
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

OFFICE OF OVERSIGHT AND INVESTIGATIONS
MAJORITY STAFF

# CONSUMERS' ACCESS TO DIAGNOSTIC HEART TESTS IN DELAWARE

**Staff Report for Chairman Rockefeller**
**April 15, 2011**

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## Executive Summary

On February 8, 2010, a forty-five year old HVAC technician named Michael Fields appeared in the emergency room of the Christiana Hospital in Newark, Delaware, complaining of severe chest pain, numbness in his right arm, and other symptoms of coronary artery disease. For more than a month, Mr. Fields' doctor had been attempting to perform a common outpatient test, known as a "nuclear stress test," on Mr. Fields to diagnose his condition. But Mr. Fields had not received the test because a company called MedSolutions, working at the direction of Mr. Fields' health insurance company, BlueCross BlueShield of Delaware, had repeatedly rejected the test as medically unnecessary.

Mr. Fields was admitted to the hospital where Dr. Andrew Doorey, a cardiologist, performed a cardiac catheterization procedure on Mr. Fields the next day. Dr. Doorey found that Mr. Fields was suffering a life-threatening blockage in his left main coronary artery and recommended immediate coronary bypass surgery, which Mr. Fields received the following day, February 10, 2010. In a complaint letter he sent to the Delaware Insurance Commissioner a few weeks later, Dr. Doorey recounted that when he treated Mr. Fields on February 9, "the patient was visibly shaking." Dr. Doorey further explained:

> I tried to reassure him that he was relatively young and would be a good candidate for surgery, only to find out that this was not the primary issue. He was shaking because he realized how close to death he had come due to the repeated refusal of Blue Cross and MedSolutions to allow him to have a stress test.[1]

The story of Mr. Fields' struggles to get needed medical care was first publicly reported in a series of articles in the Wilmington, Delaware News Journal in late March and early April, 2010. While these stories focused on the specific cases of Mr. Fields and a few other Delaware consumers, they brought public attention to a much broader debate in the health care community over when it is appropriate to perform diagnostic heart tests that use advanced imaging technology, and who decides when these tests should be performed on particular patients.

After the News Journal articles appeared, Chairman Rockefeller wrote letters to several Delaware health insurance companies requesting information about their procedures for approving or denying diagnostic heart tests. Since that time, the Senate Commerce Committee staff has been investigating how Delaware patients like Mr. Fields are tested and receive care for heart disease. This investigation has included an examination of the broader nation-wide conflict between health care providers and health care payers over the utilization of expensive diagnostic medical tests.

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[1] Letter from Andrew J. Doorey, MD, Clinical Professor of Medicine (Cardiology), Thomas Jefferson University, Christiana Hospital, to Karen Weldin Stewart, Delaware Insurance Commissioner (Mar. 5, 2010) (hereinafter "Doorey March 5 letter").

### *Background on Advanced Imaging Diagnostic Heart Tests*

Over the past decade, advanced imaging tests have been one of the fastest growing services in the American health care system. While the new technologies behind these tests undoubtedly have given doctors powerful new tools to diagnose and treat their patients, they have also raised questions about whether the benefits the tests provide to patients are always worth their additional cost and risks. One of the medical fields where this issue has been debated most energetically is in the field of cardiology.

The private and public entities that pay for health care services in the United States have been alarmed by the rapid increase in advanced imaging "stress tests" that cardiologists and other doctors use to diagnose coronary artery disease, one of the most common diseases in the adult American population. These outpatient tests use either ultrasound or nuclear medicine to generate detailed images of a patient's heart and coronary arteries. Many critics, including some cardiologists, argue that doctors adopted these new testing technologies without carefully considering whether the tests improve the overall quality of their patients' care. Critics also suggest that the rapid increase in utilization of these tests is linked to the revenue doctors earn when they order them, especially those doctors who own and operate their own testing equipment.

Insurance companies and other private health insurance payers have responded to the rapid growth of advanced imaging tests by implementing various "utilization management" strategies to reduce the growth of cardiac stress tests and other advanced imaging procedures. One of insurers' most common cost-control techniques is "pre-authorization," where doctors must get insurers' permission before performing a test on their patients. Starting in 2005, Congress has also attempted to slow down the rapidly rising costs of advanced imaging services in the Medicare program by reducing doctors' payments and implementing quality assurance programs. Cardiologists themselves have developed "appropriate use criteria" to better define the clinical situations in which the tests are medically appropriate.

### *The Senate Commerce Committee Investigation*

While the debate over the appropriateness of advanced imaging cardiac stress tests goes on in every American medical community, it became very public in Delaware when the News Journal reported on Mr. Fields and other Delaware patients whose doctors' requests for pre-authorization of cardiac stress tests had been denied by the Tennessee-based "radiation benefits management" company, MedSolutions, Inc. The stories documented doctors' frustrations with the pre-authorization process and highlighted their concerns that the denied tests were depriving patients like Mr. Fields of needed care.

In response to these complaints, the Senate Commerce Committee and the Delaware Department of Insurance independently opened investigations into the approval and denial of cardiac stress tests in Delaware. During the course of this investigation, Committee staff have reviewed documents and audio files produced by two Delaware insurers that hired MedSolutions

to review test requests, Aetna and BlueCross BlueShield of Delaware, and have interviewed a number of Delaware doctors and patients affected by the test denials, including Michael Fields.

This investigation has found that in most cases, Delaware patients showing symptoms of coronary artery disease received appropriate tests from their doctors, and that Delaware health insurance companies paid for this care. However, in some cases reviewed during this investigation, patients did not receive proper care. MedSolutions denied some requests for stress tests that were medically necessary, while Delaware doctors ordered stress tests for their patients that, according to cardiologists' own appropriate use criteria, were not justified.

Some other important findings of this investigation are:

- ***Radiation Benefits Managers' (RBMs) Business Goal is to Reduce the Use of Advanced Imaging Services.*** Health insurance companies hire "radiation benefits managers" (RBMs) like MedSolutions to reduce the amount of money they spend on nuclear stress tests and other tests using advanced imaging technology. The fees the two Delaware insurers paid to MedSolutions were based in part on how successfully the RBM reduced the utilization of the tests. The Delaware Insurance Commissioner's office determined that BlueCross BlueShield of Delaware's financial agreement with MedSolutions violated the State's rules against fees that are contingent on health care cost savings.

- ***The RBM Pre-Authorization Process is Burdensome and Confusing for Consumers and Health Care Providers.*** The pre-authorization process that MedSolutions and the Delaware insurers set up to review doctors' requests for nuclear stress tests was administratively burdensome and confusing. It interposed an additional, unseen layer of administrative review on the already complicated process doctors and patients must follow to obtain approval for care from health insurance companies. One result of this process was that many medically appropriate test requests were likely denied on "administrative" grounds. In the case of Michael Fields, the pre-authorization process unnecessarily delayed care for his life-threatening medical condition.

- ***Conflicting "Evidence-Based" Cardiac Testing Guidelines Compound the Confusion.*** One source of confusion and disagreement in the pre-authorization process was MedSolutions' "Cardiac Imaging Guidelines," which established clinical situations in which nuclear stress tests were appropriate. These guidelines diverge in key ways from the "appropriate use criteria" established by the American College of Cardiology. This conflict created situations in which MedSolutions denied requests for tests that the cardiologists' professional guidelines deemed appropriate. MedSolutions' failure to develop its "evidence-based" guidelines through a transparent process leaves it vulnerable to criticisms that the purpose of MedSolutions' guidelines is to deny test requests, rather than reflect the strongest available scientific evidence.

- ***According to Their Own Professional Guidelines, Delaware Doctors Routinely Order Unnecessary Nuclear Stress Tests.*** Evidence from this investigation and other studies makes it clear that cardiologists and other doctors order nuclear stress tests in situations that their own professional guidelines deem inappropriate. These tests incur unnecessary costs and unnecessarily expose patients to harmful radiation. An outside expert hired by the Delaware Insurance Commissioner determined that more than one out of every ten nuclear stress tests ordered by Delaware doctors did not comply with the clinical use criteria established by the American College of Cardiology. Following doctors' own clinical standards, MedSolutions properly denied Delaware doctors' requests for such inappropriate tests.

## I. Background on Diagnostic Tests for Coronary Artery Disease

According to the American Heart Association, more than 17 million adult Americans suffer from coronary artery disease (CAD), and it causes one out of every six adult deaths in the United States.[2] CAD occurs when the three major arteries supplying oxygen-rich blood to the heart (the coronary arteries) become narrowed or blocked. When the heart is not receiving sufficient amounts of blood and oxygen (ischemia), a patient may experience shortness of breath, chest pain (angina), and other symptoms, including a heart attack (myocardial infarction).

When properly diagnosed, CAD can be treated in a number of ways. Patients with less serious symptoms can be treated with a variety of drugs, and are also urged to make lifestyle changes, such as losing weight or quitting smoking, that reduce their CAD risk factors. In more serious cases, patients are hospitalized and receive a cardiac catheterization insertion procedure, which often includes procedures, such as angioplasty or stenting, that expand narrowed or blocked areas of the coronary arteries. According to the American Heart Association, the average cost of an angioplasty procedure is $51,445.[3] In the most serious cases, patients will receive coronary artery bypass surgery (CABG, pronounced "cabbage"), during which surgeons take a vein from another part of the patient's body and create new channel to supply blood to the heart. The average cost of this procedure is $112,377.[4]

The test cardiologists and other doctors trained in adult internal medicine have traditionally used to diagnose CAD is called the "standard stress test," or "exercise treadmill test." This test is conducted with electrocardiogram (ECG) equipment that measures the electrical activity of the heart as the patient's heart beats faster under stress induced either by exercise or chemical agents. In many cases, doctors can detect distinctive electrical signatures during this test that suggest the presence of CAD. One of the great advantages of this test is that it is a "non-invasive" procedure - it does not require surgical intervention and can be performed in a doctor's office rather than in a hospital setting.

According to experts Committee staff interviewed during this investigation, the basic stress test has a diagnostic accuracy rate of approximately 70%, which means that a properly

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[2] American Heart Association, *Heart Disease & Stroke Statistics: 2010 Update At-A-Glance*, at 12. AHA's definition of coronary heart disease (synonymous with coronary artery disease) corresponds with the International Statistical Classification of Diseases and Related Health Problems (ICD/10) code numbers 120 through 125. (online at http://www.americanheart.org/presenter.jhtml?identifier=3000090).

[3] *Id.* at 32 (cost figure given for percutaneous coronary intervention (PCI)). One of the many current controversies in the field of cardiology is whether the use of arterial stents in CAD patients is any more effective than less costly drug treatments. *See A Simple Health-Care Fix Fizzles Out*, Wall Street Journal (Feb. 11, 2010).

[4] *Id*. There are significant regional variations in the frequency of the PCI and CABG procedures. Dartmouth Institute for Health Policy & Clinical Practice, *Improving Patient Decision-Making in Health Care: A 2011 Dartmouth Atlas Report Highlighting Minnesota* (online at http://www.dartmouthatlas.org /downloads/reports/Decision_making_report_022411.pdf), at 11-13.

administered basic stress test will accurately detect the presence of CAD in seven out of ten patients. In the other 30% of cases, the test will either fail to detect CAD (a "false negative") or will incorrectly identify CAD (a "false positive").[5] Doctors who treat patients with symptoms of CAD are especially concerned about the possibility of false negative results, because they might discourage patients from taking steps to treat their condition.

Over the past several decades, rapid advances in imaging technology have led to the development of more sophisticated and accurate non-invasive diagnostic heart tests. Instead of simply measuring the heart's electrical signals, these new tests allow clinical staff to view images of the blood flow in and around the heart. One of these new tests, usually referred to as the "echo stress test," uses echocardiography to create moving ultrasound images of the patient's heart while under stress. This test is performed by specially trained cardiac sonographers. In some echo stress tests, a dye is injected into the patient's veins to improve the quality of the images.[6]

Another test uses nuclear medicine technology to generate images of blood flow through and around the heart. In this so-called "nuclear stress test," a radioactive compound (a "tracer") is injected into the patient's bloodstream. An x-ray camera ("gamma camera") then takes multiple pictures of the heart from different angles and combines them into a three-dimensional picture of how blood is flowing through and around the heart. The most common type of nuclear stress test for coronary artery disease is the "single photon emission computed tomography" (SPECT) exam.[7] This procedure is also called "Myocardial Perfusion Imaging" (MPI) and "Cardiac Radionuclide Imaging" (RNI). Unlike the basic stress test and the echo stress test, the nuclear stress test exposes patients to significant levels of ionizing radiation. According to the Food and Drug Administration, a nuclear stress test can expose patients to a dose of radiation equivalent to more than 2,000 chest x-rays.[8]

According to experts Committee staff interviewed during this investigation, the echo and nuclear stress tests have diagnostic accuracy rates in the 90% range, a significantly higher level than that of the basic stress test. As a general rule, doctors prefer these tests to the less accurate standard treadmill tests when they are treating patients who appear to be at higher risk of CAD.

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[5] According to the American College of Cardiology's "CardioSmart" website, "false positive exercise stress tests happen more often in women than in men." (online at http://www.cardiosmart.org/HeartDisease/CTT.aspx?id=890).

[6] American Society of Echocardiography, *Frequently Asked Questions About Exercise Stress Echocardiography.* (online at http://64.106.210.34/stressfaq.pdf).

[7] American College of Cardiology, Cardio Smart Website, *Nuclear Heart Scan* (online at http://www.cardiosmart.org/HeartDisease/CTT.aspx?id=682) (including videos illustrating how the test is conducted)

[8] U.S. Food and Drug Administration, Center for Devices and Radiological Health, *Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging* (Feb. 2010), at 4. According to this study, the average adult effective dose from a cardiac stress test using thallium 201 chloride is 41 millisevierts (a measure of the biological effects of radiation exposure), while the dose from a posteroanterior chest x-ray is .02mSv. (online at http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199994.htm).

But, as a table of Medicare fees paid to Delaware physicians shows, echo and nuclear tests are also more expensive than the basic treadmill stress test. While this table does not include all of the charges involved in the actual performance of these tests, it shows that a stress echo test is about 2.5 times more expensive than a basic stress test, while a nuclear stress test is more than six times more expensive.[9]

**Medicare Part B Fees Paid to Delaware Physicians for Diagnostic Heart Stress Tests**

| **Type of Test** | **Medicare Part B Payment to Delaware Doctors** |
|---|---|
| Basic Stress Test (CPT # 93015) | **$95.10** |
| Echo Stress Test (CPT # 93351) | **$255.13** |
| Nuclear Stress Test (CPT #s 78452 and 93015) | **$589.69** |

## II. The Rapid Increase in the Utilization of Advanced Imaging Heart Tests

Starting in the late 1990s, as imaging technologies improved and imaging equipment became less expensive to purchase and operate, cardiologists and other doctors rapidly increased their use of the echo and nuclear diagnostic heart tests. In a 2008 report on Medicare Part B spending on imaging tests, the Government Accountability Office (GAO) found that between 2000 and 2006, the percentage of cardiologists billing Medicare for in-office advanced imaging services almost doubled, rising from 24% to 43%.[10] The GAO study also found that in the same period, the percentage of the total Medicare income cardiologists derived from performing in-office imaging tests rose from 23.2% to 36%.[11] In addition, GAO found large regional differences in Medicare spending on in-office imaging services, suggesting "that not all utilization of in-office imaging services may be appropriate."[12]

[9] Delaware fee data come from the American Medical Association's "Current Procedural Terminology" (CPT) website. (online at http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.shtml). The figures in this table do not include the following costs: the fees physicians receive for interpreting the tests, the radioactive compounds used in nuclear stress tests, the contrast agents used in some stress echo tests, the Doppler color flow technology used in some echo stress tests, and the chemical compounds used to induce stress in patients who are not capable of exercising (e.g., dobutamine). In most areas, private insurer fees paid to physicians are higher than the fees paid by Medicare.

[10] Government Accountability Office, *Medicare Part B Imaging Services: Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices* (June 2008) (GAO-08-452), at 19.

[11] *Id.* at 20.

[12] *Id.* at 21.

The Medicare Payment Advisory Commission (MedPAC) has also repeatedly warned Congress about the rapidly rising costs of imaging tests in the Medicare program and the uncertain quality and appropriateness of the tests. In 2005 congressional testimony, MedPAC observed that between 1999 and 2003, Medicare payments to physicians for imaging services had been growing twice as fast as payments for all other services.[13] In a later study, MedPAC linked this growth to the rising rate of doctors who own and operate their own imaging equipment. For example, MedPAC's analysis of 2005 Medicare Part B payment data showed that physicians who owned their own imaging equipment were twice as likely to order nuclear stress tests for their patients showing symptoms of ischemic heart disease.[14]

Congress has addressed these concerns in several recent laws. In the 2005 Deficit Reduction Act, for example, Congress reduced Medicare reimbursements for outpatient imaging services,[15] and in 2008, it imposed new accreditation requirements on imaging services providers.[16] In the 2010 health care reform law, it adjusted imaging utilization rate assumptions to reduce Medicare payments for imaging services.[17]

### *A. Cardiologists' Response to Concerns about Overutilization*

Federal policymakers were not the only group raising questions about cardiologists' rapidly increasing use of imaging technology. In 2006, for example, Dr. Pamela Douglas, a former president of the American College of Cardiology (ACC) and a professor of cardiovascular medicine at Duke University, candidly admitted in a leading professional journal that the utilization of advanced imaging had grown faster than cardiologists' understanding of whether the tests were improving patient care.[18] Even though cardiologists were using the new technology to treat their patients and charging health care payers for the tests, there was no systematic study of the actual "diagnostic utility" of the tests for patients. According to Dr. Douglas, cardiologists were not asking themselves: "How can we make sure that such testing is performed well and to our patients' benefit?"[19]

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[13] U.S. House of Representatives, Committee on Ways and Means, Subcommittee on Health, Testimony of Mark E. Miller, Ph.D., Executive Director, Medicare Payment Advisory Commission, *Hearing on Managing the Use of Imaging Services* (Mar. 17, 2005).

[14] Medicare Payment Advisory Commission, *Report to the Congress: Improving Incentives in the Medicare Program* (Jun. 2009), at 93-5. (online at http://www.medpac.gov/documents/Jun09_EntireReport.pdf).

[15] Deficit Reduction Act of 2005, Pub. L. 109-171, § 5102.

[16] Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110-275, § 135.

[17] Patient Protection and Affordable Care Act, Pub. L. 111-148, § 3135, as modified by the Health Care and Education Reconciliation Act, Pub. L. 111-152, § 1107.

[18] Pamela S. Douglas, *Improving Imaging: Our Professional Imperative*, Journal of the American College of Cardiology, 48, 2152-5 (2006) (online at http://content.onlinejacc.org/cgi/reprint/48/10/2152.pdf).

[19] *Id*. at 2152.

By the time Dr. Douglas made these comments, the ACC had acknowledged that the sharp increase in the use of advanced imaging tests was raising serious questions about quality and appropriateness. In 2005, the ACC convened a diverse group of medical experts, including the chief medical officer of a health insurance company, to develop "appropriate use criteria" indicating when the use of nuclear stress tests was appropriate. The panel reviewed 52 different clinical situations in which cardiologists ordered the tests.[20] This panel found that in 27 of these 52 clinical situations, a nuclear stress test was an "appropriate" test; but it also found that in 13 of the situations, a nuclear stress test would be clearly inappropriate, while in the remaining 12 situations, appropriateness was uncertain.

The ACC criteria were published with thorough methodological explanations in the ACC's professional journal in October 2005, and were endorsed by the American Heart Association. Three years later, in 2008, the ACC published similar appropriate use criteria for echo stress tests, [21] and in 2009, the ACC revised and updated its 2005 nuclear stress test criteria.[22]

While recognizing that clinicians need to retain some discretion to recommend the proper treatment for any particular patient, the ACC criteria were designed to establish a benchmark that health insurance companies and other payers could use to determine if a doctor is using imaging tests in a responsible manner. The authors of the criteria recommended that payers reimburse doctors who ordered tests that were appropriate under the criteria, but that doctors ordering tests in "inappropriate" or "uncertain" situations have the burden of proof to show the tests were necessary.[23] They also acknowledged the potential cost and harm of inappropriate tests. The authors of the 2008 echo stress criteria commented:

> Similar to other forms of stress imaging testing, stress echocardiography can help more clearly define cardiovascular risk for a patient, but also creates opportunities for overuse and misuse in patients who may not obtain a benefit, or who could have been medically managed effectively without the addition of the test. In particular, inappropriate use may be costly and may prompt potentially harmful and costly downstream testing and treatment such as unwarranted coronary revascularization or unnecessary repeat follow-up. Concerns about inappropriate use exist among those who pay for these services and clinical leaders who evaluate the effectiveness of testing.[24]

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[20] R.G. Brindis, et al. *ACCF/ASNC Appropriateness Criteria for Single-Photon Emission Computed Tomography Myocardial Perfusion Imaging (SPECT MPI*), Journal of the American College of Cardiology, vol. 46 1587-605 (2005) (online at https://www.asnc.org/imageuploads/accf_asnc_ appropriateness_ criteria1.pdf).

[21] P.S. Douglas, et al., *2008 Appropriateness Guidelines for Stress Echocardiography*, Journal of the American College of Cardiology, vol. 51, 1127-47 (2008) (online at http://www.asnc.org/imageuploads/ AppropCriteriaStressEcho0303081.pdf).

[22] R.C. Hendel, et al., *2009 Appropriateness Use Criteria for Cardiac Radionuclide Imaging*, Journal of the American College of Cardiology, vol. 53, 2201-29 (2009) (online at http://content.onlinejacc. org/cgi/reprint/53/23/2201.pdf).

[23] *Id.* at 2219.

[24] *2008 Appropriateness Guidelines for Stress Echocardiography*, *supra* note 21, at 1130.

### *B. Health Insurance Companies' Response to Concerns about Overutilization*

Private insurance plans also responded to the rapid increases in the use of advanced imaging technology to diagnose coronary artery disease (CAD) and other conditions. Instead of adopting Medicare's approach of reducing reimbursements for advanced imaging services, health plans have implemented various "utilization review" processes to slow the growth of in-office advanced imaging tests. The purpose of these steps was to make sure the imaging tests doctors were ordering for their patients were cost-effective and "medically necessary." As John Iglehart reported in a 2006 story in the New England Journal of Medicine:

> Insurers continue to ask whether the rapid rise in expenditures for imaging studies is leading to improvements in patient outcomes that equal or surpass the greater costs associated with providing these services.[25]

One health plan in Arizona, for example, provided cardiologists with data on their utilization of nuclear stress tests and asked them to follow a checklist process before ordering a nuclear test.[26] Other insurers instituted a "prior notification" requirement, requiring doctors to call the insurer and discuss the test before performing it.[27] Another approach adopted by many private insurers was to require the "credentialing" of imaging equipment and doctors to ensure that tests were professionally performed on properly functioning imaging machines.[28]

By far the most widespread utilization review process insurers instituted to counter the growth of advanced imaging, however, was "prior authorization." Under this process, the doctor must obtain an insurance plan's approval before performing the test. Many insurance plans hired third-party "radiation benefit management" (RBM) companies to help them manage their prior authorizations. RBMs specialize in reviewing doctors' requests for advanced imaging tests, and determining whether the requested tests are medically necessary. When GAO conducted a survey of 17 national and regional health insurance plans in early 2008, it found that all 17 plans used prior authorization to manage their requests for advanced imaging tests, and it found that 16 out of the 17 insurers employed RBMs to review doctors' prior authorization requests.[29] In 2008, the president of one of the largest RBM firms, National Imaging Associates, estimated that

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[25] John Iglehart, *The New Era of Medical Imaging – Progress and Pitfalls*, New England Journal of Medicine, vol. 354, 2822-2828, at 2823 (Jun. 29, 2006).

[26] Center for Studying Health System Change, *Issue Brief: Health Plans Target Advanced Imaging Services: Cost, Quality and Safety Concerns Prompt Renewed Oversight* (Feb. 2008) (online at http://www.hschange.com/CONTENT/968).

[27] *See e.g., One Eye on the Image and the Other on the Wallet*, Managed Healthcare Executive (June 1, 2006) (discussing Highmark's use of physician "privileging" and prior notification) (online at http://managedhealthcareexecutive.modernmedicine.com/mhe/Special+Report/One-eye-on-the-image-and-the-other-on-the-wallet/ ArticleStandard/Article/detail/329910?searchString=one%20eye%20on%20the%20image)

[28] *Issue Brief: Health Plans Target Advanced Imaging Services*, *supra* note 26.

[29] GAO, *Medicare Part B Imaging Services*, *supra* note 10, at 26.

around 90 million consumers were covered by insurance plans that used RBMs to review requests for advanced imaging tests.[30]

According to insurance plans and RBMs, prior authorization and RBM management consistently reduce the rate of growth of advanced imaging. In one example provided by MedSolutions, an insurance plan reduced its imaging expenditures by 37% after implementing a prior authorization program.[31] While some of these savings were achieved through denying test requests, more were achieved through the so-called "sentinel effect," the reduced number of tests doctors request when they realize their requests will be reviewed by a third party.[32] One insurance plan in Cleveland found that a prior authorization program had significantly slowed the 20% annual growth in its imaging expenses, even though the program's denial rate was a very low 1.5%. A representative of the plan observed, "We're not saying 'No' that much, but because people have to now justify what difference the test is going to make, they aren't requesting it as much."[33]

## III. Background on the Commerce Committee's Investigation

In late March 2010, the Wilmington, Delaware News Journal published a series of articles describing several episodes in which MedSolutions, a Tennessee radiation benefits manager (RBM), denied Delaware cardiologists' requests for nuclear stress tests. One of the patients described in the News Journal series was Michael Fields, a 45-year old resident of Elkton, Maryland, who was insured by BlueCross BlueShield of Delaware (BCBSD) through his Delaware employer. Mr. Fields and his doctors alleged that by denying him medically necessary care for a serious heart condition, BCBSD and MedSolutions had endangered his life.[34]

Based on the information reported in the News Journal stories, Chairman Rockefeller opened an investigation into insurers' denials of cardiac stress tests that Delaware doctors felt were medically necessary. On March 25, 2010, he sent a letter to BCBSD requesting information about the company's prior authorization procedures, the number of requests for cardiac stress tests it had allowed or denied, and its business relationship with MedSolutions.[35]

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[30] *Insurers Hire Radiology Police to Vet Scanning – Firms Make Doctors Justify Costly CTs, MRIs and PETs; Patients Stuck in the Middle*, Wall Street Journal (Nov. 6, 2008).

[31] *New Imaging Controls Strict, but May Be Easier on Doctors*, Managed Care (Nov. 2007) (online at http://www.managedcaremag.com/archives/0711/0711.imaging.html).

[32] *Id.*

[33] *Issue Brief: Health Plans Target Advanced Imaging Services*, *supra* note 26.

[34] *Health Insurer's Denial of Test Almost Fatal for Delaware Man. After Insurance Rejections, Man Undergoes Heart Surgery*, The News Journal (Wilmington, DE) (March 21, 2010); *Blue Cross Denials Add to Patients' Stress: Third Party Overrides Doctors' Advice on Heart Tests*, The News Journal (Wilmington, DE) (Mar. 23, 2010).

[35] Letter from Chairman Rockefeller to Timothy Constantine, President & CEO, BlueCross BlueShield of Delaware (Mar. 25, 2010).

On April 16, 2010, Chairman Rockefeller sent similar letters to two other insurers operating in Delaware, Aetna, and Coventry.[36]

Through responses to these inquiries, Committee staff learned that BCBSD and Aetna had contracted with MedSolutions for prior authorization review of requests for nuclear stress tests, while Coventry did not use a third-party contractor to review requests for the test. Since that time, the Committee staff's review has focused on BCBSD and Aetna.

Both companies voluntarily provided the Committee documents and information related to their business relationships with MedSolutions. The companies also provided information about approximately 1,600 separate requests that Delaware doctors made to BCBSD or Aetna for nuclear stress tests between July 2009, and March 2010.[37] In addition, MedSolutions itself provided information about its business practices to the Committee.[38] During the course of the investigation, Committee staff also spoke with a number of patients whose heart tests were denied by MedSolutions. Several of these patients, including Mr. Fields, authorized Committee staff to review their health records. Finally, Committee staff reviewed the Delaware Insurance Commissioner's recently completed Market Conduct Examination of BCBSD's pre-authorization of nuclear stress tests.

At the time Chairman Rockefeller sent the March 25 letter to BCBSD, the Delaware Insurance Commissioner's office had already launched a preliminary inquiry into the issue, after receiving a March 5, 2010, complaint letter from Dr. Andrew Doorey, one of the cardiologists who treated Mr. Fields. On March 19, 2010, in response to this inquiry, BCBSD suspended its use of MedSolutions' pre-authorization services to conduct its own review of the matter.[39] On March 27, 2010, Delaware Insurance Commissioner Karen Weldin Stewart announced that her office would conduct a market conduct examination of Delaware health insurance companies' nuclear stress test pre-authorization practices.

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[36] Letter from Chairman Rockefeller to Ronald A. Williams, Chairman and CEO, Aetna (Apr. 16, 2010); Letter from Chairman Rockefeller to Allen F. Wise, CEO, Coventry Health Care (Apr. 16, 2010).

[37] BCBSD provided claims approval and denial data for the period between July 1, 2009, the date MedSolutions began reviewing test requests, and March 19, 2010, when it suspended to program. Aetna data are for the period between November 1, 2009, when Aetna began using MedSolutions to pre-authorize its Delaware test requests, and March 31, 2010. Until December 31, 2009, doctors used three separate CPT codes to bill for nuclear stress tests (78465, 78478, and 78480). Starting on January 1, 2010, these three separate codes were "crosswalked" into a new single billing code (78452).

[38] While MedSolutions promises in its contracts with its customers that it "shall maintain and furnish such records and documents as may be required by applicable laws, regulations and Plan requirements," Committee staff has found that MedSolutions was often not able to produce complete patient records in response to requests from their clients. For example, many of MedSolutions' audio files contain only audio of the person calling the company, but not that of the MedSolutions employee. In one case, MedSolutions was not able to produce the record of a peer-to-peer conversation between a treating physician and a MedSolutions doctor (MSI Case # 12032113).

[39] Letter from Timothy Constantine, President & CEO, BlueCross BlueShield of Delaware to Chairman Rockefeller (Apr. 20, 2010).

## IV. MedSolutions' Business Relationship with the Delaware Insurers

According to contracts provided to the Committee by BCBSD and Aetna, MedSolutions operated what it called a "prospective utilization management program" for the two health insurance companies. The insurers paid MedSolutions to review doctors' requests for nuclear stress tests and other outpatient tests employing advanced imaging technology, and to determine whether the tests were "medically necessary."[40]

Under the agreements, Aetna and BCBSD also delegated to MedSolutions the responsibility for directly communicating its findings to the requesting doctors and patients. If MedSolutions determined that a test was medically necessary, it "precertified" the test and informed the requesting doctor that the insurer would pay for it. If MedSolutions determined that the test was not medically necessary, it informed the doctor and patient that the test would not be covered.

In its marketing materials and in its contracts with both Aetna and BCBSD, MedSolutions guaranteed its customers that its utilization management program would significantly reduce their claims payments. The MedSolutions website makes the following statement about its cardiac imaging program:

> MedSolutions' Cardiac Imaging program is designed to deliver substantial savings of 25-30% by managing the high cost of a broad range of cardiac imaging procedures. The program facilitates authorization requests, eliminates delays in care and enhances detection of inappropriate studies. Most importantly, the program rewards the clinically accurate providers while protecting patients from unnecessary utilization and associated risks.[41]

In its agreements with Aetna and BCBSD, MedSolutions' administrative fees were based on its efficient performance of the pre-authorization services and the savings it could deliver to the insurers through reduced utilization. In its agreement with BCBSD, for example, MedSolutions received higher fees if the cost savings to the insurer exceeded 20%. The Delaware Insurance Commissioner's office determined that this cost savings incentive clause violated a state regulation prohibiting "contingent savings" agreements between insurers and third parties. According to the Commissioner's office, BCBSD eliminated this contingent savings language on June 3, 2010.[42]

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[40] In one of these contracts, the parties define "medically necessary" as: "services and supplies which are determined to be required for the treatment or evaluation of a medical condition, are consistent with the diagnosis and which could not have been omitted under generally accepted medical standards or provided in a less intensive setting."

[41] MedSolutions website, "Cardiac Imaging" (online at http://www.medsolutions.com/services/intelligent_util/card_imaging/index.html) (accessed Apr. 11, 2011).

[42] Office of the Delaware Insurance Commissioner, *Market Conduct Report on BCBSD, Inc.* (NAIC # 53287) (Apr. 6, 2011).

### *A. The Prior Authorization Process*

The prior authorization process MedSolutions operated on behalf of the insurers involved a number of separate administrative steps. Doctors initiated the test request process by filling out a 20-question clinical survey of the patient and submitting it to a MedSolutions "Intake Coordinator" working at the company's offices in Franklin, Tennessee. The request next moved on to a "Nurse Reviewer," who either approved or denied the test. In the case of a denial, the case would be further reviewed by a MedSolutions physician to confirm that the Nurse Reviewer's denial was appropriate.[43]

Doctors whose test requests were denied had the right to request a "peer-to-peer review" with the MedSolutions' physician who denied the request. In addition, the requesting doctor or patient had the right to appeal the test denial to a second MedSolutions' physician who had not been involved in the initial denial.[44] In the Delaware cases reviewed in the course of this investigation, doctors and/or their patients requested either peer-to-peer reviews or lodged appeals in about 24% of the instances where MedSolutions denied their requests for a nuclear stress test. In more than half of these cases, doctors and/or patients were able to reverse MedSolutions' initial denials of the test.

In both correspondence and in interviews with Committee staff, doctors and their administrators described this pre-authorization process as time-consuming and administratively burdensome. In a letter written to Chairman Rockefeller in May 2010, the president of the American College of Cardiology, Dr. Ralph Brindis, stated that prior authorization requirements "are extremely burdensome to the medical practices and hospitals and can delay patients from needed medical care and treatments."[45] According to Dr. Brindis and other health care providers interviewed by Committee staff, cardiologists waste precious clinical hours on the phone dealing with prior authorization issues, and are forced to hire additional employees to manage test requests that, in most cases, end up getting approved.

A number of doctors also suggested that pre-authorization rewards larger practices with more sophisticated administrative operations. Dr. Christopher Ullrich, a neuroradiologist from Charlotte, North Carolina, commented:

> Small primary-care practices are at a real disadvantage that discourages them from ordering even appropriate tests, while physicians or multispecialty groups with in-office imaging centers can learn how to work the system. They know what to say, and it's easier for them to gather the information that may be required in a second- or third-level review.[46]

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[43] MedSolutions, "2009 Utilization Management Program Description" (Mar. 23, 2009) (BCBSD Docs. 7-43).

[44] *Id.*

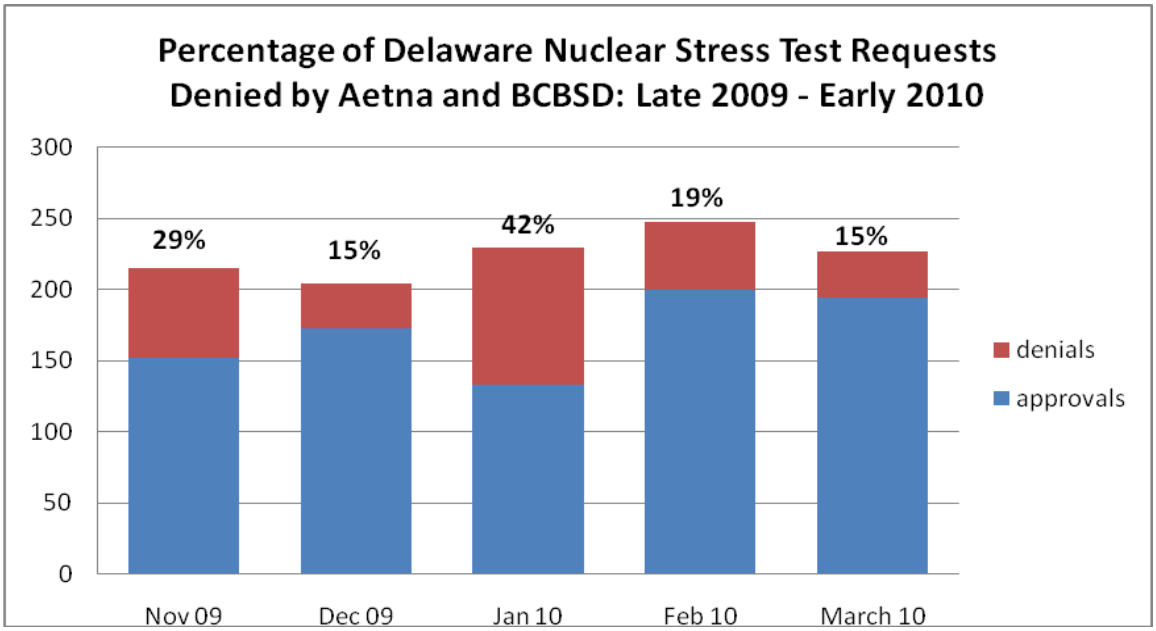
[45] Letter from Dr. Ralph Brindis, President, American College of Cardiology, to Chairman Rockefeller (May 11, 2010).

[46] *New Imaging Controls Strict, but May Be Easier on Doctors*, *supra* note 31.

The significant number of "administrative" denials by MedSolutions makes it clear that many Delaware doctors either did not understand or found it difficult to follow the company's pre-authorization procedures. About 20% of the approximately 350 Delaware final denials reviewed by Committee staff were not based on a determination of medical necessity, but on doctors' failure to comply with one or more of MedSolutions' administrative requirements. For example, MedSolutions denied more than 30 tests because doctors performed the stress tests before receiving MedSolutions' approval, and it denied more than 20 tests because the doctors had not seen their patients in the past 30 days.[47]

### *B. MedSolutions' Guidelines for Reviewing Doctors' Test Requests*

According to information Aetna and BCBSD provided to the Committee, MedSolutions finally denied approximately 22% of all the requests that Delaware health care providers made for cardiac nuclear stress tests to the two health insurers, although denial rates significantly varied from month to month. In December 2009, for example, MedSolutions denied only 31 of the 204 requests by Delaware doctors for nuclear stress tests (15%), while the next month, January 2010, MedSolutions denied 97 of the 230 requests (42%).[48] One of the 97 tests denied in January 2010, was the test requested by Michael Fields and his doctor.




According to MedSolutions and its insurance company partners, MedSolutions evaluated each of these requests in accordance with the company's published "Cardiac Imaging

[47] See Appendix I to this report for a detailed analysis of denied test requests.

[48] For the purposes of this analysis and the data presented in Appendix I, "denials" means denials that were not reversed during a later review or appeal.

Guidelines."[49] These "evidence-based, clinical guidelines" set detailed standards for determining when it is appropriate for doctors to use different advanced imaging modalities for testing patients. According to MedSolutions, their guidelines are "in keeping with best medical practice as supported by clinical literature."[50] In addition, the guidelines "undergo formal review and revision once a year to ensure we have the best and most up-to-date science informing our decision-making process."[51]

The company's chief medical officer told Committee staff, however, that MedSolutions' guidelines are not subject to an impartial, outside "peer review" process that would be required for publication in a professional journal.[52] And while the guidelines cite professional publications and claim to be "evidence-based," they do not include any formal analysis of the reliability or quality of the evidence cited to support the guidelines.[53] In contrast, the American College of Cardiology's (ACC) clinical guidelines explicitly grade the strength of the evidence it uses to make its clinical recommendations.[54] In addition, all experts involved in the development of ACC guidelines disclose their research or business affiliations that might create conflicts of interest.[55] MedSolutions' failure to adequately document its methodology leaves it vulnerable to criticisms from the clinical community that the purpose of MedSolutions' guidelines is to deny test requests, rather than reflect the strongest available scientific evidence.

MedSolutions' Cardiac Imaging Guidelines repeatedly reference the ACC's published appropriate use criteria and broadly agree with the ACC's recommendations about when it is <u>not</u> appropriate to perform an advanced imaging stress test on a patient. For example, both the ACC and MedSolutions agree that it is not appropriate to perform an echo or nuclear stress test on a patient experiencing chest pain, but who has a low pre-test probability of coronary artery disease, who can exercise on a treadmill, and whose electrocardiogram results are interpretable. In this situation, both agree that a simple exercise stress test is the appropriate test. They also agree that

[49] This methodology was not always clearly communicated to Delaware consumers. In one telephone call reviewed by Committee staff, a MedSolutions representative told an Aetna-covered Delaware consumer that MedSolutions approved or denied test requests "based on criteria set forth by Aetna." The MedSolutions representative told the consumer, "We pre-authorize it based on the criteria set forth by Aetna. Aetna tells us what to approve the test based on." (MSI Case # 12032113).

[50] MedSolutions, "2009 Utilization Management Description", *supra* note 43 (BCBSD Doc. 29).

[51] Letter from Dr. Greg P. Allen, Chief Medical Officer, MedSolutions, and Ross G. Hoffman, Medical Director, Cardiovascular Services, MedSolution to Chairman Rockefeller (Aug. 30, 2010).

[52] Commerce Committee Staff Interview with Dr. Greg P. Allen and Dr. Ross G. Hoffman (Oct. 21, 2010)

[53] On the reliability of evidence, *see, e.g.*, David Evans, *Hierarchy of Evidence: a Framework for Ranking Evidence Evaluating Healthcare Interventions*, Journal of Clinical Nursing vol. 12 (2003), 77-84. (online at http://cys.bvsalud.org/lildbi/docsonline/5/9/195-52.pdf).

[54] *See, e.g.*, Pierluigi Tricoci, et al., *Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines*, Journal of the American Medical Association, vol. 301, 831-41 (2009) (online at http://jama.ama-assn.org/content/301/8/831.full.pdf+html).

[55] *See, e.g.*, Todd B. Mendelson et al., *Conflicts of Interest in Cardiovascular Clinical Practice Guidelines*, Archives of Internal Medicine, vol. 171 (No. 6) (Mar. 28, 2011).

the tests are inappropriate for patients who have already been definitively diagnosed with acute coronary disease.[56]

But MedSolutions disagrees with the ACC's appropriateness guidelines in several key areas.[57] For example, while the ACC takes the position that the echo stress test or the nuclear stress test are appropriate for patients whose symptoms meet the criteria for an advanced imaging test, MedSolutions states that the echo stress test "is the initial imaging modality when stress testing with imaging is indicated."[58] MedSolutions bases this conclusion on its finding that the echo stress test is as effective and accurate as the nuclear stress test in many cases, is less expensive, and does not expose patients to potentially harmful ionizing radiation.[59] As Appendix I to this report demonstrates, about 10% of the approximately 350 finally denied Delaware requests for nuclear stress tests reviewed by Committee staff were denied with the explanation, "stress echo sufficient."

In interviews with Committee staff and in correspondence with the Committee, the ACC strongly disagreed with MedSolutions' position that echo stress tests should be the "initial imaging modality." According to the ACC, MedSolutions' prioritizing of echo stress tests is not based on strong medical evidence. Doctors should be able to choose between the two tests based on a number of factors, including the patient's body type and symptoms, the doctor's training, and the availability of skilled technical staff able to perform the tests. When it developed its appropriateness criteria for echo and nuclear stress tests, the ACC did not determine that one imaging modality was "more appropriate" than the other.[60] Instead, the ACC guidelines "indicate no preference for one technology over another and leave the ultimate decision to the treating physician on the basis of numerous clinical factors as mentioned."[61]

### *C. Disagreement Over When Advanced Imaging Tests are Appropriate*

By far the largest area of disagreement between the Delaware doctors treating patients for heart disease and MedSolutions' guidelines related to deciding when a patient required an advanced imaging test or a less expensive, but also less accurate, exercise stress test. As Appendix I shows, more than half of the approximately 350 final MedSolutions denials reviewed by Commerce Committee staff were based on the company's "stress treadmill sufficient" determination. As support for this finding, MedSolutions refers doctors and patients to section

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[56] MedSolutions, Inc., 2010 Cardiac Imaging Guidelines (containing all updates prior to Dec. 18, 2009), at 22.

[57] According to MedSolutions, "Cardiac imaging appropriateness criteria published by professional specialty organizations are not precisely concordant with these guidelines, as there is a large area of 'uncertain' benefit for many imaging modalities in the specialty society criteria." *Id.* at 8

[58] *Id.* at 47.

[59] *Id.*

[60] May 11, 2011 Letter from Dr. Ralph Brindis, *supra* note 45.

[61] Letter from Alfred A. Bove, MD, President, American College of Cardiology, to Gregg Allen, MD, Chief Medical Officer, MedSolutions (Feb. 19, 2010).

CD-1.3 of its Cardiac Imaging Guidelines. This section references a number of studies to support its guideline that the standard exercise treadmill test (ETT) should be the "initial stress test" in cases where the patient is capable of exercising on a treadmill and has an interpretable electrocardiogram.[62]

The ACC agrees that the echo and nuclear stress tests are not appropriate for patients who are experiencing symptoms of coronary artery disease (CAD), but who have a low pre-test probability of the disease and can perform the treadmill stress test. But the ACC strongly disagrees with MedSolutions' policy that patients showing intermediate or high pre-test probabilities of CAD should perform exercise stress tests before they receive the more accurate and costly echo or nuclear stress tests. Pre-test probabilities for CAD are established by considering a number of factors, such as the patient's age, blood pressure, cholesterol level, and whether the patient smokes or has diabetes.[63] Cardiologists interviewed by Committee staff explained that patients with higher risk profiles should have the test with the lowest probability of a "false negative" result.

### *D. The MedSolutions Guidelines in Practice: the Case of Michael Fields*

Michael Fields, the Delaware patient highlighted in the Wilmington News Journal articles, landed right in the middle of this disagreement between MedSolutions and the American College of Cardiology (ACC). As detailed below, the confusion and delays created by the pre-authorization process established by BlueCross BlueShield of Delaware (BCBSD) and MedSolutions prevented Mr. Fields from receiving potentially life-saving medical care for more than a month.

When he visited his primary care doctor, Dr. Bruce Turner, on January 4, 2010, complaining of chest pain, Mr. Fields displayed several of the symptoms that indicated a high pre-test probability of coronary artery disease (CAD), including diabetes, high blood pressure, and smoking. In his March 5, 2010, complaint letter to the Delaware Insurance Commissioner, Dr. Andrew Doorey, a cardiologist who later treated Mr. Fields, cited these factors and the ACC appropriate use criteria to explain that Mr. Fields was the "poster boy" for a nuclear stress test. Dr. Doorey wrote:

> If one looks at the guidelines for appropriateness of radionuclide scans, published in 2009 by the American Heart Association and the American College of Cardiology Foundation, among others, one can see that this man clearly falls within the "appropriate" group.[64]

Dr. Turner recommended a nuclear stress test for Mr. Fields and made an appointment for Mr. Fields to receive the test three days later, on January 7, 2010, at an outpatient center operated by Cardiology Consultants, one of Delaware's largest cardiology practices. The day before the scheduled test, an employee from Dr. Turner's office contacted MedSolutions to get pre-authorization for the test. MedSolutions quickly denied Dr. Turner's request for a nuclear stress

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[62] MedSolutions, Inc., 2010 Cardiac Imaging Guidelines**,** *supra* note 56, at 9.

[63] *See, e.g., 2008 Appropriateness Guidelines for Stress Echocardiography*, *supra* note 21, at 1140.

[64] Doorey March 5 letter, *supra* note 1.

test because Mr. Fields was capable of walking on a treadmill and had not yet received a treadmill stress test. In a denial letter dated January 6, 2010, MedSolutions provided Mr. Fields the following explanation:

> According to MedSolutions Cardiac Imaging Guidelines, nuclear cardiac imaging might be appropriate when an ECG is uninterpretable for ischemia testing or a patient is unable to perform treadmill exercise. The information you submitted does not meet these criteria. **As a result, please be advised that your request has been denied.**[65]

According to Mr. Fields, he did not learn of this denial until Dr. Turner's office called him the next day, January 7, 2010, while he was in his car driving to the testing center for his appointment. According to audio files produced to the Committee by BCBSD, Mr. Fields quickly called BCBSD and asked a BCBSD consumer representative named David why "you guys denied my request." David then asked Mr. Fields if he had spoken with Dr. Turner's office. Mr. Fields responded:

> **Fields:** Well, she just called me. I'm supposed to have the test at 12 o'clock today, and she, the nurse just called me from the office and said that they, that you guys had denied it.
>
> **David:** Well no, we're not the ones who did that. It's a company called MedSolutions. The doctor should be calling MedSolutions as to the reason why.
>
> **Fields:** Well who's MedSolutions? They're not affiliated with BlueCross BlueShield?
>
> **David:** They're the company that would do all of the precertifications for imaging services, yes. But the doctor's the one who should be contacting MSI [MedSolutions].[66]

***Botched Appeals Process*** Shortly after this conversation, Dr. Turner's office faxed an appeal letter and additional documentation to MedSolutions. Dr. Turner's letter explained that he thought the test was necessary because, "patient has a family history of heart disease and presented to the office on 1-4-2010 complaining of shortness of breath, chf [congestive heart failure], and angina."[67] A week later, on January 14, 2010, MedSolutions upheld the original denial of the test. In a letter dated January 15, 2010, MedSolutions informed Mr. Fields that a MedSolutions physician, Dr. John Schottland, had considered the appeal, including the

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[65] Letter from Gregg Allen, MD, Chief Medical Officer, MedSolutions, Inc., to Michael E. Fields (Jan. 6, 2010).

[66] MSI Case # 11634260. In another case reviewed by the Committee, in January 2010, a BCBSD employee seemed to be unaware that BCBSD had a pre-authorization program for nuclear stress tests. The BCBSD representative told the patient she did not believe the test needed prior authorization and didn't understand why the patient's request had been denied. The BCBSD employee called the patient back the next day to tell her MedSolutions had denied the request. (MSI Case # 11688098).

[67] Appeal Letter from Bruce Turner, M.D., to MedSolutions, Inc. (Jan. 7, 2010) (BCBSD Doc. 132).

additional evidence provided by Dr. Turner, and had upheld the denial. This letter also included information on how Mr. Fields could appeal this decision to BCBSD.[68]

Four days later, on January 19, 2010, Dr. Turner sent another letter to MedSolutions requesting a second review of the denial.[69] Attached to this letter were five more pages documenting Mr. Fields' condition. According to the appeals protocols established by BCBSD and MedSolutions, Mr. Fields and Dr. Turner should have made this second appeal to BCBSD. Compounding this confusion, MedSolutions failed to notify Dr. Turner he had incorrectly filed the appeal.[70] Consequently, for the next week, Dr. Turner and Mr. Fields believed MedSolutions was considering the appeal, while MedSolutions considered the test request "closed." According to a later review of the matter conducted by BCBSD, MedSolutions was not aware of Dr. Turner's request because it filed Dr. Turner's fax in an incorrect electronic archive folder. Finally, on January 27, 2010, Dr. Turner's office called to check on the status of the appeal, and was told that there was no pending appeal.[71]

***Emergency Surgery*** During this time, Mr. Fields continued to experience the alarming symptoms of coronary artery disease that had prompted him to visit Dr. Turner's office in early January. On February 8, 2010, Mr. Fields experienced severe chest pain at work while he was climbing stairs, and called Dr. Turner's office. An employee from Dr. Turner's office again called MedSolutions requesting approval for the test. After MedSolutions told her its denial was final, the employee called BCBSD and asked for approval of the test. She told the BCBSD representative:

> I'm at a total loss. This guy needs a stress test or he's gonna drop dead…I mean, we've sent them everything they've asked for. He's had chest x-rays, CAT scans, his cholesterol is over 300, his HDL's a number 8. I mean, he's got hypertension, shortness of breath and now he has arm pain, and they won't approve it, and I need to get the stress test done on him.[72]

The BCBSD representative told Dr. Turner's employee (incorrectly, a later BCBSD investigation concluded) that Mr. Fields would have to make the appeal himself, so Mr. Fields called BCBSD and described his worsening condition.[73] Mr. Fields told Kathy, the BCBSD representative:

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[68] Letter from Gregg Allen, MD, Chief Medical Officer, MedSolutions, Inc. to Michael E. Fields (Jan. 15, 2010). According to information reviewed by Committee staff, Dr. Schottland is a neurologist.

[69] Appeal letter from Bruce Turner, M.D. to MedSolutions, Inc. (Jan. 19, 2010) (BCBSD Doc. 177).

[70] Undated BlueCross BlueShield of Delaware Memo to Delaware Department of Insurance, titled, "Memo Request # 10, Complaint Response" (BCBSD Docs. 108-115).

[71] *Id.*

[72] MSI Case # 11634260.

[73] According to a later analysis by BCBSD, given the urgency of the situation, the customer service representative should have directed Dr. Turner to the company's medical director. Undated BlueCross BlueShield of Delaware Memo to Delaware Department of Insurance, *supra* note 70 (BCBSD Doc. 114)

> I've been having a lot of problems… And over the weekend, I'm shoveling snow - six shovelfuls, I've got to take a break…My arm is getting numb on the right side now. I can barely do my job. And they keep denying this stress test and we don't know if it's my heart or what it is.

A few minutes later into the call, Mr. Fields stated:

> I've got to tell you, Kathy, I can't keep living like this. This has been going on for weeks while we appeal this and I feel myself getting weaker. I can't shovel three shovelfuls, I … or … six shovelfuls of snow, and I've got, my chest feels tight and now I'm getting, like I said, numbing down the arm and, you know, lightheadedness and I don't know what else to do. You know, I'm trapped here.[74]

While the BCBSD representative was sympathetic to Mr. Fields' problems, she told him all she could do was send him an appeal form he could fill out and send to MedSolutions.

Shortly after this call, Mr. Fields went to the emergency room at Christiana Hospital in Newark, Delaware and was admitted. The next day, February 9, 2010, Dr. Andrew Doorey conducted a catheterization procedure on Mr. Fields and found that Mr. Fields was suffering from "the highest risk of all coronary stenoses," coronary artery disease with a very tight lesion in his left main coronary.[75] Mr. Fields received a coronary bypass procedure the next day. In the complaint letter he sent to the Delaware Insurance Commissioner on March 5, 2010, Dr. Doorey recounted that when he treated Mr. Fields on February 9, "the patient was visibly shaking." Dr. Doorey further explained:

> I tried to reassure him that he was relatively young and would be a good candidate for surgery, only to find out that this was not the primary issue. He was shaking because he realized how close to death he had come due to the repeated refusal of Blue Cross and MedSolutions to allow him to have a stress test. I spoke with Dr. Bruce Turner, his internist, who had repeatedly – and appropriately – ordered this stress test. In fact, he had gone through the Appeals process at least once and was summarily rebuffed by MedSolutions.[76]

Several weeks later, Mr. Fields told the News Journal he was "still in shock" over the episode and that he wanted to send BCBSD a picture of his 9-year old son to show the insurer "who would have been without a father when you killed me."[77]

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[74] MSI Case # 11634260.

[75] Doorey March 5 letter, *supra* note 1.

[76] *Id.*

[77] *Health Insurer's Denial of Test Almost Fatal for Delaware Man. After Insurance Rejections, Man Undergoes Heart Surgery*, The News Journal (Wilmington, DE) (Mar. 21, 2010).

## V. Evidence that Cardiologists Do Not Follow Their Appropriate Use Criteria

While the case of Mr. Fields clearly shows that BCBSD and MedSolutions sometimes denied medically necessary stress tests to patients, there is also ample evidence showing that cardiologists and other doctors order advanced imaging stress tests in clinical situations that are not supported by their professional guidelines.

For example, a multi-center study conducted jointly in 2008-09 by the American College of Cardiology (ACC) and UnitedHealth (UNH), one of the country's largest health insurers, found that 14% of the almost 6,000 nuclear stress tests doctors ordered during the study were inappropriate, according the ACC's appropriate use criteria for nuclear stress tests.[78] More than half of these inappropriate tests (60.6%) involved ordering tests for patients who exhibited a low pre-test probability of coronary artery disease.[79] The study found that inappropriate tests were ordered more frequently for women patients than for men.[80]

One of the most discouraging observations in the ACC/UNH study was that most of the medical practices that participated in the study failed to change their practice patterns after investigators informed them that they were ordering significant numbers of inappropriate tests. Only one of the six medical practices involved in the study initiated an educational initiative to lower the amount of inappropriate testing; according to the study, this effort significantly reduced the number of inappropriate tests ordered by the doctors in the practice.[81] Representatives from the ACC acknowledged to Committee staff that the association is working to find ways to increase doctors' compliance with the ACC's appropriate use criteria.[82]

Another area where some cardiologists appear not to be adhering to their appropriate use criteria involves the practice of routinely ordering "surveillance" or "follow up" nuclear stress tests for patients who have recently received the stress test, catheterization, or coronary bypass (CABG) procedures. The ACC discourages "routine repeat testing" of patients who are not exhibiting new symptoms of heart disease ("asymptomatic" patients), because the clinical benefits of the test are outweighed by its additional cost and the additional exposure of the patients to radiation. For example, under the ACC appropriate use criteria, it is inappropriate to order a nuclear stress test for two years after a catheterization procedure if the patient is asymptomatic,[83] and it is inappropriate to order nuclear stress tests for asymptomatic patients

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[78] Robert C. Hendel, et al., *A Multicenter Assessment of the Use of Single-Photon Emission Computed Tomography Myocardial Perfusion Imaging with Appropriateness Criteria*, Journal of the American College of Cardiology, vol. 55, 156-162 (Dec. 2009) (online at http://content.onlinejacc.org/cgi/content/full/55/2/156).

[79] *Id.* at 160.

[80] *Id.* at 159.

[81] *Id.* at 160.

[82] Commerce Committee Staff Telephone Interview with Dr. Robert C. Hendel and Joseph Allen, American College of Cardiology Appropriate Use Task Force (Oct. 6, 2010).

[83] *2009 Appropriateness Use Criteria for Cardiac Radionuclide Imaging*, *supra* note 22, at 2210 (Table 6, Indication # 59), and at 2220 (Figure 6).

more frequently than every two years.[84] According to the ACC/UNH study, however, more than 25% of the inappropriate tests ordered by doctors involved ordering stress tests at intervals shorter than those recommended in the ACC appropriate use criteria.[85]

An outside expert hired by the Delaware Insurance Commissioner to analyze MedSolutions' denials of nuclear stress tests in Delaware found similar rates of non-adherence to the ACC use criteria. Dr. Mark Tecce, a cardiologist and assistant professor at the Thomas Jefferson University Hospital in Philadelphia, Pennsylvania, reviewed the nuclear stress test requests that MedSolutions denied in late 2009 and 2010 on behalf of BlueCross BlueShield of Delaware. Applying the ACC's 2009 appropriate use criteria for nuclear stress tests to the clinical information he had available for 271 denial cases, Dr. Tecce concluded that MedSolutions had correctly denied 149 (55%) of the test requests in this group.[86] This rate of proper denials is roughly equivalent to a rate of 13-14% of the larger group of all test requests.[87] Like the cardiologists reviewed in the ACC/UNH study, more than one out of every ten nuclear tests that Delaware doctors ordered was inappropriate under the ACC criteria.

Although Dr. Tecce's analysis did not provide information explaining why the test requests were clinically inappropriate, the large number of test requests MedSolutions denied with the "stress treadmill sufficient" explanation suggest that many doctors were ordering tests for patients with a low pre-test probability of coronary artery disease.[88] There is also evidence that some Delaware doctors were inappropriately using nuclear stress tests for "routine repeat testing." MedSolutions denied about 20 nuclear stress test requests with explanations suggesting that the doctors were ordering the test at too frequent intervals.[89] For example, one case reviewed by Committee staff showed that a 46 year-old patient had been receiving a nuclear stress test every year since he underwent the CABG procedure at age 38, even though he was asymptomatic.[90]

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[84] *Id.* at 2208 (Table 3, Indication # 27) and at 2218 (Figure 4).

[85] Hendel, *A Multicenter Assessment of the Use of Single-Photon Emission Computed Tomography Myocardial Perfusion Imaging with Appropriateness Criteria*, *supra* note 78, at 160.

[86] *Market Conduct Report on BCBSD, Inc.* (NAIC # 53287), *supra* note 42. The remaining 122 cases were denied for administrative reasons, including insufficient clinical information (85), reversed on appeal (21), or incorrectly denied based on clinical information (16).

[87] This rate is an estimate based on the assumption that MedSolutions denied approximately 25% of all test requests. For this part of his analysis, Dr. Tecce treated 296 request denials as 271 case denials, since there were multiple requests for individual patients. This change in methodology makes it impossible to directly calculate proper denials as a percentage of total requests. It also appears that Dr. Tecce's 271 cases did not include 30 overturned appeals that were part of the original group of 326 denials.

[88] Appendix I.

[89] *Id.* ("Assymptomatic [sic] Patient or Patient with Stable Symptoms - 2 Year Interval" and "Post PCI - No imaging indicated").

[90] MedSolutions Case # 1203213.

## Conclusion

The pre-authorization process that MedSolutions operated for Delaware insurers initially denied about 25% of doctors' requests for nuclear stress tests. Based on the doctors' own clinical standards, many of these denials were appropriate. According to evidence reviewed in this investigation, 10-15% of nuclear stress tests ordered by doctors in Delaware and elsewhere do not meet their own professional standards for appropriateness. Denying these tests prevented unnecessary health care costs and unnecessary patient exposure to radiation.

But another 10-15% of test requests appear to have been denied inappropriately. MedSolutions and the Delaware insurers denied a significant number of medically necessary nuclear stress tests. Some of these denials were based on the requesting doctors' failure to follow MedSolutions' complicated administrative procedures, while others were based on MedSolutions' use of guidelines that differed in small, but crucial ways from the American College of Cardiology's appropriate use criteria. Many doctors and patients with sufficient time, resources and knowledge of MedSolutions' pre-authorization process were able to challenge and reverse these denials; but others, like Michael Fields and his doctor, were not. As a result of these denials, Mr. Fields and other patients did not get the timely, appropriate care they should have received – care they paid for through their health insurance premium payments.

While this investigation has focused on Delaware patients seeking care for coronary artery disease, the obstacles they faced getting appropriate medical care are common throughout the United States' health care system. In spite of the fact that American consumers and their employers are paying rapidly rising premiums and out-of-pocket costs for health insurance coverage, they receive health care in a system that is often driven more by incentives to increase the volume of medical care than by incentives to improve health outcomes; it is also a system in which health insurance companies measure their success by the amount they reduce health care utilization, without giving much thought to whether that utilization is necessary to keep their policyholders healthy.

A predictable result of this conflicted health care delivery system is that patients like Michael Fields and countless others do not reliably receive medically necessary services in a timely way, or they receive unnecessary - or sometimes even harmful - services. The evidence reviewed in this investigation provides just one illustration of the challenges of creating a health care system in which "all patients receive the right care, at the right time, in the right setting, every time."[91]

[91] Department of Health and Human Services, *National Strategy for Quality Improvement in Health Care, Report to Congress: March 2011* (online at http://www.healthcare.gov/center/reports/quality03212011a.html).

**APPENDIX I**

**MedSolutions' Reasons for Denials of Nuclear Stress Tests in Delaware (approximately 350 final denials)**