**Regional System Quality Improvement (QI) Program**

## I. PURPOSE

This policy establishes the process for ongoing evaluation and quality improvement of the Emergency Healthcare System geographically located in the Southeast Texas Regional Advisory Council's (SETRAC) Trauma Service Area.

## II. AUTHORITY

SETRAC is a regional advisory council that engages in certain system performance activities as required by 25 Tex. Admin. Code § 157.123 et seq. There are one or more committees recognized by Discloser's Bylaws (each, a "Recognized Committee", and collectively, the "Recognized Committees") that perform these system performance activities, and the records and proceedings of such Recognized Committees are confidential and not subject to disclosure pursuant to Tex. Health and Safety Code § 773.091 et seq. and Tex. Occ. Code § 160.007 et seq.

This policy shall cover all Board Recognized Committees of SETRAC. Members and invited guests are required to sign a Confidentiality Agreement, which is maintained on file at SETRAC, as a condition of attendance (see Attachment A).

## III. PROCESS

A. Ongoing Performance Review

SETRAC and our stakeholders shall conduct ongoing performance evaluation through quality indicators developed by each Committee Chair of the Board Recognized Committees, to ensure continued compliance with regional guidelines. QI indicators from the following Emergency Healthcare System Committees may include:

a. Prehospital care and transport

b. Trauma Center alerts and destination

c. Stoke alerts and destination

d. STEMI alerts and destination

e. Out of region transfers

f. Patient care based on injury/illness and demographics

g. Patient mortality

h. Maternal death

Results of the Emergency Healthcare System evaluation shall be made available to system participants.

B. Case Review

Any member of SETRAC in good standing, in accordance with the definition described in the SETRAC Bylaws, may file a written request for a case review of regional guideline compliance at any time. The review may include chart audit, patient data review, and reviews of other records and documents. Case Review meetings and records are confidential and protected, and not subject to disclosure pursuant to Tex. Health and Safety Code § 773.091 et seq. and Tex. Occ. Code § 160.007 et seq.

Case Review may be requested for any of the following reasons:

1. Provide advisory information to the EMS agencies and hospital systems related to issues and policies that could alter regional guidelines
2. Monitor processes and outcomes of patient care related to current regional guidelines
3. Presenting opportunities for analysis of data and information of scientific value for studies and strategic planning of the emergency healthcare system
4. Provide educational forums for improved patient care.
5. Periodic mortality and morbidity case reviews
6. Other cases may also be reviewed that are regarded as having exceptional educational or scientific benefit.

All requests for case review will be submitted in writing to the SETRAC CEO and presented to the Medical Directors Committee for consideration.

C. Medical Directors Committee

1. A primary objective of the Medical Directors Committee is to provide the Regional Emergency Healthcare System with a continuous effort to measure, evaluate, and improve both the processes and the outcomes of the system.

2. The Medical Director Committee is comprised of the dedicated Medical Director for each recognized Board Committee. Each Medical Director serves in the advisory role to their respective Board Committee, as well as serves on the Clinical Advisory Committee of the Regional Healthcare Preparedness Coalition.

3. Referral to the Medical Director Committee:

a. Referring Agency/Facility will complete the Request for Case Review Form (Attachment B), providing enough information for the Committee to make a determination. Referring requestor should provide contact information if the Committee requires additional information or has questions. Case Review Form should be submitted to the SETRAC CEO.

b. SETRAC CEO will notify the Medical Director Committee of request and coordinate with the Committee to schedule a date for review within 30 days of receipt of the request.

c. If the request is denied Case Review, the SETRAC CEO will provide the feedback from the Medical Director Committee to the requestor.

d. If the request is approved to move forward for review, the Medical Director associated with the concern (ie: trauma, stroke, EMS) will lead the review and, working with the other pertinent Medical Directors, identify 3 members of their respective committees to serve on the Case Review panel.

e. The Lead Medical Director of the Case Review panel will formulate a response to the requestor based on the finding of the Case Review panel.

e. All members serving on the Case Review panel must sign the SETRAC Confidentiality Agreement prior to beginning the review. Signed Confidentiality Agreements will be turned in to the SETRAC CEO and retained in accordance with policy. Any records or PHI received by the Case Review panel will be returned to the originator at the conclusion of the review.

Attachment A:

**CONFIDENTIALITY AGREEMENT**

This Confidentiality Agreement (this "Agreement"), effective as of _____, 2022 (the "Effective Date") is entered into by and between Southeast Texas Regional Advisory Council ("Discloser"), and _____ ("Recipient").

**RECITALS**

Discloser is a regional advisory council that engages in certain system performance activities as required by 25 Tex. Admin. Code § 157.123 et seq. There are one or more committees recognized by Discloser's Bylaws (each, a "Recognized Committee", and collectively, the "Recognized Committees") that perform these system performance activities, and the records and proceedings of such Recognized Committees are confidential and not subject to disclosure pursuant to Tex. Health and Safety Code § 773.091 et seq. and Tex. Occ. Code § 160.007 et seq.

Recipient directly or indirectly provides assistance to the Recognized Committees. Due to this, Recipient will receive certain information, including Protected Health Information ("PHI"), from Discloser, for the purpose of assisting Discloser with its system performance improvement activities (the "Purpose").

The HIPAA Rules require Discloser to protect and secure Protected Health Information and to ensure that others with whom it may share PHI also comply with the HIPAA Rules for protecting and securing PHI.

NOW THEREFORE, the parties agree as follows.

**DEFINITIONS**

All capitalized terms not defined below shall have the same meaning as defined in (i) the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, (ii) the Privacy, Security, Breach Notification and Enforcement Regulations set forth at 45 C.F.R. Parts 160 and 164, and (iii) the Health Information Technology for Economic and Clinical Health Act and its implementing regulations (collectively, the "HIPAA Rules"), which definitions are incorporated herein by reference. In the event of any inconsistency between the definitions set forth in this Agreement and the HIPAA Rules, the definitions in the HIPAA Rules shall control.

**1. OBLIGATIONS AND ACTIVITIES OF RECIPIENT**

**1.1 General Limitation on Use.** Recipient agrees not to use or disclose PHI except as permitted or required by this Agreement, the Purpose, or as Required by Law (the "Permitted Use").

**1.2 Appropriate Safeguards.** Recipient agrees to use appropriate safeguards and comply with the applicable requirements of the HIPAA Rules, including 45 C.F.R. Subpart C with respect to electronic Protected Health Information ("ePHI") and 45 C.F.R. Subpart E with respect to all PHI. This shall include, without limitation, using appropriate Security Measures and developing, implementing, maintaining and using appropriate and reasonable Administrative, Physical, and Technical Safeguards to insure the Integrity, Confidentiality and Availability of, and to prevent non-permitted uses and disclosures of PHI. Recipient acknowledges and agrees that it will implement and document its Security Measures and will comply with 45 C.F.R. §§ 164.306 (Security Standards), 164.308 (Administrative Safeguards), 164.310 (Physical Safeguards), 164.312 (Technical Safeguards), 164.314 (Organizational Safeguards), and 164.316 (Policy and Procedures and documentation requirements), and all other applicable requirements of the HIPAA Rules.

**1.3 Minimum Necessary.** Recipient shall only request, use and disclose the minimum amount of PHI necessary to accomplish the Permitted Use in accordance with the minimum necessary policies and procedures of Discloser and the HIPAA Rules.

**1.4 Mitigation of Harm.** Recipient agrees to take prompt action to mitigate, to the extent practicable, any harmful effect that is known to Recipient of any access, use, disclosure, modification or destruction of PHI by Recipient, its agents or Subcontractors in violation of the requirements of this Agreement.

**1.5 Report of Breach, Security Incident and Unauthorized Use or Disclosure of PHI.** Recipient agrees to (a) promptly investigate and notify Discloser of any Breach, Security Incident or unauthorized access, use, disclosure, modification or destruction of PHI of which Recipient discovers that is in violation of the requirements of this Agreement or the HIPAA Rules, (b) to provide Discloser or its designee such information as may be reasonably requested by Discloser to investigate the violation, and (c) to reasonably cooperate with Discloser in investigating and resolving the violation and complying with the Breach Notification Regulations. Notification of such Breach, Security Incident or unauthorized use, disclosure, modification or destruction of PHI must be made to Discloser without unreasonable delay following Discovery.

Recipient agrees to provide a report in writing to Discloser which shall, to the extent known, include the following:

(i) A brief description of what happened, including the date of any Breach, Security Incident or unauthorized access, use, disclosure, modification or destruction, and, if known, the date of Discovery, the number of individuals affected, the time period involved, and the nature and extent of any harm resulting from the violation;

(ii) A description of the type(s) of PHI and Identifiers involved (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, and other types of information were involved);

(iii) Information regarding whether and to what extent the PHI was Unsecured PHI, Encrypted, or was rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary;

(iv) A description of the manner in which the PHI could be identified or, if unknown, how and whether the PHI could be re-identified;

(v) To the extent known, the name of each Individual whose PHI has been, or is reasonably believed to have been accessed, used, disclosed, modified or destroyed;

(vi) To the extent known, the name of the unauthorized person and entity who used the PHI or to whom the disclosure was made;

(vii) To the extent known, whether the unauthorized person or entity is another covered entity, business associate, employee of a Recipient, Subcontractor or entity affiliated with Recipient;

(viii) Whether any opportunity existed for an unauthorized person to acquire, view, transfer or otherwise compromise the PHI;

(ix) Whether the PHI was actually acquired, viewed, transferred or otherwise compromised by an unauthorized person;

(x) Any steps Individuals should take to protect themselves from potential harm resulting from the unauthorized access, use, disclosure, modification or destruction of PHI; and

(xi) A description of what the Recipient is doing to investigate, mitigate harm to Individuals, and protect against any further unauthorized access, use, disclosure, modification or destruction of PHI.

**1.6 Agreements with Subcontractors.** Recipient shall require any Subcontractor that creates, receives, maintains, or transmits PHI on behalf of the Recipient or Discloser to enter into in an enforceable agreement requiring that the Subcontractor agree to the same restrictions, conditions and requirement that apply to Recipient with respect to PHI. If Recipient becomes aware of a pattern of activity or practice of a Subcontractor that constitutes a material breach of their written agreement, Recipient shall take reasonable steps to cure the breach or end the violation, as applicable, and if such steps are unsuccessful, terminate the contract.

**1.7 Compliance with Discloser's Obligations.** To the extent Recipient carries out any obligations of Discloser under Subpart E of 45 C.F.R. Part 164, it must comply with the requirements of the Privacy Regulations that apply to Discloser in carrying out such obligations.

**1.8 Notification of Request for PHI.** To the extent permitted by law, Recipient agrees that if it has a legal obligation to disclose any PHI, it will notify Discloser as soon as reasonably practicable after it learns of such obligation, if possible sufficiently in advance of the proposed release date such that the rights of Discloser and the Individual to whom the PHI relates will not be prejudiced. If Discloser or the Individual objects to the release of such PHI, Recipient will allow Discloser and/or the Individual to exercise any legal rights or remedies Discloser and/or the Individual might have to object to the release of the PHI, and Recipient agrees to provide such assistance as Discloser or the Individual may reasonably request in connection therewith.

**1.9 Additional Obligations.**

(i) Recipient agrees to participate in all trainings that Discloser provides related to protecting and safeguarding the privacy and security of Protected Health Information and any other confidential or proprietary information.

(ii) Recipient agrees to safeguard and to not disclose any confidential or proprietary information that Recipient receives from Discloser including, without limitation, any information of any kind that Recipient receives related to the Purpose.

(iii) Recipient agrees to contact the SETRAC CEO via phone at (281) 822-4450 or via email at lori.upton@setrac.org regarding any questions that Recipient has pertaining to confidentiality issues or Recipient's obligations pursuant to this Agreement.

## 2. TERM AND TERMINATION

**2.1 Term.** The term of this Agreement shall be effective as of the Effective Date and shall terminate after the exercise of any of the termination provisions set forth below.

**2.2 Termination by Discloser.** Discloser may terminate this Agreement if Discloser makes the determination that Recipient has breached a material term of this Agreement and Recipient does not cure the breach or end the violation within the time specified by Discloser in writing, not to exceed thirty (30) days.

**2.3 Termination by Mutual Agreement.** The parties may terminate this Agreement by mutual agreement.

**2.4 Effect of Termination.** Upon termination of this Agreement for any reason, Recipient shall (a) return to Discloser (or, if agreed by Discloser, destroy) all PHI received from Discloser, or created, maintained or received by Recipient or any Subcontractor or agent of Recipient on behalf of Discloser, that Recipient or its Subcontractors or agents maintain in any form and (b) not retain any copies of the PHI.

## 3. MISCELLANEOUS

**3.1 Survival.** The respective rights and obligations of each party under this Agreement shall survive the termination of this Agreement.

**3.2 Interpretation.** Any ambiguity in this Agreement shall be resolved in favor of a meaning that permits Discloser and Recipient to comply with the applicable requirements of the HIPAA Rules and related statutory provisions and regulations.

**3.3 Notice**. All notices, requests, demands and other communications required or permitted to be given or made under this Agreement shall be delivered to the addresses set forth under the signature pages.

**3.4 Assignment.** No party may assign or transfer any rights or obligations under this Agreement to a third party without the other party' written consent.

**3.5 Choice of Law.** This Agreement shall be governed and construed by applicable federal law and by the laws of the State of Texas.

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**IN WITNESS WHEREOF**, the parties have caused this Agreement to be duly executed as of the date first above written.

| **Disclosure** | | **Recipient** | |
|---|---|---|---|
| Southeast Texas Regional Advisory Council | | | |
| By: | _____ | By: | _____ |
| Name: | _____ | Name: | _____ |
| Title: | _____ | Title: | _____ |
| Address: | _____ | Address: | _____ |

Attachment B

**Stakeholder Request for Case Review**

Pursuant to Tex. Health and Safety Code § 773.091 et seq. and Tex. Occ. Code § 160.007 et seq,
I, _____ (requestor), am requesting a formal case review of
_____
_____
_____(provide brief information on issue for review, dates, parties involved, outcomes – no PHI) based on the following designated reason: (mark all that apply)

_____Provide advisory information to the EMS agencies and hospital systems related to issues and policies that could alter regional guidelines

_____Monitor processes and outcomes of patient care related to current regional guidelines

_____Presenting opportunities for analysis of data and information of scientific value for studies and strategic planning of the emergency healthcare system

_____Provide educational forums for improved patient care.

_____Periodic mortality and morbidity case reviews

_____Other cases may also be reviewed that are regarded as having exceptional educational or scientific benefit.

The following SETRAC Board Committees should review the request and participate in the Case Review:

_____Trauma _____Cardiac

_____EMS _____Perinatal/Maternal

_____Stroke _____Pediatrics

Submitted by: _____ Agency: _____

Contact Number: _____ Email: _____

_____ Date: _____

Signature

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**For Medical Director Committee Use Only – Received:** _____date

The following request is ☐ approved ☐ denied

_____ _____

Signature Date