RESTRICTED DELIVERY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Before the Iowa Department of Health and Human Services

IN THE MATTER OF:	Case Number: 000102-01-10
UnityPoint Health - St. Luke's Sioux City 2720 Stone Park Blvd Sioux City, IA 51104-3734 Facility Number: 000102	NOTICE OF PROPOSED ACTION **CITATION AND WARNING**

Pursuant to the provisions of Iowa Code Sections 17A.18, 147A.23 and Iowa Administrative Code (I.A.C.) 641—134.3(1) the Iowa Department of Health and Human Services is proposing to issue a **Citation and Warning** to the Trauma Care Facility identified above.

The Department may cite and warn a Trauma Care Facility when it finds that the facility has not operated in compliance with Iowa Code section 147A.23 and 641 IAC Chapter 134 including:

> *147A.23 (2)(c)Upon verification and the issuance of a certificate of verification, a hospital or emergency care facility agrees to maintain a level of commitment and resources sufficient to meet responsibilities and standards as required by the trauma care criteria established by rule under the subchapter.*
>
> *Failure of the trauma care facility to successfully meet criteria for the level of assigned trauma care facility categorization. 641 IAC 134.2(2) and 641 IAC 134.2(7)b*
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> *641 IAC 134.2(7) (j) Trauma care facilities shall be fully operational at their verified level upon the effective date specified on the certificate of verification. Trauma care facilities shall meet all requirements of Iowa Code section 147A.23 and these administrative rules.*
>
> *641 IAC 134.2 (3) Adoption by reference.*
> *a. …" Criteria specific to Level III trauma care facilities identified in the "Resources for Optimal Care of the Injured Patient 2014" (6th edition) published by the American College of Surgeons Committee on Trauma is incorporated and adopted by reference for Level III hospital and emergency care facility categorization criteria...*
> *b. " Resources for Optimal Care of the Injured Patient 2014" (6th edition) published by the American College of Surgeons Committee on Trauma is available through the Iowa Department of Public Health, Bureau of Emergency and Trauma Services (BETS), Lucas State Office Building, Des Moines, Iowa 50319-0075, or the BETS Web site (http://idph.iowa.gov/BETS/Trauma).*

The following resulted in issuance of this proposed action:

On April 5, 2021, the facility submitted the Self-Assessment Categorization Application (SACA). A virtual on-site verification was conducted by a Department Trauma Care Facility Verification team on May 24, 2021. During the May 24, 2021, verification survey, the following forty-seven deficiencies were noted on the verification Final Report dated June 30, 2021:

Criteria Deficiencies (CD**)** (2-1) concurrent Performance Improvement and Patient Safety (PIPS) program, (2-2) surgical commitment, (2-3) necessary human and physical resources (2-5) annual review of the general surgeons (2-8) surgeon response times, (2-17) trauma medical director (TMD) and trauma program manager (TPM) collaboration with guidance from the trauma peer review committee, (2-18) regularly held multidisciplinary trauma peer review committee meetings, (3-3) evaluation of over triage and under triage rates, (3-5) trauma surgeon input for diversion of the trauma center, (4-3) evaluation of transport activities and review through the PIPS process, (5-11) TMD performing annual assessments of trauma panel members, (5-18) PIPS review of non-surgical admissions that exceed 10 percent of total trauma admissions, (5-21) identification of injured patients, (6-8) general surgeon attendance requirements, (7-3) PIPS review of occasions when the physician leaves the emergency department to address in-house emergencies, (8-6) published back-up neurosurgeon schedule for neurosurgeons covering two centers, (8-9) neurosurgeon timeliness and appropriateness of care monitored through the PIPS process, (9-16) orthopedic liaison multidisciplinary trauma peer meeting attendance requirements, (11-37) interpretation between preliminary and final radiology reports monitored through the PIPS program, (11-53) surgeon serving as co-director for the intensive care unit (ICU), (11-54) a board- certified director or co-director of the ICU, (11-57) ICU admissions reviewed through the PIPS process, (11-58) trauma surgeon retains responsibility for ICU trauma patients, (11-59) trauma surgeon informed of therapeutic and management decisions of ICU trauma patients, (11-60) monitoring of timeliness of providers responded to the ICU, (11-69) notification to the trauma service of admitted or transferred trauma patients, (15-3) utilization of the trauma patient registry to support the PIPS program, (15-4) registry findings to identify injury prevention priorities, (15-7) trauma registrar education requirements, (15-9) registry staff requirements in relation to annual admitted trauma patients, (16-2) documentation of the PIPS program activities and continuous monitoring of PIPS activities, (16-3) PIPS program integrated with hospital quality and patient safety, (16-5) PIPS plan reviewed and updated at least annually, (16-6) mortalities are systematically reviewed, (16-7) continuous monitoring of over and under triage rates, (16-10) mechanisms in place to identify events for review, (16-11) validation of the identified event, (16-12) process to address trauma program operational events, (16-13) documentation of reviewed operational events, (16-14) mortality data, adverse events and problems trends reviewed at the multidisciplinary trauma peer review, (16-15) committee member attendance requirements, (16-16) multidisciplinary trauma peer review meeting minutes reviewed with general surgeons not in attendance, (16-17) systematic review during the multidisciplinary trauma peer review committee of mortalities, significant complications and process variances associated with unanticipated outcomes, (16-18) opportunities for improvement identified and appropriate corrective actions implemented, (16-19) documentation that identified opportunities result in minimal reoccurrence of similar adverse events, (18-1) organized approach to injury prevention, and (20-2) trauma panel surgeon is a member of the hospital’s disaster committee.

As a result of the May 24, 2021, verification survey, the Trauma Care Facility was placed on probation from July 1, 2021, to July 1, 2022.

A focused visit was conducted by the Department Trauma Care Facility Verification team on April 18, 2022. The facility had resolved forty-four of the forty-seven criteria deficiencies. Due to the efforts made by the facility in the first nine months of the probationary period the facility was granted an extension of the probation period. The facility remained on probation until July 31, 2023. At this time the facility had resolved the remining three criteria and a verification certificated was issued for August 3, 2023, to July 1, 2024.

On March 1, 2024, the facility submitted the Self-Assessment Categorization Application. An on-site verification was conducted by a Department Trauma Care Facility Verification team on July 2, 2024. During the July 2, 2024, verification survey, the following twenty-six deficiencies were noted on the verification Final Report dated October 1, 2024:

Criteria (2-5) Through the trauma PIPS program and hospital policy, the trauma director must have responsibility and authority for determining each general surgeon's ability to participate on the trauma panel based on an annual review.
Criteria (2-18) - Level III trauma center the multidisciplinary trauma peer review committee must meet regularly, with required attendance of medical staff active in trauma resuscitation, to review systemic and care provider issues, as well as proposed improvement to the care of the injured.
Criteria (5-11) - In addition, the TMD must perform an annual assessment of the trauma panel providers in the form of Ongoing Professional Practice Evaluation (OPPE) and Focused Professional Practice Evaluation (FPPE) when indicated by findings of the PIPS process.
Criteria (6-8) - Each member of the group of general surgeons must attend at least 50 percent of the multidisciplinary trauma peer review committee meetings.
Criteria (11-86) - Advanced practitioners who participate in the initial evaluation of trauma patients must demonstrate current verification as an Advanced Trauma Life Support® provider.
Criteria (11-87) – The trauma program must also demonstrate appropriate orientation, credentialing processes and skill maintenance for advanced practitioners, as witnessed by an annual review by the trauma medical director.
Criteria (15-5) - All trauma centers must use a risk adjusted benchmarking system to measure performance and outcomes.
Criteria 16(2-17) - The processes of event identification and levels of review must result in the development of corrective action plans, and methods of monitoring, reevaluation, and benchmarking must be present.
Criteria (16-2) - Problem resolution, outcome improvements, and assurance of safety ("loop closure") must be readily identifiable through methods of monitoring, reevaluation, benchmarking, and documentation.
Criteria 16 (2-18) - Peer review must occur at regular intervals to ensure that the volume of cases is reviewed in a timely fashion.
Criteria 16(15-3) - The trauma PIPS program must be supported by a registry and a reliable method of concurrent data collection that consistently obtains information necessary to identify opportunities for improvement.
Criteria 16(15-5) - All trauma centers must use a risk adjusted benchmarking system to measure performance and outcomes.

Criteria (16-4) - To achieve this goal, a trauma program must use clinical practice guidelines, protocols, and algorithms derived from evidenced-based validated resources.
Criteria (16-6) - Mortality Review. All trauma-related mortalities must be systematically reviewed and those mortalities with opportunities for improvement identified for peer review.
Criteria 16 - Trauma center diversion-bypass hours must be routinely monitored, documented, and reported, including the reason for initiating the diversion policy, and must not exceed 5 percent.
Criteria (16-10) – Sufficient mechanisms must be available to identify events for review by the trauma PIPS program.
Criteria (16-11) - Once an event is identified, the trauma PIPS program must be able to verify and validate that event.
Criteria (16-13) - Documentation (minutes) reflects the review of operational events and, when appropriate, the analysis and proposed corrective actions.
Criteria (16-14) - Mortality data, adverse events and problem trends, and selected cases involving multiple specialties must undergo multidisciplinary trauma peer review.
Criteria 16 - The effort [multidisciplinary peer review] may be accomplished in a variety of formats but must involve the participation and leadership of the trauma medical director, the group of general surgeons on the call panel, and the liaisons from emergency medicine, orthopedics, neurosurgery, anesthesia, critical care, and radiology.
Criteria (16-15) – Each member of the committee must attend at least 50 percent of all multidisciplinary trauma peer review committee meetings
Criteria (16-16) - When these general surgeons cannot attend the multidisciplinary trauma peer review meeting, the trauma medical director must ensure that they receive and acknowledge the receipt of critical information generated at the multidisciplinary peer review meeting to close the loop
Criteria (16-17) - The multidisciplinary trauma peer review committee must systematically review mortalities, significant complications, and process variances associated with unanticipated outcomes and determine opportunities for improvement.
Criteria (16-18) - When an opportunity for improvement is identified, appropriate corrective actions to mitigate or prevent similar future adverse events must be developed, implemented, and clearly documented by the trauma PIPS program
Criteria (16-19) - An effective performance improvement program demonstrates through clear documentation that identified opportunities for improvement lead to specific interventions that result in an alteration in conditions such that similar adverse events are less likely to occur
Criteria 17 - The successful completion of the ATLS® course, at least once, is required in all levels of trauma centers for all general surgeons, emergency medicine physicians, and midlevel providers on the trauma team.

The facility the remains noncompliant from the May 24, 2021 site visit, with fifteen criteria cited on the October 1, 2024, Final Report. The criteria deficiencies are: (2-5) annual review of the general surgeons, (2-18) regularly held multidisciplinary trauma peer review committee meetings, (5-11) TMD performing annual assessments of trauma panel members, (6-8) general surgeon attendance requirements, (16-2) documentation of the PIPS program activities and continuous monitoring of PIPS activities, (16-6) mortalities are systematically reviewed, (16-10) mechanisms in place to identify events for review, (16-11) validation of the identified event, (16-13) documentation of reviewed operational events, (16-14) mortality data, adverse events and

problems trends reviewed at the multidisciplinary trauma peer review, (16-15) committee member attendance requirements, (16-16) multidisciplinary trauma peer review meeting minutes reviewed with general surgeons not in attendance, (16-17) systematic review during the multidisciplinary trauma peer review committee of mortalities, significant complications and process variances associated with unanticipated outcomes, (16-18) opportunities for improvement identified and appropriate corrective actions implemented, and (16-19) documentation that identified opportunities result in minimal reoccurrence of similar adverse events.

The facility is hereby **CITED** for failing to meet the above criteria of Level III trauma care facility categorization. The facility is **WARNED** that failing to successfully meet the Level III trauma criterion resolution listed for the criterion in a one-year period from the date of this final agency action, may result in further disciplinary action including suspension or revocation of the Trauma Care Facility Designation.

You have the right to request a hearing concerning this notice of disciplinary action. A request for a hearing must be submitted in writing to the Department by certified mail, return receipt requested, within twenty (20) days of receipt of this Notice of Proposed Action. The written request must be submitted to the Iowa Department of Health and Human Services, Bureau of Emergency Medical and Trauma Services, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319. If the request is made within the twenty (20) daytime limit, the proposed action is suspended pending the outcome of the hearing. Prior to, or at the hearing, the Department may rescind the notice upon satisfaction that the reason for the action has been or will be removed.

If no request for a hearing is received within the twenty (20) daytime period, the disciplinary action proposed herein shall become effective and shall be final agency action.

Margot McComas

September 30, 2024

Margot McComas, Bureau Chief
Iowa Department of Health and Human Services
Bureau of Emergency Medical and Trauma Services

Date