April 2, 2012

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert Humphrey Building
200 Independence Avenue SW
Washington, DC 20201
[Submitted via *http://www.regulations.gov*]

Re: Docket No. CMS-1350-NC

Public Citizen and the National Women's Health Network (NWHN) submit these comments in response to the Request for Comments dated February 2, 2012, at 77 Fed. Reg. 5213, by the Centers for Medicare & Medicaid Services (CMS). CMS sought comment on the question whether the Emergency Medical Treatment and Active Labor Act (EMTALA), commonly known as the patient anti-dumping statute hospitals, requires or whether CMS regulations implementing EMTALA should require hospitals with specialized capabilities to accept an appropriate transfer of a patient with an emergency medical condition who has already been admitted as an inpatient to another hospital. CMS currently interprets EMTALA, specifically section 1867 (42 U.S.C. § 1395dd(b) & (g)), to impose no obligation on the receiving hospital to accept transfers after a patient has been admitted. CMS has request "data or real world examples that are relevant to this issue."

The current request for comments is a follow up to a December 23, 2010, Advanced Notice of Proposed Rulemaking, published at 75 Fed. Reg. 80762. That notice addressed both the need to revise CMS's regulation concerning transfers to hospitals with specialized care facilities and CMS's rule interpreting EMTALA to mean that, when a patient comes to a hospital emergency department and is admitted as an inpatient before being stabilized, the hospital's EMTALA duty ends. The notice was issued in accordance with the agency's representation to the U.S. Supreme Court, through a brief filed by the United States Solicitor General, "that HHS had committed to initiating a rulemaking process to reconsider the policy articulated in its current regulations, which state that a hospital's EMTALA obligations end upon the good faith admission as an inpatient of an individual with an [emergency medical condition]." 77 Fed. Reg. at 5216.

Although neither Public Citizen nor NWHN is in a position to provide data on the issues, we submit this comment to reiterate Public Citizen's earlier comment (dated February 22, 2011) encouraging CMS to issue a proposal to revise both regulations. The current regulations are inconsistent with the plain language of EMTALA, thereby encouraging hospitals to engage in activity that is prohibited by EMTALA and and undermining the protections that Congress sought to provide to patients with emergency medical conditions.

STATUTORY AND REGULATORY BACKGROUND

A. EMTALA

EMTALA, at 42 U.S.C. Section 1395dd, states in relevant part:

(a) Medical screening requirement

In the case of a hospital that has a hospital emergency department, if any individual (whether or not eligible for benefits under this subchapter) 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 medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition (within the meaning of subsection (e)(1) of this section) exists.

(b) Necessary stabilizing treatment for emergency medical conditions and labor
(1) In general

If any individual (whether or not eligible for benefits under this subchapter) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either—

(A) within the staff and facilities available at the hospital, for such further medical examination and such treatment as may be required to stabilize the medical condition, or

(B) for transfer of the individual to another medical facility in accordance with subsection (c) of this section.

[Paragraph (2) omitted here.]

(c) Restricting transfers until individual stabilized
(1) Rule

If an individual at a hospital has an emergency medical condition which has not been stabilized (within the meaning of subsection (e)(3)(B) of this section), the hospital may not transfer the individual unless—

(A)(i) the individual . . . in writing requests transfer to another medical facility,

(ii) a physician . . . has signed a certification that based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual and, in the case of labor, to the unborn child from effecting the transfer, or

(iii) if a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as defined by the Secretary in regulations) has signed a certification described in clause (ii) after a physician . . . , in consultation with the person, has made the determination described in such clause, and subsequently countersigns the certification; and

(B) the transfer is an appropriate transfer (within the meaning of paragraph (2)) to that facility.

. . . . .

(g) Nondiscrimination

A participating hospital that has specialized capabilities or facilities (such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers as identified by the Secretary in regulation) shall not refuse to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual.

Under the statute, "stabilize" means, with respect to an emergency medical condition, "to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility, or, with respect to an emergency medical condition [with respect to a pregnant woman who is having contractions], to deliver (including the placenta)." *Id*. § 1395dd(e)(3)(A); *see also id*. § 1395dd(e)(3)(B).

"Transfer" includes "discharge." *Id*. § 1395dd(e)(4).

B. CMS Regulations

In a 2002 proposed rule, CMS undertook to clarify EMTALA's applicability to patients who were admitted to a hospital after coming to the emergency department seeking treatment for a medical condition. 67 Fed. Reg. 31404, 31475. The proposal stated that, once a hospital incurs an EMTALA obligation, that obligation continues while the patient remains at the hospital. Accordingly, any transfer or discharge of the patient would have to comply with the rules restricting transfer or discharge of a patient who has not yet been stabilized. The proposal stated that "[a]dmitting an individual whose emergency medical condition has not been stabilized does not relieve the hospital of further responsibility to the individual under [EMTALA]." *Id*. at 31475. CMS emphasized that "an admission to inpatient status cannot be used to evade EMTALA responsibilities." *Id*. It further noted that "permitting inpatient admission to end EMTALA obligations would provide an obvious means of circumventing these requirements that would seemingly contradict the point of the statute to protect emergency patient health and safety." *Id*. As an example, CMS explained that women in labor were "a central focus of the statute," and "the statute *clearly*

contemplated protecting them until completion of the delivery (that is, stabilization)." (emphasis added). *Id*.

In its 2002 proposal, CMS further stated that EMTALA does not impose obligations with respect to inpatients who become unstable after admission, "but only to patients who initially come to the hospital's emergency department with an emergency medical condition, and only until the condition has been stabilized." *Id*. at 31476. The agency found this limitation in section 1395dd(c) of the Act, which restricts transfers of any "individual at a hospital" with an unstable emergency medical condition. Although that provision does not limit "emergency departments," but "hospitals," it also refers to physicians "not physically present in the emergency department at the time" of the transfer. CMS believed that this language demonstrated that EMTALA was not intended to apply to admitted patients who become unstable *after* admission. *Id*.

Finally, the proposed rule clarified that, if a patient with an emergency medical condition is admitted as an inpatient and then stabilized, the hospital's EMTALA obligation ends even if the patient remains in the hospital and later becomes unstable. *Id*. at 31476.

In its final rule, issued in 2003, CMS did an about-face with respect to inpatients who had arrived at a hospital with emergency medical conditions, stating instead that EMTALA requires stabilizing care to avoid deterioration of the patient's condition only if the patient is being transferred. 68 Fed. Reg. 53222, 53243-45. The rule states that, for hospitals that have emergency departments, if an individual comes to the emergency department and has an emergency medical condition, the hospital must "provide any necessary stabilizing treatment . . . or an appropriate transfer." 21 C.F.R. § 489.24(a)(1)(ii). However, "[i]f the hospital admits the individual as an inpatient for further treatment, the hospital's obligation . . . ends." *Id*. That is, a patient who remains in the emergency room cannot be discharged or transferred without being stabilized, but a patient who is admitted as an inpatient from the emergency room can be discharged or transferred without being stabilized.

The agency stated that its proposal had been based on analysis of the statute and the legislative history. 68 Fed. Reg. at 53244. Explaining its reversal, the agency started by looking to three court of appeals decisions—one that predated the proposed rule by six years and two that followed the proposal by only weeks. *Id*. One of the cases, *Harry v. Marchant*, 291 F.3d 767 (11th Cir. 2002), involved a patient who was neither transferred nor discharged. Rather, she came to the emergency room and was admitted to the hospital, where she died a few hours later. The court's holding did not address the issue whether EMTALA is applicable to inpatients. Rather, the court held that EMTALA's stabilization requirement is stated only with respect to transfer or discharge, and that EMTALA did not apply in a case in which no transfer or discharge occurred. Similarly, in *Bryan v. Rectors & Visitors of the University of Virginia*, 95 F.3d 349 (4th Cir. 1996), the court's holding addressed stabilization, not inpatients. There, the court held that, because EMTALA's "stabilization" requirement is "defined entirely in connection with a possible transfer and without reference to the patient's long-term care within the system," *id.* at 352, and because the patient in the

case had been neither transferred nor discharged (which falls within the definition of transfer), the facts of the case did not state a claim under EMTALA.

In the third case cited in the 2003 rulemaking, *Bryant v. Adventist Health System/West*, 289 F.3d 1162 (9th Cir. 2002), a patient came to the hospital emergency room, was treated, and was discharged. Later that day, the physician realized that he had failed to detect a serious problem, and the patient was advised to return to the hospital immediately. When he arrived, he was admitted as an inpatient. He was transferred three days later to a hospital that had more ICU space, discharged a few weeks later, and died about 10 days after that. The family later sued the first hospital. Rejecting the EMTALA claim with regard to the three-day stay, the Ninth Circuit held that EMTALA's "stabilization requirement normally ends when a patient is admitted for inpatient care." *Id*. at 1167. (*Bryan* and *Bryant* are discussed further below.)

In explaining its conclusion that EMTALA obligations end when a hospital admits a patient with an emergency medical condition as an inpatient, CMS did not purport to be interpreting statutory language or exercising expertise. CMS stated: "*As a result of these court cases*, and because we believe that existing hospital CoPs [conditions of participation in Medicare] provide adequate, and in some cases, superior protection to patients, we are interpreting hospital obligations under EMTALA as ending once the individuals are admitted to the hospital inpatient care." 68 Fed. Reg. at 53244-45 (emphasis added). Indeed, far from exercising the agency's expertise, CMS expressly stated that the *agency* was deferring to the *courts*: "We believe that, as the agency charged with enforcement of EMTALA, it is appropriate to pay deference to the numerous Federal courts of appeal that have decided upon this issue." *Id*. at 53245. CMS failed to cite, however, the decisions of two federal courts of appeals that took the opposite view from the final rule. *See Lopez-Soto v. Hawayek*, 175 F.3d 173 (1st Cir. 1999); *Thornton v. Southwest Detroit Hosp*., 895 F.2d 1131 (6th Cir. 1990).

In 2008, CMS announced a proposed revision to its regulation that would have recognized that inpatients are protected by EMTALA in certain limited circumstances. 73 Fed. Reg. 23528, 23669-71 (2008). Specifically, CMS proposed to amend 42 C.F.R. § 489.24(f), which addresses EMTALA obligations of recipient specialty hospitals. The proposed rule interpreted EMTALA to require a specialty hospital to receive patients transferred from a referring hospital, even if the patients had been admitted as inpatients at the referring hospital. CMS explained that it was promulgating the rule to make clear that inpatient status does not relieve "all hospitals" of EMTALA obligations, only the hospital at which the patient was an inpatient.

Again, after receiving comments, CMS reversed its position. 73 Fed. Reg. 48433, 48656-61 (2008). Instead, CMS took the position that recipient specialty hospitals do not have an EMTALA duty to accept or stabilize patients with emergency medical conditions being transferred from hospitals at which they are inpatients.

DISCUSSION

The December 2010 ANPRM requested comment on (1) whether CMS should revise its policy with respect to whether EMTALA imposes on hospitals a duty to stabilize patients who come to the hospital with emergency medical conditions and are then admitted as inpatients, and (2) whether CMS should revise its policy with respect to the responsibility under EMTALA of a hospital with specialized capabilities to accept appropriate transfers of patients who have been admitted as inpatients at another hospital but cannot be stabilized by that hospital. Notwithstanding the Solicitor General's representation to the U.S. Supreme Court, CMS has now decided not to revise its regulations to address the first issue—whether a hospital's EMTALA obligations cease to exist when the patient with an emergency medical condition is admitted as an inpatient. CMS has also decided to make "no proposals with respect to our policies regarding the applicability of EMTALA to hospitals with specialized capabilities," but is seeking data relevant to the issue.

Public Citizen and NWHN are not in a position to provide data or examples. Indeed, it seem to us that only CMS itself and hospitals would have examples, and hospitals, which oppose a regulatory change on this issue, are unlikely to share it. Nonetheless, we note that the hospitals' repeated statements of opposition over a period of years suggests that the real-world effect of not relieving specialized care facilities from their EMTALA obligations when one hospital seeks to transfer a patient who came to an emergency room, was admitted, but could not be stabilized, suggests that refusals to accept appropriate transfers are common. It is worth noting that, despite significant opposition from hospitals, CMS's EMTALA Technical Advisory Group advised in 2008 that the regulation be revised with respect to the EMTALA obligations of specialized care hospitals.

Regardless of the policy preferences of hospitals or even the agency, the bottom line is that the current regulations are inconsistent with EMTALA itself. Accordingly, the regulations must be revised.

A. Language of EMTALA

The plain language of 42 U.S.C. § 1395dd(b)(1), which sets forth the relevant requirement that patients with emergency conditions be stabilized and prohibits their transfer or discharge except in accordance with the detailed requirements of subsection (c), is not limited to emergency room patients. The statutory language uses the term "emergency medical conditions" but does not mention "emergency rooms," "emergency departments," or similar terms. *See Lopez-Soto*, 175 F.3d at 173 ("This language [of subsection (b)] unambiguously imposes certain duties on covered hospitals vis-à-vis *any* victim of a detected medical emergency, regardless of how that person enters the institution or where within the walls he may be when the hospital identifies the problem. ... Nothing in the subsection's text suggests a necessary relationship between a hospital's obligations and the identity of the department within the hospital to which the afflicted individual presents himself.") (case citations omitted).

Notably, in subsection (a), Congress made EMTALA's medical screening requirement applicable only to "a hospital that has a hospital emergency department" and mandated that individuals who "come[] to the emergency department" be screened "within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department." In all, Congress used the term "emergency department" four times in the one sentence subsection (a). Yet in subsection (b), Congress did not use that term at all. Rather, in phrases that otherwise largely parallel phrases in subsection (a), subsection (b) refers to individuals who "come[] to a hospital," and to the facilities "available at the hospital." And, critically, subsection (b) on its face imposes requirements on "the *hospital*" (emphasis added) with respect to any patient who comes to it with an emergency condition. The Sixth Circuit's reading gives meaning to this deliberate change in terminology; petitioner's reading does not.

Similarly, subsection (c), "Restricting transfers until individual stabilized," expressly imposes obligations on "hospitals," not simply "emergency departments." Specifically, it restricts transfer of "an individual *at a hospital*" (emphasis added) who has an unstabilized "emergency medical condition." Like subsection (b), this subsection does not distinguish between emergency-room patients and patients in other hospital departments.

Moreover, the definition of stabilization, § 1395dd(e)(3)(A), (B) (defining "to stabilize" and "stabilized"), cannot reasonably be read to support the argument that the requirement of providing "necessary stabilizing treatment" before transfer/discharge ends when a patient with an emergency medical condition has been admitted as an inpatient. First, stabilization is defined with reference to individuals with "emergency medical conditions," but not individuals in "emergency departments." Indeed, none of the defined terms—"emergency medical condition," "participating hospital," "to stabilize," "stabilized," or "transfer"—is defined with reference to an emergency department. Second, the requirement of stabilization prior to transfer applies equally to patients with emergency medical conditions other than labor and to women in labor. With regard to a pregnant woman having contractions, § 1395dd(e)(3)—the same provision that defines stabilization with regard to emergency medical conditions other than labor—specifies that the patient has not been stabilized, and thus the EMTALA obligation continues, until she "has delivered (including the placenta)." If EMTALA ceases to apply to patients upon admission as an inpatient, then if a woman in labor were transferred from an emergency department to the maternity ward, she could be discharged prior to delivery. This outcome is not a reasonable reading of the statute. Congress did not state that a pregnant woman has EMTALA rights as long as she is in labor, unless the hospital moves her to the maternity ward. Congress did not state that a pregnant woman has EMTALA rights as long as her labor is short, and the hospital has no time to admit her. Instead, Congress fashioned a statute that promised women in labor that they would be cared for until they have "delivered." Yet patients with "emergency medical conditions" are treated under EMTALA the *same* as women in labor—same statutory provisions, same EMTALA rights and obligations. Accordingly, like a pregnant woman admitted for the duration of her labor (that is, until she is "stabilized"), a patient admitted for treatment of an "emergency medical condition" cannot be transferred/discharged under § 1395dd(b)(1) until he has been stabilized or the requirements of subsection (c) are otherwise met.

Finally, CMS's exclusion of inpatients from EMTALA is particularly harmful in light of its determination to exclude transfers of unstable inpatients to hospitals with specialized capabilities. Under this aspect of CMS's rule, if a hospital admits a patient with an emergency medical condition as an inpatient, is unable to stabilize the patient, and seeks to transfer the patient to a facility better equipped to address the patient's needs, the second facility has no EMTALA obligation to accept the transfer. If the initial hospital had determined before admitting the individual as an inpatient that it could not stabilize the emergency medical condition, the second hospital would have an EMTALA obligation to accept the transfer. The patients affected by this aspect of the current CMS policy are those most in danger of loss of life, limb, or other significant serious harm. As CMS seemed to recognize in its 2008 proposal, 73 Fed. Reg. 23669, this policy cannot be squared with either the text or the purpose of EMTALA's nondiscrimination provision, § 1399dd(g).

The nondiscrimination provision requires "participating hospitals" with "specialized capabilities" to accept all "appropriate transfer[s]" if the hospital has the ability to treat the patient. Congress enacted this provision to prevent "reverse dumping," and CMS's current policy thwarts that goal. As the United States Court of Appeals for the Tenth Circuit Court recognized in *St. Anthony Hospital v. HHS*, 309 F.3d 680 (10th Cir. 2002), allowing the receiving hospital to make the decision of what is an "appropriate transfer" would "nullif[y]" the requirement of § 1399dd(g), thereby creating a significant loophole in the protections afforded by EMTALA. Yet that is the effect of CMS's current policy. Consistent with the 2007 recommendations of the Technical Advisory Group, CMS should revise its policy to confirm to the language and intent of EMTALA.

B. CMS Regulation

The CMS regulatory commentary from 2002 and 2003 and the final rule reveal several weaknesses in the policy adopted in the final rule. To begin with, in issuing the final rule, CMS stated that it was "paying deference" to "the numerous Federal courts of appeals that have decided upon this issue." 68 Fed. Reg. at 53245. This approach was suspect for two reasons. First, in each of the court of appeals cases on which CMS relied, the facts made a distinction between stabilization in connection with transfer (or discharge) and stabilization with regard to the patient's long-term care an easy one. None of those cases involved a situation in which, although the patient was admitted, he was still undergoing "emergency treatment," in that he was not stable and the hospital was still "consider[ing] whether it would undertake longer-term full treatment." *Bryant*, 289 F.3d at 1167 (quoting *Bryan*, 95 F.3d at 352). In *Bryant*, the plaintiff did not allege that the patient was not adequately stabilized for transfer to the second hospital. In *Bryan*, no transfer occurred. Thus, neither court considered a situation in which the hospital had not stabilized the patient's condition to a point where transfer (which by definition includes discharge) was safe.

Second, while citing three decisions—one of which did not address the issue at all and another of which was decided on a different ground—CMS did not cite another court of appeals decision that directly addressed the question and held that EMTALA obligations do *not* cease when a patient with an emergency medical condition is admitted as an inpatient. *See Thornton*, 895 F.2d at 1135. Moreover, CMS failed to cite *Lopez-Soto*, 175 F.3d 173, in which another federal court of

appeals held that EMTALA's stabilization requirement is not restricted to emergency room patients. *See also Smith v. Richmond Mem. Hosp.*, 416 S.E.2d 689, 692 (Va. 1992) ("[W]e find nothing in the language of the Act which limits application of these subsections solely to a patient who initially arrives at the emergency room and who has not been stabilized, as the Hospital argues here. ... This interpretation of the Act is consistent with the legislation's purpose. Patient dumping is not limited to a refusal to provide emergency room treatment. ... It occurs, and is equally reprehensible, at any time a hospital determines that a patient's condition may result in substantial medical costs and the hospital transfers the patient because it fears it will not be paid for those expenses. Dumping a patient in this manner is neither related to, nor dependent upon, the patient arriving through the emergency room and never being stabilized.").

CMS's failure to acknowledge that some cases, indeed the most on-point cases, came to a different conclusion is particularly significant because CMS expressly stated that it was "paying deference" to the federal courts of appeals decisions and that it was reversing the view stated in the proposed rule partly "[a]s a result of these court cases." 68 Fed. Reg. at 53244, 53245. CMS's conclusion that it should defer to a purportedly "consistent judicial interpretation of this matter," *id.* at 53245, was based on a false premise because CMS omitted the most relevant cases.

Third, CMS's position creates an unworkable loophole. Under that reading, if a hospital wants to "dump" an uninsured patient who has come to the emergency department, the hospital can temporarily admit the person as an inpatient and then discharge her. Indeed, even while stating its policy that EMTALA does not apply to inpatients, CMS acknowledged that its reading rested on a distinction that could be manipulated to circumvent the protections of the statute. *See id.* CMS's only answer was to say that "[i]f it is discovered upon investigation of a specific situation that a hospital did not admit an individual in good faith with the intention of providing treatment (that is, the hospital used the inpatient admission as a means to avoid EMTALA requirements), then liability under EMTALA may attach." *Id*. This statement is inconsistent with CMS's explanation of the basis for its reading. CMS's primary substantive justification for its change of heart from the proposed rule to the final was the existence of other remedies (medical malpractice actions and CMS sanctions) for poor treatment of inpatients. If these remedies justify excluding properly admitted inpatients from the reach of § 1395dd(b), however, they also justify excluding inpatients admitted for the purpose of avoiding EMTALA, because those remedies exist whether or not the patient was admitted for the purpose of circumventing § 1395dd(b).

Moreover, if the language of § 1395dd(b) does not apply to hospital inpatients, as the CMS rule states, then it is hard to see how that language applies to hospital inpatients even in the circumstance where the hospital admits the patient to terminate its EMTALA obligation, because nothing in § 1395dd(b) supports a distinction based on how the patient came to be admitted. (Indeed, the provision does not mention "inpatients," but only "individual[s]" with "emergency medical condition[s].") That is, however well-intentioned, CMS cannot make sense of the loophole created by its policy by creating an exception not founded in the words of the statute. "[E]xceptions [to statutory language] are not to be implied. An exception cannot be created by construction." Singer, 2A *Sutherland Statutory Construction* § 47.11 (5th ed. 1992).

Finally, the CMS policies have proven bad for patients. We understand that, since the 2003 rulemaking, hospitals are acting faster to admit as inpatients individuals with emergency medical conditions, thereby (under CMS's policy) ending the hospitals' EMTALA obligations prematurely. If as a result of the faster admission, the hospital does not determine before admission that it does not have the capability to treat the patient's emergency medical conditions, it may be more difficult for the hospital to secure an appropriate transfer to a hospital that has the specialized capability to do so. Accordingly, CMS's policies have had concrete negative effect on the provision of care to patients with emergency medical conditions.

CONCLUSION

For the reasons stated above, we urge you to issue a notice of proposed rulemaking to amend CMS's rules with respect to the applicability of EMTALA of inpatients and the responsibilities of hospitals with specialized capabilities.

Sincerely,

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