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PREVENTING UNDER-EQUIPPED MEDICAL FACILITIES FROM KILLING HEART ATTACK PATIENTS: CORRECTING INEFFICIENCIES IN THE CURRENT REGULATORY PARADIGM FOR PROVIDING CRITICAL HEALTH CARE SERVICES TO PATIENTS WITH ACUTE CORONARY SYNDROME

Robert Steinbuch[†]

INTRODUCTION

Heart attacks are the number one killer in the United States.¹ Each year about 1.2 million Americans suffer from heart attacks, and approximately 500,000 die as a result.² Consumers of emergency medical care for symptoms of possible heart attacks, a.k.a. Acute

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¹ AM. HEART ASS'N., ACUTE CORONARY SYNDROME, WHAT IS ACUTE CORONARY SYNDROME?, <http://www.americanheart.org/presenter.jhtml?identifier=3010002>

² RETAVASE, PRODUCT FACT SHEET, http://www.pdl.com/documents/Retavase_Fact_Sheet.pdf (pharmaceutical company fact sheet for prescription medication Retavase, which is designed to help prevent heart attacks); AM. HEART ASS'N., HEART ATTACK AND ANGINA STATISTICS, <http://www.americanheart.org/presenter.jhtml?identifier=4591> (last visited Nov. 15, 2006).

Coronary Syndrome (ACS),³ suffer from both over- and under-regulation, resulting in two market imperfections: (1) over-regulation results in heart attack patients transported by ambulances being taken to the closest, rather than the appropriately-equipped, facilities; (2) under-regulation results in heart attack patients who are seeking emergency medical care on their own being faced with misleading hospital advertising that results in the provision of sub-optimal care. Both of these imperfections lead to the inefficient allocation of limited health care resources, resulting in a reduction in social wealth.

Given these market and regulatory failures, this Article discusses why the current regulatory model should be abandoned in favor of a paradigm in which (1) heart attack patients transported to hospitals by emergency medical services are directed to the best-equipped facilities, allowing for the maximization of both patient care and facility compensation; and (2) the manner in which medical facilities are permitted to advertise their capabilities to address ACS is regulated so as to ensure that information asymmetries between health care providers and consumers do not distort the market for optimal health care.

The Article is divided into five parts. This introductory section has briefly presented the significant impact of heart attacks on American health care and the need for better regulation of its treatment. Part I presents the medical issues involved in ACS; it focuses on the time-sensitive nature of heart attacks and the specific means to address these acute events. Part II analyzes the economic causes and effects of regulatory inefficiencies in the provision of heart attack care. Part III proposes solutions to these problems, including providing proposed statutory language for enactment. Finally, the Article presents some concluding thoughts.

I. TREATING ST-ELEVATED MYOCARDIAL INFARCTIONS

A "heart attack" describes the permanent tissue damage—should it occur—caused by ACS. The critical type of ACS leading to a heart attack⁴ is defined by a blockage in an artery to the heart that needs to be opened.⁵ The blockage typically occurs when blood clots around an

³ ACS refers to any group of clinical symptoms compatible with insufficient blood supply to the heart. Patients who have symptoms of ACS are given an electrocardiogram (ECG). An ECG provides a graph of the heartbeat, with different portions labeled P, Q, R, S and T. AM. HEART ASS'N, ACUTE CORONARY SYNDROME, *supra* note 1.

⁴ *Id.*

⁵ Ellen C. Keeley et al., *Primary Angioplasty Versus Intravenous Throm-*

eruptive plaque injury inside a blood vessel feeding the heart.⁶ These blockage-caused heart attacks uniquely create a rise in the “ST” segment on the ECG and are known as ST-elevated myocardial infarctions—STEMIs.⁷

When a patient suffers from this blockage-caused heart attack, doctors must quickly intervene and open the obstructed artery (reperfusion therapy);⁸ the longer the delay in treatment, the dramatically less effective the procedure becomes.⁹ The failure to promptly diagnose and care for these treatable heart attacks increases the damage to heart muscle of, and the likelihood of death to, these patients.¹⁰

Doctors can open the blocked blood vessels causing these heart attacks by threading a balloon-tipped catheter through an artery of the patient’s leg, or less commonly the arm, to the heart; when at the point of the obstruction, doctors inflate and deflate the balloon to crush the blockage against the wall of the artery—thus, reopening the artery.¹¹ This process is known as Percutaneous Coronary Intervention (PCI).¹²

bolytic Therapy for Acute Myocardial Infarction: A Quantitative Review of 23 Randomised Trials, 361 LANCET 13, 13 (2003); *The Best Treatment Most Heart Victims Aren’t Getting: Drugs More Likely to Be Used Over Angioplasty Procedure*, CNN.com, Oct. 10, 2003, <http://www.cnn.com/2003/HEALTH/conditions/10/10/heart.attacks.ap/> [hereinafter *Best Treatment*].

⁶ Gregg W. Stone & Bernard J. Gersh, *Facilitated Angioplasty: Paradise Lost*, 367 LANCET 543, 543 (2006).

⁷ U.S. NEWS AND WORLD REP., BEST HEALTH, HEART CENTER, CORONARY ARTERY DISEASE (CAD), <http://www.usnews.com/usnews/health/heart/cad/cad.about.htm>.

⁸ See Francis M. Fesmire et al., *Clinical Policy: Critical Issues in the Evaluation and Management of Adult Patients with Non-ST-Segment Elevation Acute Coronary Syndromes*, 48 ANNALS OF EMERGENCY MED. 270, 278 (2006); Elizabeth H. Bradley et al., *Achieving Door-to-Balloon Times That Meet Quality Guidelines: How Do Successful Hospitals Do It?*, 46 J. AM. C. CARDIOLOGY 1236, 1236 (2005).

⁹ Bradley et al., *supra* note 8, at 1236.

¹⁰ Lawrence K. Altman, *New Therapy Appears Capable of Stopping Heart Attack’s Progress*, N.Y. TIMES, June 15, 1982, at C1; Keeley et al., *supra* note 5, at 13; *Best Treatment*, *supra* note 5.

¹¹ SOCIETY FOR VASCULAR SURGERY, VASCULARWEB, PATIENT AND FAMILY HEALTH INFORMATION, ANGIOPLASTY AND STENTING, http://www.vascularweb.org/_CONTRIBUTION_PAGES/Patient_Information/NorthPoint/Angioplasty_and_Stenting.html; Keeley et al., *supra* note 5, at 13.

¹² This process is commonly known as, *inter alia*, catheterization or coronary angioplasty. See U.S. DEP’T OF HEALTH AND HUMAN SERV., NATIONAL HEART LUNG AND BLOOD INSTITUTE, DISEASES AND CONDITIONS INDEX, ANGIOPLASTY: OTHER NAMES FOR CORONARY ANGIOPLASTY, http://www.nhlbi.nih.gov/health/dci/Diseases/Angioplasty/Angioplasty_OtherNames.html (defining coronary angioplasty as synonymous with PCI); TEXAS HEART INSTITUTE, DIAGNOSTIC TESTS: CARDIAC CATHETERIZATION (2006), <http://www.texasheartinstitute.org/HIC/Topics/Diag/dicath.cfm> (referring to the PCI procedure as cardiac catheterization and providing informa-

In the alternative, doctors can administer clot-busting (fibrinolytic¹³) drugs.¹⁴ The goal of both treatments is the same—to unblock the artery and stop the brutal and irreparable damage to the patient's heart.¹⁵

Recent data confirms PCI as the optimal treatment for all patients with acute heart blockages,¹⁶ because patients undergoing PCI have fewer complications, lower mortality rates, and improved post-treatment results when compared to similarly situated patients receiving fibrinolytics.¹⁷ Simply put, “[t]here is no question that primary PCI, when available, is the treatment of choice.”¹⁸

tion on the catheterization process). Medical literature also refers to this same procedure as percutaneous transluminal coronary angioplasty (PTCA). Keeley et al., *supra* note 5, at 13. Angiograms or diagnostic catheterizations, in contrast to therapeutic catheterizations, simply allow the cardiologist to view the inside of the coronary vessels and the heart for possible future intervention. U.S. NAT'L LIBRARY OF MED. & NAT'L INST. OF HEALTH, MEDLINE PLUS, MED. ENCYCLOPEDIA, CARDIAC CATHETERIZATION (2006), <http://www.nlm.nih.gov/medlineplus/ency/article/003419.htm> (defining “cardiac catheterization”).

¹³ Also referred to in the literature as “thrombolytic.” See Cindy L. Grines et al., *Fibrinolytic Therapy: Is It a Treatment of the Past?*, 107 CIRCULATION: J. AM. HEART ASS'N 2538, 2538 (2003).

¹⁴ Altman, *supra* note 10, at C1 (clot busting drug approved by the Food and Drug Administration for use in treating heart attack patients in 1982); see Peter Moyer et al., *Implications of the Mechanical (PCI) vs Thrombolytic Controversy for ST Segment Elevation Myocardial Infarction on the Organization of Emergency Medical Services: The Boston EMS Experience*, 3 CRITICAL PATHWAYS IN CARDIOLOGY 53, 55 (2004).

¹⁵ *Best Treatment*, *supra* note 5.

¹⁶ Moyer et al., *supra* note 14, at 54; *Best Treatment*, *supra* note 5.

¹⁷ A meta-analysis of 10 randomized trials conducted through 1997 showed marked superiority of primary angioplasty versus thrombolytic therapy: mortality at 30 days was a relative 34 percent lower: 4.4 percent versus 6.5 percent ($P = 0.0218$). The combination of either death or reinfarction was also significantly reduced by a relative 42 percent: 7.2 percent versus 11.9 percent ($P = 0.001$), an absolute 4.7 percent reduction in events. With regard to safety, total stroke was significantly reduced by a relative 65 percent: 0.7 percent versus 2.0 percent ($P = 0.007$), and, most strikingly, intracranial hemorrhage was reduced by 93 percent: 0.07 percent versus 1.1 percent ($P = 0.001$). On the basis of this meta-analysis, primary PCI, as performed in these trials, was clearly superior to thrombolytic therapy.

Moyer et al., *supra* note 14, at 55; see Fesmire et al., *supra* note 8, at 272-73; Christopher P. Cannon, *Primary Percutaneous Coronary Intervention for All?*, 287 JAMA 1987, 1987 (2002); Keeley et al., *supra* note 5, at 13.

¹⁸ Grines et al., *supra* note 13, at 2538.

II. ACS PATIENTS ARE DIRECTED TO SUB-OPTIMAL CARE AS A RESULT OF OUTDATED OR INSUFFICIENT REGULATION, DEPENDING ON THE MODE BY WHICH THEY ENTER THE SYSTEM FOR THE PROVISION OF EMERGENCY MEDICAL CARE

Less than twenty-five percent of American hospitals have PCI capability.¹⁹ However, nearly eighty percent of Americans live within one hour's drive of a facility that performs PCI.²⁰ Those facilities are close enough to provide the time-sensitive advanced care that heart attack patients require,²¹ but patients must get to those facilities. Thus, the dilemma becomes transporting patients undergoing treatable heart attacks (STEMIs) to the right facility, *i.e.*, a PCI-capable facility.²²

Patients that suffer from possible heart attacks can be divided into two groups based on how they arrive at the hospital. ACS patients can come to hospitals seeking emergency care either by: (1) being transported by EMS (EMS-transported patients), or (2) walking in or being brought in by a family member or friend (walk-in patients).²³ Both of these means of entering the system for the provision of emergency medical care for ACS patients often result in patients being directed to under-equipped hospitals.

In the case of EMS-transported patients, outdated regulations direct patients to the closest facility rather than PCI-capable institu-

¹⁹ Ronald G. McKay, *Evolving Strategies in the Treatment of Acute Myocardial Infarction in the Community Hospital*, 42 J. AM. C. CARDIOLOGY 642, 642 (2003).

²⁰ Brahmajee K. Nallamothu et al., *Driving Times and Distances to Hospitals with Percutaneous Coronary Intervention in the United States: Implications for Pre-hospital Triage of Patients with ST-Elevation Myocardial Infarction*, 113 CIRCULATION: J. AM. HEART ASS'N 1189, 1191 (2006); *Best Treatment*, *supra* note 5.

²¹ Patients should receive PCI within ninety minutes of symptom onset. RETAVASE, *supra* note 2.

²² See ANGIOPLASTY.ORG, HEART ATTACK AND ANGIOPLASTY, PRIMARY ANGIOPLASTY IN TREATMENT OF ACUTE MYOCARDIAL INFARCTION (HEART ATTACK), http://www.ptca.org/ptca_ami.html (stating that a patient "with treatable MI should try and get to a hospital that can perform angioplasty" because it will greatly improve the patient's chances of survival).

²³ "Walk-in patients" include both those who walk in and those brought in by others. In actuality, there is also another group of patients who "arrive" at hospitals with STEMIs. These are in-hospital patients who suffer heart attacks while already admitted. If these patients are in non-PCI-capable facilities, they suffer from the same inefficiencies as those in the EMS model, although, at least intuitively, the risk that the community hospital will delay, or fail to, transfer them to a fully-equipped institution appears even higher.

tions.²⁴ Thus, proximity becomes compensated over capability, and patients often receive sub-optimal care.

For walk-in patients, unregulated hospitals exploit informational asymmetries to attract these customers by falsely advertising the ability to treat heart attacks, impeding the efficient market direction of resources. This allocative inefficiency results in: (1) heart attack patients, as a cohort, receiving sub-optimal care; (2) PCI-capable facilities receiving insufficient compensation; and (3) non-PCI-capable facilities both seeking and improperly garnering economic rents.

A. Current Regulatory Inefficiencies in the Provision of Emergency Transportation to Heart Attack Patients Result in Insufficient Incentives for Improvements in the Quality of Treatment and Sub-Optimal Care

In most jurisdictions, when an ambulance encounters heart attack patients, these patients are transported to the closest facility regardless of capability.²⁵ Directing heart attack patients to the closest facility is an historical vestige of pre-PCI technology.²⁶ Prior to the relatively recent advent of angioplasty, the treatment for ACS was modest, consisting of morphine to control pain and reduce anxiety, diet restriction, and anticoagulant-drug therapy, *i.e.*, anti-clotting drugs that behave similarly to aspirin.²⁷ As such, directing patients to the closest facility

²⁴ Thomas M. Burton, *Fatal Blockages: Stroke Victims Are Often Taken to Wrong Hospital – Outdated Ambulance Rules, Inadequate ERs Make Dangerous Ailment Worse – Lessons From Trauma Centers*, WALL ST. J., May 9, 2005, at A1.

²⁵ Moyer et al., *supra* note 14, at 53–54. See SUSAN ATHEY & SCOTT STERN, THE ADOPTION AND IMPACT OF ADVANCED EMERGENCY RESPONSE SERVICES 63 (1998) (showing typical EMS protocol to divert trauma patients to designated trauma centers, with no such explicit protocol for cardiac patients – although some cardiac patients are taken to trauma centers, as patients with the most severe indications in Pennsylvania, for example, are to be transported to hospitals with “appropriate capabilities”; otherwise patients are taken to the closest facility), available at <http://dspace.mit.edu/retrieve/2320/SWP-4007-40963055.pdf>. The lack of black-line protocols for cardiac patients comparable to the system for trauma patients results in too many cardiac patients being brought to the default closest facility. Absent these default regulations and protocols, ambulances and emergency medical services might be more likely to choose to direct patients to more distant facilities; moreover, regulations to the contrary, as proposed here, to direct cardiac patients to cardiac facilities, would result in far greater numbers of patients being brought to the highest-care facility. Unfortunately, the ground-breaking EMTALA statute appears to offer no assistance on this issue either, as it is focused on the opposite problem. Specifically, EMTALA addresses patient “dumping,” where patients are refused entrance to a hospital – not where patients are inappropriately selected by hospitals. 42 U.S.C. § 1395dd (2007).

²⁶ *Best Treatment*, *supra* note 5.

²⁷ See AM. COLL. OF CARDIOLOGY, ISCHEMIC HEART DISEASE, <http://www.acc>

was prudent due to the uniformity in treatment delivered by all institutions. Proximity resulted in the expeditious provision of the then-latest “technology”—albeit limited at best. Transportation to distant facilities wasted patient and EMS time and resources.

Today, in contrast, the rational heart attack patient—the consumer—most values the availability of the latest technology to address the ACS, *i.e.*, PCI-capability to address a possible STEMI. If the provision of emergency medical care were an ordinary market-directed service, PCI-capable facilities would be rewarded when patients chose to go to those better-equipped facilities (and the attendant insurance compensated those institutions). Those facilities would flourish economically. The under-equipped facilities, in contrast, would either wither commensurately or be forced to obtain comparable technology to remain competitive.²⁸

Both outcomes benefit patients by providing for increased access to the appropriate level of technology. If under-equipped facilities obtain competitive technology, by definition, they no longer will be under-equipped. If, however, under-equipped facilities cannot compete, they will cease operating. This will result in patients (and their remuneration) being directed to the remaining fully-equipped facilities. Thus, resources become channeled to their highest use, thereby improving patient care.

1. Hospitals Seek Out and Do Not Transfer Chest Pain Patients Due to the Lucrative Nature of Acute Coronary Syndrome

Under the current system for heart attack care, patients directed to sub-optimal facilities would benefit from improved care upon prompt

.org/media/patient/chd/ischemic.htm (using a case study to articulate typical care for a heart attack patient in 1949 in contrast to current treatments).

²⁸ See ATHEY & STERN, *supra* note 25, at 12 (allocation of hospitals will affect the incentives of hospitals to adopt various technologies); *cf.* Howard Beales et al., *The Efficient Regulation of Consumer Information*, 24 J.L. & ECON. 491, 492 (1981) (competition on quality increases consumer welfare). However, this is not to say that an alternative outcome is not possible. Indeed, many public health theorists are critical of those hospitals that focus on the high-dollar illnesses such as heart care. See Steven Pearlstein, *Free-Market Philosophy Doesn't Always Work for Health Care*, WASH. POST, June 8, 2005, at D1. The concern is that if patients with heart attacks are directed to dedicated heart centers or heart hospitals, then the remaining institutions will be forced to compete for the less lucrative patients. *Id.* These hospitals may not survive, and the result could be excellent heart care at top-level heart centers and no care for other conditions. *Id.* This is a legitimate public health concern. However, from the perspective of both cardiac patient and cardiac health care provider, directing patients to the specialty facility is optimal, the broader health care issues notwithstanding.

transfer to PCI-facilities. These patients, however, must rely on the sub-optimal facilities themselves to initiate transfer. This often does not occur due to the under-equipped hospitals', a.k.a. community hospitals, economic incentive to obtain and retain these ACS patients.

Hospitals, like other businesses, seek out revenue and are biased towards maximizing income.²⁹ These financially motivated business decisions are not necessarily consistent with the best interests of patients.³⁰ Since "Medicare pays generously for cardiac care,"³¹ and Medicare payments are not intended to encourage hospitals and doctors to coordinate care with other institutions,³² community hospitals often seek out and keep treatable heart attack patients rather than transferring them.³³

Economic modeling predicts this outcome. Total compensation (CP) for the treatment of a heart attack patient can be viewed as a function of four variables: (1) compensation for initial screening and basic treatment (IS); (2) compensation for PCI (PC); (3) compensation for fibrinolytics, *i.e.*, clot-busters (CB); and (4) compensation for longer-term observation and symptomatic treatment resulting from at least partially unsuccessful treatment of the underlying blockage

²⁹ Anthony Joseph, *The Chest Pain Center as an Operational Model*, 3 CRITICAL PATHWAYS IN CARDIOLOGY 14, 14-17 (2004); James F. Blumstein & Frank A. Sloan, *Redefining Government's Role in Health Care: Is a Dose of Competition What the Doctor Should Order?*, 34 VAND. L. REV. 849, 852-53 (1981); see Peggy Peck, *Medicare Will Pay for tPA in Stroke Thrombolysis*, MEDPAGE TODAY, Aug. 4, 2005, <http://www.medpagetoday.com/PublicHealthPolicy/MedicaidMedicare/tb/1489>.

³⁰ Cf. Shelley Wood, *Want 90-Minute Door-to-Balloon Times? Here's How*, THE HEART.ORG, Feb. 20, 2006, <http://www.theheart.org/article/650979.do> (listing eight common themes associated with improved delay time, and imply significantly increased spending on each patient); Pegram v. Herdrich, 530 U.S. 211, 219-20 (2000).

³¹ Reed Abelson, *Generous Medicare Payments Spur Specialty Hospital Boom*, N.Y. TIMES, Oct. 26, 2003, at A1.

³² *Id.* at 20 (citing "Dr. Gerard F. Anderson, a former federal health official who helped develop the [current Medicare] system and now teaches at the Johns Hopkins Bloomberg School of Public Health").

³³ See Burton, *supra* note 24 ("[Community] hospitals have resisted movement toward a system of specialized stroke centers because nondesignated institutions could lose business. . . . 'There are still very parochial interests by hospitals and physicians to keep patients locally even if they're not equipped to handle them,' says neurosurgeon Robert A. Solomon."); cf., Robert Steinbuch, *The Executive-Internalization Approach to High-Risk Corporate Behavior: Establishing Individual Criminal Liability for the Intentional or Reckless Introduction of Excessively Dangerous Products or Services into the Stream of Commerce*, 10 N.Y.U. J. LEGIS. & PUB. POL'Y (forthcoming 2007) (discussing how financial motivations can outweigh decision-makers' consideration of health and safety issues).

causing the heart attack (Obsv).³⁴ Thus, the total revenue for the treatment of heart attacks across institutions can be characterized as $\Sigma(\text{IS} + \text{PC} + \text{CB} + \text{Obsv})$.

Since PC and CB are typically mutually exclusive variables, a facility will receive either PC or CB but not both. PC is greater than CB, but the underlying service (PCI) requires significantly greater capital and labor costs.³⁵ Additionally, Obsrv is inversely related to PC and CB, although the relationship is not 1:1. That is, while facilities receive PC or CB based on whether the underlying services are provided, the failure of those services to fully address the heart attack (or the failure to provide the services comprising those variables at all) determines whether the patient will need the services providing compensation for the Obsrv variable.

Since percutaneous coronary intervention is successful approximately ninety-five percent of the time, and fibrinolytics are only successful approximately fifty-five percent of the time,³⁶ the probability of the Obsrv variable in the CP formula can be further refined and separated for PCI (CP.PCI) and non-PCI (CP.NPCI) facilities providing services to heart attack patients by introducing “*p*” to represent the probability of successful intervention:

$$\begin{aligned} \text{CP.PCI} &= \text{IS} + \text{PC} + p(\text{Obsv}), \text{ where } p < .05.^{37} \\ \text{CP.NPCI} &= \text{IS} + \text{CB} + p(\text{Obsv}), \text{ where } p < .45.^{38} \end{aligned}$$

Thus, while both PCI and non-PCI facilities both earn comparable revenue through IS, the remaining variables are in contrast. PCI facilities generally earn their revenue through successful PCI and rapid discharge (high PC, low Obsv). Non-PCI facilities earn their revenue from partially-successful fibrinolytic therapy, augmented through significant observation (low CB, high Obsv). Accordingly, while

³⁴ See ELLIOTT M. ANTMAN ET AL., ACC/AHA GUIDELINES FOR THE MANAGEMENT OF PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION: A REPORT OF THE AMERICAN COLLEGE OF CARDIOLOGY/AMERICAN HEART ASSOCIATION TASK FORCE ON PRACTICE GUIDELINES (COMMITTEE TO REVISE THE 1999 GUIDELINES FOR THE MANAGEMENT OF PATIENTS WITH ACUTE MYOCARDIAL INFARCTION) e82-e85 (2004), available at <http://www.acc.org/qualityandscience/clinical/guidelines/stemi/Guideline1/index.pdf>.

³⁵ PCI generally costs between \$20,000 and \$30,000. Tim Bonfield, *Heart Attack Strategy: Fast Care – Angioplasty Project Skips Transfer Time*, CINCINNATI ENQUIRER, June 28, 2004, at 1A. Fibrinolytics cost about \$2,000, and Medicare increases payment for patient treatment with these drugs by \$6000. Peck, *supra* note 29.

³⁶ Bonfield, *supra* note 35.

³⁷ *p* is less than .05 because some patients die.

³⁸ *p* is less than .45 because some patients die.

CB/patient is less than PC/patient, $(CB + p(\text{ObSv}))/\text{patient}$ will be closer to (and may even surpass) $(PC + p(\text{ObSv}))/\text{patient}$.

This profit-seeking model has proven lucrative for non-PCI facilities when, as is currently the case, competitive market forces are removed through the regulatorily-mandated direction of heart attack patients to these sub-optimal facilities.

“There is no incentive to change The small hospitals don't want to divert patients to larger hospitals, because that is lost revenue.”

Heart attack treatment, in fact, is one of the most profitable hospital services. While more could add primary angioplasty [*i.e.*, PCI] to their repertoires, most will not, because building and staffing the labs is too expensive.³⁹

Thus, even though adding PCI-facilities would allow community hospitals to market this significantly enhanced ability, they have generally found it more advantageous *not* to add this capability,⁴⁰ because, under the current regulatory scheme that mandates patient direction to sub-optimal facilities, there is little need for any marketing distinction at all.⁴¹

Further, once community hospitals take in heart attack patients, under current reimbursement policies, they have a direct economic disincentive to transfer these lucrative customers to PCI-capable facilities.⁴² Indeed, community hospitals are structured to hold onto

³⁹ *Best Treatment*, *supra* note 5 (quoting Dr. Cindy Grines of William Beaumont Hospital in suburban Detroit).

⁴⁰ See Sue Hughes, *Speeding up the Treatment of MI: Is Prehospital Thrombolysis or Expanded Primary PCI the Answer?*, THEHEART.ORG, Feb. 1, 2005, <http://www.theheart.org/article/385813.do>.

⁴¹ See *infra* note 66 (describing how the cohort of patients transported by ambulance, which accounts for approximately half of the patients in need of PCI, have no say regarding the facility to which they are transported; as discussed below, the other half, which is self-transported, has a choice, but it is often irrational due to informational asymmetries).

⁴² Cf. Lisa Nainggolan, *High-Risk ACS Patients Least Likely to be Transferred*, THEHEART.ORG, March 17, 2004, <http://www.theheart.org/article/220451.do> (indirectly implying that patients who are high risk are more likely to die before or during the procedure and, thus, are not as financially lucrative as healthier patients who survive the procedure and require continuing care); Richard E. Waters II et al., *Rationale and Strategies for Implementing Community-Based Transfer Protocols for Primary Percutaneous Coronary Intervention for Acute ST-Segment Elevation Myocardial Infarction*, 43 J. AM. C. CARDIOLOGY 2153, 2157 (2004); see also *Best Treatment*, *supra* note 5; Sharon Salyer, *Heart Attack Strategy Changes*, Oct. 13, 2003, <http://www.heraldnet.com/Stories/03/10/13/17605065.cfm>.

these heart attack patients—allowing the sub-optimal facilities to maximize the revenue they obtain through the ObSv variable.⁴³

For example, one study showed that almost half of the ACS patients who went to community hospitals were never even seen by a cardiologist—greatly increasing the likelihood that these patients would never be transferred to PCI-capable facilities.⁴⁴ Additionally, based on this financial incentive, community hospitals may also fail to transfer a disproportionately large percentage of the older and sicker ACS patients.⁴⁵ Instead, these patients typically stay in the hospital until they die (incurring significant charges along the way).⁴⁶ Indeed, given the success rate of fibrinolytics, when administered, the typical post-heart attack hospital stay for approximately half of the heart attack patients treated in community hospitals is six weeks⁴⁷—resulting in the high ObSv factor predicted above.

This very concern about financial disincentives for community hospitals to transfer heart attack patients to optimal treatment facilities (PCI-capable) recently has been raised by seven U.S. Senators in a letter to leading heart-health organizations: “We have seen some situations where STEMI patients were ruled out for transfer [by community hospitals] to a PCI-equipped facility . . . We are concerned about the possibility that patients are being refused a transfer to a higher level facility for inappropriate reasons, such as a financial incentive or insufficient skill.”⁴⁸

⁴³ Cf. Bonfield, *supra* note 35; Nainggolan, *supra* note 42; see also Waters et al., *supra* note 42, at 2157.

⁴⁴ Nainggolan, *supra* note 42; cf. Waters et al., *supra* note 42, at 2154-57 (noting that PCI-capable facilities “have lower mortality rates and improved procedural outcomes”); see also *Best Treatment*, *supra* note 5 (noting that small hospitals usually lack angioplasty services).

⁴⁵ Cf. Waters et al., *supra* note 42, at 2157 (noting the financial incentive not to transfer heart attack patients); *Best Treatment*, *supra* note 5.

⁴⁶ Cf. Waters et al., *supra* note 42, at 2157.

⁴⁷ Cf. NAT’L INSTS OF HEALTH, HEARTMEMO, 50 YEARS OF PROGRESS IN HEART, LUNG, AND BLOOD RESEARCH: NHLBI CELEBRATES ITS GOLDEN ANNIVERSARY 1 (1997).

⁴⁸ Letter from Arlen Specter, U.S. Senator (R-Pa.), Chairman of the Senate Judiciary Comm., John McCain, U.S. Senator (R-Ariz.), Chairman of the Senate Commerce Comm., Sam Brownback (R-Kan.), U.S. Senator, Herb Kohl (D-Wis.), Member of the Special Comm. on the Aging, Mike DeWine (R-Ohio), Chairman of the Ret., Security, and Aging Subcomm. of the Comm. of Health, Educ., Labor and Pensions, Mary L. Landrieu (D-La.), Member of the Cong. Heart & Stroke Caucus, and Orin G. Hatch (R-Utah), Member of the Cong. Heart & Stroke Caucus, Former Chairman, and current member of, Comm. of Health, Educ., Labor and Pensions, Ranking Republican on the Fin., Judiciary, and Intelligence Comms., to the Am. Heart Ass’n and The Am. Coll. of Cardiology (May 31, 2005), available at <http://www.scpop.org/media/files/senators.pdf>.

2. Rent Seeking

This positive model of community hospitals seeking out and retaining the lucrative ACS patients is further supported by evidence of rent seeking, and the concomitant deadweight losses, by sub-optimal facilities desiring to maintain their inefficient market share.⁴⁹ Unsurprisingly, the very same rent seeking by community hospitals has been observed in the context of their resistance to the diversion of other acute patients to specially-equipped facilities.

For example, many community hospitals also seek out stroke patients rather than having them diverted to institutions with advanced stroke capabilities.⁵⁰ Indeed, medically, strokes and heart attacks are virtually identical acute events. The devastating effects of both make them two of the three most critical health care problems facing Americans today: while heart attacks are the primary killer of Americans,⁵¹ strokes constitute the number one cause of disabilities and the third cause of death in the United States.⁵² The treatments for both acute ailments are similar⁵³ and based on the fact that most strokes and heart attacks share the same cause—a blockage in a blood vessel to the respective organ, *i.e.*, the brain and heart, respectively, that restricts the flow of blood.⁵⁴ If these blockages can be addressed quickly, patients' prognoses are positive; delays in treatment almost invariably disable or kill.⁵⁵

⁴⁹ See *Best Treatment*, *supra* note 5; Moyer et al., *supra* note 14, at 57.

⁵⁰ [Community] hospitals have resisted movement toward a system of specialized stroke centers because nondesignated institutions could lose business. . . .

...

"There are still very parochial interests by hospitals and physicians to keep patients locally even if they're not equipped to handle them," says neurosurgeon Robert A. Solomon. . . .

"We have the same political crap as in most communities. Paramedics still take people to the local ER, [which may not be the best-equipped facility]."

Burton, *supra* note 24.

⁵¹ AM. HEART ASS'N, ACUTE CORONARY SYNDROME, *supra* note 1.

⁵² Burton, *supra* note 24; see also Ohio State University Medical Center, Statistics of Strokes, <http://medicalcenter.osu.edu/patientcare/healthinformation/diseasesandconditions/stroke/statistics/> (last visited Dec. 21, 2006) (strokes kill more than 275,000 Americans each year).

⁵³ See AM. HEART ASS'N, HEART AND STROKE FACTS 19-20, 52 (2003).

⁵⁴ See *id.* at 19-20, 43-46, 52.

⁵⁵ See Giuseppe De Luca et al., *Relation of Interhospital Delay and Mortality in Patients with ST-Segment Elevation Myocardial Infarction Transferred for Primary Coronary Angioplasty*, 95 AM. J. CARDIOLOGY 1361, 1361-63 (2005); cf. Burton, *supra* note 24 (describing same issue for stroke patients); cf. Ohio State University Medical Center, Healthcare Services, Interventional Neuroradiology,

3. Delay in Treatment from Non-Direct Transport to PCI Facilities

Financial incentives do not fully determine all outcomes regarding the transfer of heart attack patients from community hospitals to PCI-capable institutions. Thus, some heart attack patients in need of intervention do get transferred from ill-equipped facilities to PCI-capable institutions for PCI. Even when transferred, however, these patients wait nearly twice as long to receive the necessary time-critical treatment than those who are transported directly to the PCI-capable facility.⁵⁶ This outcome is predictable and recognized in medical literature,⁵⁷ as the duplication of efforts must result in delay.⁵⁸ That is, if a patient is treated at a sub-optimal facility that ultimately decides to transfer her, the transferring facility will only do so after performing the necessary tests (at the minimum, an ECG and a blood analysis for cardiac enzyme markers).⁵⁹ Upon transfer, even with proper notification from the transferring facility, the receiving facility will often repeat some of these tests before sending the patient to the catheterization laboratory for PCI. To rely on another facility's diagnosis would be irresponsible and could expose the receiving facility to a claim of malpractice should an injury occur.⁶⁰ By bringing the patient directly to the PCI-capable facility, this inefficiency is eliminated.⁶¹ Moreover,

<http://medicalcenter.osu.edu/patientcare/hospitalsandservices/programs/services/index.cfm?ID=306> (last visited Dec. 21, 2006).

⁵⁶ "If transferred from [a community hospital], the average heart attack patient [had to wait] about 198 minutes before undergoing PCI, compared to" a 107-minute wait for heart attack patients brought directly to hospitals that perform PCI. ALICE K. JACOBS ET AL., AM. HEART ASS'N, MEETING REPORT 11/17/2002 - EMERGENCY ANGIOPLASTY OK WITHOUT SURGICAL BACK-UP (2002), <http://www.americanheart.org/presenter.jhtml?identifier=3006674>; see also McKay, *supra* note 19, at 642 ("Despite the American College of Cardiology/American Heart Association (ACC/AHA)-recommended door-to-balloon times of 90 ± 30 min, data on patients treated with PCI in the National Registry of Myocardial Infarction (NRM1) indicate a median treatment time delay of >2 h in 87 percent of patients transferred for mechanical intervention." (footnotes omitted)).

⁵⁷ See *supra* note 56 and accompanying text.

⁵⁸ De Luca et al., *supra* note 55, at 1362-63; cf. Burton, *supra* note 24, (describing same issue for stroke patients).

⁵⁹ Each one of these factors adds a delay in transfer and treatment time even when done promptly. Further, potential heart attack patients typically do not timely receive the time-critical ECGs necessary for proper diagnoses. Sue Hughes, *ECG Time Targets Not Being Met in Chest-Pain Patients*, THE HEART.ORG, Feb. 10, 2006, <http://www.theheart.org/article/645527.do>. The ECG is typically the first test given to determine if a patient is experiencing a heart attack and often determines what treatment option is pursued – including whether to perform PCI. AM. HEART ASS'N, *supra* note 2.

⁶⁰ Cf. Hughes, *supra* note 40.

⁶¹ Cf. Ellen J. MacKenzie et al., *National Inventory of Hospital Trauma*

once the sub-optimal facility decides to transfer, yet another delay occurs—that associated with waiting for an ambulance to transfer the patient; this delay is often the longest in this dysfunctional process.⁶²

Accordingly, the critical public health concern with existing regulations is that (1) they prevent potential market forces from influencing and improving the provision of emergency medical care for ACS,⁶³ and (2) they are not self-updating to reflect inevitable advances in medical science. Now that medicine indeed has changed, the existing regulatory scheme needs to change accordingly.

B. The Failure to Regulate Asymmetric Information for Walk-In Patients Also Results in Inefficient and Sub-Optimal Care

Paradoxically, to the extent that patients choose health care facilities during possible heart attacks, *i.e.*, when being transported by means other than EMS, they are prevented from making informed decisions. The absence of regulation allows under-equipped health care providers to exploit consumers,' *i.e.*, patients,' inherent informational asymmetries. Thus, given that chest pain is the number two reason for all emergency room visits,⁶⁴ community hospitals have discovered that by self-designating as "Chest Pain Centers" or the like, without any PCI capability whatsoever, they can misdirect patients from fully-capable hospitals to their sub-optimal facilities. The result is that: (1) heart attack patients, as a cohort, obtain sub-optimal care; (2) PCI-capable facilities receive sub-optimal compensation; and (3) non-PCI-capable facilities both seek and improperly garner economic rents.

For example, one hospital, Mather Hospital in New York, sends flyers to all households in the community advertising its "Chest Pain Emergency Room" and the ability to "stop a heart attack in progress," notwithstanding the absence of PCI-capability; Mather boasts the following "upgrades" to assist in the care of heart attack and other pa-

Centers, 289 JAMA 1515, 1521 (2003) ("[A]n initial evaluation of a severely injured trauma patient at a lower level trauma center and [subsequent] transfer [of] the patient to a higher level trauma center . . . would result in time delays that could have deleterious effects on patient outcome." (footnotes omitted)).

⁶² Cf. Hughes, *supra* note 40 (noting that "the longest delays are often waiting for an ambulance to turn up to transfer a patient").

⁶³ "[T]he American healthcare system (largest possible system) is no longer a free enterprise system. . . . Adam Smith's 'invisible hand' of free market forces has largely been replaced by the 'visible hand' of government." Joseph, *supra* note 29, at 15.

⁶⁴ Lisa Nainggolan, *Room for Improvement in Emergency Care of Chest Pain*, THE HEART.ORG, March 2, 2006, <http://www.theheart.org/article/657443.do>.

tients: a cellular-phone system and a “state-of-the-art blood pressure monitor.”⁶⁵

This false advertising phenomenon is equally as important an issue in the provision of emergency medical care to heart attack patients as the regulatory misdirection of EMS-transported heart attack patients to non-PCI-capable facilities because fifty percent of heart attack patients in need of PCI are brought to hospitals by means other than EMS.⁶⁶

While walk-in heart attack patients, clearly, are permitted to travel to a PCI-capable facility, most do not even know what one is, no less where one is located, due to informational asymmetries between hospitals and patients. Ill-equipped community hospitals exploit consumers’ ignorance through advertising in order to seek out these heart attack patients. If heart attack treatment were an ordinary service, market forces would correct this information imbalance. Given the emergency nature of heart attack treatments and the complexity of medical science, however, the market does a poor job of filtering out false advertising for the reasons described below. As a consequence, the market for heart attack care cannot operate efficiently.⁶⁷

1. Consumer’s Rational Ignorance Regarding Health Care Services

Patients and their relatives typically are unaware of the specific level and quality of treatment that facilities provide and the alternatives at other facilities—even after having received treatment—due to imperfect information.⁶⁸ Treatment is often a “black box” to the medically uneducated due to the rational ignorance of potential patients researching such issues *ex ante*. That is, it is generally irrational for

⁶⁵ *Help in a Hurry: When It’s an Emergency – Should an Unexpected Injury or Illness Occur, Turn to Mather Hospital*, COMMUNITY NEWS (John T. Mather Memorial Hospital, Port Jefferson, N.Y.), Fall 2005, at 3; *see infra* p. 35.

⁶⁶ Moyer et al., *supra* note 14, at 54. Research conducted explicitly for this article shows that of 18,390 PCI-treatable heart attacks presenting in 160 hospitals between 1997 and 2005, 8,834 were transported by EMS, and 9,556 were walk-in patients. Others estimate that as many as seventy percent of heart attack victims drive themselves to the hospital or are driven by relatives. Bonfield, *supra* note 35.

⁶⁷ *See* Beales et al., *supra* note 28, at 492 (noting that a buyer’s ability to review information about price, quality, etc. encourages sellers to strive to improve their performance).

⁶⁸ *See* MARK SEIDENFELD, MICROECONOMIC PREDICATES TO LAW AND ECONOMICS 66 (“There are situations in which, at the time of a decision by a consumer or producer, certain information cannot be known. . . . When information is unavailable at any price, we say it is incomplete, but not imperfect. . . . When information could be obtained, but there is a significant cost to obtaining the information, we say the information is imperfect.”).

ordinary consumers to investigate treatment options for ACS and the availability of those options at relevant facilities because the cost of obtaining and comprehending sufficient information is prohibitive.⁶⁹ Most people will never need this treatment, and the complicated nature of such medical information to a layperson is so great that the investment of resources to evaluate it seems simply too high.⁷⁰

Post hoc analyses suffer from similar flaws. Heart attack patients are not only equally uninformed as to the interventional technologies available to treat frank heart attacks as potential patients in the ex-ante situation above, but these ex-post patients also literally suffer from post-heart attack infirmities—making them uniquely poor judges of their own medical care.⁷¹ Given such informational limitations, these under-treated heart attack patients cannot make the necessary comparative analysis to affect the future market for the provision of this type of emergency medical care.⁷²

Finally, for those heart attack patients that are brought to facilities without interventional capabilities who die, the consumer is no longer available to affect the future market for the provision of this medical care. And the remaining relatives often suffer from the initially enumerated informational disparity coupled with a desire to believe that they did everything that they could for their relatives. Thus, any hint of poor care becomes suppressed by the relatives and lost on the part of the patient.

2. Temporal Limitations on Acquiring and Processing Information Coupled with Consumers' Assumption of Existing Regulation

As discussed, ACS does not afford patients ample time to evaluate options for care absent previous investigation.⁷³ Thus, a simple sign

⁶⁹ See Loretta M. Kopelman, *What Is Unique About the Doctor and Patient Medical Encounter? A Moral and Economic Perspective*, AM. J. BIOETHICS, Mar.–Apr. 2006, at 85, 85–86.

⁷⁰ See James F. Blumstein, *Health Care Law and Policy: Whence and Whither?*, 14 HEALTH MATRIX 35, 38–39 (2004) (informational asymmetries and incapacities prevent patients from exercising the control they would in a typical market-based context); cf. ANTHONY DOWNS, AN ECONOMIC THEORY OF DEMOCRACY 9 (1957) (discussing imperfect consumer information); cf. HOWELL E. JACKSON ET AL., ANALYTICAL METHODS FOR LAWYERS 329–30 (2003) (discussing imperfect consumer information).

⁷¹ M. Gregg Bloche, *Trust and Betrayal in the Medical Marketplace*, 55 STAN. L. REV. 919, 930 (2002).

⁷² See Beales et al., *supra* note 28, at 505.

⁷³ Cf. *id.* at 509–10 (“[I]f consumers are imperfectly informed, even small sellers can achieve a degree of informational market power over price, leading to monopolistic rather than perfect competition. For example, because the bereaved

advertising a facility as a “Chest Pain Center” is often sufficient to get ACS patients to choose that particular facility over another. This, coupled with many health care consumers’ mistaken belief that medical care facilities are already regulated in their ability to advertise their capabilities to address ACS,⁷⁴ results in the market overvaluing the “information” provided by the self-designation of “Chest Pain Center.”

3. Insufficiency of Litigation as a Market-Correcting Device

Currently, institutions are liable for the inaccurate claims that they make.⁷⁵ If a patient seeks out a hospital’s care based on its specific advertising, and that advertising turns out to be misleading or false, the injured party has a cause of action against that hospital.⁷⁶

However, most cases settle, and settlements routinely require confidentiality. As such, these cases do not distribute market-adjusting information.⁷⁷ Indeed, there are no published cases in which Chest Pain Centers or the like were sued for false advertising; one unpub-

cannot easily shop among funeral homes, the industry is fragmented (each seller averages only 100 funerals per year), and prices are high.”).

⁷⁴ Cf. Letter from Joseph I. Boullata, Assoc. Professor of Pharmacy Practice, Temple Univ. Sch. of Pharmacy, to the Food & Drug Admin. (Aug. 13, 1999), available at <http://www.fda.gov/ohrms/dockets/dockets/99n1174/c000051.pdf>.

⁷⁵ See, e.g., *Smith v. Baptist Mem’l Hosp. Sys.*, 720 S.W.2d 618, 625 (Tex. App. 1986) (“[W]hen an institution purported to be a full-service hospital which makes emergency room treatment available to serve the public, the hospital will be estopped to deny that the physicians and other medical personnel on duty providing treatment are its agents.”); *Capan v. Divine Providence Hosp.*, 430 A.2d 647, 649 (Pa. Super. Ct. 1980) (“[D]espite the fact that a physician holds independent contractor status with respect to a hospital, he may nonetheless be an agent of the hospital with respect to the patient”).

⁷⁶ See, e.g., *Creech v. Roberts*, 908 F.2d 75, 76–80 (6th Cir. 1990) (Creech heard about City of Faith Hospital through its “Expect a Miracle” advertising campaign and sought treatment in the hospital. The court held that were it not for the advertising campaign promising a miracle, plaintiff would not have traveled to the City of Faith Hospital and would not have been injured in the fraudulent scheme conducted by the hospital’s doctors.); *Clark v. Southview Hosp. & Family Health Ctr.*, 628 N.E.2d 46, 47–54 (Ohio 1994) (Plaintiff’s daughter sought care at defendant’s emergency room after driving past a closer hospital because she had been advised by her mother to seek treatment at defendant’s hospital if she were ever sick. The court discussed liability flowing from the following facts: plaintiff’s mother had been told by the hospital’s administration department that the emergency room was staffed by doctors twenty-four hours a day and was fully equipped; she also had believed, based on promotional literature, that the doctors were the employees of the hospital because the information did not state otherwise.)

⁷⁷ See Daniel R. Fischel, *Lawyers and Confidentiality*, 65 U. CHI. L. REV. 1, 27–32 (1998).

lished case demonstrates that great efforts are taken by hospitals in false advertising cases to ensure their confidentiality upon settlement.⁷⁸ More generally, the Supreme Court has noted that the judiciary is not the right forum to determine whether doctors and hospitals are properly evaluating the risk of rationing health care to increase profits.⁷⁹

C. Case Study of Community Hospital Care⁸⁰

The individual cases supporting the above economic analysis abound. In one such case, the patient, Mark, had classic signs of a heart attack—chest pain, difficulty breathing and dizziness.⁸¹ His wife, Edna, immediately called the ambulance. Eight minutes later, when the ambulance arrived, Edna requested to go to the fully equipped local university hospital that Mark had been to before. The ambulance crew refused and took Mark to a community hospital that may have been a few minutes closer to his house. In addition, the community hospital advertises itself as having a “Chest Pain Emergency Room.” The description is wholly self-designated.

Mark was having a heart attack. He needed PCI. This community hospital, however, does not perform PCI, while the university hospital does. The emergency room doctor at the community hospital did not administer fibrinolytics and did not transfer Mark to the university hospital for PCI. The cardiologist arrived at the community hospital three hours after Mark. Again, no fibrinolytics were administered, and Mark was not transferred to the university hospital.⁸² As such, the

⁷⁸ See *Roberts v. Lederman*, No. 04-CV-00033, 2004 WL 2238564, at *7 (E.D.N.Y. 2004) (discussing the significant efforts by the parties to keep the substance of the settlement agreement confidential in litigation over false advertising by hospital).

⁷⁹ *Pegram v. Herdrich*, 530 U.S. 211, 221 (2000).

⁸⁰ This case study is based on actual events. Copies of the medical records are on file with this law journal.

⁸¹ Ohio State University Medical Center, Heart Attack, <http://medical.center.osu.edu/patientcare/healthinformation/diseasesandconditions/heartdisease/heartattack/> (last visited Dec. 21, 2006).

⁸² Patients with treatable heart attacks should undergo PCI within ninety minutes of arrival to the first hospital. ANTMAN ET AL., *supra* note 34, at e19, e25. Thus, it follows that transfer from a non-PCI facility to a PCI-capable institution needs to take place well before the expiration of this ninety-minute limit. In this case, the cardiologist arrived not only after the optimal time to perform PCI, but well after the time to transfer. This delay, however, inures to the community hospital's financial benefit, as after a small time frame elapses, transfer is useless. Thus, community hospitals have no incentive to correct these delays. Indeed, their incentive is to encourage and exploit these delays. Moreover, if a decision to transfer is made, the cardiologist who can perform PCI at the receiving institution must be called. Since

cardiologist effectively ruled out PCI for Mark—given the time limitations of the procedure. Since ordinary cardiologists do not perform angioplasty—only specially trained interventionalists at equipped facilities perform angioplasty⁸³—the community hospital’s doctors prevented care for which they were not trained and for which the hospital could not provide. Several hours later, as a consequence of the untreated heart attack, Mark suffered a stroke. Again no treatment was provided.

Approximately eighteen hours after Mark arrived at the community hospital, the cardiologist transferred Mark to the university hospital—far after any PCI could have been performed.⁸⁴ When the Chief of Cardiology and the Chief of the Catheterization Lab at the university hospital saw Mark, they both said that they would have performed PCI had he arrived timely. Mark died at the university hospital as a result of his heart attack. This series of events is not atypical.⁸⁵

III. RESPONSES TO THE MARKET FAILURES IN THE TREATMENT OF HEART ATTACKS

As demonstrated, regulations restricting access to optimal critical care and insufficient marketplace information to consumers result in sub-optimal medical care for heart attack patients. Suggested below are the solutions.

interventionalists in virtually all institutions are only in the facility during normal business hours, this adds yet another delay before PCI can be performed. See David J. Magid et al., *Relationship Between Time of Day, Day of Week, Timeliness of Reperfusion, and In-Hospital Mortality for Patients With Acute ST-Segment Elevation Myocardial Infarction*, 294 JAMA 803, 803 (2005) (sixty-eight percent of heart attack patients in need of PCI are treated during off hours and experience significant delays in PCI as a direct consequence); Press Release, Yale Univ., Heart-Attack Patients Seeking After-Hours Care Experience Delay in Critical Treatment, available at <http://www.yale.edu/opa/newsr/05-08-16-02.all.html> (Aug. 16, 2005).

⁸³ Sidney C. Smith, Jr. et al., ACC/AHA Guidelines for Percutaneous Coronary Intervention (Revision of the 1993 PTCA Guidelines): A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty), 37 J. AM. C. CARDIOLOGY 2239i, 2239xvii (2001).

⁸⁴ See McKay, *supra* note 19, at 642.

⁸⁵ Cf. Press Release, University of Virginia Health System, In Speed and Quality, UVa’s Emergency Cardiac Care Outpaces Goals of New Lifesaving Initiative (Nov. 17, 2006), available at http://www.healthsystem.virginia.edu/internet/news/archives06/cardiac_care.cfm (“less than a third of STEMI patients receive treatment within [the AHA-recommended] 90 minutes”).

A. Prioritizing Technology over Proximity: Direct Transport of Heart Attack Patients to Percutaneous Coronary Intervention Equipped Facilities—the Application of the Trauma Care Model to Heart Attacks

In 1976, an orthopedic surgeon was flying his family in a private plane. He crashed in Nebraska and his family was taken to a local hospital.⁸⁶ The family received sub-standard care. As a consequence, the orthopedist sought the help of his colleagues to correct this problem.⁸⁷ These doctors realized that taking severely injured patients to the nearest, rather than the best equipped, hospital could mean death. So began the impetus to create specialized trauma centers and to overhaul ambulance protocols so that paramedics would take the most severely injured patients to those designated trauma centers.⁸⁸ Today, accident victims typically go directly to a trauma center—often bypassing less capable facilities.⁸⁹ This has saved lives and decreased disabilities resulting from accidents.⁹⁰

By rewarding through compensation quality over proximity, the market allowed for the significant expansion of the number of U.S. trauma centers.⁹¹ As of 2003, every state and the District of Columbia had at least one trauma center, and thirty-five States had a formal trauma care system.⁹² Indeed, studies show that trauma centers have reduced the proportion of deaths in serious accidents judged preventable by in excess of fifty percent.⁹³ Similar proposals for directed transport of stroke patients also have been made but not adopted.⁹⁴

The same approach for heart attack care—wherein heart attack patients are transported directly to hospitals with PCI facilities, even if they are farther than other hospitals without such capabilities—will save lives and reward with greater remuneration properly equipped institutions.⁹⁵

⁸⁶ AM. COLL. OF SURGEONS, ADVANCED TRAUMA LIFE SUPPORT PROGRAM FOR DOCTORS 11 (6th ed. 1997).

⁸⁷ *Id.*

⁸⁸ Burton, *supra* note 24.

⁸⁹ AM. COLL. OF SURGEONS, *supra* note 86, at 11.

⁹⁰ Burton, *supra* note 24.

⁹¹ Waters et al., *supra* note 42, at 2153.

⁹² MacKenzie et al., *supra* note 61, at 1515-16.

⁹³ *Id.* at 1515.

⁹⁴ S. 1064, 109th Cong. § 3 (2005); S. 1909, 108th Cong. § 3 (2003).

⁹⁵ European countries have been more receptive to directed transport for heart attack patients. See Moyer et al., *supra* note 14, at 53–55; H.R. Andersen et al., *Myocardial Infarction Centres: The Way Forward*, 91 HEART 12, 12 (2005).

A few forward looking localities in America have adopted ad hoc, through waivers of state regulation, small-scale pilot programs implementing direct transport programs for heart attack patients:⁹⁶ for example, Broward County, Florida adopted such a program, and it has shown dramatic success:

“In our community, this system has worked,” says [Dr.] Bush. “I know we are saving lives.”

Elsewhere, though, patients typically get such treatment only if they end up at an angioplasty hospital by chance.

“It’s really wrong what’s going on,” says Dr. Barry Kaplan, cath[eterization] lab director at New York’s Long Island Jewish Medical Center.⁹⁷

As one commentator stated, the “[m]oral of the story [is that] . . . [p]atients with treatable MI should try to get [directly] to a hospital that can perform angioplasty.”⁹⁸

Thus, the aforescribed regulatorily-created market failure should be replaced with the market mimicking approach suggested herein.⁹⁹ America may have the world’s best medical technology,¹⁰⁰

⁹⁶ Moyer et al., *supra* note 14, at 53–55.

⁹⁷ *Best Treatment, supra* note 5; Lisa Nainggolana, “Level-1 Trauma” *Method Improves Outcomes in STEMI Patients*, THE HEART.ORG, Nov. 8, 2004, <http://www.theheart.org/article/360873.do> (local adoption of a directed care system like the one suggested in this article significantly reduced the time patients had to wait to undergo PCI). Of course, while localities could be left to correct this problem on their own (either publicly or privately), such an approach will obviously be less efficient and more time-consuming. The result would be that, in the meantime, patients would continue to be misdirected for care – resulting in greater injury and death all along the way. As the trauma model demonstrates, a national, comprehensive approach to this problem will save lives. Cf. LAWRENCE O. GOSTIN & PETER D. JACOBSON, *LAW AND THE HEALTH SYSTEM 2* (2005) (“Virtually every aspect of public health practice is defined and guided by law. A fundamental challenge facing public health agencies is how to use the law as a tool to improve the public’s health.”). Indeed, the American Heart Association’s task force on strokes recommends just such a protocol for strokes, *i.e.*, that stroke patients should “be transported to the nearest primary stroke center or hospital with an equivalent designation, given the available acute therapeutic interventions.” Lee H. Schwamm et al., *Recommendations for the Establishment of Stroke Systems of Care: Recommendations from the American Stroke Association’s Task Force on the Development of Stroke Systems*, 36 *STROKE* 690, 695 (2005), available at <http://stroke.ahajournals.org/cgi/content/full/36/3/690>.

⁹⁸ ANGIOPLASTY.ORG, *supra* note 22.

⁹⁹ Given the uncertainty that accompanies any regulatory change, some may be concerned about increased liability. While such a fear is misplaced, given that outcomes will be improved with a heart attack-diversion plan, the National Vaccine Injury Compensation Program (the “VICP”) offers a useful model to displace private liability should one be necessary to co-opt relevant stakeholders. 42 U.S.C. § 300aa-

but these inefficiencies are one cause of the sub-optimal and sub-standard health delivery system in the United States.¹⁰¹ This may be due, in part, to the significant influence of highly-focused and well-funded interest groups on policy in the United States. The outcome of such lobbying is often legislative and regulatory inaction driven by the political inertia of the status quo.

1. "Money money money money, money"¹⁰²

As with any successful program, funding sources must exist. Trauma care took a dramatic step forward in 1990 with the passage of the Trauma Care Systems Planning and Development Act of 1990 (Trauma Care Act).¹⁰³ The Trauma Care Act established a federal matching funds program for State trauma systems, with control for the program vested in the Secretary of Health and Human Services (HHS).

The Trauma Care Act did more than provide federal funding, it also established systems to encourage movement towards a universal trauma care system. As such, the Trauma Care Act:

- a. established the Advisory Council on Trauma Care Systems and a National Clearinghouse on Trauma Care and Emergency Medical Services;¹⁰⁴

15 (2005). The VICP program provides for a federal system of compensation for injury resulting from vaccination that, at the option of the injured, displaces the traditional tort system that governs medical malpractice, personal injury, and product liability cases. Individuals injured by a covered vaccine file a claim with the federal government for recovery. The program has virtually eliminated litigation against drug manufacturers and health care professionals administering vaccines. The Department of Justice credits the program with stabilizing the supply of vaccines and increasing the development of new vaccines. U.S. Department of Justice, About the National Vaccine Injury Compensation Program, <http://www.usdoj.gov/civil/torts/const/vicp/about.htm> (last visited Feb. 11, 2006). Of course, such a system is not inexpensive, and the costs will be borne by taxpayers.

¹⁰⁰ See CIA.gov, CIA World Factbook, <http://www.cia.gov/cia/publications/factbook/geos/us.html> (last visited Jan. 10, 2006).

¹⁰¹ William M. Sage, *Regulating Through Information: Disclosure Laws and American Health Care*, 99 COLUM. L. REV. 1701, 1702-03 (1999).

¹⁰² THE O'JAYS, FOR THE LOVE OF MONEY (Sony 1973).

¹⁰³ Pub. L. No. 101-590, 104 Stat. 2915 (1990).

¹⁰⁴ The Clearinghouse was designed to:

- (1) [f]oster the development of appropriate, modern trauma care and emergency medical services (including the development of policies for the notification of family members of individuals involved in medical emergencies) through the sharing of information among agencies and individuals involved in planning, furnishing, and studying such services and care;

- b. required the Federal government to develop, and States to adopt, standards for: the designation of trauma centers, patient triage, patient transfer, and patient transportation policies;
- c. required the Secretary of HHS to review the trauma care portion of States' plans for the provision of emergency services; and¹⁰⁵
- d. tied States' highway funding to requiring the State officer responsible for the State highway safety program to participate in the development of any State emergency medical services plan.¹⁰⁶

Finally, critical to the trauma care system is the statutory requirement "to provide appropriate transportation and transfer policies to ensure the delivery of patients to designated trauma centers and other facilities within and outside of the jurisdiction of such system."¹⁰⁷

2. Model Federal and State Directed Transport Statutes for Heart Attack Patients

State¹⁰⁸ and federal¹⁰⁹ statutes mandating transport of trauma patients to certified trauma care facilities and providing resources for

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- (2) collect, compile, and disseminate information on the achievements of, and problems experienced by, State and local agencies and private entities in providing trauma care and emergency medical services and, in so doing, give special consideration of the unique needs of rural areas;
 - (3) provide technical assistance relating to trauma care and emergency medical services to State and local agencies; and
 - (4) sponsor workshops and conferences on trauma care and emergency medical services.

Id.

¹⁰⁵ The Trauma Care Act requires "modifications to the State [trauma care] plan as may be necessary for the State involved to ensure that the plan provides for access to the *highest possible quality* of trauma care." *Id.* (emphasis added).

¹⁰⁶ *Id.*; This negative incentive, *i.e.*, "stick," of possible removal of existing highway Federal funding augments the positive incentive, *i.e.*, "carrot," of potential new funding for trauma care. The Federal government often adopts this dual incentive approach to persuade State compliance with the goals of new Federal programs.

¹⁰⁷ *Id.*

¹⁰⁸ See ARIZ. REV. STAT. ANN. § 36-2205 (Supp. 2005) ("Permitted treatment and medication; certification requirement; protocols"); ARIZ. REV. STAT. ANN. § 36-2222 (Supp. 2005) ("Trauma advisory board; membership; compensation; duties"); ARK. CODE ANN. § 20-13-804 (2005) ("Powers and duties of the division"); CAL. HEALTH & SAFETY CODE § 1797.222 (Deering 1990) ("Adoption of ordinances governing transport of patient"); COLO. REV. STAT. § 25-3.5-704 (2005) ("Statewide emergency medical and trauma care system – development and implementation – duties of the department – rules adopted by board"); DEL. CODE ANN. tit. 16, § 9706

such systems serve as useful models for statutes directing heart attack patients to PCI-equipped facilities proposed below.

Both state and federal statutes are necessary to implement an optimal universal heart attack pre-hospital directed transportation system. The model federal statute for heart attack directed care provides for a federal grant program, a model implementation plan for the states, and an advisory council on directed care for heart attacks.¹¹⁰

(1995) (“[Office of Emergency Medical Services] - Additional functions.”); FLA. STAT. ANN. § 395.4045 (West 2006) (“Emergency medical service providers; trauma transport protocols; transport of trauma alert victims to trauma centers; interfacility transfer”); 210 ILL. COMP. STAT. ANN. 50/3.30 (West 2000) (“EMS Region Plan; Content”); IOWA CODE ANN. § 147A.24 (West 2005) (“Trauma system advisory council established”); IOWA CODE ANN. § 147A.27 (West 2005) (“Department to adopt rules”); MD. CODE REGS. 30.08.03.02 (1997) (amended 2002) (“Prehospital Triage and Transport”); MASS. ANN. LAWS ch. 111C, § 3 (LexisNexis 2004) (“Department of Health to Regulate Statewide EMS System.”); MASS. ANN. LAWS ch. 111C, § 11 (LexisNexis 2004) (“Department to Develop Statewide Coordinated Trauma Care System; Regulations and Guidelines”); MICH. COMP. LAWS ANN. § 333.20910 (West Supp. 2006) (“Powers and duties of department”); MINN. STAT. ANN. § 144.604 (West Supp. 2006) (“Trauma triage and transportation”); MISS. CODE ANN. § 41-59-5 (2005) (“Establishment and administration of program”); MO. ANN. STAT. § 190.243 (West 2004) (“Transportation to trauma centers or hospitals, how authorized”); MONT. CODE ANN. § 50-6-402 (2005) (“Department duties — rules”); NEB. REV. STAT. § 71-8235 (2003) (“Trauma system, defined”); NEV. REV. STAT. ANN. § 450B.237 (LexisNexis Supp. 2005) (“Establishment of program for treatment of trauma; regulations; proposal to designate hospital as trauma center; approval by Administrator of Health Division; standards; compliance”); N.H. REV. STAT. ANN. § 153-A:1 (LexisNexis 2002) (“Declaration of Policy and Purpose”); N.M. ADMIN. CODE § 7.27.7.11 (LexisNexis 2005) (“Pre-hospital Transport Guidelines”); N.M. STAT. ANN. § 24-10B-4 (LexisNexis Supp. 2003) (“Bureau; duties”); N.Y. COMP. CODES R. & REGS. tit. 10, § 708.5 (2006) (“Specific review criteria”); N.D. ADMIN. CODE § 33-38-01-05 (2005) (“Local emergency medical services transport plans”); OHIO REV. CODE ANN. § 3727.09 (West 2006) (“Protocols for trauma care”); OHIO REV. CODE ANN. § 4765.40 (West 2006) (“Written protocols for triage of adult and pediatric trauma victims”); OHIO ADMIN. CODE § 4765-14-05 (2003) (“Exceptions to mandatory transport”); OKLA. STAT. ANN. tit. 63, § 1-2530.4 (West Supp. 2006) (“Oklahoma Trauma Systems Improvement and Development Advisory Council — Members — Terms — Expenses — Duties”); 35 PA. CONS. STAT. ANN. § 6925 (West 2003) (“Duties of department”); TEX. HEALTH & SAFETY CODE ANN. § 773.112 (Vernon 2003) (“Duties of Board; Rules”); UTAH CODE ANN. § 26-8a-307 (2005) (“Patient destination”); VA. CODE ANN. § 32.1-111.3 (Supp. 2006) (“Statewide emergency medical care system”); WYO. STAT. ANN. § 35-1-804 (2005) (“Department of health to promulgate rules; contents”).

¹⁰⁹ Pub. L. No. 101-590 (1990); Pub. L. No. 105-392 (1998).

¹¹⁰ Below is a portion of the proposed federal statute, provided fully in the Appendix of this Article, addressing the issues in developing a heart-attack-directed care system.

Heart Attack Care Systems Planning and Development Act

SECTION 3. ESTABLISHMENT OF PROGRAMS WITH RESPECT TO HEART ATTACK CARE.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by inserting a new subchapter:

SUBCHAPTER XXVII—HEART ATTACK CARE

Part A – General Authority and Duties of Secretary

SEC. 300ii. ESTABLISHMENT.

(b) GRANTS, COOPERATIVE AGREEMENTS, AND CONTRACTS—The Secretary may make grants, and enter into cooperative agreements and contracts, for the purpose of carrying out subsection (a).

SECTION 300ii-1. ADVISORY COUNCIL ON HEART ATTACK CARE SYSTEMS.

(a) ESTABLISHMENT—The Secretary shall establish an advisory council to be known as the Advisory Council on Heart Attack Care Systems (hereafter in this section referred to as the “Council”).

SECTION 300ii-2. CLEARINGHOUSE ON HEART ATTACK CARE AND EMERGENCY MEDICAL SERVICES.

(a) ESTABLISHMENT—The Secretary shall by contract provide for the establishment and operation of a National Clearinghouse on Heart Attack Care and Emergency Medical Services (hereafter in this section referred to as the “Clearinghouse”).

(b) DUTIES—The Clearinghouse shall—

(1) foster the development of appropriate, state of the art heart attack care and emergency medical services (including the development of policies for the notification of family members of individuals involved in medical emergencies) through the sharing of information among agencies and individuals involved in planning, furnishing, and studying such services and care;

(3) provide technical assistance relating to heart attack care and medical services to state and local agencies; and

(a) HEART ATTACK CARE MODIFICATIONS TO STATE PLAN FOR EMERGENCY MEDICAL SERVICES—With respect to the heart-attack care component of a state plan for the provision of emergency medical services, the modifications referred to in section 300ii-4(b) are such modifications to the state plan as may be necessary for the state involved to ensure that the plan provides for access to the highest possible quality of heart attack care, and that the plan

(1) specifies that the modifications required pursuant to paragraphs

(2) through (10) will be implemented by the principal state agency with respect to emergency medical services or by the designee of such agency;

(2) specifies any public or private entity that will designate heart attack care regions and heart attack centers in the state;

(3) subject to subsection (b), contains standards and requirements for the designation of heart attack centers, by such entity, including standards and requirements for

Ideally, the federal statute would be coupled with state statutes that focus on implementing a specific plan at the local level and will vary depending on the implementation plan provided by the Secretary of HHS.¹¹¹

(A) *the number and types of heart attack patients for whom such centers must provide care in order to ensure that such centers will have sufficient experience and expertise to be able to provide quality care for heart attack patients;*

(B) *the resources and equipment needed by such centers; and*

(C) *the availability of rehabilitation services for heart attack patients;*

(4) *subject to subsection (b), contains standards and requirements for the implementation of regional heart attack care systems, including standards and guidelines for care in transporting patients to designated heart attack centers;*

(5) *subject to subsection (b), contains standards and requirements for medically directed triage and transport of heart attack patients directly to designated heart attack centers;*

(6) *specifies procedures for the evaluation of designated heart attack centers and heart attack care systems;*

(9) *provides appropriate transportation and transfer policies to ensure the delivery of patients to designated heart attack centers and other facilities within and outside of the jurisdiction of such system, and to provide periodic reviews of the transfers and the auditing of such transfers that are determined to be appropriate;*

(10) *conducts public education activities concerning heart attack prevention and obtaining access to optimal heart-attack care; . . .*

(b) **CERTAIN STANDARDS WITH RESPECT TO HEART ATTACK CARE CENTERS AND SYSTEMS—**

(2) **QUALITY OF HEART ATTACK CARE—***The highest quality of heart attack care shall be the primary goal of state standards adopted under this subsection.*

(3) **APPROVAL BY SECRETARY—***The Secretary may not make payments under section 300ii-4(a) to a state if the Secretary determines that the state has not taken into account national standards for heart attack care; or the state has not, in adopting such standards, taken into account the model plan developed under subsection (c).*

(c) **MODEL HEART ATTACK CARE PLAN—***Not later than one year after the date of the enactment of the Heart Attack Care Systems Planning and Development Act, the Secretary shall develop a model plan for the designation of heart attack care centers and for triage, transfer and transportation policies that may be adopted for guidance by the state.*

¹¹¹ A model state statute addressing the issues in developing a heart attack directed care system is provided below:

Heart-Attack-Care Systems and Emergency-Medical Systems:

(1) *Within 180 days of the enactment of this Act, or the establishment of an emergency medical service (EMS) provider,¹¹¹ should that occur after the enactment of this Act, each EMS provider shall develop and implement pro-*

3. Specialization of Critical Care Across Illnesses Resulting from Directed Transport Systems

The success of directed transport in trauma care has already encouraged proposals for the same for other acute illnesses. United States Senator Thad Cochran (R-MS) proposed directed transport for stroke patients in both the last Congress (the 109th)¹¹² and the 108th.¹¹³ The Stroke Treatment and Ongoing Prevention Act, if enacted, would, *inter alia*, require the Secretary of HHS to establish a grant program for states to develop statewide stroke care systems; develop a model for training EMS personnel in the identification and treatment of stroke patients; and issue recommendations and guidelines on best practices for establishing and operating a stroke care system.¹¹⁴ Of course, this is exactly the approach already adopted for trauma care and the one proposed here for heart attack care.

Thus, the question is begged as to whether the existing trauma care system, along with the adoption of directed care systems for, *inter alia*, strokes and heart attacks, will eventually result in the pre-hospital diversion of all critical EMS patients based upon illness or

ocols for: (a) the pre-hospital transport of heart-attack patients directly to hospitals approved as percutaneous-coronary-intervention-capable centers (PCI-Centers), and (b) interfacility patient transfer.

(2) The Department of Health (the DOH) shall specify by rule the subjects and the minimum criteria related to: (a) prehospital-heart-attack-patient direct transport to a PCI-Center, and (c) interfacility heart-attack-patient transfer transport.

(3) The DOH may disapprove any part of an EMS provider's heart-attack-patient-transport protocol if the DOH determines that the EMS provider's heart-attack-patient-transport protocol is insufficient to ensure the expeditious transportation of heart-attack patients to PCI-Centers. The DOH shall issue protocols to the EMS provider if the EMS-provider's protocols are insufficient. Heart-attack-patient-transport protocol rules pertaining to the air transportation of heart-attack-patients shall be consistent with, but not limited to, applicable Federal Aviation Administration regulation.

(4) The DOH shall adopt and enforce all rules necessary to administer this section. The DOH shall adopt and enforce rules to specify the submission and approval process for STEMI-patient-transport protocols or modifications to STEMI-patient-transport protocols by emergency medical services providers.

(5) Transport of STEMI patients shall be governed by principles of timely and medically appropriate care; consideration of reimbursement mechanisms shall not supersede those principles.

See MO. ANN. STAT. § 190.243 (2005) (providing an existing Missouri law similar to section (5) of the proposed state statute).

¹¹² See generally S. 1064, 109th Cong. § 3 (2005).

¹¹³ See generally S. 1909, 108th Cong. § 3 (2003).

¹¹⁴ S. 1064, 109th Cong. § 3 (2005).

injury to optimally capable facilities. And, if so, is this outcome optimal? The answer is yes to both.

Directed care systems improve public and patient health by concentrating resources in regional facilities rather than dispersing resources among many institutions of significantly varying capability and correct for the absence of the competitive forces that prevent this natural consolidation. The result is better patient care through the development of procedural expertise at a lower cost.¹¹⁵ The success of such programs will lead to the application of similar protocols to other emergency critical care illnesses.

B. Regulating Information Asymmetries

The second area of inefficiency discussed in Section II is caused by sub-optimal facilities, *i.e.*, those without PCI facilities, advertising as specialty hospitals with specific expertise in treating heart attacks, *e.g.*, “Chest Pain Centers.” These hospitals solicit and acquire heart attack patients and the attendant compensation, displacing better care by other institutions. Given this failure of both the market and current regulation to correct for this inefficiency, an alternative approach is proposed below.

1. Mandatory Accreditation of “Chest Pain” and “Heart” Centers: S. 1277—The Heart Attack Safety Act

Currently, the health care consuming public has no opportunity to know based on labeling and related advertising which hospitals that advertise as being capable to treat heart attacks, *e.g.*, “Chest Pain Centers,” are fully equipped with PCI capability.

A market can only be allocatively efficient if prices are accurate, *i.e.*, they approach the marginal cost of producing them.¹¹⁶ A requirement for accurate pricing (and the concomitant allocation of goods and services to their highest-value use) “is that consumers understand . . . what they are buying.”¹¹⁷ If information is imbalanced in favor of sellers over buyers, disclosure laws can restore the symmetry of knowledge and allow consumers to make efficient purchases.¹¹⁸ In-

¹¹⁵ MacKenzie et al., *supra* note 61, at 1521 (concentration of trauma patients in a few facilities improves patients’ outcomes by increasing experience and expertise in these centers and decreases costs by reducing or eliminating unnecessary duplication of expensive resources); *see also* Michael S. Lauder, *Primary Angioplasty – Time Is of the Essence*, 283 JAMA 2988, 2989 (2000).

¹¹⁶ Sage, *supra* note 101, at 1716.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

deed, information asymmetry and the market power that it creates have long been identified as the main cause for health care market failure.¹¹⁹

Like the denomination “Trauma Center” for accredited facilities independently determined to meet the American College of Surgeon’s stringent criteria, Chest Pain Center and similar designations claiming the ability to treat heart attacks should be the designation used *only* by fully equipped facilities that apply an organized and systematic approach to the early diagnosis and treatment of heart attacks.¹²⁰

The aforementioned letter from the seven prominent U.S. Senators to the American Heart Association and the American College of Cardiology recognized this very fact, as well:

Currently, any facility can call itself a Chest Pain Center without accreditation. There is no way for the public to know which Chest Pain Center is legitimate and which is not. Hospitals with Chest Pain Centers should only be able to make such claims if they are accredited as Chest Pain Centers.¹²¹

Former Senator Mike DeWine, a Republican from Ohio, known both for his commitment to health and safety issues and his inclusive approach to legislation, introduced the Heart Attack Safety Act (HASA).¹²² If enacted, HASA would amend Title XVIII of the Social

¹¹⁹ *Id.*

¹²⁰ By definition, technology is always evolving. Indeed, this evolution is the cause of current treatment disparities. Under current standards, the minimum appropriate technology is the availability of PCI. *See Moyer et al., supra* note 14, at 53, 55. Currently, the Society of Chest Pain Centers does *not* support restricting accreditation only to facilities with PCI capability due to the belief that accreditation of non-PCI facilities may still result in improved patient care. For example, the Society supports accreditation for those facilities that implement systemic procedures requiring immediate transfer of patients with contraindications for fibrolytics and presenting with a ST-elevated myocardial infarctions, *i.e.*, a patient with a profile of “Mark” described above. (Under the directed transport model presented in this Article, a patient with this profile would be brought directly to a PCI facility should he be transported by EMS.) While rapid transfer procedures would likely have saved Mark’s life, the author of this Article disagrees with designating these facilities as “Chest-Pain Centers.” Such a designation falsely suggests (to “walk-in” patients, in particular) the ability of the facility to fully address under contemporary technologies all ACS patients’ problems. Accordingly, this author supports offering some designation to facilities seeking to improve their system of addressing ACS. However, the ability to advertise this improved-systems approach should not be at the expense of clarity to acute-healthcare consumers.

¹²¹ Letter from United States Senators, to the Am. Heart Ass’n and Am. Coll. of Cardiology, *supra* note 48.

¹²² *See generally* S. 1277, 109th Cong. § 2 (2005).

Security Act to require hospitals, as a condition of participation under the Medicare program, to meet specific requirements set by the Secretary of HHS in order to advertise that they have the capability of addressing emergency and acute coronary syndromes.¹²³

Moreover, HASA specifically states that a hospital that characterizes itself as having a “Chest Pain Center” is advertising as having the capability of addressing emergency or acute coronary syndromes, as defined by the Act.¹²⁴ HASA does not set forth the technology that a hospital must have in order to qualify for the designation as a Chest Pain Center or the like. Rather, HASA would empower the Secretary of HHS to set standards appropriate for the contemporary technology. As such, the required technology would be updated with advances in medical science.¹²⁵

Accordingly, HASA addresses the market imperfection by mandating the provision of accurate information to consumers. Its enactment will improve the market for health-care services—driving down costs and saving lives at the same time—by expanding the quality of information about heart attack care provided to consumers. It is a modest proposal whose time has come.

2. Market Efficiency Through Information Regulation

Regulating consumer information asymmetries is designed to correct for the distorting effect of advertising on the market, and, as such, can be viewed as a type of product safety law.¹²⁶ Product safety laws trace back to early English law,¹²⁷ and have changed dramatically in the last 150 years.¹²⁸ As mass production became possible around the

¹²³ *Id.*

¹²⁴ *Id.* The Society of Chest Pain Centers altruistically endorsed S. 1277, notwithstanding that the HASA could remove from the Society its exclusive authority for accrediting Chest Pain Centers. Letter from Robert Stomel, President, Society of Chest Pain Centers, to Mike DeWine, U.S. Senator from Ohio (June 27, 2005) available at http://www.sccpc.org/hcfa/DeWine_ltr_S1277.pdf.

¹²⁵ Although various standards are theoretically available, I believe that only two will ensure public safety given the state of medical science today. The first would permit only PCI-capable facilities with proper heart attack treatment protocols to use the designation “chest pain center” or the like. The second option would permit PCI-capable hospitals with proper heart attack treatment protocols and those few hospitals with proper heart attack treatment protocols without PCI capability that are over an hour away from any PCI-capable facility to use the designation “chest pain center.”

¹²⁶ See PAULINE M. IPPOLITO & JANIS K. PAPPALARDO, FED. TRADE COMM’N., ADVERTISING NUTRITION & HEALTH: EVIDENCE FROM FOOD ADVERTISING 1977-1997 I (2002).

¹²⁷ JAMES J. MCGILLAN ET AL., CONSUMER PRODUCT SAFETY LAW 10 (1977).

¹²⁸ 12 AM. JUR. *Trials* § 2 (1966).

beginning of the 20th century, the relationship between buyers and sellers grew more attenuated, and the doctrine of caveat emptor no longer occupied the position of accepted dogma that it once had.¹²⁹ Courts began to realize that consumers were largely unaware of the relative safety of the products and services they purchased and that this “ignorance and naiveté” necessitated changes in order to protect the public.¹³⁰

While patronizing, the description of the public as “bewitched, bewildered and bedeviled by the glittering packaging in riotous color and the alluring enticement of the products’ qualities as depicted on labels”¹³¹ highlights the difficulties faced by the consumers in today’s technologically advanced age. Advertising campaigns have “lulled,” if not numbed, once cautious consumers about their safety.¹³²

Whereas advertising certainly can notify consumers about the quality of the products or services offered,¹³³ the goal of advertising is to provide, at the least possible cost, certain information to consumers that will make the advertisers’ products or services more attractive than those of their competitors.¹³⁴ Advertising need not impede consumers’ ability to gather full information¹³⁵ but is antithetical to pursuing this goal if its satisfaction conflicts with maximizing revenue.¹³⁶ Thus, ideally, utilizing advertising for its “best” purposes may lower consumers’ cost of acquiring information,¹³⁷ but if information is in-

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ MARSHALL S. SHAPO, PRODUCTS LIABILITY AND THE SEARCH FOR JUSTICE 73 (1993) (quoting *Hamon v. Digliani*, 174 A.2d 294, 297 (Conn. 1961)).

¹³² *Id.* at 74 (quoting *Lechuga, Inc. v. Montgomery*, 467 P.2d 256, 261–62 (Ariz. 1970)).

¹³³ IPPOLITO & PAPPALARDO, *supra* note 126, at E-20, 130 (advertising is described as a “major feature of consumer good markets” and “a response to the market’s need for information”).

¹³⁴ See *id.* at 133–37; see also Pauline M. Ippolito, *What Can We Learn From Food Advertising Policy Over the Last 25 Years?*, 12 GEO MASON L. REV. 939, 946–47 (“[this is the] fundamental force underlying the information theory of advertising”).

¹³⁵ See IPPOLITO & PAPPALARDO, *supra* note 126, at 130.

¹³⁶ Robert H. Schmerling, *The Promise and Pitfalls of Patient Empowerment*, INTELIHEALTH.COM, Oct. 16, 2002, <http://www.intelihealth.com> (follow “Health Commentaries” hyperlink; then follow “Medical Myths” hyperlink; then follow “The Promise and Pitfalls of Patient Empowerment” hyperlink) (last visited on May 17, 2006); see Melvin Aron Eisenberg, *The Bargain Principle and Its Limits*, 95 HARV. L. REV. 741, 777 (1982) (“advertising often relies on an appeal to non-deliberative elements”).

¹³⁷ *Id.*

sufficient or inaccurate, the quality of goods or services supplied can be distorted negatively.¹³⁸

Regulation requiring information disclosure allows consumers to make rational purchase decisions on the basis of product or service quality without having to undertake the prohibitive expense of independently determining quality.¹³⁹ Indeed, the case for regulation requiring disclosure is strongest when a product characteristic or service quality is not readily discoverable by inspection or repeated use.¹⁴⁰ Moreover, placing the onus to disclose on the parties possessing the information is typically cheaper, and, therefore, more efficient than requiring uninformed consumers to ferret out and gather the relevant information on their own.¹⁴¹ This results in the proper valuation of goods and services and appropriate resource allocation.

Even profit-maximizing opponents of the first proposal of this Article—diverting critical ACS patients to fully equipped facilities—tacitly acknowledge the need for adequate information to the consuming public regarding the capabilities of local community hospitals: “Nancy E. Foster, vice president for quality of the American Hospital Association, which represents both large and small hospitals [says:] ‘Community hospitals *may* be equally good at delivering [critical] care, and it would be important for patients to know how well prepared their local hospital is.’”¹⁴²

Indeed, the Federal government (often through the Federal Trade Commission) routinely regulates all sorts of consumer advertising regarding both health and non-health issues of much lower significance than the provision of emergency medical care for acute heart attacks.¹⁴³ The myriad statutes and regulations demonstrate that “the

¹³⁸ JACKSON ET AL., *supra* note 70, at 330-31.

¹³⁹ Cf. STEVEN SHAVELL, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW 20, 20, 34-35 (2004) (state regulation of information disclosure in health care helps avoid undesirable outcomes and is appropriate because the cost of individual searches is not economically rational); see JACKSON ET AL., *supra* note 70, at 330-31.

¹⁴⁰ RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 113 (6th ed. 2002). See SEIDENFELD, *supra* note 68, at 66 (“[P]erfect information is crucial to all aspects of market dynamics and non-market transactions”).

¹⁴¹ Anthony T. Kronman, *Mistake, Disclosure, Information, and the Law of Contracts*, 7 J. LEGAL STUD. 1, 2-4 (1978).

¹⁴² Burton, *supra* note 24 (emphasis added).

¹⁴³ See, e.g., 21 U.S.C. § 352 (2001) (regulating the labeling of drugs and medical devices); 15 U.S.C. § 4402 (2001) (controlling advertising and mandating labeling of smokeless tobacco); 16 C.F.R. §§ 307.1-307.12 (2005) (regulations implementing the control of advertising and mandating labeling of smokeless tobacco); 15 U.S.C. § 5711 (2001) (“prohibit[s] unfair and deceptive acts and practices in any advertisement for pay-per-call services”); 16 C.F.R. §§ 308.1-308.9 (2005) (regulations implementing the control of advertisement for pay-per-call services); 16 C.F.R.

law of deception has now developed to the point of virtually eliminating any line between advertisements which are deceptive and advertisements which simply fail to inform.”¹⁴⁴

For example, the Consumer Product Safety Act¹⁴⁵ (CPSA) was enacted to protect the public from dangerous products by regulating manufacturers and educating the public.¹⁴⁶ Congress stated that one of its purposes in passing the CPSA was to address the “complexities of consumer products and the diverse nature and abilities of consumers using them [that] frequently result in an inability of users to anticipate risks and to safeguard themselves adequately.”¹⁴⁷

In fact, the Code of Federal Regulations devotes an entire section to the advertising and labeling of automobile tires, noting that “[t]he purchase of tires . . . is an extremely important matter to the consumer. Not only are substantial economic factors involved, but in most instances the purchaser will entrust the safety of himself and others to the performance of the product.”¹⁴⁸ The regulation requires that consumers be given particular information prior to purchase in order to avoid being deceived and injured.¹⁴⁹

§ 424.1 (2005) (regulation of retail food store advertising); 16 C.F.R. § 233.1 (2005) (advertisers are not permitted to claim that they’ve reduced prices when the prior price was not a bona fide price at which the article was offered to the public on a regular basis for a reasonably substantial period of time; sellers may not claim a sale price when the reduction in price is so insignificant as to be meaningless); 16 C.F.R. § 233.2 (2005) (in advertising, sellers may not claim that they are offering a product below the retail price even when the retail price is used by other sellers, if most outlets in the community do not sell at the retail price); 16 C.F.R. § 233.3 (2005) (in advertising, sellers may not distinguish their price from the suggested retail price if the latter is not used in the community); 16 C.F.R. § 233.4 (2005) (regulating the use of the term “free” in advertising, and “2-for-1” advertisements must be transparent); 16 C.F.R. § 233.5 (2005) (ordinary prices may not be advertised as “wholesale”); 16 C.F.R. §§ 255.0–255.5 (2005) (regulating use of endorsements in advertising); 16 C.F.R. § 410.1 (2005) (regulating deceptive advertising as to sizes of viewable pictures shown by television receiving sets); 16 C.F.R. §§ 423.1–423.10 (2005) (regulating information that must be provided to consumers prior to selling them clothing); 16 C.F.R. §§ 436.1–436.3 (2005) (regulating advertising regarding franchise and business opportunity ventures); 16 C.F.R. § 455.2 (2005) (regulating certain advertising by used car sellers); 16 C.F.R. §§ 460.1–460.24 (2005) (regulating advertising of home insulation); 16 C.F.R. §§ 502.100–502.102 (2005) (regulating advertising on packaging).

¹⁴⁴ Beales et al., *supra* note 28, at 495; *see* §§ 29 U.S.C. 1021-1022 (2005); N.Y. PUB. HEALTH LAW § 4408 (McKinney 1985 & Supp. 1999) (statutes requiring disclosure of terms of retirement and health packages).

¹⁴⁵ 15 U.S.C. §§ 2051–84 (2001).

¹⁴⁶ *Id.* at § 2051.

¹⁴⁷ *Id.*

¹⁴⁸ 16 C.F.R. § 228.1(a) (2003) (repealed 2004).

¹⁴⁹ *Id.* at § 228.1(b)(1). The information that the consumer must be given

Given this long history of regulating consumer safety regarding areas of a significantly less critical nature than the provision of emergency medical care for ACS patients, along with the currently favored regulatory strategy of expanding the amount of information about the health care system,¹⁵⁰ enacting guidelines for hospitals that advertise the ability to address heart attacks fits well into today's complex legal landscape.

CONCLUSION

This nation has developed and procured state-of-the-art technology for medical treatment, as well as some of the most exceptional medical practitioners the world has ever seen. This extraordinary combination of talent and equipment results in the opportunity for virtually all heart attack patients to receive treatment that could greatly diminish, if not eliminate, the possibility of negative outcomes. Nonetheless, Americans suffering acute heart attacks have a high likelihood of receiving outdated treatment that too often results in significant injury or death. The elements that determine which level of care any given patient receives are: (1) the level of technology that fortuitously is available at the closest hospital; and (2) the level of false advertising by community hospitals that has permeated the local market. These non-market and non-equity factors should not determine the life or death of heart attack patients.

Given that emergency medical care for frank heart attacks is virtually price inelastic and that consumers are prevented from making rational decisions on its provision by regulation and information asymmetries, the paradigm for ACS treatment must be changed. A system to direct heart attack patients to PCI-capable facilities will benefit patients, the well-equipped facilities, and society as a whole: patients will get the treatment that they deserve; hospitals that provide optimal care will be appropriately compensated and not financially undermined by non-PCI facilities siphoning off their income through the non-market direction of consumers; and society will have fewer preventable heart attack deaths. This very model has been in place for many years for trauma care but, to date, has not been developed in any systematic national program for any other acute illnesses. The analysis and model statutes provided herein should aid in expediting such a development.

includes: (1) the tire's "load-carrying capacity," (2) the type of cord material used in manufacturing the tire, and (3) the number of plies. *Id.*

¹⁵⁰ Sage, *supra* note 101, at 1704.

Similarly, policymakers routinely and appropriately regulate information asymmetries that cause market failures so as to increase social welfare. The enactment of the Heart Attack Safety Act will ensure that only properly equipped facilities can hold themselves out as capable of treating acute heart attacks, thereby preventing ill-equipped facilities from soliciting patients suffering these acute events. As such, the market for heart attack care will operate more competitively and, therefore, more efficiently.

The enactment of the legislative proposals discussed in Section III will pursue the highest goal of medicine, law, and economics: to optimize the lots and lives of people.¹⁵¹

APPENDIX

Below is the proposed model federal statute addressing the issues in developing a heart attack-directed care system referenced in the Article, *supra*, at note 110:

HEART ATTACK CARE SYSTEMS PLANNING AND DEVELOPMENT ACT

SECTION 1. SHORT TITLE:

This Act shall be known as the Heart Attack Care Systems Planning and Development Act.

SECTION 2. FINDINGS:

The Congress finds that

(1) the federal government and the governments of the states have established a history of cooperation in the development, implementation, and monitoring of integrated, comprehensive systems for the provision of emergency medical services throughout the United States;

(2) heart attack is the leading cause of death of Americans;

(3) cardiovascular disease—the leading cause of heart attacks—results in an aggregate annual cost of \$300 trillion in medical expenses, insurance, lost wages, and other expenses;

(4) barriers to the provision of prompt and appropriate emergency medical services exist in many areas of the United States;

¹⁵¹ See Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 467 (2002) (“It is obvious that law has therapeutic consequences meriting study when, for instance, it affects the behavior of physicians or the availability of treatment.”).

(5) few states and communities have developed and implemented heart attack care systems; and

(6) the number of heart attacks in the United States is a serious medical and social problem, and the number of deaths resulting from such incidents can be substantially reduced by improving the heart attack care components of the systems for the provision of emergency medical services in the United States.

SECTION 3. ESTABLISHMENT OF PROGRAMS WITH RESPECT TO HEART ATTACK CARE.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by inserting a new subchapter:

SUBCHAPTER XXVII—HEART ATTACK CARE

Part A – General Authority and Duties of Secretary

SEC. 300ii. ESTABLISHMENT.

(a) **IN GENERAL**—*The Secretary shall, with respect to heart attack care—*

(1) *conduct and support research, training, evaluations, and demonstration projects;*

(2) *foster the development of appropriate, modern systems of such care through the sharing of information among agencies and individuals involved in the study and provision of such care;*

(3) *provide to state and local agencies technical assistance; and*

(4) *sponsor workshops and conferences.*

(b) **GRANTS, COOPERATIVE AGREEMENTS, AND CONTRACTS**—*The Secretary may make grants, and enter into cooperative agreements and contracts, for the purpose of carrying out subsection (a).*

SECTION 300ii-1. ADVISORY COUNCIL ON HEART ATTACK CARE SYSTEMS.

(a) **ESTABLISHMENT**—*The Secretary shall establish an advisory council to be known as the Advisory Council on Heart Attack Care Systems (hereafter in this section referred to as the “Council”).*

(b) **DUTIES**—*The Council shall—*

(1) *periodically conduct assessments of the needs in the United States with respect to heart attack care and the extent to which the states are responding to such needs, including special consideration of the unique needs of rural areas;*

(2) *submit to the Secretary the findings made as a result of such assessments; and*

(3) *advise the Secretary with respect to activities carried out under this title, including the development of the model heart attack plan.*

(c) *MEMBERSHIP—*

(1) *IN GENERAL—The Secretary shall appoint to the Council twelve appropriately qualified representatives of the public who are not officers or employees of the United States. Of such members—*

(A) *At least three shall be individuals experienced or specially trained in cardiology (including a critical care nurse);*

(B) *At least three shall be individuals experienced or specially trained in emergency medicine (including a nurse who is specially trained in emergency medicine); and*

(C) *At least three shall be individuals experienced or specially trained in the development, administration, or financing of heart attack care systems.*

(2) *EX OFFICIO MEMBERS—The Secretary may designate as ex officio members of the Council appropriately qualified representatives of the Department of Health and Human Services, the Department of Transportation, the Federal Emergency Management Agency, and such other agencies of the federal government as the Secretary determines to have functions affecting emergency medical services.*

(3) *KNOWLEDGE CONCERNING RURAL AREAS—Of the members described in paragraph (1), twenty-five percent of the members shall be knowledgeable about the unique needs of rural areas with respect to the purpose of the Council.*

(d) *TERMS*—

(1) *GENERAL TERM*—*Except as provided in paragraph (2), members of the Council appointed under subsection (c)(1) shall serve for a term of four years.*

(2) *INITIAL MEMBERS*—*Of the members first appointed to the Council under subsection (c)(1), the Secretary shall appoint four members to serve for a term of four years, four members to serve for a term of three years, and four members to serve for a term of two years.*

(e) *VACANCIES*—

(1) *SERVICE FOR REMAINDER OF TERM*—*Any member of the Council appointed under subsection (c)(1) to fill a vacancy occurring before the expiration of the term of the predecessor of the member shall be appointed for the remainder of the term of the predecessor.*

(2) *CONTINUED SERVICE AFTER EXPIRATION OF TERM*—*A member of the Council appointed under subsection (c)(1) may continue to serve after the expiration of the term of the member until a successor is appointed.*

(f) *CHAIR*—*The Secretary, or the designee of the Secretary, shall serve as the chair of the Council.*

(g) *MEETINGS*—*The Council shall meet at the call of the Chair and shall meet not less than once each three months.*

(h) *COMPENSATION AND REIMBURSEMENT OF EXPENSES*—

(1) *FEDERAL OFFICIALS*—*Ex officio members of the Council under subsection (c)(2) may not receive compensation for service on the Council in addition to the compensation otherwise received for duties carried out as officers or employees of the United States.*

(2) *APPOINTMENT MEMBERS*—*Members of the Council appointed under subsection (c)(1) may not receive compensation for service on the Council. Such members may be reimbursed for travel, subsistence, and other*

necessary expenses incurred in carrying out the duties of the Council.

(i) *STAFF*—*The Secretary shall provide to the Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.*

(j) *TERMINATION*—*Notwithstanding section 14(a) of the Federal Advisory Committee Act, the Council shall continue in existence until otherwise provided by law.*

SECTION 300ii-2. CLEARINGHOUSE ON HEART ATTACK CARE AND EMERGENCY MEDICAL SERVICES.

(a) *ESTABLISHMENT*—*The Secretary shall by contract provide for the establishment and operation of a National Clearinghouse on Heart Attack Care and Emergency Medical Services (hereafter in this section referred to as the “Clearinghouse”).*

(b) *DUTIES*—*The Clearinghouse shall—*

(1) *foster the development of appropriate, state of the art heart attack care and emergency medical services (including the development of policies for the notification of family members of individuals involved in medical emergencies) through the sharing of information among agencies and individuals involved in planning, furnishing, and studying such services and care;*

(2) *collect, compile, and disseminate information on the achievements of, and problems experienced by, state and local agencies and private entities in providing heart attack care and emergency medical services and, in so doing, give special consideration of the unique needs of rural areas;*

(3) *provide technical assistance relating to heart attack care and medical services to state and local agencies; and*

(4) *sponsor workshops and conferences on heart attack care and emergency medical services.*

(c) *FEES AND ASSESSMENTS*—*A contract entered into by the Secretary under this section may provide that the Clearinghouse charge fees or assessments in*

order to address the costs of operating the Clearinghouse.

SECTION 300ii-3. ESTABLISHMENT OF PROGRAMS FOR IMPROVING HEART ATTACK CARE IN RURAL AREAS.

(a) IN GENERAL—The Secretary may make grants to public and nonprofit private entities for the purpose of carrying out research and demonstration projects with respect to improving the availability and quality of emergency medical services in rural areas

(1) by developing innovative uses of communications technologies and the use of new communications technology;

(2) by developing model curricula for training emergency medical services personnel, including first responders, emergency medical technicians, emergency nurses and physicians, and paramedics

(A) in the assessment, stabilization, treatment, preparation for transport, and resuscitation of heart attack patients, with special attention to problems that arise during long transports and to methods of minimizing delays in transport to the optimal facility; and

(B) in the management of the operation of the emergency medical services system;

(3) by making training for original certification, and continuing education, in the provision and management of emergency medical services more accessible to emergency medical personnel in rural areas through telecommunications, home studies, providing teachers and training at locations accessible to such personnel, and other methods;

(4) by developing innovative protocols and agreements to increase access to prehospital care and equipment necessary for the transportation of heart attack patients to the optimal facilities; and

(5) by evaluating the effectiveness of protocols with respect to emergency medical services and systems.

Part B – Formula Grants With Respect to Modifications of State Plans

SECTION 300ii-4. ESTABLISHMENT OF PROGRAM.

(a) **REQUIREMENT OF ALLOTMENTS FOR STATES**—*The Secretary shall for each fiscal year make an allotment for each state in an amount determined by the Secretary. The Secretary shall make payments, as grants, each fiscal year to each state from the allotment for the state if the Secretary approves for the fiscal year involved an application submitted by the state.*

(b) **PURPOSE**—*The Secretary may not make payments under this part for a fiscal year unless the state involved agrees that, with respect to the heart attack care component of the State plan for the provision of emergency medical services, the payments will be expended only for the purpose of developing, implementing, and monitoring the modifications to such component described in section 300ii-6.*

SECTION 300ii-5. REQUIREMENT OF MATCHING FUNDS FOR FISCAL YEARS SUBSEQUENT TO FIRST FISCAL YEAR OF PAYMENTS.

(a) **NON-FEDERAL CONTRIBUTIONS**—

(1) **IN GENERAL**—*The Secretary may not make payments under section 300ii-4(a) unless the state involved agrees, with respect to the costs described in paragraph (2), to make available non-federal contributions (in cash or in kind under subsection (b)(1)) toward such costs in an amount equal to*

(A) *for the second fiscal year of such payments to the state, not less than \$1 for each \$1 of federal funds provided in such payments for such fiscal year; and*

(B) *for any subsequent fiscal year of such payments to the state, not less*

than \$3 for each \$1 of federal funds provided in such payments for such fiscal year.

(2) **PROGRAM COSTS**—*The costs referred to in paragraph (1) are*

(A) the costs to be incurred by the state in carrying out the purpose described in section 300ii-4(c), or

(B) the costs of improving the quality and availability of emergency medical services in rural areas of the state.

(3) **INITIAL YEAR OF PAYMENTS**—*The Secretary may not require a state to make non-federal contributions as a condition of receiving payments under section 300ii-4(a) for the first fiscal year of such payments to the state.*

(b) **DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION**—*With respect to compliance with subsection (a) as a condition of receiving payments under section 300ii-4(a)—*

(1) a state may make the non-federal contributions required in such subsection in cash or in kind, fairly evaluated, including plant, equipment, or services;

(2) the Secretary may not, in making a determination of the amount of non-federal contributions, include amounts provided by the federal government or services assisted or subsidized to any significant extent by the Federal Government.

SECTION 300ii-6. REQUIREMENTS WITH RESPECT TO CARRYING OUT PURPOSE OF ALLOTMENTS.

(a) **HEART ATTACK CARE MODIFICATIONS TO STATE PLAN FOR EMERGENCY MEDICAL SERVICES**—*With respect to the heart attack care component of a state plan for the provision of emergency medical services, the modifications referred to in section 300ii-4(b) are such modifications to the state plan as may be necessary for the state involved to ensure that the plan provides for access to the*

highest possible quality of heart attack care, and that the plan

(1) specifies that the modifications required pursuant to paragraphs (2) through (10) will be implemented by the principal state agency with respect to emergency medical services or by the designee of such agency;

(2) specifies any public or private entity that will designate heart attack care regions and heart attack centers in the state;

(3) subject to subsection (b), contains standards and requirements for the designation of heart attack centers, by such entity, including standards and requirements for

(A) the number and types of heart attack patients for whom such centers must provide care in order to ensure that such centers will have sufficient experience and expertise to be able to provide quality care for heart attack patients;

(B) the resources and equipment needed by such centers; and

(C) the availability of rehabilitation services for heart attack patients;

(4) subject to subsection (b), contains standards and requirements for the implementation of regional heart attack care systems, including standards and guidelines for care in transporting patients to designated heart attack centers;

(5) subject to subsection (b), contains standards and requirements for medically directed triage and transport of heart attack patients directly to designated heart attack centers;

(6) specifies procedures for the evaluation of designated heart attack centers and heart attack care systems;

(7) provides for the establishment and collection of data from each designated heart attack center in the State of a central data reporting and analysis system

- (A) to identify the number of heart attack patients within regional heart attack care systems in the state;*
 - (B) to identify the nature and severity of the heart attack;*
 - (C) to monitor heart attack patient care (including prehospital care) in each designated heart attack center within regional heart attack care systems in the State (including relevant emergency department discharges and rehabilitation information) for the purpose of evaluating the diagnosis, treatment and treatment outcome of such heart attack patients;*
 - (D) to identify the total amount of uncompensated heart attack care expenditures for each fiscal year by each designated heart attack center in the state; and*
 - (E) to identify patients transferred within a regional heart attack system, including reasons for such transfer;*
- (8) provides for the use of procedures by paramedics and emergency medical technicians to assess the type and severity of the heart attack experienced by acute coronary syndrome patients;*
- (9) provides appropriate transportation and transfer policies to ensure the delivery of patients to designated heart attack centers and other facilities within and outside of the jurisdiction of such system, and provides periodic reviews of the transfers and the auditing of such transfers that are determined to be appropriate;*
- (10) conducts public education activities concerning heart attack prevention and obtaining access to optimal heart attack care; and*
- (11) with respect to the requirements established in this subsection, provides for coordination and cooperation between the state and*

any other state with which the state shares any standard metropolitan statistical area.

(b) CERTAIN STANDARDS WITH RESPECT TO HEART ATTACK CARE CENTERS AND SYSTEMS—

(1) IN GENERAL—The Secretary may not make payments under section 300ii-4(a) for a fiscal year unless the state involved agrees that, in carrying out paragraphs (3) through (5) of subsection (a), the state will adopt standards for the designation of heart attack centers and for triage, transfer, and transportation policies, and that the state will, in adopting such standards—

(A) take into account national standards concerning such;

(B) consult with medical, surgical, and nursing specialty groups, hospital associations, emergency medical services state and local directors, concerned advocates and other interested parties;

(C) conduct hearings on the proposed standards after providing adequate notice to the public concerning such hearing; and

(D) take into account the model plan described in subsection (c).

(2) QUALITY OF HEART ATTACK CARE—The highest quality of heart attack care shall be the primary goal of state standards adopted under this subsection.

(3) APPROVAL BY SECRETARY—The Secretary may not make payments under section 300ii-4(a) to a state if the Secretary determines that the state has not taken into account national standards for heart attack care, or the state has not, in adopting such standards, taken into account the model plan developed under subsection (c).

(c) MODEL HEART ATTACK CARE PLAN—Not later than one year after the date of the enactment of the Heart Attack Care Systems Planning and Development Act, the Secretary shall develop a model plan

for the designation of heart attack care centers and for triage, transfer, and transportation policies that may be adopted for guidance by the state.