STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	330140	A. BUILDING _____ B. WING _____	C 08/19/2010

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ST JOSEPH'S HOSPITAL HEALTH CENTER	301 PROSPECT AVENUE SYRACUSE, NY 13203

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A 000	INITIAL COMMENTS CCN #330140 NOTE: THE FEDERAL DEFICIENCIES BELOW ARE CITED AS A RESULT OF A MEDICARE ALLEGATION SURVEY PERFORMED IN CONNECTION WITH AN ARTICLE 28 INVESTIGATION OF COMPLAINT #NY00090118. THE PLAN OF CORRECTION, HOWEVER, MUST RELATE TO THE CARE OF ALL PATIENTS AND PREVENT SUCH OCCURRENCES IN THE FUTURE. INTENDED COMPLETION DATES AND THE MECHANISM(S) ESTABLISHED TO ASSURE ONGOING COMPLIANCE MUST BE INCLUDED.	A 000		
A 267	482.21(a)(2) QAPI QUALITY INDICATORS The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital services and operations. This STANDARD is not met as evidenced by: Based on findings from document review and interviews, the hospital's Quality Assurance Performance Improvement (QAPI) program did not conduct thorough reviews of an adverse occurrence involving a patient (Patient A) who was being considered for withdrawal of life-sustaining treatment when she regained consciousness. Significant lapses in the medical care and evaluations of Patient A (described in Tag A347) resulted in consideration of withdrawing life sustaining treatment and taking the patient to the Operating Room (OR) for donation after cardiac death (DCD). In a	A 267		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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A 267	Continued From page 1	A 267		

preparation room in the OR, the patient began to exhibit signs of neurological improvement and so the DCD was not further pursued. Despite this sequence of events, intensive objective peer review and root cause analysis of the case was not done by the hospital's quality assurance program until prompted by the Department of Health (DOH). Even then, the hospital review was cursory, only describing the chronology of events and still concluding that appropriate brain and cardiac death protocols were followed. The root causes of the inappropriate considerations of the patient for withdrawal of care and organ donation were not analyzed and identified.

Findings include:

-- Per review of Patient A's MR, the medical care provided in this case did not meet generally accepted standards. See findings in Tag A 347.

On 10/18 and 10/19/09, as a result of the incomplete neurological evaluation of the patient and inaccurate diagnosis of anoxic (irreversible) brain damage, physician documentation in the MR reveals Patient A was evaluated for brain death. When she did not meet the apnea criterion in the brain death determination process, on 10/19/09, with the family requesting organ donation, plans were made to pursue DCD. (Again, this was the direct result of the inaccurate diagnosis of anoxic/irreversible brain damage.)

Also, per nursing and physician documentation in the MR, at 6 p.m. on 10/19/09, Nurse #1 documented "toes curled when foot stimulated, tachycardic, hypertensive, flaring nostrils, mouthing with lips and moving tongue, breathing

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A 267	Continued From page 2 above the ventilator" and that he/she notified Resident #2 and Neurologist #2 at 6:15 p.m. In the meantime, Nurse #1 also medicated Patient A with intravenous Ativan 2 mg at 6:21 p.m. By 8 p.m. Resident #2 and Neurologist #2 evaluated the patient in response to the nurse's observations. In the notes subsequently documented, they did not address the medication the patient had received and did not indicate appreciation that the neurological condition was improving. At 12:00 a.m. on 10/20/10, Patient A was moved to the OR suite for pursuit of DCD. However, in the OR suite Patient A opened her eyes and looked at the lights; pursuit of DCD was subsequently halted. -- On 3/02/10, in response to a media inquiry about Patient A's hospitalization, DOH staff conducted an unannounced onsite visit at the hospital. The medical record was reviewed and copied, the hospital administrative staff were interviewed, and the hospital's quality assurance reviews in this case were requested. -- Per interview of the Chief Nursing Officer at 4 p.m. on 3/02/10, the hospital had several case reviews and debriefings and determined that they upheld the national guidelines and their own policies and procedures regarding DCD. -- Per interview of the Vice President for Medical Affairs at 3:15 p.m. on 3/04/10, several meetings were held with the MICU staff after this event and the determination was made that the policies and procedures were followed and that the process worked. No formal reviews needed to be done in this case.	A 267		

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A 267	Continued From page 3 -- On 3/03/10, the requested hospital review of this case was delivered to the DOH office. It consisted of a one page document that was labeled "File Notes: ... (Patient A)." The "review" indicated that debriefing/support sessions were held with the OR staff, MICU nurses and physicians (1 session), and between the MICU staff and the Organ Procurement Organization staff (2 sessions). The document contained a reference to "perception differences" but lacked any analysis or resolution of this issue; it concluded that the correct process and P&Ps had been followed in the management and care of the patient. The document lacked indication of who had authored it and when. In response to further questioning and prompting from the DOH: On 4/01/10 the hospital facsimilied another review document. It indicated a review had been conducted by the Medical Director of Critical Care and the Clinical Pharmacy Practice Manager. The document described Patient A's hospital course and contained an analysis of the medications Patient A may have ingested in her prehospital overdose and the medications administered during the hospitalization. The pharmacist reviewer found it probable that the overdose medications described would have been metabolized and excreted by the 3rd day of the patient's admission but also noted that, "without knowing the actual medications and quantities ingested," it was difficult to be entirely certain. He/she also noted "Many of the meds she allegedly may have taken could have caused her unresponsive state/hypoxia." Regardless of these findings, the review did not address the	A 267		

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A 267	Continued From page 4 lack of additional toxicologies and the inadequacy of the neurological evaluations performed in this case. Again, the review also lacked an indication of the date it was performed. -- During additional onsite activites on 8/18 and 8/19/10, interviews of the Vice President for Medical Affairs / Chief Medical Officer and the Chief Quality Officer at 12:15 p.m.(on 8/18/10), revealed the hospital had not performed any further reviews of this case. Findings from the interviews and document reviews described above reveal the hospital did not undertake an intensive and critical review of the near catastrophic event in this case, did not identify the significant lapses in medical care that resulted in inappropriate pursuits of brain and cardiac death determinations, and did not identify the inadequate physician evaluations of Patient A that occurred when nursing staff questioned possible signs of improving neurological function.	A 267		
A 347	482.22(b) MEDICAL STAFF ACCOUNTABILITY The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients. (1) The medical staff must be organized in a manner approved by the governing body. (2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy. (3) The responsibility for organization and conduct of the medical staff must be assigned	A 347		

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A 347	Continued From page 5 only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine. This STANDARD is not met as evidenced by: Based on findings from from document review and interviews, in 1 out of 11 medical records reviewed involving withdrawal of life-sustaining treatment for patients with neurological insults, the care provided to the patient (Patient A) did not meet generally accepted standards of professional practice. Specifically, the medical care provided to Patient A did not include all interventions necessary in a case of possible drug overdose, and lacked a comprehensive diagnostic evaluation of all causes of unresponsiveness which followed the apparent overdose. Findings include: -- Per review of Patient A's medical record (MR), on 10/16/09 the patient was found unresponsive at home with empty bottles of Nabumetone (non-steroid anti-inflammatory), Xanax (antianxiety), Benadryl (antihistamine) and Baclofen (muscle relaxant). Enroute to the emergency department (ED) Emergency Medical Services (EMS) intubated Patient A who was hypothermic (temperature 94.1), had a weak pulse (68) and shallow respirations of 2-3/minute. The patient arrived in the ED at 3:10 p.m. Routine drug toxicology screens done in the ED were positive for acetaminophen, salicylates, ethanol; the urine toxicology was positive for benzodiazepines and opiates.(There were no other toxicology studies or repeat studies in this	A 347		

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A 347	Continued From page 6 MR; this was confirmed through interviews.) Poison Control recommended activated charcoal for this possible multidrug overdose. At 4:00 p.m. Patient A was admitted to the MICU for supportive ventilation, warming, IV fluids, and further evaluation and treatment. Evaluation of the patient's unresponsiveness by the Attending Physician (Physician #1) identified fixed, dilated and non-reactive pupils with no corneal reflexes. Multiple attempts to place a nasogastric (NG) or oral-gastric (OG) tube, including use of a laryngoscope by anesthesiology, were unsuccessful. The order for activated charcoal was discontinued at 9:30 p.m. as the NG/OG tube could not be inserted. (A later note by Resident #1 indicated consideration of a gastroenterology consult to remove the overdose medications endoscopically, but there is no further mention of this in the MR). On 10/17/09 Patient A developed seizure activity; the neurology service (Neurologist #1) consulted and recommended anticonvulsant medications. Subsequent evaluation by Neurologist #1 later in the day identified that the patient's history and examination were consistent with severe encephalopathy, probably toxic from drug overdose; an EEG (electroencephalogram) was ordered. Head CT scans on 10/17 and 10/18/09 were normal except for some subcutaneous air which was likely due to a scalp laceration requiring stitches the week prior. On 10/18/09 at 8:30 a.m., Physician #1's progress note described plans to check EEG	A 347		

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A 347	Continued From page 7 results, monitor the patient for 72 hours to see if any improvement, and ask IR (interventional radiology) to insert an OG tube (there is no documentation indicating this was completed). At 10:30 that morning Neurologist #1 documented "EEG -burst suppression pattern polyspike & sharp wave in bursts superimposed on a flat background. This EEG usually indicative of poor prognosis. No apparent clinical seizures on depacon, dilantin, propofol. O/E VSS. deeply comatosed. No response to pain pupils dilated & fixed absent oculocephalics. Flaccid all 4 extremities. Imp. S/P drug overdose, cardiorespiratory arrest, anoxic encephalopathy 'severe,' & seizures. Spoke with family & explained above in detail." On 10/19/09 (note untimed)) Physician #2 (covering for Physician #1) documented there was a family meeting wherein the family had decided to proceed with withdrawal of life support. However, on 10/19/09, the patient began to gradually exhibit neurological improvement; life support was not withdrawn and neurological improvement continued. -- Per interview with Neurologist #1 on 8/19/10 at 7:15 a.m., the interpretation of the 10/18/09 EEG is usually indicative of poor prognosis but this test needs to be reconciled with the patient's daily clinical presentation. When questioned about the reversibility of Patient A's "severe anoxic encephalopathy," the neurologist noted it was too early to say and the plan was to "wait and see for 7 to 10 days." (The neurologist did not document this plan in the MR.)	A 347		

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A 347	Continued From page 8 -- Reviews of Patient A's MR by a physician board certified in neurology and a physician board certified in critical care medicine / pulmonary disease / internal medicine identified the following lapses in care in this case: * While initial diagnostic testing on presentation to the ED was appropriate, including toxicology studies and head CT, no further levels of drugs or urine toxicology screens were done following admission to see if the patient was free of all drugs. (The medications that were measured, Salicylates, Acetaminophen, Tricyclics, were unlikely to be causing the patient's coma; the medications more likely to be responsible for the coma, Baclofen, and Xanax, were not assessed on admission or later during the course of treatment.) * The patient never received activated charcoal because the NG tube could not be placed, even by anesthesiology with endoscopic guidance. Assistance from gastroenterology / interventional radiology in the placement of the NG tube was not subsequently obtained. Thus, ingested medication may have continued to be absorbed during the hospitalization. Again, no drug levels / toxicology were monitored since the time of admission. * Physician documentation in a progress note, indicating the patient had suffered a cardiopulmonary arrest, was not accurate (the patient had been found by EMS with steady pulse, still breathing, albeit slowly). Instead of prematurely concluding the patient had suffered irreversible anoxic brain damage, the differential diagnosis should have included	A 347		

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A 347	Continued From page 9 toxic/metabolic/sedative-induced coma. The patient's mental status may have been obtunded due to drugs in the system. * A repeat brain image was not ordered even though two previous head CTs had been completely normal. (Severe anoxic brain injury causes CT-visible edema/swelling within a few days of the anoxic injury, even if initial images are normal; a normal head CT would have called the diagnosis of anoxic brain damage into question and halted the consideration of the withdrawal of life sustaining treatment.) In Summary: The patient did not suffer a cardiopulmonary arrest (as documented) and did not have irreversible brain damage; the patient did not meet criteria for withdrawal of care. Insufficient time had elapsed and insufficient testing was done to make sure all drugs were out of the patient's system before withdrawal of life sustaining treatment was discussed.	A 347		