RESTRICTED DELIVERY CERTIFIED MAIL RETURN RECEIPT REQUESTED

Before the Iowa Department of Health and Human Services

IN THE MATTER OF

Broadlawns Medical Center 1801 Hickman Road Des Moines, IA 50314-1597 Facility Number: 000011 Case: 000011-14-12

NOTICE OF PROPOSED ACTION

CITATION AND WARNING

Pursuant to the provisions of Iowa Code Sections 17A.18 and 147A.23, and Iowa Administrative Code (I.A.C.) 641—134.3, 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 Trauma Care 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

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 IV 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 IV 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 events have resulted in the issuance of this proposed action:

On June 4, 2023 Broadlawns Medical Center was issued a Letter of Warning for failure to comply with criteria for Level IV trauma care facility categorization, as evidenced by criteria deficiencies (CD) related to active and engaged participants in the trauma system (CD 1-1, 1-2), PIPS process, regional participation, pre-hospital training (CD 2-1, 2-8, 2-16, 2-17, 2-18, 2-21), EMS training with PIPS integration (CD 3-1), PIPS review of transfers (CD 4-3), trauma team response times and evaluation of activations (CD 5-15, 5-16), team response documentation (CD Ch. 6), inclusive trauma system activation, transfer review in PIPS process [CD 13(4-3), 13(15-1), 13(16-10)], meaningful use of the trauma registry, injury prevention (CD 15-1, 15-3, 15-4, 15-6, 15-10), PIPS program [CD 16(2-17), 16(2-18), 16(15-1), 16(15-3), 16-10, 16-11], injury prevention (CD 18-1), and disaster planning (CD 20-4).

On November 30, 2023, Broadlawns Medical Center resolved criteria deficiencies (2-16) and (20-4) during a focused virtual review.

The following criteria deficiencies remain unresolved:

Criteria (1-1) - The individual trauma centers and their health care providers are essential system resources that must be active and engaged participants.

Deficiency – The trauma center and the health care providers do not participate in the local, regional or state promotion of the inclusive trauma system. The new TPM is not involved at the state or service area level.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (1-2) - They must function in a way that pushes trauma center-based standardization, integration, and PIPS out to the region while engaging in inclusive trauma system planning and development.

Deficiency – The trauma center has not demonstrated engagement in standardization, integration, and PIPS out to the region while engaging in inclusive trauma system planning and development.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (2-1) - This trauma center must have an integrated, concurrent performance improvement and patient safety (PIPS) program to ensure optimal care and continuous improvement in care.

Deficiency – This trauma center has not demonstrated an integrated, concurrent PIPS program to ensure optimal care and continuous improvement in care.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the

State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (2 - 8) - For Level IV trauma centers, it is expected that the physician (if available) or midlevel provider will be in the emergency department on patient arrival, with adequate notification from the field. The maximum acceptable response time is 30 minutes for the highest-level activation, tracked from patient arrival. The PIPS program must demonstrate that the physician's (if available) or midlevel provider's presence is complying at least 80 percent of the time.

Deficiency – The program is unable to demonstrate the provider's presence at the bedside within 30 minutes of patient arrival for the highest-level activations, is complying at least 80 percent of the time.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (2-17) – For Level IV trauma centers a trauma medical director and trauma program manager knowledgeable and involved in trauma care must work together with guidance from the trauma peer review committee to identify events, develop corrective action plans, and ensure methods of monitoring, reevaluation, and benchmarking.

Deficiency – The trauma center does not consistently demonstrate event identification, development of corrective action plans, ensuring methods of monitoring, reevaluation, and benchmarking.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (2-18) – Level IV trauma centers 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 propose improvements to the care of the injured.

Deficiency – The trauma center does not have a multidisciplinary trauma peer review committee that has been meeting regularly, to review systemic and care provider issues, as well as propose improvements to the care of the injured.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (2 - 21) - The Level IV trauma center must also be the local trauma authority and assume the responsibility for providing training for prehospital and hospital-based providers. **Deficiency** – The trauma center does not provide or participate in training for pre-hospital providers.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (3-1) - The trauma program must participate in the training of prehospital personnel, the development and improvement of prehospital care protocols, and the performance improvement and patient safety programs.

Deficiency – The hospital does not integrate EMS into the trauma quality improvement process. **Resolution** – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (4-3) – A very important aspect of inter-hospital transfer is an effective PIPS program that includes evaluating transport activities. Perform a PIPS review of all transfers. **Deficiency** – The hospital does not review all trauma transfers through the PIPS process. **Resolution** - Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (5-15) - In Level IV trauma centers the team must be fully assembled within 30 minutes.

Deficiency – The trauma center did not demonstrate that the trauma team is fully assembled within 30 minutes of patient arrival.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (5-16) – Other potential criteria for trauma team activation that have been determined by the trauma program to be included in the various levels of trauma activation must be evaluated on an ongoing basis in the PIPS process to determine their positive predictive value in identifying patients who require the resources of the full trauma team.

Deficiency – The criteria for trauma team activation at various levels of trauma activation are not evaluated on an ongoing basis in the PIPS process to determine their positive predictive value in identifying patients who require the resources of the full trauma team.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (6) - For Level IV trauma centers, the maximum acceptable response time is 30 minutes. Response time will be tracked from patient arrival rather than from notification or

activation. An 80 percent attendance threshold must be met for the highest-level activations (CD 2-8).

Deficiency – The program is unable to demonstrate the provider's presence at the bedside within 30 minutes of patient arrival, for the highest-level activations, is complying at least 80 percent of the time.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria 13 (4-3) – All transfers must be evaluated as part of the receiving trauma center's performance improvement and patient safety (PIPS) process (CD 4 - 3), and feedback should be provided to the transferring center.

Deficiency – The hospital does not review all trauma transfers through the PIPS process. Feedback is not formally provided to the multidisciplinary committee.

Resolution - Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria 13 (15-1) – The foundation for evaluation of a trauma system is the establishment and maintenance of a trauma registry (CD 15-1).

Deficiency – The trauma center has not demonstrated consistent data collection and analysis during the reporting period.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria 13(16-10) - Issues that must be reviewed will revolve predominately around (1) system and process issues such as documentation and communication; (2) clinical care, including identification and treatment of immediate life-threatening injuries (ATLS®); and (3) transfer decisions.

Deficiency – The trauma center has not demonstrated event identification, validation, or review of events through the PIPS process during the reporting year.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (15-1) – Trauma registry data must be collected and analyzed by every trauma center. **Deficiency** – The trauma center has not demonstrated consistent data collection and analysis during the reporting period.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the

State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (15-3) – The trauma registry is essential to the performance improvement and patient safety (PIPS) program and must be used to support the PIPS process.

Deficiency – The trauma registry is not used to support the PIPS process.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (15-4) – Furthermore, these findings must be used to identify injury prevention priorities that are appropriate for local implementation.

Deficiency – The trauma registry findings are not used to identify injury prevention priorities that are appropriate for local implementation.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (15-6) - Trauma registries should be concurrent. At a minimum, 80 percent of cases must be entered within 60 days of discharge.

Deficiency – The benchmark of 80 percent of cases entered into the trauma registry within 60 days of discharge is not met by the trauma care facility.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (15-10) - Strategies for monitoring data validity are essential.

Deficiency – The trauma registry is not used to support the PIPS process. The trauma registry is imperative for data collection. The data must be validated to support the PIPS program. **Resolution** – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

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.

Deficiency – The trauma program has not demonstrated the presence of processes of event identification and levels of review resulting in the development of corrective actions plans, and methods of monitoring, reevaluation, and benchmarking.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the

State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria 16(2-18) – Peer review must occur at regular intervals to ensure that the volume of cases is reviewed in a timely fashion.

Deficiency – Peer review has not occurred at regular intervals to ensure that the volume of cases is reviewed in a timely fashion.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria 16(15-1) – The trauma center must demonstrate that all trauma patients can be identified for review.

Deficiency – The trauma center does not demonstrate that all trauma patients can be identified for review.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

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.

Deficiency – The trauma PIPS program is not supported by the registry and a reliable method of concurrent data collection that consistently obtains information necessary to identify opportunities for improvement.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (16-10) – Sufficient mechanisms must be available to identify events for review by the trauma PIPS program.

Deficiency – The trauma PIPS program has not demonstrated sufficient mechanisms to identify events for review.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (16-11) - Once an event is identified, the trauma PIPS program must be able to verify and validate that event.

Deficiency – The trauma PIPS program has not demonstrated a process for event verification and validation.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

Criteria (18-1) – Trauma centers must have an organized and effective approach to injury prevention and must prioritize those efforts based on local trauma registry and epidemiologic data.

Deficiency – The trauma center has not demonstrated an organized and effective approach to injury prevention that is prioritized by local trauma registry findings.

Resolution – Provide an electronic Plan of Correction within 15 business days of receiving the Focused Final Report from the November 30, 2023 virtual visit. This will be submitted to the State of Iowa Trauma System Coordinator. An additional focused visit will occur before April 1, 2024 to assure compliance with this criterion.

The facility is hereby **CITED** for failing to meet the above criteria of Level IV trauma care facility categorization. The facility is **WARNED** that failing to successfully meet the Level IV trauma criteria resolution listed for the above criteria by the subsequent focused review that will occur before April 1, 2024, 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) day time 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) day time period, the disciplinary action proposed herein shall become effective and shall be final agency action.

Margot McComas

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

December 14, 2023

Date