Complying with Hospital Regulatory Obligations During Surge Capacity Operations

Kristin Miles
Washington State Attorney General’s Office
University of Washington Division
November 17, 2009
Introduction

- Hospital Regulation 101
- Conditions of Participation
- EMTALA
- CMS Waivers under § 1135
- What Do Hospitals Need from Health Officials

This presentation is the opinion of the presenter and should not be considered the official position of Washington Attorney General.
WHO REGULATES HOSPITALS?

Graphic: American Hospital Association

*Now known as TJC
Hospital Regulation 101

Medicare Conditions of Participation
State hospital licensing laws

Standards for all areas of hospital operations, including:

- building/space standards and use;
- staffing qualifications and procedures;
- medical records;
- food service;
- quality assessment and utilization review;
- discharge planning;
- and organ procurement.

(to name a few)

Special requirements for psychiatric or rehab facilities,
critical access hospitals, skilled nursing facilities

Plus optional accreditation and disease-specific certification
by The Joint Commission

Nov 2009
EMTALA – The General Rule

i. Anyone who presents for examination or treatment for any medical condition in an emergency department must receive a screening exam to determine if an emergency medical condition exists.

ii. If such a condition is found, the hospital must provide stabilizing treatment.

iii. In general, a hospital may not discharge or transfer a patient until the patient is stabilized.
EMTALA BASICS

• For any person “coming to the emergency department”
  • “Medical Screening Examination”
  • “Stabilization” of “emergency medical condition”
• Transfers restricted until patient is “stable”
• Fines or other sanctions for violation
  • Hospital
  • Physician
  • Private enforcement

42 USC §1395dd || 42 CFR § 489.24
“Comes to the Emergency Dept.”

- Individual presents at ED and requests exam or treatment for any medical condition (or has a request made on his behalf)
- Individual presents on hospital property other than ED and requests exam or treatment for what may be an emergency medical condition (or has a request made on his behalf)

Once a person arrives on site you cannot redirect them away without risking EMTALA sanctions.
“Medical Screening Exam”

- Process hospital must undertake in order to determine whether a medical emergency does or does not exist
  - Scope varies based on condition
  - Must be completed by qualified medical personnel
  - Includes lab and other diagnostic tests, and specialists, if needed

- Determines whether hospital must provide further treatment
  - Must stabilize any emergency medical condition discovered, or treat patient to extent of ability and transfer to hospital with capability and capacity for further treatment and stabilization

If there is no “emergency medical condition” the hospital’s EMTALA obligations end.
Section 1135 Waiver

A provision of federal law that allows the federal government to alleviate some federal requirements that may hinder provision of patient care during an emergency

1. The President has declared an emergency or disaster under the Stafford Act or the National Emergencies Act +
2. The Secretary of HHS has declared a Public Health Emergency +
3. The Secretary invokes her/his waiver authority

42 U.S.C. §1320b–5
Section 1135 Waivers

Purpose

Intended to reduce administrative burdens on providers and increase flexibilities in the delivery of health care with the intent of promoting greater access to care by individuals affected by the emergency or disaster.
Some Examples from Katrina

Waivers allowed

- Use of PPS-exempt psychiatric or rehab units, or facilities, for acute or intensive care.
- Payment, and waiver of sanctions, for services provided in good faith but not in compliance with normal Medicare requirements because of Katrina.
- Payment to non-participating providers for crisis services provided to evacuees.
- Waiver of pre-authorization or out-of-network authorization requirements for Medicare, Medicaid and SCHIP.
- Payment of ambulance costs for patients transferred for evacuation.
WHAT CAN BE WAIVED

- Conditions of Participation, provider certification requirements
- EMTALA sanctions for direction/relocation of patient to another location for MSE under state plan
- EMTALA sanctions for transfer of unstable individual if the transfer is necessitated by the declared 2009-H1N1 public health emergency
- Waiver lasts for duration of declared public health emergency

See current declaration for more
http://www.flu.gov/professional/federal/h1n1_1135waiver_10272009.html
CANNOT BE WAIVED

• Eligibility for Medicare beneficiaries Medicare

• Statutory provisions that specify to whom Medicare payment is made.
  • Medicare payment cannot be made under the physician fee schedule directly to an RN or any other person who might be approved by state emergency to provide physician-scope of care.

• Statutory coverage provisions
EMTALA WAIVER CANNOT

- EMTALA waiver does not eliminate the obligation for hospital with capacity and capability to accept a transfer

- EMTALA waiver does not eliminate obligation to maintain a log of persons who ‘come to the emergency department’ seeking treatment

- EMTALA waiver does not eliminate obligation to provide necessary stabilizing treatment for emergency medical conditions and labor within the hospital’s capability and capacity
Waiver Requests - CoP

- Waive facility CoPs so that hospital’s on-campus physical space can be used for inpatient and qualify for Medicare facility fee or professional fee payment
- Waive facility CoPs so that off-campus site can qualify as hospital-based and therefore qualify for Medicare facility fee or professional fee payment (outpatient or inpatient)
- Medicare ok usually = Medicaid ok

Nov 2009
CoPs – Waivers You Might Request

<table>
<thead>
<tr>
<th>CoP WAIVED</th>
<th>SO THAT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limits on use of IPPS – Exempt Units</td>
<td>Psychiatric or Rehab Units can be utilized for acute care, and that acute care is paid as acute care</td>
</tr>
<tr>
<td>Reporting Requirements § 482.13(g) (1)(i)-(ii), A-0214</td>
<td>ICU patients whose death is caused by their disease process but who required soft wrist restraints to prevent pulling tubes/IVs may be reported later than close of business next business day, provided any death where restraint may have contributed is continued to be reported within standard time limits.</td>
</tr>
<tr>
<td>Medical Records Timing § 482.24; A-0469</td>
<td>Medical records can be fully completed later than 30 days following discharge</td>
</tr>
<tr>
<td>Verbal Orders § 482.24 A-0407, A-0454, A-0457</td>
<td>Verbal orders may be used more than ‘infrequently’ (read-back verification is done) and authentication may occur later than 48h</td>
</tr>
<tr>
<td>Medical Staff § 482.22(a); A-0341</td>
<td>So that physicians whose privileges will expire and new physicians can practice before full medical staff/governing body review and approval</td>
</tr>
<tr>
<td>Physical Environment § 482.41; A-0700 et seq</td>
<td>Non-hospital buildings/space can be used for patient care, provided sufficient safety and comfort is provided for patients and staff</td>
</tr>
</tbody>
</table>
Increasing Bed Capacity

The number of inpatient beds at a hospital depends on:

- State hospital license
- Medicare certification

- Hospitals often are not using all licensed/certified beds
  - Just need staff, supplies, etc to bring ‘on-line’

- To exceed licensed/certified beds:
  - State process
  - Medicare process (+ Waiver if cannot meet CoPs)
A Hypothetical

- Patient ‘self-sorting’
- Separate H1N1 assessment clinic on-site
- Directing patients from ED to other on-campus sites
- Redirection of pts in ED to other sites off-campus
A Hypothetical
No EMTALA Waiver Needed

- Tailor Medical Screening Exams
  - Meet patients outside ED and log them in
  - Conduct basic triage for illness/severity/complaint
  - Highest level emergencies enter ED for further screening and stabilizing treatment.
  - Lesser severity emergencies are directed to other places on campus for further screening and stabilizing treatment.
  - Patients without emergency medical conditions are directed to on-campus or off-campus locations as appropriate. (EMTALA does not apply if request is clearly not for emergency nature or when MSE indicates there is no emergency medical condition)
EMTALA Waiver Required

- Transfer patients to off-campus location before conducting medical screening exam
- Conduct triage and direct patients off-site for further medical screening and stabilizing treatment (have not determined emergency medical condition does not exist)
- Transfer unstable patients with emergency medical condition off-site for further stabilizing treatment

- Consider CoP waivers for facility standards so that alternate facilities can qualify for facility and professional fee payment
2009 H1N1 Waiver Requests

As of November 9, 2009, per CMS:

- 73 requests from 10 states
- 5 approved; 1 under consideration
- 64 withdrawn bc of direct communication with regional office and requestor - many were anticipatory/”just in case” requests for waiver
- Strongly committed to be fast as possible (and remember: waivers can be retroactive)
  - All approved w/in average of 24h – longest 26h, shortest 21h
Making a Waiver Request

- No CMS prescribed form or elements
- Can be made by individual provider, health system or even LHO on behalf of area facilities.

Some suggestions:

- We request a waiver of: Specify the rule or language from Interpretive Guidelines you want waived
- So that our hospital can: Describe the procedure/operation that prompts the request
- This will promote access to care by: Describe how your request fits the waiver purpose and safely increases flexible access to care while decreasing administrative burden
## Waiver Request Example - EMTALA

<table>
<thead>
<tr>
<th>EMTALA waiver request</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospital Information</strong> (address, contact person, #, etc)</td>
</tr>
<tr>
<td>Hospital requests waiver so that Hospital can transfer patients who may be unstable, prior to stabilization, in order to reserve certain Hospital capacity for specialized care that is only available at Hospital, including burn and complex multi-system trauma. Hospital is currently operating at x% of capacity with z% of ICU beds occupied.</td>
</tr>
<tr>
<td>Hospital will provide available treatment (short of stabilization) to patients in order to decrease chance of decompensation during transfer. Hospital will transfer patients by method appropriate to their level of care needs and in compliance with EMTALA elements such as transfer of medical records.</td>
</tr>
<tr>
<td>Without waiver, 100% of Hospital intensive care capacity could be consumed by non-trauma/non-burn patients presenting at Hospital for H1N1-related emergencies (respiratory distress, etc) requiring stabilization.</td>
</tr>
<tr>
<td>County-area hospitals, through healthcare coalition, agree that preserving trauma and burn capacity at Hospital is critical and advance planning anticipates transfers of non-trauma/non-burn patients to other hospitals in order to preserve capacity at Hospital and promote access to appropriate care</td>
</tr>
</tbody>
</table>
Washington State Support for Hospitals During Emergencies
What Hospitals Need from Health Officials

- Cross-jurisdiction coordination assistance
- Guidance
- Health Officer Orders
  - Priorities
  - Standards of Care
  - System Organization
    - EMTALA waivers are insufficient to protect critical resources such as trauma/burn capacity.
- Administrative relief
Hospitals Have Useful Expertise to Share with Health Officials

- Hospital expertise in Medicare/Medicaid billing rules
- Requirements for hospital or non-hospital care sites to qualify for Medicare/Medicaid facility or professional fee payment (inpatient or outpatient)
- Operations and healthcare delivery
A ‘MUST READ’:
www.cms.hhs.gov/H1N1

Downloads
Waiver or Modification of Requirements under Section 1135 of the Social Security Act (10/27/09) [PDF, 321KB]

Background and Q's & A's on President Obama's 10/24/09 Emergency Declaration for H1N1 Flu (Posted: 10-28-09) [PDF, 124KB]

H1N1 Fact Sheet - Requesting an 1135 Waiver (11-04-09) [PDF, 66KB]

H1N1 Fact Sheet - Hospital Alternative Care Sites during H1N1 Public Health Emergency (10-27-09) [PDF, 200KB] Discusses hospital on-site and various entity off-site arrangements (CoP, billing, waivers)

H1N1 - Medicare FFS - Emergency Qs & As (11-13-09) [PDF 334KB]

H1N1 - Medicare FFS - Emergency Qs & As that May be Implemented Only with a § 1135 Waiver (11-13-09) [PDF 231KB] Discusses hospital on-site and various entity off-site arrangements (CoP, billing, waivers)

H1N1 Fact Sheet-Medicare FFS Provider Billing (9-25-09) [PDF, 70KB]

CMS Pandemic Influenza Operations and Response Plan [PDF, 3614KB]

Guidance to States on New H1N1 Billing Codes [PDF, 86KB]

H1N1 Fact Sheet-Medicaid/CHIP Provider Billing (10-26-09) [PDF, 108KB]

Section 1135 SSA (42 USC 1320b–5)
http://www.socialsecurity.gov/OP_Home/ssact/title11/1135.htm

Frequent Updates