey was not abated. RFH Ex. 6. The Statement of Deficiency, Form CMS-2567 (SOD) for the survey concluded on August 25, 2007, indicates that the immediate jeopardy identified on August 2 was ongoing but the evidence cited for ongoing immediate jeopardy related to the incident involving Patient 39 and her falls and no allegations regarding manual restraint are found in the SOD. CMS Ex. 2, at 1. Azzie Conley, section chief for the state agency, indicated on the record at hearing that during the survey that ended on August 25, the surveyors identified no additional concerns regarding manual restraint of patients. Tr. 457. I find it unnecessary to determine whether or not the surveyors concluded that Petitioner corrected any deficiency related to manual restraint, as I conclude that there were no condition-level deficiencies in this case.

R.N. CMS offered exhibits (CMS Ex.) 1 through 91, and CMS Exs. 1 through 33, and 35 through 91, were admitted as evidence. Tr. 28. I ordered that CMS Ex. 14 be treated as sealed and not subject to release to parties other than those involved in this case without consent of both parties or me. Tr. 31. Petitioner offered exhibits (P. Ex.) 1 through 29, which were admitted into evidence. Tr. 42. The parties submitted post-hearing briefs and reply briefs. (CMS Brief, P. Brief, CMS Reply, P. Reply).

II. Discussion

A. Issue

Whether there was a basis for termination of Petitioner's provider agreement as a psychiatric hospital and its participation in Medicare.

B. Applicable Law

A "psychiatric hospital' is an institution primarily engaged in providing "psychiatric services for the diagnosis and treatment of mentally ill persons" by or under supervision of a physician. Social Security Act (Act) § 1861(f)(1). A psychiatric hospital must meet many of the same statutory requirements that apply to a regular hospital and specific record keeping and staffing requirements. Act § 1861(f)(2)-(4). "Inpatient psychiatric hospital services" are services provided to a patient in a psychiatric hospital. Act § 1861(c). A Medicare eligible beneficiary is entitled to benefits under Part A of the Act for psychiatric hospital services, subject to some limitations. Act §§ 1811, 1812. A psychiatric hospital is a provider of services within the meaning of the Act. Act § 1861(u). The Secretary of Health and Human Services (Secretary) is responsible for establishing criteria for participation in Medicare that are applicable to hospitals and psychiatric hospitals. Act §§ 1861(e)(9)and (f)(4), 1863. The Act provides that the Secretary will arrange to use state health agencies or other suitable state agencies for the purpose of determining by survey whether a provider of services meets the requirements for participation in Medicare. Act § 1864. In lieu of a state agency survey, the Secretary may accept accreditation by an appropriate organization as sufficient to establish that a hospital meets participation requirements. Act § 1865. A provider of services that is determined to meet the conditions for participation, under either method, becomes eligible to participate in Medicare and receive payments from Medicare if the provider files an agreement with the Secretary that includes the terms specified by the Act and the agreement is accepted by the Secretary. Act § 1866; 42 C.F.R. § 488.3(a).

The conditions of participation for hospitals are set forth in the Secretary's regulations at 42 C.F.R. Part 482 and most of the conditions list one or more standards. Survey, certification, and enforcement procedures are set forth at 42 C.F.R. Part 488. Provider agreements, including their approval and termination, are the subject of 42 C.F.R. Part 489. Part 482 describes three conditions of participation related to hospital administration, 13 conditions related to basic hospital functions, and seven conditions related to optional hospital services, which apply only if the provider hospital offers such services. Psychiatric hospitals that participate in Medicare are subject to some of the conditions imposed on regular hospitals as well as certain unique requirements imposed by the Act. Act § 1861(f); 42 C.F.R. § 482.1(a)(2).

The determination of whether a hospital meets a condition of participation "depends upon the manner and degree to which the provider . . . satisfies the various standards within each condition." 42 C.F.R. § 488.26(b). A state survey agency conducts a survey pursuant to an agreement with the Secretary, and subject to the Secretary's regulations, to determine whether a hospital is in compliance with the conditions of participation set forth in 42 C.F.R. Part 482. 42 C.F.R. §§ 482.1(b), 488.10, 488.11, 488.20. After completing its survey, the state survey agency certifies its findings to CMS and the certification survey by the state survey agency is treated as a recommendation to CMS. 42 C.F.R. §§ 488.11, 488.12. A state agency certification to CMS that a provider no longer is in compliance with one or more conditions of participation, supersedes a state's prior certification of compliance. 42 C.F.R. § 488.20(c). The regulations require that a state survey agency certify noncompliance when "the deficiencies are of such character as to substantially limit the provider's . . . capacity to furnish adequate care or which adversely affect the health and safety of patients. 42 C.F.R. § 488.24(b).

CMS may terminate a provider's agreement if CMS determines that the provider no longer meets the statutory or regulatory conditions for participation. 42 C.F.R. § 489.53(a)(1) and (3). CMS must give notice of its decision to terminate a provider agreement not less than 15 days prior to the effective date of the termination, with certain exceptions for hospitals with emergency departments and skilled nursing facilities. The notice must state the reason for and effective date of the termination and the extent to which services may continue after the termination. 42 C.F.R. § 489.53(c). Section 1866(i) of the Act includes special provisions for the termination of a provider agreement between the Secretary and a psychiatric hospital. If the Secretary determines that a psychiatric hospital no longer meets the requirements for a psychiatric hospital and the hospital's deficiencies: (1) pose immediate jeopardy to the health and safety of its patients, the Secretary must terminate the hospital's provider agreement; or (2) do not pose immediate jeopardy, the Secretary may terminate the hospital's provider agreement or provide no payment under Medicare for any patient admitted after the deficiency is

found, or both. Act § 1866(i)(1). Pursuant to 42 C.F.R. § 489.3, "*[i]mmediate jeopardy* means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident."

A provider has the right to have the CMS decision to terminate its provider agreement reviewed in accordance with the provisions of 42 C.F.R. Part 498. 42 C.F.R. §§ 488.24(c), 489.53(e). The provider's right to appeal includes rights to notice and a hearing by an administrative law judge (ALJ) and judicial review. Act § 1866(h)(1); 42 C.F.R. §§ 498.3(b)(8), 498.5(b). The hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et al*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Cal Turner Extended Care*, DAB No. 2030 (2006)*; The Residence at Salem Woods*, DAB No. 2052 (2006). The parties in this case have not objected to the following allocation of the burden of proof and my statement as to the quantum of evidence set forth in the prehearing order and as discussed at hearing. Tr. 10-12. CMS must make a *prima facie* case that the facility has failed to comply substantially with federal participation requirements. "*Prima facie*" means that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted. *Black's Law Dictionary* 1228 (8th ed. 2004); *see also Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd*, *Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (GEB), slip op. at 25 (D.N.J. May 13, 1999). To prevail, a provider must overcome CMS's *prima facie* case by showing by a preponderance of the evidence that it was either in compliance or had an affirmative defense. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004), *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 143 F. Appx. 664 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Hillman Rehabilitation Center*, DAB No. 1611.

C. Analysis

My conclusions of law are set forth in bold followed by my findings of fact and analysis.

The state agency conducted three surveys of Petitioner. The first survey concluded on February 21, 2007, and the state agency found that Petitioner was in compliance with program participation requirements. P. Ex. 29[2]; RFH Ex. 1. A second survey was

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[2] The CMS objection to the admission of P. Ex. 29, on grounds that it was not relevant was overruled. P. Ex. 29 includes the Form CMS-2567 from the survey

(continued...)

completed by the state agency on August 2, 2007, and resulted in findings and conclusions that Petitioner was not in compliance with conditions for participation and that its deficiencies posed immediate jeopardy. CMS Ex. 1. There is no question that the survey that ended on February 21, 2007, and the survey that ended on August 2, 2007, both focused on the circumstances of the death of a patient referred to as Patient 1 in the February 2007 survey and Patient 2 in the August 2 survey. CMS Ex. 1; P. Ex. 29. The third survey, that concluded on August 25, 2007, concluded that the immediate jeopardy cited by the August 2 survey was not abated. The August 25 survey cited condition-level violations based upon an incident involving Patient 39 and her serious head injury, and concluded that Petitioner's deficiencies related to that incident also posed immediate jeopardy. The August 25 survey also cited deficiencies as standard-level violations that did not amount to condition-level violations and those deficiencies, which are not a basis for termination of Petitioner's provider agreement, are not discussed in detail in this decision. CMS Ex. 2. I conclude, based upon all the evidence of record, that Petitioner was not in violation of program participation requirements and that there was no basis for termination of Petitioner's provider agreement.

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[2](...continued)
concluded on February 21, 2007, and related documents. P. Ex. 29 is the state survey agency's official report of its investigation of two alleged deaths at Petitioner's facility, one of which was subsequently cited as the basis for deficiency findings in the August 2, 2008 survey, at the level of immediate jeopardy, requiring Petitioner's termination. P. Ex. 29 also includes surveyor's notes made during the survey from February 20 to 21, 2007. The documents included in P. Ex. 29 were all made 20 days or less from the date of Patient 2's death (Patient 1 in the February 2007 survey), the patient whose death was the primary focus of the deficiency citations from the August 2 survey. The fact that the documents in P. Ex. 29 are more contemporaneous with the February 1 death of Patient 2, makes those documents potentially more reliable and accurate,than the documents prepared by the surveyors in conjunction with the survey that ended on August 2, 2007, six months after Patient 2's death. I recognize that the fact that the surveyors from the February 2007 survey did not cite a deficiency is not binding upon CMS as, by regulation, state certifications are no more than recommendations and the certification of noncompliance supercedes the prior certification of compliance. 42 C.F.R. §§ 488.12, 488.20(c). However, the fact that CMS is not bound does not negate the existence of the evidence.

1. Petitioner did not violate 42 C.F.R. § 482.12 as alleged by the survey completed on August 2, 2007.

2. Petitioner did not violate 42 C.F.R. § 482.13 as alleged by the survey completed on August 2, 2007.

3. Petitioner did not violate 42 C.F.R. § 482.23 as alleged by the survey completed on August 2, 2007.

4. Petitioner established by a preponderance of the evidence that it was in compliance with the conditions of participation cited by the survey that concluded on August 2, 2007.

The surveyors allege in the SOD for the survey that ended August 2, 2007, three condition-level violations: 42 C.F.R. §§ 482.12 (Tag A006 – Governing Body); 482.13 (Tag A038 – Patient's Rights); and 482.23 (Tag A199 – Nursing Services). The three alleged condition-level violations all arise from the restraint and subsequent death of Patient 2 on February 1, 2007.[3] The surveyors also allege that the deficiencies posed immediate jeopardy.

(a) Facts related to the restraint and death of Patient 2 on February 1, 2007.

Many of the facts related to the restraint and death of Patient 2 are not disputed. To the extent there is a dispute as to a material fact, I resolve it based upon credible testimonial and documentary evidence admitted at hearing.

Petitioner is a psychiatric hospital operated by the State of North Carolina, one of four such hospitals serving North Carolina; with 300 beds and an approximate 90 percent occupancy rate; the average patient stay is 13 to 16 days; and all of the patients are involuntarily committed because they are a danger to themselves or others. Tr. 325; P. Brief at 1.

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[3] CMS, at hearing and in its briefs, argues many theories in addition to the deficiencies cited in the SOD, for why Petitioner should be found not in substantial compliance. The deficiencies alleged in the SOD are the only basis for termination of which Petitioner was properly noticed and the only deficiencies upon which CMS officials based the determination to terminate Petitioner's provider agreement. Tr. 104, 186-88, 227-32, 296.

Patient 2 was involuntarily admitted or committed to Petitioner on January 1, 2007, with a suspected diagnosis of schizophrenia. According to his discharge summary dated February 1, 2007, he was 26-years old at admission, he was delusional and having auditory hallucinations, and he had been peeping into houses. CMS Ex. 3, at 4, 6-7, 21-24; CMS Ex. 69, at 20-32. The discharge summary reflects that during the first part of his admission, Patient 2 was volatile and engaged in bizarre behavior including public masterbation, falling to the ground, and refusing redirection. Psychiatric restraints were used several times.

Beginning January 18, 2007, Patient 2 was being managed on Risperdal and Zyprexa with Depakote to control seizures. On January 24, 2007, his physician ordered Haldol and Benadryl by mouth every eight hours as necessary or by intramuscular injection if Patient 2 refused the dose by mouth. CMS Ex. 3, at 7-8, 220-228. Patient 2 received a dose of the generic equivalents for Haldol and Benadryl by mouth at 07:55 a.m. on February 1. CMS Ex. 3, at 238.

During the last 12 days of January 2007, Patient 2 was reported to have shown significant improvement, he stopped making so many bizarre statements and his personal hygiene improved. During an interview the day before his death he was noted to remain very disorganized in his thinking, his psychotic symptoms had decreased, he continued to have sexually inappropriate behaviors, was able to sit still, and his hygiene was noted to be grossly improved. CMS Ex. 3, at 7-8, 92, 147.

Tony Frasca, M.D., who treated Petitioner 2 and dictated the discharge summary, states that on February 2[4] Patient 2 became agitated while in the dining room at lunch, he appeared to be looking for food as he had on previous occasions, he refused redirection though he had been redirectable in the past, he became intensely irate and agitated, and he threw a trash can. Patient 2 was manually restrained on the floor.

Dr. Frasca states in the discharge summary that during the restraint Patient 2 apparently suffered a cardiac event and, despite cardiopulmonary resuscitation (CPR) and rapid response by emergency medical services (EMS), he died. Dr. Frasca notes that there was no evidence that, at the time of death, Patient 2 suffered extrapyramidal symptoms due to his medication and his hypertension was fairly well controlled. CMS Ex. 3, at 8. Patient 2's discharge diagnosis included paranoid schizophrenia, hypertension, and hyperlipidemia. CMS Ex. 3, at 9. Patient 2 weighed 259 pounds prior to his death and

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[4] Clearly a typographical error as there is no question the restraint and death of Patient 2 occurred on February 1, 2007.

was six feet, five inches tall. CMS Ex. 3, at 10, 27, 45, 106. Patient 2's records show that staff used manual restraint to gain control of him on January 9, 15, and 21. CMS Ex. 3, at 241-248.

The Death Report Form to the state survey agency indicates that during lunch on February 1, 2007, Patient 2 was rummaging for food in a trash can at 12:00 p.m. When staff attempted redirection, Patient 2 became agitated and threw a trash can. Staff applied manual restraint and Patient 2 was lowered to the floor where he continued to struggle. When he abruptly stopped resisting, emergency procedures were followed, referred to as "Code Blue," and Patient 2 was sent to the emergency room, where he was pronounced dead at 12:57 p.m. CMS Ex. 3, at 11. The Code Blue Record shows that emergency management technicians were called at 12:15 p.m. and Patient 2 was then in cardiac and respiratory arrest; CPR was initiated at 12:15 p.m.; ventilation was started with an Ambu bag at 12:16 p.m.; and EMS arrived at 12:24 p.m. CMS Ex. 3, at 69.

The progress notes of staff present in the dining room with Patient 2, and their statements during the subsequent investigation, provide the details of what happened on February 1, 2007. At about 12:10 p.m., Patient 2 complained that he was still hungry after eating his lunch and he was trying to get more food from the servers. Staff redirected him, but as Patient 2 was going to his table, he took four to five packs of mayonnaise and said he was going to eat them. Staff took the packs of mayonnaise and Patient 2 then started walking around taking food out of the trash can and eating it. Patient 2 did not respond to redirection and staff stopped following him. He turned over a trash can and picked-up another trash can over his head and threw it. An emergency was declared[5] and staff grabbed Patient 2 and lowered him to the ground. C.N.A. Terry Milton applied a hold from behind and then other staff assisted in forcing Patient 2 to the ground. Patient 2 continued to kick and tried to bite staff, especially C.N.A. Terry Milton who did the initial take-down maneuver and wound up over Patient 2 on the floor. Though on the floor, Patient 2 continued to fight and was strong enough to raise some of the staff off the floor. The evidence also reflects that as the take-down and restraint progressed the staff continued to discuss the situation, including whether Patient 2 was calm enough to move to the restraint room, whether medication was going to be administered to calm him down, and whether C.N.A. Milton was putting pressure on the torso of Patient 2. The evidence also shows that after staff released Patient 2 and C.N.A. Milton moved away

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[5] The system for declaring an emergency and summoning help is not clear, either a panic button was pushed or a code was dialed on the phone. There is, however, no question that an emergency was declared and staff who were not in the dining room responded to the scene.

from him, Patient 2 took at least one breath before respiration ceased completely. CMS Ex. 3, at 152-159; CMS Ex. 75, at 2-9; CMS Ex. 76, at 2-7; CMS Ex. 77, at 2-3; CMS Ex. 82, at 2-4; CMS Ex. 83, at 2-8; CMS Ex. 88, at 2-3.[6]

C.N.A. Randy Spake's progress note indicates that after Patient 2 was lowered to the ground, C.N.A. Spake held Patient 2's right arm to the floor, C.N.A. Eric Icard held his right leg, C.N.A. Travis Gardner and R.N. Matt Anderson held his left leg, and C.N.A. Joseph Randazzo held his left arm. C.N.A. Terry Milton was laying across the left side of Patient 2's chest with his left arm under Patient 2[7]. According to C.N.A. Spake, when those holding Patient 2 attempted to let him up to take him to the restraint room, Patient 2 started kicking again. C.N.A. Spake's progress note indicates that he then heard that the nurse was bringing an injection for Patient 2. However, Patient 2 relaxed and R.N. King directed that his eyes and breathing be checked, which was done by R.N. Josh Tipton. C.N.A. Spake indicates that Patient 2 took one or more breaths after staff released him and C.N.A. Milton moved away. L.P.N. Brenda Connor and R.N. Tipton then started C.P.R. when there was no longer a detectable respiration or pulse. CMS Ex. 3, at 153.

A progress note dated February 1, 2007, at 1:00 p.m., and signed by Matt Anderson, R.N., indicates that at 12:08 p.m. Patient 2 was pacing in the dining room, he grabbed trash from the trash can, staff attempted to redirect him and Patient 2 did not respond, at 12:10 p.m. Patient 2 threw a trash can at staff, and staff manually restrained Patient 2. R.N. Anderson records that he assisted Terry Milton, C.N.A. and four other C.N.A.s with the manual restraint. CMS Ex. 3, at 150. In his progress note, R.N. Anderson stated that he was holding Patient 2's left leg with a C.N.A. (CMS Ex. 3, at 150) but a diagram he signed on February 6, 2007, reflects that he was actually holding Patient 2's right leg (CMS Ex. 81, at 4). Between 12:11 p.m. and 12:12 p.m., two more R.N.s and a L.P.N. arrived at the scene. At 12:15 p.m., Patient 2 became non-responsive and a Code Blue was called. Josh Tipton, R.N., started rescue breathing and Brenda Connor, L.P.N. started chest compressions. The Code Blue team arrived at 12:20 p.m. R.N. Anderson

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[6] Two statements were admitted that were witnessed by the Patient Advocate and appear to be statements of patients. CMS Exs. 78 and 79. Petitioner did not object to the admissibility of the statements. Nevertheless, I accord the statements little weight due to the fact that they were obtained from patients in a psychiatric hospital whose impairments, orientation to time and place, and ability to observe and perceive is unknown. CMS Ex. 80 could be a statement of a witness or the notes of an investigator, the document is unsigned, and I do not consider it to be of probative value.

[7] C.N.A. Regina Oates also stated that she had hold of the lower part of one leg at some point. CMS Ex. 83, at 4.

states that he remained on scene until Patient 2 was transported by EMS. CMS Ex. 3, at 150. R.N. Anderson's progress note is consistent with his statement during the investigation of the incident. CMS Ex. 81.

A progress note dated February 1, 2007, signed by R.N. Joseph Tipton, indicates that he arrived at the dining room around 12:10 p.m. and Patient 2 was in manual restraints, not responding to redirection, continuing to fight, and attempting to bite C.N.A. Terry Milton, who was straddling Patient 2. R.N. Tipton records that C.N.A. Milton was repeatedly asked if he had weight on Patient 2 and Milton responded he was not on the patient. R.N. Tipton wrote that he observed no acute physical distress. R.N. King was near the patient's head and R.N. Tipton was to the side. At 12:15 p.m. Patient 2 became non-responsive, C.N.A. Milton moved away from the patient, and it was determined that Patient 2 was not breathing and had no pulse. R.N. Anderson obtained the Ambu bag and R.N. Tipton operated the bag while L.P.N. Connor began chest compressions. R.N. Tipton also stated that throughout the restraint staff made attempts to release Patient 2 but he continued to be aggressive. CMS Ex. 3, at 156. R.N. Tipton indicated in a drawing dated February 6, 2007, that C.N.A. Terry Milton had his weight on his knees and that C.N.A. Milton said he did not have any weight on Patient 2. CMS Ex. 84, at 5. C.N.A. Milton had his left hand on the patient's right jaw but there did not appear to be any pressure (CMS Ex. 84, at 6) and he moved his hand when R.N. King told him to (CMS Ex. 84, at 4).

R.N. Tipton testified at hearing that he had worked at Petitioner as a registered nurse since 2006. He received North Carolina Interventions (NCI)[8] training, and training in the use of psychotropic medication, de-escalation, and similar topics and he received annual refresher training. On February 1, 2007, he was assigned to work Ward 4. During the day on February 1, the patients went to the treatment mall at 9:30 a.m. and then to the dining room for lunch around 11:30 a.m. Wards 4, 6, and 8 ate in the same dining hall. However, when he arrived at the dining hall, the patients from Ward 4 had already completed lunch and departed for the treatment mall. When he entered the dining hall, Patient 2 was already in manual restraints and R.N. Matt Anderson was present. R.N. Tipton went to C.N.A. Milton and asked if he was putting weight on Patient 2 and the response was no. Despite the fact that there were numerous staff holding Patient 2's extremities he was raising some staff off the floor. R.N. Tipton then spoke with R.N. Anderson about ending the restraint and moving Patient 2 to a restraint or seclusion room.

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[8] NCI is a standardized training program to prevent the use of restraints and seclusion but includes training for physical restraint techniques, therapeutic holds, carries, and techniques for special populations. CMS Ex. 51.

However, Patient 2 continued to fight so restraint continued. R.N. Tipton did not attempt to take Patient 2's vital signs when he first arrived and testified that he did not think Patient 2 was going to cooperate with an attempt to take vitals. He did not observe that Patient 2 was in distress as he continued to fight. He did observe that Patient 2 was breathing during the struggle. R.N. Karen King arrived on scene and went to contact the psychiatrist to get an order for medication for Patient 2. R.N. Tipton testified that he attempted to speak to Patient 2, but without success. Patient 2 stopped fighting, an emergency was called, and he, R.N. Anderson, R.N. King, and L.P.N. Connor assessed Patient 2, found no pulse or respiration, and began C.P.R. He observed five minutes of restraint from the time he arrived to Patient 2 becoming unresponsive. He testified that he never saw Patient 2's tongue protruding and saw no change in his color or appearance. He testified that prior to the incident with Patient 2 there was no specified hold for restraining a patient on the floor but after the incident they learned a specific hold and also how to use a transport board for moving a patient. He testified that the new hold would involve holding shoulders, arms, and legs, but he was not sure that they could have restrained Patient 2 with the new hold. Tr. 380-424.

There is no dispute that C.N.A. Terry Milton initiated the manual restraint of Patient 2. A progress note signed by C.N.A. Milton on February 1, 2007, states that at about 12:15 p.m. Patient 2 grabbed a trash can and threw it; C.N.A. Milton then wrapped his arms around Patient 2 from behind with one arm over Patient 2's right shoulder and the other under his left arm with his hands locked in the front. C.N.A. Milton was unable to take Patient 2 to the floor and other staff pulled down on Patient 2's head until he started to sink to the floor, at which point C.N.A. Milton loosened his grip and slid around to the front of Patient 2. C.N.A. Milton indicated that with Petitioner 2 on the floor, the right side of the patient's face was on Milton's right chest, Patient 2 continued to fight hard and he was trying to turn to bite C.N.A. Milton, at one point Patient 2 was struggling so hard that Patient 2's eyes looked blood red and as if they were going to pop-out. C.N.A. Milton observed nothing over Patient 2's face or neck during the restraint. Patient 2 made a last strong attempt to get up and bite and then seemed to pass out. CMS Ex. 89, at 1-2. In his statement signed on February 5, 2007, C.N.A. Milton stated that while on the floor his right side was on Patient 2's right side, his right arm was across Patient 2's left shoulder, his left arm under Patient 2's right arm with the left forearm under Patient 2's back, and his hands were locked together. Patient 2 kept trying to bite Milton's right chest and so C.N.A. Milton pushed up on his hands against the floor in order to move his chest away from Patient 2's mouth. When Patient 2 seemed to relax or pass out, Milton

had another staff member hold Patient 2's head, C.N.A. Milton loosed his hands using his right hand on the floor to support and raise himself, and his left hand he placed on the right side of Patient 2's face and over his ear so that he could immediately sense if Patient 2 started to move. C.N.A. Milton then got completely up and away from Patient 2. CMS Ex. 89, at 4-5.

C.N.A. Milton testified at the hearing that he worked as a C.N.A. at Broughton for three years. He testified that he regularly received training in the NCI, including training in how to initiate a hold and how to restrain a patient, although the training did not include how to hold a patient on the floor. C.N.A. Milton explained that on February 1, 2007, he was assigned to work Ward 8. During the day from Monday through Friday, the patients go to the treatment mall and eat lunch in the dining hall. While he was in the dining hall with his Ward 8 patients on February 1, Patient 2, who was not one of his patients, left his area and came to the Ward 8 area. Patient 2 picked-up a large 55-gallon plastic trash can and, before C.N.A. Milton could stop him, Patient 2 threw the trash can. C.N.A. Milton testified that he was confident that Patient 2 intended to throw the trash can at other people in the dining hall. C.N.A. Milton testified that when he grabbed Patient 2 from behind, he intended to put both his arms around the arms of Patient 2, but Patient 2 moved and C.N.A. Milton's right arm went over Patient 2's right shoulder and his left arm went under Patient 2's left arm and he hooked his hands in the front of Patient 2. C.N.A. Milton testified that this was not a type of hold that he was trained to apply. Patient 2 tried to throw off C.N.A. Milton and other staff grabbed Patient 2 and pulled him to the floor. C.N.A. Milton described how he slid around to the front of Patient 2 and had to push up with his hands against the floor in order to avoid the bite of Patient 2, consistent with his written statements. C.N.A. Milton testified that Patient 2 was trying to bite his throat and that his right thigh was on Patient 2's right thigh and his right lower rib cage was on Patient 2's right abdomen below the rib cage. He testified that he was putting no weight on Patient 2 because he had to keep pushing himself up and away from Patient 2 with his hands against the floor behind Patient 2 to avoid Patient 2's bite. C.N.A. Milton testified that he weighed 215 pounds in February 2007 and that he is six feet, one inch tall. He testified that when Patient 2 stopped fighting, he ended the manual restraint consistent with the description in his written statements. He recalled that during the restraint the nurses were discussing that Patient 2 was going to the restraint room as soon as they got him calmed. On cross-examination, he agreed that a nurse should have initiated the manual restraint, but that he wanted to protect his patients from Patient 2, who had intruded into their area. Tr. 338-378.

CMS attacks the credibility of both C.N.A. Milton and R.N. Tipton in its response to Petitioner's post-hearing brief. Specifically, CMS asserts that it is not credible that C.N.A. Milton was not impeding Patient 2's ability to breath and that R.N. Tipton was not in a position to monitor whether C.N.A. Milton was impeding Patient 2's ability to breath. CMS Reply at 2. I, however, find that both C.N.A. Milton and R.N. Tipton testified forthrightly and consistently with their prior written statements made at the time of the investigation. Further, the testimony of C.N.A. Milton was very detailed and his description of how he held Patient 2 is consistent with his assertion that he was not putting pressure on Patient 2 in a manner that would have significantly impeded Patient 2's breathing. Both C.N.A. Milton and R.N. Tipton testified that R.N. Tipton was providing supervision to C.N.A. Milton by reminding him not to put pressure on Patient 2's chest. The fact that C.N.A. Milton weighed less than Patient 2; that Patient 2 continued to fight during the restraint, raising himself and staff off the floor; and that the autopsy revealed no injury to the chest (CMS Ex. 5, at 2; P. Ex. 2, at 2), support an inference that C.N.A. Milton was not putting pressure on Patient 2's chest to the extent that he impeded Patient 2's breathing no more than briefly during the restraint on the floor. The fact that Patient 2 continued to struggle permits the inference that he continued to breath and maintain a heart beat so long as the struggle continued.[9] Tr. 346.

The Medical Examiner opined in a report dated February 1, 2007, that Patient 2 suffered an accidental death due to cardiac arrhythmia with contributing factors of agitated state, schizophrenia, physical restraint, and arrhythmogenic right ventricular dysplasia (ARVD). P. Ex. 2, at 8. The autopsy report signed May 8, 2007, indicates that death occurred during physical restraint with compressional asphyxia and ARVD. The Office of Chief Medical Examiner entry on the autopsy report indicates that cause of death was cardiac arrhythmia due to agitated state, with contributing factors of schizophrenia, physical restraint, and ARVD. P. Ex. 2, at 1. An amended autopsy report was signed on July 23, 2007. The amended report indicates that it was amended because the initial report stated that a staff member on top of Patient 2 weighed 300 pounds, a fact that the state bureau of investigation determined was incorrect. The amended autopsy report did not reflect a change in cause of death. The Office of the Chief Medical Examiner entry on the amended autopsy report dated August 1, 2007, did not indicate a cause of death or contributing factors. CMS Ex. 5. The death certificate listed the cause of death as cardiac arrthythmia with underlying causes of agitated state and schizophrenia. P. Ex. 3. Ellen Riemer, M.D. signed the initial autopsy report that included the erroneous finding of fact that a 300-pound staff member had been on Patient 2's torso during the restraint.

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[9] No inference is possible regarding the quality of Patient 2's respiration or the regularity of his heart beat, the inference is only that respiration and pulse continued.

Therefore, her opinion that the "cause of death . . . . is most likely compressional asphyxia", I do not consider credible or weighty. P. Ex. 2, at 1. Dr. Riemer pointed to no other evidence discovered during the autopsy that supported her equivocal conclusion that cause of death was "most likely" compressional asphyxia. Rather, her conclusion was, more likely than not, based on her belief that Patient 2 had 300 pounds on his chest and abdomen during the restraint. Dr. Riemer acknowledged that Patient 2 suffered from ARVD, which is likely to cause arrhythmias during physical exertion or stressful situations. P. Ex. 2, at 1; CMS Ex. 5, at 1. The evidence is more consistent with the Medical Examiner's conclusion reflected on the initial autopsy (P. Ex. 2, at 1), the Medical Examiner's report (P. Ex. 2, at 8), and the death certificate (P. Ex. 3, at 1), that cause of death was cardiac arrhythmia secondary to ARVD that was triggered by the stressful situation of manual restraint. Thus, I find these documents consistent with the testimony of C.N.A. Milton that he was not impeding Patient 2's breathing during the restraint.

(b) Findings of the survey that ended on February 21, 2007.

The state agency received a report from Petitioner regarding the death of Patient 2 (referred to as Patient 1 in the February survey documents). P. Ex. 29, at 2-6. The state agency also received an anonymous complaint from a nurse aide registry investigator who reported that she had received information about Patient 2 from a former staff member of Petitioner. P. Ex. 29, at 9. The complaint investigation was conducted on February 20 and 21, 2007.

The investigation report shows that the surveyors reviewed medical records, restraint logs/incident reports, and policies and procedures, and interviewed staff. Based upon their investigation, the surveyors concluded that Petitioner's staff were properly trained, staff had complied with applicable policies and procedures, and followed proper protocols. Accordingly, no deficiencies were cited. I note, however, that the surveyors did not have access to the Medical Examiner's report or the autopsy report that opined compressional asphyxia was likely.

(c) Analysis of the allegations of the survey that ended on August 2, 2007.

The surveyors allege in the SOD dated August 2, 2007, that immediate jeopardy began at 12:10 p.m. on February 1, 2007, when Patient 2 was placed in manual restraint. Petitioner's staff was advised on August 2, 2007, at 12:30 p.m and they immediately

implemented an action plan that the surveyors found was not sufficient to remove the immediate jeopardy. CMS Ex. 1, at 1. The surveyors concluded that Petitioner violated three conditions of participation.

The surveyors allege that Petitioner violated 42 C.F.R. § 482.12 (Tag A006) which imposes the condition of participation that:

> The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

CMS Ex. 1, at 1.

The surveyors allege that Petitioner violated 42 C.F.R. § 482.13 (Tag A038) which imposes the condition of participation that:

> A hospital must protect and promote the rights of each patient.

CMS Ex. 1, at 3.

The surveyors allege that Petitioner violated the following standards of care under the condition of participation established by 42 C.F.R. § 482.13:

> The use of restraint or seclusion must be implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.

42 C.F.R. § 482.13(e)(4)(ii) (Tag A814). CMS Ex. 1, at 15;

> The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.

42 C.F.R. § 482.13(e)(10) (Tag A822). CMS Ex. 1, at 19;

> The patient has the right to safe implementation of restraint or seclusion.

42 C.F.R. § 482.13(f) (Tag A835). CMS Ex. 1, at 24;

> Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion before performing any of the actions specified in this paragraph.

42 C.F.R. § 482.13(f)(1) (Tag A837). CMS Ex. 1, at 33.

The surveyors allege that Petitioner violated 42 C.F.R. § 482.23 (Tag A199) which imposes the condition of participation that:

> The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

CMS Ex. 1, at 4.

The surveyors allege that Petitioner violated the standard of care established by 42 C.F.R. § 482.23(b)(3) (Tag A204), that an R.N. must supervise and evaluate the care of each patient. CMS Ex. 1, at 4.

The surveyors made the following five findings upon which they concluded that the foregoing conditions of participation and standards of care were violated.

1. The hospital failed to have a policy or procedure for the safe and appropriate manual restraint of a patient on the floor.

2. The hospital staff failed to continuously monitor the health status of Patient 2 while he was in manual restraints.

3. The hospital failed to implement safe restraint techniques for Patient 2 while he was in manual restraints.

4. The hospital failed to ensure staff were trained and competent in the application of manual restraints.

> 5. The hospital failed to ensure Patient 2 was supervised by nursing staff that were trained and competent in the use of restraints, including continuous monitoring of the patient's health status and restraint techniques, while he was in manual restraints.

CMS Ex. 1, at 2, 3-4.

The surveyors' findings related to the standard-level violations include the finding that Petitioner followed the NCI, and the NCI included no specific instructions for manually restraining a patient on the floor, and Petitioner did not have such instructions available to staff. CMS Ex. 1, at 6-7, 14, 15-16, 19, 25, 32-33, 34-35, 42-43. The surveyors found that Petitioner had no plan or process for transporting a physically combative patient from the dining room to a seclusion or restraint room. CMS Ex. 1, at 13, 15, 18-19, 32-33, 41, 42-43. The surveyors found no documentation in the form of an Emergency Restrictive Intervention (ERI) Progress Note, reflecting health status monitoring or assessment by a nurse during the manual restraint of Patient 2 on February 1, 2007. CMS Ex. 1, at 14-15, 19, 23. The surveyors found no physician's order for the manual restraint of Patient 2 on February 1, 2007. CMS Ex. 1, at 31, 40. The surveyors also concluded that all nine of the staff members they interviewed agreed that C.N.A. Terry Milton was "positioned on top of the patient diagonally across the patient's chest." CMS Ex. 1, at 13, 17, 32, 42. The surveyors findings and conclusions that violations occurred have been shown to be erroneous.

Regarding the alleged violation of the condition of participation established by 42 C.F.R. § 482.12 (Tag A006), I first note that it is not alleged that Petitioner did not have a governing body. Rather, the allegation is that Petitioner's governing body was not effective because it failed to ensure that: (1) there was a policy or procedure for safe and appropriate manual restraint of a patient on the floor; (2) staff continuously monitored the health status of Patient 2; (3) staff implemented safe restraint technique for Patient 2; (4) staff were trained and competent in the application of manual restraint; and (5) trained and competent nursing staff continuously monitored Patient 2's health and the restraint technique that was used on him on February 1, 2007.

The evidence does not show that on February 1, 2007, Petitioner had a policy or procedure for manual restraint of a patient on the floor. The evidence shows that Petitioner followed the NCI, which is the training program created and supported by the North Carolina Department of Health and Human Services, Division of Mental Health, to be used in all Division of Mental Health facilities. CMS Ex. 51, at 1. The CMS expert, Ms. Johnson, testified that in her opinion the NCI establishes the standard of care for North Carolina mental health facilities. Tr. 257-258. Petitioner's policy, effective

August 30, 2006, subject: "Emergency Restrictive Interventions," describes "manual restraint" as holding a patient for any length of time in a manner that restricts the patient's freedom of movement, and includes NCI approved holds and carries used during an emergency by staff who are NCI-certified. CMS Ex. 65, at 2-3. Comparing the provisions of Petitioner's policy with the requirements of North Carolina Administrative Code (10A NCAC 28D.0203 and 28D.0206), I find that Petitioner's policy satisfies the requirements of the state law, and state law does not require a policy describing a technique for manual restraint on the floor. The federal regulation requires that the use of restraints or seclusion be implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with state law. 42 C.F.R. § 482.13(e)(4)(ii) (Tag A814). The federal regulations do not specify restraint techniques. Tr. 257-258. Petitioner had the policy required by state law and consistent with the standard of care. Accordingly, I conclude Petitioner did not violate 42 C.F.R. § 482.13(e)(4)(ii) (Tag A814).

I also find the surveyors' finding that staff failed to continuously monitor Patient 2's status while he was on the floor to be inconsistent with the credible evidence. The facts show that R.N. Matt Anderson was present in the dining room when C.N.A. Milton initiated the take-down hold and restraint, and R.N. Tipton arrived as the emergency alarm was sounding. R.N. Tipton's testimony that he asked C.N.A. Milton whether his weight was on Patient 2, that he discussed ending the restraint with R.N. Anderson, and that he was observing Patient 2 for signs of distress and impaired ability to breath, is credible and unrebutted. R.N. Tipton's conclusion that attempting to take Patient 2's pulse while Patient 2 was struggling was not possible or reasonable is also consistent with the fact that the struggle was vigorous. When Patient 2 ceased struggling, staff immediately reacted to determine Patient 2's vital signs and then began emergency resuscitation procedures.

The surveyors' finding that staff failed to implement safe restraint technique is in error. The CMS expert, Dr. Johnson, testified that when Patient 2 threw the trash can, staff had a reason to restrain him. Tr. 246. She further testified that whether or not to impose manual restraint in any situation is a judgment call for staff. Tr. 190-192. Dr. Johnson also testified that there is the general standard of care that restraint be done safely and humanely, but there is no specific standard of care regarding how a patient should be restrained on the floor. Tr. 257-259. However, she further testified that putting pressure on a patient's chest or abdomen is not consistent with the standard of care. Tr. 270-271. Dr. Johnson testified that the safest way to hold a patient to the floor is to hold him or her by the shoulders and legs and that bucking of the body should not be an issue so long as the patient is not hurting someone. She testified that staff, including the C.N.A.s, should know that lying on or straddling a patient posed the risk of compressional asphyxia. Tr.

270-272. Dr. Johnson testified that when manual restraint is necessary staff should consider obtaining an order for medication to calm the patient. A nurse should be monitoring the patient for escalation, for breathing, and for any signs of distress. Staff should also talk to the patient in an attempt to calm him or her. Someone should also be supervising the restraint. Tr. 162-166. Dr. Johnson testified that if C.N.A. Milton was not putting pressure on Patient 2 for more than a few moments at a time, the standard of care was not violated. Tr. 232-233. Michael Lancaster, M.D., Chief of Clinical Policy, Division of Mental Health Care, Developmental Disabilities and Substance Abuse Services for the State of North Carolina testified that it cannot be said that being on top of a resident is never appropriate to gain control of a resident. Rather, the key is to be aware of the danger and to stop putting pressure on the resident's chest or abdomen as quickly as possible. Tr. 548-551. It is apparent from the testimony of C.N.A. Milton and R.N. Tipton that they were well aware that they needed to avoid putting pressure on the chest or abdomen of Patient 2 for an extended period to avoid asphyxia. It is also apparent that both men were attempting to avoid pressure on the patient's chest and abdomen. The staff involved in the restraint sought to obtain medication for the resident; R.N. Tipton was talking to the resident in a effort to calm him; and at the same time ensuring that breathing continued. The evidence is unequivocal that staff was attempting to control Patient 2's extremities until he either calmed or could be safely moved to a restraint or seclusion room. The evidence supports a conclusion that staff was attempting to restrain Patient 2 as safely as reasonably possible consistent with the parameters outlined by the CMS expert, Dr. Johnson.

The surveyors' finding that staff were not trained and competent in safe manual restraint technique is inconsistent with the evidence. There is no dispute that C.N.A. Milton, R.N. Tipton, and other staff involved in the restraint of Patient 2 had received the required NCI training. P. Ex. 13. As Dr. Johnson testified, there is no specific hold prescribed that is the standard of care for manual restraint on the floor. However, the evidence shows that staff involved in the manual restraint of Patient 2 were doing what was reasonable to safely restrain Patient 2, and their conduct demonstrates their competence.

The surveyors' finding that there was a failure of trained and competent nursing staff to monitor Patient 2's health status and the restraint technique is inconsistent with the evidence. R.N. Anderson was present throughout the restraint, R.N. Tipton arrived shortly after the restraint began, and other nurses were also present at various times monitoring Patient 2's condition and the restraint. The facts related to the take-down and restraint are fully documented, including progress notes by all identified as being involved. Although there are no entries on an ERI form for vital signs during the manual

restraint, for reasons already discussed, vital signs were not taken and it is unreasonable to insist that vital signs be taken and entered on a form. The documentation adequately describes the restraint and emergency resuscitation efforts and demonstrates that Patient 2's status and the restraint technique used were being monitored by trained R.N.s.

I conclude that Petitioner did not violate the standards established by 42 C.F.R. §§ 482.13(e)(10), 482.13(f), 482.13(f)(1), or 482.23(b)(3). I conclude that Petitioner did not violate the condition established by 42 C.F.R. § 482.12. I conclude that Petitioner did not violate the condition established by 42 C.F.R. § 482.13, to protect and promote Patient 2's rights. The facts show that staff took reasonable steps to safely restrain Patient 2 and that staff had a reasonable basis for doing so.

The surveyors' conclusion that Petitioner violated the condition that it have an organized nursing staff is unsupported. The conclusion is based upon an incorrect factual finding of the surveyors that the restraint of Patient 2 was not supervised by qualified nursing staff. As already discussed, the restraint of Patient 2 was supervised by qualified nursing staff. Accordingly, I conclude that Petitioner did not violate 42 C.F.R. § 482.23.

The finding that Petitioner had no plan or process for transporting a physically violent patient from the dining facility is correct to the extent that Petitioner had no written plan. However, CMS points to no statutory or regulatory requirement, state or federal, that requires such a specific plan. Further, the facts show that R.N. Tipton, R.N. Anderson, and other staff were fully cognizant of the need to terminate the manual restraint as soon as possible, they were actively formulating a plan for doing so and for what the next step would be with Patient 2. The plan being considered, according to R.N. Tipton, was to either permit Patient 2 to calm with or without the aid of a sedative for which R.N. King was requesting a physician's order, and then to move Patient 2 to a seclusion or restraint room away from the dining room. There is no statutory or regulatory requirement, state or federal, nor any standard of care that requires that a state mental health facility have a restraint or seclusion room adjacent to every venue where patients may be found.

The surveyors finding that there was no physician order for the manual restraint of Patient 2 on February 1, 2007, is correct. However, pursuant to the North Carolina Administrative Code (10A NCAC 28D.0206(l)), when a restraint is used on an emergency basis prior to inclusion in a treatment plan, a state facility employee authorized to administer emergency interventions may do so for up to 15 minutes without further authorization. There is no dispute that C.N.A. Milton had the required NCI training and there is no allegation that he, R.N. Tipton, and R.N. Anderson were not

authorized to administer emergency interventions. The evidence supports a conclusion that C.N.A. Milton correctly determined that emergency intervention in the form of restraint of Patient 2 was appropriate. The evidence also shows that the restraint did not exceed 15 minutes.

CMS raises several arguments before me that are not based upon the findings and conclusions of the surveyors and that would not have been considered by CMS when making the decision to terminate Petitioner's provider agreement.[10] The CMS arguments not based upon the surveyors' findings and conclusions, or related to deficiencies cited by the August 2, 2007 survey, are not relevant or are without merit, but they are discussed here briefly in the interest of completeness.

CMS argues that nursing staff "was not fulfilling its obligations to assess patients, to develop appropriate interventions, to implement interventions on a consistent basis, and to assess the effectiveness of those interventions." CMS Brief at 3-4. The survey that ended August 2, 2007, includes no conclusions that Patient 2 was not assessed for purposes of care planning, that a care plan was not developed, or that interventions were not implemented, evaluated, and replaced as necessary. In fact, CMS's discussion in its brief of Patient 2's assessments, care planned interventions, and treatment is inconsistent with the CMS allegation that nursing staff failed in this regard. CMS Brief at 15-20.

CMS argues that nursing staff "was not fulfilling its responsibility to supervise the CNAs and was not fulfilling its obligation to effectively work with physicians to provide the care and services the patients needed." CMS Brief at 3-4. In the context of the restraint of Patient 2, the evidence shows that nursing staff was present, monitoring, and directing the restraint, and providing supervision of the C.N.A.s. The evidence shows that nursing staff did contact the patient's physician for medication.

CMS argues that Petitioner's medical staff was not well organized and was not accountable for the quality of care provided to patients. CMS Brief at 5. This allegation does not appear in the SOD dated August 2, 2007. The evidence presented does not support a conclusion that medical staff was not well organized or accountable.

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[10] Remand to CMS pursuant to 42 C.F.R. § 498.56(d) for consideration of new issues was not considered appropriate in this case, based upon review of the parties' prehearing briefs, as the arguments of counsel for CMS did not constitute new issues but rather theories that were not consistent with or supported by the facts of this case.

CMS argues, citing its expert Dr. Johnson, that Petitioner permitted use of restrictive interventions for the convenience of staff rather than for the protection of Patient 2 or the other patients around him. CMS Brief at 26. Only the restraint on February 1, 2007 was cited as the factual basis for any deficiency found by the survey that ended on August 2, 2007. Further, CMS's argument is at odds with Dr. Johnson's testimony that staff had a basis for imposing manual restraint once Patient 2 undisputedly threw the trash can in the dining room. Tr. 467-68. CMS also argues that Dr. Johnson's testimony was that staff increased the risk of Patient 2 being agitated by taking him to the dining room; that staff's actions in the dining room were likely to escalate Patient 2's agitation; that there were not enough nurses in the dining room; that she "questioned whether Patient 2's actions really rose to the level necessitating manual restraint" (CMS Brief at 26); that staff should have formulated a plan; that C.N.A. Milton's initiation of the restraint increased the likelihood that the restraint would not be successful because Patient 2 did not know him; that there should have been one staff member monitoring the situation; and that the hospital's failures made it likely that Patient 2 would suffer serious injury. CMS Brief at 26. Dr. Johnson was accepted as an expert in psychiatric nursing and permitted to render opinions based upon the evidence. However, I find her opinions not wholly credible for, as demonstrated by her testimony, she did not interview staff; she did not conduct a thorough investigation of the facts and circumstances; her opinions were based upon an erroneous understanding of the true facts, e.g. regarding C.N.A. Milton's positioning, monitoring of Patient 2, and supervision of the restraint; ultimately, she agreed that staff had a basis for imposing manual restraint; and the facts show that the restraint was conducted consistent with her testimony regarding her understanding of the standard of care. I find more persuasive Dr. Lancaster's testimony that it was appropriate and consistent with the standard of care for Patient 2 to be served lunch in the dining room. Tr. 500-501. It is unreasonable to think that in a psychiatric hospital all patients who are subject to becoming agitated should be deprived of the opportunity to eat in the dining room with other psychiatric patients. It is also apparent that staff in the dining room or the immediate vicinity was sufficient to control and protect other patients and to conduct the restraint of Patient 2. While denying Patient 2 more food, preventing him from eating mayonnaise packets, or preventing him from eating from the garbage can was likely to cause agitation, his treatment plan required that a diet be maintained and the risk for agitation was not necessarily greater on February 1, 2007, than any other day. If one accepted the CMS argument that agitation must be avoided, it would be virtually impossible for a psychiatric hospital to impose treatment necessary for the patient's health and safety and the safety of other resident's. Although C.N.A. Milton was not Patient 2's assigned C.N.A., the evidence does not show that Patient 2 did not know C.N.A. Milton or that he would have reacted any differently with his assigned C.N.A. The evidence shows that R.N. Tipton and R.N. Anderson did formulate a plan for how to proceed and that they were supervising the restraint.

CMS argues that Petitioner should have foreseen, based on Patient 2's behaviors, that taking Patient 2 to the dining room would result in serious harm to him or others. CMS overlooks the fact that Petitioner is a psychiatric hospital and, as such, Petitioner is charged with the care and treatment of patients affected with acute or chronic mental illness. Petitioner must provide care for persons with moderate to often severe psychiatric problems, such as Patient 2. The behaviors of Patient 2 cited by CMS and the related incidents result largely from his psychosis and schizophrenia. While Patient 2's behavior is sad and unfortunate, there is nothing about it that is particularly unusual in the context of a psychiatric hospital that should have placed Petitioner on notice that Patient 2's presence in the dining hall on February 1, 2007, posed a danger to him or other residents, more significant than usually present in such an environment. Furthermore, I find weighty Dr. Lancaster's opinion that it was appropriate for Patient 2 to eat in the dining room with other patients as part of his overall treatment, despite the associated risk. Tr. 500-501. Contrary to the arguments of CMS (CMS Brief at 21-22) there is no state or federal requirement that dictates the number of psychiatric patients that may be served in a dining hall, that requires space be established for a patient to de-escalate, or that dictates the placement of restraint or seclusion rooms. As Dr. Lancaster indicated, the appropriate environment for the treatment of a psychiatric patient is determined based upon medical decision making.

CMS argues that Petitioner did not ensure that there was adequate staff in the dining room. The record shows that there was at least one R.N. and four C.N.A.s present in the dining room before the manual restraint began, and at least two more R.N.s and an L.P.N. arrived shortly after the manual restraint began. Tr. 346-349, 387-389. Furthermore, the state survey team and CMS did not cite Petitioner for lack of adequate staffing.

CMS argues that the trash can did not come close to hitting another patient or that the trash can would not have injured anyone. CMS Reply at 1-2 (unnumbered). The regulations do not permit a facility to wait until a patient actually causes injury before staff intervenes, including the intervention of the application of manual restraint. The regulations allow the use of manual restraint to protect a patient or staff from harm. 42 C.F.R. § 482.13(e). In this instance, it was not unreasonable for Petitioner's staff to conclude that Patient 2 was a danger to the physical safety of others, especially considering that Patient 2 was a large man with a history of physically aggressive behavior. The CMS expert witness, Dr. Johnson, acknowledged that the staff had reason to restrain Patient 2 under these conditions. Tr. 246. Petitioner's staff, not CMS, is entrusted with the safety of all Petitioner's patients, and staff, not CMS, has to make the decision as to what measures are reasonably necessary for the protection of its patients when the environment becomes unsafe, as it did when Patient 2 threw the trash can.

5. Petitioner did not violate 42 C.F.R. § 482.12 as alleged by the survey completed on August 25, 2007.

6. Petitioner did not violate 42 C.F.R. § 482.13 as alleged by the survey completed on August 25, 2007.

7. Petitioner did not violate 42 C.F.R. § 482.22 as alleged by the survey completed on August 25, 2007.

8. Petitioner did not violate 42 C.F.R. § 482.23 as alleged by the survey completed on August 25, 2007.

9. Petitioner established by a preponderance of the evidence that it was in compliance with the conditions of participation cited by the survey that concluded on August 25, 2007.

The surveyors allege in the SOD dated August 25, 2007, that Petitioner violated four conditions of participation and multiple standards. The surveyors allege that Petitioner violated 42 C.F.R. § 482.12 (Tag A006[11]) which imposes the condition of participation that:

> The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

CMS Ex. 2, at 2. The allegation is not that Petitioner did not have a governing body, rather that the governing body was not effective based upon the following findings of the surveyors, each of which is followed by the citation for the standard allegedly violated:

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[11] The SOD lists the Tag as A043. However, Tag A043 relates to a standard-level requirement related to grievances. *See State Operations Manual* (SOM), App. A, Tag A-0043. The correct Tag designation is A006. The Tag numbers for the alleged condition-level violations of 42 C.F.R. §§ 482.13, 482.22, 482.23, and all the standard-level violations are not consistent with the Tag identifiers used in the SOM (Rev. 1, 05-21-04, the revision in effect at the time of the survey and the hearing). The correct Tag identifiers are used in this decision for ease of reference to the SOM.

Failure to assure systems were in place to ensure assessment, evaluation, and modification of the treatment plan for Patient 39 to avoid recurrence of falls and injury. 42 C.F.R. § 482.13(c)(2);

Failure to ensure medical staff accountability and oversight for the quality of care provided to Patient 39 by failure to assess, evaluate, and modify her treatment plan. 42 C.F.R. § 482.22(b);

Failure to oversee coordination of medical staff by failing to ensure physician extenders communicate with supervising physicians and document examination and treatment of Patient 39. 42 C.F.R. § 482.22(b);

Failure to ensure an organized nursing service by failure to ensure qualified R.N. supervision and evaluation of Patient 39. 42 C.F.R. § 482.32(b);

Failure to ensure that nursing staff met the care needs of Patient 39 by failure to provide qualified staff to ensure delivery of safe care. 42 C.F.R. § 482.23.(b)(3);

Failure to ensure that nursing staff updated Patient 39's nursing care plan. 42 C.F.R. § 482.23(b)(4);

Failure to enforce medical staff bylaws/hospital policies to ensure physician completion of medical records within 30 days of discharge for Patients 50, 49, 48, and 51. 42 C.F.R. § 482.24(c);

Failure to ensure medical records systems were established by failing to ensure completion and authentication of discharge summaries within 30 days of discharge for Patients 50, 49, 48, and 51. 42 C.F.R. § 482.24(c)(2)(vii);

Failure to assess a change of condition of Patient 4 prior to emergency transfer and upon return to Petitioner and failure to follow policy to ensure paperwork was completed. 42 C.F.R. § 482.23(b) and (b)(3);

Failure to ensure systems were established to ensure minimum radiation exposure to patients by failure to ensure shielding was used during x-ray procedures and failure to monitor radiation exposure of staff. 42 C.F.R. § 482.26(b)(1) and (3).

CMS Ex. 2, at 3-7, 87-93.

The surveyors allege that Petitioner violated 42 C.F.R. § 482.13 (Tag A038) which imposes the condition of participation that:

> A hospital must protect and promote the rights of each patient.

CMS Ex. 2, at 7. The surveyors made the following finding which is followed by the citation to the standard allegedly violated:

> Petitioner failed to provide care in a safe setting by failing to evaluate and modify the treatment plan for Patient 39. 42 C.F.R. § 482.13(c)(2).

CMS Ex. 2, at 8-24.

The surveyors allege that Petitioner violated 42 C.F.R. § 482.22 (Tag A181) which imposes the condition that:

> The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of care provided to patients by the hospital.

CMS Ex. 2, at 24. The surveyors made the follow findings, each of which is followed by the standard allegedly violated:

> Petitioner's medical staff failed to provide oversight of the care of Patient 39. 42 C.F.R. § 482.22(b);
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> Petitioner's medical staff failed to coordinate medical services by failing to ensure physician extenders communicated with the supervising physician for Patient 39. 42 C.F.R. § 482.22(b);
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> Petitioner's medical staff failed to ensure physician extenders documented examination and treatment of Patient 39. 42 C.F.R. § 482.22(b);
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> Petitioner's medical staff failed to assess a change of condition in Patient 4 prior to transfer and upon return from the hospital. 42 C.F.R. § 482.22(b);

> Petitioner's medical staff failed to follow hospital policy and complete required paper work related to the transfer of Patient 4. 42 C.F.R. § 482.22(b);
>
> Petitioner's medical staff failed to follow staff bylaws and policy by failing to ensure physician completion of discharge records within 30 days for Patients 50, 49, 48, and 52. 42 C.F.R. § 482.22(c).

CMS Ex. 2, at 24-44.

The surveyors allege that Petitioner violated 42 C.F.R. § 482.23 (Tag A199), which imposes the condition of participation that:

> The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

CMS Ex. 2, at 44. The surveyors made the following findings, which are followed by citation to the standard allegedly violated:

> Petitioner failed to provide adequate qualified staff to assess and supervise the ongoing care needs of Patient 39, to ensure the delivery of safe care and prevent harm due to falls. 42 C.F.R. § 482.23(b);
>
> Nursing staff failed to supervise and evaluate the care of Patient 39. 42 C.F.R. § 482.23(b)(3);
>
> Nursing staff failed to assess a change in condition of Patient 4 prior to transfer and upon return. 42 C.F.R. § 482.23(b)(3);
>
> Nursing staff failed to update the nursing care plan of Patient 39. 42 C.F.R. § 482.23(b)(4);
>
> Nursing staff failed to follow the physician's order to obtain blood pressure prior to administration of hypertension medication in 45 of 91 instances for Patient 45. 42 C.F.R. § 482.23(c).

CMS Ex. 2, at 44-87.[12]

(a) Facts related to Patient 39.

On August 18, 2007 at 11:30 p.m., Patient 39 was admitted to Petitioner, pursuant to an order of involuntary commitment, upon her discharge from Haywood Regional Medical Center. CMS Ex. 7, at 17, 22. The discharge summary from Haywood indicates that Patient 39 was a 44-year-old woman with diagnoses of lithium toxicity, bipolar disorder with manic phase, schizophrenia with acute psychosis, lithium toxicity, abnormal electrocardiogram, anorexia and weight loss. CMS Ex. 7, at 2. Patient 39 was assessed by Petitioner's staff upon admission to Petitioner's facility on August 18, at 11:30 p.m. The assessment revealed, among other things, that: she was not oriented to person, place, time or situation; she was responding to internal stimuli; she had an unsteady gate and was dizzy when walking and was assessed as requiring assistance for ambulation; she was assessed at high risk for falls; her speech was unintelligible; she was hallucinating, she was prescribed several medications including Haldol, Synthroid, Protonix, Seroquel and Ativan. CMS Ex. 7, at 17-42. A Safety Precautions Order dated August 19, 2007 at 1:08 a.m., indicates that her safety precaution level was "strict," but failed to indicate the staff distance from the patient that was required.[13] CMS Ex. 7, at 64. Patient 39's fall care plan initiated on August 19, 2007, required that nursing staff assist her with all activities including ambulation and the fact she was a fall risk was to be documented on the Kardex, nursing assignment sheet, ward round book, and a sticker was to be placed on her medical record and her door. CMS Ex. 7, at 47. "Safety Precaution Flow Sheets" document every 15 to 30 minutes that Patient 39 was receiving one-on-one supervision from 1:25 a.m. through 5:45 p.m.[14] on August 19, 2007. CMS Ex. 7, at 72-74. Incident reports show that she hit her head three times on August 19, 2007: at 10:30 a.m. she hit her head on the wall in the time-out room causing a laceration at her right eyebrow (CMS Ex. 7, at 191); at 12:30 p.m. she stumbled into the wall and hit her left forehead, causing slight swelling and bruising (CMS Ex. 7, at 192); and at 2:05 p.m. she walked into the

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[12] The surveyors also alleged a standard-level violation of 42 C.F.R. § 482.42(a)(1) related to infection control, which is not cross-referenced under any of the alleged condition-level violations. CMS Ex. 2, at 94-98. Because this standard-level violation is an insufficient basis for termination, it is not discussed further.

[13] R.N. Thomas Jones testified that "strict" means that a patient is accompanied by a staff member at all times. Tr. 430, 432.

[14] Petitioner's C.N.A. accompanied Patient 39 to the hospital. CMS Ex. 7, at 96-97.

time-out room, with her one-on-one staff member present, she fell backward without warning, and the staff member was unable to catch her, which caused major injury and transfer to the hospital (CMS Ex. 7, at 193-96). Tr. 436-442.

Nursing progress notes by the R.N. at 1:35 a.m. and 1:50 a.m. on August 19, 2007, show that Patient 39 was admitted to the ward and staff was aware that she had an unsteady gait and was at risk for falls. A note at 2:30 a.m. shows that the R.N. contacted the Physician's Assistant (P.A.) on duty and he ordered an EKG for as soon as possible in the morning. A 10:00 a.m. note by the R.N. reflects that Patient 39 was grossly psychotic and manic, she refused her medication, had not slept all night, walked the halls, and she was on one-on-one supervision for vulnerability. A R.N. note at 12:05 p.m. shows Patient 39 continued to actively hallucinate; she was pacing the halls and attempted to leave through locked exit doors; at 9:05 a.m. the doctor was contacted and he gave a new order for medication; Patient 39 was encouraged to lie down without success; the doctor was contacted again and he gave an order for new medication that was given at 11:30 a.m; Patient 39 stumbled into the wall due to her unsteady gait and untied shoe strings and received a half-inch cut near her right eyebrow; and, the P.A. assessed Patient 39 but gave no new orders. A physician note by the psychiatrist, Dr. Gadrorowski at 2:00 p.m., reflects that Patient 39 had been excessively agitated all morning, she was receiving one-on-one supervision, she was running away from staff, she fell several times resulting in bruises, medication was not effective, staff felt present measures were not effective or sufficient to prevent injury, and a Geri-chair was ordered to restrain her. Tr. 439-440. A psychiatrist note at 2:45 p.m. indicates that the P.A. had called to report that Patient 39 had fallen and hit her head on the floor while in seclusion. The psychiatrist assessed Patient 39 and EMS was called to transport her to the hospital for evaluation. CMS Ex. 7, at 48-52. A R.N. progress note dated August 19, 2007 with times from 3:00 p.m. to 4:50 p.m., records that: Patient 39 continued hallucinating throughout the shift; at 11:30 a.m. she was given Ativan per Dr. Martin's[15] orders; she continued to wander in and out of rooms; she required constant redirection from her one-on-one staff; her speech was difficult to understand; she attempted to hit one-on-one staff, C.N.A. Cline, at 1:30 p.m.; she walked into the time-out room, sat on the mattress, hit her head on the wall causing bruising but no bleeding, and was assessed by the P.A.; she was assisted to the dining room but refused lunch and was seen there by Dr. Martin and he ordered additional medication that was given at 1:10 p.m.; she continued to wander in and out of rooms; she was seen by another physician at 1:45 p.m who gave an order at 2:00 p.m. to use a Geri-chair for restraint (CMS Ex. 7, at 63), with table top and soft restraints; at about 2:05 p.m. Patient 39 entered the time-out room and was looking at the wall and then fell straight

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[15] Dr. Martin was the on-call psychiatrist. Tr. 436.

back hitting her head on the floor before C.N.A. Cline could catch her; after the fall and hitting her head Patient 39 had a large amount of swelling to the back of her head and her pupils were sluggish to respond to light; the P.A. and Dr. Martin arrived on the ward at 2:15 p.m. and assessed Patient 39; oxygen was started, EMS was contacted at 2:23 p.m.; EMS arrived at 2:40 p.m. and Patient 39 was transported to the hospital. CMS Ex. 7, at 56-57.

C.N.A. Cline's progress note at 3:05 p.m. on August 19, 2007, recounts Patient 39's behavior and status prior to her fall, states that Patient 39 entered the time-out room with one-on-one staff standing in door, Patient 39 stood in front of the wall, and Patient 39 fell straight back to the floor. CMS Ex. 7, at 53. C.N.A. Cline's updated statement also provides further details about the third and final fall. According to C.N.A. Cline's statement, Patient 39 entered the time-out room. C.N.A. Cline states that she was attempting to record her observations of Patient 39. Patient 39 was standing beside the doorway mumbling and within arms length of C.N.A. Cline. When Patient 39 started to fall straight back, C.N.A. Cline threw her clipboard and tried to grab Patient 39 but only managed to grab the side of her before Patient 39 hit the floor. P. Ex. 27 at 4. C.N.A. Garrison's progress note dated August 19, 2007, at 3:05 p.m., indicates that Patient 39 entered the time-out room with her one-on-one staff member following. CMS Ex. 7, at 54. A "Nursing Falls Progress Note and Post Fall Evaluation" form indicates that Patient 39 entered the time-out room with her one-on-one supervision and fell backward striking her head on the floor at 2:05 p.m., and that C.N.A.s Cline and Garrison witnessed the fall. CMS Ex. 7, at 59.

Following her third fall, Patient 39 was diagnosed at Grace Hospital as having multiple non-depressed skull fractures with an intracerebral hemorrhage. CMS Ex. 7, at 96-97, 101. Patient 39 was transferred to Carolinas Medical Center (CMC) hospital for treatment and care where she was diagnosed with a subarachnoid hemorrhage, a subdural hemorrhage, a right temporal frontal contusion, and a right temporal parietal skull fracture. She was discharged from the hospital on August 23, 2007, and returned to Petitioner. CMS Ex. 7, at 104, 177-88.

R.N. Thomas Jones was one of the nurses on duty on the ward where Patient 39 fell on August 19. He testified that C.N.A. Cline and C.N.A. Garrison were providing supervision for Patient 39, and she received two-to-one supervision much of the time. He testified that he had contact with both the doctor and P.A. on August 19 because he felt Patient 39 was unsafe given her constant movement, restlessness, and intrusiveness. Tr. 433-434. R.N. Jones testimony was consistent with the documents and credible.

C.N.A. Kelly Cline testified that she was assigned to provide one-on-one supervision for Patient 39 on August 19. She testified that Patient 39 would walk in the hall and she would have to hold on to her and watch her closely as Patient 39 was clumsy. She testified that she was right beside Patient 39 when the patient hit her head on the wall around 10:30 a.m. C.N.A. Cline testified that when she touched Patient 39, she pushed away and took off down the hall. Tr. 474-477. She testified that at 2:00 p.m. she relieved C.N.A. Garrison who was watching Patient 39 while C.N.A. Cline was on break. Patient 39 was then in the timeout room standing still and staring at the wall, C.N.A. Cline was preparing to document her 2:15 p.m. observation, when Patient 39 fell straight back and hit her head on the floor. C.N.A. Cline testified that she was within arms length of Patient 39 at the time of the fall, and she attempted to grab Patient 39's wrist but missed. Tr. 479. C.N.A. Cline explained in detail that she was standing right inside the door to the timeout room door, Patient 39 was standing beside her and to her left facing the opposite direction. She explained that she was on vacation during the survey and that she was not interviewed by the surveyors, but she did prepare her written statement (P. Ex. 27). Tr. 483. C.N.A. Cline also testified that in her opinion Patient 39 should have been on the medical ward where she could have been better controlled, not on the admissions ward. Tr. 490-491. I find that C.N.A. Cline's testimony is consistent with the documentary evidence, it is unrebutted, and credible. C.N.A. Cline credibly explained that just before Patient 39 fell the third-time, she was standing just inside the door with Patient 39 to her left and no more than four feet away, thus clarifying her progress note at CMS Ex. 7, at 53.

Petitioner's expert witness, Michael Lancaster, M.D., opined that Petitioner's staff treatment of Patient 39 was reasonable. The nurse was communicating with the physician and P.A., and the decision to attempt to control Patient 39 with medication before imposing restraint was reasonable. He also opined that Petitioner's treatment of Patient 39 did not violate her rights. Tr. 525. I find Dr. Lancaster's testimony credible and consistent with the record.

The CMS expert, Dr. Johnson, testified that in her opinion Patient 39 did not receive excellent care because she was not within arms-length of staff when she fell the third time. Tr. 172-173. I do not find that opinion credible because the factual basis for the opinion is in error as she misunderstood the facts reflected in the documents that she reviewed. Based upon her erroneous interpretation of the facts, she then inferred that the nursing staff had not properly instructed the nonprofessional staff or C.N.A.s. Tr. 173-174. She also testified that based upon her review of Petitioner's records for Patient 39 that, in her opinion, the nursing staff was not adequately supervising nonprofessional staff or assessing Patient 39. Tr. 173-178. Dr. Johnson's opinions about the performance of the nursing staff are not weighty given the documentary evidence and the testimony of

R.N. Jones and C.N.A. Cline. The evidence shows that nursing staff was actively engaged in the observation and assessment of Patient 39, including ensuring that the C.N.A.s were providing strict one-on-one supervision, ensuring that the doctors and P.A. were actively involved and present on multiple occasions to treat and assess Patient 39, ensuring that alternative medications were obtained when other medications failed, and ensuring a Geri-chair was called for as soon as the physician authorized use of a Geri-chair for restraint. Dr. Johnson's opinions were based only upon records review and did not include interviews of Petitioner's staff or the surveyors. Tr. 182.

(b) Analysis of allegations related to Patient 39 from the survey that concluded on August 25, 2007.

I conclude based upon review of the facts related to Patient 39, that Petitioner acted reasonably in providing care and services to Patient 39. The findings and conclusions of the surveyors were based upon faulty factual findings and are not supported by the facts I have found based upon both the documentary evidence and the credible testimony of the direct care staff. The evidence shows that Petitioner had a system in place that assessed Patient 39 upon her admission and she continued to be assessed by the professional staff, including physicians, the P.A., and the R.N.s, throughout the period from approximately 11:30 p.m. on August 18 until she was transported from the facility after her third fall around 2:40 p.m. on August 19, 2007. The evidence also shows that professional staff evaluated the effectiveness of intervention with modification of the treatment by addition of various medications and, at around 2:00 p.m., an order was issued by a physician for application of restraints to attempt to control Patient 39. The efforts of professional and nonprofessional staff, their implementation of interventions including one-on-one supervision and medication, and changes ordered to Patient 39's care plan are well documented in the clinical record throughout the period, and particularly during the morning and early afternoon of August 19. The evidence shows that the P.A. and physicians were communicating with each other and R.N. Jones and that R.N. Jones was actively supervising the care of Patient 39. The evidence also shows that R.N. Jones and C.N.A. Cline were knowledgeable in the care to be provided Patient 39 and, in fact, they delivered the care required by the care plan as modified by the physicians and P.A. Furthermore, the use of one-on-one supervision, with staff no more than arms length from the patient, was a reasonable intervention to ensure that Patient 39 was safe in her environment short of imposing physical restraint. Although C.N.A. Cline freely opined that Patient 39 might have been better cared for on the hospital ward where she could have been restrained in bed, and R.N. Jones also indicated that staff was having a hard time handling Patient 39, how quickly professional staff proceeds from the least restrictive interventions, such as medication, to the most restrictive, such as physical restraint, is a matter of medical judgment. Dr. Lancaster's opinion that Petitioner's staff

proceeded reasonably in this regard is credible. I conclude that Petitioner's care and treatment of Patient 39 did not result in condition-level violations of 42 C.F.R. §§ 482.12 (Governing Body), 482.13 (Patient's Rights), 482.22 (Medical Staff) or 482.23 (Nursing Services), or any violation of standards under those conditions.

(c) Analysis of other alleged deficiencies from the survey completed on August 25, 2007.

The surveyors alleged the following additional standard-level violations in the SOD dated August 25, 2007:

> Failure to enforce medical staff bylaws/hospital policies to ensure physician completion of medical records within 30 days of discharge for Patients 50, 49, 48, and 51. 42 C.F.R. § 482.24(c);
>
> Failure to ensure medical records systems were established by failing to ensure completion and authentication of discharge summaries within 30 days of discharge for Patients 50, 49, 48, and 51. 42 C.F.R. § 482.24(c)(2)(vii);
>
> Failure to assess a change of condition of Patient 4 prior to emergency transfer and upon return to Petitioner and failure to follow policy to ensure paperwork was completed. 42 C.F.R. § 482.23(b) and (b)(3);
>
> Failure to ensure systems were established to ensure minimum radiation exposure to patients by failure to ensure shielding was used during x-ray procedures and failure to monitor radiation exposure of staff. 42 C.F.R. § 482.26(b)(1) and (3);
>
> Petitioner's medical staff failed to assess a change of condition in Patient 4 prior to transfer and upon return from the hospital. 42 C.F.R. § 482.22(b);
>
> Petitioner's medical staff failed to follow hospital policy and complete required paper work related to the transfer of Patient 4. 42 C.F.R. § 482.22(b);
>
> Petitioner's medical staff failed to follow staff bylaws and policy by failing to ensure physician completion of discharge records within 30 days for Patients 50, 49, 48, and 52. 42 C.F.R. § 482.22(c);

> Nursing staff failed to assess a change in condition of Patient 4 prior to transfer and upon return. 42 C.F.R. § 482.23(b)(3);
>
> Nursing staff failed to follow the physician's order to obtain blood pressure prior to administration of hypertension medication in 45 of 91 instances for Patient 45. 42 C.F.R. § 482.23(c).

The surveyors cited these standard-level deficiencies under one or more of three condition-level violations, 42 C.F.R. §§ 482.12 (Governing Body), 482.22 (Medical Staff), or 482.22 (Nursing Staff). However, CMS does not argue to me that any of these standard-level violations, individually or collectively, amounted to a condition-level violation. Tr. 63-64.

The SOD indicates that the surveyors did a closed-record review of Patient 4's clinical records. The surveyors found that she had experienced excessive vaginal bleeding on the morning of July 29, 2007, she told the P.A. she thought she was having a miscarriage, and the P.A. had her transported to the emergency room for evaluation. The surveyors found no documentation that Patient 4's vital signs were taken, that blood loss or duration of bleeding was assessed, they found no documentation of assessment of her last menstrual period, and no assessment of level of consciousness documented. The surveyors could also locate no physician order for transfer to the hospital or documentation of the examination by the P.A. The surveyors found no documentation of the time of transfer or return and no documentation of an assessment upon her return. The SOD indicates that the P.A. was interviewed and he stated he felt Patient 4 needed to be transferred urgently and he did not delay to do a vaginal examination or wait for physician authorization. The P.A. could not recall completing paperwork but he did agree he did not call the receiving hospital. CMS Ex. 2, at 38-40, 71-73.

Regarding the records of Patients 48, 49, 50, and 51, the allegation was that Petitioner failed to enforce its medical staff bylaws and policy by failing to ensure that physicians completed discharge summaries within 30 days of discharge. For the patients cited, discharge summaries allegedly were not completed from three to six months after discharge. CMS Ex. 2, at 41, 43-44. The surveyors also alleged that discharge summaries were not authenticated for the same four patients. CMS Ex. 2, at 87-90. The SOD indicates that the surveyors interviewed managers and staff who were aware of the problem and working to correct it. CMS Ex. 2, at 41-43.

Patient 45's physician ordered on May 26, 2007, that his blood pressure and pulse be taken before he was given the blood pressure medication, Atenolol, and that the medication was not to be given when his pulse was less than 70 or his systolic was less

than 110 and diastolic was less than 75. The surveyors note an instance when the medication was not administered due to reported low blood pressure. However, the surveyors found that for 45 out of 91 opportunities, there was no recorded blood pressure or pulse prior to administration of the medication. CMS Ex. 2, at 87.

Regarding x-rays and shielding, the surveyors allege that Petitioner's policy required shielding, but interviews with the Radiology Manager and Medical Director revealed that shielding was no longer standard of practice and that the policy had not been followed for about three years. The alleged violation was failure to follow the policy to shield. CMS Ex. 2, at 91-92. The surveyors also alleged that Petitioner's radiology staff failed to hang their radiation monitoring badge on the badge storage board as required by Petitioner's policy. CMS Ex. 2, at 92-93.

Each set of facts reflect a failure of Petitioner's staff to follow a policy of Petitioner, a failure to document, or a failure by Petitioner to update its policies related to its radiology staff. None allege actual or potential harm to patients or staff. Staff and management were already working to correct late discharge summaries and the other alleged deficiencies are readily correctable. CMS has not alleged that these deficiencies "are of such character as to substantially limit [Petitioner's] capacity to furnish adequate care or . . . adversely affect the health and safety of patients." 42 C.F.R. § 488.24(a). I conclude that these alleged standard-level deficiencies do not provide a basis for termination of Petitioner's provider agreement.

III. Conclusion

For the foregoing reasons, I conclude that CMS did not have a basis to terminate Petitioner's provider agreement and its participation in Medicare on August 25, 2007. Petitioner established by a preponderance of the evidence that it was in compliance with all applicable conditions of participation based on surveys of Petitioner's facility completed on August 2, 2007 and August 25, 2007.

/s/
Keith W. Sickendick
Administrative Law Judge