STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 000	INITIAL COMMENTS	A 000		

This report is the result of complaint investigation #WI00031795 conducted on 2/15/2018 through 2/19/2018 at UnityPoint Health Meriter Hospital using Medicare Conditions of Participation 42 CFR 482 for Hospitals.

42 CFR 482.13 Condition of Participation: Patient Rights NOT MET.
42 CFR 482.21 Condition of Participation: Quality Assessment and Performance Improvement Program NOT MET

An Immediate Jeopardy (IJ) was determined on 2/19/18 at 10:35 AM regarding the facility's failure to develop and implement an effective policy to prevent, report,and thoroughly investigate suspected abuse related to injuries of unknown origin of patients in the Newborn Intensive Care Unit (NICU). The IJ began on 4/12/17 when the facility failed to protect and thoroughly investigate the first report of an injury of unknown origin for Patient #4, placing all patients in the NICU at risk for serious harm or injury. The facility's Chief Nursing Officer C and Director of Performance Improvement B were notified of the IJ on 2/19/18 at 2:44 PM. The IJ was not removed at the time of exit. On 2/28/2018 at 8:38 AM the plan of correction to abate the immediacy was approved. The IJ was removed on 3/01/18 at 1 PM at the time of exit on 3/01/18 after an onsite verification visit confirmed that the facility reviewed and revised policies and procedures to thoroughly investigate and immediately report suspected abuse related to injuries of unknown origin, educated all direct care staff and providers prior to the start of their next shift, and initiated a safety plan to protect patients in areas where infants

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

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients . (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 000	Continued From page 1 and children are cared for (NICU, Emergency Department and the Obstetric Unit).	A 000		
A 115	PATIENT RIGHTS CFR(s): 482.13 A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on record review and interview the facility failed to develop and implement effective policy and procedures to prevent, screen, identify, train, protect, thoroughly investigate, report,and respond to any allegations of suspected abuse related to injuries of unknown origin in 5 of 6 patients (#4, #3, #6, #1, and #2) in the Newborn Intensive Care Unit when the first case was reported for Patient #4 on 4/12/17. Total sample 20. Findings include: The facility failed to ensure a safe environment to protect vulnerable patients by failing to thoroughly investigate injuries of unknown origin to protect and report 5 of 6 patients (#4, #3, #6, #1, and #2.) in the Newborn Intensive Care Unit (NICU) identified with injuries of unknown origins from when the first case was reported for Patient #4 on 4/12/17 in 6 patients records reviewed . (See Tag A-0144) The facility failed to thoroughly investigate and protect 5 of 6 patients (#4, #3, #6, #1, and #2) in the Newborn Intensive Care Unit when the first case was reported for Patient #4 on 4/12/17. (See Tag A 0145)	A 115		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 115	Continued From page 2 The cumulative effects of these deficiencies resulted in an Immediate Jeopardy potentially affecting all patients in the Newborn Intensive Care Unit during this survey (patient census 2/15/18 was 16, 2/16/18 was 17 and 2/19/18 was 18).	A 115		
A 144	PATIENT RIGHTS: CARE IN SAFE SETTING CFR(s): 482.13(c)(2) The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on record review and interview the facility failed to protect vulnerable patients and report to authorities for a thorough investigation of injuries of unknown origin for 5 of 6 patients (#4, #3, #1, #2, and #6) in the Newborn Intensive Care Unit (NICU) identified with injuries of unknown origins from when the first case was reported for Patient #4 on 4/12/17. A total sample of 20 patient records reviewed. Findings Include: Review of Policy titled "Code of Conduct" dated 02/2015 revealed 11. Responsibilities of Leaders, 11.2 Standards for Patient care revealed "Leaders are called upon to create a culture with the organization to establish a working environment in which all Covered Persons are encouraged to raise concerns... to achieve the organization's goals in a safe...environment." Review of policy titled "Child at Risk Abuse and Neglect" Policy #57 dated January 2010 Policy Statement revealed "Meriter Hospital will take actions to protect the "abused... child from the	A 144		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 144	Continued From page 3 possibility of further abuse and neglect to the extent mandated by law." Review of Bylaws and Rules and Regulation of the Medical Staff dated January 2017, approved by the Medical Executive Committee on November 15, 2016, approved by the Medical Staff at the annual meeting on January 17, 2017 and approved by the UnityPoint Health-Meriter Health Services Board on and effective January 25, 2017 under Membership and Privileges Section 1 Qualifications C. revealed "Members of the Medical Staff shall ...comply with the safety policies and guidelines put in place by the hospital and/or Medical Staff". Review of policy titled Caregiver Misconduct (Reporting and Investigating)" Policy # HR-48 dated 8/05/16 revealed under Policy Statement "Employees are responsible for immediately reporting concerns regarding... injuries of unknown source of its patients... Page 4 I. Wisconsin Department of Health Services (DHS) - Caregiver Misconduct (DHS-13) 4.0 "Injury of unknown source" is an injury where both of the following conditions are met: The source of the injury was not observed by any person or the source of the injury cannot be explained by the patient; and, The injury is suspicious because of the extent of the injury or the location of the injury... or the number of injuries observed at one particular point in time or the incidence of injuries over time... 2.0 Incident Investigation UnityPoint - Meriter will investigate all claims or concerns... in a timely manner." Review of policy titled "Child at Risk Abuse and Neglect" Policy #57 dated January 2010 Policy Statement revealed "Meriter Hospital will take	A 144		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 144	Continued From page 4	A 144		

actions to protect the "abused ...from the possibility of further abuse... 9. All hospital staff shall formally write up their observations immediately... All hospital staff involved are responsible for filling out appropriate documentation in a timely manner."

Patient #4
Patient #4's medical record was reviewed and revealed Patient #4 was born (b)(6), (b)(7)c at 12 AM weighing 3# 6 ounces and transferred from another hospital on 3/19/17 at 3:14 to the NICU with an admitting diagnosis of Prematurity, respiratory distress requiring mechanical ventilation (breathing) and a sepsis (infection) evaluation.

Review of incident report for Patient #4 "Skin Tissue Event #115245" dated 4/12/17 at 9 AM by Registered Nurse (RN) W, revealed "Severity Level " " Intervention Needed". Follow-up Actions:" "Not Specified". "Resolutions and Outcomes:" "Intervention Needed." Final Severity Level revealed "Harm - Temporary, Intervention Needed." No interventions were documented to protect or report the injuries of unknown origin on Patient #4.

During interview with (b)(6), (b)(7)c Y on 2/16/18 at 1:25 PM, Y confirmed there was no further follow-up on Event #115245 on patient #4.

Patient #3
Patient #3's medical record was reviewed and revealed Patient #3 was delivered on (b)(6), (b)(7)c at 3:31 AM by normal vaginal delivery weighing 4# 12.2 ounces, 43 centimeters long admitted to NICU for prematurity and discharged 10/13/17.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 144	Continued From page 5	A 144		

Review of plan of care by RN OO 9/21/17 at 5:36 AM revealed "scattered newborn rash noted. Bruising on left foot and scalp as well." Review of Neonatology Addendum to Physician Resident AA's progress note by Physician O on 9/22/17 at 7:16 AM revealed "I agree with resident note, bruise-like macules noted on palms bilaterally."

During interview on 2/15/18 at 9:16 AM, Chief Nursing Executive C (CNE C) confirmed, Physician V recalled that there was a patient [#3] with unexplained bruising documented in the medical record, as a part of the hospital investigation, the hospital consulted Child Abuse Expert N on 02/12/18 who viewed photographs obtained from Patient #3's parent PP. Child Abuse Expert N reported this case to Madison Police Department on 2/12/18 (144 days after nursing documentation of injury of unknown origin in patient #3's medical record) as the bruising was consistent with child abuse, confirmed in an interview with NICU Nurse Manager D on 2/16/2018 at 4:30 PM.

On 2/16/18 at 1:55 PM during an interview (b)(6), (b)(7)c (b)(6), (b)(7)c Y confirmed there was no incident report or follow up for the injuries of unknown origin on patient #3 documented on 9/21/17 at 5:36 AM and that the incident was not reported to Wisconsin Department of Health Services.

Patient #6

Closed medical review of the "Birth Record" for Patient #6 revealed Patient #6 was born C-Section on (b)(6), (b)(7)c at 22:44 (10:44 PM) weighing 1.61 Kg (3 pounds 6 ounces) and was 39.4 cm (15.5 inches).

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 144	Continued From page 6	A 144		

An interview was conducted 2/15/18 at 9:16 AM, Chief Nursing Officer C (CNO C) confirmed, as a part of the Hospital's investigation, since Patient #6 was in NICU (Newborn Intensive Care Unit) from 1/19/18 to 1/26/18, and medical record identified Patient #6 had scattered bruising on lower extremities the hospital contacted Patient #6's Parents EE and notified them of their safety plan.

Review of the investigation revealed the (EE) of Patient #6 informed hospital staff they were uncomfortable with caregiver RN H, who was the primary caregiver on the night shift for Patient #6 on January 23-24, 2018 (confirmed with staff schedules). The hospital decided, due to these concerns, Physician Z consulted Child Abuse Expert N on 02/12/18 who recommended skeletal survey and a CT (computerized tomography). The hospital investigation revealed Patient #6 had multiple fractures, including rib and arm fractures, which were confirmed in an interview with NICU Nurse Manager D on 2/16/2018 at 4:30 PM.

On 2/16/18 at 1:40 PM during an interview (b)(6), (b)(7)c (b)(6), (b)(7)c Y confirmed there was no incident report in for injuries of unknown origin found on Patient #6 while in the NICU (Newborn Intensive Care Unit) from 1/19/18 to 1/26/18 and no other documentation of intervention to protect Patient #6 during this hospital stay. The facility failed to report event to Wisconsin Department of Health Services.

Patient #1
Review of Patient #1's medical record revealed that Patient #1 was admitted on (b)(6), (b)(7)c and was born at 14:55 (2:55 PM) weighting 3 pounds 6.5 ounces and was 15.75 inches and induced

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 144	Continued From page 7	A 144		

vaginal delivery . Patient #1 was admitted to the NICU at 2:55 PM after birth for prematurity, RDS (respiratory distress syndrome) and sepsis evaluation. On 1/7/18 at 9:45 PM had a hypoxic event, was intubated and diagnosed with PDA (patent ductus arteriosus) a heart defect. Patient #1 also had retinopathy (disease of the retina that results in impairment or loss of vision r/t to the premature birth).

Review of Patient #1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" "Outcome" revealed on 01/14/2018 at 5:04 PM "Abrasions noted on bottom of L foot unchanged. Bruising noted to R hand and bottom of L foot."

Review of incident report Skin/Tissue Event #169891 titled "Current Summary" for patient #1 was not entered until "02-08-2018" (6 days after staff identified injuries of unknown origin) by RN HH. Date of occurrence "02-02-2018" estimated time 9 AM, listed the "Severity Level" "Temporary, Intervention Needed" "Follow-Up Actions:" "Not Specified" Resolutions and Outcomes of the Event" "Harm - Temporary, Intervention Needed." There was no additional documentation of further investigation of the injuries or intervention to protect Patient #1.

On 2/16/18 at 1:40 PM during an interview (b)(6), (b)(7)c (b)(6), (b)(7)c Y, Y confirmed incident eve #169891 on Patient #1 occurred on 2/02/18 and was entered on 2/08/18 (6 days after staff identified the injuries).

Patient #2
Review of Patient #2's medical record revealed that Patient was born via C-section (caesarean

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 144	Continued From page 8 section) [the delivery of a baby through a surgical incision in the mother's abdomen and uterus] on (b)(6), (b)(7)c at 11:39 AM, weighing 1 pound and 8.3 ounces. Review of the incident report #170100 titled "Current Summary" revealed on Saturday 02/03/18 at 8:00 AM, Patient #2's parent (DD) noticed "abrasions/scratching on left wrist" and notified RN P. RN P completed an assessment and identified "right palm /heal of hand with reddened intact areas", "scattered purple/red bruising on the opposite side of right hand and a few scattered areas of bruising up the right forearm and inner wrist", purple red bruising on left palm extending from area between thumb and first finger", small red bruises on second and third distal fingers, mostly located ulnar side of left wrist", "scattered linear abrasion", scattered purple/red bruising extending up left forearm". Further review of the same incident report revealed Patient #2's parent (CC) told RN P that s/he had "done skin care the previous day and felt very confident all these markings were new this morning". RN P documented taking photos of the injuries 2/3/18. The 2/3/18 incident was not recorded into their incident reporting system until 02/09/18 (6 days after the injuries were reported to hospital staff). Further review of the incident report #170100 revealed additional injuries "right subconjunctival hemorrhage" (per review of patient #2's medical record facial/head injuries were not discovered until on 02/04/2018) however the incident report does not include clarification that these were two separate incidents/injuries as no date or time included in this notation.	A 144		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 144	Continued From page 9	A 144		

Review of the incident report for Patient #2 (#170100) "revealed under "Resolution and Outcome", final severity level as "D. No Harm-Reached Patient Monitoring Required" and under the "Follow-Up Actions:" "Not Specified" There was no additional documentation of further investigation of the injuries or intervention to protect Patient #2. There is no separate incident report on this event.

Review of Patient #2's NICU "Nursing Notes" revealed on 2/04/18 RN U had documented that Patient #2 had additional injuries documented as bruising on face, periorbital edema.

Review of the incident report log revealed the staff did not document on an incident report for Patient #2 the injuries of unknown origin identified by hospital staff 02/04/2018.

Review of Patient #2s "Attending Neonatologist (L) Addendum" in the "Physicians Progress Note" dated 02/08/18 at 7:06 AM revealed scalp swelling noted last evening unknown etiology.

On 2/16/2018 at 4:30 PM during an interview Nurse Manager NICU D confirmed on Thursday 2/08/18 (6 days after the first injury was reported and 4 days after the second injury was identified) Physician L consulted Child Abuse Expert N regarding unexplained injuries of Patient #2 and N recommended additional tests including a skeletal survey and head computed tomography (CT) which revealed recent skull fractures and arm fractures.

Review of Patient #2's "Consult-Encounter Note" dated 2/9/2018 at 12:22 PM by Neurosurgery Physician AA revealed, "suspected nondisplaced

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 144	Continued From page 10	A 144		

fracture of the right parietal skull", "Fluid collection overlying the parieto-occipital skull...this collection to the suspected fracture suggests a traumatic scalp hematoma".

On 2/16/18 at 1:40 PM during an interview (b)(6), (b)(7)c (b)(6), (b)(7)c confirmed incident event #170100 on Patient #2 was not entered until 6 days after the injury of unknown origin was identified by nursing staff. Y confirmed there was no incident report documented on the injury of unknown origin that occurred 2/07/18.

An interview was conducted with Registered Nurse P on 2/16/18 at 1:26 PM., P stated in the past s/he had been a forensic nurse, trained as a Sexual Assault Nurse Examiner (SANE) and worked in the Emergency Room for 2 years. RN P stated s/he reported incident of scratching and bruising on the wrists of Patient #2 to APNP R on 2/03/18 when s/he first identified it on assessment at 8 AM. RN P stated Physician O was aware of the bruising of Patient #1 and Patient #2 during rounds on 2/03/18. RN P took pictures of Patient #2 and stated s/he encouraged the nurse of Patient #1 to also take pictures of Patient #1. RN P stated s/he was so concerned RN P sent an e-mail to Nurse Manager D and Assistant Nurse Manager TT on the evening of Friday 2/03/18 to notify them of her/his concerns hoping they would be addressed first thing Monday morning. On Monday 2/05/18 s/he "made sure" Assistant Nurse Manager TT had the pictures and voiced her/his concerns. RN P stated physicians "took a wait and watch position."

On 2/16/18 at 4:25 PM during an interview Nurse Manager D, confirmed that s/he was called by

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 144	Continued From page 11 Assistant Nurse Manger T on Monday, 2/05/18 and questioned what s/he should do about the bruising found on Patient #1 and #2. Nurse Manger D confirmed "I told [T] to ask the staff." During interview with Medical Director of NICU K on 2/16/18 at 11:05 AM, K stated it was not his/her responsibility to complete an event report, "that would be the nurse's job." During interview with APNP R on 2/16/18 at 1:40 PM R when asked if R had submitted an incident report, R stated it was "out of [his/her] realm" to complete an event report, "it is the nurses job". On 2/15/18 at 9:16 AM during an interview CNE C confirmed the hospital was aware of the Wisconsin Statues 48.981 (2) and that they were mandated reporters and had not reported prior to this interview. C confirmed they had not completed form F-62447 caregiver misconduct Incident Report to report to the Wisconsin Department of Health Services.	A 144		
A 145	PATIENT RIGHTS: FREE FROM ABUSE/HARASSMENT CFR(s): 482.13(c)(3) The patient has the right to be free from all forms of abuse or harassment. This STANDARD is not met as evidenced by: Based on record review and interview the facility failed to develop and implement an effective policy to prevent, screen, identify, train, protect, thoroughly investigate, report,and respond to any allegations of suspected abuse related to injuries of unknown origin and failed to thoroughly investigate injuries of unknown origin and protect	A 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 145	Continued From page 12 5 of 6 patients (#1, #2, #3 #4 and #6) in the Newborn Intensive Care Unit (NICU) identified with injuries of unknown origins when the first case was reported for Patient #4 on 4/12/17. Findings include: Review of Bylaws and Rules and Regulation of the Medical Staff dated January 2017, approved by the Medical Executive Committee on November 15, 2016, approved by the Medical Staff at the annual meeting on January 17, 2017 and approved by the UnityPoint Health-Merrier Health Services Board on and effective January 25, 2017 under Membership and Privileges Section 1 Qualifications C. revealed "Members of the Medical Staff shall ...comply with the safety policies and guidelines put in place by the hospital and/or Medical Staff". Review of policy titled "Child at Risk Abuse and Neglect" dated March 2001 revised 8/2016 under II. C. Statutory requirements for reporting child abuse under Wisconsin Statute 48.981 3. revealed "Each person who has a concern about suspected child abuse or neglect is responsible for either making a report directly or for verifying that the report was actually made to County Human Services or law enforcement". Under D. Investigation and documentation 1. revealed "when a concern about abuse or neglect is identified by a person required to report...that person immediately consults with, by telephone or personally... determined by the primary clinical area the child is receiving care through." Patient #2 Review of Patient #2's medical record revealed that Patient was born via C-section (caesarean	A 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 145	Continued From page 13	A 145		

section) [the delivery of a baby through a surgical incision in the mother's abdomen and uterus] on (b)(6), (b)(7)c at 11:39 AM, weighing 1 pound and 8.3 ounces.

Review of Patient #2's NICU "Nursing Notes" revealed on 2/04/18 RN U had documented that Patient #2 had additional injuries documented as bruising on face, periorbital edema.

Review of the incident report log revealed no incident report was completed for the new injuries of unknown origin found on 02/04/2018 for Patient #2.

Review of Patient #2s "Attending Neonatologist (L) Addendum" in the "Physicians Progress Note" dated 02/08/18 at 7:06 AM revealed scalp swelling noted last evening unknown etiology. Review of Patient #2's Attending Neonatologist (L) summary of the ultrasound dated 02/08/18 revealed "normal intercranial ultrasound".

Review of the incident report #170100 titled "Current Summary" revealed on Saturday 02/03/18 at 8:00 AM, Patient #2s parent (DD) noticed "abrasions/scratching on left wrist" and notified RN P. RN P completed an assessment and identified "right palm /heal of hand with reddened intact areas", "scattered purple/red bruising on the opposite side of right hand and a few scattered areas of bruising up the right forearm and inner wrist", purple red bruising on left palm extending from area between thumb and first finger", small red bruises on second and third distal fingers, mostly located ulnar side of left wrist", "scattered linear abrasion", scattered purple/red bruising extending up left forearm". Further review of the same incident report

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 145	Continued From page 14	A 145		

revealed Patient #2s parent (CC) told RN P that s/he had "done skin care the previous day and felt very confident all these markings were new this morning". RN P documented taking photos of the injuries 2/3/18. The 2/3/18 incident was not recorded into their incident reporting system until 02/09/18, 6 days after the event. Included in this incident report were additional injuries "right subconjunctival hemorrhage" (per review of medical record were not discovered until on 02/04/2018) however the incident report does not include clarification that these were two separate incidents/injuries as no date or time included in this notation. No additional incident report was completed for second 02/04/18) injury of unknown origin for Patient #2

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Review of the incident report for Patient #2 (#170100) "revealed under "Resolution and Outcome", final severity level as "D. No Harm-Reached Patient Monitoring Required" and under the "Follow-Up Actions" revealed, "Not Specified"

On 2/16/2018 at 4:30 PM Nurse Manager NICU D confirmed on Thursday 2/08/18 Physician L consulted Child Abuse Expert N regarding unexplained injuries of Patient #2 and N recommended additional tests including a skeletal survey and head computed tomography (CT) which revealed recent skull fractures and arm fractures.

Review of Patient #2's "Consult-Encounter Note" dated 2/9/2018 at 12:22 PM by Neurosurgery Physician AA revealed, "suspected nondisplaced fracture of the right parietal skull", "Fluid collection overlying the parieto-occipital skill...this collection to the suspected fracture suggests a

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 145	Continued From page 15	A 145		

traumatic scalp hematoma".

Patient #4
Review of Patient #4s "Admission Record" revealed that Patient #4 was born on (b)(6), (b)(7)c at another hospital and was transferred to this hospital on 03/19/17 at 3:14 PM with an admitting diagnosis of "Prematurity in Newborn Estimate to be 30+ weeks", respiratory distress that required mechanical ventilation, and sepsis evaluation.

Review of Patient #4's medical record with Patient Safety Officer Y revealed Patient #4 had a two view x-ray completed on 4/12/17 of the tibia, first view "normal", second view "somewhat limited evaluation". Record review confirmed RN H was primary caregiver on night shift April 11-12, 2017. "Physician Notes" from 04/12/17 at 7:29 AM by Physician K, revealed bruising.

Review of Patient #4's incident report for event #115245 titled "Current Summary" dated 4/12/17 and documented by RN W, revealed injuries of unknown origin were identified at 9:00 AM on 4/12/17, as "bilateral bruising on calves, ankles and left foot" (photos were taken and placed in the medical record), and X-rays ordered. Further review of Patient #4s incident report "Resolution and Outcome" for the 04/12/17 event "Severity Level" revealed "E. Harm-temporary, Intervention Needed" and the "Follow-Up Actions" revealed, "Not Specified".

Patient #1
Review of Patient #1's medical record revealed that Patient #1 was admitted on (b)(6), (b)(7)c and was born at 14:55 (2:55 PM) weighting 3 pounds 6.5 ounces and was 15.75 inches and induced

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 145	Continued From page 16	A 145		

vaginal delivery . Patient #1 was admitted to the NICU 14:55 (2:55 PM) after birth for prematurity, RDS (respiratory distress syndrome) and sepsis evaluation and retinopathy (disease of the retina that results in impairment or loss of vision r/t to the premature birth) and diagnosed with PDA (patent ductus arteriosus) a heart defect and on 1/7/18 at 23:45 (9:45 PM) had a hypoxic event and was intubated.

Review of Patient #1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" "Outcome" revealed on 01/14/2018 at 5:04 PM "Abrasions noted on bottom of L foot unchanged. Bruising noted to R hand and bottom of L foot."

Review of Patient #1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" "Outcome" revealed on 1/15/2018 6:46 AM "Continues to be ruddy/jaundice with bruising/abrasion to bottom of left foot. Bruising to right hand noted."

Review of Patient # 1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" revealed on 2/2/2018 9:17 PM "Bruising remains on left arm and hand."

Review of Patient #1's medical record dated Friday 02/02/18 "AM Nursing Progress Notes" by RN P identified "bruising erythema and abrasions of bilateral hands and forearms" of Patient #1, at 8:00 AM cares and notified APNP R and Physician O.

Review of Patient #1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" "Outcome" revealed on 2/4/2018 5:35 AM

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 145	Continued From page 17	A 145		

"Bruising noted on left hand"

Review of Patient #1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" "Outcome" revealed on 2/9/2018 12:33 PM "Back of left hand with resolving bruise noted"

Review of Patient #1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" "Outcome" revealed on 2/10/2018 at 2:58 PM "Bruising to top of L hand noted, primarily extending up from 4th and 5th fingers"

Review of Patient #'s "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" revealed on 2/13/2018 8:24 PM "Continues to have very light bruising to her left arm/hand - almost unable to see today"

Review of incident report titled "Current Summary" dated 02/08/18 for Patient #1 revealed Patient #1 had injury on unknown origin that was identified on 2/2/2018 but was not recorded in their incident reporting system by RN CC (6 days after the event).

Interview with (APNP) R on 2/16/18 at 1:40 PM confirmed R notified Physician O and Physician K on 2/02/18 of injuries on Patient #1.

On 2/16/18 at 11:05 AM during an interview Physician K confirmed Patient #1's injuries on 2/02/18 may have been from patient clutching wires or peripheral intravenous device arm board used for stabilization. Physician K stated S/he was contacted by a RN about the injuries identified on Patient #1 Friday 02/02/18 and assessed Patient #1 and called Physician O to discuss her/his findings.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 145	Continued From page 18	A 145		

Patient #3
Record review of Patient #3's "Birth Record" revealed Patient #3 was born vaginal delivery on (b)(6), (b)(7)c at 3:31 AM weighting 4 pounds 12.2 ounces and was 43 cm (16.9 inches) long Review of the medical record "Birth History" reveal: [Patient #3]"is a (b)(6), (b)(7)c infant born at 34w5d via normal spontaneous vaginal delivery, admitted to NICU for prematurity.

Review for patient #3 revealed in "Physician Progress Notes" dated 9/22/2017 at 7:16 AM "non-blanching linear macules on bilateral palms, no other rashes or lesions." Neonatology Addendum 09/22/17 (not timed) "I examined baby, reviewed data and directed plans on rounds. I agree with resident note, Bruise-like macules noted on palms bilaterally.

Review of nursing documentation for Patient #3 by RN H 9/19/17 through 9/22/17, failed to document bruising or skin assessments.

Review of the Hospital's investigation report dated on 2/09/18 revelaed that Physician V had recalled Patient #3 had unexplained bruising. The Hospital investigation report verified RN H had been a primary caregivers during Patient #3's hospitalization in the NICU 9/17/17 thru 10/13/17. During this hospitalization, Patient #3 had bruising of left foot and scalp bruising. Patient #3's mother had taken pictures of the bruising at that time, which were presented to Child Abuse Specialist N on 2/09/18. On 2/09/18 N reviewed the photographs of Patient #3 from the past hospitalization and determined bruising was consistent with child abuse. RN H was primary caregiver on nights for Patient #3 September

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 145	Continued From page 19	A 145		

21-22, 2017. The medical record review during the hospital investigation for Patient #3 revealed, there were no marks/bruises or injuries documented in medical record prior to 9/21/17. RN H did not note any bruising in any documentation.

No incident report was documented for the 9/22/17 when injury of unknown origin bruising of left foot and scalp bruising of Patient #3.

Patient #6
Closed medical review of the "Birth Record" for Patient #6 revealed Patient #6 was born C-Section o(b)(6), (b)(7)(c) at 20:44 (10:44 PM) weighing 1.61 Kg (3 pounds 6 ounces) and was 39.4 cm (15.5 inches).

During interview on 2/15/18 at 9:16 AM, Chief Nursing Officer C (CNO C) confirmed as a part of the Hospital's investigation that ever since Patient #6 was in the care of RN H, the hospital contacted Patient #6's parents EE and notified them of safety plan because Patient #6 had scattered bruising on lower extremities during the hospital stay on 01/20/18. The investigation revealed the Parents (EE) of Patient #6 informed hospital staff they were uncomfortable with caregiver RN H, who was the primary caregiver on the night shift for Patient #6 on January 23-24, 2018. The hospital decided due to these concerns, Physician Z consulted Child Abuse Expert N on 02/12/18 who recommended skeletal survey and a CT. The hospital investigation revealed Patient #6 had multiple fractures ,including rib and arm fractures which was confirmed in an interview with NICU Nurse Manager D on 2/16/2018 at 4:30 PM.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 145	Continued From page 20	A 145		

No incident report was documented for Patient #6 related to scattered bruising on lower extremities during the hospital stay on 01/20/18.

Interview on 2/15/18 at 9:16 AM with CNO C revealed that they had not reported the suspected abuse immediately because the hospital was working on their investigation and they were collecting the information to report. When asked about reporting suspected abuse CNO C, confirmed S/he understand the need to report abuse or neglect ASAP (as soon as possible).

On 2/16/18 at 11:05 AM during an interview Medical Director of Neonatal Intensive Care Unit K confirmed it was not his/her expectation of the physicians to complete incident reports, "they are "filled out by nurses."

Interview on 2/16/18 at 1:26 PM with Registered Nurse (RN) P confirmed Patient #2 had unexplained bruising similar to Patient #1 and notified attending Physician O on 2/03/18 between 9:30 AM and 11 AM. RN P was concerned and stated on the evening of 2/03/18 RN P sent an E-mail to Nurse Manager D and Assistant Nurse Manager T regarding his/her concerns of unusual markings, and similarity of the bruising on Patient #1 and Patient #2 to make sure this was follow up on, and thought this would be addressed first thing Monday 2/05/18, but it was not.

On 2/16/18 at 1:40 PM during an interview Advanced Practice Nurse Prescribe (APNP) R stated S/he discussed common factors with RN's P & X on Monday 2/05/18, who identified RN H had cared for both Patient #1 and Patient #2.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 145	Continued From page 21 Interview on 2/16/18 at 2:12 PMwith the Director of Performance Improvement B confirmed there was no policy or process that directed staff on their responsibility to prevent, screen, identify, train, protect, thoroughly investigate, report,and respond to any allegations of suspected abuse related to injuries of unknown origin. On 2/16/2018 at 4:25 PM during an interview Nurse Manager NICU D stated based on the current evidence and staffing logs the hospital suspended suspected Caregiver RN H, disabled RN Hs badge access and RN Hs access to the hospital electronic medical record. Manager NICU D confirmed that on Monday 2/05/18 when Assistant Manager T called Manager D asking what to do [staff concerns and injuries on Patient #1 and #2], Nurse Manager D stated S/he told Assistant Manager T "to ask staff".	A 145		
A 263	QAPI CFR(s): 482.21 The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.	A 263		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 263	Continued From page 22 This CONDITION is not met as evidenced by: Based on record review and interview the facility failed to thoroughly investigate, report,and respond to any allegations of suspected abuse related to injuries of unknown origin in 5 of 6 patients (#1, 2, 3, 4 and 6) per policy. In a total sample of 20 records. Findings include: The facilities failed to document, analyze, and track incident reports for patients with injuries of unknown origin to ensure that aspects of staff performance and patient care that would provide relevant data to improve patient safety or that incident reports were thoroughly investigated in 3 of 9 events reviewed for 5 of 20 patients (Patient #4, #3, #6, #1 and # 2). See (A073) The hospital's medical staff and administrative officials failed to take responsibility for the quality of care provided to 5 or 6 patients (Patient #4, #3, #1, #2, and #6) in a total of 20 Newborn Intensive Care Unit records reviewed. (See Tag A-309) The cumulative effect of these deficiencies affected all patients in the Newborn Intensive Care Unit during this survey (patient census 2/15/18 was 16, 2/16/18 was 17 and 2/19/18 was 18) and prevented the hospital from having data-driven quality assessment and performance improvement program. .	A 263		
A 273	DATA COLLECTION & ANALYSIS CFR(s): 482.21(a), (b)(1),(b)(2)(i), (b)(3)	A 273		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 273	Continued From page 23 (a) Program Scope (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes ... (2) The hospital must measure, analyze, and track quality indicators ... and other aspects of performance that assess processes of care, hospital service and operations. (b)Program Data (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization. (2) The hospital must use the data collected to-- (i) Monitor the effectiveness and safety of services and quality of care; and .... (3) The frequency and detail of data collection must be specified by the hospital's governing body. This STANDARD is not met as evidenced by: Based on record review and interview the facility failed to document, analyze, and track incident reports for patients with injuries of unknown origin to ensure that aspects of staff performance and patient care that would provide relevant data to improve patient safety or that incident reports were thoroughly investigated in 3 of 9 events reviewed for 5 of 20 patients (Patient #4, #3, #6, #1 and # 2).	A 273		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 273	Continued From page 24 Findings include: Review of policy titled "Incident or Accident Reporting System" #30 dated 8/31/15 under Policy Statement revealed "The system facilitates risk management interventions and provides an overview of Meriter's exposure pattern as a basis for quality improvement activities to improve patient care and organizational safety... Definition of an Incident:...1. "perceived" injury... D...2. If the incident involves a patient, include an assessment of the patient's condition following the incident and any clinical action taken as a result of the incident... 5...all incidents are required to be entered into the online incident reporting system via MyMeriter as soon as possible. Supervisor review and follow-up is expected within 72 hours of the incident." Patient #4 Review of Patient # 4 medical record revealed, Patient #4 had injuries of unknown origin documented in the nursing notes on 4/12/17 at 9 AM described as bruising, scattered; right leg; left leg bilateral; calf and ankle and documented in physician notes 4/12/17 at 7:19 AM Bruises on lower extremities bilaterally, linear in shape-likely due to cords (from monitor leads) wrapped in swaddle with infant. Record review of the corresponding Incident report written on 4/12/2017 at 9 AM revealed injuries described as bilateral bruising on calves, ankles and left foot, bruises consistent with monitor cord size. "Severity Level" revealed "Temporary Intervention Needed" "Follow-Up Actions" revealed "Not Specified". "Final Severity Level" revealed "Harm - Temporary, Intervention Needed." However, there	A 273		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 273	Continued From page 25 was no documentation of intervention or follow up. Patient #3 Record review Patient #3's medical record revealed, Patient #3 had injuries of unknown origin documented in the nursing notes on 9/21/17 at 5:36 AM described as bruising on left foot and scalp and in physician notes on 9/22/17 at 7:16 AM described as non-blanching linear macules on bilateral palms bilaterally. Review of incident log revealed, the staff did not documentation on an incident report the injuries of unknown origin that were documented in Patient #3's medical record on 9/21/17. Patient #6 Record review Patient #6's medical record revealed, Patient #6 had injuries of unknown origin documented in the nursing notes on 1/20/18 at 11 AM that were described as scattered bruising lower extremities. Review of incident log revealed, the staff did not documentation on an incident report the injuries of unknown origin that were documented in Patient #6's medical record on 1/20/2018. Patient #1 Review of Patient #1's medical record revealed, Patient #1's had injuries of unknown origin documented in the nursing notes on 2/02/18 at 2:08 AM described as bruising of left forehand, wrist and palm and documented in the physician notes on 2/02/18 at 7:55 AM described as hyperpigmentation of left lower forearm and bruising over dorsal left hand and palm.	A 273		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 273	Continued From page 26	A 273		

Record review of the corresponding incident report written on 02/02/18 at 9:00 AM revealed, injuries described in nurses notes on 02/02/18 at 9:30 AM described as bruising left hand, palm, and arm.
"Severity Level" revealed "Intervention Needed."
"Follow-Up Actions" revealed "Not Specified",
"Final Severity Level" revealed "Harm - Temporary, Intervention Needed." However, there was no documentation of intervention or follow up.

Patient #2 (injury #1)
Review of Patient #2's medical record revealed, Patient #2 had injuries of unknown origin documented in the nursing notes on 2/03/18 at 9:00 AM described as bruising, erythema, and abrasions on bilateral hands and forearms and in the physician notes on 02/04/18 at 7:37 AM described as bruising on the right greater than left forearm and left inner wrist that were linear in nature.

Review of the incident log identified a corresponding Incident report written on 02/09/18 (6 days after the injury was documented in #2's medical record) revealed abrasions, scratching on left wrist, bruising right forearm, bruising right and left hands, bruising right wrist, and left forearm.
"Severity Level" revealed, "No Harm-Reached Patient Monitoring Required"
"Follow-Up Actions" revealed, "Not Specified"
"Final Severity Level" revealed, "No Harm - Reached Patient Monitoring Required". However, there was no documentation of intervention or follow up.

Patient #2 (injury #2)

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 273	Continued From page 27 Review of Patient #2's medical record revealed, four days (4 days) after the first documented injury Patient #2 had sustained a second injury of unknown origin documented in the nursing notes on 2/07/18 at 2:00 PM as fluid wave in posterior scalp and in physician notes on 2/08/18 at 7:06 AM fluid wave over the posterior occiput. Review of incident report log confirmed there was no incident report documentation on this event. Interview wit (b)(6), (b)(7)c Y on 2/16/18 at approximately 1:55 PM, Y confirmed there were no incident reports of patient event on Patient #3 or #6, or on the second event on patient #2.	A 273		
A 309	QAPI EXECUTIVE RESPONSIBILITIES CFR(s): 482.21(e)(1), (e)(2), (e)(5) The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: 1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained . (2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated. (5) That the determination of the number of distinct improvement projects is conducted annually.	A 309		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 309	Continued From page 28	A 309		

This STANDARD is not met as evidenced by:
Based on record review and interview, the hospital's medical staff and administrative officials failed to take responsibility for the quality of care provided to 5 of 6 patients (Patient #4, #3, #6, #1, and #2) in 20 Newborn Intensive Care Unit records reviewed.

Findings include:

Review of Policy titled "Code of Conduct" dated 02/2015 revealed "This Code of Conduct has been adopted by" the facilities Board of Directors "to provide standards by which directors, officers, employees, reporting physicians and volunteers will conduct themselves in order to protect and promote organization-wide integrity." Page 8 Quality of Care and Clinical Values "to provide high-quality medical services that are appropriate, safe and in compliance with all applicable laws, regulations and professional standards." Page 9 3.4 Protection from Abuse revealed "Any concerns about potential abuse, neglect or exploitation should be immediately." 11. Responsibilities of Leaders, 11.2 Standards for Patient care revealed "Leaders are called upon to create a culture with the organization of high ethical standards, to respect the importance of compliance with legal requirements and to establish a working environment in which all Covered Persons are encouraged to raise concerns and contribute ideas to achieve the organization's goals in a safe and healthy work environment."

Review of Bylaws and Rules and Regulation of the Medical Staff dated January 2017, approved

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 309	Continued From page 29	A 309		

by the Medical Executive Committee on November 15, 2016, approved by the Medical Staff at the annual meeting on January 17, 2017 and approved by the UnityPoint Health-Meriter Health Services Board on and effective January 25, 2017 under Membership and Privileges Section 1 Qualifications C. revealed "Members of the Medical Staff shall ...comply with the safety policies and guidelines put in place by the hospital and/or Medical Staff".

Review of policy titled "Incident or Accident Reporting System" #30 dated 8/31/15 under Policy Statement revealed "The system facilitates risk management interventions and provides an overview of Meriter's exposure pattern as a basis for quality improvement activities to improve patient care and organizational safety... Definition of an Incident:...1. "perceived" injury... D...2. If the incident involves a patient, include an assessment of the patient's condition following the incident and any clinical action taken as a result of the incident... 5...all incidents are required to be entered into the online incident reporting system via MyMeriter as soon as possible. Supervisor review and follow-up is expected within 72 hours of the incident."

Review of policy titled "Child at Risk Abuse and Neglect" Policy #57 dated January 2010 Policy Statement revealed "Meriter Hospital will take actions to protect the "abused ..." from the possibility of further abuse... 9. All hospital staff shall formally write up their observations immediately... All hospital staff involved are responsible for filling out appropriate documentation in a timely manner."

Patient #4

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 309	Continued From page 30	A 309		

Review of incident report for Patient #4 "Skin Tissue Event #115245" dated 4/12/17 at 9 AM by Registered Nurse (RN) W, revealed "Severity Level " " Intervention Needed". Follow-up Actions:" "Not Specified". "Resolutions and Outcomes:" "Intervention Needed." Final Severity Level revealed "Harm - Temporary, Intervention Needed." No interventions were documented to protect or report the injuries of unknown origin on Patient #4. There was no additional documentation of further investigation of the injuries or intervention to protect Patient #4.

Review of Patient # 4 medical record revealed, Patient #4 had injuries of unknown origin documented in the nursing notes on 4/12/17 at 9 AM described as bruising, scattered; right leg; left leg bilateral; calf and ankle.

Continued Review of Patient # 4 medical record revealed, Patient #4 had injuries of unknown origin documented in the physician notes 4/12/17 at 7:19 AM Bruises on lower extremities bilaterally, linear in shape-likely due to cords (from monitor leads) wrapped in swaddle with infant.

During interview with (b)(6), (b)(7)c Y on 2/16/18 at 1:25 PM, Y confirmed there was no further follow-up on Event #115245 on patient #4.

Patient #3

Patient #3's medical record was reviewed an revealed in the nursing plan of care 9/21/17 at 5:36 AM "Bruising on left foot and scalp" in the physician note on 9/22/17 at 7:16 AM non-blanching linear macules on bilateral palms

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 309	Continued From page 31 and bruise-like macules on palms bilaterally. Interview with (b)(6), (b)(7)c Y on 2/16/18 at approximately 1:55 PM, Y confirmed there was no event report for patient #3. Patient #6 Record review Patient #6's medical record revealed, Patient #6 had injuries of unknown origin documented in the nursing notes on 1/20/18 11 AM described as scattered bruising lower extremities. Interview wit (b)(6), (b)(7)c Y on 2/16/18 at approximately 1:55 PM, Y confirmed there was no event report for patient #6. Patient #1 Review of incident report Skin/Tissue Event #169891 titled "Current Summary" for patient #1 was not entered until "02-08-2018" (6 days after staff identified injuries of unknown origin) by RN HH. Date of occurrence "02-02-2018" estimated time 9 AM, listed the "Severity Level" "Temporary, Intervention Needed" "Follow-Up Actions:" "Not Specified" Resolutions and Outcomes of the Event" "Harm - Temporary, Intervention Needed." There was no additional documentation of further investigation of the injuries or intervention to protect Patient #1. Review of Patient #1's medical record revealed, Patient #1's had injuries of unknown origin documented in the nursing notes on 2/02/18 at 2:08 AM described as bruising of left forehand, wrist and palm and documented in the physician notes on 2/02/18 at 7:55 AM described as	A 309		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 309	Continued From page 32	A 309		

hyperpigmentation of left lower forearm and bruising over dorsal left hand and palm and on 02/03/18 at 8:52 AM By Physician O, "mild bruising noted on left hand and forearm ... Left forearm has a linear bruise about 1 cm long consistent with possible pushing against a lead. [Patient #1] also has a 3 X 2 mm bruise on the inside of the right wrist and a linear bruise on her palm ...We will check growth curves in the a.m. Linear erythema/bruise on left arm is most consistent with a mechanical injury, possibly entanglement in a lead.".

During Interview wit (b)(6), (b)(7)c on 2/16/18 at 1:55 PM, Y confirmed Event #169891 on Patient #1, which took place on 2/02/18, was entered on 2/08/18.

Patient #2

Incident report revealed "Severity Level" as "No Harm-Reached Patient Monitoring Required" Follow-Up Actions revealed "Not Specified", Final Severity Level revealed "No Harm - Reached Patient Monitoring Required" APNP R, Neonatologist O, Nurse Manager D, Assistant Nurse Manager T were notified of the incident report events. However, there was no documentation of intervention or follow up. There was no additional documentation of further investigation of the injuries or intervention to protect Patient #2.

Review of Patient #2's medical record revealed, Patient #2 had injuries of unknown origin documented in the in the physician notes 02/04/18 at 7:37 AM described as bruising on the right greater than left forearm and left inner wrist that were linear in nature and physician notes on

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 309	Continued From page 33 2/08/18 at 7:06 AM fluid wave over the posterior occiput (back of the head). During interview with (b)(6), (b)(7)c Y on 2/16/18 at 1:40 PM, Y confirmed incident event #170100 on Patient #2 occurred on 2/03/18 at approximately 9 AM and was entered on 2/09/18 stating "the investigation is ongoing." During interview with Medical Director of NICU K on 2/16/18 at 11:05 AM, K when asked about the reporting of these incidents, K stated it was not his/her responsibility to complete an event report, "that would be the nurse's job." During interview with APNP R on 2/16/18 at 1:40 PM R when asked if R had submitted an incident report, R stated it was "out of [his/her] realm" to complete an event report, "it is the nurses job". During interview with the Chief Nursing Executive (CNE) C on 2/15/18 at 9:16 AM, when C was asked if the facility had reported the incidents, C confirmed they had not completed form F-62447 Misconduct Incident Report to report to the Wisconsin Department of Health Services. During interview with Chief Medical Officer A on 2/15/18 at 1:15 PM, when A was asked if the facility had reported the incidents, A stated no.	A 309		
A 386	ORGANIZATION OF NURSING SERVICES CFR(s): 482.23(a) The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is	A 386		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 386	Continued From page 34	A 386		

responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

This STANDARD is not met as evidenced by:
Based on record review and interview, the facility failed to immediately immediately adhere to their policies and procedures to delineate their administrative responsibilities for patient care in 5 of 6 patients (#4, #3, #6, #1 and #2). (Patient census 2/15/18 was 16, 2/16/18 was 17 and 2/17/18 was 18).

Findings include:

Review of policy titled Caregiver Misconduct (Reporting and Investigating)" Policy # HR-48 dated 8/05/16 revealed Policy Statement Meriter will comply with all investigation and reporting requirements of ... injuries of unknown source of its patients... 4.0 "Injury of unknown source" is an injury where both of the following conditions are met: The source of the injury was not observed by any person or the source of the injury cannot be explained by the patient; and, The injury is suspicious because of the extent of the injury or the location of the injury... or the number of injuries observed at one particular point in time or the incidence of injuries over time... 2.0 Incident Investigation "will investigate all claims or concerns... in a timely manner."

Review of policy titled "Child at Risk Abuse and Neglect" Policy #57 dated January 2010 Policy Statement revealed "Meriter Hospital will take actions to protect the "abused ..." from the possibility of further abuse... 9. All hospital staff shall formally write up their observations

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 386	Continued From page 35	A 386		

immediately... All hospital staff involved are responsible for filling out appropriate documentation in a timely manner."

Review of Policy titled "Code of Conduct" dated 02/2015 revealed 11. Responsibilities of Leaders, 11.2 Standards for Patient care revealed "Leaders are called upon to create a culture with the organization to establish a working environment in which all Covered Persons are encouraged to raise concerns... to achieve the organization's goals in a safe...environment."

Record review of Skin Tissue Event #115245 on Patient # 4 event date 4/12/17, entered 4/12/17 at 9 AM by Registered Nurse (RN) W, Severity Level " Intervention Needed". Follow-up Actions "Not Specified", Resolutions and Outcomes "Intervention Needed." No further intervention was documented.

Record review of Skin Tissue Event #169891 on Patient #1 event date 02/02/18, entered 02/08/18 at 9 AM (6 days after event occurred) by RN HH, Severity Level "Intervention Needed". Resolutions and Outcomes "Intervention Needed." However, no additional documentation was found to investigate the injuries or the immediate intervention taken to protect patient #1 or report to authorities

Record review of Safety Security Event #170100 on Patient #2 event date 2/03/18, entered 02/09/18 at 8 AM (6 days after event occurred) by RN P. No additional documentation was found to investigate the injuries or the immediate action taken to protect patient #2.

Patient Safety Officer Y on 2/16/18 at 1:55 PM, Y

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 386	Continued From page 36	A 386		

confirmed Event # 115245 on Patient #4 had no other follow-up.

(b)(6), (b)(7)c on 2/16/18 at 1:55 PM, Y confirmed, Event #169891 on Patient #1, event date 2/02/18, was entered 2/08/18, and Event #170100 on Patient #2 Event date was 2/03/18 entered 2/09/18 (6 days later), there was no additional documentation available on these events (#169891 and #170100) (6 days after the injuries were identified).

An interview was conducted with Registered Nurse P on 2/16/18 at 1:26 PM, RN P stated s/he was so concerned about patient #1 and #2 injuries s/he sent an e-mail to Nurse Manager D and Assistant Nurse Manager T on the evening of 2/03/18 to notify them of her/his concerns. On Monday 2/05/18 s/he "made sure" Assistant Nurse Manager T had the pictures and voiced her/his concerns. RN P stated physicians "took a wait and watch position."

Interview on 2/15/18 at 9:16 AM with CNE C, C stated the facility was aware of the Wisconsin Statues 48.981 (2) and that they were mandated reporters.

Interview on 2/16/18 at 2:12 PM with (b)(6), (b)(7)c (b)(6), (b)(7)c B, B confirmed there were no other nursing or physician policies to direct reporting of patient events when patients had injuries of unknown origin.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 000	INITIAL COMMENTS This report is the result of complaint investigation #WI00031795 conducted on 2/15/2018 through 2/19/2018 at UnityPoint Health Meriter Hospital using Medicare Conditions of Participation 42 CFR 482 for Hospitals. 42 CFR 482.13 Condition of Participation: Patient Rights NOT MET. 42 CFR 482.21 Condition of Participation: Quality Assessment and Performance Improvement Program NOT MET An Immediate Jeopardy (IJ) was determined on 2/19/18 at 10:35 AM regarding the facility's failure to develop and implement an effective policy to prevent, report,and thoroughly investigate suspected abuse related to injuries of unknown origin of patients in the Newborn Intensive Care Unit (NICU). The IJ began on 4/12/17 when the facility failed to protect and thoroughly investigate the first report of an injury of unknown origin for Patient #4, placing all patients in the NICU at risk for serious harm or injury. The facility's Chief Nursing Officer C and Director of Performance Improvement B were notified of the IJ on 2/19/18 at 2:44 PM. The IJ was not removed at the time of exit. On 2/28/2018 at 8:38 AM the plan of correction to abate the immediacy was approved. The IJ was removed on 3/01/18 at 1 PM at the time of exit on 3/01/18 after an onsite verification visit confirmed that the facility reviewed and revised policies and procedures to thoroughly investigate and immediately report suspected abuse related to injuries of unknown origin, educated all direct care staff and providers prior to the start of their next shift, and initiated a safety plan to protect patients in areas where infants	A 000	The submission of this Plan of Correction is not an admission of liability by UnityPoint Health-Meriter (Meriter). The submission of this Plan of Correction does not constitute an agreement by Meriter that the surveyor's facts, findings or conclusions are accurate, the findings constitute a deficiency, or that the scope and severity regarding any of the deficiencies are cited correctly. Meriter received an initial statement of deficiencies (SOD) from DQA on behalf of CMS on February 23, 2018. Meriter submitted a Plan of Correction (Plan # 1) in response to the first SOD, which was approved on February 28, 2018. Meriter received a second SOD on March 5, 2015 from DQA. A second Plan of Correction (Plan # 2) was submitted on March 15, 2018. Meriter received a third SOD from CMS on March 7, 2018. This Plan of Correction (Plan # 3) is submitted in response to the third SOD. As detailed in Plan # 1 and Plan # 2 (both summarized below), Meriter has and is committed to further developing mechanisms to promptly identify abuse and follow all legal requirements for investigating and reporting such abuse including protection of patients. In designing and implementing Plan # 3, with regard to injuries of unknown source (as defined by the Wisconsin Caregiver Program Manual), Meriter is implementing a strategy to implement quality assurance/ performance improvement measures, executive responsibility measures (both administration and medical staff) and nursing service organization measures all designed to protect patients, identify abuse and injuries of unknown source, appropriately investigate and report (internally and externally) and track whether the measures/ mechanisms are achieving these objectives. See Attachment 1 for additional comments.	

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

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 000	Continued From page 1 and children are cared for (NICU, Emergency Department and the Obstetric Unit).	A 000		
A 115	PATIENT RIGHTS CFR(s): 482.13 A hospital must protect and promote each patient's rights. This CONDITION is not met as evidenced by: Based on record review and interview the facility failed to develop and implement effective policy and procedures to prevent, screen, identify, train, protect, thoroughly investigate, report,and respond to any allegations of suspected abuse related to injuries of unknown origin in 5 of 6 patients (#4, #3, #6, #1, and #2) in the Newborn Intensive Care Unit when the first case was reported for Patient #4 on 4/12/17. Total sample 20. Findings include: The facility failed to ensure a safe environment to protect vulnerable patients by failing to thoroughly investigate injuries of unknown origin to protect and report 5 of 6 patients (#4, #3, #6, #1, and #2.) in the Newborn Intensive Care Unit (NICU) identified with injuries of unknown origins from when the first case was reported for Patient #4 on 4/12/17 in 6 patients records reviewed . (See Tag A-0144) The facility failed to thoroughly investigate and protect 5 of 6 patients (#4, #3, #6, #1, and #2) in the Newborn Intensive Care Unit when the first case was reported for Patient #4 on 4/12/17. (See Tag A 0145)	A 115	• **Corrective Action Measures:** See responses to A-0144 and A-0145 below. • **How Plan/ Action Will Prevent Recurrence:** See responses to A-0144 and A-0145 below. • **How Compliance Will Be Monitored:** See responses to A-0144 and A-0145 below. • **Task Owners:** See responses to A-0144 and A-0145 below.	**See responses to A-0144 and A-0145 below.**

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A 115	Continued From page 2 The cumulative effects of these deficiencies resulted in an Immediate Jeopardy potentially affecting all patients in the Newborn Intensive Care Unit during this survey (patient census 2/15/18 was 16, 2/16/18 was 17 and 2/19/18 was 18).	A 115		
A 144	PATIENT RIGHTS: CARE IN SAFE SETTING CFR(s): 482.13(c)(2) The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: Based on record review and interview the facility failed to protect vulnerable patients and report to authorities for a thorough investigation of injuries of unknown origin for 5 of 6 patients (#4, #3, #1, #2, and #6) in the Newborn Intensive Care Unit (NICU) identified with injuries of unknown origins from when the first case was reported for Patient #4 on 4/12/17. A total sample of 20 patient records reviewed. Findings Include: Review of Policy titled "Code of Conduct" dated 02/2015 revealed 11. Responsibilities of Leaders, 11.2 Standards for Patient care revealed "Leaders are called upon to create a culture with the organization to establish a working environment in which all Covered Persons are encouraged to raise concerns... to achieve the organization's goals in a safe...environment." Review of policy titled "Child at Risk Abuse and Neglect" Policy #57 dated January 2010 Policy Statement revealed "Meriter Hospital will take actions to protect the "abused... child from the	A 144	• **Corrective Action Measures:** Corrective Action Measures from Plan # 1: **1.** The following corrective action measures from Plan # 1 have been implemented to protect current patients: the suspension of the suspected caregiver and the suspected caregiver's badge and EMR access, distribution of the suspected caregiver's photograph to security officers, placement of a security officer at the NICU entrance, provision of guidance on abuse identification and reporting, implementation of a safety plan for the NICU, a complete environmental risk assessment for the NICU, and initiation of a root cause analysis and related communications with The Joint Commission. **Task Owners:** As identified in Plan # 1 **2.** The following policies have been revised pursuant to Plan # 1: a. Caregiver Misconduct Reporting Policy was revised to expand on the definition of abuse, responsibility for investigating and reporting suspected caregiver misconduct, establishing internal communication protocols to ensure that Meriter leadership is aware and involved, and to add clarity regarding the hospital's internal incident/ accident reporting system. **Task Owner:** Chief Nursing Executive/ Chief Medical Officer	**February 28, 2018** **February 26, 2018**

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A 144	Continued From page 3 possibility of further abuse and neglect to the extent mandated by law." Review of Bylaws and Rules and Regulation of the Medical Staff dated January 2017, approved by the Medical Executive Committee on November 15, 2016, approved by the Medical Staff at the annual meeting on January 17, 2017 and approved by the UnityPoint Health-Meriter Health Services Board on and effective January 25, 2017 under Membership and Privileges Section 1 Qualifications C. revealed "Members of the Medical Staff shall ...comply with the safety policies and guidelines put in place by the hospital and/or Medical Staff". Review of policy titled Caregiver Misconduct (Reporting and Investigating)" Policy # HR-48 dated 8/05/16 revealed under Policy Statement "Employees are responsible for immediately reporting concerns regarding... injuries of unknown source of its patients... Page 4 I. Wisconsin Department of Health Services (DHS) - Caregiver Misconduct (DHS-13) 4.0 "Injury of unknown source" is an injury where both of the following conditions are met: The source of the injury was not observed by any person or the source of the injury cannot be explained by the patient; and, The injury is suspicious because of the extent of the injury or the location of the injury... or the number of injuries observed at one particular point in time or the incidence of injuries over time... 2.0 Incident Investigation UnityPoint - Meriter will investigate all claims or concerns... in a timely manner." Review of policy titled "Child at Risk Abuse and Neglect" Policy #57 dated January 2010 Policy Statement revealed "Meriter Hospital will take	A 144	b. Child-At-Risk Abuse And Neglect Policy was revised to clarify and expand the definition of abuse (including injuries of unknown source), protocols for determining abuse versus accidental injuries, task owners for implementing the policy, consultation of appropriate resources including but not limited to child abuse experts, and internal and external reporting and documentation obligations. The policy was also revised to more clearly reference the incident reporting process, requiring that incident reports are always made when indicated, and that the caregiver noting the incident immediately contacts his or her manager and where appropriate, law enforcement. **Task Owner:** Chief Nursing Executive/ Chief Medical Officer c. The Incident or Accident Reporting System policy was revised to include reporting of suspected or observed abuse or neglect, or injuries of unknown source not present on admission, so that reports can be reviewed and followed-up on as part of hospital's quality improvement process. **Task Owner:** Chief Nursing Executive/ Chief Medical Officer **3.** Meriter required all employed staff with patient contact, volunteers, credentialed providers, fellows and residents who work in areas of the hospital where infants (or babies or children) are primarily treated to attend "phase one" of mandatory education. These areas of the hospital include, without limitation, the ED and NICU, as well as the birth suites/ labor and delivery staff. This education focused on detection of child abuse including but not limited to injuries of unknown source, internal and external mandatory reporting obligations, caregiver misconduct definitions and obligations, and policy content including revised content specified above. **Task Owner:** Chief Nursing Executive/ Chief Medical Officer	**February 26, 2018** **February 26, 2018** **February 28, 2018**

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A 144	Continued From page 4 actions to protect the "abused ...from the possibility of further abuse... 9. All hospital staff shall formally write up their observations immediately... All hospital staff involved are responsible for filling out appropriate documentation in a timely manner." Patient #4 Patient #4's medical record was reviewed and revealed Patient #4 was bor (b)(6), (b)(7)c at 12 AM weighing 3# 6 ounces and transferred from another hospital on 3/19/17 at 3:14 to the NICU with an admitting diagnosis of Prematurity, respiratory distress requiring mechanical ventilation (breathing) and a sepsis (infection) evaluation. Review of incident report for Patient #4 "Skin Tissue Event #115245" dated 4/12/17 at 9 AM by Registered Nurse (RN) W, revealed "Severity Level " " Intervention Needed". Follow-up Actions:" "Not Specified". "Resolutions and Outcomes:" "Intervention Needed." Final Severity Level revealed "Harm - Temporary, Intervention Needed." No interventions were documented to protect or report the injuries of unknown origin on Patient #4. During interview with (b)(6), (b)(7)c Y on 2/16/18 at 1:25 PM, Y confirmed there was no further follow-up on Event #115245 on patient #4. Patient #3 Patient #3's medical record was reviewed and revealed Patient #3 was delivered o (b)(6), (b)(7)c at 3:31 AM by normal vaginal delivery weighing 4# 12.2 ounces, 43 centimeters long admitted to NICU for prematurity and discharged 10/13/17.	A 144	Corrective Action Measures from Plan # 2: **1.** In an effort to ensure that patients are immediately protected once there is reason to suspect abuse, the Caregiver Misconduct Reporting Policy was further revised. The following is an overview of the revisions to the Caregiver Misconduct Policy made pursuant to Plan # 2: a. More clearly define "injury of unknown source" to mean unexplained suspicious injuries, and to more clearly identify that both injuries of unknown source and "caregiver misconduct" are "incidents" that must be internally investigated and evaluated for external reporting. b. For child abuse suspicions in particular, to explicitly incorporate the parameters of Wis. Admin. Code s. DHS 13.05(3)(c) and Wis. Stat. s. 48.981, specifically the requirement to immediately report by telephone or personally to the county department of social services or human services or the sheriff or city, village or town police department "the facts and circumstances contributing to a suspicion that child abuse or neglect has occurred or to a belief that it will occur" and to "notify the department in writing or by phone within seven calendar days that the report has been made." While mandatory reporters are aware of their obligations, this revision will tie together the child abuse reporting and the caregiver misconduct reporting when both are applicable. c. Explicitly incorporate and attach the DQA flowchart (F-00161A: Flowchart Of Entity Investigation And Reporting Requirements For Caregiver Misconduct And Injuries Of Unknown Source).	**March 9, 2018**

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A 144	Continued From page 5 Review of plan of care by RN OO 9/21/17 at 5:36 AM revealed "scattered newborn rash noted. Bruising on left foot and scalp as well." Review of Neonatology Addendum to Physician Resident AA's progress note by Physician O on 9/22/17 at 7:16 AM revealed "I agree with resident note, bruise-like macules noted on palms bilaterally." During interview on 2/15/18 at 9:16 AM, Chief Nursing Executive C (CNE C) confirmed, Physician V recalled that there was a patient [#3] with unexplained bruising documented in the medical record, as a part of the hospital investigation, the hospital consulted Child Abuse Expert N on 02/12/18 who viewed photographs obtained from Patient #3's parent PP. Child Abuse Expert N reported this case to Madison Police Department on 2/12/18 (144 days after nursing documentation of injury of unknown origin in patient #3's medical record) as the bruising was consistent with child abuse, confirmed in an interview with NICU Nurse Manager D on 2/16/2018 at 4:30 PM. On 2/16/18 at 1:55 PM during an interview (b)(6), (b)(7)c (b)(6), (b)(7)c confirmed there was no incident report or follow up for the injuries of unknown origin on patient #3 documented on 9/21/17 at 5:36 AM and that the incident was not reported to Wisconsin Department of Health Services. Patient #6 Closed medical review of the "Birth Record" for Patient #6 revealed Patient #6 was born C-Section on (b)(6), (b)(7)c (10:44 PM) weighing 1.61 Kg (3 pounds 6 ounces) and was 39.4 cm (15.5 inches).	A 144	d. Accommodate differences in procedures between inpatient and outpatient departments of the hospital. e. Streamline and clarify the investigation process. f. Streamline and clarify the internal and external reporting process, including but not limited to required use of the electronic incident reporting portal on Meriter's intranet, and clarifying mandatory versus permissive reporting. **Task Owner:** Manager of Social Work and Spiritual Care/ Director Employee & Labor Relations. **2.** The Elder Adult-at-Risk Policy was further revised. The following is an overview of the revisions to the Elder Adult-at-Risk Policy made pursuant to Plan # 2: a. Clarify the process for screening all elderly patients and all adults at risk for signs of abuse, neglect or misappropriation of property, including distinctions in process as necessary between inpatient and outpatient populations. b. Clarify the obligations to identify and report suspected abuse or neglect of elderly patients or adults at risk in accordance with applicable law. c. Clarify that, where appropriate, allegations of abuse or neglect of adults at risk (including elders) are investigated and reported in accordance with the Caregiver Misconduct Reporting Policy. **Task Owner:** Manager of Social Work and Spiritual Care	**March 9, 2018**

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A 144	Continued From page 6 An interview was conducted 2/15/18 at 9:16 AM, Chief Nursing Officer C (CNO C) confirmed, as a part of the Hospital's investigation, since Patient #6 was in NICU (Newborn Intensive Care Unit) from 1/19/18 to 1/26/18, and medical record identified Patient #6 had scattered bruising on lower extremities the hospital contacted Patient #6's Parents EE and notified them of their safety plan. Review of the investigation revealed the (EE) of Patient #6 informed hospital staff they were uncomfortable with caregiver RN H, who was the primary caregiver on the night shift for Patient #6 on January 23-24, 2018 (confirmed with staff schedules). The hospital decided, due to these concerns, Physician Z consulted Child Abuse Expert N on 02/12/18 who recommended skeletal survey and a CT (computerized tomography). The hospital investigation revealed Patient #6 had multiple fractures, including rib and arm fractures, which were confirmed in an interview with NICU Nurse Manager D on 2/16/2018 at 4:30 PM. On 2/16/18 at 1:40 PM during an interview (b)(6), (b)(7)c (b)(6), (b)(7)c confirmed there was no incident report in for injuries of unknown origin found on Patient #6 while in the NICU (Newborn Intensive Care Unit) from 1/19/18 to 1/26/18 and no other documentation of intervention to protect Patient #6 during this hospital stay. The facility failed to report event to Wisconsin Department of Health Services. Patient #1 Review of Patient #1's medical record revealed that Patient #1 was admitted on (b)(6), (b)(7)c and was born at 14:55 (2:55 PM) weighting 3 pounds 6.5 ounces and was 15.75 inches and induced	A 144	**3.** The Child-At- Risk Abuse And Neglect Policy was further revised. The following is an overview of the revisions to the Child At Risk Abuse And Neglect Policy made pursuant to Plan # 2: a. More clearly define "injury of unknown source" to mean unexplained suspicious injuries, and to more clearly identify that both injuries of unknown source (defined consistent with the Caregiver Manual) and "caregiver misconduct" are "incidents" that must be internally investigated and evaluated for external reporting. b. Accommodate procedural differences for hospital inpatient versus outpatient departments. **Task Owner:** Manager of Social Work and Spiritual Care **4.** The Domestic Abuse - Adults Policy was further revised. The following is an overview of the revisions to the Domestic Abuse - Adults Policy made pursuant to Plan # 2: a. Clarify indicators of domestic abuse. b. Clarify the procedural screening process for inpatients and outpatients. c. Clarify when external reporting is mandated e.g. wounds and burns. d. Clarify the process for reporting and options for patient support when reporting is not mandated. **Task Owner:** Manager of Social Work and Spiritual Care	**March 9, 2018** **March 9, 2018**

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A 144	Continued From page 7 vaginal delivery . Patient #1 was admitted to the NICU at 2:55 PM after birth for prematurity, RDS (respiratory distress syndrome) and sepsis evaluation. On 1/7/18 at 9:45 PM had a hypoxic event, was intubated and diagnosed with PDA (patent ductus arteriosus) a heart defect. Patient #1 also had retinopathy (disease of the retina that results in impairment or loss of vision r/t to the premature birth). Review of Patient #1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" "Outcome" revealed on 01/14/2018 at 5:04 PM "Abrasions noted on bottom of L foot unchanged. Bruising noted to R hand and bottom of L foot." Review of incident report Skin/Tissue Event #169891 titled "Current Summary" for patient #1 was not entered until "02-08-2018" (6 days after staff identified injuries of unknown origin) by RN HH. Date of occurrence "02-02-2018" estimated time 9 AM, listed the "Severity Level" "Temporary, Intervention Needed" "Follow-Up Actions:" "Not Specified" Resolutions and Outcomes of the Event" "Harm - Temporary, Intervention Needed." There was no additional documentation of further investigation of the injuries or intervention to protect Patient #1. On 2/16/18 at 1:40 PM during an interview (b)(6), (b)(7)c (b)(6), (b)(7)c, Y confirmed incident event #169891 on Patient #1 occurred on 2/02/18 and was entered on 2/08/18 (6 days after staff identified the injuries). Patient #2 Review of Patient #2's medical record revealed that Patient was born via C-section (caesarean	A 144	**5.** An enhancement to the electronic medical record functionality for the NICU was implemented to provide a field (flowsheet rows) for documenting unsuccessful attempts at IV insertion, heel sticks, lab draws or other skin piercing techniques that could explain a mark or bruise on the baby's skin. Up until this point, only successful attempts were documented. This enhancement is intended to assist caregivers in determining whether or not a bruise or mark is suspicious. **Task Owner:** Clinical Informatics Nurse Specialist **6.** A team of NICU leadership (consisting of one or more of the following: Director, Nurse Manager, Assistant Nurse Manager, Family Nurse Liaison, Clinical Nurse Specialist, or other leadership) will make unannounced rounds on NICU patients and their families. Each patient will have unannounced rounds at least once per week. The purpose of the rounds will be to facilitate family communication and to identify any concerns family may have, and to provide a forum through which families may voice concerns about the care their baby is receiving. **Task Owner:** Director of Perinatal Services **7.** The DQA flowchart (regarding investigation and reporting of injuries of unknown source and caregiver misconduct) will be included in training and a version adapted to incident reporting in Perinatal Services will be displayed and easily accessible to staff and providers with direct patient contact in the NICU. **Task Owner:** Chief Nursing Executive	**March 9, 2018** **March 9, 2018 and ongoing** **April 4, 2018**

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A 144	Continued From page 8 section) [the delivery of a baby through a surgical incision in the mother's abdomen and uterus] on (b)(6), (b)(7)(C) AM, weighing 1 pound and 8.3 ounces. Review of the incident report #170100 titled "Current Summary" revealed on Saturday 02/03/18 at 8:00 AM, Patient #2's parent (DD) noticed "abrasions/scratching on left wrist" and notified RN P. RN P completed an assessment and identified "right palm /heal of hand with reddened intact areas", "scattered purple/red bruising on the opposite side of right hand and a few scattered areas of bruising up the right forearm and inner wrist", purple red bruising on left palm extending from area between thumb and first finger", small red bruises on second and third distal fingers, mostly located ulnar side of left wrist", "scattered linear abrasion", scattered purple/red bruising extending up left forearm". Further review of the same incident report revealed Patient #2's parent (CC) told RN P that s/he had "done skin care the previous day and felt very confident all these markings were new this morning". RN P documented taking photos of the injuries 2/3/18. The 2/3/18 incident was not recorded into their incident reporting system until 02/09/18 (6 days after the injuries were reported to hospital staff). Further review of the incident report #170100 revealed additional injuries "right subconjunctival hemorrhage" (per review of patient #2's medical record facial/head injuries were not discovered until on 02/04/2018) however the incident report does not include clarification that these were two separate incidents/injuries as no date or time included in this notation.	A 144	**8.** Meriter's safety huddle (which is generally conducted daily Monday- Friday excluding holidays) has and will include reports on the NICU, as well as reports from all over the hospital about concerning patient safety developments. This conversation allows managers such as the Patient Safety Officer to issue reminders, when reportable incidents occur, to report pursuant to hospital policy. The safety huddle will also serve as an accountability measure so that identified problems will be checked at the next huddle. Discussions will emphasize, among other things, that individuals who submit incident reports must describe the facts and circumstances with reasonable specificity on order to enable meaningful follow up. Information from the safety huddle is promptly posted to the Meriter intranet. **Task Owner:** Patient Safety Officer **9.** Meriter's intranet will have a new clinical resource link to tip sheets/ reminders about key compliance obligations specifically highlighting the importance of screening for abuse, neglect or unexplained suspicious injuries. Additionally, the policies dealing with abuse and neglect are now linked to the home page of Meriter's intranet. **Task Owner:** Patient Safety Officer **10.** Updated "badge buddies" will be distributed detailing indicators of abuse and neglect and highlighting the process for following up including contact information. **Task Owner:** Director, Care Coordination, Clinical Documentation Improvement, Nursing Education, Patient Care Services Support, and Spiritual Care.	**April 4, 2018** **April 4, 2018** **April 4, 2018**

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A 144	Continued From page 9 Review of the incident report for Patient #2 (#170100) "revealed under "Resolution and Outcome", final severity level as "D. No Harm-Reached Patient Monitoring Required" and under the "Follow-Up Actions:" "Not Specified" There was no additional documentation of further investigation of the injuries or intervention to protect Patient #2. There is no separate incident report on this event. Review of Patient #2's NICU "Nursing Notes" revealed on 2/04/18 RN U had documented that Patient #2 had additional injuries documented as bruising on face, periorbital edema. Review of the incident report log revealed the staff did not document on an incident report for Patient #2 the injuries of unknown origin identified by hospital staff 02/04/2018. Review of Patient #2s "Attending Neonatologist (L) Addendum" in the "Physicians Progress Note" dated 02/08/18 at 7:06 AM revealed scalp swelling noted last evening unknown etiology. On 2/16/2018 at 4:30 PM during an interview Nurse Manager NICU D confirmed on Thursday 2/08/18 (6 days after the first injury was reported and 4 days after the second injury was identified) Physician L consulted Child Abuse Expert N regarding unexplained injuries of Patient #2 and N recommended additional tests including a skeletal survey and head computed tomography (CT) which revealed recent skull fractures and arm fractures. Review of Patient #2's "Consult-Encounter Note" dated 2/9/2018 at 12:22 PM by Neurosurgery Physician AA revealed, "suspected nondisplaced	A 144	**11.** The electronic incident reporting portal on Meriter's intranet includes a setting to trigger the reporter to indicate injuries of unknown source (unexplained injuries that are suspicious in nature). However, that selection from the drop-down box currently states "Accidental Injuries of Unknown Origin." Meriter will submit a request to the UnityPoint Health IT Dept. to remove the term "Accidental" from this selection. **Task Owner:** Patient Safety Officer **12.** Video monitoring cameras will be installed in NICU rooms and the newborn nursery. The monitors will be continuously observed by staff and any concerning issues will be immediately reported to NICU staff to immediately address the concern. **Task Owner:** Director of Perinatal Services Date of Completion:	**April 4, 2018** **April 4, 2018**

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UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 144	Continued From page 10 fracture of the right parietal skull", "Fluid collection overlying the parieto-occipital skull...this collection to the suspected fracture suggests a traumatic scalp hematoma". On 2/16/18 at 1:40 PM during an interview (b)(6), (b)(7)c (b)(6), (b)(7)c confirmed incident event #170100 on Patient #2 was not entered until 6 days after the injury of unknown origin was identified by nursing staff. Y confirmed there was no incident report documented on the injury of unknown origin that occurred 2/07/18. An interview was conducted with Registered Nurse P on 2/16/18 at 1:26 PM., P stated in the past s/he had been a forensic nurse, trained as a Sexual Assault Nurse Examiner (SANE) and worked in the Emergency Room for 2 years. RN P stated s/he reported incident of scratching and bruising on the wrists of Patient #2 to APNP R on 2/03/18 when s/he first identified it on assessment at 8 AM. RN P stated Physician O was aware of the bruising of Patient #1 and Patient #2 during rounds on 2/03/18. RN P took pictures of Patient #2 and stated s/he encouraged the nurse of Patient #1 to also take pictures of Patient #1. RN P stated s/he was so concerned RN P sent an e-mail to Nurse Manager D and Assistant Nurse Manager TT on the evening of Friday 2/03/18 to notify them of her/his concerns hoping they would be addressed first thing Monday morning. On Monday 2/05/18 s/he "made sure" Assistant Nurse Manager TT had the pictures and voiced her/his concerns. RN P stated physicians "took a wait and watch position." On 2/16/18 at 4:25 PM during an interview Nurse Manager D, confirmed that s/he was called by	A 144	**13.** Meriter is currently conducting a second round of mandatory training ("phase two education") which will be completed by March 19, 2018 (subject to individual scheduling conflicts, with all staff education being completed no later than April 4, 2018). The purpose of phase two is to promote awareness of and compliance with the corrective action items identified above, including the policy revisions discussed herein which address the obligation to immediately report identified child abuse, and to timely and appropriately report incidents of caregiver misconduct or injuries of unknown source. Caregivers will be educated specifically on indicators of abuse and signs and symptoms that indicate a reasonable suspicion of abuse. The education will include an online or paper module relating to abuse detection and requiring patient safety. The education will cover child abuse, adult-at-risk and elder abuse, domestic abuse, and caregiver misconduct. The training will be conducted for all staff and providers who have patient contact in either the inpatient or clinic setting, all new staff and providers who have patient contact, and Meriter will also implement annual refresher education on these topics. **Task Owner:** Director, Care Coordination, Clinical Documentation Improvement, Nursing Education, Patient Care Services Support, and Spiritual Care	**March 19, 2018 or April 4, 2018, as explained herein.**

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 144	Continued From page 11 Assistant Nurse Manger T on Monday, 2/05/18 and questioned what s/he should do about the bruising found on Patient #1 and #2. Nurse Manger D confirmed "I told [T] to ask the staff." During interview with Medical Director of NICU K on 2/16/18 at 11:05 AM, K stated it was not his/her responsibility to complete an event report, "that would be the nurse's job." During interview with APNP R on 2/16/18 at 1:40 PM R when asked if R had submitted an incident report, R stated it was "out of [his/her] realm" to complete an event report, "it is the nurses job". On 2/15/18 at 9:16 AM during an interview CNE C confirmed the hospital was aware of the Wisconsin Statues 48.981 (2) and that they were mandated reporters and had not reported prior to this interview. C confirmed they had not completed form F-62447 caregiver misconduct Incident Report to report to the Wisconsin Department of Health Services.	A 144	• **How Completed and Planned Corrective Action Measures Will Prevent Recurrence:** The corrective actions identified above are designed to ensure that abuse is detected quickly and that immediate steps are taken to ensure patient safety. The corrective actions are intended to improve the processes for understanding, identifying and reporting abuse or caregiver misconduct where such conduct is suspected or where there is an injury of unknown source and caregiver misconduct cannot be ruled out. Because not all markings, bruises or other signs necessarily indicate child abuse, the processes identified above will incorporate specific guidance for distinguishing between indications of potential abuse versus indications of other medical processes that explain the signs/ symptoms. Staff will be educated to understand that in the event child abuse cannot be ruled out, reporting to law enforcement (and internally) must occur immediately. These actions will also ensure that leadership is appropriately and immediately notified and involved in detecting, investigating and reporting suspected abuse and caregiver misconduct. See Attachment 2 for additional comments.	
A 145	PATIENT RIGHTS: FREE FROM ABUSE/HARASSMENT CFR(s): 482.13(c)(3) The patient has the right to be free from all forms of abuse or harassment. This STANDARD is not met as evidenced by: Based on record review and interview the facility failed to develop and implement an effective policy to prevent, screen, identify, train, protect, thoroughly investigate, report,and respond to any allegations of suspected abuse related to injuries of unknown origin and failed to thoroughly investigate injuries of unknown origin and protect	A 145	• **Corrective Action Measures:** See A-0144 above. • **How Plan/ Action Will Prevent Recurrence:** See A-0144 above. • **How Compliance Will Be Monitored:** See A-0144 above. • **Task Owners:** See A-0144 above.	**See A-0144 above.**

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 145	Continued From page 12 5 of 6 patients (#1, #2, #3 #4 and #6) in the Newborn Intensive Care Unit (NICU) identified with injuries of unknown origins when the first case was reported for Patient #4 on 4/12/17. Findings include: Review of Bylaws and Rules and Regulation of the Medical Staff dated January 2017, approved by the Medical Executive Committee on November 15, 2016, approved by the Medical Staff at the annual meeting on January 17, 2017 and approved by the UnityPoint Health-Merrier Health Services Board on and effective January 25, 2017 under Membership and Privileges Section 1 Qualifications C. revealed "Members of the Medical Staff shall ...comply with the safety policies and guidelines put in place by the hospital and/or Medical Staff". Review of policy titled "Child at Risk Abuse and Neglect" dated March 2001 revised 8/2016 under II. C. Statutory requirements for reporting child abuse under Wisconsin Statute 48.981 3. revealed "Each person who has a concern about suspected child abuse or neglect is responsible for either making a report directly or for verifying that the report was actually made to County Human Services or law enforcement". Under D. Investigation and documentation 1. revealed "when a concern about abuse or neglect is identified by a person required to report...that person immediately consults with, by telephone or personally... determined by the primary clinical area the child is receiving care through." Patient #2 Review of Patient #2's medical record revealed that Patient was born via C-section (caesarean	A 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

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UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 145	Continued From page 13 section) [the delivery of a baby through a surgical incision in the mother's abdomen and uterus] on (b)(6), (b)(7)c 7:39 AM, weighing 1 pound and 8.3 ounces. Review of Patient #2's NICU "Nursing Notes" revealed on 2/04/18 RN U had documented that Patient #2 had additional injuries documented as bruising on face, periorbital edema. Review of the incident report log revealed no incident report was completed for the new injuries of unknown origin found on 02/04/2018 for Patient #2. Review of Patient #2s "Attending Neonatologist (L) Addendum" in the "Physicians Progress Note" dated 02/08/18 at 7:06 AM revealed scalp swelling noted last evening unknown etiology. Review of Patient #2's Attending Neonatologist (L) summary of the ultrasound dated 02/08/18 revealed "normal intercranial ultrasound". Review of the incident report #170100 titled "Current Summary" revealed on Saturday 02/03/18 at 8:00 AM, Patient #2s parent (DD) noticed "abrasions/scratching on left wrist" and notified RN P. RN P completed an assessment and identified "right palm /heal of hand with reddened intact areas", "scattered purple/red bruising on the opposite side of right hand and a few scattered areas of bruising up the right forearm and inner wrist", purple red bruising on left palm extending from area between thumb and first finger", small red bruises on second and third distal fingers, mostly located ulnar side of left wrist", "scattered linear abrasion", scattered purple/red bruising extending up left forearm". Further review of the same incident report	A 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

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UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 145	Continued From page 14	A 145		

revealed Patient #2s parent (CC) told RN P that s/he had "done skin care the previous day and felt very confident all these markings were new this morning". RN P documented taking photos of the injuries 2/3/18. The 2/3/18 incident was not recorded into their incident reporting system until 02/09/18, 6 days after the event. Included in this incident report were additional injuries "right subconjunctival hemorrhage" (per review of medical record were not discovered until on 02/04/2018) however the incident report does not include clarification that these were two separate incidents/injuries as no date or time included in this notation. No additional incident report was completed for second 02/04/18) injury of unknown origin for Patient #2
.
Review of the incident report for Patient #2 (#170100) "revealed under "Resolution and Outcome", final severity level as "D. No Harm-Reached Patient Monitoring Required" and under the "Follow-Up Actions" revealed, "Not Specified"

On 2/16/2018 at 4:30 PM Nurse Manager NICU D confirmed on Thursday 2/08/18 Physician L consulted Child Abuse Expert N regarding unexplained injuries of Patient #2 and N recommended additional tests including a skeletal survey and head computed tomography (CT) which revealed recent skull fractures and arm fractures.

Review of Patient #2's "Consult-Encounter Note" dated 2/9/2018 at 12:22 PM by Neurosurgery Physician AA revealed, "suspected nondisplaced fracture of the right parietal skull", "Fluid collection overlying the parieto-occipital skill...this collection to the suspected fracture suggests a

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	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

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UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 145	Continued From page 15 traumatic scalp hematoma". Patient #4 Review of Patient #4s "Admission Record" revealed that Patient #4 was born on (b)(6), (b)(7)c another hospital and was transferred to this hospital on 03/19/17 at 3:14 PM with an admitting diagnosis of "Prematurity in Newborn Estimate to be 30+ weeks", respiratory distress that required mechanical ventilation, and sepsis evaluation. Review of Patient #4's medical record with Patient Safety Officer Y revealed Patient #4 had a two view x-ray completed on 4/12/17 of the tibia, first view "normal", second view "somewhat limited evaluation". Record review confirmed RN H was primary caregiver on night shift April 11-12, 2017. "Physician Notes" from 04/12/17 at 7:29 AM by Physician K, revealed bruising. Review of Patient #4's incident report for event #115245 titled "Current Summary" dated 4/12/17 and documented by RN W, revealed injuries of unknown origin were identified at 9:00 AM on 4/12/17, as "bilateral bruising on calves, ankles and left foot" (photos were taken and placed in the medical record), and X-rays ordered. Further review of Patient #4s incident report "Resolution and Outcome" for the 04/12/17 event "Severity Level" revealed "E. Harm-temporary, Intervention Needed" and the "Follow-Up Actions" revealed, "Not Specified". Patient #1 Review of Patient #1's medical record revealed that Patient #1 was admitted on (b)(6), (b)(7)c and was born at 14:55 (2:55 PM) weighting 3 pounds 6.5 ounces and was 15.75 inches and induced	A 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 145	Continued From page 16 vaginal delivery . Patient #1 was admitted to the NICU 14:55 (2:55 PM) after birth for prematurity, RDS (respiratory distress syndrome) and sepsis evaluation and retinopathy (disease of the retina that results in impairment or loss of vision r/t to the premature birth) and diagnosed with PDA (patent ductus arteriosus) a heart defect and on 1/7/18 at 23:45 (9:45 PM) had a hypoxic event and was intubated. Review of Patient #1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" "Outcome" revealed on 01/14/2018 at 5:04 PM "Abrasions noted on bottom of L foot unchanged. Bruising noted to R hand and bottom of L foot." Review of Patient #1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" "Outcome" revealed on 1/15/2018 6:46 AM "Continues to be ruddy/jaundice with bruising/abrasion to bottom of left foot. Bruising to right hand noted." Review of Patient # 1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" revealed on 2/2/2018 9:17 PM "Bruising remains on left arm and hand." Review of Patient #1's medical record dated Friday 02/02/18 "AM Nursing Progress Notes" by RN P identified "bruising erythema and abrasions of bilateral hands and forearms" of Patient #1, at 8:00 AM cares and notified APNP R and Physician O. Review of Patient #1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" "Outcome" revealed on 2/4/2018 5:35 AM	A 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 145	Continued From page 17 "Bruising noted on left hand" Review of Patient #1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" "Outcome" revealed on 2/9/2018 12:33 PM "Back of left hand with resolving bruise noted" Review of Patient #1's "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" "Outcome" revealed on 2/10/2018 at 2:58 PM "Bruising to top of L hand noted, primarily extending up from 4th and 5th fingers" Review of Patient #'s "Nursing Notes" "Plan of Care" "Problem: Skin Integrity" - "Impaired, Risk of" revealed on 2/13/2018 8:24 PM "Continues to have very light bruising to her left arm/hand - almost unable to see today" Review of incident report titled "Current Summary" dated 02/08/18 for Patient #1 revealed Patient #1 had injury on unknown origin that was identified on 2/2/2018 but was not recorded in their incident reporting system by RN CC (6 days after the event). Interview with (APNP) R on 2/16/18 at 1:40 PM confirmed R notified Physician O and Physician K on 2/02/18 of injuries on Patient #1. On 2/16/18 at 11:05 AM during an interview Physician K confirmed Patient #1's injuries on 2/02/18 may have been from patient clutching wires or peripheral intravenous device arm board used for stabilization. Physician K stated S/he was contacted by a RN about the injuries identified on Patient #1 Friday 02/02/18 and assessed Patient #1 and called Physician O to discuss her/his findings.	A 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 145	Continued From page 18 Patient #3 Record review of Patient #3's "Birth Record" revealed Patient #3 was born vaginal delivery on (b)(6), (b)(7)c at 3:31 AM weighting 4 pounds 12.2 ounces and was 43 cm (16.9 inches) long Review of the medical record "Birth History" reveal: [Patient #3]"is a (b)(6), (b)(7)c born at 34w5d via normal spontaneous vaginal delivery, admitted to NICU for prematurity. Review for patient #3 revealed in "Physician Progress Notes" dated 9/22/2017 at 7:16 AM "non-blanching linear macules on bilateral palms, no other rashes or lesions." Neonatology Addendum 09/22/17 (not timed) "I examined baby, reviewed data and directed plans on rounds. I agree with resident note, Bruise-like macules noted on palms bilaterally. Review of nursing documentation for Patient #3 by RN H 9/19/17 through 9/22/17, failed to document bruising or skin assessments. Review of the Hospital's investigation report dated on 2/09/18 revelaed that Physician V had recalled Patient #3 had unexplained bruising. The Hospital investigation report verified RN H had been a primary caregivers during Patient #3's hospitalization in the NICU 9/17/17 thru 10/13/17. During this hospitalization, Patient #3 had bruising of left foot and scalp bruising. Patient #3's mother had taken pictures of the bruising at that time, which were presented to Child Abuse Specialist N on 2/09/18. On 2/09/18 N reviewed the photographs of Patient #3 from the past hospitalization and determined bruising was consistent with child abuse. RN H was primary caregiver on nights for Patient #3 September	A 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 145	Continued From page 19 21-22, 2017. The medical record review during the hospital investigation for Patient #3 revealed, there were no marks/bruises or injuries documented in medical record prior to 9/21/17. RN H did not note any bruising in any documentation. No incident report was documented for the 9/22/17 when injury of unknown origin bruising of left foot and scalp bruising of Patient #3. Patient #6 Closed medical review of the "Birth Record" for Patient #6 revealed Patient #6 was born C-Section on (b)(6), (b)(7)c 2017 (10:44 PM) weighing 1.61 Kg (3 pounds 6 ounces) and was 39.4 cm (15.5 inches). During interview on 2/15/18 at 9:16 AM, Chief Nursing Officer C (CNO C) confirmed as a part of the Hospital's investigation that ever since Patient #6 was in the care of RN H, the hospital contacted Patient #6's parents EE and notified them of safety plan because Patient #6 had scattered bruising on lower extremities during the hospital stay on 01/20/18. The investigation revealed the Parents (EE) of Patient #6 informed hospital staff they were uncomfortable with caregiver RN H, who was the primary caregiver on the night shift for Patient #6 on January 23-24, 2018. The hospital decided due to these concerns, Physician Z consulted Child Abuse Expert N on 02/12/18 who recommended skeletal survey and a CT. The hospital investigation revealed Patient #6 had multiple fractures ,including rib and arm fractures which was confirmed in an interview with NICU Nurse Manager D on 2/16/2018 at 4:30 PM.	A 145		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

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UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 145	Continued From page 20	A 145		

No incident report was documented for Patient #6 related to scattered bruising on lower extremities during the hospital stay on 01/20/18.

Interview on 2/15/18 at 9:16 AM with CNO C revealed that they had not reported the suspected abuse immediately because the hospital was working on their investigation and they were collecting the information to report. When asked about reporting suspected abuse CNO C, confirmed S/he understand the need to report abuse or neglect ASAP (as soon as possible).

On 2/16/18 at 11:05 AM during an interview Medical Director of Neonatal Intensive Care Unit K confirmed it was not his/her expectation of the physicians to complete incident reports, "they are "filled out by nurses."

Interview on 2/16/18 at 1:26 PM with Registered Nurse (RN) P confirmed Patient #2 had unexplained bruising similar to Patient #1 and notified attending Physician O on 2/03/18 between 9:30 AM and 11 AM. RN P was concerned and stated on the evening of 2/03/18 RN P sent an E-mail to Nurse Manager D and Assistant Nurse Manager T regarding his/her concerns of unusual markings, and similarity of the bruising on Patient #1 and Patient #2 to make sure this was follow up on, and thought this would be addressed first thing Monday 2/05/18, but it was not.

On 2/16/18 at 1:40 PM during an interview Advanced Practice Nurse Prescribe (APNP) R stated S/he discussed common factors with RN's P & X on Monday 2/05/18, who identified RN H had cared for both Patient #1 and Patient #2.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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A 145	Continued From page 21 Interview on 2/16/18 at 2:12 PMwith the Director of Performance Improvement B confirmed there was no policy or process that directed staff on their responsibility to prevent, screen, identify, train, protect, thoroughly investigate, report,and respond to any allegations of suspected abuse related to injuries of unknown origin. On 2/16/2018 at 4:25 PM during an interview Nurse Manager NICU D stated based on the current evidence and staffing logs the hospital suspended suspected Caregiver RN H, disabled RN Hs badge access and RN Hs access to the hospital electronic medical record. Manager NICU D confirmed that on Monday 2/05/18 when Assistant Manager T called Manager D asking what to do [staff concerns and injuries on Patient #1 and #2], Nurse Manager D stated S/he told Assistant Manager T "to ask staff".	A 145		
A 263	QAPI CFR(s): 482.21 The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.	A 263	• **Corrective Action Measures:** See response to A-0273 and A-0309 below. • **How Plan/ Action Will Prevent Recurrence:** See response to A-0273 And A-0309 below. • **How Compliance Will Be Monitored:** See response to A-0273 and A-0309 below. • **Task Owners:** See response to A-0273 and A-0309 below.	**See response to A-0273 and A-0309 below.**

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

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A 263	Continued From page 22 This CONDITION is not met as evidenced by: Based on record review and interview the facility failed to thoroughly investigate, report,and respond to any allegations of suspected abuse related to injuries of unknown origin in 5 of 6 patients (#1, 2, 3, 4 and 6) per policy. In a total sample of 20 records. Findings include: The facilities failed to document, analyze, and track incident reports for patients with injuries of unknown origin to ensure that aspects of staff performance and patient care that would provide relevant data to improve patient safety or that incident reports were thoroughly investigated in 3 of 9 events reviewed for 5 of 20 patients (Patient #4, #3, #6, #1 and # 2). See (A073) The hospital's medical staff and administrative officials failed to take responsibility for the quality of care provided to 5 or 6 patients (Patient #4, #3, #1, #2, and #6) in a total of 20 Newborn Intensive Care Unit records reviewed. (See Tag A-309) The cumulative effect of these deficiencies affected all patients in the Newborn Intensive Care Unit during this survey (patient census 2/15/18 was 16, 2/16/18 was 17 and 2/19/18 was 18) and prevented the hospital from having data-driven quality assessment and performance improvement program. .	A 263		
A 273	DATA COLLECTION & ANALYSIS CFR(s): 482.21(a), (b)(1),(b)(2)(i), (b)(3)	A 273	• **Corrective Action Measures:**	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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A 273	Continued From page 23 (a) Program Scope (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes ... (2) The hospital must measure, analyze, and track quality indicators ... and other aspects of performance that assess processes of care, hospital service and operations. (b)Program Data (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization. (2) The hospital must use the data collected to-- (i) Monitor the effectiveness and safety of services and quality of care; and .... (3) The frequency and detail of data collection must be specified by the hospital's governing body. This STANDARD is not met as evidenced by: Based on record review and interview the facility failed to document, analyze, and track incident reports for patients with injuries of unknown origin to ensure that aspects of staff performance and patient care that would provide relevant data to improve patient safety or that incident reports were thoroughly investigated in 3 of 9 events reviewed for 5 of 20 patients (Patient #4, #3, #6, #1 and # 2).	A 273	**1.** All corrective action measures articulated in Plan # 1 and Plan # 2 or elsewhere within this Plan # 3 are incorporated herein to the extent relevant. **2.** The Quality of Healthcare Committee is a standing committee of the Meriter Board of Directors. This committee establishes organization-wide clinical quality expectations and oversees clinical quality across the continuum of care offered in the hospital. Going forward, a specific written plan will be developed for creating a conduit so that incident reporting data and opportunities for improvement drawn therefrom will be conveyed to the Quality of Healthcare Committee for the purpose of setting quality indicators for incident reporting of injuries of unknown source. The goal of this corrective action step is to have the Quality of Healthcare Committee explicitly consider this data in providing direction to all clinical care settings. The written plan will include the following elements: (1) The Quality of Healthcare Committee will issue guidelines for the Patient Safety Committee to provide data evidencing that staff in all clinical settings are aware of and comply with system expectations to submit and follow up on such incident reports; (2) At its next meeting on May 10, 2018, the Patient Safety Officer and Director of Performance Improvement will present incident reporting data and the planned strategies for quality improvement; and (3) For each meeting thereafter for the subsequent 12 months, the Quality of Healthcare Committee will explicitly include this item (incident reporting data review) as a standing item on meeting agenda. **Task Owner:** Director of Performance Improvement, Patient Safety Officer	**April 4, 2018**

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A 273	Continued From page 24 Findings include: Review of policy titled "Incident or Accident Reporting System" #30 dated 8/31/15 under Policy Statement revealed "The system facilitates risk management interventions and provides an overview of Meriter's exposure pattern as a basis for quality improvement activities to improve patient care and organizational safety... Definition of an Incident:...1. "perceived" injury... D...2. If the incident involves a patient, include an assessment of the patient's condition following the incident and any clinical action taken as a result of the incident... 5...all incidents are required to be entered into the online incident reporting system via MyMeriter as soon as possible. Supervisor review and follow-up is expected within 72 hours of the incident." Patient #4 Review of Patient # 4 medical record revealed, Patient #4 had injuries of unknown origin documented in the nursing notes on 4/12/17 at 9 AM described as bruising, scattered; right leg; left leg bilateral; calf and ankle and documented in physician notes 4/12/17 at 7:19 AM Bruises on lower extremities bilaterally, linear in shape-likely due to cords (from monitor leads) wrapped in swaddle with infant. Record review of the corresponding Incident report written on 4/12/2017 at 9 AM revealed injuries described as bilateral bruising on calves, ankles and left foot, bruises consistent with monitor cord size. "Severity Level" revealed "Temporary Intervention Needed" "Follow-Up Actions" revealed "Not Specified". "Final Severity Level" revealed "Harm - Temporary, Intervention Needed." However, there	A 273	**3.** The Quality of Healthcare Committee annually publishes a Patient Safety Plan to establish areas of focus for achievement of quality and safety objectives hospital-wide. The Committee will include on its agenda for its next meeting on May 10, 2018 a discussion about including incident reporting, follow-up / investigation and audit as areas of focus for the 2019 Patient Safety Plan. Thereafter, the Director of Performance Improvement and the Patient Safety Officer will initiate the process for revising the Patient Safety Plan accordingly, establishing this issue as a safety priority for all areas of the hospital including but not limited to the Board of Directors, the Medical Staff, Administration, the Patient Safety Committee, the Hospital Clinical Council, the Department Directors and Managers, the Nursing Shared Governance Quality/ Practice Counsel, all Meriter employees and volunteers, the Department of Performance Improvement, Legal Counsel and Risk Management. **Task Owner:** Director of Performance Improvement, Patient Safety Officer	**April 4, 2018**

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A 273	Continued From page 25 was no documentation of intervention or follow up. Patient #3 Record review Patient #3's medical record revealed, Patient #3 had injuries of unknown origin documented in the nursing notes on 9/21/17 at 5:36 AM described as bruising on left foot and scalp and in physician notes on 9/22/17 at 7:16 AM described as non-blanching linear macules on bilateral palms bilaterally. Review of incident log revealed, the staff did not documentation on an incident report the injuries of unknown origin that were documented in Patient #3's medical record on 9/21/17. Patient #6 Record review Patient #6's medical record revealed, Patient #6 had injuries of unknown origin documented in the nursing notes on 1/20/18 at 11 AM that were described as scattered bruising lower extremities. Review of incident log revealed, the staff did not documentation on an incident report the injuries of unknown origin that were documented in Patient #6's medical record on 1/20/2018. Patient #1 Review of Patient #1's medical record revealed, Patient #1's had injuries of unknown origin documented in the nursing notes on 2/02/18 at 2:08 AM described as bruising of left forehand, wrist and palm and documented in the physician notes on 2/02/18 at 7:55 AM described as hyperpigmentation of left lower forearm and bruising over dorsal left hand and palm.	A 273	**4.** The Patient Safety Officer will propose a process to allocate Patient Safety Program staff resources to respond to, own and track all incident reports submitted that indicate a potential injury of unknown source or an allegation of caregiver misconduct. Currently, upon submission of an incident report through the portal on Meriter's intranet where the person submitting the report has indicated Level E or "Harm," the Patient Safety Program staff is automatically notified by email alert. This will stay in place, but going forward: (1) the same email alert will occur whenever an incident report is submitted categorized as "injury of unknown source" or caregiver misconduct and (2) for reports indicating "Harm" or injury of unknown source, the Patient Safety Program staff will be the owners of the process, and will be directing and coordinating appropriate follow-up during regular business hours (see below for after hours, weekends and holidays). The Patient Safety Program staff receiving the report will promptly follow up to coordinate investigation of whether the incident requires further investigation and/or reporting to external agencies in accordance with applicable policy. The Patient Safety Program staff will inform the attending physician of the incident if he/ she is not already aware. **Task Owner:** Patient Safety Officer	**April 4, 2018**

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A 273	Continued From page 26 Record review of the corresponding incident report written on 02/02/18 at 9:00 AM revealed, injuries described in nurses notes on 02/02/18 at 9:30 AM described as bruising left hand, palm, and arm. "Severity Level" revealed "Intervention Needed." "Follow-Up Actions" revealed "Not Specified", "Final Severity Level" revealed "Harm - Temporary, Intervention Needed." However, there was no documentation of intervention or follow up. Patient #2 (injury #1) Review of Patient #2's medical record revealed, Patient #2 had injuries of unknown origin documented in the nursing notes on 2/03/18 at 9:00 AM described as bruising, erythema, and abrasions on bilateral hands and forearms and in the physician notes on 02/04/18 at 7:37 AM described as bruising on the right greater than left forearm and left inner wrist that were linear in nature. Review of the incident log identified a corresponding Incident report written on 02/09/18 (6 days after the injury was documented in #2's medical record) revealed abrasions, scratching on left wrist, bruising right forearm, bruising right and left hands, bruising right wrist, and left forearm. "Severity Level" revealed, "No Harm-Reached Patient Monitoring Required" "Follow-Up Actions" revealed, "Not Specified" "Final Severity Level" revealed, "No Harm - Reached Patient Monitoring Required". However, there was no documentation of intervention or follow up. Patient #2 (injury #2)	A 273	**5.** The manager of the location where the event occurred will be automatically notified and is typically the person tasked with timely investigation to determine next steps. For injuries of unknown source, the staff member submitting the report will also directly contact the manager (by phone or in person) for all concerns of abuse or injury of unknown source or caregiver misconduct. If the manager is not available, the staff member submitting the report will contact the assistant manager. If neither are available, the staff member submitting the report will contact one of the key resource personnel which may include the Nurse Administrative Coordinator (NAC) or the Administrator on Call depending on the clinical area. All progress involving the investigation or reporting of an incident will be communicated to the Patient Safety Program staff responsible for tracking and documentation. For incident reports submitted by NICU staff, the Director of Perinatal Services will also be notified. Where the patient at issue is a minor and there is a concern of abuse, caregiver misconduct or injury of unknown source, the notification provisions of the Child Abuse-At-Risk Policy will be followed. **Task Owner:** Patient Safety Officer See Attachment 3 for additional comments.	**April 4, 2018**

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A 273	Continued From page 27 Review of Patient #2's medical record revealed, four days (4 days) after the first documented injury Patient #2 had sustained a second injury of unknown origin documented in the nursing notes on 2/07/18 at 2:00 PM as fluid wave in posterior scalp and in physician notes on 2/08/18 at 7:06 AM fluid wave over the posterior occiput. Review of incident report log confirmed there was no incident report documentation on this event. Interview with (b)(6), (b)(7)c Y on 2/16/18 at approximately 1:55 PM, Y confirmed there were no incident reports of patient event on Patient #3 or #6, or on the second event on patient #2.	A 273		
A 309	QAPI EXECUTIVE RESPONSIBILITIES CFR(s): 482.21(e)(1), (e)(2), (e)(5) The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following: 1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained . (2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated. (5) That the determination of the number of distinct improvement projects is conducted annually.	A 309	• **Corrective Action Measures:** **1.** All corrective action measures articulated in Plan # 1 and Plan # 2 or elsewhere within this Plan # 3 are incorporated herein to the extent relevant. **2.** All employed direct care staff members, volunteers, credentialed providers, fellows, and residents who work in areas of the hospital where infants, babies, and children are primarily treated (including, without limitation, the ED and NICU units, and OB staff) have been required to participate in phase one and all medical staff members are being required to participate in phase two education modules identified in Plan # 1 and Plan # 2 and incorporated herein by reference. This education is focused on the identification, investigation and reporting (internal and external) of injuries of unknown source and caregiver misconduct. **Task Owner:** Director, Care Coordination, Clinical Documentation Improvement, Nursing Education, Patient Care Services Support, and Spiritual Care	**March 19, 2018**

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A 309	Continued From page 28 This STANDARD is not met as evidenced by: Based on record review and interview, the hospital's medical staff and administrative officials failed to take responsibility for the quality of care provided to 5 of 6 patients (Patient #4, #3, #6, #1, and #2) in 20 Newborn Intensive Care Unit records reviewed. Findings include: Review of Policy titled "Code of Conduct" dated 02/2015 revealed "This Code of Conduct has been adopted by" the facilities Board of Directors "to provide standards by which directors, officers, employees, reporting physicians and volunteers will conduct themselves in order to protect and promote organization-wide integrity." Page 8 Quality of Care and Clinical Values "to provide high-quality medical services that are appropriate, safe and in compliance with all applicable laws, regulations and professional standards." Page 9 3.4 Protection from Abuse revealed "Any concerns about potential abuse, neglect or exploitation should be immediately." 11. Responsibilities of Leaders, 11.2 Standards for Patient care revealed "Leaders are called upon to create a culture with the organization of high ethical standards, to respect the importance of compliance with legal requirements and to establish a working environment in which all Covered Persons are encouraged to raise concerns and contribute ideas to achieve the organization's goals in a safe and healthy work environment." Review of Bylaws and Rules and Regulation of the Medical Staff dated January 2017, approved	A 309	**3.** The Root Cause Analysis team (consisting of physicians, administrators and other staff, which will include nursing going forward) will meet weekly (as indicated) for the specific purpose of: (a) reviewing all incident reports indicating injury of unknown source; and (b) developing any necessary action items to address systemic opportunities for improvement in the process for identifying, investigating and reporting injuries of unknown source. **Task Owner:** Patient Safety Officer **4.** All members of administration who have responsibility for units or areas of the hospital providing patient care will complete the education module. **Task Owner:** President/ CEO **5.** The manager (or other key personnel) will respond to any incident report indicating injury of unknown source within time limitations set by the Patient Safety Program staff who are tracking that particular incident reporting. **Task Owner:** Patient Safety Officer **6.** In the event that audit / monitoring reveals that any medical staff member did not report an incident or follow up on an incident based on the assumption that someone else (e.g. nursing staff) is responsible, the decision not to report shall be submitted to the Chief Medical Officer or designee for follow-up. **Task Owner:** Chief Medical Officer	**April 4, 2018** **April 4, 2018** **April 4, 2018** **April 4, 2018**

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A 309	Continued From page 29 by the Medical Executive Committee on November 15, 2016, approved by the Medical Staff at the annual meeting on January 17, 2017 and approved by the UnityPoint Health-Meriter Health Services Board on and effective January 25, 2017 under Membership and Privileges Section 1 Qualifications C. revealed "Members of the Medical Staff shall ...comply with the safety policies and guidelines put in place by the hospital and/or Medical Staff". Review of policy titled "Incident or Accident Reporting System" #30 dated 8/31/15 under Policy Statement revealed "The system facilitates risk management interventions and provides an overview of Meriter's exposure pattern as a basis for quality improvement activities to improve patient care and organizational safety... Definition of an Incident:...1. "perceived" injury... D...2. If the incident involves a patient, include an assessment of the patient's condition following the incident and any clinical action taken as a result of the incident... 5...all incidents are required to be entered into the online incident reporting system via MyMeriter as soon as possible. Supervisor review and follow-up is expected within 72 hours of the incident." Review of policy titled "Child at Risk Abuse and Neglect" Policy #57 dated January 2010 Policy Statement revealed "Meriter Hospital will take actions to protect the "abused ..." from the possibility of further abuse... 9. All hospital staff shall formally write up their observations immediately... All hospital staff involved are responsible for filling out appropriate documentation in a timely manner." Patient #4	A 309	**7.** The President/CEO of Meriter highlighted the importance of policy compliance (related to incident reporting) in her "Top 5" priorities at the Manager/ Director Forum on March 15, 2018. The Patient Safety Officer will develop a presentation for the next Manager / Director Forum (to be held on April 19, 2018) containing targeted information on the incident reporting system and the obligation to inform the caregivers in their department or unit of the content of the policies as revised and discussed above. Medical directors of clinical units attending the Forum will receive information about communicating the essential content of the policies to medical staff. **Task Owner:** President/CEO; Patient Safety Officer • **How Plan/ Action Will Prevent Recurrence:** The corrective action steps above establish a system of ensuring that medical staff are trained and periodically reminded of the specific duty to identify, investigate and report abuse. This plan is designed to ensure that medical staff are not complacent and are not assuming that identifying and reporting abuse is in the exclusive jurisdiction of the nursing staff. Medical staff will play a key role in actively evaluating injuries of unknown source and will be scrutinized by the peer review process in the event that they fail to meet this expectation. Similarly, administration will be educated and reminded that they are ultimately responsible for ensuring that systems are available for detecting, investigating and reporting suspected abuse and that these systems are continually evaluated and changes made to address identified deficiencies. The goal is for administration to actively lead and be accountable for ensuring that this system is working.	**March 15, 2018 and April 4, 2018**

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A 309	Continued From page 30 Review of incident report for Patient #4 "Skin Tissue Event #115245" dated 4/12/17 at 9 AM by Registered Nurse (RN) W, revealed "Severity Level " " Intervention Needed". Follow-up Actions:" "Not Specified". "Resolutions and Outcomes:" "Intervention Needed." Final Severity Level revealed "Harm - Temporary, Intervention Needed." No interventions were documented to protect or report the injuries of unknown origin on Patient #4. There was no additional documentation of further investigation of the injuries or intervention to protect Patient #4. Review of Patient # 4 medical record revealed, Patient #4 had injuries of unknown origin documented in the nursing notes on 4/12/17 at 9 AM described as bruising, scattered; right leg; left leg bilateral; calf and ankle. Continued Review of Patient # 4 medical record revealed, Patient #4 had injuries of unknown origin documented in the physician notes 4/12/17 at 7:19 AM Bruises on lower extremities bilaterally, linear in shape-likely due to cords (from monitor leads) wrapped in swaddle with infant. During interview with (b)(6), (b)(7)c Y on 2/16/18 at 1:25 PM, Y confirmed there was no further follow-up on Event #115245 on patient #4. Patient #3 Patient #3's medical record was reviewed an revealed in the nursing plan of care 9/21/17 at 5:36 AM "Bruising on left foot and scalp" in the physician note on 9/22/17 at 7:16 AM non-blanching linear macules on bilateral palms	A 309	• **How Compliance Will Be Monitored:** The Quality of Healthcare Committee is ultimately responsible for reviewing and auditing compliance with this set of corrective action steps. The data that the Patient Safety Committee provides to the Quality of Healthcare Committee (pursuant to the written guidelines contemplated elsewhere in this Plan) will include data allowing audit of whether medical staff and administration are actively taking responsibility for the identification, investigation and reporting of potential abuse. Individual task owners as identified above will be held fully accountable for compliance with each stated corrective action step.	

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A 309	Continued From page 31 and bruise-like macules on palms bilaterally. Interview with (b)(6), (b)(7)c Y on 2/16/18 at approximately 1:55 PM, Y confirmed there was no event report for patient #3. Patient #6 Record review Patient #6's medical record revealed, Patient #6 had injuries of unknown origin documented in the nursing notes on 1/20/18 11 AM described as scattered bruising lower extremities. Interview with (b)(6), (b)(7)c Y on 2/16/18 at approximately 1:55 PM, Y confirmed there was no event report for patient #6. Patient #1 Review of incident report Skin/Tissue Event #169891 titled "Current Summary" for patient #1 was not entered until "02-08-2018" (6 days after staff identified injuries of unknown origin) by RN HH. Date of occurrence "02-02-2018" estimated time 9 AM, listed the "Severity Level" "Temporary, Intervention Needed" "Follow-Up Actions:" "Not Specified" Resolutions and Outcomes of the Event" "Harm - Temporary, Intervention Needed." There was no additional documentation of further investigation of the injuries or intervention to protect Patient #1. Review of Patient #1's medical record revealed, Patient #1's had injuries of unknown origin documented in the nursing notes on 2/02/18 at 2:08 AM described as bruising of left forehand, wrist and palm and documented in the physician notes on 2/02/18 at 7:55 AM described as	A 309		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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A 309	Continued From page 32	A 309		

hyperpigmentation of left lower forearm and bruising over dorsal left hand and palm and on 02/03/18 at 8:52 AM By Physician O, "mild bruising noted on left hand and forearm ... Left forearm has a linear bruise about 1 cm long consistent with possible pushing against a lead. [Patient #1] also has a 3 X 2 mm bruise on the inside of the right wrist and a linear bruise on her palm ...We will check growth curves in the a.m. Linear erythema/bruise on left arm is most consistent with a mechanical injury, possibly entanglement in a lead.".

During Interview with (b)(6), (b)(7)c Y on 2/16/18 at 1:55 PM, Y confirmed Event #169891 on Patient #1, which took place on 2/02/18, was entered on 2/08/18.

Patient #2

Incident report revealed "Severity Level" as "No Harm-Reached Patient Monitoring Required" Follow-Up Actions revealed "Not Specified", Final Severity Level revealed "No Harm - Reached Patient Monitoring Required" APNP R, Neonatologist O, Nurse Manager D, Assistant Nurse Manager T were notified of the incident report events. However, there was no documentation of intervention or follow up. There was no additional documentation of further investigation of the injuries or intervention to protect Patient #2.

Review of Patient #2's medical record revealed, Patient #2 had injuries of unknown origin documented in the in the physician notes 02/04/18 at 7:37 AM described as bruising on the right greater than left forearm and left inner wrist that were linear in nature and physician notes on

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	520089	A. BUILDING _____ B. WING _____	C 02/19/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
UNITYPOINT HEALTH - MERITER	202 S PARK ST MADISON, WI 53715

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
A 309	Continued From page 33 2/08/18 at 7:06 AM fluid wave over the posterior occiput (back of the head). During interview wit (b)(6), (b)(7)c Y on 2/16/18 at 1:40 PM, Y confirmed incident event #170100 on Patient #2 occurred on 2/03/18 at approximately 9 AM and was entered on 2/09/18 stating "the investigation is ongoing." During interview with Medical Director of NICU K on 2/16/18 at 11:05 AM, K when asked about the reporting of these incidents, K stated it was not his/her responsibility to complete an event report, "that would be the nurse's job." During interview with APNP R on 2/16/18 at 1:40 PM R when asked if R had submitted an incident report, R stated it was "out of [his/her] realm" to complete an event report, "it is the nurses job". During interview with the Chief Nursing Executive (CNE) C on 2/15/18 at 9:16 AM, when C was asked if the facility had reported the incidents, C confirmed they had not completed form F-62447 Misconduct Incident Report to report to the Wisconsin Department of Health Services. During interview with Chief Medical Officer A on 2/15/18 at 1:15 PM, when A was asked if the facility had reported the incidents, A stated no.	A 309		
A 386	ORGANIZATION OF NURSING SERVICES CFR(s): 482.23(a) The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is	A 386	• **Corrective Action Measures:** **1.** All corrective action measures articulated in Plan # 1 and Plan # 2 or elsewhere within this Plan # 3 are incorporated herein to the extent relevant - many of the plan elements described above directly impact nursing services and set forth plans to address this deficiency.	

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A 386	Continued From page 34 responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital. This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to immediately immediately adhere to their policies and procedures to delineate their administrative responsibilities for patient care in 5 of 6 patients (#4, #3, #6, #1 and #2). (Patient census 2/15/18 was 16, 2/16/18 was 17 and 2/17/18 was 18). Findings include: Review of policy titled Caregiver Misconduct (Reporting and Investigating)" Policy # HR-48 dated 8/05/16 revealed Policy Statement Meriter will comply with all investigation and reporting requirements of ... injuries of unknown source of its patients... 4.0 "Injury of unknown source" is an injury where both of the following conditions are met: The source of the injury was not observed by any person or the source of the injury cannot be explained by the patient; and, The injury is suspicious because of the extent of the injury or the location of the injury... or the number of injuries observed at one particular point in time or the incidence of injuries over time... 2.0 Incident Investigation "will investigate all claims or concerns... in a timely manner." Review of policy titled "Child at Risk Abuse and Neglect" Policy #57 dated January 2010 Policy Statement revealed "Meriter Hospital will take actions to protect the "abused ..." from the possibility of further abuse... 9. All hospital staff shall formally write up their observations	A 386	**2.** The Patient Safety Officer will develop a presentation to Nursing Managers and Unit Directors for the April 19, 2018 Manager/ Director forum that will contain targeted information on the incident reporting process and system, and their accountability for educating caregivers in their department or unit to understand and comply with the revised policies as described herein. The President / CEO of Meriter also highlighted the importance of policy compliance (related to incident reporting) in her "Top 5" priorities presented at the March 15, 2018 Manager/ Director forum. **Task Owner:** Patient Safety Officer, President/ CEO **3.** The job descriptions for nurse managers and Chief Nursing Executive will be revised to explicitly reflect organizational responsibility for ensuring that nurses understand and follow policies, and specifically policies relating to identifying and reporting injuries of unknown source. **Task Owner:** Chief Nursing Executive **4.** The Chief Nursing Executive in conjunction with the Patient Safety Officer will develop reminders for incident reporting that will be distributed quarterly to all nursing staff by email. This messaging will ensure that all nursing staff understand that incident reporting of any injury of unknown source is mandatory and if they are uncomfortable submitting a report for any reason, they must promptly notify their nursing manager. **Task Owner:** Chief Nursing Executive	**March 15, 2018 and April 4, 2018** **April 4, 2018** **April 4, 2018**

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A 386	Continued From page 35 immediately... All hospital staff involved are responsible for filling out appropriate documentation in a timely manner." Review of Policy titled "Code of Conduct" dated 02/2015 revealed 11. Responsibilities of Leaders, 11.2 Standards for Patient care revealed "Leaders are called upon to create a culture with the organization to establish a working environment in which all Covered Persons are encouraged to raise concerns... to achieve the organization's goals in a safe...environment." Record review of Skin Tissue Event #115245 on Patient # 4 event date 4/12/17, entered 4/12/17 at 9 AM by Registered Nurse (RN) W, Severity Level " Intervention Needed". Follow-up Actions "Not Specified", Resolutions and Outcomes "Intervention Needed." No further intervention was documented. Record review of Skin Tissue Event #169891 on Patient #1 event date 02/02/18, entered 02/08/18 at 9 AM (6 days after event occurred) by RN HH, Severity Level "Intervention Needed". Resolutions and Outcomes "Intervention Needed." However, no additional documentation was found to investigate the injuries or the immediate intervention taken to protect patient #1 or report to authorities Record review of Safety Security Event #170100 on Patient #2 event date 2/03/18, entered 02/09/18 at 8 AM (6 days after event occurred) by RN P. No additional documentation was found to investigate the injuries or the immediate action taken to protect patient #2. Patient Safety Officer Y on 2/16/18 at 1:55 PM, Y	A 386	• **How Plan/ Action Will Prevent Recurrence:** The Chief Nursing Executive will be ultimately responsible for ensuring top-down compliance with all nursing responsibilities including the identification, investigation and reporting of potential abuse. The Chief Nursing Executive (or designee) will regularly review data that is generated in accordance with this plan (including but not limited to Patient Safety Committee data on incident reporting, performance improvement staff statistics regarding the follow-through on incident reports of injury of unknown source, chart review data identifying reports that should have been made based on injuries identified in the medical record, etc.) and will take active steps as necessary with nursing staff to address any identified deficiencies. Such steps may include discipline for failure to follow policies, additional education for nursing staff, or other strategies designed to address any systemic or individual concerns. • **How Compliance Will Be Monitored:** The Quality of Healthcare Committee will monitor the performance of the nursing staff in complying with incident reporting protocol including the performance of the Chief Nursing Executive in being accountable for nursing staff performance. Human Resources will assist the Chief Nursing Executive in evaluating and addressing the individual performance of employed nursing staff.	

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A 386	Continued From page 36 confirmed Event # 115245 on Patient #4 had no other follow-up. (b)(6), (b)(7)c Y on 2/16/18 at 1:55 PM, Y confirmed, Event #169891 on Patient #1, event date 2/02/18, was entered 2/08/18, and Event #170100 on Patient #2 Event date was 2/03/18 entered 2/09/18 (6 days later), there was no additional documentation available on these events (#169891 and #170100) (6 days after the injuries were identified). An interview was conducted with Registered Nurse P on 2/16/18 at 1:26 PM, RN P stated s/he was so concerned about patient #1 and #2 injuries s/he sent an e-mail to Nurse Manager D and Assistant Nurse Manager T on the evening of 2/03/18 to notify them of her/his concerns. On Monday 2/05/18 s/he "made sure" Assistant Nurse Manager T had the pictures and voiced her/his concerns. RN P stated physicians "took a wait and watch position." Interview on 2/15/18 at 9:16 AM with CNE C, C stated the facility was aware of the Wisconsin Statues 48.981 (2) and that they were mandated reporters. Interview on 2/16/18 at 2:12 PM with (b)(6), (b)(7)c (b)(6), (b)(7)c B, B confirmed there were no other nursing or physician policies to direct reporting of patient events when patients had injuries of unknown origin.	A 386		

ATTACHMENT 1

A OOO

In designing this Plan # 3, Meriter's strategy is to implement systems that will reliably identify suspicious injuries. Staff may identify an injury as "suspicious" (according to the Wisconsin Caregiver Program Manual) due to: (1) the extent of the injury; (2) the location of the injury - e.g., the injury is located in an area not generally vulnerable to trauma; (3) the number of injuries observed at one point in time; or (4) the incidence of injuries over time. Staff will use hospital resources to distinguish suspicious injuries from injuries (such as bruises/ markings) that might have other explanations such as heel sticks, bruises caused by the birth process or by other disease processes. It would be problematic to assume that every single bruise or mark is an indication of abuse because, for example, it would subject patients to follow-up testing that would often be unnecessary or potentially harmful (e.g., repeated exposure to radiation, especially in children). However, in striking this balance, Meriter has erred on the side of over-identifying abuse.

To this end, Meriter has implemented and will further implement processes for identifying, investigating, reporting and signs of abuse and monitoring/ tracking systems for those processes. Meriter is committed to taking all steps necessary to ensure a culture of safety.

Please note that Plan # 1 and Plan # 2 are incorporated herein by reference, as some of the aspects of that plan are relevant to the deficiencies cited, as further explained below.

ATTACHMENT 2

A-0144

- **How Compliance Will Be Monitored:**

    1. Meriter's Patient Safety Committee will examine aggregate data compiled from the incident reporting system to identify trends and patterns, including but not limited to staff management of injuries of unknown source. The Patient Safety Committee will work with others as necessary to review and report internally on whether policies were followed, and will identify instances where policy was not followed, and flag the appropriate managers for follow-up.

    2. All incidents submitted through the portal will automatically notify the appropriate supervisors and managers, and will also automatically notify the performance improvement department. Performance improvement staff will ensure that every incident receives appropriate and timely attention, which may include referral for a root cause analysis or referral to the appropriate peer review body, which will conduct chart review and other analysis as appropriate, and will report any concerns to the appropriate managers. Any concerns relating to a member of the medical staff will be referred to Chief Medical Officer (or designee) for follow-up.

    3. All staff will receive a quiz on content of the phase two education after training.

    4. The Patient Care Regulatory Compliance Committee (PCRCC) implements quarterly mock surveys for various hospital staff. The focus/ content of each quarter's survey varies. There is a time limit for completing each survey and the results are communicated back to the PCRCC, which then coordinates a presentation on the issue to patient care leadership from hospital departments. While the issues triggering the survey will not be covered every quarter, they will be the subject of mock surveys from time to time including the second quarter of 2018.

    5. The Performance Improvement Department will conduct quarterly chart reviews of a randomly selected sample of NICU patients using key word search functionality. The focus of the chart review will be to identify notes that indicate injury of unknown source and cross-check whether an incident report was submitted in connection with those events. Results will be reported to the Patient Safety Committee and in turn communicated to the Quality of Healthcare Committee.

    6. A log will be maintained of all unannounced rounds and NICU leadership will follow up on any items of concern documented in the log.

ATTACHMENT 3

A-0273

6. The Patient Safety Committee will develop a process to provide for careful and reliable tracking of incident reporting containing injuries of unknown source. The tracking will allow the Patient Safety Program to determine compliance with the quality indicators established by the Quality of Healthcare Committee. The Patient Safety Committee will issue reports at least quarterly of incident reporting data and whether the reports are meeting established requirements. The reports will be reviewed by the Patient Safety Committee, the Quality of Healthcare Committee and the Director of Performance Improvement to specifically identify any action items or systemic changes needed to evaluate whether quality indicators are being met. Specifically, this process is designed to provide a systematic process for proper (internal and external) investigation and reporting of injuries of unknown source.

Task Owner: Patient Safety Officer
Date of Completion: April 4, 2018

7. The Patient Safety Officer will develop a protocol accomplishing the following process: Where an incident report alleges caregiver misconduct related to a physician, the Patient Safety Program staff will ensure that the matter is routed to the Chief Medical Officer (or designee) for appropriate follow-up, potentially including referral to peer review. For non-physicians, the matter will be referred to the appropriate director or manager of the department. If the individual caregiver is an employee of Meriter, the Patient Safety Program will also alert the Director of Employee and Labor Relations. Incident reports that are sentinel events will be routed to the Root Cause Analysis team.

Task Owner: Patient Safety Officer
Date of Completion: April 4, 2018

8. The Incident and Accident Reporting Policy and related flowchart will be revised to trigger consideration of submission of an incident report as soon as a potential incident is identified rather than after initial investigation has been completed.

Task Owner: Patient Safety Officer
Date of Completion: April 4, 2018

9. A mock survey will be developed to ensure compliance with all policies cited above, specifically relating to detection, investigation and reporting of injuries of unknown source, specifically including the appropriate use of the incident reporting system. This survey will be developed by the PCRCC as part of the quarterly survey process, and will be implemented for the second quarter of

2018. Survey results will be reported to the PCRCC, the Patient Safety Committee, and the monthly meeting of patient care leaders across the hospital. Ultimately, the recommendations will be reported to the Quality of Healthcare Committee for incorporation into the specific expectations for safety standards/ indicators of quality.

Task Owner: Chief Nursing Executive
Date of Completion: April 4, 2018

- **How Plan/ Action Will Prevent Recurrence:** The corrective actions constitute significant process changes which will increase accountability for ensuring that injuries of unknown source are properly and consistently identified, investigated and reported. The plan is designed to create a culture of top-down enforcement of quality and compliance by tasking the quality subcommittee of the Board of Directors with data collection and review to identify systemic opportunities for improvement, particularly with respect to in. The plan tasks the Patient Safety Committee with analysis and development of systems to track and address identified deficiencies in accordance with the indicators set by the Board's quality subcommittee. The plan creates a new process where each incident of suspected misconduct or an unexplained suspicious injury will have a process owner (from the performance improvement staff) who will track the incident from the time that the internal report is submitted to the actions by leadership to investigate and externally report (if applicable) as well as to ensure immediate protection of the patient who is the subject of the incident.

- **How Compliance Will Be Monitored:** The Director of Performance Improvement will assess the success of the Patient Safety Program initiatives described herein by reviewing incident reports identifying injuries of unknown source, as well as the documented follow-up, on a regular basis. The Patient Safety Committee will regularly review incident reporting data as identified elsewhere in this Plan and will develop specific plans for addressing any identified deficiencies. The Quality of Healthcare Committee will be ultimately responsible for reviewing all relevant data and adjusting quality/ safety indicators as necessary.

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A 000	INITIAL COMMENTS This report is the result of complaint investigation #WI00031795 conducted on 2/15/2018 through 2/19/2018 at UnityPoint Health Meriter Hospital using Medicare Conditions of Participation 42 CFR 482 for Hospitals. 42 CFR 482.13 Condition of Participation: Patient Rights NOT MET. 42 CFR 482.21 Condition of Participation: Quality Assessment and Performance Improvement Program NOT MET An Immediate Jeopardy (IJ) was determined on 2/19/18 at 10:35 AM regarding the facility's failure to develop and implement an effective policy to prevent, report,and thoroughly investigate suspected abuse related to injuries of unknown origin of patients in the Newborn Intensive Care Unit (NICU). The IJ began on 4/12/17 when the facility failed to protect and thoroughly investigate the first report of an injury of unknown origin for Patient #4, placing all patients in the NICU at risk for serious harm or injury. The facility's Chief Nursing Officer C and Director of Performance Improvement B were notified of the IJ on 2/19/18 at 2:44 PM. The IJ was not removed at the time of exit. On 2/28/2018 at 8:38 AM the plan of correction to abate the immediacy was approved. The IJ was removed on 3/01/18 at 1 PM at the time of exit on 3/01/18 after an onsite verification visit confirmed that the facility reviewed and revised policies and procedures to thoroughly investigate and immediately report suspected abuse related to injuries of unknown origin, educated all direct care staff and providers prior to the start of their next shift, and initiated a safety plan to protect patients in areas where infants	A 000	The submission of this Plan of Correction is not an admission of liability by UnityPoint Health-Meriter (Meriter). The submission of this Plan of Correction does not constitute an agreement by Meriter that the surveyor's facts, findings or conclusions are accurate, the findings constitute a deficiency, or that the scope and severity regarding any of the deficiencies are cited correctly. Meriter received an initial statement of deficiencies (SOD) from DQA on behalf of CMS on February 23, 2018. Meriter submitted a Plan of Correction (Plan # 1) in response to the first SOD, which was approved on February 28, 2018. Meriter received a second SOD on March 5, 2015 from DQA. A second Plan of Correction (Plan # 2) was submitted on March 15, 2018. Meriter received a third SOD from CMS on March 7, 2018. This Plan of Correction (Plan # 3) is submitted in response to the third SOD. As detailed in Plan # 1 and Plan # 2 (both summarized below), Meriter has and is committed to further developing mechanisms to promptly identify abuse and follow all legal requirements for investigating and reporting such abuse including protection of patients. In designing and implementing Plan # 3, with regard to injuries of unknown source (as defined by the Wisconsin Caregiver Program Manual), Meriter is implementing a strategy to implement quality assurance/ performance improvement measures, executive responsibility measures (both administration and medical staff) and nursing service organization measures all designed to protect patients, identify abuse and injuries of unknown source, appropriately investigate and report (internally and externally) and track whether the measures/ mechanisms are achieving these objectives. See Attachment 1 for additional comments.	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: CEO | (X6) DATE: 3-16-18

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.