## NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE APPELLATE DIVISION

SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION DOCKET NO. A-5956-10T2

WARREN HOSPITAL,

Petitioner-Appellant,

v.

NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES,

Respondent-Respondent.

Argued June 3, 2013 - Decided July 8, 2013

Before Judges Sabatino, Fasciale and Maven.

On appeal from the Division of Medical Assistance and Health Services, Department of Human Services.

David E. Dopf argued the cause for appellant (Reed Smith LLP, attorneys; Murray J. Klein and Mr. Dopf, of counsel and on the brief).

Michael J. Kennedy, Deputy Attorney General, argued the cause for respondent (Jeffrey S. Chiesa, Attorney General, attorney; Melissa Raksa, Assistant Attorney General, of counsel; Mr. Kennedy, on the brief).

## PER CURIAM

Warren Hospital ("Warren") appeals a June 30, 2011 final agency decision of the New Jersey Department of Health and

Senior Services ("the Department") imposing sanctions against hospital under N.J.A.C. 8:43G-2.4(c) for conducting the emergency primary angioplasty services on two patients respectively in 2006 and 2007 without having a license to perform those procedures. Warren contends that the sanctions are preempted by a federal statute, 42 U.S.C.A. § 1395dd. Warren construes the federal statute to authorize the emergency procedures, despite state-imposed restrictions, in a situation where a patient faces imminent death, the hospital cannot stabilize the patient, and the medical risks of attempting to transfer the patient to a qualified facility outweigh the potential benefits. Warren also contends that the Department's action conflicts with the professional duties of its staff physicians in their practice of medicine, who saved the lives of the two patients in question.

For the reasons that follow, we remand this matter to the Department to develop the factual record more extensively. Based upon that amplified record, the Department should reevaluate whether the transfer risks involved here were substantially self-created by the hospital's own action and inactions and, if so, whether such self-created risks negate

<sup>&</sup>lt;sup>1</sup> The Department is now known as the Department of Health. <u>L.</u> 2012, <u>c.</u> 17.

Warren's asserted justifications for performing the angioplasties. Regardless of the outcome of the remand, we also make clear that the Department is not foreclosed from filing a new administrative action seeking prospective measures against Warren for lacking sufficient patient transfer capability, in violation of N.J.A.C. 8:33E-1.8(a), a separate regulation that was not charged in this case.

I.

129-bed acute-care hospital Warren is a located in Phillipsburg. Among other things, the hospital is licensed to perform low-risk cardiac catheterization, a procedure used to diagnose heart conditions. Patients at Warren who require cardiac surgery and primary angioplasty<sup>2</sup> are usually transferred to Easton Hospital in Pennsylvania, which is a five-mile drive is licensed and equipped for such from Easton procedures. Although the record is not entirely clear, appears that no New Jersey hospital in Warren County or other in-state hospital near Warren is licensed to perform primary angioplasties.

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<sup>&</sup>lt;sup>2</sup> Primary angioplasty is the "[r]econstitution or recanalization of a blood vessel[.]" <u>Stedman's Medical Dictionary</u> 88 (28th ed. 2006). Dr. Devendra Amin, who performed the procedures on the two patients in this case, described it as "essentially putting a balloon inside the . . . vessel and . . . deploying the balloon to open up the blockage."

On January 19, 2006, Patient A<sup>3</sup> was brought to Warren's emergency room by a friend. He was complaining of chest pain shortness of breath. Patient A's condition and deteriorated, and his blood pressure fell to 50 systolic. Emergency doses of medications to increase Patient A's blood pressure were not effective. A cardiac monitor revealed an uncontrolled atrial fibrillation of 128 beats per minute, and Patient A was also experiencing acute myocardial infarction ("AMI") and "extraordinarily low" blood pressure. Dr. Amin, who is a cardiologist at Warren and the Director of its catheterization laboratory, was contacted, and he examined Patient A.

Dr. Amin initially perceived that insertion of an intraaortic balloon pump to augment the pumping power of Patient A's
heart could stabilize Patient A enough to allow for emergency
transportation to Easton. Dr. Amin consequently took Patient A
to Warren's catheterization laboratory and inserted the pump.
Unfortunately Patient A's systolic blood pressure remained in
the 50-60 range, meaning to Dr. Amin that Patient A had not been

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<sup>&</sup>lt;sup>3</sup> The record uses anonymous designations for the two patients involved.

<sup>&</sup>lt;sup>4</sup> Acute myocardial infarction is tissue necrosis in the heart muscle due to lack of blood flow to the heart. <u>Stedman's</u>, <u>supra</u>, at 968-69. It is more commonly referred to as a heart attack.

stabilized and was too unstable for transportation. Dr. Amin consulted with other doctors in Warren's emergency room, including the Director of Warren's Emergency Department, Dr. Daria Starosta. The doctors concluded that if transportation of Patient A were attempted, Patient A "would almost certainly die en route to that facility."

Dr. Amin then undertook further investigation of Patient A's condition by inserting a diagnostic pulmonary catheter through Patient A's femoral artery. This procedure revealed a high degree of hardening of the patient's major arteries, a lesion indicating a plaque rupture, one major clot completely blocking an artery and several branches simultaneously, and an elevated pressure indicative of congestive heart failure.

Faced with these circumstances, Dr. Amin decided to proceed with primary angioplasty in light of Patient A's serious condition. Dr. Amin concluded, "in [his] best medical judgment and to a reasonable degree of medical certainty, that the benefit of administering angioplasty" at Warren "outweighed the risks associated with transporting [Patient A] to Easton Hospital, because the trip to Easton Hospital would likely kill him." In fact, Dr. Amin asserted at a subsequent hearing that the risk of transporting Patient A was "outrageous" and that there would be "no benefit" to it. He further said that he

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could not have ethically signed a certification to allow transfer of Patient A to Easton.<sup>5</sup>

It is undisputed that Warren did not possess the necessary equipment to perform primary angioplasty on Patient A. Dr. Amin, who also happened to be a member of Easton's staff and who "regularly" performed angioplasty there, notified Easton of the situation and arranged for the emergency transportation of the necessary equipment from Easton to Warren. Dr. Starosta then travelled to Easton to retrieve the equipment, "which she did on an extremely expedited basis."

Dr. Amin performed the emergency angioplasty on Patient A without incident. The procedure was "highly successful," resulting in an immediate restoration of flow to Patient A's heart. Patient A made "essentially a 100% recovery." The Department does not dispute this favorable outcome. Warren thereafter sent a letter to the Department disclosing that an emergency angioplasty had been performed there on Patient A.

<sup>&</sup>lt;sup>5</sup> <u>See</u> 42 <u>U.S.C.A.</u> § 1395dd(c)(1)(A)(ii) (allowing transfer of an unstable patient if a physician has signed a certification that the benefits of transfer to another facility outweigh the risks to the patient).

<sup>&</sup>lt;sup>6</sup> We ascribe no legal significance to the Department's emphasis on the fact that Dr. Starosta apparently did not inspect the contents of the equipment supply bag at Easton before she returned with it to Warren.

The circumstances involving Patient B were substantially similar, although not identical. On April 27, 2007, Patient B was brought to Warren at 8:15 a.m. while complaining of chest Patient B was already a patient of Dr. Amin, had a history of coronary artery disease, and had already had a stent in place in his heart. Without consulting Dr. Amin, Patient B had discontinued his anti-platelet therapy intended to prevent blood clots from forming since he experienced had gastrointestinal bleed in October 2006.

Soon after Patient B arrived at Warren, emergency room physicians determined that he was suffering from AMI and that he was unstable. His blood pressure was 63/48, and resuscitative efforts increased it to only 70-75 systolic. Dr. Amin was contacted when the emergency room physicians could not stabilize Patient B.

Dr. Amin inserted an intra-aortic balloon pump into Patient
B to augment his heart's pumping power and potentially stabilize
him for transfer. Patient B nevertheless remained "extremely
unstable."

According to Dr. Amin, he and the emergency room officials "believed, in [their] best medical judgment, and to a reasonable degree of professional certainty, that [Patient B] was too unstable to transport to Easton Hospital, and that undertaking

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emergency transport would likely kill him." Patient B went into ventricular fibrillation, which, according to Dr. Amin, is a "dangerous" condition in which the heart muscle does not contract in a coordinated fashion, and had to be shocked with a defibrillator.

Dr. Amin concluded that, "in [his] best medical judgment and to a reasonable degree of medical certainty, that [he] would need to perform angioplasty on [Patient B] in order to sufficiently stabilize him for transport to Easton Hospital." The surgeon further determined that the benefits of performing the procedure at Warren "greatly outweighed the risks associated with transporting [Patient B] in his highly unstable condition." In essence, Dr. Amin believed that Patient B would have died if transport to Easton had been attempted. He maintained that, under the circumstances, he could not have justifiably signed a certification allowing Patient B's transfer to Easton.

Dr. Amin performed the angioplasty procedure on Patient B using a catheter that was already on site at Warren. The catheter was at Warren because it was used for angioplasties in other parts of the body, procedures for which Warren did have a license from the Department.

Through the emergency angioplasty, Dr. Amin was able to restore Patient B's heart function to approximately forty to

fifty percent, which was "close to normal" for Patient B.

Patient B then began to stabilize and he was transported to

Easton, where he received cardiac surgery the next day. The

Department does not dispute this successful outcome, either.

Dr. Amin concluded that the time saved by performing the angioplasty at Warren had saved Patient B's heart muscle. He asserted that "[a]ny delay in the performance of the angioplasty would have resulted in a much poorer result[.]" Following the procedure, Warren informed the Department that another emergency angioplasty had been performed at the hospital.

As Warren concedes, at all relevant times, it lacked a license from the Department to perform primary angioplasty. In fact, Warren was conditionally licensed to perform only low-risk diagnostic catheterizations. Both the families of Patients A and B were informed of this fact before the procedures were carried out, and there is no suggestion in the record that the procedures went forward without their consent.

The record is incomplete concerning Warren's capability to transfer such patients to another hospital. Local ambulances serving Warren allegedly did not travel across the Delaware River to Easton Hospital in Pennsylvania. Nor were such ambulance crews apparently equipped to transport emergency cardiac patients suffering from AMI. For these asserted

reasons, when it needed to transfer such patients to Easton, Warren maintained that its staff had to call an emergency transport service from Morris County. That service allegedly had a minimum arrival time of forty-five minutes, but would often take an hour or longer. The drive from Warren to Easton, according to Dr. Starosta, was also time-consuming, due to congested roads and toll lines, although the road distance is only five miles. According to Dr. Amin, irreversible damage to the heart muscle occurs after fifteen minutes without blood. However, when it is possible, arrangements are made to transfer stable patients from Warren to Easton for angioplasty and other procedures for which Warren is not licensed.

In August 2007, the Department informed Warren that the primary angioplasties performed on Patients A and B violated N.J.A.C. 8:43G-2.4(c), a regulation which states, in relevant part, that "[n]o hospital shall accept patients in any new service, unit, or facility until the hospital has a written approval and/or license issued by" the Department. Warren, in resolution turn, requested informal dispute allegations. Given the medical expertise required to determine whether the procedures were necessary to save the two patients' lives. the Department requested its eighteen-member Cardiovascular Health Advisory Panel (the "CHAP") to review the

matter. See N.J.A.C. 8:33E-1.14(a) (authorizing the formation of such CHAPs to provide "expert clinical and/or technical advice").

The CHAP concluded that although Patients A and B were both "critically ill," the clinical records nevertheless indicated to the panel that they could have been transported to Easton. According to the CHAP's meeting minutes, the procedures performed on Patients A and B required "a substantial amount of interventional supplies," which Warren had in its although it "was not even a full[-]service facility and was definitely not approved for emergency or elective coronary intervention." The CHAP determined that Warren had "willfully stocked interventional supplies in anticipation of performing emergency interventional procedures, despite the fact that they were not approved to do so." Based upon these perceptions, the CHAP recommended that Warren be assessed the maximum penalty allowable under the regulations, be placed under conditional licensure, and that an independent review be performed.

On September 24, 2008, the Department assessed against Warren a penalty of \$5000 for these two unlicensed treatments, and ordered Warren to hire a full-time, independent consultant to develop procedures for handling emergency cardiac patients whose needs cannot be sufficiently met at Warren. Warren then

wrote to the Department to request a hearing before the Office of Administrative Law ("OAL"). The dispute was accordingly transferred to the OAL.

After certain discovery, the Department filed a motion for summary decision. The Administrative Law Judge ("ALJ") denied that motion and proceeded to a plenary hearing in May 2010. Drs. Amin and Starosta testified at the hearing for Warren. The chairperson of the CHAP, Dr. Charles Dennis, a board-certified physician in internal medicine and cardiovascular disease, testified on the Department's behalf, as did two of the Department's representatives.

In an April 1, 2011 initial decision, the ALJ determined that it would have been impossible in these two patient situations for Warren to have complied with both N.J.A.C. 8:43G-2.4(c) and the federal statute relied upon by Warren, the Emergency Medical Treatment and Active Labor Act ("EMTALA"), 42 U.S.C.A. § 1395dd. Consequently, the ALJ ruled that the enforcement of N.J.A.C. 8:42G-2.4(c) against Warren here was in conflict with EMTALA. Because she determined that Warren had

<sup>&</sup>lt;sup>7</sup> Dr. Dennis's testimony in the OAL is not provided in the appellate record. Dr. Dennis apparently testified that Patients A and B were sufficiently stable to enable their transportation to another hospital.

acted appropriately under EMTALA, the ALJ invalidated the Department's sanctions against Warren.

On June 30 2011, the Department issued its final agency decision and rejected the ALJ's recommendation. The final agency decision was issued by Acting Commissioner Christina G. Tan, M.D., M.P.H.

The Acting Commissioner noted that the New Jersey Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 to -26, and EMTALA are broadly consistent with one another because both statutes share as their primary objectives the provision of safe health care. According to the Acting Commissioner, Warren improperly forced itself to choose between violating EMTALA and the HCFPA only because the hospital had not developed an effective policy for transferring patients to other hospitals when needed.

The Acting Commissioner also found that, pursuant to 42 <u>U.S.C.A.</u> § 1395dd(a), a hospital is required only to perform such services as it is actually capable of performing. This signified to the Acting Commissioner that Warren was not required under EMTALA to perform primary angioplasty for Patients A and B when it was not specifically equipped for that procedure. The Acting Commissioner also found that EMTALA does not bar the transfer of unstable patients to other locations for

treatment. For these reasons, the Acting Commissioner reversed the ALJ's decision and reinstated the terms of the sanctions imposed upon Warren.

On appeal, Warren argues that the agency's final decision reversed because it fails to give sufficient should be consideration to the hospital's obligations under EMTALA. Ιn particular, Warren argues that EMTALA preempts the State's imposition of sanctions here because emergency the two angioplasties were performed out of necessity, in situations where the patients could neither be safely transported nor In addition, Warren contends that the Department's stabilized. regulatory sanctions conflict with the professional obligations of the physicians in caring for patients in distress.

In considering Warren's arguments, and the Department's opposition, we are cognizant of the deference that we generally accord to State agencies within their zone of expertise. Generally speaking, "[an] administrative agency's final quasijudicial decision will be sustained unless there is a clear showing that it is arbitrary, capricious, or unreasonable, or that it lacks fair support in the record." In re Herrmann, 192 N.J. 19, 27-28 (2007) (citing Campbell v. Dep't of Civil Serv., 39 N.J. 556, 562 (1963)). However, that deference does not extend to purely legal questions such as issues of federal

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preemption. Finderne Mgmt. Co. v. Barrett, 355 N.J. Super. 170, 185 (App. Div. 2002), certif. denied,. 177 N.J. 219 (2003) (applying the principle to a preemption issue). In re Langan Eng'q & Envtl. Servs., Inc., 425 N.J. Super. 577, 581 (App. Div. 2012) (applying that general principle). We also do not sustain an administrative agency's findings if the record is inadequate to support them. E.g., Blackwell v. Dep't of Corr., 348 N.J. Super. 117, 120 (App. Div. 2002) (reversing an agency decision "because of inadequate findings").

II.

Congress adopted EMTALA in 1986 primarily to address widespread problems of disparate treatment of patients by hospitals and other health care providers. Among other things, EMTALA sought to end the practice of "patient dumping," whereby certain hospitals had refused to treat patients with medical emergencies for purely financial reasons. Toretti v. Main Line Hosps., Inc., 580 F.3d 168, 173 (3d Cir. 2009); Barber v. Hosp. Corp. of Am., 977 F.2d 872, 880 (4th Cir. 1992). Accordingly, EMTALA requires hospitals to provide emergency medical screening and stabilization in a manner that is not discriminatory. Toretti, supra, 580 F.3d at 173.

Pursuant to Section 1395dd(a) of EMTALA, a hospital must screen incoming patients as follows:

[I]f any individual . . . comes to the emergency department and a request is made on the individual's behalf for examination or treatment for a medical condition, the hospital must provide for an appropriate screening examination within the medical the hospital's capability of emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition (within the subsection meaning of (e)(1) of this section) exists.

An "emergency medical condition" is defined in EMTALA as a medical condition with "acute symptoms of sufficient severity" such that non-treatment could reasonably be expected to result in (1) placing the health of the individual "in serious jeopardy," (2) "serious impairment to bodily functions," or (3) "serious dysfunction of any bodily organ or part." 42 <u>U.S.C.A.</u> § 1395dd(e)(1). The import of 42 <u>U.S.C.A.</u> § 1395dd(a), which is not central to the present matter, is simply that a hospital may not turn away emergency room patients but must instead screen them consistently with its capabilities. <u>Cherukuri v. Shalala</u>, 175 <u>F.</u>3d 446, 449 (6th Cir. 1999). Such screening was clearly provided here at Warren for both Patients A and B.

If the physicians at a hospital determine that a patient does have an emergency medical condition, EMTALA directs the hospital to provide:

(A) within the staff and facilities available at the hospital, for such further

medical examination <u>and such treatment</u> as may be required to stabilize the medical condition, or,

- (b) for <u>transfer</u> of the individual to another medical facility in accordance with subsection (c) of this section.
- [42  $\underline{\text{U.S.C.A.}}$  § 1395dd(b)(1) (emphasis added).]

The hospital's duty to stabilize a patient under Section 1395(b)(1)(A), however, applies only to the extent that stabilization is "[w]ithin the capabilities of the staff and facilities available at the hospital[.]" 42 C.F.R. 489.24(d)(i) (2009); accord Cherukuri, supra, 175 F.3d at 451.

A "transfer" of a patient within the meaning of EMTALA refers to the movement of the patient outside of the hospital's facilities the direction of its employees, including at discharge from the hospital. 42 U.S.C.A. § 1395dd(e)(4). Transfer of a patient is permitted by EMTALA only under limited In particular, if a patient with an emergency circumstances. medical condition has not been stabilized, the hospital may not transfer the patient unless: (1) the patient (or his designee) gives written, informed consent; (2) a physician has signed a certification to the effect that, "based upon the information transfer, the medical benefits available at the time of reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual;" or (3) if no physician is physically present, a "qualified medical person" has signed such a certification in consultation with a physician. 42  $\underline{\text{U.S.C.A.}}$  § 1395dd(c)(1)(A).

Pursuant to EMTALA, a patient is "stabilized" if "no material deterioration of [his] condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility[.]" 42 U.S.C.A. § 1395dd(e)(3)(B). As the statutory language implies, this definition of "stabilized" is "purely contextual or situational," and requires the physician "to make a fast on-the-spot risk analysis." Cherukuri, supra, 175 F.3d at 449-50.

Applying these various concepts from EMTALA, Warren has presented a colorable justification for the emergency actions that it took respecting Patient A and Patient B, if one accepts at face value the transport constraints cited by the hospital. The record makes it abundantly clear that both Patients A and B were suffering from emergency medical conditions, as described under 42 <u>U.S.C.A.</u> § 1395dd(e)(1), as they were suffering from heart attacks and facing imminent death. At that point, then, Warren's duty was to either stabilize the patients to the extent that the hospital was capable of doing so, or to transfer the patients elsewhere.

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As noted, however, transfer was not allowable under EMTALA before stabilizing the patients unless consent was given or it was determined that the benefits of transfer outweighed the risks. Patient consent was not given. Nor were any doctors at Warren willing to certify that the benefits of transfer outweighed the risks, as they believed that death would occur if transfer was attempted. Transfer, therefore, did not appear to be an option under EMTALA, subject to the caveat that we will discuss, infra.

With respect to Patient A, Warren was not equipped to stabilize his condition. Additionally, the patient's physicians could not certify that transfer was an acceptable option. Pursuant to this analysis, Warren's duties to Patient A under EMTALA were seemingly met after the doctors at Warren exhausted their options for treatment with the equipment available on site. At that point, it would have been consistent with EMTALA's provisions for the doctors to do nothing more, which was unacceptable in light of Patient A's acute distress and his apparently imminent risk of death.

As for Patient B, Warren had in its stock equipment for angioplasty in parts of the body other than the heart, and Dr. Amin was able to use this equipment to treat Patient B's serious and emergent heart condition. Because Warren was therefore

capable of stabilizing, and in fact treating, Patient B with the equipment it already had on-site, it was seemingly obligated under 42 <u>U.S.C.A.</u> § 1395dd(b)(1)(A) to do so, at least as a matter of federal law.

We recognize that State law did not authorize Warren to perform these angioplasty procedures. The HCFPA grants the Department the authority to promulgate regulations and licenses, and to use its licensing function to enforce those regulations.

N.J.S.A. 26:2H-1; N.J.S.A. 26:2H-5(b); N.J.S.A. 26:2H-13; N.J. Ass'n of Health Care Facilities v. Finley (In re Health Care Admin. Bd.), 83 N.J. 67, 77, cert. denied, 449 U.S. 944, 101 S. Ct. 342, 66 L. Ed. 2d 208 (1980). The primary purpose of the HCFPA is to "provide for the protection and promotion of the health of the inhabitants" of New Jersey, and to ensure the provision of "health care services of the highest quality, of demonstrated need, efficiently provided and properly utilized at a reasonable cost[.]" N.J.S.A. 26:2H-1.

The applicable regulatory definitions here are contained within N.J.A.C. 8:33E-1.2. Under that regulation, "cardiac catheterization" is defined as the "insertion of a thin, flexible tube (catheter) into a vein or artery and guiding it into the heart for purposes of determining cardiac anatomy and function." Ibid. Additionally, "primary angioplasty" is

specifically defined in the regulation as "the mechanical reopening of an occluded vessel using a balloon-tipped catheter in patients with acute myocardial infarction ("AMI") who have not received antecedent thrombolytic therapy." <a href="Ibid.">Ibid.</a> Finally, a "low risk cardiac catheterization facility" is one providing invasive cardiac diagnostic services. <a href="Ibid.">Ibid.</a> Such facilities are not permitted to treat so-called "high-risk" patients, which category includes those patients suffering from AMI. <a href="Ibid.">Ibid.</a>

Pursuant to N.J.A.C. 8:43G-2.4(c), "[n]o hospital facility shall accept patients in any new service, unit, or facility until the hospital has a written approval and/or license issued by the Certificate of Need and Acute Care Licensure Program of the Department." It is undisputed here that Warren lacked a license to perform primary angioplasty. Instead, Warren's license allowed it to perform only low-risk diagnostic cardiac catheterization. In both instances here, Warren's doctors performed primary angioplasty to treat AMI and related symptoms. For this reason, it is clear that Warren violated N.J.A.C. 43G-2.4(c), and it is admitted as much in the administrative proceedings.

Warren nevertheless argues on appeal that because it was not providing a "new service" to Patients A and B, it did not run afoul of N.J.A.C. 8:43G-2.4(c). In this regard, Warren

construes "new service" to mean only those procedures that are offered and advertised to the public at large. We reject this crabbed reading of the regulation because it would render the regulation nugatory because it would allow hospitals to offer essentially any service to their patients on an ad hoc basis. Such a result does not comport with the policy goals of the HCFPA, as it would not promote "health care services of the highest quality, of demonstrated need, efficiently provided and properly utilized at a reasonable cost[.]" N.J.S.A. 26:2H-1.

Hence, there is a potential conflict here in the application of EMTALA, a federal law, and HCFPA and its related licensure regulations, which are state law. That potential conflict must be resolved by principles of federal preemption. When federal preemption of state legislation is at issue, the role of a court is to "'identify the domain expressly preempted.'" Dan's City Used Cars, Inc. v. Pelkey, U.S. , 133 <u>S. Ct.</u> 1769, 1778, 185 <u>L. Ed.</u> 2d 909, 918 (2013) (quoting Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 541, 121 S. Ct. 2404, 2414, 150 L. Ed. 2d 532, 550 (2001)). The statutory language "'necessarily contains the best evidence of Congress' pre-emptive intent.'" <u>Ibid.</u> (quoting <u>CSX Transp.</u>, Inc. v. Easterwood, 507 U.S. 658, 664, 113 S. Ct. 1732, 1737, 123 <u>L. Ed.</u> 2d 387, 396 (1993)). The preemption provision here,

42 <u>U.S.C.A.</u> § 1395dd(f), recites that the provisions of EMTALA "do not preempt any State or local law requirement, except to the extent that the requirement directly conflicts with a requirement of this section."

With respect to Patient B, the direct conflict is seemingly clear, as Warren had the capacity and duty to treat him, instead of consigning him to a time-consuming and potentially doomed transport to Easton after a delay of forty-five minutes or more waiting for such transport. The conflict as to Patient A is more complicated. As to Patient A, Warren initially lacked the capacity to treat him, until the necessary equipment was brought to the site. However, once that equipment was secured, Patient A seemingly required life-saving action in lieu of awaiting a time-consuming transport.

Following this analysis, if there is indeed a direct clash between EMTALA and New Jersey hospital law, the latter must yield. But the legal analysis should not stop there, because it is founded upon an implicit premise that the risks of a time-consuming transport for both patients were externally created and could not be avoided by Warren. As the Acting Commissioner recognized, that may not be so. The unacceptable risk of transport may well have been self-created by Warren.

In a number of contexts, a party is barred from seeking the protection of the law when the party itself created the need for See, e.g., Jock v. Zoning Bd. of Adjustment, that protection. 184 N.J. 562, 590-92 (2005) (noting that relief will be denied to a homeowner seeking a hardship variance under N.J.S.A. 40:55D-70(c)(1) when the homeowner himself created the hardship); McKenzie v. Corzine, 396 N.J. Super. 405, 414-15 (App. Div. 2007) (holding that injunctive relief is appropriate where the "imminent" irreparable injury alleged by the plaintiff was caused solely by the plaintiff's delay in filing an action in the Superior Court); Maudsley v. State, 357 N.J. Super. 560, 580-82 (App. Div. 2003) (ruling that police officers cannot claim exigent circumstances as a basis for belief in the existence of probable cause when the officers themselves created the exigency). Analogous principles potentially could be applied here against Warren, and defeat its claims of federal preemption and its other justifications for the unlicensed actions it took.

The problem is that, for purposes of our review, the factual record has not been sufficiently developed on the critical topic of self-created hardship. The record simply tells us a few core facts, i.e, that Easton is five miles away from Warren, that there is no other identified hospital in New

Jersey in the immediate vicinity of Warren with authority to perform primary angioplasties, and that the transport service used by Warren is from Morris County and that it can take forty-five minutes or more to respond. The record is silent on many other facts that could potentially bear upon whether it would be fair or practical to expect Warren to have a more efficient transport system.

For example, we do not know if any other transport providers could supply quicker service, or whether Warren adequately investigated such options. We also do not have in the record the contract or other document that specifies the transport service's responsibilities. Nor do we know if that service could feasibly open a satellite office in Warren County or otherwise improve on its response times, perhaps in exchange for a higher fee paid by the hospital.

At oral argument before us, the Deputy Attorney General suggested that Warren itself might obtain transport vehicles and provide that service to Easton, when needed, itself. But the record does not tell us how much such "in-house" capability would cost, and how often it would be expected to be used. The record does indicate that Warren receives AMI patients about forty times per year, and the patients who are candidates for angioplasty are routinely transferred to Easton — which may

suggest that the Morris-based transport service might have been sufficient in most instances.

The insufficiency of the record is likely attributable to the Department's failure to have charged Warren with violating the specific regulation that covers such transport capability, N.J.A.C. 8:33E-1.8(a), which provides that:

[e]very facility applying to provide or providing invasive cardiac diagnostic services pursuant to this subchapter which is not also licensed to provide cardiac surgery services on site shall develop and maintain written agreements with cardiac surgery centers which shall include, but not necessarily be limited to: provisions for insuring quality control, rapid referral for emergency backup and transport surgery, procedu<u>res</u>, regular communication and cardiologist between the performing catheterization and the surgeons to whom patients are referred. In addition, one of the referral agreements must be within one hour travel time from the diagnostic facility and at least one of the referral agreements shall be written with a New Jersey cardiac center.

## [Emphasis added.]

Inexplicably, the Department's August 24, 2007 violation notice and its ensuing September 24, 2008 notice of assessment do not cite this transport regulation. Instead, the Department confined its reliance to the licensure restrictions of N.J.A.C. 8:43G-2.4(c). The Department did not cite N.J.A.C. 8:33E-1.8(a) until its brief responding to Warren's opposition to the motion

for summary decision. As a result of this belated citation, the ALJ did not conduct fact-finding on the subject, because, as she noted, the Department "neither charged [Warren] with this violation nor amended its pleading to encompass it."

The Acting Commissioner's decision went further than the ALJ, as she included a citation to the transport regulation in her analysis. The Acting Commissioner specifically found that Warren "failed to develop effective policies and procedures to enable its emergency department physicians to implement these same tested and true regulatory referral and transport procedures, thereby embedding its physicians with a 'Morton's Fork,' forcing a choice between violating EMTALA and violating hospital licensing standards." (Emphasis added). We cannot evaluate whether this criticism is fair and practical, because the record does not contain enough facts for us to make such an assessment. Because the Acting Commissioner's key conclusion on this subject is not grounded in a proper record, nor any findings of fact by the ALJ, we do not owe it special deference. See, e.g., H.K. v. Dep't of Human Servs., 184 N.J. 367, 384 (2005) (noting that review of a final agency decision is less

<sup>&</sup>lt;sup>8</sup> We also note that neither the Acting Commissioner nor the ALJ addressed the "one-hour travel time" language within N.J.A.C. 8:33E-1.8(a), and how that language squares with the agency's position that Warren's transport arrangements are unacceptable.

deferential when the agency has strayed from the ALJ's factual findings); Clowes v. Terminix Int'l, Inc., 109 N.J. 575, 587-88 (1988) (same).

For these reasons, we remand this matter to the agency, in anticipation of a further reference to the OAL, to develop the record more fully on the "self-created" hardship issue, and for the agency to then reconsider its decision in light of those amplified proofs and ALJ findings. Nothing precludes the Department from filing a new administrative action against Warren seeking prospective relief against the hospital under N.J.A.C. 8:33E-1.8, if its ongoing transport practices are considered deficient. If Warren continues to be aggrieved after the remand is completed or the matter is not otherwise resolved, it may pursue a new appeal.

Reversed and remanded. We do not retain jurisdiction.

I hereby certify that the foregoing is a true copy of the original on file in my office.

CLERK OF THE APPELLATE DIVISION