

Mandating Insurance Coverage: Will HB 1290 Prevent Heart Attacks or Cause Heartache in Insurance Premiums?

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Introduction

Cardiovascular disease (CVD) is one of the leading causes of death in the United States. CVD is associated with both genetic and environmental/behavioral factors that contribute to the development and severity of the disease.¹ A number of these factors have been identified and are used to predict an individual's risk of adverse cardiovascular events, such as coronary heart disease or stroke. One of the most well-known of these risk-prediction models is the Framingham Risk Score, which looks at factors such as gender, age, total cholesterol levels, diabetes, systolic blood pressure, smoking, low-density lipoprotein ("bad cholesterol"), high-density lipoprotein ("good cholesterol"), and body mass index (a function of weight and height) to estimate the risk of an individual for having a cardiovascular event.²

With an interest in reducing the mortality and morbidity rates associated with CVD, the State of Texas recently passed a bill to mandate health-benefit plan coverage of certain diagnostic tests designed to detect coronary artery disease and atherosclerosis, two types of CVD. While this at first appears to be a straight forward proposal, support for the bill from professional societies was mixed.

The Disease: Coronary Artery Disease (CAD) and Atherosclerosis

Blood carries oxygen to the heart through the coronary arteries; if these arteries become clogged with substances (such as calcium or fat) that impede proper blood flow to the heart, the resulting disease is called coronary artery disease (CAD).³ The accumulated calcium, fat, cholesterol, or other substances are known as plaque; this build up of material in the vessel wall is called atherosclerosis.⁴ There are two types of plaque: "hard plaque" builds up and interferes with blood flow by making the vessel narrower, while "soft plaque" can lead to swelling in the artery, possibly causing the artery to burst.⁵ The interference with blood flow to the heart caused by hard plaque, as well as the bursting of the vessel in the case of soft plaque, can each lead to a heart attack.⁶ It is estimated that thirteen million people in the United States have some form of CAD.⁷ It is the leading cause of death in American

¹ TEX. HEALTH & SAFETY CODE ANN., ch. 93 (Vernon 2009). (Sec. 93.001 Definitions: "(1) 'Cardiovascular disease' means the group of disease that target the heart and blood vessels and that are the result of complex interactions between multiple inherited traits and environmental factors").

² M.J. Pecina, *et al.*, *Predicting the 30-year Risk of Cardiovascular Disease: The Framingham Heart Study*, 119 CIRCULATION 3078-3084 (2009). (For an excellent break-down of Framingham values see: M. Glick, *Screening for traditional risk factors for cardiovascular disease: A review for oral health care providers*, 133 J. AM. DENT. ASSOC. 291-300, 292 (2009)).

³ Nat. Heart Lung and Blood Inst., Diseases and Conditions Index, Coronary Artery Disease, *What Is Coronary Artery Disease?*, http://www.nhlbi.nih.gov/health/dci/Diseases/Cad/CAD_WhatIs.html (last visited July 13, 2009).

⁴ Nat. Heart Lung and Blood Inst., Diseases and Conditions Index, Atherosclerosis, *What Is Atherosclerosis?*, http://www.nhlbi.nih.gov/health/dci/Diseases/Atherosclerosis/Atherosclerosis_WhatIs.html (last visited July 13, 2009).

⁵ Texas Heart Inst. at St. Luke's Epis. Hosp., Heart Information Center, *Coronary Artery Disease*, <http://www.texasheart.org/HIC/Topics/cond/CoronaryArteryDisease.cfm> (last visited July 13, 2009).

⁶ *Id.*

⁷ *Id.*

women and approximately one-third of women over the age of 65 will present with some form of CAD.⁸

The Legislation: HB 1290

On June 19, 2009, Governor Rick Perry (R-TX) signed into law HB 1290 (Certain Tests for Early Detection of Cardiovascular Disease).⁹ The law is designed to mandate health-benefit plan coverage of certain types of medical tests in order to facilitate early detection of CVD.¹⁰ The law is currently scheduled to take effect on September 1, 2009.¹¹

HB 1290 provides up to \$200 worth of coverage every five years for a non-invasive cardiovascular screening tests including CT coronary artery calcification (CT CAC)¹² scanning and carotid ultrasonography designed to detect atherosclerosis and abnormal artery architecture.¹³ The bill mandates that health insurance and other health benefit plans cover screening procedures for men between the ages of 45 to 75, and women between the ages of 55 to 75.¹⁴ The screening procedures are likewise covered for other “at risk” populations, including diabetics and those with Framingham risk factor scores indicative of “intermediate or higher” risk of coronary heart disease.¹⁵

HB 1290 was written by Texas State Representative Rene Oliveira, himself recovering from coronary artery bypass graft (CABG) surgery when he introduced the bill.¹⁶ The legislation was originally introduced in 2007, but failed to pass in that legislative session.¹⁷ Support for HB 1290, during both legislative sessions, from the cardiology and cardiovascular community was mixed.

The American Heart Association (AHA) took no formal position regarding the bill. Speaking to theheart.org, Joel Romo stated that the AHA “does not take any position on the legislation.”¹⁸ The American College of Cardiologists (ACC) supported the bill on its second introduction.¹⁹

Speaking in the advent of the bill’s second introduction, Dr. Raymond Stainback, is quoted as saying that he was “not in favor of legislative mandates for health-related issues.”²⁰ Contacted after the bill’s

⁸ K.M. Kurrelmeyer, *Noninvasive evaluation of women with coronary artery disease*, 17 CURR. OPIN. CARDIO. 464-469, 464 (2002).

⁹ H.B. 1290, 81st Reg. Sess. (Tex. 2009). (History of the bill is available at <http://www.legis.state.tx.us/billlookup/Actions.aspx?LegSess=81R&Bill=HB1290>).

¹⁰ *Id.*

¹¹ *Id.*

¹² CT CAC can evaluate arterial calcium deposits; while it is non-invasive, the technique does involve exposure to a dose of radiation. See N. Waugh, *et al.*, *The effectiveness and cost-effectiveness of computed tomography screening for coronary artery disease: systematic review*. 10 HEALTH TECH. ASSESS. 39 (2006). CAC CT is estimated to deliver between 0.8 and 10.5 mSv; these are received by organs such as the breast, lung, or other organs. See also, K.P. Kim, *et al.*, *Coronary Artery Calcification Screening: Estimated Radiation Dose and Cancer Risk*. 169:13 ARCH. INT. MED. 1188 (2009).

¹³ H.B. 1290, 81st Reg. Sess. (Tex. 2009). (Sec. 1376.003 (b)).

¹⁴ *Id.* (Sec. 1376.003 (a), (1)).

¹⁵ *Id.* (Sec. 1376.003 (a), (2)).

¹⁶ Shelly Wood, *Heart-attack Prevention Bill, Mandating Coverage for CAD Screening, Passes Quietly in Texas*, June 23, 2009, HeartWire, available at <http://www.theheart.org/article/981413.do>.

¹⁷ H.B. 1438, S.B. 725, 80th Reg. Sess., (Tex. 2007).

¹⁸ See Wood, *supra* note 16.

¹⁹ *Id.*

²⁰ Shelly Wood, *Should the ACC/AHA Have Taken a Tougher Stance on SHAPE?*, Jan. 15, 2008, HeartWire, available at <http://www.theheart.org/article/837683.do>.

passage, Dr. Stainbeck offered more favorable feedback, saying: “[t]he feeling is that the language is not unreasonable, and it likely reflects clinical practice ‘on the ground’ in some settings, in which the patient may be paying 100 percent out of pocket for such tests already.”²¹

One of the leading proponents of the bill was the Houston-based Society for Heart Attack Prevention and Eradication (SHAPE).²² According to a May 28, 2009 press release from SHAPE, “the preventative screening of asymptomatic men and women” could result in the prevention of 4,300 cardiovascular disease related deaths annually, reduce heart attack incidence by up to 25 percent, and “save approximately \$1.6 billion in healthcare costs annually.”²³

Responding to opposition to HB 1290, the Chairman of SHAPE, Dr. Morteza Naghavi, wrote a letter to the editor of the *Journal of the American Medical Association*.²⁴ Dr. Naghavi argued that incorporation of coronary artery calcium testing would benefit asymptomatic individuals whose Framingham risk score were valued as “low” or “intermediate.” Additionally, such measurements might benefit individuals at risk for myocardial infarction (heart attack). Risk factor scoring alone, Dr. Naghavi and colleagues argued “[has] never been tested in a randomized” clinical study designed to evaluate “potential outcome benefits of global cardiovascular risk assessment.”²⁵

These comments came as a response to a critique from Dr. Peter D. Jacobson of the Center for Law, Ethics, and Health, at the University of Michigan School of Public Health at Ann Arbor.²⁶ Dr. Jacobson’s commentary addressed the issue of mandates and HB 1290. The first criticism was that the science did not support that mandated methods would necessarily deliver better health information than non-invasive testing and false positives could actually be detrimental to patients who choose to undergo unnecessary procedures based on an erroneous test result.²⁷ Part of the issue also involved questions concerning conflicts of interest; the study published by the SHAPE group was industry sponsored. In his reply to Dr. Naghavi’s letter in JAMA, Dr. Jacobson also points out that the rationale for involving legislative acts²⁸ in order to mandate coverage may have been unnecessary. In the absence of demonstrable opposition to the technique, is there reason to mandate coverage of it using health benefit plans?²⁹

²¹ See Wood, *supra* note 16.

²² See generally, Soc. for Heart Attack Prev. and Eradication (SHAPE), <http://www.shapesociety.org>.

²³ Soc. for Heart Attack Prev. and Eradication (SHAPE), *Preventive Cardiology Experts: Governor Perry Can Save Thousands of Lives, Reduce Healthcare Costs*, May 28, 2009, http://www.shapesociety.org/Governor_Perry_Can_Save_Thousands/.

²⁴ E. Falk, *et al.*, *Legislative Screening for Atherosclerosis*, 299:18 JAMA 2147-48 (May 2008).

²⁵ *Id.*

²⁶ P.D. Jacobson, *Transforming clinical practice guidelines into legislative mandates: Proceed with abundant caution*, 299:2 JAMA 208-10 (Jan. 2008).

²⁷ *Id.* at 208 (“Screening also yields false positive results....In 2000, the [ACC] and [AHA] concluded that electron-beam computed tomography is not superior to alternative non-invasive diagnostic techniques and has a high rate of false positives.”)

²⁸ Consider also that the legislative process may politicize health care coverage and may be the result of successful lobbying on the part of special interest groups. See M.J. Laugesen *et al.*, *A comparative analysis of mandated benefit laws, 1949-200*, 41 HEALTH SERVS. RESEARCH 1081-1102, 1084 (2006) (“[t]he legislative process provides a venue for mandates that benefit certain interest groups, be they patients, providers, or producers of certain interventions”). See also p. 1096 (“[p]olitical, rather than scientific, consensus over the effectiveness of mandated services is an important ingredient of health insurance mandate laws”).

²⁹ P.D. Jacobson, *Reply*, 299:18 JAMA 21-48 (2008).

Another criticism with mandating certain tests is that those tests may crowd out alternative techniques, and that once a test has been mandated it may be difficult to repeal, even where scientific evidence no longer support the methodology.³⁰ It is apparently difficult to un-ring the mandated coverage bell. Citing a study by the Blue Cross Blue Shield Association, Laugesen and colleagues point out that “legislation is ‘virtually never repealed.’”³¹ Dr. Jacobson, in forming his arguments against HB 1290 noted that autologous bone marrow transplantation (ABMT) was mandated in Minnesota in 1995. When scientific evidence weighed against the benefits of ABMT, the attempt to repeal this mandate in 2002 was met with failure.³² More pointedly, Massachusetts currently mandates hormone therapy, which has been linked to an increased risk of myocardial infarction.³³

Coronary artery calcification (CAC) is also subject to false negative results. If the plaque has not yet sufficiently calcified or if the calcium lesion does not significantly impede arterial blood flow – the result may be below the detection limits of the test.³⁴ In addition, the information derived from the test may increase anxiety, without affecting fundamental behavioral factors such as smoking.³⁵ A study conducted in the United Kingdom concluded that “[i]t remains unclear whether CT screening would provide sufficient extra information over risk factor scoring for it to be worthwhile.”³⁶ It has also been recently reported that CAC CT testing may lead to an increased risk of cancer for some individuals.³⁷

Additionally, there were some questions regarding familiarity with the calcium artery scan testing itself, and how results derived from that method would be incorporated into general practice, especially of primary-care physicians.³⁸ CAC CT does appear to be commonly used in the radiology community.³⁹

The Debate: Mandating Insurance Coverage

³⁰ Jacobson, *supra* note 26, at 209.

³¹ Laugesen, *supra* note 28, at 1088 (“[t]his suggests that the rate of repeal is extremely small, however, the fact that repealed legislation is not included does imply that our sample will slightly understate the level of mandated benefits that have actually been in force in this period”).

³² Jacobson, *supra* note 26, at 209.

³³ *Id.*

³⁴ N. Waugh, *et al.*, *The effectiveness and cost-effectiveness of computed tomography screening for coronary artery disease: systematic review*. 10 HEALTH TECH. ASSESS. 39 (2006).

³⁵ *Id.*

³⁶ *Id.*

³⁷ K.P. Kim, *et al.*, *Coronary Artery Calcification Screening: Estimated Radiation Dose and Cancer Risk*. 169:13 ARCH. INT. MED. 1188 (2009) (“[a]ssuming screening every 5 years from the age of 45 to 75 for men and 55 to 75 years for women, the estimated excess lifetime cancer risk using the median dose of 2.3 mSv was 42 cases per 100,000 men (range, 14-200 cases) and 62 cases per 100,000 women (range, 21-300 cases)”). These risks need to be considered with regards to the risks of cardiovascular disease; it is possible that by minimizing radiation doses the risk of cancer may also decrease.

³⁸ See Wood, *supra* note 16 (quoting a telephone interview between Dr. Amit Khera and HeartWire: “I gave a talk last week [early June 2009] to primary care doctors, and there were probably 250 people in the room, and when I asked how many people had ordered a calcium scan, just one person raised a hand ...Most people don’t even know what to do with the Framingham risk score, so they’re going to follow an algorithm that they don’t know how to follow to order a test result that they don’t know what to do with”).

³⁹ Kim, *supra* note 37 (“27% of diagnostic radiologists already read CAC CT screening scans regularly, making it the most common type of CT scanning currently performed in the United States”).

The state has an express interest in the health, welfare, and safety of the citizens of the state.⁴⁰ This interest can take the form of health-benefit plan coverage for those tests and procedures mandated by the state. For example, twenty-seven states mandate coverage for FDA-approved contraceptives.⁴¹ According to a report issued by the Council for Affordable Health Insurance, Texas mandates insurance coverage for about twenty-seven benefits, ranging from mammograms to home health care.⁴² Two mandates, maternal/newborn hospital stay and breast reconstruction related to mastectomies and lumpectomies are currently enacted in all 51 United States jurisdictions (50 states and District of Columbia).⁴³

One of the oldest mandates (from 1949) covered dentists and osteopaths in Pennsylvania; Texas is currently one of the states with the highest number of mandated benefit laws.⁴⁴ The mandated benefit movement picked up steam in the 1990s, when managed care was perceived as restricting access to health care services.⁴⁵ There are two general approaches to mandating benefit coverage: one is to require that the intervention be covered in all policies written by the health benefit plan provider and the other is to require that the health benefit plan provider include the mandated benefit as an option in certain (presumably higher priced) policies.⁴⁶

The interest in preventing potentially deadly disease is a legitimate state interest. In Texas, the Health and Safety Code establishes the Texas Department of Health to “better protect and promote the health of the people of this state.”⁴⁷ Furthermore, chapter 93 of the state’s Health and Safety Code specifically addresses the prevention of cardiovascular disease and stroke.⁴⁸

The health-benefit plan community, in particular the insurance industry, points to the increased cost of health insurance as a result of state mandated coverage. The addition of mandated benefits may increase the cost incrementally per mandated benefit, and may result in overall insurance costs that exclude some participants from the health insurance market.⁴⁹ What impact mandated benefits coverage has on cumulative health care costs is not so apparent. For example, if an individual modifies his/her behavior based on a mandated diagnostic/prognostic test, that lifestyle modification might have positive cost analysis outcomes vis-à-vis decreased medical care costs over the lifespan of the individual.⁵⁰

⁴⁰ The Legislature of the State of Texas is the state's lawmaking body. Its primary function is to enact laws to provide for the health, welfare, education, environment, and economic and general well-being of the citizens of Texas. It also establishes public policy through the passage of bills and resolutions and proposes amendments to the state constitution, which are then submitted to the voters for approval or disapproval.

⁴¹ Guttmacher Inst., State Policies in Brief, *Insurance Coverage of Contraceptives*, http://www.guttmacher.org/statecenter/spibs/spib_ICC.pdf (last visited July 14, 2009).

⁴² Council for Affordable Health Ins., *Health Insurance Mandates in the States 2008*, available at http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2008.pdf.

⁴³ Laugesen, *supra* note 28, at 1092.

⁴⁴ *Id.* at 1089.

⁴⁵ *Id.*

⁴⁶ *Id.* at 1094.

⁴⁷ TEX. HEALTH & SAFETY CODE ANN. § 11.002 (Vernon 2009) (Purpose of Board and Department available at <http://tlo2.tlc.state.tx.us/statutes/hs.toc.htm>).

⁴⁸ TEX. HEALTH & SAFETY CODE ANN., ch. 93 (Vernon 2009).

⁴⁹ Council for Affordable Health Ins., *Health Insurance Mandates in the States 2008*, available at http://www.cahi.org/cahi_contents/resources/pdf/HealthInsuranceMandates2008.pdf.

⁵⁰ For comparison, in an effort to quantify the cost: benefit ratio of mandating coverage for autism, Boudier and colleagues suggest that “even dramatic increases in the treated prevalence of autism and associated healthcare expenditures would result in relatively small increases to healthcare insurance premiums.” See J.N. Boudier *et al.*, *Brief Report: Quantifying the Impact of Autism Coverage on Private Insurance Premiums*, 39 J. AUTISM DEV. DISORD. 953-57, 956 (2009).

Conclusion

Ultimately, there is a moral imperative to preserving life and improving the health of individuals. However, there is also an interest in assuring that the methods established to achieve those goals are founded upon proven scientific and medical methods likely to produce the promised results. The additional testing mandated by legislative acts does, in effect, raise the price of insurance.⁵¹ Mandating a “dream” panel of diagnostic testing, while beneficial to those able to afford medical insurance coverage, may price out lower income or marginal income individuals and families, in effect denying them access to not only the enhanced panel of testing, but also more basic health benefit coverage.

Framingham risk assessment, long a touchstone in cardiovascular disease assessment, is also based on a multitude of factors, including behavior modification. The addition of optional testing may emphasize to those who scored at “low” or “intermediate” risk, the importance of adhering to strategies likely to improve overall cardiovascular health, such as weight management, dietary choices, and the incorporation of lipid-lowering drugs where indicated in order to maintain healthier cholesterol and LDL-cholesterol levels. These behaviors should probably be inherent to overall behavior, regardless of Framingham score level.

Mandating additional health benefit coverage for specialized testing might be icing without regard for the status of the cake. In its current proposed rules, Centers for Medicare and Medicaid Services (CMS) has put forth reductions in charges allowed for cardiology (-11%), cardiac surgery (-2%) and vascular surgery (-1%) under Medicare.⁵² While the ACC may have been less than enthusiastic about HB 1290, it was “shocked” by the proposed payment plan changes, noting that these changes represented a “major decision ...based on...shoddy and incomplete data.”⁵³ Alfred Bove, M.D., President of the ACC, noted that the proposed calendar year 2010 changes will impact “services that have improved countless lives by diagnosing and treating cardiovascular disease [and] are scheduled to have payment cuts in the range of 25 to 42 percent.”⁵⁴ In addition, third party payers may reference these cuts and make similar changes to their payment schedules.⁵⁵ If reduced income negatively

Economically quantifiable outcomes for mandating CT-CAC and carotid ultrasonography will remain to be seen. In evaluating the impact of one screening, combined with adherence to statin therapy in high-CAC patients, it has been estimated that “24,000 deaths and 96,000 nonfatal cardiovascular events” could be prevented. *See also* Kim *supra* note 37 (citing a study by G.A. Diamond and S. Kaul, *The things to come of SHAPE: Cost and Effectiveness of Cardiovascular Prevention*. 99:7 AM. J. OF CARDIO. 1013 (2007)).

⁵¹ That is not to say that even high cost mandates may not be seen as ultimately beneficial by legislators and their constituents, especially if special interest groups ‘sell’ the mandate effectively. *See* Laugesen, *supra* note 28, at 1097 (“[o]f course, cost influences the political consensus over mandated benefit laws: mental health parity (not currently mandated by all 51 jurisdictions) is more costly than maternal and newborn length of stay (which is currently mandated in all 51 jurisdictions). Costly mandated benefits may be adopted or significantly revised less often, however, political consensus, either built by interest groups or constituent demands, can sometimes overwhelm the arguments against high-cost services. The cost of mandated benefit laws varies according to the cost per person benefiting and number of people affected”).

⁵² Centers for Medicare and Medicaid Servs., accessed through <http://www.federalregister.gov/inspection.aspx#special> (last accessed July 13, 2009). See pages 716-17 (citing combined impact of changes in work, practice expense, and malpractice relative value units).

⁵³ Ana Fullmer, Am. Coll. of Cardiology News Release, *ACC Comment on Medicare Proposed Physician Cuts*, July 1, 2009, available at <http://www.acc.org/media/releases/highlights/2009/july09/physiciancut.cfm>.

⁵⁴ *Id.*

⁵⁵ Lisa Nainggolan, *ACC Aghast at Proposed Cuts to Cardiology Payments in Medicare Physician Fee Schedule for 2010*, July 3, 2009, HeartWire, <http://www.theheart.org/article/983741.do> (quoting Dr. Melissa Walton-Shirley “Blue Cross and

affects access to fundamental cardiovascular care,⁵⁶ the availability of payment for specialized testing may not make an impact.

While the proposed CMS payment changes have not yet gone into effect, the debate over them brings up similar issues to those attendant to the passage of HB 1290: (1) whether sufficient science is being referenced when making decisions regarding payment for medical tests and services, and (2) if these monetary decisions will end up dictating the quality of care delivered in a physician's office. In the end, the decision regarding what tests to order should be left in the domain of the physician; the patient, as health-benefit plan consumer, should be left some leeway to determine what package of services he or she chooses to purchase with their limited health care dollar.

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Blue Shield private insurance look to Medicare to set payments for office visits, echos, etc. So, any decrease in Medicare payment will soon be followed by third-party cutbacks as well").

⁵⁶ Emily P. Walker, *CMS Announces New Payment Rules that Benefit Primary Care Docs*, July 2, 2009, Medpage Today, <http://www.medpagetoday.com/PublicHealthPolicy/Medicare/14944> (“[m]ost of the cuts would come from reduced payments for left heart catheterizations, transthoracic echocardiograms, and EKG’s, said Amy Murphy, ACC’s associate director of media relations”).