

STATE OF MICHIGAN
DEPARTMENT OF ENERGY, LABOR AND ECONOMIC GROWTH
OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner

In the matter of the Clinical Laboratory
Provider Class Plan Determination
Report pursuant to Public Act 350 of 1980

No. 10-099-BC

/

Issued and entered
This 7th day of December 2010
by Ken Ross
Commissioner

ORDER ISSUING DETERMINATION REPORT

I

BACKGROUND

Pursuant to Public Act 350 of 1980, as amended (Act), being MCLA 550.1101 et seq.; MSA 24.660 (101) et seq., the Commissioner of the Office of Financial and Insurance Regulation (Commissioner) issued Order No. 10-049-BC on July 20, 2010, giving notice to Blue Cross and Blue Shield of Michigan (BCBSM), and to each person who requested a copy of such notice, of his intent to make a determination with respect to the clinical laboratories provider class plan for calendar years 2008 and 2009.

II

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Based upon the foregoing considerations it is FOUND and CONCLUDED that:

1. Jurisdiction and authority over this matter are vested in the Commissioner pursuant to the Act.
2. BCBSM has complied with all applicable provisions of the Act.
3. All procedural requirements of the Act have been met.

4. The staff reviewed relevant data pertaining to the clinical laboratories provider class plan as discussed in the attached report, including any written comments received during the input period on the provider class plan. The input period was designed to provide the public with an opportunity to present data, views, and arguments with respect to the clinical laboratories provider class plan.
5. Pursuant to Section 510(2) of the Act, a copy of the determination report and this order shall be sent to the health care corporation and each person who has requested a copy of such determination by certified or registered mail.

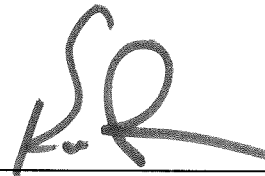
III

ORDER

Therefore, it is ORDERED that:

1. The attached clinical laboratories provider class plan determination report shall be incorporated by reference as part of this order and shall serve as the Commissioner's determination with respect to the clinical laboratories provider class plan for the calendar years 2008 and 2009.
2. Pursuant to Section 510(2) of the Act, the Commissioner shall notify BCBSM and each person who has requested a copy of such determination by certified or registered mail.
3. Pursuant to Section 515(1) and (2), any appeal must be filed within 30 days of the date of this determination report. The request for an appeal shall identify the issue or issues involved and how the person is aggrieved.

The Commissioner retains jurisdiction of the matters contained herein and the authority to enter such further order or orders as he shall deem just, necessary and appropriate.



Ken Ross
Commissioner



JENNIFER M. GRANHOLM
GOVERNOR

STATE OF MICHIGAN
OFFICE OF FINANCIAL AND INSURANCE REGULATION
DEPARTMENT OF ENERGY, LABOR & ECONOMIC GROWTH
ANDREW S. LEVIN, ACTING DIRECTOR

KEN ROSS
COMMISSIONER

**Blue Cross and Blue Shield of Michigan's
Clinical Laboratories Provider Class Plan
for calendar years 2008 and 2009**

**A Determination Report issued by
Commissioner Ken Ross**

December 2010

CLINICAL LABORATORIES
PROVIDER CLASS PLAN
DETERMINATION REPORT

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EXECUTIVE SUMMARY

Pursuant to Public Act 350 of 1980, this report provides a review and determination of whether the arrangements Blue Cross and Blue Shield of Michigan (BCBSM) has established with health care providers have substantially achieved the access, quality of care, and cost goals set forth in the Nonprofit Health Care Corporation Reform Act for calendar years 2008 and 2009. The statutory goals specify that these arrangements, known as provider class plans, must assure subscribers reasonable access to, and reasonable cost and quality of, health care services covered under BCBSM's certificates.

The analysis and determination of goal performance is based on BCBSM's 2008-2009 clinical laboratories provider class plan annual report, additional data requested of BCBSM, and information on file with respect to this provider class plan. This material was supplemented as necessary by data from published sources. The determination report analyzes the level of achievement for each goal separately and discusses interaction and balance among the goals.

Access Goal

Achievement of the access goal requires BCBSM to be able to assure that, in any given area of the state, a BCBSM member has reasonable access to laboratory services whenever necessary. In analyzing BCBSM's performance on the access goal, consideration was given to the formal participation rates of clinical laboratories, payment methods and its communication with both providers and members. BCBSM was able to maintain formal participation rates of 94% or more with clinical laboratories and demonstrated a commitment to excellent service through easily accessible electronic publications and tools and effective provider servicing, including a new, electronic provider enrollment and credentialing system and electronic funds transfers. Based on these facts, it is determined that BCBSM met the access goal during 2008 and 2009.

Quality of Care Goal

The quality of care goal requires BCBSM to assure that providers meet and abide by reasonable standards of health care quality. To achieve this goal, BCBSM must show that it makes providers aware of practice guidelines and protocols for laboratory services, that it verifies that providers adhere to such guidelines and that it maintains effective methods of communication with its providers. In order to meet the quality of care goal, the provider class plan must assure that "providers will meet and abide by reasonable standards of health care quality." During calendar years 2008 and 2009, BCBSM continued to ensure that its qualification standards for participation were met, implemented quality controls by auditing laboratories to ensure that the services rendered to BCBSM patients were medically necessary and properly billed and had an established appeal process to deal with provider disputes. BCBSM acknowledged that one of its "standardized" objectives listed in all provider class plans is not commonly practiced with laboratory providers. BCBSM stated it will rewrite this particular objective in the clinical laboratories provider class plan to reflect its current practices to communicate with laboratory providers about issues of interest and concern. As there was no input from laboratory providers indicating they desire a change to the current methods of communication, it is therefore determined that BCBSM met the statutory goal for calendar years 2008 and 2009.

Cost Goal

The cost goal requires that the arrangements BCBSM maintains with each provider class will assure a rate of change in the total corporation payment per member that is not higher than the compound rate of inflation and real economic growth. Achievement of the cost goal is measured by application of the cost formula specified in the Act, which is estimated to be (0.3)% for the period under review. As the rate of change in the total corporation payment per member for the clinical laboratories provider class has been calculated to be an increase of 8.6% over the two years being reviewed, BCBSM did not meet the cost goal stated in the Act for 2008 and 2009.

BCBSM's efforts to control costs are many, yet there are other factors that impact BCBSM's ability to contain costs within the constraints of the cost goal specified in the Act. The most prominent factors include an aging population and the overall health status of Michigan residents. Many Michigan residents have one or more chronic conditions. Michiganders are also living longer because of the development of cutting-edge technologies in medical diagnosis and treatment and due to the significant advances made in prescription drug therapies used to treat chronic conditions. Thus, as people with chronic conditions tend to have greater health care needs and are the most frequent users of health care services (regardless of age); the costs associated with these needs are disproportionately high.

Michigan ranks poorly on many measures of lifestyle factors and health status related to the development of chronic conditions, including obesity, diabetes, hypertension and cancer. Growing rates in these areas will continue to fuel increased use of health care services and will continue to be a major driver of higher health care spending as physicians order laboratory testing to diagnose these diseases and monitor disease progression. Also, as BCBSM membership in the traditional program declines, the proportion of members utilizing their laboratory benefits increased.

Because of this, it is not necessary to require that a change to the current clinical laboratories provider class plan be filed pursuant to Section 511 of the Act. However, it is anticipated BCBSM will revise the clinical laboratories provider class plan to restate its quality of care objectives to more accurately reflect its current practices to communicate with laboratory providers about issues of interest and concern. BCBSM is encouraged to continue to work closely with clinical laboratories, as well as all provider class plan groups, to find new, innovative programs and evidence based practice guidelines that instill responsible cost controls so that all the goals and objectives of the corporation can be achieved.

Determination Summary

In summary, BCBSM generally achieved two of the three goals of the corporation during the two-year period under review for the clinical laboratories provider class. Although the clinical laboratories provider class did not substantially achieve the cost goal, a change in the plans is not required because, as outlined above, there has been competent, material, and substantial information obtained or submitted to support a determination that the failure to achieve the cost goal was reasonable, due to factors listed in Section 509(4).

Introduction

The purpose of this report is to determine whether Blue Cross and Blue Shield of Michigan (BCBSM) met the access, quality of care, and cost goals outlined in the Nonprofit Health Care Corporation Reform Act, MCLA 550.1101 et seq. (Act), with respect to the clinical laboratories provider class plan for the calendar years 2008 and 2009.

In addition to the final determination, this report will: define a provider class plan, explain the statutory review process, and provide a detailed summary of the data considered in reaching the determination as well as a statement of findings, which support that determination.

Provider Class Plans - Legal Background

Section 107(7) of the Act, defines a provider class plan as “a document containing a reimbursement arrangement and objectives for a provider class, and, in the case of those providers with which a health care corporation contracts, provisions that are included in that contract.” Simply stated, a provider class plan is a document that includes measurable objectives for meeting the nonprofit health care corporation's access, quality of care, and cost goals outlined in the Act.

Section 504(1) of the Act requires BCBSM to contract with or enter into a reimbursement arrangement with providers in order to assure subscribers reasonable access to, and reasonable cost and quality of, health care services in accordance with the following goals:

1. BCBSM must contract with or enter into reimbursement arrangements with an appropriate number of providers throughout the state to assure the availability of certificate covered health care services to each subscriber. Section 502(1) of the Act specifically indicates that a participating contract with providers includes not only agreements in which the providers agree to participate with BCBSM for all BCBSM members being rendered care, but also agreements in which the provider agrees to participate only on a per-case basis. Participation with BCBSM means that a provider of health care services agrees to accept BCBSM's approved payment as payment in full for services provided to a BCBSM member.
2. BCBSM must establish and providers must meet and abide by reasonable standards of quality for health care services provided to members.
3. BCBSM must compensate providers in accordance with reimbursement arrangements that will assure a rate of change in the total corporation payment per member to each provider class that is not higher than the compound rate of inflation and real economic growth.

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Section 509(4) of the Act requires the Commissioner of the Office of Financial and Insurance Regulation (Commissioner) to consider various types of information in making a determination with respect to the statutory goals. This information includes:

1. Annual reports filed by BCBSM, which pertain to each respective provider class;
2. Comments received from subscribers, providers, and provider organizations;
3. Health care legislation;
4. Demographic, epidemiological and economic trends;
5. Administrative agency or judicial actions; sudden changes in circumstances; and changes in health care benefits, practices and technology.

The Commissioner shall also assure an overall balance of the goals so that one goal is not focused on independently of the other statutory goals and so that no portion of BCBSM's fair share of reasonable costs to the provider are borne by other health care purchasers. After careful consideration of all of the information that was submitted or obtained for the record, the Commissioner must make one of the following determinations for each provider class plan pursuant to Section 510(1) of the Act:

- (a) That the provider class plan achieves the goals of the corporation as provided in Section 504 of the Act.
- (b) That although the provider class plan does not substantially achieve one or more of the goals of the corporation, a change in the provider class plan is not required because there has been competent, material, and substantial information obtained and submitted to support a determination that the failure to achieve one or more of the goals was reasonable due to the factors listed in Section 509(4) of the Act.
- (c) That the provider class plan does not substantially achieve one or more of the goals of the corporation as provided in Section 504 of the Act.

If the Commissioner determines that the plan does not substantially achieve one or more of the goals, without a finding that such failure was reasonable, BCBSM must transmit to the Commissioner within six months a provider class plan that substantially achieves the goals, achieves the objectives, and substantially overcomes the deficiencies enumerated in the findings. If after six months or such additional time as provided for in Section 512, BCBSM has failed to submit a revised provider class plan as stated above, the Commissioner must then prepare a provider class plan for that provider class.

Overview of the Clinical Laboratories Provider Class Plan

The clinical laboratories provider class covers the examination of human specimens for purposes of diagnosis, prevention and/or treating disease or impairment or to assess health.

For the period 2008-2009, payments to clinical laboratories represented an average of 0.3% of the total benefit payments made to health care providers on behalf of BCBSM members. For the purpose of provider class plan reviews by the Office of Financial and Insurance Regulation (OFIR), paid claims data are categorized by nine geographic regions. A map, which depicts these geographic regions, is included in Attachment A.

Participating clinical laboratories must be certified under and comply with the Clinical Laboratory Improvement Amendments (CLIA) and licensed by the state of Michigan. During the review period, clinical laboratories could participate with BCBSM only under its formal participation program. A formally participating provider has signed an agreement to accept BCBSM reimbursement as payment in full, excluding applicable co-payments or deductibles, for all covered services rendered to BCBSM members by the provider.

A requirement was added to the provider class plan qualification standards on July 1, 2009 that all clinical laboratories have and maintain licensure as a clinical laboratory by the state of Michigan in accordance with Act 368 of 1978 of the Public Health Code. BCBSM states that the state of Michigan previously intended to repeal this act and as a result, the state did not enforce the licensing requirement. Michigan recently changed its position and will begin enforcing the licensure requirement. BCBSM states it is following Michigan regulations in enforcing this requirement.

Most fees in BCBSM's Maximum Payment Schedule are based on the Resource Based Relative Value Scale (RBRVS) developed by the Centers for Medicare and Medicaid Services, in which services are ranked according to the resources needed to provide them. Resource values are assigned to each service based on the comparative value of all other services and they reflect time, training, skill, risk, procedure complexity, practice overhead and the cost of professional liability insurance. The relative values are then multiplied by a BCBSM-specific conversion factor to calculate fees.

During the two year period under review, laboratory services were reimbursed under BCBSM's Maximum Payment Schedule. BCBSM revised its reimbursement methodology for laboratory procedures not covered by the Resource Based Relative Value Scale (RBRVS). Previously, these tests were reimbursed at the Medicare fee screen plus a percentage determined by BCBSM. The fees for these procedures are now established by applying a factor determined by BCBSM to Medicare rates.

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BCBSM is required to include as part of each provider class plan its objectives toward achieving the goals specified in the Act. BCBSM's objectives with regard to the clinical laboratories provider class plan are as follows:

Access:

- To provide direct reimbursement to participating providers who render medically necessary, high-quality services to BCBSM members.
- Communicate with participating providers about coverage determinations, billing, benefits, provider appeals processes, BCBSM's record keeping requirements and the participation agreement and its administration.
- Maintain and periodically update a printed or Web site directory of participating providers.

Quality of Care:

- Ensure BCBSM members receive quality care by requiring participating providers to meet BCBSM's qualification and performance standards.
- Meet with specialty liaison societies to discuss issues of interest and concern.
- Maintain and update, as necessary, an appeals process that allows participating providers to appeal individual claims disputes and disputes regarding utilization review audits.

Cost:

- To strive toward meeting the cost goal within the confines of Michigan and national health care market conditions.
- To provide equitable reimbursement to participating providers through the reimbursement methodology outlined in the participation agreement.

History of the Clinical Laboratories Provider Class Plan

BCBSM had an existing reimbursement arrangement with clinical laboratories when the Act took effect on August 27, 1985. BCBSM first filed the clinical laboratories provider class plan with OFIR pursuant to Section 506(1) of the Act on July 13, 1987. Section 506(2) states:

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"Upon receipt of a provider class plan, the commissioner shall examine the plan and shall determine only if the plan contains a reimbursement arrangement and objectives for each goal provided in Section 504, and, for those providers with which a health care corporation contracts, provisions that are included in that contract."

Section 506(2) further states:

"For purposes of making the determination required by this subsection only, the commissioner shall liberally construe the items contained in a provider class plan."

Since the clinical laboratories provider class plan met the filing requirements of Section 506 of the Act stated above, OFIR notified BCBSM by letter on July 28, 1987 that the clinical laboratories provider class plan was placed into effect and retained for the Commissioner's records pursuant to Section 506(4).

The clinical laboratories provider class plan was modified by BCBSM on January 14, 1991, December 28, 1992, December 27, 1995, June 21, 1996, and August 26, 1997. BCBSM made various changes to the plan including the notification that laboratories be certified by and comply with the Clinical Laboratory Improvement Amendments (CLIA), notification that BCBSM's customary profile was eliminated so that participating providers would be reimbursed the lesser of billed charges or BCBSM's maximum screen, amendments to BCBSM's participation agreement, revisions to the appeals process, and the elimination of an insurance requirement that had been required by the provider class plan

On July 2, 2009, BCBSM filed modifications to the plan and participation agreement to update the qualification standards and reimbursement methodology that will be used for non-RBRVS services. BCBSM states that reimbursement for the procedure codes that are not based on relative value units (RVU) will be based on a BCBSM factor applied to the Medicare fee.

Review Process

On July 20, 2010, the Commissioner issued Order No. 10-049-BC, which provided written notice to BCBSM, health care providers, and other interested parties of his intent to make a determination with respect to the clinical laboratories provider class plan for the calendar years 2008 and 2009. Section 505(2) requires the Commissioner to establish and implement procedures whereby any person may offer advice and consultation on the development, modification, implementation, or review of a provider class plan. Thus, Order No. 10-049-BC also called for any person with comments on matters concerning this provider class plan to submit written comments to OFIR in accordance with Section 505(2) of the Act by September 22, 2010.

Summary of Advice and Consultation:

No testimony was submitted with regard to BCBSM's clinical laboratories provider class plan.

Discussion of Goals Achievement/Findings and Conclusions

Access Goal:

The access goal in Section 504(1) of the Act states that "[T]here will be an appropriate number of providers throughout this state to assure the availability of certificate-covered health care services to each subscriber."

In order to achieve compliance with the access goal, BCBSM needs to be able to assure, that in any given area of the state, a BCBSM member has reasonable access to laboratory services covered under the terms of that member's certificate of coverage whenever such treatment is required. In analyzing BCBSM's performance on the access goal, OFIR staff examined several aspects of how access to laboratory services could be obtained, including the formal participation rates of providers, to get an overall picture of how well BCBSM was assuring the availability of certificate-covered health care services to each member throughout the state.

The formal participation rates of independent clinical laboratories for calendar years 2008 and 2009 are presented below.

**Independent Clinical Laboratories
Formal Participation Rates by Geographic Region**

Formal Participation Rates	2007	2008	2009
Number Formally Participating Labs	88	81	71
All Licensed Providers	90	83	75
Formal Participation Rates	97.8%	97.6%	94.7%

BCBSM states that the participation rates among participating independent clinical laboratories exceeded 94% during the two year period under review.

BCBSM states it cannot identify the names and locations of the few non-participating clinical laboratories because there is no central listing available from the state of Michigan. BCBSM does have a participation agreement with one specialty laboratory provider located outside of Michigan and the claims associated with that specialty laboratory are submitted directly to BCBSM. Members who receive services from laboratory providers contracted by other Blue Cross Blue Shield (BCBS) plans are serviced by the local BCBS plan through the BlueCard program.

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BCBSM notes that laboratory services are also available and reported under the hospital, medical doctor, doctors of osteopathy and ambulatory surgery facilities (ASF) provider class plans. Rapid advances in automated technology have yielded instrumentation that is easy to operate, producing high quality test results. These advances enable physicians to conduct diagnostic laboratory tests in the office or ASF while the patient is being seen.

BCBSM states it is not able to separately identify all hospital-owned laboratories because hospital laboratories are covered under the hospital's license and bill under the hospital's provider identification number. Some hospitals have agreed to accept BCBSM's market-based pricing for laboratory services under the participating hospital agreement, meaning these hospitals accept the pricing established for independent clinical laboratories. BCBSM is able to identify those facilities. These facilities are located in most major metropolitan areas as well as most of the Lower Peninsula and Chippewa County in the Upper Peninsula.

BCBSM encourages its members to confirm the participation status of their health care providers before they receive services, particularly if their regular physician refers them for specialty care. BCBSM members can obtain current participating clinical laboratories information by calling BCBSM's toll-free customer service number. Current participating clinical laboratories information is available on BCBSM's website at www.bcbsm.com. BCBSM notes that its website directory is updated on a weekly basis and thus provides a great resource to BCBSM members seeking out participating providers. When seeking the participation status for clinical laboratories at www.bcbsm.com, members must select the appropriate coverage type (e.g. traditional) and then select independent lab specialty group under the "Looking for Health Care?" section. Members can filter this information by network affiliation, languages spoken, office hours and location.

BCBSM states that its web link at www.bcbsm.com offers both providers and members easy access to valuable information that supports and educates them in their relationship with BCBSM.

BCBSM states that enhanced channels of communication help establish and maintain a good rapport with participating providers. During the two year period under review, all providers received BCBSM's monthly newsletter, *The Record*, which communicates important, current information pertinent to the timely and efficient servicing of BCBSM members, including billing, reimbursement, policy changes, group-specific benefit changes and other provider-specific information. *The Record* was created with input from provider focus groups as an ongoing effort to improve communications with providers and to make BCBSM information more accessible to them. *The Record* is distributed to providers electronically via www.bcbsm.com.

Participating providers can access a comprehensive online provider manual on web-DENIS, which contains detailed instructions for servicing BCBSM members. The manual is

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updated as necessary allowing providers to obtain information on a real time basis. Topics detailed in the manual include:

- Member eligibility requirements
- Benefits and exclusions
- Criteria guidelines for services
- Documentation guidelines
- Claim submission information
- Appeals process
- Utilization review
- BCBSM departments to contact for assistance

BCBSM states it offers providers the options of speaking with provider service representatives, writing to its inquiry department, or working with an assigned provider consultant. BCBSM trainers educate providers with seminars on various topics such as how to use web-DENIS, benefits, claims processing, adjustments, InterQual[®] and Medicare Advantage. Computer based training tools have also been developed to expand the reach of the training sessions.

Web-DENIS offers BCBSM providers an Internet-based program via a secured provider portal on www.bcbsm.com. This program provides a quick delivery of contract eligibility, claims status, online manuals, newsletters, fee schedules, medical and benefit policy information for any procedure or revenue code, reports and much more information needed to make doing business with BCBSM easier. During 2008, BCBSM introduced a new search tool, Explainer, to web-DENIS. Explainer offers more information than the previous search tool and includes medical, benefit and payment policy information. Payment policy information provides member cost-sharing and dollar maximums with detail available at the procedure and revenue codes for selected time periods. Also during 2008, BCBSM simplified web-DENIS by standardizing the look of the screens for members' claims processed on the local and NASCO claims systems.

Another avenue for clinical laboratories to obtain needed information from BCBSM is CAREN⁺. CAREN⁺, BCBSM's integrated voice response system, receives 5 million calls from providers each year and provides information on eligibility, benefits, deductibles and copayments. In 2007, a new CAREN⁺ Inquiry Process was implemented using the new CAREN⁺ *Inquiry Submission* form and automated software. The new form is available on

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the Provider Services portal and provides one point of contact. This central point of contact automatically routes inquiries for appropriate handling and resolution.

BCBSM's Value Partnerships strategy is a fundamental approach to doing business that fosters on ongoing commitment to excellent performance and dialogue with providers. To better serve its communities and customers, BCBSM promotes business relationships with providers so they will:

- Collaborate with BCBSM to improve the health status of patients and the quality and cost effectiveness of care
- Help BCBSM deliver outstanding customer service to members
- Value BCBSM as a health plan of choice and recommend it to patients and others

During the two year period under review, BCBSM's key initiatives to improve provider experience were:

- A new online professional provider enrollment and credentialing system
- Electronic funds transfer for all professional providers, including clinical labs

Findings and Conclusions - Access

In order to achieve compliance with the access goal, BCBSM needs to be able to assure that in any given area of the state a member has reasonable access to certificate-covered clinical laboratory services, whenever such services are required. Based on the information analyzed during this review, BCBSM was able to maintain participation rates of 94% or more with independent clinical laboratories during the two year period under review. BCBSM demonstrated a commitment to excellent service through easily accessible electronic publications and tools and effective provider servicing. BCBSM also implemented a new, electronic provider enrollment and credentialing system during the two year period under review and expanded electronic funds transfer to all professional providers, including independent clinical laboratories. It is therefore determined that BCBSM met the access goal stated in the Act for calendar years 2008 and 2009 for the clinical laboratories provider class plan.

Quality of Care Goal:

The quality of care goal in Section 504(1) of the Act states that "[P]roviders will meet and abide by reasonable standards of health care quality."

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In analyzing BCBSM's performance on the quality of care goal, OFIR staff examined BCBSM's achievement of its quality of care objective, the methods BCBSM utilized in establishing and maintaining appropriate standards of health care quality, and BCBSM's methods of communication with clinical laboratories. We reviewed these factors to assure that BCBSM not only encouraged provider compliance with the expected standards of laboratory services, but also that it kept abreast of new technological advances available to treat those BCBSM members that require such services. All of the above factors impact the quality of health care services delivered to BCBSM members. The pertinent issues that were considered in reaching a determination with respect to the quality of care goal, based on the review of data provided by BCBSM and other sources during this review period, are described below.

To ensure acceptable levels of care provided by clinical laboratories, BCBSM requires that these providers meet the participation qualifications and performance standards listed on page 3 of this report. To be reimbursed for covered laboratory services, BCBSM required clinical laboratories to be certified under and compliant with the federal Clinical Laboratories Improvement Amendments (CLIA) and licensed by the state of Michigan. Testing personnel must be qualified and equipment must also be maintained. Laboratories must have quality standards in place to ensure that covered services are properly performed and appropriate for their intended purpose.

BCBSM performed utilization review audits of clinical laboratories during the two year period under review to ensure benefits paid by BCBSM on behalf of its customers are done so appropriately. BCBSM looks at several factors in determining whether a particular service is payable including, but not limited to, medical necessity, compliance with BCBSM program policies, coding standards, documentation and accuracy of billing.

Audits ensured contractual agreements were met and inappropriate payments are recovered. In some case, audits resulted in changes in provider behavior; changes in BCBSM policy; the addition or removal of edits to claim systems; provider education; provider corrective action plans; prepayment utilization review; de-participation from BCBSM programs or referral to BCBSM's Corporate and Financial Investigation (CFI) department.

BCBSM states that significant field audit findings for clinical laboratories during the two year period under review pertained to diagnosis codes that were not payable with the billed procedure codes.

The following table summarizes BCBSM's 2008-2009 quality assurance activity for the clinical laboratories class during the two-year period under review.

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	2008	2009
Number of Audits	1	2
Initial Identified Savings	\$1,600	\$1,500
Finalized Recoveries	\$1,600	\$400
Pending Recoveries	\$0	\$1,100
Referred to CFI	\$0	\$0

BCBSM states the primary audit finding was screening Pap smears billed with modifier 76. This caused the provider to be paid twice for the same procedure. Modifier 76 is billed for repeat procedures by the same physician on the same day. An example of its appropriate usage is on procedure codes that cannot be quantity billed. Since no more than one screening Pap smear should be conducted, BCBSM recovered the duplicate payment.

A secondary audit finding was the incorrect usage of ICD-9 codes for a Pap smear screening test. Examples of the wrong diagnosis are as follows:

- Patient 1 was billed with procedure code G0124 (screening Pap smear) and ICD-9 diagnostic code 795.01 (Papanicolaou smear of cervix with atypical squamous cells of undetermined significance). The correct diagnosis code should have been a V-code. V-codes represent preventative health care and should be billed with procedure codes for screening services.
- Patient 2 was billed with procedure code 88141 (cytopathology, cervical or vaginal requiring interpretation by physician) and V-code 76.2. The correct diagnosis should have been an ICD-9 code because the procedure was not for screening purposes but rather for diagnostic purposes.

BCBSM states this distinction is important because BCBSM only pays for one screening Pap smear a year. BCBSM will cover Pap smears required for diagnostic reasons as often as medically necessary.

One of BCBSM's objectives for the clinical laboratory provider class plan is to meet with specialty liaison societies to discuss issues of interest and concern. BCBSM states it did not receive any requests from laboratory specialty societies to meet during the two year under review. BCBSM states it solicits input on an ad hoc basis from clinical laboratory providers through web-DENIS. BCBSM intends to revise the objective for this provider class plan to reflect its current practices to communicate with laboratory providers about issues of interest and concern.

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BCBSM's 2009 quality initiatives included the patient-centered medical home program and the Healthcare Advisor resource. BCBSM states the patient centered medical home is an approach in which patients take an active role in their own health care, working closely with their primary care physicians (pediatricians, internists and family practice doctors) throughout the journey across the health care system. Doctors coordinate patients' health status, manage chronic conditions, track all medications, offer extended office hours and practice ongoing health management to keep patients healthy and prevent complications. Early identification and better management of chronic diseases contribute to increased use of lab services.

Many studies have found that having a regular source of care with the same physician over time leads to better health and lower overall cost of care. BCBSM states that a 2004 report in the *Annals of Family Medicine* concluded that if every American had a medical home, health care costs would decrease by 5.6%, resulting in national savings of \$67 billion per year and improved care quality.¹

In addition to the patient-centered medical home, BCBSM gives members access to a variety online tools, which provide valuable information to educate and empower members to manage their health and make better health care decisions. The Healthcare Advisor includes the following tools:

- *Health tools* option provides information on a wide variety of health conditions and treatment options
- *Provider Selection Advisor* allows members to select a physician by credentials, hospital affiliations, education and training as well as specific provider cost and quality components.
- *Hospital Advisor* allows members to compare hospitals on a number of factors related to hospital quality and cost of care through a link to the Michigan Hospital Inform website. This website provides publicly available Medicare hospital inpatient and outpatient charge and payment data, and quality data from Hospital Compare, a website created through the efforts of the Centers for Medicare and Medicaid Services (CMS).
- *Hospital Quality Advisor* displays rates for process of care measures that show how often hospitals provide care that is recommended for patients being treated for a heart attack, heart failure, pneumonia, or patients having surgery. Hospitals voluntarily submit data from their medical records about the treatments their adult patients receive for these conditions, including patients with or without Medicare.

¹ "BCBSM launches nation's largest program for Patient-Centered Medical Home," [Blues News Direct](#), April 22, 2009.

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- *Medicare Advisor* provides side-by-side comparisons of drugs, helping members consider their out-of-pocket costs, drug side effects and interactions, and cost savings opportunities.
- *Treatment Cost Advisory* helps members estimate the costs for hundreds of common conditions, procedures, tests and health care visits. Cost estimates represent “reasonable and customary” charges based upon average fees charged by health care practitioners in a specific geographic area.

BCBSM states the tools described above encourage collaboration among BCBSM, providers and members to improve member health status and the quality and cost effectiveness of care. These tools will also help BCBSM deliver outstanding customer service to members and demonstrate value by promoting better health care options and outcomes.

BCBSM states that Healthcare Advisor is a suite of online resources powered by WebMD. It features cost and quality information about drugs, physicians, hospitals and common health care services. These resources allow members to research providers such as physicians, hospitals and common health care services. These resources allow members to research providers such as physicians and hospitals that may order lab tests based on the member’s condition.

The Treatment Cost Advisory resource allows members to select from a multitude of conditions, procedures, tests, or health care visits (including laboratory services) to estimate the costs of those services. It is intended as a tool for members and is not associated with whether or not a service is a BCBSM covered benefit.

BCBSM maintains an appeal process that allows laboratories the right to appeal adverse claim decisions. The purpose of the appeal process is to resolve claim or audit disagreements. BCBSM states that most complaints regarding a BCBSM policy or practice can be resolved through its provider inquiry department or a BCBSM field service representative. A matter involving medical policy that cannot be resolved through these channels is referred by BCBSM to its medical policy consultants. Providers may also file appeals with OFIR alleging that BCBSM has violated specific provisions of Sections 402 and 403 of the Act. The appeal process includes a definition of contract issues that can be appealed and creates a single focal point within BCBSM for all appeals and disputes. Laboratories may submit a written request for an external peer review for disputes involving issues of medical necessity. If the laboratory provider selects this option, the decision of the external review agency is final and the laboratory may not then appeal to OFIR or in a state court. The appeal process is delineated in the Clinical Laboratory Participating Agreement and available to clinical laboratories on web-DENIS. Providers are also made aware of each step of the appeal process during utilization review audits and claim disputes.

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BCBSM's formal appeals process provides clinical laboratories with a mechanism for appealing audit or claims payment decisions. BCBSM erred in its annual report for clinical laboratories that four laboratory cases were pending OFIR review from 2008. After further review, BCBSM acknowledges that the status of the four appeals reported under the clinical laboratories provider class plan revealed that none of the providers were clinical laboratories. Two cases involved radiology clinics, one case involved a sleep clinic and one case involved a pain clinic. No cases involving clinical laboratories were appealed during the reporting period.

Findings and Conclusions - Quality of Care

In order to meet the quality of care goal, the provider class plan must assure that "providers will meet and abide by reasonable standards of health care quality." During calendar years 2008 and 2009, BCBSM continued to ensure that its qualification standards for participation were met, implemented quality controls by auditing laboratories to ensure that the services rendered to BCBSM patients were medically necessary and provided in an appropriate setting and had an established appeal process to deal with provider disputes. BCBSM acknowledged that one of its "standardized" objectives listed in all provider class plans is not commonly practiced with laboratory providers. BCBSM stated it will rewrite this particular objective to reflect its current business practices to communicate with laboratory providers about issues of interest and concern. As there was no input to dispute that clinical laboratories desire a change to the current methods of communication, it is therefore determined that BCBSM met the statutory goal for calendar years 2008 and 2009.

Cost Goal:

The cost goal in Section 504(1) of the Act states that "[P]roviders will be subject to reimbursement arrangements that will assure a rate of change in the total corporation payment per member to each provider class that is not higher than the compound rate of inflation and real economic growth."

After application of the cost formula found in Section 504 of the Act and using economic statistics published by the U. S. Department of Commerce, it is hereby determined that the measure that will be used to determine BCBSM's achievement of the cost goal shall be as follows:

The rate of change in the total corporation payment per member for the clinical laboratories provider classes for calendar years 2008 and 2009 shall not exceed (0.3)%.

The pertinent issues that were considered in reaching a determination with respect to the cost goal are described below.

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The cost goal formula, as stated in the Act, is

$$\frac{[(100 + I) \times (100 + \text{REG})]}{100} - 100 = \text{Compound rate of inflation and real economic growth}$$

"I" is "inflation" which is the arithmetic average of the percentage change in the implicit price deflator for GNP over the two calendar years immediately preceding the year in which the Commissioner's determination is being made.

"REG" is "real economic growth" which is the arithmetic average of the percentage change in per capita Gross National Product (GNP) in constant dollars over the four calendar years immediately preceding the year in which the Commissioner's determination is being made.

Given the August 2010 population data obtained from monthly population estimates published by the Bureau of Census, as obtained from the U. S. Census Bureau and economic statistics for the GNP and implicit GNP price deflator from the U. S. Department of Commerce, Bureau of Economic Analysis as published in August 2010 by the Federal Research Bank of St. Louis (research.stlouisfed.org/fred2/data/GNPC96.txt and research.stlouisfed.org/fred2/data/GNPDEF.txt), the following calculations have been derived:

I = Inflation as defined in the cost goal formula:

% change in implicit GNP price deflator

2008	2.7
2009	0.2

2 yr. average 1.5

REG = Real Economic Growth as defined in the cost goal formula:

% change in per capita GNP in constant dollars

2006	0.5
2007	2.3
2008	(0.8)
2009	(4.2)

4 yr. average (1.8)

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Using the latest population and economic statistics available, the cost goal for the period under review is estimated to be (0.3)%, as shown below:

Inflation = 1.5

Real Economic Growth = (1.8)

$$\frac{[(100 + 1.5) \times (100 + (1.8))]}{100} - 100 = (0.3)\%$$

Section 517 of the Act requires BCBSM to transmit an annual report to OFIR, which includes data necessary to determine the compliance or noncompliance with the cost and other statutory goals. The report must be in accordance with forms and instructions prescribed by the Commissioner and must include information as necessary to evaluate the considerations of Section 509(4).

As stated in Section 504(2)(e) of the Act, the “[R]ate of change in the total corporation payment per member to each provider class’ means the arithmetic average of the percentage changes in the corporation payment per member for that provider class over the 2 years immediately preceding the commissioner’s determination.” The cost and membership data for the clinical laboratories provider class plan for the calendar years 2008 and 2009, as filed with OFIR by BCBSM, are delineated below. Cost data reflect claims incurred in the calendar year and paid through February 28th of the following year.

**Clinical Laboratories
 Utilization and Payment Experience**

	2007	2008	2009	Two Year Average Rate of Change
Total Members	213,293	155,090	146,378	
Total Services	561,008	551,191	564,291	
Total Payments	\$8,323,943	\$7,414,602	\$6,628,309	
Cost Performance				
Services/1000 Members	2,630.22	3,554.00	3,855.03	21.8%
Payment/Service	\$14.84	\$13.45	\$11.75	(11.0)%
Payments/1000 Members	\$39,025.78	\$47,808.33	\$45,282.24	8.6%

Overall, the two-year arithmetic average increase for the clinical laboratories provider class plan equals 8.6%. BCBSM’s combined payment experience for clinical laboratories by type of service is shown below. Payments per 1,000 members increased an average of

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8.6% as a result of an average increase in services per 1,000 members of 21.8% and an 11% percent decline in average payment per service.

Procedure Category	Two Year Average Rate of Change			Three Year Payout	% of Total Payout	Percent Contribution to Trend
	Payments/ 1000 members	Services/ 1000 members	Payment/ Service			
Automated Multichannel	0.8%	19.1%	15.5%	\$395,974	1.8%	0.3%
Chemistry	10.3%	26.9%	(13.3)%	\$6,123,923	27.4%	32.2%
Cytopathology	19.6%	17.1%	2.2%	\$2,154,094	9.6%	20.3%
Hematology & Coagulation	2.3%	17.7%	(13.0)%	\$805,003	3.6%	1.2%
Immunology	4.3%	24.6%	(16.5)%	\$1,291,895	5.8%	3.0%
Microbiology	6.4%	22.6%	(13.6)%	\$1,886,469	8.4%	6.1%
Organ/Disease Panels	2.6%	19.2%	(14.2)%	\$4,159,974	18.6%	6.4%
Surgical Pathology	8.3%	13.8%	(4.0)%	\$4,190,926	18.7%	18.2%
Urinalysis	5.7%	22.1%	(13.4)%	\$99,362	0.4%	0.3%
All Others	23.2%	24.8%	(3.4)%	\$1,259,235	5.6%	12.0%
Total	8.6%	21.8%	(11.0)%	\$22,366,855	100.0%	100.0%

As illustrated above, three procedure categories accounted for over 70% of the increase in laboratory payments during the two year period under review. Increased utilization was the driver in the payment trend. Chemistry procedures had the most significant impact on the payment trend, accounting for 32.2% of the growth in costs. Payment rates increased 10.3% while use increased 26.9%. Payment per service declined 13.3%. Almost one-third of the total spending on laboratory payments during the two year period under review was for chemistry procedures. Most routine tests to diagnose and monitor common chronic conditions such as hypertension, high cholesterol and diabetes, fall within this procedure category.

Cytopathology services accounted for 20.3% of the total cost trend growth. Cytopathology is the examination of cells from the body under the microscope to identify the signs and characteristics of disease, most commonly pap smears. Payment rates increased 19.6% and utilization grew by 17.1%. Payment per service increased 2.2%.

Surgical pathology procedures accounted for 18.2% of cost growth. Surgical pathology is the study of tissues removed from living patients during surgery to help diagnose a disease and determine a treatment. Payment per 1,000 members grew 8.3%, largely the result of a 13.8% increase in utilization. Payment per service for this category declined 4%.

BCBSM states that in 2009, the top 25 procedure codes related to the major procedure categories represented nearly 51% of all clinical laboratory services and 56% of total lab procedures. Utilization was the driving force behind the increases in 2009 laboratory payments. The most highly utilized clinical laboratory service was lipid panels. Other

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highly utilized services included blood counts, thyroid testing, metabolic panels, pap smears and PSA tests. Members appeared to increase their utilization of preventive services which may help to decrease future costs for treating more severe conditions.

The regional cost and utilization data is shown below. Regions 1 (Southeast Michigan) and region 6 (Grand Rapids/Western Michigan) had the highest payout where over 50% of BCBSM's membership using independent clinical laboratories reside.

Region	Two Year Average Rate of Change			Three Year Payout	% of Total Payout
	Payments/ 1000 members	Services/ 1000 members	Payment/ Service		
1	9.3%	21.9%	(10.6)%	\$19,084,997	85.3%
2	(60.1)%	(42.3)%	(22.3)%	\$9,714	0.0%
3	93.7%	158.8%	(24.6)%	\$228,741	1.0%
4	2.6%	8.7%	(3.1)%	\$645,058	2.9%
5	12.9%	19.6%	(5.9)%	\$576,023	2.6%
6	(0.4)%	0.4%	(0.8)%	\$1,730,407	7.7%
7	(51.6)%	(60.7)%	534.8%	\$2,500	0.0%
8	34.9%	18.8%	14.1%	\$74,370	0.3%
9	12.9%	24.6%	(8.1)%	\$15,044	0.1%
Total	8.6%	21.8%	(11.0)%	\$22,366,854	100.0%

BCBSM states that membership under the clinical laboratories provider class decreased 27.3% in 2008 and 5.6% in 2009. The number of members receiving services from a clinical laboratory remained relatively unchanged, but due to membership declines, the proportion of utilizing members grew 13% during the reporting period.

The use of laboratory testing helps to keep health care costs down by detecting health problems early, confirming diagnoses and providing information to guide the treatment of diseases. BCBSM states that effective September 1, 2009, BCBSM changed its fee screens for laboratory services covered under its traditional program to match those being paid under BCBSM's PPO coverage, thereby eliminating the five percent fee differential between products. This change resulted in administrative efficiencies for BCBSM and cost savings for BCBSM customers as BCBSM no longer needs to update and communicate to providers two separate fee schedules. Cost savings are achieved by eliminating the higher traditional fees.

The health status of BCBSM members largely contributed to the increased utilization of laboratory services. Chronic illnesses are one of the greatest threats to Americans' health. Chronic illnesses are categorized as ongoing, generally incurable illnesses or conditions such as heart disease, cancer, asthma, arthritis and diabetes. Primary care physicians'

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compliance with clinical practice guidelines, emphasis on preventive medicine and chronic disease management are all driving the growth in clinical laboratory testing. Diabetes, high cholesterol and high blood pressure account for a significant proportion of clinical laboratory spending growth due to an increase in the number of people being tested, according to a study of laboratory spending for Medicare beneficiaries.²

BCBSM states that national spending for clinical laboratory services is currently estimated to be approximately \$40 billion. The United States clinical laboratory industry is comprised of four major groups: hospital, independent, physician office labs, and research and reference labs. Research and reference laboratories perform highly specialized, low volume services to other laboratories and account for about 7% of the market. Hospital based and independent laboratories have 54% and 32% of the total market, respectively, with physician office laboratories having the remaining 7% of the market.

BCBSM states that the clinical laboratory services market is growing as new competitors enter the market. An essential part of the health care industry, it is estimated that approximately 80% of physicians' diagnoses are a result of laboratory tests. In addition to diagnosing disease, clinical laboratory testing is performed to evaluate disease progression, monitor the effectiveness of medications and to individualize medication therapy to meet the needs of patients.

A number of factors will continue to drive higher spending for laboratory services, including:

- ✓ An aging population
- ✓ Increased life expectancy
- ✓ Greater use of preventive and risk factor testing, particularly in the areas of oncology, endocrinology and gynecology
- ✓ Growing disease incidence
- ✓ Increased availability of specialty tests
- ✓ Developments in personalized medicine, which uses the patient's own genes, proteins and environment to prevent, diagnose and treat diseases, particularly cancers.

BCBSM's efforts to control costs are many, yet there are other factors that impact BCBSM's ability to contain costs within the constraints of the cost goal specified in the Act. The most prominent factors include an aging population and the overall health status of Michigan residents. Many Michigan residents have one or more chronic conditions. Michiganders are also living longer because of the development of cutting-edge technologies in medical diagnosis and treatment and the significant advances made in prescription drug therapy used to treat chronic conditions. Thus, as people with chronic conditions tend to have greater health care needs and are the most frequent users of

² Thorpe, Kenneth E. and David K. Howard. "The Rise in Spending Among Medicare Beneficiaries: The Role of Chronic Disease Prevalence and Changes in Treatment Intensity," *Health Affairs*, Vol. 25, No. 5 (September/October 2006).

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health care services (regardless of age); the costs associated with these needs are disproportionately high.

Michigan ranks poorly on many measures of lifestyle factors and health status related to the development of chronic conditions, including obesity, diabetes, hypertension and cancer. Growing rates in these areas will continue to fuel increased use of health care services and will continue to be a major driver of higher health care spending as physicians order laboratory testing to diagnose and monitor these diseases.

Findings and Conclusions - Cost

Based on the cost information analyzed during this review, it is determined that BCBSM did not meet the cost goal stated in the Act for the clinical laboratories provider class during the two year period under review. This decision is based on the fact that the rate of change in the total corporation payment per member for the clinical laboratories provider class has been calculated to be 8.6% over the two years being reviewed, and therefore exceeded the compound rate of inflation and real economic growth of (0.3)%.

BCBSM's efforts to cost health care costs are many, yet there are other factors that impact BCBSM's ability to contain costs within the constraints of the cost goal specified in the Act. The most prominent factors include an aging population, and the overall health status of Michigan residents. Many Michigan residents have one or more chronic conditions. Michiganders are also living longer because of the development of cutting-edge technologies in medical diagnosis and treatment and the significant advances made in prescription drug therapy used to treat chronic conditions. Thus, as people with chronic conditions tend to have greater health care needs and are the most frequent users of health care services (regardless of age); the costs associated with these needs are disproportionately high. People with chronic conditions tend to use laboratory services more frequently to monitor the progression of their diseases.

Michigan ranks poorly on many measures of lifestyle factors and health status related to the development of chronic conditions, including obesity, diabetes, hypertension and cancer. Growing rates in these areas will continue to fuel increased use of health care services and will continue to be a major driver of higher spending for laboratory services as physicians order laboratory testing to diagnose and monitor these diseases.

Because of this, it is not necessary to require that a change to the current clinical laboratories provider class plan be filed pursuant to Section 511 of the Act. BCBSM is encouraged to continue to work closely with physicians, as well as all provider class plan groups, to find new, innovative programs and evidence based practice guidelines that instill responsible cost controls so that all the goals and objectives of the corporation can be achieved.

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Determination Summary

In summary, BCBSM achieved two of the three goals of the corporation during the two-year period under review for the clinical laboratories provider class. Although the clinical laboratories provider class plan did not substantially achieve the cost goal, a change in this plan is not required because, as concluded above, there has been competent, material, and substantial information obtained or submitted to support a determination that the failure to achieve the cost goal was reasonable, due to factors listed in Section 509(4).

ATTACHMENT A

