



**BlueCross BlueShield
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John Ross
General Auditor &
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April 12, 2011

Ms. Linda Nemes
Senior Insurance Research Analyst
Delaware Department of Insurance
841 Silver Lake Boulevard
Dover, DE 19904

RE: Report on Market Conduct Examination as of April 6, 2010 on Blue Cross Blue Shield of Delaware

Dear Ms. Nemes:

Mr. Tim Constantine, President and CEO of BCBSD, Inc. (BCBSD) has asked me to provide the response requested in your letter of January 10 which enclosed a draft copy of the Report on Market Conduct Examination as of April 6, 2010 on Blue Cross Blue Shield of Delaware ("Report").

This Report's Recommendations address several important concerns which we are grateful to have been able to discuss with the Examiners since we received the Report. The most fundamental and complex matters are raised by Recommendations 2 and 3 and discussed in the Management Responses to those Recommendations. Due to the complex and technical nature of the Examination topic, the policy implications of the Report's contents, and the applicability of these Recommendations to all health insurers operating in Delaware, we anticipate that further regulatory consideration will be undertaken. Based on those assumptions BCBSD is not, at this time, requesting a hearing with respect to the Report. However, we are hereby reserving all of our rights to request such a hearing under 18 Del. C. §§321(c) and (d) prior to the Report becoming 'final'.

Management Responses to Recommendations

BCBSD hereby provides the following responses to the Report's Recommendations:

Examination Recommendation #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)*

Management Response to Recommendation #1

BCBSD appreciates the Report noting as a subsequent event that BCBSD had deleted the recommended provision on June 3, 2010, prior to any external finding, and that no fees paid under the contract were ever increased or decreased as a result of that contract clause.

Examination Recommendation #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)

Management Response to Recommendation #2

BCBSD believes this Recommendation to be inappropriate for several reasons. Nonetheless, BCBSD recognizes the Department's underlying concerns and is considering them in our plans to address the utilization of nuclear cardiac imaging.

- A. It is inappropriate for the Department to impose specific criteria which the Company is to use in making utilization review determinations.
- i. Imposing such a requirement is inconsistent with how utilization review is regulated in the states which do explicitly regulate it.

MedSolutions is licensed as a utilization review agency in every state in which this is required, generally under the jurisdiction of the state's insurance regulator. None of these jurisdictions have ever required that MedSolutions, or the insurers for whom it works, use a particular or specific set of appropriateness or utilization review criteria.

- ii. Imposing such a requirement is inconsistent with how utilization review is regulated by the organizations which are recognized to set the professional standards for such behavior (i.e. (NCQA and URAC).

NCQA (National Committee for Quality Assurance) and URAC (formerly, Utilization Review Accreditation Commission) are the accrediting organizations for utilization review services and MedSolutions is accredited by both. Neither of these accrediting bodies dictate in their standards the use of specific medical criteria. Rather, they stipulate that the utilization review organization and the health plans have written utilization management decision-making criteria that are objective and based on medical evidence as well as having a systematic, annual process for review and updating of the criteria with independent, qualified physician input to these revisions. Additionally, as implemented at BCBSD, it may be required that the criteria be reviewed and approved by a panel of participating plan physicians in advance of the program implementation.

- B. It is inappropriate for the Department to impose these particular criteria which the Company is to use in making utilization review determinations.
- i. These particular criteria were not designed to be the standard for determining which test may be most appropriate among several which may be considered medically necessary. However, that is the purpose to which the Department is requiring us to put them.

Beginning at the bottom of page 20 the Report cites and addresses MedSolutions' (Dr. Allen's) observation regarding the American College of Cardiology Foundation (ACCF) not having published "guidelines that would determine which type of stress testing would be helpful as a first test in certain patients." The ACCF's preface to its 2009 guidelines (cited on page 17 of the Report as footnote 4) confirms this, stating (on page 3 of the ACCF guidelines) "A comparative evaluation of the appropriate use of multiple imaging techniques will be undertaken in the near future to assess the relative strengths of each modality for various clinical scenarios." Despite the ACCF's acknowledgment that their 2009 guidelines regarding nuclear cardiac imaging testing were not designed to evaluate the relative strengths of different imaging tests, the Department is proposing that BCBSD may not utilize "more restrictive" criteria when evaluating a request for such testing. The implication of this requirement is that BCBSD would be precluded from applying the

important contractual language that limits coverage to the most appropriate service which can be safely provided.

- ii. Specifying that carriers use these particular criteria is inconsistent with what Delaware law dictates for Independent Utilization Review Organizations to use when performing external reviews of carrier decisions.

18 Del. C. §6417 (c)(4)b identifies the criteria to be used by Independent Utilization Review Organizations (IURO) when performing external reviews of appeals of companies' medical necessity decisions. The statute says that the IURO decision is to be "based on applicable, generally accepted practice guidelines developed by the federal government, national or professional medical practice societies, boards or associations and any applicable clinical protocols or practice guidelines developed by the carrier." The restricted criteria imposed by this Recommendation stand in sharp contrast to the flexibility given to those deciding the appeals of carriers utilization review decisions.

Examination Recommendation #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)

Management Response to Recommendation #3

BCBSD agrees with the Department's judgment (see Report, page 25) that a cardiologist would satisfy the standards required to be an appropriate reviewer of an internal appeal of a nuclear cardiac test denial. However, we do not agree that cardiologists are the sole medical professionals who would satisfy those standards; the reviewers in the 12 identified instances met the Delaware and other standards. Therefore, we believe that the Recommendation is inappropriate in this situation. [Note: for many of the same reasons, BCBSD also disagrees with the determination of 'exceptions' made on page 25 of the Report.]

- A. We believe that it is inappropriate for the Department to impose identical qualification requirements upon those who conduct initial 'denials' as exist for those who conduct the review of those denials.
 - i. The Recommendation creates a new standard inconsistent with existing requirements for claims determinations in Delaware and elsewhere.
 - a. Delaware law quoted in the Examination Report (18 Delaware Code §332(c)(6)) requires that a company's Internal Review Process (IRP) must have grievances (internal reviews of adverse determinations) assigned to "licensed, certified or registered health care personnel with expertise in the field implicated by the request for review to conduct the review." Delaware law does not set out such a qualification requirement for those who make the initial decision which later becomes the subject of a review.
 - b. We are aware of no other jurisdiction which imposes similar qualification standards on those who make the initial determinations (denials) as on those who review those denials upon appeal.
 - ii. The Recommendation is not supported by findings indicating the need for such a change.
 - a. The Examination Report, while recommending that different criteria should have been utilized by the Company, contains no findings supporting the conclusion that those who denied pre-authorizations either:

- acted at variance with the criteria they were utilizing

- were not capable of understanding or applying those criteria as a result of their qualifications, or
 - would not have been capable of properly applying the criteria the Examination Report recommends.
- b. The MedSolutions review process does entitle practitioners to “peer-to-peer” (i.e., Cardiologist-to-Cardiologist) access even if a non-cardiologist had performed a prior review.
- B. We disagree with the conclusion that only a cardiologist has the ‘expertise in the field implicated by the request for review’ required in order to conduct a review of an adverse determination.¹
- i. The conclusion is not factually correct, as demonstrated by the information supplied during the Examination and as follows, showing that the MedSolution’s reviewers had the requisite ‘expertise in the field implicated by the request for review’.
- a. Each of the 12 cases involved licensed physicians who were employed full time as Medical Directors at MedSolutions, fully trained in the application of MedSolution’s evidence based criteria and able to apply those criteria. As licensed physicians each of them could, and did, have the expertise required to adjudicate the appeal. Although cardiologists and radiologists may be the practitioners who most commonly perform and interpret these studies, other practitioners can and do.
 - b. As Medical Directors at MedSolutions, the physicians involved in those 12 cases were subject to a program which includes:
 - guideline training by a MedSolutions’ cardiologist in the application of the MedSolutions criteria for these tests (as of 2008)
 - monthly audits of their work, including inter-rating reliability testing as well as review of selected cardiac imaging cases by a MedSolutions cardiologist
 - MedSolutions lead cardiologist monitor’s new medical directors’ cases until satisfied that direct supervision or monitoring is no longer necessary.
- ii. This conclusion is not consistent with the interpretation of this wording rendered by other regulators or experts. For example, we understand that NCQA’s most recent certification survey of MedSolutions found that MedSolutions was compliant with the Appeal requirements.
- a. Accrediting bodies such as NCQA, as well as applicable state and federal laws, require that the physician doing the appeal review must not be subordinate to the person involved with the initial decision and must meet a certain professional standard. Regarding medical expertise, NCQA’s standards for Utilization Management (UM8, Elements B. 6 and C. 6) contain their requirement that the reviewer be “a practitioner in the same or a similar specialty that typically treats the medical condition, performs the procedure or provides the treatment.” MedSolutions is certified by NCQA. As part of their most recent certification survey NCQA reviewed a sample of appeals and determined that MedSolutions was compliant with these regulations.

¹ This conclusion is evidenced from the following wording on page 25 of the Report in 1. Phase 1 – Pre-Authorization Requests Denied – Administrative Review “...there were 31 cases appealed and upheld. Of the 31 upheld case files, 12 cases did not indicate an MedSolutions Cardiologist was consulted....This action resulted in 12 exceptions with the following statute: . . .18 Del. C. §332(c)(6)”

- b. The other relevant standard for conducting internal reviews which also applies to the process MedSolutions conducted on behalf of BCBSD and which also governed these denials is the federal law requirements of ERISA's Claims Procedures (29 CFR 2560.503-1). The regulation implementing ERISA says that the person being consulted must be "a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment."

Examination Recommendation #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)

Management Response to Recommendation #4

- A. BCBSD had modified the process for handling appeals prior to receiving the Report, to assure that BCBSD has more active involvement in and direct responsibility for the process. The modification involves MedSolutions continuing to do the initial handling of appeals but, only allowing MedSolutions to overturn a denial on appeal while requiring BCBSD to make any decision to uphold a denial. The modified process was fully implemented effective 9/1/10.
- B. BCBSD's Delegation Oversight Committee (DOC) is charged with assuring that MedSolutions and other vendors are performing functions on behalf of BCBSD in accordance with BCBSD expectations, state law and the standards promulgated by various accrediting bodies including but not limited to NCQA and URAC. The DOC performs the following functions in relation to MedSolutions:
 - Annual approval of MedSolutions Utilization Management program.
 - Annual evaluation of effectiveness of MedSolutions Utilization Management program.
 - Annual Provider Satisfaction Survey.
 - Quarterly monitoring of MedSolutions delegation activities.
 - Quarterly review of complaints related to MedSolutions.

Examination Recommendation #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)

Management Response to Recommendation #5

BCBSD had re-adjudicated the claims that were identified as improperly denied prior to receiving the Report, and is in the process of reviewing and revising the claim handling procedures and the claim processing system to ensure claims are adjudicated properly.

Examination Recommendation #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)

Management Response to Recommendation #6

BCBSD had reviewed and revised the coordination of the complaint handling process with MedSolutions prior to receiving the Report, to ensure that BCBSD is aware of all complaints and that all complaints are responded to promptly and properly. The revised process was fully implemented effective 7/1/10.

Please do not hesitate to contact me if you have any questions regarding the content of this correspondence. I can be reached in my office at 302.421.3355 or by email at john.ross@bcbsde.com.

Sincerely,

A handwritten signature in black ink that reads "John Ross". The signature is written in a cursive style with a large, looping initial "J".

cc: John Tinsley
Dan Stemcosky

BCBSD
Timothy J. Constantine
Jonathan Neipris

Attachment