Contemporary Emergency Medical Treatment and Labor Act (EMTALA) Clinical Issues Involving Pregnant Patients

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Objectives:

- To describe several contemporary challenges involving the care of pregnant individuals who present to a hospital emergency department (ED) seeking evaluation, as informed by cases where there have been EMTALA citations.
- To summarize the clinical patterns and issues common to these types of citations, as well as the common hospital approaches to their corrective action plans to regain compliance.

Background:
In 1986, Congress enacted the Emergency Medical Treatment & Labor Act (EMTALA) to ensure public access to emergency services regardless of a patient's ability to pay. EMTALA, and its implementing regulations, established the obligation for Medicare participating hospitals to offer—and the rights of individuals to receive—an appropriate medical screening examination (MSE) by qualified medical personnel (QMP) and, if necessary, stabilizing treatment for Emergency Medical Conditions (EMCs).[1] EMTALA obligations extend to all patients presenting to Medicare-participating hospitals with dedicated emergency departments (EDs). Many ambulatory departments in hospitals that routinely provide care for EMCs on an urgent unscheduled basis are considered dedicated EDs under EMTALA and must comply with requirements of the law.[2]

EMTALA is actively enforced through a bifurcated process by Centers for Medicare & Medicaid Services (CMS) and Department of Health and Human Services Office of Inspector General (HHS-OIG). Hospitals in violation of EMTALA may receive a deficiency citation from CMS that serves as notice that they are not in compliance with their Medicare provider agreement and, therefore, their Medicare provider agreements will be terminated if the facility fails to resolve the compliance issues by submitting an acceptable plan of corrective action. Prior work has demonstrated that the vast majority of EMTALA deficiency citations are resolved via corrective actions, with terminations of Medicare provider agreements occurring rarely.[3] Additionally, HHS-OIG can impose civil monetary penalties for EMTALA violations.

Studies of EMTALA events spanning a period between 2002–2018 demonstrate that approximately one in seven CMS EMTALA citation events, as well as one in six HHS-OIG civil monetary penalties, appear to be related to obstetric emergencies.[4,5] Recent state legislation impacting pregnancy-related care has created additional challenges for providers and hospitals in the management of EMCs of pregnant patients, including

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[1] Also see 42 USC § 1395dd (e); and 42 CFR § 489.24 for statutory and regulatory definitions.
[2] According to CMS EMTALA Interpretive Guidelines, a dedicated ED, subject to EMTALA, would include not just departments licensed as EDs, but also those held out to the public as providing care for EMCs on an urgent basis without requiring a previously scheduled appointment or a department or facility that has provided at least one-third of all of its visits during the preceding calendar year for the treatment of EMCs on an urgent basis without requiring a previously scheduled appointment. This includes individuals who may present as unscheduled ambulatory patients to units (such as labor and delivery or psychiatric intake or assessment units of hospitals) where patients are routinely evaluated and treated for emergency medical conditions.
[3] Terp S, Seabury SA, Arora S, Eads A, Lam CN, Menchine M. Enforcement of the Emergency Medical Treatment and Labor Act, 2005 to 2014. Ann Emerg Med. 2017 Feb;69(2):155-162.e1. doi: 10.1016/j.annemergmed.2016.05.021. PMID: 27496388; PMCID: PMC7176068.
[4] Terp S, Seabury SA, Arora S, Eads A, Lam CN, Menchine M. Enforcement of the Emergency Medical Treatment and Labor Act, 2005 to 2014. Ann Emerg Med. 2017 Feb;69(2):155-162.e1. doi: 10.1016/j.annemergmed.2016.05.021. PMID: 27496388; PMCID: PMC7176068.
[5] Terp S, Wang B, Burner E, Arora S, Menchine M. Penalties for Emergency Medical Treatment and Labor Act Violations Involving Obstetrical Emergencies. West J Emerg Med. 2020 Feb 21;21(2):235-243. doi: 10.5811/westjem.2019.10.40892. PMID: 32191181; PMCID: PMC7081879.

pregnancy loss and pregnancy-related complications, and has generated a growing number of inquiries of concern from patients and providers. The clinical community, including clinicians and hospital administrators, commonly seeks additional information about what insights can be gleaned from illustrative publicly releasable materials, such as hospitals' corrective action plans after CMS EMTALA citations.

Goal:
To describe challenges using illustrative synthetic cases that aggregate common elements of CMS EMTALA citations involving the care of pregnant patients. This work is intended to improve understanding of the CMS EMTALA enforcement process, identify scenarios that have previously posed compliance risk, and summarize corrective action plans offered by hospitals that were successful in resolving related citations. While all investigations are highly fact-specific, information from these illustrative cases is intended to provide insight to inform clinicians and administrators at institutions who may encounter questions and challenges with the provision of emergency care of pregnant patients.

Methodology:
A multidisciplinary team reviewed and summarized publicly released CMS hospital survey data[6] involving the care of pregnant patients seeking evaluation at dedicated EDs. The team also reviewed corrective action that had been taken by hospitals identified upon resurveys, at which time the hospitals were determined to be back in compliance with EMTALA. Common themes and generalizable insights from the EMTALA deficiencies cited are summarized in the form of synthetic case vignettes in this report, and common corrective actions taken by hospitals are listed.

Clinical patterns:
The illustrative cases follow a few common clinical themes. The content is a fusion of multiple representative cases with CMS citations but is not a description of any specific case or citation. This is also not intended to be a comprehensive list of all possible EMTALA deficiencies or a prioritization of any particular pregnancy-related condition, since survey assessments are contextual and nuanced beyond details available for our review. The example vignettes describe a group of cases reflecting a range of circumstances that led to CMS EMTALA citations. These examples include:

1. Pregnant patients seeking evaluation are advised to seek care elsewhere without an MSE by a QMP and/or are not entered in a hospital's central log.

   Example vignettes: A pregnant patient presenting for evaluation to a dedicated ED at a facility without obstetric services is advised by staff to proceed to an alternate facility before an MSE is completed or prior to stabilization of an identified EMC. Alternatively, pregnant patients may

[6] https://www.cms.gov/medicare/health-safety-standards/guidance-for-laws-regulations/hospitals/hospitals

present to an obstetric unit and be advised to seek care elsewhere because the unit is busy. In some cases, pregnant patients are not entered in a log.

Common elements identified in cases resulting in CMS EMTALA citations:

- Failing to ensure all personnel including security staff, technicians, registration and triage personnel understand the requirements that all patients presenting to a dedicated ED requesting evaluation be entered into a central log and have an appropriate MSE by a QMP.
- Reliance on staff not credentialed as QMPs to perform the MSE or directing patients elsewhere without an MSE by a QMP.

2. Previable preterm prelabor rupture of membranes (referred to as previable or periviable PPROM) manifest by leakage of fluid with or without vaginal bleeding in pregnancy.[7,8]

   Example vignettes: A patient with a second-trimester previable pregnancy presents with light vaginal bleeding and/or leaking fluid but without fever or evidence of infection. During evaluation, rupture of membranes is diagnosed with a speculum exam and visualization of pooling of amniotic fluid, a positive nitrazine test, a positive fern test, or amniotic fluid molecular testing. Treatment options offered in citation cases might appear to be influenced by factors other than medical opinion or patient preference, especially if hospital policies and state laws are perceived to be in conflict.

   Common elements identified in cases resulting in CMS EMTALA citations:

   - Failure to fully assess the pregnant patient, including consideration of maternal health and comorbidities, to identify the potential presence of an EMC.
   - An apparent focus on long-term non-viability of fetus as rationale for patient discharge without evaluation or mitigation of potential maternal risks.
   - Failure to make use of available on-call physician specialists to participate in screening and/or, if necessary, stabilization.
   - Assuming that previable PPROM could not be an EMC in the absence of abnormal maternal vital signs.

[7] As viability represents a physiological continuum influenced by gestational age in addition to a myriad of clinical factors, gestational ages associated with viability remains dynamic influenced by advances in neonatal intensive care and availability of services and regional availability of services. See: Pettker CM, Turrentine MA, Simhan HN. The Limits of Viability. Obstet Gynecol. 2023 Sep;142(3): p 725-726. doi: 10.1097/AOG.0000000000005280. PMID: 37535950.

[8] American College of Obstetricians and Gynecologists; Society for Maternal-Fetal Medicine. Obstetric Care consensus No. 6: Periviable Birth. Obstet Gynecol. 2017 Oct;130(4): e187-e199. doi: 10.1097/AOG.0000000000002352. PMID: 28937572.

- Deviating from usual accepted standards of medical practice informed by evidence-based clinical standards[9] for either screening or stabilization.
- Failure to escalate questions or concerns (such as to department chair, hospital administrators, risk managers, legal representatives) for cases of perceived conflict between medical standards, state law, and/or federal law.

3. Evaluation for abdominal pain and/or contractions in the second trimester or preterm labor in the third trimester.

   Example vignettes: A patient in the second trimester of pregnancy previously known or suspected to have PPROM presents with abdominal pain and/or cramping. Examination reveals early cervical dilatation, moderate cervical effacement, and high fetal station, and ultrasound detects fetal cardiac activity. Orders may be placed and patient consent obtained consistent with intent to deliver, but the patient is then discharged prior to delivery without explanation of the rationale for the change in care plans, offers for alternative stabilizing care, or documentation that the patient withdrew consent or declined care.

   Common elements identified in cases resulting in CMS EMTALA citations:
   - Failure to provide a complete assessment by a physician, certified nurse-midwife, or other QMP defined in hospital medical staff bylaws, sufficient to conclude after a reasonable time of observation that the patient is not in labor and does not have an EMC.
   - Indiscriminate use of standing orders or general labor and delivery order sets and consent processes without documenting patient-specific decision-making, or documenting patient preference for treatment options, and/or obtaining informed refusal of care without evidence of coercion.

4. First trimester pain or bleeding.

   Example vignettes: A patient presents with early first trimester vaginal bleeding or has a new diagnosis of pregnancy made during an ED visit for abdominal pain or vaginal bleeding. Ultrasound may or may not be

[9] CMS does not endorse any particular authority or practice standard. However, hospitals commonly cite evidence from professional bodies. In terms of previable PPROM, they might cite practice guidelines from a professional society, such as the Society for Maternal-Fetal Medicine, for example:
Battarbee AN, Osmundson SS, Mccarthy AM, Louis JM; SMFM Publications Committee. Society for Maternal-Fetal Medicine Consult Series #71: Management of previable and periviable preterm prelabor rupture of membranes. Am J Obstet Gynecol. 2024 Jul 16: S0002-9378(24)00759-2. doi: 10.1016/j.ajog.2024.07.016. PMID: 39025459.

performed within the capability of the facility as part of the MSE. If done, ultrasound may not identify or localize the site of an early pregnancy (a pregnancy of unknown location, PUL) or perhaps visualizes an ectopic pregnancy. The patient may also have one or more significant risk factors for ectopic pregnancy. In cases where necessary specialty services required for stabilization (such as surgery) are not available at the presenting facility, needed transfers for specialty care might also be delayed.

Common elements identified in cases resulting in CMS EMTALA citations:

- Failure to perform an appropriate MSE within the capability of the hospital, including ancillary services routinely available to the ED, to determine whether an EMC exists during their specific presentation.
- Erroneous belief that an ectopic pregnancy is unlikely to represent an EMC in the absence of unstable maternal vital signs or documented rupture.
- Failure to make use of available diagnostic resources or on-call specialists as needed in screening and/or stabilization.
- Documenting presence of signs and test results concerning for PUL or diagnostic of ectopic pregnancy but failing to act on the results in a timely manner, provide stabilizing treatment, or document decision-making.
- Failure to provide timely transfer for stabilizing treatment, such as surgery for complications of an ectopic pregnancy.

Operational/process patterns:
Across many different clinical presentations, a few common themes emerged related to hospital policies and operational processes that commonly impact pregnant patients.

1. Making full use of the hospital's capabilities, including on-call services routinely available to the ED, to adequately screen individuals to determine if an EMC exists, and to stabilize any EMCs identified.

   CMS regulations implementing EMTALA require that the hospital "Provide an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether an emergency medical condition exists. The examination must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations and who meets the requirements of § 482.55 concerning emergency services personnel and direction." 42 CFR 489.24(a)(1)(i)

   On-call physicians (such as obstetricians), sonographers, and other hospital

resources must be made available as necessary if they are part of the capability of the hospital.

2. Understanding and complying with EMTALA's definitions of EMC and "to stabilize"

   The definitions of "emergency medical condition" and "to stabilize" and "stabilized" under EMTALA are quite different than the common clinical use of terms like "medical emergency," "emergent," "unstable," or "stable."[10] Clinicians might not refer to a person as being "unstable," but that person still may have an EMC requiring stabilizing treatment under EMTALA. Whether an EMC is stabilized is not determined by the ultimate clinical outcome, nor is it defined by a narrow clinical factor, like vital signs alone.

   While the EMTALA statutory and regulatory language do not require that clinical deterioration actually occur before a condition meets the definition of an EMC, some individuals do experience deterioration during their hospital encounter (whether still in the ED or after admission). In those circumstances, it is important that hospitals have robust processes to assure timely recognition, communication, marshalling of resources, and intervention. In addition to potentially implicating EMTALA, failure to rescue[11] may also raise concerns with respect to a hospital's compliance with the CMS Conditions of Participation.[12]

3. Appropriately logging all individuals seeking emergency care

   CMS regulations require a central log of each individual who comes to the emergency department, as defined in 42 CFR 489.24(b), and individuals must not be informally "evaluated" or "screened" and turned away by non-credentialed staff, including security officers, registration or reception staff, or clinical staff who are not designated as a QMP by the hospital's governing body. If a single site has both an emergency department and a labor and delivery unit that both participate in the care of a patient, logs should capture patients at both locations.

Common themes in hospital-submitted plans of correction:
To regain compliance with EMTALA, hospitals almost always choose to create and submit a plan of correction and undergo a resurvey to verify the plan was successfully implemented. CMS does not direct the specific contents of a hospital's plan of correction but considers an acceptable plan to be documentation of a facility's readiness and request for a revisit. Table 1 provides examples of corrective actions that have been implemented by some hospitals in response to CMS EMTALA citations.

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[10] Also see Admin Info: 24-06-EMTALA (https://www.cms.gov/files/document/admin-info-24-06-emtala.pdf
[11] https://psnet.ahrq.gov/primer/failure-rescue
[12] Also see https://www.cms.gov/medicare/health-safety-standards/conditions-coverage-participation/hospitals

Responses to EMTALA citations vary and must be individually tailored to the specific deficiencies cited; however, the most successful approaches almost always involve engagement at all levels of the organization.[13] Effective corrective action plans are typically overseen by senior hospital executives and teams of administrative and clinical leaders who convey and demonstrate a firm organization-wide commitment to EMTALA's requirements. Administrators at hospitals that are successful at maintaining EMTALA compliance generally maintain policies and procedures to support EMTALA. However, when circumstances arise that reveal barriers to compliance, administrators convene multidisciplinary teams within the organization to identify solutions with a growth mindset, similar to other key leadership challenges in health care. The hospital leaders, including administrative, clinical, and quality leaders, take action to develop local protocols, processes, and policies to assure that all patients receive appropriate MSEs by QMPs to identify EMCs. Protocols are evidence-based and nuanced, involving the coordination of all staff and services that are within the capability of the organization. Plans are detailed and specific such that individuals understand their role and how to accomplish their tasks, how to report problems, and with whom to consult when challenging problems arise. Protocols are consistent and harmonized across departments and clinical areas. Administrators respond to concerns when difficulty is encountered complying with protocols. Once plans are developed, staff are informed and educated effectively, and feedback from the staff solicited to assure the plans are feasible and supported by hospital resources (including people, processes, supplies, and equipment). Performance on policies is monitored and plans updated as necessary. Periodic audits are done to establish that the policies are successfully implemented.

Table 1. Examples of Corrective Actions Implemented by Hospitals in Response to Common CMS EMTALA Citations for Dedicated Emergency Department Care of Pregnant Patients.

Referenced from 42 USC § 1395dd, 42 CFR 489.24, 42 CFR 489.20, and State Operations Manual Appendix V - Interpretive Guidelines - Responsibilities of Medicare Participating Hospitals in Emergency Cases.

Abbreviations: ED (Emergency Department), MSE (medical screening exam), EMC (emergency medical condition), QMP (qualified medical personnel), PPROM (Preterm Prelabor Rupture of Membranes)

EMTALA/EMTALA-Related CMS Regulatory Requirements Commonly Cited	**Common Corrective Actions Proposed by Hospitals**
Hospitals with dedicated EDs are subject to EMTALA.	

[13] Also see CMS online training available at https://qsep.cms.gov/pubs/CourseMenu.aspx?cid=0CMSEMTALA_BTN and https://qsep.cms.gov/pubs/CourseMenu.aspx?cid=0CMSADVEMTALA_ONL

	• Hospital leadership assures that all hospital staff are trained in EMTALA and understand specific EMTALA requirements. New hires receive training in EMTALA. Training is periodically reinforced. • Medical staff have training to understand how to respond to various scenarios. In some cases, training may include unannounced in situ simulations of high risk or complicated EMTALA scenarios.
Individuals who present for care at an ED must be entered into a central log with specific required elements, including patient disposition (i.e., whether they refused treatment, were refused treatment, were transferred, admitted and treated, stabilized and transferred, or discharged)	• Hospitals develop systems to log patients that are maintained and monitored. Staff are trained to correctly use the log systems. • Hospitals update processes and maintain a record of all patients who present for care in dedicated EDs (which includes many labor and delivery units and sometimes other locations in a hospital). • If a single location has both an ED and a separate unit—such as labor and delivery—and both participate in the care of a patient, logs should capture care at each location.
When patients express the intent to decline care required under EMTALA, or leave prior to completing care, hospitals are required to take specific actions, including formal written informed refusal.	• Hospitals put processes and policies in place to deal with occasions when patients leave or decline care. • Staff are instructed not to coerce patients to make decisions against their interests and to make sure patients understand recommendations for their care. • Processes include documentation and signatures of clinical staff and patients on required patient-refusal paperwork and workflow engineering to minimize delays that may incentivize patients to leave.
Hospitals must provide an appropriate MSE to determine if an EMC exists.	• Patients are not turned away from triage by staff prior to an MSE by a QMP. • Hospital policies define elements of appropriate MSEs and assure that resources needed to provide them are available. • When local practices bifurcate evaluation of pregnant patients on the basis of gestational age (for example, between an ED for early pregnancy and a separate labor and delivery unit for later pregnancy), screening and stabilization processes are harmonized. • Hospitals assure that the MSE of pregnant patients is reasonably calculated to determine whether the pregnant patient has an EMC, not just focused exclusively on fetal viability.

Hospitals are to provide appropriate MSEs within the capability of the hospital's ED, including routinely available resources. This may include on-call services needed to adequately screen individuals to identify and then stabilize EMCs.	• Hospitals may develop clinical protocols to define when on-call specialists, sonographers, and other hospital resources should be utilized and have policies that govern the availability of these resources. • When policies advise for specialty consultation (e.g., obstetrical expertise), an on-call system provides access to that expertise. If the policy states that in-person consultation is advised and a consultation is requested, the on-call specialist will personally see the patient. • On-call schedules are current, monitored, and updated as needed. Expectations of on-call consultants are enforced.
MSEs are conducted by QMPs.	• Medical staff and hospital rules define criteria for and credentialing of qualified medical personnel, and policy requires all patients to be assessed by a QMP as defined by hospital bylaws.
If the hospital determines that an individual has an EMC, the hospital must offer further examination and such treatment as may be required to stabilize the medical condition within the staff and facilities available at the hospital or arrange for an appropriate transfer to another medical facility that can provide the necessary care.	• Hospitals may have policies that describe evidence-based guidelines for management of EMCs and assure that resources are available to satisfy those guidelines or provide transfer to a facility that can. • Some hospitals choose to have their physician leaders internally and prospectively enumerate the specific risks of some clinical conditions (e.g., previable PPROM or ectopic pregnancy) to make more clear for their staff what clinical consequences could reasonably be expected, in the absence of immediate medical attention, especially if there is a perception among clinical staff of a conflict with state laws that define "medical emergency" narrowly. • Should conflict arise in determining the necessary stabilizing treatment for an EMC, policies are in place to allow escalation to those with authority to solve dilemmas, e.g., involvement by department chair, local experts, hospital administration, risk management, and legal experts as appropriate, and such consultation is timely and adequate to the circumstances of any given patient. • Hospitals update clinical policies and evidence-based pathways to define what treatment is typically required "to stabilize" certain medical conditions, that is "to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result" from the transfer or discharge of the patient.

	• Hospitals evaluate and strengthen processes for recognizing, communicating, marshalling resources, and intervening early on clinical deterioration.
If the hospital determines that an individual has an EMC but cannot provide services needed to stabilize the medical condition, they are to arrange an appropriate transfer to another medical facility that can provide the necessary care.	• Hospitals develop transfer policies that assure appropriate, timely, and safe transfer of patients as needed and monitor their safety. • Transfers are effected through qualified personnel and appropriate transportation equipment, as the EMC may require.
Hospitals have written policies and procedures to identify and stabilize EMCs and provide appropriate care consistent with hospital policy.	• Hospitals develop processes and policies to assure that all patients receive MSEs to detect EMCs and such further examination and treatment as may be required to stabilize the EMC. • Resources that are required to implement policies are provided. • Staff are educated on policies and provided an opportunity to give feedback, or comment on challenges that hinder compliance. • Compliance with the policy is reviewed and staff educated to understand and fully implement the policy. • Hospital polices are periodically refined, staff educated, and compliance audited.

Obligations of hospitals and rights of individuals:
The Department of Health and Human Services has announced a series of actions to educate the public about their rights to emergency medical care and to assist hospitals in meeting their obligations under EMTALA.[14, 15,16] As a part of those actions, instructions are provided on the CMS website regarding how to file an EMTALA complaint.

[14] CMS Announces New Actions to Help Hospitals Meet Obligations under EMTALA. Press Release. Jan 22, 2024. Available at: CMS Announces New Actions to Help Hospitals Meet Obligations under EMTALA | CMS.
[15] Biden-Harris Administration Reaffirms Commitment to EMTALA Enforcement. Press Release. Jul 2, 2024. Available at: Biden-Harris Administration Reaffirms Commitment to EMTALA Enforcement.
[16] Biden-Harris Administration Launches New Option to Report Potential Violations of Federal Law and Continue to Promote Patient Access to Stabilizing Emergency Care. Press Release. May 21, 2024. Available at: Biden-Harris Administration Launches New Option to Report Potential Violations of Federal Law and Continue to Promote Patient Access to Stabilizing Emergency Care.

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Please note the injunction entered by the U.S. District Court for the Northern District of Texas which was affirmed by the 5th Circuit in January 2024, prohibits CMS from enforcing its interpretation of EMTALA in certain circumstances, including within the state of Texas, when the allegation involves a pregnant patient claiming to have been denied an abortion as the necessary stabilizing treatment for an emergency medical condition.