MEMORANDUM

To: Danielle Meyer, Oregon Association of Hospitals and Health Systems, Director of Public Policy
From: Davis Wright Tremaine LLP
Date: May 12, 2020
Subject: Transfers Due to Insufficient Personal Protective Equipment During the COVID-19 Emergency Period

I. CONTEXT

One of the members of the Oregon Association of Hospitals and Health Systems (“OAHHS”) raised the question presented below to OAHHS. OAHHS has asked Davis Wright Tremaine LLP to review the question. This is a fact-specific question. Rather than provide legal advice to the member, we are providing general legal advice to OAHHS. OAHHS may pass along this analysis to members with a statement to encourage members to review our information with the hospital’s individual legal counsel to obtain legal advice specific to the hospital’s situation.

II. QUESTION PRESENTED

OAHHS asked whether insufficient personal protective equipment (“PPE”), either lack of PPE or an effort to conserve PPE, is a legally appropriate reason for either requesting to transfer a patient to another hospital, or denying a request from another hospital to transfer a patient. The example we were provided is: Hospital A contacted Hospital B with a request to transfer a patient solely due to Hospital A’s lack of the recommended PPE that the care team would need to perform a gastrostomy tube (G-tube) placement. A transfer requested or declined due to lack of PPE or an effort to conserve PPE could arise when the Emergency Medical Treatment and Labor Act (“EMTALA”) applies, or when EMTALA does not apply (e.g., patient is an inpatient and the Medicare Conditions of Participation apply). We consider this question in the context of the COVID-19 pandemic, including the altered law and standards applicable during this emergency period, as they exist today.

III. SHORT ANSWER

The appropriateness of a transfer depends on the patient’s and the transferring facility’s specific circumstances (including whether the transferring hospital has obtained acceptance of the transfer from the receiving hospital). However, based on the applicable legal requirements
and principles, it seems unlikely regulators would consider a transfer appropriate if the transferring hospital could offer no reason for the transfer other than an inadequate supply of PPE. Similarly, if a prospective receiving hospital could offer no reason for refusing to accept a requested transfer other than a lack of PPE at the receiving hospital, regulators probably would not consider the refusal appropriate.

To avoid adverse consequences, a hospital must be able to demonstrate its transfer action was in the best interest of the patient—not the best interests of the facility or its personnel—unless an informed patient (or legally authorized representative of the patient) requested the transfer, even though the transferring facility did not determine the transfer would be in the patient’s best interest. The Centers for Medical and Medical Services ("CMS") EMTALA Interpretive Guidelines indicate that hospitals are expected to be resourceful when faced with unusual surges in demand, and the appropriateness of a transfer purportedly based on lack of Capability or Capacity (see how these terms are interpreted for EMTALA purposes below) will be measured not only by statistics such as the hospital’s numbers of beds, nurses, ORs, etc., but also by (for example) evidence of how the hospital has managed to accommodate additional patients in the past, as a practical matter. The government will likely take the position that any state-licensed, Medicare-certified hospital should be able to prevent the spread of infections among its patients and personnel, so a hospital’s statement that it must transfer a patient or patients or must not accept the transfer of a patient because the hospital cannot meet basic infection-control standards might well have significant negative repercussions beyond, for example, a citation for violating EMTALA. At this time, before an Oregon hospital may resume performing elective and non-emergent procedures that require PPE, it must have adequate PPE, and it must sustain recommended PPE use for its healthcare workforce, subject to a limited exception for temporary disruptions. An Oregon hospital that performs elective and non-urgent procedures that utilize PPE could threaten its ability to continue to do so if it must transfer patients due to a lack of PPE or an attempt to conserve PPE, or if it must decline to accept patients for the same reason.

As the situation in Oregon changes, these conclusions may also change. For example, a regional or statewide plan to move COVID-19 patients to specific locations, which may include coordination and allocation of PPE directed by the Oregon Health Authority ("OHA"), could change the risks. Note, however, that even when such a plan is in place, EMTALA still would apply to ED patients with unstabilized EMCs, as it does notwithstanding community call plans and state or county protocols for transfers of (for example) psychiatric patients, unless the Secretary of the federal Department of Health and Human Services ("Secretary") issues an EMTALA transfer waiver under Section 1135 of the Social Security Act.

**IV. ANALYSIS**

A transfer requested or declined due to lack of PPE or an attempt to conserve PPE could arise in the EMTALA context, or when EMTALA no longer applies or never applied (e.g., the patient has been screened and determined not to have an emergency medical condition ("EMC"), or has been admitted as an inpatient, either from the ED or directly from home or another facility). The framework for analyzing the legal requirements for a transfer depends upon whether the transfer must comply with EMTALA, or the applicable Medicare Conditions of Participation. Additionally, during the rapidly evolving COVID-19 pandemic, federal and state regulators have promulgated requirements and guidance applicable to EMTALA, PPE, and other
issues, and have updated those pronouncements frequently. We provide relevant information below. The level of risk associated with a transfer or refusal to accept a transfer due to lack of PPE or attempt to conserve PPE will depend on the specific facts, and also on the law and guidance in place at the time.

A. PPE Requirements

   i. Federal PPE Law and Guidance

   The Medicare Conditions of Participation (42 C.F.R. §482.42 and §485.640, respectively) require hospitals and critical access hospitals (“CAH”) to adhere to accepted standards of infection control practice to prevent the spread of other infectious diseases, including COVID-19. EMTALA does not establish any particular requirements for hospitals to maintain supplies of specific PPE. See CMS “EMTALA Requirements and Implications Related to Coronavirus Disease 2019 Revised,” dated March 30, 2020 (“CMS EMTALA COVID-19 Guidance”). To address the challenges posed by COVID-19, the Secretary has granted “Section 1135” national “blanket waivers” to allow hospitals flexibility on certain issues, for example, requirements applicable to sterile compounding to facilitate conservation of scarce face mask supplies. See e.g., Section 1135 National Blanket Waivers dated May 11, 2020.

   CMS “strongly urges hospitals” to follow the guidance issued by the Centers for Disease Control and Prevention (“CDC”) on applicable isolation precautions. See CMS EMTALA COVID-19 Guidance; see also e.g. CDC Infection Control Guidance for Healthcare Professionals about Coronavirus (COVID-19)(“CDC HCP Guidance”); CDC Information for Healthcare Professionals about Coronavirus (COVID-19). Hospitals and CAHs also are expected to comply with Occupational Safety and Health Administration (“OSHA”) requirements. See, e.g., CMS EMTALA COVID-19 Guidance. The CDC has provided strategies to optimize the supply of PPE and equipment, including “workarounds” when no facemasks are available. See e.g., CDC Strategies to Optimize the Supply of PPE and Equipment, CDC Strategies for Optimizing the Supply of Facemasks.

   ii. Oregon PPE Law and Guidance

   PPE availability in Oregon has varied throughout this emergency period. On March 19, 2020, due the “severe shortage [of PPE] in Oregon and across the nation,” Governor Brown

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issued Executive Order 20-10 directing actions to conserve PPE and other healthcare resources for the state’s COVID-19 responses, including a requirement that “all elective and non-urgent procedures across all care settings that utilize PPE, including but not limited to, hospitals, . . . be cancelled, or rescheduled no earlier than June 15, 2020, for the purpose of conserving and redirecting PPE for the state’s COVID-19 emergency response.” OHA also issued guidance dated April 4, 2020, for Healthcare Personnel on the Use of PPE in Resource-Constrained settings, which provides guidance at increasing dire levels of PPE shortages.

OHA has updated guidance applicable to clinical care and healthcare infection prevention and control for COVID-19 that describes the use of PPE, with the most recent guidance dated May 9, 2020. See OHA “Provisional Guidance: Clinical Care and Healthcare Infection Prevention and Control for COVID-19”.

Since mid-March the PPE situation has evolved, and Governor Brown has now issued Executive Order 20-22, allowing elective and non-urgent procedures across all care settings that utilize PPE, but only to the extent they comply with guidance or administrative rules issued by OHA. For a hospital to resume performing elective and non-emergent procedures, OHA requires the hospital to have “adequate PPE” as defined by OHA, which includes a requirement that the hospital sustain recommended PPE for its healthcare workforce in compliance with Oregon OSHA requirements, without implementing emergency PPE-conserving measures, with reference to both OHA and CDC guidance on recommended PPE use. See OHA “Guidance on Resumption of Non-Emergent and Elective Procedures at Hospitals,” dated April 30, 2020 (“OHA Guidance on Resumption of Procedures”). If a temporary disruption threatens the ability of a hospital to maintain adequate PPE supply, the hospital may continue non-emergent and elective procedures only if the hospital meets certain conditions. See OHA Guidance on Resumption of Procedures. The related OHA Frequently Asked Questions specify that PPE used during procedures must be medical grade, following Oregon OSHA rules and be approved by the National Institutes of Occupational Safety and Health or by the U.S. Food and Drug Administration. See OHA “Frequently Asked Questions Regarding Guidance for Resumption of Non-Emergent and Elective Procedures” dated May 6, 2020 (“OHA FAQs”). For example, “While performing aerosol-generating procedures, health care personnel should also wear a fit-tested N95 respirator or higher respiratory protection.” OHA FAQs. “Annual fit testing is generally required by federal Occupational Safety and Health Administration (OSHA) for employees using N95 respirators.” For COVID-19, OSHA suspended the requirement for annual fit testing; however, “an initial fit testing is still required.” See OHA FAQs FN2.

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7 OHA Guidance for Healthcare Personnel on the Use of PPE in Resource-Constrained settings. See https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le2288t.pdf
8 OHA Provisional Guidance: Clinical Care and Healthcare Infection Prevention and Control for COVID-19 available at: https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le2288J.pdf.
9 OHA Guidance on Resumption of Non-Emergent and Elective Procedures at Hospitals dated April 30, 2020, available at: https://sharedsystems.dhsoha.state.or.us/DHSForms/Served/le2322u.pdf
To mitigate risk associated with PPE supply issues, hospitals should comply with state and federal guidance to the greatest extent possible. An Oregon hospital that performs elective and non-urgent procedures that utilize PPE could threaten its ability to continue to do so if it must transfer patients due to a lack of PPE or an effort to conserve PPE. Similarly, an Oregon hospital that performs elective and non-urgent procedures that utilize PPE could threaten its ability to continue to do so if it declines to accept the transfer of a patient due to a lack of PPE or an effort to conserve PPE. As the situation in Oregon changes, these conclusions also may change.

B. EMTALA

i. Transferring Hospital.

Under EMTALA a transferring hospital may not transfer a patient with an unstabilized emergency medical condition ("EMC") unless (1) the transferring hospital lacks the present Capability or Capacity (or both) to stabilize the patient’s EMC; and (2) the treating physician in the transferring hospital’s emergency department ("ED") executes a written Physician Certification that, based upon the information available at the time of transfer, (a) the medical benefits reasonably expected from the provision of appropriate medical treatment at the receiving hospital outweigh the increased risks to the patient of the transfer; or (b) after the patient (or the authorized representative of an incapacitated patient) has been informed of the risks of transfer and of the transferring hospital’s obligation to provide stabilizing treatment for the EMC within its Capability and Capacity, the patient or authorized representative requests a transfer. The certification must contain a summary of the risks and benefits upon which it is based, or, if the patient requested the transfer, the request must be in writing and indicate the reasons for the request as well as that the patient (or the authorized representative) is aware of the risks and benefits of the transfer. See 42 C.F.R. § 489.24(e).

Capability means the physical space, equipment, staff, supplies, and specialized services (e.g., intensive care, pediatrics, obstetrics, trauma care, burn unit, psychiatry), including ancillary services available at the hospital. With respect to staffing, Capability means the level of care that hospital personnel can provide within the scope of their licensure/certification and training, including care available through on-call providers.

Capacity means the ability of the hospital to accommodate an individual requesting or needing examination or stabilizing treatment for an EMC, or the treatment of a transferred individual with an EMC. Capacity encompasses the number and availability of qualified staff, beds, equipment, and the Hospital’s past practices of accommodating additional individuals in excess of its occupancy limits. 11

A transferring hospital that does not have appropriate PPE to provide services to a patient, such as a G-tube placement, may believe it lacks Capability and/or Capacity due to the lack of PPE supplies. (Equipment is relevant to both.) However, lack of PPE alone is not

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enough to prevent the transfer from presenting an EMTALA violation risk. The treating
physician must also certify that based upon the information available at the time of transfer, the
medical benefits reasonably expected from the provision of appropriate medical treatment at the
receiving hospital outweigh the increased risks to the patient of the transfer, or the transfer must
be requested by the patient or authorized representative, as set forth above. To protect against an
EMTALA violation, the hospital should clearly document the reasons for the specific transfer,
including how the PPE shortage occurred, to the extent possible—and why it prevents the
hospital from providing the necessary stabilizing treatment. The CMS EMTALA COVID-19
Guidance states that it will take into consideration local, state, and federal guidance applicable at
the time of the transfer as well as clinical considerations specific to the transferred patient. It
may be difficult for a hospital to justify a transfer as in the bests interest of the patient on the
basis of PPE alone.

According to CMS’s EMTALA Interpretive Guidelines, “[t]he capacity to render care is
not reflected simply by the number of persons occupying a specialized unit, the number of staff
on duty, or the amount of equipment on the hospital’s premises. Capacity includes whatever
a hospital customarily does to accommodate patients in excess of its occupancy limits
§489.24(b). If a hospital has customarily accommodated patients in excess of its occupancy
limits by whatever means (e.g., moving patients to other units, calling in additional staff,
borrowing equipment from other facilities) it has, in fact, demonstrated the ability to provide
services to patients in excess of its occupancy limits.” CMS EMTALA Interpretive Guidelines,
Tag A-2407/C-2407 (emphasis added). Since there is specific CDC guidance about PPE
optimization and crisis strategies and facemask “workarounds”, regulators are likely to expect
hospitals to meet infection-control standards and accommodate patients rather than transfer them,
despite COVID-19 challenges.

In addition, to comply with EMTALA, the transfer must be “appropriate” as defined by
42 C.F.R. § 489.24(e) (e.g., medical records are sent, the transfer is effected through qualified
personnel and transportation equipment, etc). All individuals with similar medical conditions
should be treated consistently. If a community-wide plan exists for certain hospitals to treat
certain EMcs, the transferring hospital must first meet its obligations (screen, stabilize, and
appropriately transfer) prior to transferring the patient to the hospital consistent with the plan.
See EMTALA Interpretative Guidelines.

A receiving hospital that suspects it may have received an improper transfer (i.e., transfer
of an unstable individual with an EMC who was not provided an appropriate transfer according
to §489.24(e)(2)) is required to report the incident to CMS or the State Agency (SA) within 72
hours of the occurrence. See EMTALA Interpretative Guidelines.

As noted above, a transferring hospital that transfers due to lack of PPE or an effort to
conserve PPE may place its ability to perform non-urgent and elective procedures that require
PPE at risk, in addition to risking citation for an EMTALA violation.

Social Security Act Section 1135 Waiver. No national blanket Section 1135 waivers
currently waive the EMTALA requirements applicable to an appropriate transfer. It is possible
an 1135 waiver could be granted to waive sanctions under EMTALA for the transfer of an
individual who has not been stabilized if the transfer arises out of an emergency. This waiver
has been requested for all hospitals in the State of Oregon. However, as time elapses and more
states implement reopening measures, this blanket waiver probably becomes less likely (unless there is a wave of new infections).

ii. Receiving Hospital.

Under EMTALA the receiving hospital is not required to accept the transfer of a patient with an EMC when the receiving hospital does not have the current Capacity or specialized Capability to provide stabilizing treatment for the patient.

If the receiving hospital lacks appropriate PPE or is attempting to conserve PPE, it is feasible that the hospital lacks Capacity and Capability, but either one would be sufficient to decline the request. For example:

- Lack of Capability: The Hospital is experiencing technical or operational problems that prevent it from providing the needed services for the patient, i.e., the hospital has run out of the necessary PPE.
- Lack of Capacity: There is no bed available in the appropriate setting, i.e., due to PPE shortages, certain beds are no longer available (e.g., ICU beds).

A receiving hospital that does not have appropriate PPE to provide services to a patient, such as a G-tube placement, may believe it lacks Capability and/or Capacity due to the lack of PPE supplies. If the receiving hospital lacks Capability or Capacity or both, the hospital may decline the transfer. The receiving hospital may rely on the clinical certification of the transferring physician and could put itself at risk if it second-guesses it. The CMS EMTALA COVID-19 Guidance states that it will take into consideration local, state, and federal guidance applicable at the time of the transfer as well as clinical considerations specific to the transferred patient. As noted above, however, if a hospital declines a transfer due to a lack of PPE or in an attempt to conserve PPE, it may place its ability to perform non-urgent and elective procedures at risk.

1135 Waiver. There is no Section 1135 national blanket waiver currently in place that would alter the standards applicable to a receiving hospital accepting or declining a transfer of a patient with an unstable EMC, and such a waiver would be outside the scope of potential Section 1135 waivers.

C. Hospital Medicare Conditions of Participation

A hospital’s EMTALA obligation ends when the individual has been admitted in good faith for inpatient hospital services whether or not the individual has been stabilized. EMTALA does not apply to hospital inpatients unless the hospital did not admit the patient in good faith with the intention of providing treatment. Hospital and CAH Conditions of Participation (“CoPs”) protect individuals who are already patients of a hospital and who experience an EMC. See 42 C.F.R. § 482 et seq; 42 C.F.R. § 485.601 et seq. Under the CoPs, specifically 42 C.F.R. § 482.11, Medicare-participating hospitals are required to comply with federal laws applicable to the health and safety of patients, and with state hospital licensing requirements. Hospitals must adopt and implement adequate discharge planning policies and
procedures, including for transfer or referral of patients to other facilities, per 42 C.F.R. § 482.43(b) (Hospitals) and 42 C.F.R. § 485.642(b) (CAH).\textsuperscript{12}

42 C.F.R. § 482.43(b) Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information. The hospital must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient’s current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient’s follow-up or ancillary care.

42 C.F.R. § 485.642(b) Standard: Discharge of the patient and provision and transmission of the patient’s necessary medical information. The CAH must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient’s follow-up or ancillary care.

Thus, a physician should determine and document any transfer to be medically appropriate for the patient, and implemented with the patient’s or legally authorized representative’s consent, via an appropriate method of transport, etc. In the current environment, an Oregon hospital that performs elective and non-urgent procedures that utilize PPE could threaten its ability to continue doing so if it must transfer patients due to a lack of PPE or an attempt to conserve PPE, or if it must decline to accept patients for the same reason.

If the ability of Oregon hospitals to accommodate COVID-19 patients moves towards a crisis, some standards for accepting and declining transfers may well change temporarily. For example, there could be a statewide or regional plan to move COVID-19 patients to specific locations, along with a coordination and allocation of PPE, directed by OHA.

\textsuperscript{12} Through a Section 1135 waiver, CMS has waived the requirements at 42 C.F.R. § 482.43(a)(8), § 482.61(e), and § 485.642(a)(8) to provide detailed information regarding discharge planning as set forth in the waiver. However, CMS has maintained other discharge planning requirements, including those at 42 C.F.R. § 482.43(b) and § 485.642(b).