MARKET CONDUCT EXAMINATION REPORT

ON

BCBSD, INC.

NAIC#53287

800 Delaware Avenue
Wilmington, DE 19801-1368

As of

April 6, 2010

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January 5, 2011

Honorable Karen Weldin Stewart CIR-ML
Insurance Commissioner
State of Delaware
841 Silver Lake Boulevard
Dover, Delaware 19904

Dear Commissioner Stewart:

In compliance with the instructions contained in Certificate of Examination Authority Number 10.704, and pursuant to statutory provisions including 18 Del. C. §§318-322, a target market conduct examination was conducted on the nuclear medicine cardiac stress imaging testing (nuclear cardiac imaging testing) pre-authorization process of:

BCBSD, Inc.

The review was conducted to ensure BCBSD, Inc.'s nuclear cardiac imaging testing pre-authorization program is following the appropriate medical protocols in determining medical necessity and to ensure compliance with BCBSD, Inc.'s "Individual Review Plan" (IRP) as filed with the Delaware Department of Insurance (Department) and required by 18 Del. C. §332.

The examination of BCBSD, Inc.; hereafter referred to as "BCBSD" or "Company," was conducted at the Company's office located in Wilmington, Delaware. Subsequent review and follow-up was conducted at the offices of the Department or other suitable locations.

The report of review herein is respectfully submitted.

EXECUTIVE SUMMARY

A target market conduct examination was conducted on BCBSD, Inc. and covered the experience period of March 29, 2007, through April 6, 2010.

The examination was called to address the concerns and public issues surrounding BCBSD's business practices related to the pre-authorization for nuclear cardiac imaging tests. In order to address those concerns and issues on a statewide level, examinations were called on several carriers utilizing the services of MedSolutions, Inc. (MedSolutions or MSI) for their nuclear medicine cardiac diagnostic imaging pre-authorization program.

The purpose of the examination was to ensure BCBSD's nuclear cardiac imaging testing pre-authorization program is following the appropriate medical protocols in determining medical necessity and to ensure compliance with BCBSD's "Individual Review Plan" (IRP) as filed with the Delaware Department of Insurance and required by 18 Del. C. §332.

The examination generally focused on the Company's pre-authorization practices and procedures related to nuclear cardiac imaging tests. The specific areas for the review included: Vendor Contracts, Credentialing, Company Oversight, Policy and Procedures, Forms, Complaints, Pre-Authorization Requests and Claims.

The pre-authorization for diagnostic testing was initiated by BCBSD, Inc. on July 1, 2009. Prior to July 1, 2009, the Company did not require pre-authorization for diagnostic tests. Provisions for the pre-authorization program requirements for nuclear cardiac imaging testing were contained in the Group Contract, as well as in the Certificates of Coverage benefit booklet provided to enrollees. The group contracts and certificates of coverage were filed with the Department as required. Several points to define the parameters of the pre-authorization process include the following:

1. Pre-Authorization for diagnostic tests is not required for In-Hospital Stays or Emergency Room care.
2. Pre-Authorization is not required for low tech cardiac tests such as: Electrocardiograms (ECGs, EKGs) and Echocardiograms performed while exercising (treadmill stress tests).
3. Policy Contracts and benefit booklets indicate:

    a. The provider cannot balance bill the insured if the pre-authorization process was not followed.
    b. If a pre-authorization is denied, the only time the insured can be balanced billed is if they are aware of the pre-authorization denial, but decide to have the tests anyway.

Sampling of selected files based on certain criteria was utilized to identify and verify any issues that may have occurred as a result of the nuclear cardiac imaging testing pre-authorization program. The review of the pre-authorization case files was conducted in two phases. The first phase of the examination was conducted by the Department's Market Conduct Examiners to ensure contractual obligations are met; Company policy and procedures are applied in a

consistent and timely manner and the Company's IRP, as filed with the Delaware Department of Insurance and required by 18 Del. C. §332, is being followed. The second phase of the examination was performed by clinical personnel to ensure BCBSD's diagnostic testing pre-authorization program is following the appropriate medical protocols in determining medical necessity.

Issues and concerns noted during the course of the examination are summarized as follows:

MedSolutions, Inc. Contract

- The contract with MSI contains terms under which contingent fees are based on savings under the contract. These terms are not in compliance with 18 Del. Admin. Code 1406 §9.1 Compensation to the Administrator which states that *"An administrator shall not enter into an agreement or understanding with an insurer in which the effect is to make the amount of the administrator's commissions, fees, or charges contingent upon savings effected in the adjustment, settlement and payment of losses covered by the insurer's obligations*." The noncomplying terms require MSI to refund 10% of their administrative fee, if overall annual costs savings to the Company as compared to costs associated with the Company's previously unmanaged radiology benefits services is not 20% or more.

  During the course of this examination, the Company removed the cited "contingent savings" provision from the contract by an amendment dated June 3, 2010 and indicated that the "contingent savings" provision was never implemented since it was rescinded within the first year of the contract before any annual cost savings could be calculated.

  It is acknowledged that the Company has corrected the agreement in order to comply with 18 Del. Admin. Code 1406 §9.1 Compensation to the Administrator by deleting the "contingent saving" terms on June 3, 2010. However, it should be noted that until June 3, 2010 MSI performed its services under contract terms that made "*the amount of the administrator's commissions, fees, or charges contingent upon savings effected in the adjustment, settlement and payment of losses covered by the insurer's obligations*." As a result, the Company was not operating in compliance with the Delaware Insurance Code during this time period.

Complaint Handling

The Company initially identified six complaints from MSI. The complaints were reviewed and reconciled with the Department's list of complaints. After review and reconciliation of all complaints, the Company's listing exhibited some discrepancies and the Company was requested to account for the differences. The Company then provided a revised list and the number of MSI complaints was increased to 27. Of the 27 complaints related to MSI, two complaints were related to the same member and issue and one complaint involved an ERISA planholder. The discrepancies in the complaint listings resulted in the following Department Concern:

The Company's complaint handling procedures with regard to the coordination of complaint handling with its vendor, MSI, should be revised to ensure proper maintenance and timely monitoring of complaint activity.

Pre-Authorization Nuclear Cardiac Imaging Testing Policy & Procedures

- The clinical review of the MSI Policy & Procedures in determining the medical necessity of the requested pre-authorization for nuclear cardiac imaging testing was performed by Marc Tecce, M.D., F.A.C.C., Clinical Assistant Professor of Medicine at Thomas Jefferson University School of Medicine. Dr. Tecce concluded as follows:
  "the MSI Guidelines for cardiac stress tests are based on accepted literature and science and appear to be reasonable and in agreement with those proposed by the American College of Cardiology Task Force in many but not all areas. There are, however, important differences that exist primarily in ordering the first test in intermediate and high risk patients as compared to the ACC/AHA Guidelines. First, the MSI guidelines that require treadmill stress testing without imaging to always be performed, if possible, prior to stress testing with imaging are not appropriate for intermediate and high risk patients. In these patients stress testing with imaging is frequently the appropriate first test. Second, the MSI guidelines that require echo imaging to always be performed prior to nuclear imaging are not appropriate for intermediate and high risk patients. In these patients nuclear imaging is frequently the appropriate first test. In intermediate and high risk patients the clinical evaluation which is performed by the patient's physician or cardiologist is critical in determining which initial test is appropriate. The MSI guidelines dispense with critical physician judgment in these situations at the expense of appropriate patient care."

Pre-Authorization Nuclear Cardiac Imaging Test Denials

- A number of denied cases reviewed did not indicate an MSI Cardiologist was consulted in the initial denial determination or the subsequent appeal determination. 18 Del. C. §332(6) provides for the health carrier to assign licensed, certified, or registered health care personnel with expertise in the field implicated by the request for review to conduct the review.

- Applying the American College of Cardiology Foundation (ACCF) criteria to the 271 denied pre-authorization requests resulted in a determination that a nuclear stress test was appropriate in 16 requests (6%). In addition, 21 requests (7.7%) were initially denied and subsequently approved upon appeal. Utilizing ACCF criteria 17 of the 21 requests met ACCF criteria initially and a nuclear stress test should have been approved upon submission. In conclusion, the application of the ACCF criteria would have determined a nuclear stress test appropriate in 33 requests (16+17) or 12% of the initial 271 denied requests.

Claims

- Due to a claims processing error, the company had to re-adjudicate 254 claims denied for "No Authorization". Upon completion of the re-adjucation, 122 claims were determined to be inappropriately denied and were ultimately paid.

For each of the cited exceptions and concerns in the report, recommendations have been made to address the issues noted by the examiners. Accordingly, the results of operational improvements implemented by the Company, which occurred after the examination period (i.e., after April 30, 2010), are not reflected in the data contained in this Report.

INTRODUCTION

Market Conduct Examination Reports generally note only those items, to which the Department, after review, takes exception. An exception is any instance of Company activity that does not comply with an insurance statute or regulation. Exceptions contained in the Report may result in imposition of penalties. Generally, practices, procedures, or files that were reviewed by Department examiners during the course of an examination will not be referred to in the Report if no improprieties were noted. However, the Examination Report may include management recommendations addressing areas of concern noted by the Department for which no statutory exception was identified. This enables Company management to review these areas of concern in order to determine the potential impact upon Company operations or future compliance issues.

In performing this examination, the Delaware Department of Insurance selected specific areas of the Company's operations for review. This report only covers the areas of the Company's operations within the scope of this examination.

Throughout the course of the examination, Company officials were provided memo requests for additional information to clarify specific findings or apparent exceptions. Conferences were conducted with Company officials to discuss and review the various exceptions identified by the examiners throughout the course of the examination process.

The courtesy and cooperation extended by the Officers and Employees of the Company during the course of the examination is acknowledged.

SCOPE OF EXAMINATION

The Market Conduct Examination was conducted pursuant to the authority granted by 18 Del. C. §§318-322 and covered the experience period of March 29, 2007, through April 6, 2010, unless otherwise noted. The purpose of the examination was to ensure BCBSD's nuclear cardiac imaging testing pre-authorization program is following the appropriate medical protocols in

determining medical necessity and to ensure compliance with BCBSD's "Individual Review Plan" (IRP) as filed with the Delaware Department of Insurance and required by 18 Del. C. §332.

The examination focused on the Company's pre-authorization practices and procedures related to nuclear cardiac imaging testing. The Company was requested to identify the universe of files for each segment of the review. Based on the universe sizes identified, random sampling was utilized to select the files reviewed for this examination.

During the course of the examination, for control purposes, some of the review segments identified in this Report may have been broken down into various sub-categories by line of insurance or Company administration. These specific sub-categories, if not reflected individually in the Report, were included and grouped within the respective general categories of the Examination Report.

COMPANY HISTORY AND LICENSING

BCBSD, Inc. was originally incorporated in Wilmington, Delaware under the name of Group Hospital Service, Incorporated, by the filing of a Certificate of Incorporation with the Delaware Secretary of State on August 16, 1935. The Company's name changed several times since 1935. Although the Company's name was changed to BCBSD, Inc. in March 1996, the Company also does business as Blue Cross Blue Shield of Delaware, Inc. The Company has been operating as a private not-for-profit corporation and does not have the authority to issue capital stock.

Since 1968, when Delaware adopted Chapter 63 of the Delaware Code regulating Health Service Corporations, the Company has been regulated as such by the Delaware Insurance Department.

On March 22, 2000, BCBSD entered into a business affiliation with CareFirst, Inc. (CFI), the parent corporation of Blue Cross Blue Shield of Maryland and Blue Cross Blue Shield of the National Capital Area. On September 21, 2006, BCBSD and CFI terminated their business affiliation. BCBSD is no longer controlled by CFI and is an independent licensee of the BlueCross and BlueShield Association. During the examination period, BCBSD consolidated its operations from several locations in New Castle County to a single location on 800 Delaware Avenue in Wilmington, DE.

On their 2009 annual statement filed with the Department, the Company reported health premium earned for all lines of business as $482,122,236 and total member months of 1,383,509.

PRE-AUTHORIZATION NUCLEAR CARDIAC IMAGING TESTING PROGRAM CONTRACTS

A. Vendor Contract Agreements

The Company was requested to provide all vendor agreements and contracts between the Company and MedSolutions (MSI), regarding claim review services related to the approval of nuclear cardiac imaging testing determined to be medically necessary by a policyholder's physician. These agreements and contracts included:

- The parameters established by BCBSD regarding the approval or declination of such tests for which approval is required, and
- The credentialing requirements for those professionals who ultimately approve or deny such diagnostic tests.

The Company provided the MedSolutions agreement, the Utilization Management (UM) program descriptions for 2009 and 2010, the credentialing for the professionals involved in the decision making process for the nuclear cardiac imaging testing pre-authorization program and a summary of the pre-authorization program. .

> The contract with MedSolutions for pre-authorization of diagnostic testing was initiated by the Company on July 1, 2009. Prior to July 1, 2009, the Company did not require pre-authorization for diagnostic tests. The contract contained the usual sections of an agreement including: obligations of the parties, the term of the agreement, termination of agreement provisions, MSI program and utilization management details, reporting sections and the compensation and financial sections. Specifically, MSI is to provide radiology management services for the Company's managed health care programs for outpatient non-emergency procedures, including Nuclear Cardiology radiology health care services.

The parameters of the pre-authorization for diagnostic test process include the following:

1. Pre-Authorization for diagnostic tests is not required for In-Hospital Stays or Emergency Room care.
2. Pre-Authorization is not required for low tech cardiac tests such as: Electrocardiograms (ECGs, EKGs) and Echocardiograms performed while exercising (treadmill stress tests).
3. Policy Contracts and benefit booklets indicate:
    a. The provider cannot balance bill the insured if the pre-authorization process was not followed.
    b. If a pre-authorization is denied, the only time the insured can be balanced billed is if they are aware of the pre-authorization denial, but decide to have the tests anyway.

In the compensation section of the contract, the Company pays MedSolutions a fixed dollar administrative fee for each case reviewed for medical necessity. The administrative fee increases by a set percentage each subsequent year the contract remains in force. The contract contains performance guarantees in which MedSolutions' compensation is reduced by set percentage amounts if:

(1) The denial of preauthorization requests results in magnetic resonance (MR) and computed tomography (CT) tests being performed at a rate that falls below a specified threshold.
(2) The average monthly speed to answer customer and provider calls exceeds 40 seconds for three consecutive months.
(3) The rate at which customers and providers abandon calls exceeds a set rate.
(4) MSI fails to respond to at least 95% of pre-authorization requests within two business days for two consecutive months.

The Agreement also includes provisions under which the amount of fees paid to MSI are contingent on the overall annual cost savings to the Company as compared to costs associated with the Company's previously unmanaged radiology benefits services. The ”contingent savings” provision provides for MedSolutions to refund 10% of their administrative fee, if overall annual costs savings to the Company as compared to costs associated with the Company's previously unmanaged radiology benefits services is not 20% or more. If overall annual costs savings as compared to costs associated with the Company’s previously unmanaged radiology benefit services are less than 10%, the provision provides for MedSolutions to refund 100% of the administrative fee.

Vendor contracts with MedSolutions (MSI), including the parameters of their responsibility in the pre-authorization process, along with the credentials of the personnel involved in the decision making process of medical necessity determination were reviewed to ensure compliance with 18 Del. C. §332, Arbitration of disputes involving health insurance coverage and 18 Del. Admin. Code 1301, Internal Review, Arbitration and Independent Utilization Review of Health Insurance Claims.

As part of the review of the vendor contracts, the following exception was noted:

1 Exception - 18 Del. Admin. Code 1406 §*9.1*
An administrator shall not enter into an agreement or understanding with an insurer in which the effect is to make the amount of the administrator’s commissions, fees, or charges contingent upon savings effected in the adjustment, settlement and payment of losses covered by the insurer’s obligations.

The contract with MSI contains a provision under which contingent fees are based on savings under the contract. The ”contingent savings” provision listed in Exhibit 4, Performance Guarantees, Item 5(b) in the contract does not comply with 18 Del. Admin. Code 1406 §*9.1*. The provision provides for MSI to refund 10% of their administrative fee, if overall annual costs savings to the Company as compared to costs associated with the Company's previously

unmanaged radiology benefits services is not 20% or more. If overall annual costs savings as compared to costs associated with the Company's previously unmanaged radiology benefit services are less than 10%, the provision provides for MedSolutions to refund 100% of the administrative fee.

During the course of this examination, the Company removed the cited "contingent savings" provision from the contract by an amendment dated June 3, 2010 and indicated that the "contingent savings" provision was never implemented since it was rescinded within the first year of the contract before any annual cost savings could be calculated.

It is acknowledged that the Company has corrected the agreement in order to comply with 18 Del. Admin. Code 1406 §9.1 Compensation to the Administrator by deleting the "contingent saving" terms on June 3, 2010. However, it should be noted that until June 3, 2010 MSI performed its services under contract terms that made *"the amount of the administrator's commissions, fees, or charges contingent upon savings effected in the adjustment, settlement and payment of losses covered by the insurer's obligations*." As a result, the Company was not operating in compliance with the Delaware Insurance Code during this time period.

Recommendation: It is recommended that the Company revise their contract with MedSolutions to ensure compliance with requirements of 18 Del. Admin. Code 1406 §9.1 regarding contingent fees based on savings in the contract.

Subsequent event: The Company deleted the non-compliant provision by amendment to the contract, dated June 3, 2010. However during the period under review MSI performed its services under the contract terms, therefore the Company was not operating in compliance with the Delaware Insurance Code during the period under examination.

B. Company Oversight & Compliance Procedures

The Company was requested to provide a summary of the Company's oversight of MedSolutions (MSI) regarding compliance with established Company procedures. This request included all reports, records and documentation between the Company and MedSolutions used to monitor the vendor's compliance with the provisions and terms of the contracts with the Company. In addition, all audit reports conducted by the Company of MedSolutions, and any corrective action plans and progress reports, if applicable were requested.

The Company conducted a pre-evaluation study prior to their agreement with MedSolutions to evaluate MSI's capacity to meet applicable National Committee for Quality Assurance (NCQA) standards. This study along with a summary of their oversight activities of MedSolutions pre-authorization process was provided, including the applicable reports.

Assessment and quarterly reports for the following areas were received and reviewed:
Complaint Summary
Pre-Authorization Summary Reports
Appeal Log

Call Statistics
Turn Around Time
Top Referring Physicians and Facilities
NCQA Report
Customer and Provider Satisfaction Surveys
Financial Savings
Quality Report

An internal delegation oversight committee meets quarterly to review the various reports and ensure contractual and legal requirements, and standards of various accrediting bodies such as NCQA and American Accreditation Health Commission/Utilization Review Accreditation Commission (URAC) are followed.

No exceptions were noted.

PRE-AUTHORIZATION NUCLEAR CARDIAC IMAGING TESTING POLICY AND PROCEDURES

The Company was requested to provide all policy and procedures utilized by MedSolutions, specifically applicable to the approval or denial of nuclear cardiac imaging testing determined to be medically necessary by a policyholder's physician. The Company provided 19 sections of specific imaging guidelines described as clinical decision support tools for advanced diagnostic imaging. Additionally, the Company provided documents detailing established procedures and guidelines related to timeline requirements and the administration of various processes involved in the pre-authorization diagnostic imaging program.

The procedures and guidelines were reviewed in two phases. Phase 1 is the administrative review and phase 2 is the clinical review.

A. Phase 1 – Policy and Procedures Administrative Review

The first phase was conducted by Department market conduct examiners to ensure guidelines were in place and being followed in a uniform, consistent and timely manner and were not specifically prohibited by statute or regulation.

As provided by the provisions of 18 Del. C. §332, all health carriers must establish and maintain an Internal Review Process (IRP) approved by the Insurance Commissioner. An IRP is a procedure for an internal review of an adverse determination or denial of a service or claim. The timeline criteria for an IRP are summarized as follows:

- Written Notice of the internal review procedure. - must be given to covered persons annually and following any adverse determination or denial of a service or claim.
- Requests for review of adverse determinations - must be submitted orally or written within 30 days of receipt by the covered person of written notice of an adverse determination.

- Prompt response to written grievances. - The IRP shall provide that within 5 business days of receipt of a written grievance, the carrier shall provide written acknowledgement of the grievance.
- Speedy review of grievances. - The IRP shall require that all grievances be decided no more than (i) 72 hours after the receipt of all necessary information relating to an emergency review, (ii) 30 days after the receipt of all necessary information in the case concerning whether a requested benefit is covered pursuant to the contract, and (iii) 45 days after the receipt of all necessary information in all other instances.
- Written notice of decisions. - The IRP shall provide that within 5 days after a grievance is decided; the insured shall be provided with written notice of the disposition of that grievance.
- Manner of notice of decisions. - Written notice of the review decision shall be deposited in the mail within 48 hours after the receipt of all information necessary to complete the review.

MedSolution's Utilization Management guidelines detailed the timelines for decision making of pre-authorization requests for urgent and non-urgent pre-authorizations, in addition to timelines for appeals. The timelines are summarized as follows:

Pre-Authorization Medically Urgent Timelines:

- Pre-authorization of medically urgent decisions is made within 4 business hours based on information provided/available to render a decision
- Notifications are generated for the member and provider within 1 business day of the decision. Members receive written notification; providers may receive electronic notifications.

Pre-Authorization Non-Urgent Timelines:

- Pre-authorization of non-urgent decisions is made within 2 business days when all information is available to render a decision.
- Notifications are generated for the member and provider within 2 business days of the decision.

Appeal Decision Making Timelines:

- Expedited Appeal decisions are made within 72 hours of the receipt of the request.
- Pre-Service Appeal decisions are made within 5 business days of the receipt of the request.
- Post-Service Appeal decisions are made within 30 days of the receipt of the request

Appeal Approval Notification Timelines:

- Expedited Appeal - Verbal notification to provider expeditiously as possible, but not to exceed 72 hours of the receipt of the request. Written notification within one day of verbal notification.
- Pre-Service Appeal - Verbal notification to provider expeditiously as possible, but not to exceed 5 business days of the receipt of the request. Written notification within one day of verbal notification.
- Post Service Appeal - Verbal and written notification to provider expeditiously as possible, but not to exceed 30 days of the receipt of the request.

Appeal Denial Notification Timelines:

- Expedited Appeal - Verbal notification to provider expeditiously as possible, but not to exceed 24 hours of the receipt of the request. Written or electronic notification within one day of verbal notification.
- Pre Service Appeal - Verbal notification to provider expeditiously as possible, but not to exceed 5 business days of the receipt of the request. Written notification within 1 business day of verbal notification.
- Post Service Appeal - Verbal and written notification to provider expeditiously as possible, but not to exceed 30 days of the receipt of the request.

The benchmarks related to the timeline requirements established for various processes of the Nuclear Cardiac Imaging Testing Program met or exceeded the standards set by various accrediting bodies such as: American Accreditation Health Commission/Utilization Review Accreditation Commission (URAC), NCQA and 18 Del. C. §332.

No exceptions were noted in the first phase of the review.

B. Phase 2 – Policy and Procedures Clinical Review

The second phase of the review was conducted by Marc A. Tecce, M.D., F.A.C.C, Clinical Assistant Professor of Medicine, Thomas Jefferson University School of Medicine, Philadelphia, Pennsylvania. The clinical review of the MedSolutions Policy and Procedures involved two tasks. The first task was the review of MedSolutions Policy and Procedures in determining medical necessity and the appropriateness of the criteria utilized in making that determination. The second task was to review all denied files utilizing the medical criteria of the American College of Cardiology to determine whether a denial for the requested service would have resulted. The second task of the clinical review is addressed in the "Denied Nuclear Cardiac Imaging Tests" Section of the Report.

Dr. Tecce's comments and review are as follows:

> "The MedSolutions Cardiac Imaging Guidelines published in 2009 (MSI) was the subject of this review. The first step in the process of reviewing denials for certain cardiac imaging studies was to carefully review the criteria that MSI employs when considering requests for cardiac imaging studies. The first part of this review

concerns denials for nuclear medicine cardiac stress imaging studies. MSI has a contractual agreement with Blue Cross/Blue Shield of Delaware to review requests for imaging procedures (the concentration was on cardiac imaging) and either approve or deny such procedures. MSI's review of these cases (requests) is initially conducted by nurses and is guided by the imaging criteria/guidelines that MSI published most recently in 2009. The nurse either has the option of approving the requested study if they feel that the proposed test meets criteria and is appropriate or alternatively can send the request to a physician for further review if the nurse feels the study may be inappropriate. The physician then can either approve the study or issue a denial if it is not felt to meet their guidelines as stated.

To best understand this process and what is involved, a brief explanation of cardiac stress testing is helpful. Stress tests are used to aid in the diagnosis and treatment of cardiovascular disease, particularly in patients with coronary artery atherosclerosis (also known as hardening of the arteries or blockage in the coronary arteries). The coronary arteries supply blood to the heart muscle, and atherosclerosis is a complex process that results in plaque accumulation lining the walls of the coronary arteries leading to obstruction and decreased blood flow. Atherosclerosis kills more Americans each year than any other disease.

Stress testing is a tool utilized by physicians to help diagnose and treat patients with coronary artery disease. There are several ways in which stress tests can be performed and several different imaging modalities that can be utilized during these tests. The first question for the physician when considering a stress test is "Can the patient exercise or walk sufficiently on a treadmill?". The most basic form of stress test, also known as an EKG Treadmill Stress Test, combines exercise on the treadmill with continuous monitoring of the patient's twelve lead electrocardiogram. If patients have coronary heart disease (atherosclerosis) then their electrocardiogram may exhibit changes during exercise when the heart rate increases that are consistent with blockage of the coronary arteries. This type of EKG Treadmill Stress Test in its basic form does not incorporate any imaging of the heart. These studies evaluate the patient's electrocardiogram during exercise and recovery (the period of time immediately post exercise) as well as evaluating their heart rate and blood pressure response to exercise and their exercise capacity.

There is significant clinical information that can be obtained from these basic Treadmill EKG Stress Tests such as exercise tolerance, heart rate and blood pressure response to exercise, the presence or absence of arrhythmias during exercise, and whether or not the patient experiences exercise induced symptoms such as chest pain. The diagnostic accuracy of EKG Treadmill Stress Tests without any additional imaging of the heart for the detection of coronary artery disease has a sensitivity of 68% and a specificity of 77%. This means that 68% of patients with significant coronary artery disease will have an abnormal EKG response to exercise and that

77% of patients with a negative test will not have significant disease. [1] The diagnostic accuracy of stress testing when combined with nuclear imaging increases both the sensitivity and specificity for the detection and exclusion of coronary artery disease to approximately 80% to 85% which is a substantial difference.[2] [3]

Exercise Nuclear Stress Testing involves having the patient exercise on a treadmill (the traditional EKG Treadmill Test) and at peak exercise the patient is injected through a peripheral intravenous catheter with a nuclear imaging isotope that is then taken up by the heart muscle. The patients subsequently undergo imaging by cameras that are able to reconstruct images of the heart by acquiring the emitted energy from the injected isotope and using computer generated images of the heart muscle to assess myocardial blood flow. If there are areas of the heart that do not take up the tracer (isotope) equally to adjacent heart muscle then there is a high likelihood that the coronary arteries that supply these areas have significant narrowing due to atherosclerotic plaque accumulation.

Stress testing can also be done using ultrasound imaging of the heart in place of the nuclear imaging. These studies are referred to as stress echocardiograms and they also increase the diagnostic accuracy of stress testing over EKG treadmill similar to nuclear stress tests. Patients again exercise on a treadmill but instead of being injected with an isotope at peak exercise the patients' hearts are imaged with ultrasound. If the patient has significant coronary narrowing due to atherosclerosis, the heart exhibits an abnormal contraction pattern that is detected by ultrasound imaging during peak exercise at high heart rates. The advantages to stress echocardiography as opposed to nuclear imaging are that the study does not require placement of an intravenous catheter, is less time consuming, does not involve exposure to ionizing radiation, and is typically done at an overall lower cost.

As a modality, exercise nuclear stress testing has been considered the standard for stress imaging for the better part of the last three decades. Nuclear cardiology and the training of physicians in cardiovascular fellowship programs in this discipline has been an integral part of the core curriculum of these training programs for years, while stress echocardiography is a newer, more recently employed method of stress imaging. As a result of this, more cardiologists have been trained over the years in

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[1] Gianrossi R, Detrano R, Mulvihill D, et al. Exercise induced ST depression in the diagnosis of coronary artery disease. A meta-analysis. Circulation 80:87, 1989

[2] Ritchie SL, Bateman TM, Bonow RO, et al: Guidelines for clinical use of cardiac radionuclide imaging. Report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular procedures (Committee on Radionuclide Imaging), developed in collaboration with the American Society of Nuclear Cardiology. J AM Coll Cardiol 25:521 1995

[3] Mahmarian JJ: State of the art for CAD detection: Thallium-201. In Zaret BL, Beller GA (eds): Nuclear Cardiology: State of the Art and Future Directions, 2nd ed. St. Louis, Mosby, 1999, pp 237-272

the performance and interpretation of nuclear stress studies given its' longevity as an integral component of cardiovascular fellowship training. In addition, more clinical studies have been performed in this time period evaluating the accuracy, safety, and utility of nuclear studies as compared to stress echocardiography which have consistently demonstrated the proven effectiveness and clinical usefulness of nuclear stress imaging in evaluating and treating patients with cardiovascular disease. This wealth of clinical data has provided a sound scientific foundation upon which the guidelines concerning the appropriateness of nuclear stress testing as published the American College of Cardiology which has been previously referenced are based. Newer software has been developed within the last few years to eliminate some of the problems that have existed previously in interpreting nuclear stress studies which centered around other organs in the body interfering with the imaging process (termed attenuation correction) and the advances in computer generated imaging which have revolutionized modern medical imaging as a whole have improved image quality and taken it to new levels not seen previously.

If patients are unable to exercise on a treadmill, then stress testing can be performed by administering certain agents that can simulate some of the physiologic effects of exercise but in all of these cases imaging (either echocardiography or nuclear imaging) is required. Coronary blood flow and myocardial perfusion imaging to detect underlying coronary artery disease can also be assessed by cardiac MRI and cardiac PET Scanning, although, these modalities are also expensive and currently not as widely available or utilized to the extent of nuclear stress testing or stress echocardiography.

In 2009 the American College of Cardiology Foundation along with several other societies including the American Heart Association and the American College of Radiology published appropriate use criteria for cardiac radionuclide imaging (nuclear stress testing).[4] These guidelines had been published four years prior to this report but the revised guidelines of 2009 were amended or updated as clearly stated in the abstract portion of the document, "to reflect changes in test utilization and new clinical data, and to clarify when possible areas where some ambiguity or uncertainness existed in the prior published guidelines". This report (heretofore referred to as the ACCF Guidelines) was formulated by the American College of Cardiology Foundation Appropriate Use Task Force which consisted of a panel of physicians from various disciplines of medicine including cardiologists, radiologists, and emergency room physicians. As stated in the preface section of this report,

[4] Hendel RC, Berman DS, DiCarli MF, Heidenreich PA, Henkin RE, Pellikka PA, Pohost GM, Williams KA. ACCF/ASNC/ACR/AHA/ASE/SCCT/SCMR/SNM 2009 appropriate use criteria for cardiac radionuclide imaging: a report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, the American Society of Nuclear Cardilogy, the American College of Radiology, the American Heart Association, The American Society of Echocardiography, the Society of Cardiovascular Computed Tomography, the Society for Cardiovascular Magnetic Resonance, and the Society of Nuclear Medicine. J Am Coll Cardiol 2009;53:2201-29

"Appropriate use criteria publications reflect an ongoing effort by the ACCF (American College of Cardiology Foundation) to critically and systematically create, review and categorize clinical situations where diagnostic tests and procedures are utilized by physicians caring for patients with cardiovascular disease." This report also states that the Foundation believes that "A careful blending of a broad range of clinical experiences and available evidence based information will help guide a more efficient and equitable allocation of health care resources in cardiovascular imaging."

The MSI Guidelines for cardiac imaging published in 2009 as well as a report authored by Greg Allen, M.D., Chief Medical Officer of MSI dated May 19, 2010, were reviewed. In his report, Dr. Allen addresses some of the differences that exist between the MSI guidelines and the ACCF guidelines. Some of the points stated by Dr. Allen are correct in that there are many similarities between these two documents and that they both rely on much of the same science that has evolved around the use of stress nuclear myocardial imaging in patients with known or suspected heart disease. The MSI criteria do reference articles in the medical and cardiovascular literature that have been previously published regarding the recommendations and guidelines for cardiac stress testing, and for the most part these are well done accepted studies in peer review journals that do form much of the basis for current practice guidelines. The task force that produced the ACCF 2009 Guidelines to which was previously referred obviously had all of the data and results from these same studies that were utilized and referenced by the MSI criteria as well as all other relevant articles that have been published prior to 2009 on which to base their guidelines. In his comparison of these two documents (the MSI criteria and the ACCF Guidelines), Dr. Allen states that the ACC and the AHA have relied on a modified Delphi (expert opinion) process to develop their guidelines rather than solely from the evidence based literature that might apply to the indications and performance of these studies. There is disagreement with Dr. Allen on this point, as the ACCF document clearly states that they have used all of the existing literature and evidence based studies available in combination with input from experts, not just from the field of cardiology, but also in the field of radiology and nuclear medicine. While it is true that the ACCF guidelines do use a Delphi process with some of the recommendations derived from a consensus opinion of these experts, these opinions are clearly formulated to reflect the evidence based data available to this task force. All of the same studies and data on exercise nuclear stress testing to date were available to the ACCF Task Force from which to formulate the recommendations and guidelines so that the ACCF Guidelines are clearly based on the existent evidence based data as well as input from an expert panel to arrive at their ultimate recommendations; they are not solely opinions from experts without a scientific foundation.

Dr. Allen has also stated that the MSI Guidelines are reviewed and updated on an annual basis, while years can separate the revised guidelines from the ACC and AHA. While this is true, most of the studies and data on exercise stress testing for

which the MSI and ACCF criteria are based upon are older studies as there has not been much in terms of new data in the area of stress testing that would contradict or disprove the large amount of data that has been accumulated in the last several years concerning exercise stress testing with imaging. Although the ACC and AHA Guidelines are updated on an every three to four year basis, this certainly does not affect the accuracy, validity, or completeness of these guidelines once published. Dr. Allen also states that the MSI criteria appear in a single document posted on the MSI website that is easily available to all physicians, and that the ACCF Guidelines are not as readily accessible and are scattered across multiple publications. While this indeed may also be true, ease of use of a document on the MSI website is not relevant in determining which guidelines should be followed in the best interest of the patient.

Dr. Allen also stated in his report that the largest difference between the two sets of guidelines involves the most appropriate first test in evaluating certain patients and I concur that it is in this area where the guidelines have distinct and important differences. In patients with established heart disease or prior myocardial infarctions with a change in symptoms, patients with arrhythmias or congestive heart failure, patients with significant valvular heart disease, patients with coronary stents or previous bypass grafting surgery with a clinical change in symptoms, patients with abnormal electrocardiograms that make EKG treadmill stress tests unhelpful, and in hospitalized patients with acute cardiac problems, the MSI and ACCF Guidelines are very similar, and in these areas the MSI criteria and guidelines for imaging are reasonable. It is difficult in trying to establish a diagnosis in some patients who are symptomatic due to a potential underlying cardiac abnormality. While some patients present with symptoms that are "classic" for underlying heart disease; many patients have symptoms that are atypical and difficult to interpret. Many studies have confirmed that women in particular have very atypical symptoms as presenting features of heart disease. For that reason, the history and physical examination in these patients is critical in trying to decide the first appropriate test or procedure needed to establish a diagnosis. No one is better suited to order that first test than the physician or care provider treating that patient who has been able to best assess the patient clinically.

Great strides have been made in the past 25 years trying to identify established risk factors for developing atherosclerotic cardiovascular disease. Based on extensive review of epidemiologic studies, the National Heart Lung and Blood Institute published a revised report in 2002 on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III).[5] This report focused on determining the absolute risk of developing coronary heart disease in patients over a

[5] Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report. Circulation 2002;106;3143

ten year span (ten year risk of experiencing a hard cardiovascular event such as a myocardial infarction or stroke), and did so by employing established risk factors including hypercholesterolemia, smoking, hypertension, family history of cardiovascular disease and the presence of diabetes. The ACCF guidelines for radionuclide imaging have used these risk factor profiles in arriving at some of their recommendations regarding the use of exercise nuclear stress tests, agreeing that the test is appropriate in patients with an intermediate or high risk of developing coronary heart disease based on their risk factors even in the absence of symptoms

Some of the differences in the MSI criteria and the ACCF criteria lie in the decision about a first test in patients suspected of having cardiovascular disease with the ACCF Guidelines relying more heavily on the patient's ten year risk of developing heart disease as per the Adult Treatment Panel III report. The MSI Guidelines state that if possible the first test should always be an exercise treadmill stress test, and in certain low risk patients without classic or typical symptoms this is reasonable. In the intermediate and high risk patients, however, stress testing with imaging such as nuclear stress tests is appropriate and indicated due to the higher prevalence of disease in these patients. In women with atypical symptoms and non-specific electrocardiograms (estrogen can affect certain parts of the electrocardiogram) that stress testing with imaging is better given the non-specific baseline EKG abnormalities which can affect exercise treadmill stress tests and may be a better first line test in these situations. Studies have shown that the EKG response to exercise is suboptimal in women particularly those who are premenopausal with a low to intermediate pretest probability of having coronary heart disease, and stress testing with imaging should be considered in those patients[6]. As previously stated the addition of imaging either with ultrasound or nuclear imaging greatly enhances the ability of the test to establish a diagnosis as compared to treadmill exercise stress testing without imaging.

Dr. Allen in his report also brings out the important point that there are several ways of doing stress tests such as stress echocardiography (treadmill stress tests with ultrasound) and that the ACC has yet to publish guidelines that would determine which type of stress testing would be helpful as a first test in certain patients. While this is true, several things must be taken into consideration concerning this important point. Stress PET imaging is costly and not widely available for routine clinical use. While stress echocardiography is sometimes a reasonable alternative, the treating physician may have reasons for choosing one study over another such as patients body habitus (may not be suitable for ultrasound imaging), or the patient may have other conditions that prohibit adequate ultrasound imaging such as COPD. There also exist geographic differences in the availability of quality centers that provide both forms of testing. It may not be reasonable to expect that the ACC could simply

[6] Kwok Y, Kim C, Grady D, et al: Meta analysis of exercise testing to detect coronary artery disease in women. Am J Cardiol 83:660, 1999

provide a "cookbook" approach to ordering certain tests for patients, particularly when there are several viable options.

Physicians clearly should be aware of the options that exist when ordering such tests, and should be familiar enough with these options to order the test they feel most appropriate for a given patient. There is disagreement with the MSI guidelines statement that when a cardiac stress test with imaging is required, a stress echo should be the initial test. Such a broad position does not take into consideration many of the clinical variables that need to be evaluated on a patient by patient basis to decide which first test is appropriate and stress echo as a modality certainly has limitations. A review of stress echocardiography found that in 37% of patients having the study they were not able to adequately visualize the heart completely. [7]

These points emphasize the importance in the role of the treating physician who has examined the patient and taken a history in determining the most appropriate test if cardiovascular disease is suspected. When patients present with symptoms suggestive of a possible cardiac ailment such as chest pain, the description and characteristics of the pain is extremely important as there is literature to support that more "classic" cardiac symptoms generally increase the patient's pre-test probability of having an abnormal stress test, placing them in a higher risk category. Much of this important clinical information can potentially get lost in the process of sending requests to agencies that take over the decision making concerning what type of test is appropriate or indicated hence there are concerns involving the need for prior authorization. Proponents of such policies would argue that it reduces costs and limits some abusive practices in terms of cardiovascular testing, although there are other effective methods for achieving those same goals while not restricting the ability of the treating physician to order what tests he or she feels is most appropriate for their patients.

Radiation exposure for patients is something that physicians need to be keenly aware of when ordering certain tests. Particularly in younger patients, healthcare providers must take a careful history from patients pertaining to what prior tests they have had that have involved exposure to radiation such a CT Scans, plain x-rays, nuclear medicine studies, and radiation treatment of certain disease processes. Dr. Allen is correct in that as a community, physicians have not done a good enough job in screening patients for prior radiation exposure and in using that information to guide them in ordering tests that may involve exposure. While it is true that the ACCF Guidelines do not give consideration to prior radiation exposure, it is also true that MSI takes no radiation history into account when processing a request for nuclear stress tests. While Dr. Allen states that the reason for limiting the use of nuclear stress tests is to protect the patient from ionizing radiation, MSI approves such

[7] Bonow RO: Diagnosis and risk stratification in coronary artery disease: Nuclear cardiology versus stress echocardiography. J Nucl Cardiol 4(Suppl):172, 1997

studies on a routine basis with absolutely no history or awareness of the patients prior radiation exposure. The treating physicians are responsible for knowing those important details when ordering certain tests particularly in younger patients who are more prone to the possible devastating effects of high doses of ionizing radiation over time.

In summary, the MSI Guidelines for cardiac stress tests are based on accepted literature and science and appear to be reasonable and in agreement with those proposed by the American College of Cardiology Task Force in many but not all areas. There are, however, important differences that exist primarily in ordering the first test in intermediate and high risk patients as compared to the ACC/AHA Guidelines. First, the MSI guidelines that require treadmill stress testing without imaging to always be performed, if possible, prior to stress testing with imaging are not appropriate for intermediate and high risk patients. In these patients stress testing with imaging is frequently the appropriate first test. Second, the MSI guidelines that require echo imaging to always be performed prior to nuclear imaging are not appropriate for intermediate and high risk patients. In these patients, for the reasons stated above, nuclear imaging is frequently the appropriate first test. In intermediate and high risk patients the clinical evaluation which is performed by the patient's physician or cardiologist is critical in determining which initial test is appropriate. The MSI guidelines dispense with critical physician judgment in these situations at the expense of appropriate patient care. As a member of the American College of Cardiology, I feel that their appropriate use criteria and practice guidelines in many aspects of cardiovascular medicine are for the most part well written and carefully constructed documents based on available evidence based medicine as well as input from experts in the field of cardiovascular medicine. With respect to the ordering of diagnostic tests, the treating physician who has examined the patient, taken an extensive history, and formulated a clinical impression is the one most qualified to order the appropriate test for that patient for reasons that have been clearly articulated. The quality of care can only be enhanced when the history and physical examination are used to their fullest capacity by the treating physician to determine the appropriate test to be performed."

As part of the clinical review, the following concern was noted:

CONCERN: The Department is concerned with MedSolutions procedure CD1.3 Stress Testing which states: "Whenever possible, the initial stress test should be an exercise treadmill test." Dr. Tecce states that "… in certain low risk patients without classic or typical symptoms this is reasonable. In the intermediate and high risk patients, however, stress testing with imaging such as nuclear stress tests is appropriate and indicated due to the higher prevalence of disease in these patients. While that may be appropriate in some low risk patients, the medical necessity determination for a nuclear cardiac imaging test should be based on the criteria of the ACCF and the treating physician's first hand clinical knowledge of his patients and their history."

CONCERN: MSI has expressed their concern with regard to the harmful effects of radiation exposure and utilized that as one of their primary reasons for creating criteria for approving (denying) requests for nuclear imaging testing that are more stringent than the ACCF Guidelines. The DOI does not believe that MSI's position regarding radiation exposure justifies utilizing criteria that are more restrictive than the ACCF guidelines. As Dr. Tecce indicated in his report:

> "Radiation exposure for patients is something that physicians need to be keenly aware of when ordering certain tests. Particularly in younger patients, healthcare providers must take a careful history from patients pertaining to what prior tests they have had that have involved exposure to radiation such a CT Scans, plain x-rays, nuclear medicine studies, and radiation treatment of certain disease processes. Dr. Allen is correct in that as a community, physicians have not done a good enough job in screening patients for prior radiation exposure and in using that information to guide them in ordering tests that may involve exposure. While it is true that the ACCF Guidelines do not give consideration to prior radiation exposure, it is also true that MSI takes no radiation history into account when processing a request for nuclear stress tests. While Dr. Allen states that the reason for limiting the use of nuclear stress tests is to protect the patient from ionizing radiation, MSI approves such studies on a routine basis with absolutely no history or awareness of the patients prior radiation exposure. The treating physicians are responsible for knowing those important details when ordering certain tests particularly in younger patients who are more prone to the possible devastating effects of high doses of ionizing radiation over time."

Recommendation:

It is recommended that the Company revise its contract with MSI to ensure that the criteria they are using with regard to reviewing and approving requests for nuclear cardiac imaging testing are not more restrictive than criteria established by the ACCF or other recognized professional medical specialty organizations. In addition, once the information provided in the physician's request meets ACCF criteria, the Company should promptly approve the request for nuclear cardiac imaging testing.

PRE-AUTHORIZATION REQUEST FOR NUCLEAR CARDIAC IMAGING TESTING

The examination review of the nuclear cardiac pre-authorization diagnostic program case files was focused on the following 2 sections:

1. Nuclear Cardiac Imaging Tests Denied
2. Nuclear Cardiac Imaging Tests Approved

The initial review was conducted by the Department examiners to ensure the Company was following their Diagnostic Imaging Procedures and their Utilization Management Program procedures for appeals in a consistent and timely manner and for compliance with 18 Del. C. §332, Arbitration of disputes involving health insurance coverage and 18 Del. Admin. Code

§1301, Internal Review, Arbitration and Independent Utilization Review of Health Insurance Claims.

The secondary review was conducted by clinical personnel to ensure the policies and procedures utilized in the determination of medical necessity for the nuclear cardiac diagnostic imaging approval process was appropriate and appropriately being applied.

The following table is a synopsis of the Nuclear Cardiac Imaging Testing Pre-Authorization Requests.

Category	Number	Percent
Total Requests	1220	
Initially Denied	326	26.7% of All Requests
Initially Approved	894	73.3% of All Requests
Denials Appealed for Reconsideration	61	5% of All Requests 18.7% of Denials
Appeals Upheld	31	50.8% of Appeals
Appeals Overturned	30	49.2% of Appeals
Final Denials (Initial Denials minus Appeals Overturned)	296	24.3% of All Requests
Final Approvals (Initial Approvals + Appeals Overturned)	924	75.7% of All Requests

A. Nuclear Cardiac Imaging Testing Pre-Authorization Requests Denied

The Company was requested to provide a list of all pre-authorization requests for nuclear cardiac imaging tests. The Company identified 14,044 medical procedure requests for pre-authorization diagnostic tests, 2,561 were for medical procedures related to nuclear cardiac imaging. In order to maintain uniformity among physicians, hospitals, patients and other administrative entities in describing various medical, surgical and diagnostic services and procedures, the American Medical Association (AMA) maintains a Current Procedural Terminology (CPT) set of codes. Each medical, surgical and diagnostic service or procedure is assigned a code, which is often referred to as its CPT Code. MSI, effective January, 2010, changed three cardiac imaging procedure codes that were bundled in a single pre-authorization request to one procedure code that encompassed all three codes. In order to be consistent within the experience period, two procedure codes were excluded from the universe count. As a result, of the 2,561 CPT Code procedures related to nuclear cardiac imaging, the number of individual requests for pre-authorization was 1,220. An auditing program was used to query the number of denied pre-authorization requests. The result of that query was 296. All 296 denied pre-authorization cases were requested, received and reviewed. The files were reviewed in two phases, an administrative review and a clinical review.

1. Phase 1 – Pre-Authorization Requests Denied - Administrative Review

As part of the administrative and policy contract review, the files were reviewed to ensure the Company was following their Cardiac Imaging Procedures and their Utilization Management Program procedures for appeals in a timely and consistent manner and for compliance with 18 Del. C. §332, Arbitration of disputes involving health insurance coverage.

The following table is a synopsis of the Nuclear Cardiac Pre-Authorization Requests.

Category	Number	Percent
Total Requests	1220	
Requests Initially Denied	326	26.7 of All Requests
Requests Appealed for Reconsideration	61	5% of All Requests 18.7% of Denials
Requests Denied Appeals Upheld	31	50.8% of Appeals
Requests Denied Appeals Overturned	30	49.2% of Appeals
Requests Final Denied	296	24.3%
Requests Initially Approved	894	73.3% of All Requests
Requests Final Approved	924	75.7% of All Requests

As part of the review of the 296 denied pre-authorization nuclear cardiac imaging test files, there were 31 cases appealed and upheld. Of the 31 upheld case files, 12 cases did not indicate an MSI Cardiologist was consulted. The Company failed to assign licensed, certified or registered health care personnel with expertise in the field implicated by the request for review to conduct the review. This action resulted in 12 exceptions with the following statute:

12 Exceptions – 18 Del. C. §332(6) Assignment of qualified personnel.

The IRP shall provide that when the subject of the grievance relates to medical or clinical matters, including medical necessity and appropriateness of treatment, the health carrier shall assign licensed, certified or registered health care personnel with expertise in the field implicated by the request for review to conduct the review. The review shall be conducted by personnel other than those who made the initial adverse determination.

Recommendation: It is recommended that the Company require MSI to revise the nuclear cardiac imaging testing pre-authorization process to ensure that denials of nuclear cardiac imaging testing based on medical necessity are being conducted by licensed, certified, or registered health care personnel with expertise in the field implicated by the request for review, as required by 18 Del. C. §332(6).

2. Phase 2 - Pre-Authorization Requests Denied - Clinical Review

The second phase of the review was conducted by Dr. Marc A. Tecce, M.D., F.A.C.C, Clinical Assistant Professor of Medicine, Thomas Jefferson University School of Medicine, Philadelphia, Pennsylvania. Dr. Tecce was assisted in his review of the patient files by a Certified Registered Nurse Practitioner, who, under his direct supervision, compiled data and summarized applicable information. Dr. Tecce's comments and report findings are summarized as follows:

The clinical review involved examining specific case requests for cardiovascular imaging studies that were submitted for pre-authorization. These requests for nuclear stress tests were made by treating physicians in Delaware and were denied because they were not felt to meet appropriateness criteria as defined by MedSolutions, Inc. on behalf of the Company. As part of the clinical review, the 296 service requests for pre-authorization were determined to be associated with 271 individuals.

The American College of Cardiology Appropriateness Use Criteria for Nuclear Cardiac Imaging is considered the most accurate and appropriate guideline established to date and is based largely on the presence of risk factors and using them to determine patients' pre-test probability of having disease. The ACC criteria and clinical judgment of a practicing Cardiologist were utilized in the review of the 271case files. The following report was submitted as part of the clinical review.

Five categories were created and each case was placed in one of these categories based on the received case file information.

- The first category (1) involved agreement with the denial in that the case did not warrant a nuclear stress test based on the data provided. Additionally, all cases that involved denials based solely on policy decisions were placed into this category as it was not part of the clinical review to challenge or change the administrative policies of MedSolutions. The reasons for denial based on policy decisions included requests for approval after the test was performed (retro-request, 21 cases), requests that were made more than 30 days since the patient was last seen in the office (14 cases), and cases that were deemed administrative denials purely because there was insufficient information provided (8 cases). These 8 cases were reviewed and determined to lack sufficient information to make an appropriate approval in all 8 cases.

- The second category (2) involved agreement with the denial but solely because insufficient information was provided to warrant an approval. In many cases basic information such as the performance of an EKG or clinical history was lacking, therefore prohibiting approval of a nuclear stress test.

- The third category (3) involved either insufficient or conflicting clinical data that precluded making a definitive denial or approval. The distinction between this category (3) and category (2) is that many of these cases had a fair amount of clinical information provided (most cases in category (2) had almost no basic information) but it was unclear

whether or not a nuclear stress test was warranted (for example symptoms may have been inconsistently documented). Many of these cases had underlying cardiac disease but there was enough clinical uncertainty in reviewing the data that a definite decision could not be made. It is suspected that several of these patients had enough disease and symptoms to warrant a nuclear stress test but they fell into the uncertain category as per the American College of Cardiology Guidelines at least based on the information provided.

- The fourth category (4) involved cases where the denial was inappropriate and a nuclear stress test should have been approved.

- The fifth category (5) involved cases that were initially denied and then approved upon appeal/peer to peer/ reconsideration. Of the 21 cases approved upon appeal/peer to peer/reconsideration, 17 cases were deemed appropriate requests and a nuclear stress test was indicated with the initial submission, 3 cases did not meet criteria to warrant a nuclear stress test, and 1 case was borderline where more information was required for a definitive decision to be made.

The following table summarizes the 271 cases reviewed:

Category	Description	Number
1	Agree with Denial (includes 43 cases denied for policy reasons)	192
2	Agree with Denial Solely due to poor/lack of Information	23
3	Insufficient Clinical Data to make Definitive Decision	19
4	Disagree with Denial; Nuclear Stress Test Appropriate	16
5	Cases approved upon Appeal	21
	Total	271

As part of the clinical review, the following concern was noted:

CONCERN: Of the 271 denied cases reviewed, the application of the ACCF criteria determined a nuclear stress test was appropriate in 16 cases (6%). In addition, 21 cases (7.7%) were initially denied and subsequently approved upon appeal. Utilizing ACCF criteria 17 of the 21 cases appealed would have met ACCF criteria to warrant a nuclear stress test. In conclusion, the application of the ACCF criteria would have determined a nuclear stress test appropriate in 33 cases (16+17) or 12% of the initial 271 denied cases.

Recommendation It is recommended that the Company revise its contract with MSI to ensure that the criteria they are using with regard to reviewing and approving requests for nuclear cardiac imaging testing is not more restrictive than criteria established by the ACCF or other recognized professional medical specialty organizations. In addition, once the information provided in the physician's request meets ACCF criteria, the Company should promptly approve the request for nuclear cardiac imaging testing.

CONCERN: Based on the number of denials successfully appealed, the DOI is concerned that the Company is not adequately monitoring MSI's performance under this contract. The

Company does not have a formal, documented, process in place to ensure compliance with established guidelines.

Recommendation: It is recommended that the Company develop a formal process to review and monitor the Nuclear Cardiac Imaging Testing Pre-authorization Process being performed by MedSolutions, with a special emphasis on denials.

B. Nuclear Cardiac Imaging Tests Approved

The Company was requested to provide a list of all pre-authorization requests for nuclear cardiac imaging tests. The Company identified 14,044 CPT Code requests for pre-authorization diagnostic tests, 2,561 were for CPT Code procedures related to nuclear cardiac imaging testing. MSI, effective January, 2010, changed three cardiac imaging procedure codes that were bundled in a single pre-authorization request to one procedure code that encompassed all three codes. In order to be consistent within the experience period, two procedure codes were excluded from the universe count. As a result, of the 2,561 CPT Code procedures related to nuclear cardiac imaging, the number of individual requests for pre-authorization was 1,220.

An auditing program was used to query the number of approved pre-authorization requests. The result of that query was 924. Of the 924 pre-authorizations approved, 30 requests were initially denied and upon reconsideration/peer to peer review, the requests were approved. A random sample of 100 pre-authorization cases was requested, received and reviewed. The files were reviewed to ensure the Company was following their Cardiac Imaging Procedures and their Utilization Management Program procedures for appeals in a consistent and timely manner and for compliance with 18 Del. C. §332, Arbitration of disputes involving health insurance coverage.

No exceptions were noted.

CLAIMS

The claim file review consisted of two segments of review:

A. Cardiac Claims Submitted after Nuclear Cardiac Imaging Tests were Denied
B. Nuclear Cardiac Imaging Claims Denied for No Authorization

The claim files were reviewed to ensure compliance with 18 Del. C. §2304(16) Unfair claim settlement practices.

A. Cardiac Claims Submitted after Nuclear Cardiac Imaging Tests were Denied

The Company was requested to provide a list of all serious cardiac related claims submitted by insured that previously had pre-authorization for cardiac diagnostic tests denied. For purposes of this review, a serious cardiac claim was a claim made for services provided in a hospital or emergency room setting that required immediate cardiac care, such as a heart catherization or heart bypass surgery. The following is a short synopsis of these claims:

- 31 serious Cardiac Claims on 6 individuals were submitted after their pre-authorizations were denied.
- 29 serious Cardiac Claims on 6 individuals were submitted after their pre-authorizations were initially denied but later pre-authorization was approved after reconsideration.
- 419 serious Cardiac Claims on 87 individuals were submitted after their pre-authorizations for diagnostic tests were approved.

The following table illustrates the number of days from the pre-authorization denial date to the claim date for the 6 members who submitted 31 serious cardiac claims.

Pre-Authorization Denial Date	Claim Incurred Date	Number of Days
6/29/2009	2/17/2010	233
12/2/2009	4/19/2010	138
1/4/2010	1/6/2010	2
1/6/2010	2/8/2010	33
2/18/2010	2/23/2010	5
3/10/2010	3/26/2010	16

The following table illustrates the number of days from the pre-authorization denial date to the pre-authorization approval date to the claim date for the 6 members who submitted 29 serious cardiac claims.

Pre-Authorization Denial Date	Pre-Authorization Approval Date	Claim Incurred Date	Number of Days Denial Date to Claim Date
8/20/2009	9/22/2009	10/15/2009	56
1/11/2010	1/15/2010	3/11/2010	59
7/1/2009	8/26/2009	12/5/2009	157
6/30/2009	7/20/2009	8/10/2009	41
12/8/2009	12/8/2009	2/6/2010	60
8/12/2009	8/19/2009	9/21/2009	40

No exceptions were noted.

B. Nuclear Cardiac Imaging Testing Claims Denied for No Authorization

The Company was requested to provide a list of all Nuclear Cardiac Imaging Claims denied for "No Authorization" for the experience period of July1, 2009 through April 6, 2010. The Company indicated 254 cardiac imaging claims were denied for "No Authorization". The list was received and reviewed to analyze the number of insured that were either denied the nuclear cardiac imaging tests for not obtaining an authorization or were denied the services from MSI when seeking pre-authorization and had the imaging tests performed anyway. In the review, the Company was requested to provide an explanation on the unusually high number of claims denied for "No Authorization". The Company response indicated a claim processing error had occurred and the Company was in the process of re-adjudicating these claims. As a result of the re-adjudication of the 254 denied claims, 122 claims were ultimately paid and 132 did not require adjustment and remained denied for "No Authorization".
The following table is a synopsis of the 132 claims denied for "No Authorization".

Number	Description	Percent
115	No Authorization was Obtained	87.1%
10	MSI determined Not Medically Necessary	7.6%
7	MSI Requirements Not Followed	5.3%
Total - 132		100%

As part of the review of the Denied Claims for No Authorization Section, 122 claims were found inappropriately denied due to a claim system processing error. This action resulted in 122 exceptions to 18 Del. C. §2304(16)(c) as noted below, for failure to implement reasonable standards in the prompt investigation of claims arising under their insurance contracts.

122 Exceptions - 18 Del. C. §2304(16)(c)
(16) Unfair claim settlement practices. - No person shall commit or perform with such frequency as to indicate a general business practice any of the following:

c. Failing to adopt and implement reasonable standards for the prompt investigation of claims arising under insurance policies;

Recommendation: It is recommended that the Company review and revise their claim handling procedures and claim processing systems to ensure claims are properly adjudicated and in compliance with 18 Del. C. §2304(16)(c) Unfair claim settlement practices.

COMPLAINTS

The Company was requested to provide a list of all complaints received from Delaware consumers and providers for the period of March 29, 2007 through April 6, 2010, concerning the pre-authorization program managed by MSI. The Company initially identified six complaints from MSI. The complaints were reviewed and reconciled with the Department's list of complaints. After review and reconciliation of all complaints, the Company's listing exhibited some discrepancies and the Company was requested to account for the differences. The Company then provided a revised list and the number of MSI complaints was increased to 27. Of the 27 complaints related to MSI, two complaints were related to the same member and issue and one complaint involved an ERISA planholder.

The following table is a synopsis of the 27 complaints related to MSI.

Reason for Complaint	Number	Percent
MRI Pre-Authorization Inquiries	3	11%
Pre-Authorization Denial CT Scan, MRI, Pet Scan	17	63%
Pre-Authorization Denial Nuclear Cardiac Imaging	3	11%
CT Scan Pre-Authorization Turn around Time	2	7%
Duplicate Nuclear Cardiac Denial	1	4%
ERISA Planholder	1	4%
Total	27	100%

The complaint files and the complaint logs were reviewed for compliance with 18 Del. C. §2304(17) Failure to maintain complaint handling procedures. Section 2304(17) requires maintenance of a complete record of all the complaints which it has received since the date of its last examination as otherwise required in this title. This record shall indicate the total number of complaints, their classification by line of insurance, the nature of each complaint, the disposition of these complaints and the time it took to process each complaint. For purposes of this subsection, "complaint" shall mean any written communication primarily expressing a grievance.

The following Concern was noted.

CONCERN: Due to discrepancies in the complaint listing and delays exhibited in providing a complete listing to the examiners, the Department is concerned that the complaint handling procedures, especially with regards to the coordination of complaint handling with its vendor, MSI, needs improvement to ensure that the record of complaints is complete and the Company promptly responds to all complaints.

Recommendation: It is recommended that the Company review and revise the coordination of their complaint handling procedures with its vendor, MSI, in order to ensure that it is aware of all complaints and that all complaints are responded to promptly and properly.

FORMS

The Company was requested to provide the following documents utilized in the denial process for nuclear cardiac pre-authorization diagnostic imaging:

- Correspondence explaining the reason for the denial sent from the Company to the policyholder and/or physicians.
- Copies of the policies under which each of the denials were made, including any explanations of prior approval review, policy holder agreements, and certificates of coverage.
- Copies of the notice to the policyholder of their right to appeal the denial.

The Company provided copies of all forms requested. The forms were reviewed to ensure proper appeal notices were utilized as required by 18 Del. C. §332 and all contract forms utilized during the experience period were filed with the Department as required by 18 Del. C. §6306.

Provisions for the pre-authorization program requirements for nuclear cardiac imaging testing were contained in the Group Contract, as well as in the Certificates of Coverage benefit booklet provided to enrollees. The group contracts and certificates of coverage were filed with the department as required.

No exceptions were noted.

SUMMARY OF RECOMMENDATIONS

The recommendations made below identify corrective measures the Department finds necessary as a result of the Exceptions and Concerns noted in the Report. Location in the Report is referenced in parenthesis.

1. It is recommended that the Company revise their contract with MedSolutions to ensure compliance with requirements of 18 Del. Admin. Code 1406 §9.1 regarding contingent fees based on savings in the contract. *The Company deleted the non-compliant provision by amendment to the contract dated June 3, 2010.* (A. Vendor Contract Agreements)

2. It is recommended that the Company revise its contract with MSI to ensure that the criteria they are using with regard to reviewing and approving requests for nuclear cardiac imaging testing are not more restrictive than criteria established by the ACCF or other recognized professional medical specialty organizations. In addition, once the information provided in the physician's request meets ACCF criteria, the Company should promptly approve the request for nuclear cardiac imaging testing. (B. Phase 2-Policy & Procedures Clinical Review and 2. Phase 2-Pre-Authorization Requests Denied Clinical Review)

3. It is recommended that the Company require MSI to revise the nuclear cardiac imaging testing pre-authorization process to ensure that denials of nuclear cardiac imaging testing based on medical necessity are being conducted by licensed, certified, or registered health care personnel with expertise in the field implicated by the request for review, as required by 18 Del. C. §332(6). (1. Phase 1- Pre-Authorization Requests Denied Administrative Review)

4. It is recommended that the Company develop a formal process to review and monitor the Nuclear Cardiac Imaging Testing Pre-authorization Process being performed by MedSolutions, with a special emphasis on denials. (2. Phase 2-Pre-Authorization Requests Denied Clinical Review)

5. It is recommended that the Company review and revise their claim handling procedures and claim processing systems to ensure claims are properly adjudicated and in compliance with 18 Del. C. §2304(16)(c) Unfair claim settlement practices. (B. Nuclear Cardiac Imaging Testing Claims Denied for No Authorization)

6. It is recommended that the Company review and revise the coordination of their complaint handling procedures with its vendor, MSI, to ensure that it is aware of all complaints and that all complaints are responded to promptly and properly. (COMPLAINTS)

CONCLUSION

The examination conducted by Daniel Stemcosky, Gwen Douglas, and Jack Rucidlo is respectfully submitted.

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