



JENNIFER M. GRANHOLM
GOVERNOR

STATE OF MICHIGAN
OFFICE OF FINANCIAL AND INSURANCE REGULATION
DEPARTMENT OF ENERGY, LABOR & ECONOMIC GROWTH
STEVE "SKIP" PRUSS, DIRECTOR

KEN ROSS
COMMISSIONER

July 20, 2010

MEMORANDUM

To: Health Care Providers, BCBSM Subscribers, Interest Groups,
and Other Interested Parties

From: Susan M. Scarane *SMS*
Health Plans Division

Subject: Public Input on Blue Cross Blue Shield of Michigan's
Clinical Laboratories Provider Class Plan

Under 1980 P.A. 350, as amended, the Nonprofit Health Care Corporation Reform Act (Act), Blue Cross Blue Shield of Michigan (BCBSM) must develop and maintain a "provider class plan" for each type of health care provider that provides services to BCBSM subscribers. A provider class plan must include a description of the reimbursement arrangement used by BCBSM to pay providers; measurable objectives for meeting the access, quality of care, and cost goals specified by Section 504 of the Act; and, in the case of those providers with which BCBSM contracts, a copy of the provider contract. Each plan must also show how BCBSM proposes to balance the goals stated above.

Attached is a copy of Order No. 10-049-BC, dated July 20, 2010, providing notice of intent to make a determination on the clinical laboratories provider class plan, pursuant to Section 509(2) of the Act. BCBSM's clinical laboratories provider class plans filed on December 15, 2006 and July 2, 2009 will be the subject of this review. These provider class plan documents are available at the OFIR website at www.michigan.gov/ofir.

Section 505(2) of the Act requires that the Commissioner of Financial and Insurance Regulation (OFIR) establish a procedure to gain input into the review and development of provider class plans prepared by BCBSM. Attachment A to the Order For Notice of Intent to Review contains a list of questions pertaining to the clinical laboratories provider class plan. We would appreciate any comments you may have with respect to these questions or any other matters concerning the clinical laboratories provider class plan.

Written testimony will be accepted through September 22, 2010, when mailed, faxed or e-mailed to:

Office of Financial and Insurance Regulation
Health Plans Division
Attention: Susan M. Scarane
P. O. Box 30220
Lansing, MI 48909
Fax: (517) 241-4168
E-mail: scaranes@michigan.gov

BCBSM is required to file an annual report for each provider class with the Commissioner of Financial and Insurance Regulation regarding the level of achievement of the above-mentioned goals. Pursuant to Section 517 of the Act, these reports need to include the data necessary to make a determination of BCBSM's compliance or noncompliance with the goals and compliance with objectives contained in each provider class plan. BCBSM's 2008-2009 annual report for the clinical laboratories provider class is available at the OFIR website at www.michigan.gov/ofir.

If you prepare and distribute a newsletter or other publication, I would ask that you include information about the opportunity to provide written testimony on BCBSM's clinical laboratories provider class plan in any such publication for the benefit of your readership. All of the BCBSM materials identified in this memorandum are available at the OFIR website at www.michigan.gov/ofir or you may obtain a copy of these documents by contacting Mindy Hilton at (517) 241-4549. Thank you for your assistance in this regard.

If you have any questions regarding the above referenced matter, please contact me at (517) 335-2052.

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

Before the Commissioner

In the matter of notice of intent to make a
determination with respect to the Clinical
Laboratories Provider Class Plan of Blue Cross
Blue Shield of Michigan pursuant to Section 509(2)
of 1980 P. A. 350

No. 10-049-BC

_____/

Issued and entered
this 20th day of July 2010
by Ken Ross
Commissioner

**ORDER FOR NOTICE OF
INTENT TO REVIEW**

I

BACKGROUND

Section 509(1) of 1980 P. A. 350, as amended (Act), being MCLA 550.1101 et seq.; MSA 24.660 (101) et seq., allows the Commissioner of Insurance and Financial Regulation (Commissioner) to determine whether the arrangements Blue Cross Blue Shield of Michigan (BCBSM) has established with health care providers have substantially achieved the cost, access and quality of care goals set forth in the Act.

The Commissioner is required to evaluate enough BCBSM provider class plans to account for at least 75% of the corporation's provider payments during a 3-year period. The latest 3 year period began on January 1, 2010 and ends December 31, 2012. The Commissioner intends to review the provider class plan for clinical laboratories at this time.

Section 509(2) of the Act requires the Commissioner to give written notice to BCBSM, and to each person who has requested a copy of such notice, of his intent to make a determination with respect to the provider class plans filed by BCBSM. Section 509(2) grants the Commissioner six months in which to reach his determinations:

Provider Class Plan
Page 2

Section 505(2) of the Act requires the Commissioner to establish and implement procedures whereby any person, including a subscriber, may offer advice and consultation on the development, modification, implementation, or review of provider class plans.

In addition to the requirement to gain input on the review and development of provider class plans, there is need to establish an accurate record of the comments presented to the Commissioner. The record can then serve as part of the basis for the determinations that will be made by the Commissioner with regard to BCBSM's achievement of the goals of Section 504.

II

FINDINGS OF FACT AND CONCLUSIONS OF LAW

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

1. Pursuant to Section 509(2) of the Act, the Commissioner shall give written notice to BCBSM, and to each person who has requested a copy of such notice, that he intends to make a determination with respect to a particular provider class plan. The Commissioner shall have 6 months in which to reach a determination.
2. Pursuant to Section 505(2) of the Act, the Commissioner must establish a procedure to gain input into the review and development of provider class plans prepared by BCBSM. The statute is silent as to the method chosen by the Commissioner to fulfill this responsibility.
3. The procedure established by the Commissioner should facilitate the presentation of information by any person and encourage input.

III

ORDER

Therefore, it is ORDERED that:

1. A determination shall be made with respect to the clinical laboratories provider class plan. The evaluation period shall include calendar years 2008 and 2009. A determination with respect to the clinical laboratories provider class plan will be made by January 20, 2011.
2. This order shall serve as notice of intent to make a determination with respect to the above stated provider class plan pursuant to Section 509(2) of the Act.

Provider Class Plan
Page 3

3. Questions of interest pertaining to the clinical laboratories provider class plan are included in Attachment A. Pursuant to Section 505(2), written comments will be accepted with regard to these questions or any other matters concerning the clinical laboratories provider class plan through September 22, 2010, when sent to:

Office of Financial and Insurance Regulation
Health Plans Division
Attention: Susan M. Scarane
P. O. Box 30220
Lansing, MI 48909
scaranes@michigan.gov

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

**BLUE CROSS BLUE SHIELD OF MICHIGAN
CLINICAL LABORATORIES PROVIDER CLASS PLAN
QUESTIONS OF INTEREST
JULY 20, 2010**

ACHIEVEMENT OF STATUTORY GOALS

The Office of Financial and Insurance Regulation needs to answer the following questions to determine whether Blue Cross Blue Shield of Michigan's (BCBSM) provider contracts and reimbursement arrangements for clinical laboratories have met the access, quality and cost goals specified in Section 504 of the Act:

1. Does BCBSM have participation agreements with an appropriate number of clinical laboratories throughout Michigan to assure that each subscriber has access to covered services?
2. Has BCBSM established and maintained reasonable standards of health care quality for participating clinical laboratories?
3. Do the reimbursement arrangements for clinical laboratories assure that the rate of change in BCBSM payment per member to those providers is not higher than the compound rate of inflation and real economic growth?

The Commissioner needs to consider the overall balance of the goals achieved by BCBSM under the clinical laboratories provider class plan. Weight is to be given to each of the three statutory goals so that one goal is not focused on independently of the other statutory goals. Comments on how achievement of these goals can best be measured and evaluated will assist the Commissioner in making a determination.

ACHIEVEMENT OF BCBSM'S OBJECTIVES

BCBSM must include objectives in each provider class plan. These are expected achievement levels for the goals of reasonable access, cost and quality of health care services. The Office of Financial and Insurance Regulation needs to also determine whether BCBSM has achieved the objectives contained in the clinical laboratories provider class plan and how the objectives relate to the statutory goals. Comments regarding the appropriateness and importance of BCBSM's objectives will assist the Office of Financial and Insurance Regulation in making these determinations.

A. ACCESS:

The BCBSM access objectives in the clinical laboratories provider class plan under review are to:

BCBSM – Clinical Laboratories
Questions of Interest
Page 2

- Provide direct reimbursement to participating providers who render high-quality services to BCBSM members
- Communicate with participating providers about coverage determinations, billing, benefits, provider appeal 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

What types of information and data should the Office of Financial and Insurance Regulation examine to determine whether or not BCBSM has met its access objective?

Would meeting BCBSM's access objective be sufficient to assure that cost effective, quality services provided by clinical laboratories are available, throughout the state, to BCBSM subscribers?

B. QUALITY OF CARE:

The BCBSM objectives in the clinical laboratories provider class plan under review are to:

- 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

What types of information and data should the Office of Financial and Insurance Regulation examine to determine whether BCBSM has met its quality of care objective?

Would meeting BCBSM's quality of care objective be sufficient to assure that clinical laboratories actually meet and abide by reasonable standards of health care quality? Is it also necessary or desirable to consider:

1. Whether BCBSM has satisfactorily recognized changes that have taken place in the health care industry?

BCBSM – Clinical Laboratories
Questions of Interest
Page 3

2. The ability of BCBSM to process claims in a reasonable and timely manner? Whether BCBSM has satisfactorily provided for a reasonable period for the implementation of policy and claims processing system changes?
3. The need for prompt, reasonable explanations from BCBSM regarding reimbursement issues, medical necessity determinations, audit determinations, etc.?
4. Whether BCBSM has established reasonable internal procedures for promptly resolving disputes?

C. COST:

BCBSM's achievement of this statutory goal is determined by the application of the cost goal formula found in Section 504 of the Act.

BCBSM's cost objectives in the clinical laboratories provider class plan under review are to:

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

The Office of Financial and Insurance Regulation examines existing cost, utilization and communication patterns, the appropriateness of BCBSM's reimbursement arrangements with providers and the overall impact of access and quality of care concerns on cost goal achievement as part of the review process. Comments on the appropriateness of BCBSM's reimbursement arrangements with clinical laboratories, focusing on whether or not such reimbursement arrangements assure a rate of change in BCBSM payment per member that is not higher than the compound rate of inflation and real economic growth, would be welcome.

**Blue Cross
Blue Shield**
of Michigan



600 E. Lafayette Blvd.
Detroit, Michigan 48226-2998

June 25, 2010

Ms. Susan M. Scarane
Departmental Specialist
Health Plans Division
Office of Financial and Insurance Regulation
611 West Ottawa Street
Lansing, MI 48933

Dear Ms. Scarane:

Enclosed is the detailed report for the Clinical Laboratory Provider Class Plan. I also included the 2006 and 2009 participation agreements and the 2006 and 2009 provider class plans as these documents are applicable to the time period under review.

Please let me know if you need any additional information at this time. Thank you.

Sincerely,

Lisa Varnier
Assistant General Counsel

Enclosures



A nonprofit corporation and independent licensee
of the Blue Cross and Blue Shield Association

Clinical Laboratories Provider Class Plan Detailed Report 2008-2009

EXECUTIVE SUMMARY

Goal Achievement

BCBSM met the access and quality of care goals during the reporting period. Although the cost goal for the clinical laboratory provider class was not independently met, there is competent, material and substantial information to support a determination that the failure to achieve the goal was reasonable in accordance with Section 510(1)(b) of PA 350.

Cost Performance

BCBSM did not meet the cost goal during the reporting period. Payments per 1000 members increased an average of 8.6 percent compared to the cost goal, which limited the increase in payments to 1.3 percent. The higher payment trend was due to increased use, which grew 21.8 percent. Payment per service declined 11.0 percent during the reporting period.

Lab procedures related to chemistry, cytopathology and surgical pathology accounted for approximately 70 percent of the growth in the cost trend.

Access Performance

BCBSM met the P.A. 350 access goal by providing an appropriate number of providers to ensure access to clinical laboratory services. In addition to clinical laboratories, members can also access lab services through participating hospitals and physician offices.

Quality of Care Performance

BCBSM ensured that participating clinical laboratories met and abided by reasonable standards of health care quality. Initiatives that promoted quality of care included:

- ◆ Qualification standards required for participation ensured that providers were appropriately licensed and certified. Licensure by the state of Michigan was added as a qualification standard as a result of a change by the state of Michigan to require and enforce licensure requirements for clinical labs.
- ◆ Quality controls implemented through utilization review audits ensured that benefits paid by BCBSM on behalf of its customers were appropriately administered.

PLAN OVERVIEW

Providers

Clinical laboratories

Qualifications

Clinical laboratories must be certified under and comply with the Clinical Laboratory Improvement Amendments (CLIA) and licensed by the state of Michigan. Testing personnel must be qualified and equipment must be adequately maintained. Labs must establish and maintain quality standards to ensure services are properly performed and appropriate for the purpose intended.

Participation Status

Formal basis only

Scope of Service

The scope of service is defined as examination of human specimens for purposes of diagnosis, prevention, or treating disease or impairment or to assess health.

Benefit Issues

No benefit issues were raised during this reporting period.

Plan Updates

As of July 1, 2009, the plan was amended to reflect revisions in BCBSM qualification standards and reimbursement methodology.

BCBSM added a requirement that all labs must have and maintain licensure as a clinical laboratory by the state of Michigan in accordance with Public Health Code, Act 368 of 1978. The state of Michigan previously intended to repeal this act and as a result, the state did not enforce the licensure requirement. The state recently changed its position and will begin enforcing the licensure requirement. BCBSM will follow the state in enforcing this requirement.

Laboratory services are reimbursed under BCBSM's Maximum Payment Schedule. BCBSM revised its reimbursement methodology for laboratory procedures not covered by the Resource Based Relative Value Scale. Previously, these tests were reimbursed at the Medicare fee *plus* a

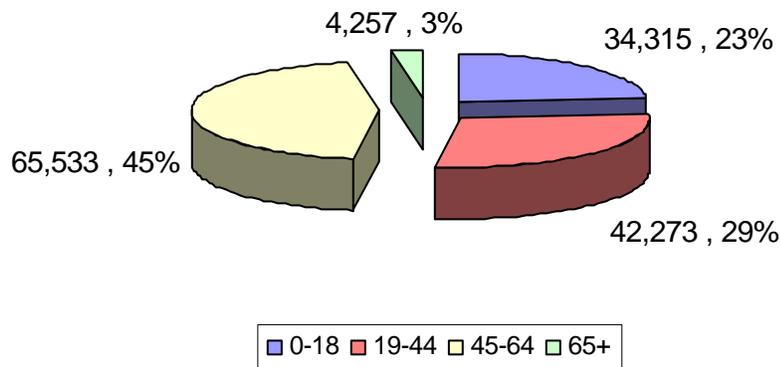
percentage determined by BCBSM. The fees for these procedures are now established by applying a factor determined by BCBSM to Medicare rates.

Membership

This report covers clinical laboratory experience for BCBSM members enrolled in the Traditional program. During the 2007 to 2009 reporting period, membership for the clinical laboratory provider class declined 31.4 percent or by approximately 67,000 members. In 2009, 146,378 members were enrolled in BCBSM's Traditional product, which represented 6 percent of total BCBSM membership. While membership declined, the proportion of members utilizing their lab benefits increased. In 2007, 33 percent of members had one or more lab services, compared to 46 percent of members who had lab services in 2009.

Reasons behind declining membership include Traditional members moving to managed care products, members losing health benefits through their employers, work force reductions, aggressive competitor pricing and a declining economy.

Chart 1
Clinical Laboratories Provider Class
2009 Members by Age Category



EXTERNAL INFLUENCES

Market Share

Table 1 illustrates BCBSM's commercial (private) market share for members with clinical laboratory benefits. As shown, BCBSM's share of the commercial market in Michigan for the Traditional product remained constant between 2008 and 2009 at 2.2 percent.

Table 1
Traditional Clinical Laboratories Share of Michigan Market

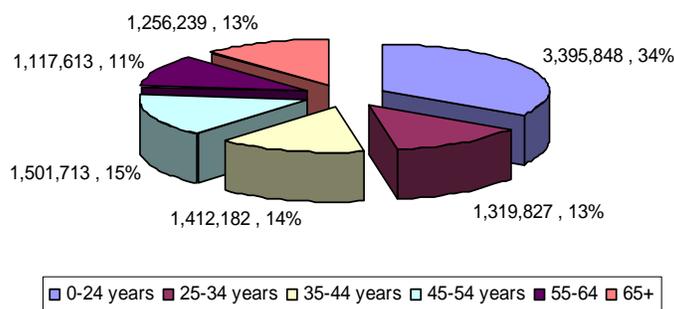
Region	2009 Michigan Population*	2009 BCBSM Lab Members	Market Share	2008 Michigan Population*	2008 BCBSM Lab Members	Market Share
1	2,958,016	64,337	2.2%	3,020,371	70,193	2.3%
2	393,213	9,098	2.3%	401,502	9,017	2.2%
3	435,027	10,032	2.3%	444,198	10,466	2.4%
4	332,932	5,204	1.6%	339,950	5,400	1.6%
5	737,343	18,542	2.5%	752,886	17,309	2.3%
6	869,150	19,879	2.3%	887,471	23,157	2.6%
7	482,237	9,915	2.1%	492,403	10,550	2.1%
8	321,476	6,288	2.0%	328,253	6,564	2.0%
9	223,123	3,083	1.4%	227,827	2,435	1.1%
Statewide	6,752,518	146,378	2.2%	6,894,860	155,090	2.2%

* Excludes Medicare and Medicaid recipients

Demographics

The characteristics of a population may significantly affect that population's consumption of health care resources. Michigan residents aged 45-64 comprised 26 percent of the state's overall population compared to 25 percent for the same age group in the United States. Michigan's median age of 37.5 is slightly higher than the national median age of 36.6. Chart 2 provides a distribution of Michigan's population in 2008 by age group.

Chart 2
2008 Michigan Population by Age Category



Epidemiological Factors

Chronic illnesses are one of the greatest threats to Americans' health. More than 133 million Americans, approximately 45 percent of the population, have at least one chronic condition. Chronic illnesses are categorized as ongoing, generally incurable illnesses or conditions such as heart disease, cancer, asthma and diabetes. Without changes in mindset and an emphasis on preventive care, chronic conditions are expected to rise significantly by the year 2023 as illustrated in Chart 3.¹ Although chronic diseases are among the most common and costly health problems, they are also among the most preventable and most can be effectively controlled.²

Primary care physicians' compliance with clinical practice guidelines, emphasis on preventive medicine and chronic disease management are all driving the growth in clinical lab testing. Diabetes, high cholesterol and high blood pressure account for a significant proportion of lab spending growth due to an increase in the number of people being tested, according to a study of lab spending for Medicare beneficiaries.³

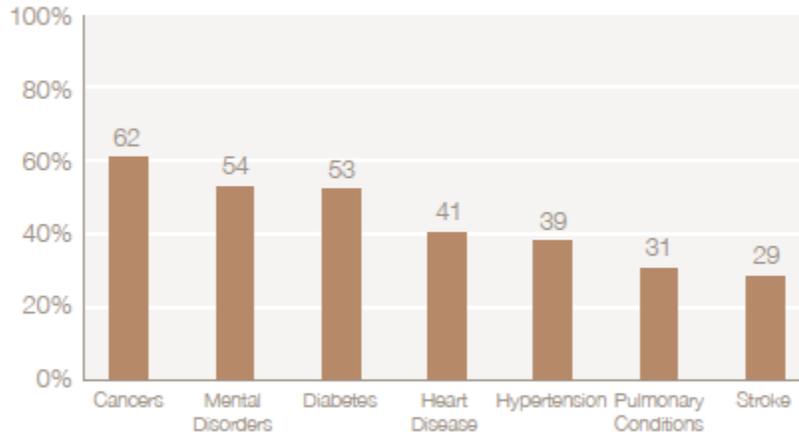
¹ http://www.hlc.org/PFCDAImanac_ExecSum.pdf

² <http://cmcd.sph.umich.edu/what-is-chronic-disease.html>

³ K.E. Thorpe, D. K. Howard. "The Rise in Spending Among Medicare Beneficiaries: The Role of Chronic Disease Prevalence and Changes in Treatment Intensity." *Health Affairs*, 25, no. 5.

Chart 3⁴

Projected Rise in Cases of Seven of the Most Common Chronic Diseases, 2003-2023*



*This study evaluated the burden of seven of the most common chronic diseases/conditions (cancer, diabetes, heart disease, hypertension, mental disorders, pulmonary conditions, and stroke).
Source: The Milken Institute

National Health Care Spending

In 2009, total national health expenditures were projected to rise 5.7 percent reaching \$2.5 trillion dollars. Total health care spending represented 17.3 percent of gross domestic product in 2009. The expected acceleration in growth for 2009 was due in part to projected faster growth in the use of services as many sought treatment for the H1N1 virus and in part to expected increases in subsidized coverage provided through the Consolidated Omnibus Budget Reconciliation Act (COBRA).⁵

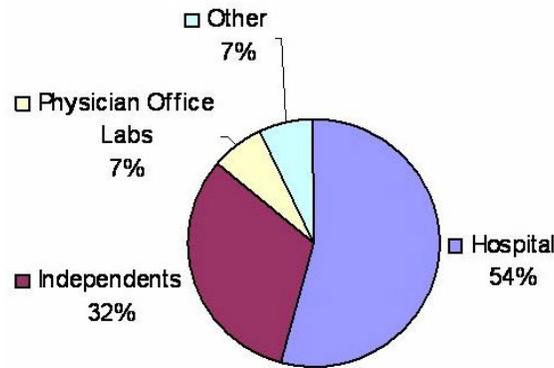
National spending for clinical laboratory services is currently estimated to be approximately \$40 billion. The U.S. clinical laboratory industry is comprised of four major groups: hospital, independent, physician office labs, and research and reference labs. Research and reference labs perform highly specialized, low volume services to other labs. These groups divide the total lab market (total revenue) as is depicted in the following chart:⁶

⁴ http://www.hlc.org/PFCDAImanac_ExecSum.pdf

⁵ <http://www.cms.gov/NationalHealthExpendData/downloads/proj2009.pdf>

⁶ <http://www.clbslab.com>.

Chart 4
Lab Industry Total Revenue (\$40B)



The clinical laboratory services market is growing as new competitors enter. An essential part of the health industry, it is estimated that approximately 80% of physician's diagnoses are a result of laboratory tests. In addition to diagnosing disease, clinical lab testing is performed to evaluate disease progression, monitor drug treatment and individualize therapies.⁷

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 disease⁸

⁷ <http://www.the-infoshop.com/study/kl76151-clinical-labo.html>.

COST GOAL PERFORMANCE

“Providers 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.” This is expressed by the following formula:

$$\left[\frac{(100 + I) * (100 + REG)}{100} \right] - 100$$

Objectives

- ◆ Strive toward meeting the cost goal within the confines of Michigan and national health care market conditions
- ◆ Provide equitable reimbursement to participating providers through the reimbursement methodology outlined in the participating agreement

Performance

Although the cost goal for the clinical laboratories provider class was not met, there is competent, material and substantial information to support a determination that the failure to achieve the goal was reasonable in accordance with Section 510(1)(b) of PA 350.

**Table 2
Clinical Laboratories Provider Class
2007-2009 Performance to Cost Goal**

	2009	2008	2007
Payments			
Total	\$6,628,309	\$7,414,602	\$8,323,943
Per 1,000 members	\$45,282.24	\$47,808.33	\$39,025.78
% change	-5.3%	22.5%	
Services			
Total	564,291	551,191	561,008
Per 1,000 members	3,855.03	3,554.00	2,630.22
% change	8.5%	35.1%	
Payment/Service			
	\$11.75	\$13.45	\$14.84
% change	-12.7%	-9.3%	
Members			
	146,378	155,090	213,293
Achievement of Cost Goal			
Two Year Average Percent Change:	8.6%	<i>2009 percent of Total Payout reported to OFIR*</i>	
P.A. 350 Cost Goal	1.3%	0.3%	
Goal Not Met		<i>2009 ASC Business</i>	46.1%

*Payout reported to OFIR includes Traditional claims for the hospital, MD, DO, clinical laboratory, fully licensed psychologist, podiatrist, chiropractor, rehabilitation therapy and ESRD provider classes. Traditional and PPO claims are included for the outpatient psychiatric care and substance abuse provider classes. Traditional, PPO and POS claims are included for the SNF, home health care, ASF, hospice, DME/P&O, ambulance, nurse specialists, HIT, dental, vision, hearing and pharmacy provider classes. See the technical notes section for more details.

The following factors impacted cost performance:

Cost Trends

Payments per 1000 members to clinical laboratories increased an average of 8.6 percent as a result of an average increase in services per 1000 members of 21.8 percent and an 11.0 percent decline in average payment per service.

Reimbursement

Each year maximum payment levels were recalculated to take into account actual utilization and relative value units that the Center for Medicare and Medicaid Services assigned to procedure codes. The process involves applying a BCBSM-specific conversion factor to the relative value unit assigned to each procedure code to update fees. This process does not necessarily result in an increase in maximum payment level for each procedure code.

The aggregate increases for RVU-based fees were 2.5 percent effective July 1, 2007 and 2.5 percent effective July 1, 2008. In September 2009, the 5 percent fee differential between Traditional and PPO fees was eliminated for professional providers, including clinical labs. This change resulted in a 2.5 percent decline in aggregated fees for Traditional providers.

Major Payout Categories

Three procedure categories accounted for over 70 percent of the increase in lab payments during the reporting period. Increased use was the driver of the 8.6 percent clinical lab payment trend.

Chemistry procedures had the most significant impact on the payment trend, accounting for 32.2 percent of the growth in costs. Payment rates increased 10.3 percent while use increased 26.9 percent. Payment per service declined 13.3 percent. Almost one-third of total spending during the reporting period was for chemistry procedures. Most routine tests to diagnose and monitor common chronic health conditions, such as hypertension, high cholesterol and diabetes, fall within this category.

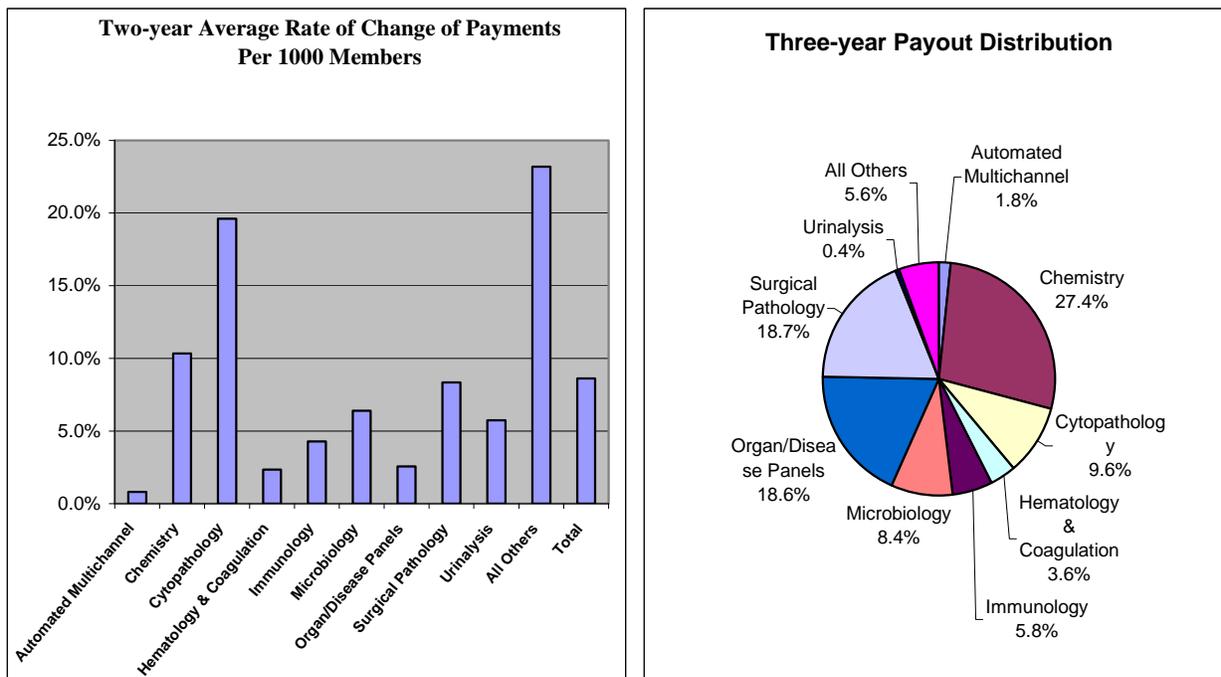
Cytopathology services accounted for 20.3 percent of total cost trend growth. Cytopathology is the examination of cells from the body under the microscope to identify the signs and characteristics of disease, most commonly pap smears. Payment rates increased 19.6 percent and use grew by 17.1 percent.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

Surgical pathology procedures accounted for 18.2 percent 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 rates grew 8.3 percent as a result of a 13.8 percent increase in use. Payment per service declined 4.0 percent.

Table 3
Clinical Laboratory Trends by Major Procedure Category
2007-2009

Procedure Category	Two-year Average Rate of Change			Three-year Payout	% of Total Payout	Percent Contribution to Trend
	Payments Per 1000 Members	Services Per 1000 Members	Payment Per 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%

**Table 3A
Clinical Laboratory Trends by Major Procedure Category
2007-2009**

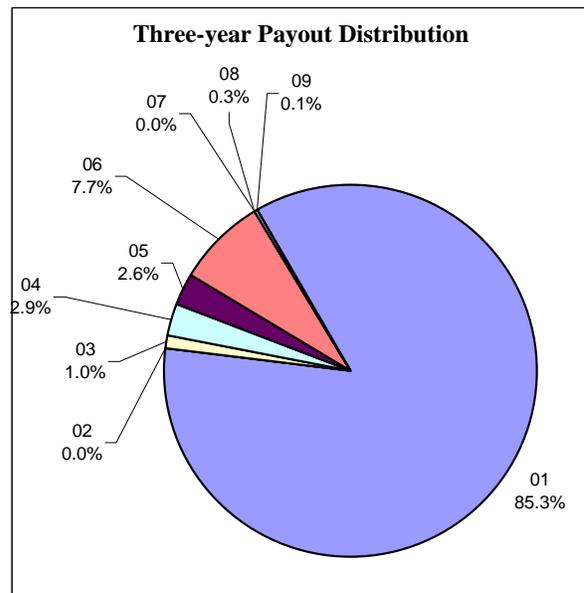
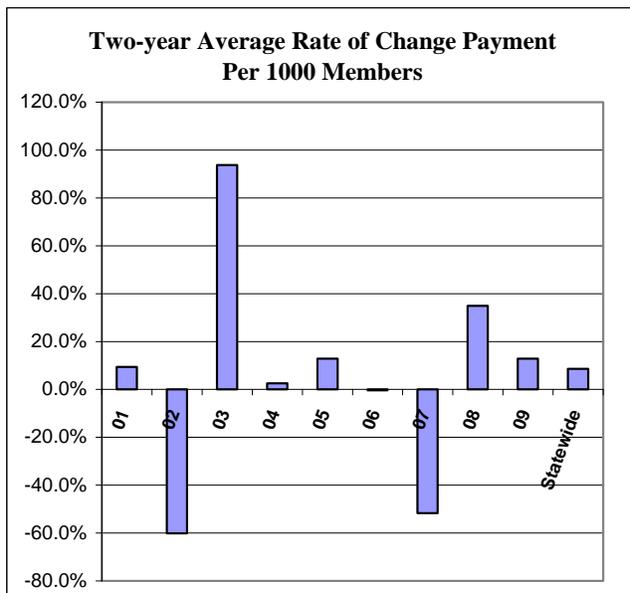


In 2009, the top 25 procedure codes related to the major procedure categories represented nearly 51 percent of all clinical laboratory services and 56 percent of total lab payments. Utilization was the driving force behind the increases in 2009 clinical laboratories. The most highly utilized clinical laboratory service was lipid panels. Other 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. Appendix C illustrates the top clinical lab procedures by use for years 2007, 2008 and 2009.

The regional cost and utilization data below mirror the membership detailed in Table 1. The percent of payout is greatest in regions 1 and 6 where over half of the 2009 clinical laboratories membership resides.

**Table 4
Clinical Laboratory Trends by Region
2007-2009**

Region	Two-year Average Rate of Change			Three-year Payout	% of Total Payout
	Payments Per 1000 Members	Services Per 1000 Members	Payment Per Service		
01	9.3%	21.9%	-10.6%	\$ 19,084,997	85.3%
02	-60.1%	-42.3%	-22.3%	\$ 9,714	0.0%
03	93.7%	158.8%	-24.6%	\$ 228,741	1.0%
04	2.6%	8.7%	-3.1%	\$ 645,058	2.9%
05	12.9%	19.6%	-5.9%	\$ 576,023	2.6%
06	-0.4%	0.4%	-0.8%	\$ 1,730,407	7.7%
07	-51.6%	-60.7%	534.8%	\$ 2,500	0.0%
08	34.9%	18.8%	14.1%	\$ 74,370	0.3%
09	12.9%	24.6%	-8.1%	\$ 15,044	0.1%
Statewide	8.6%	21.8%	-11.0%	\$22,366,855	100.0%



Membership

Membership under the clinical laboratories provider class decreased 27.3 percent in 2008 and 5.6 percent in 2009. The number of members who received services from a clinical lab remained relatively unchanged, but due to membership declines, the proportion of utilizing members grew 13 percent during the reporting period.

Cost Controls

Clinical laboratories helped to keep health care costs down by detecting health problems early, confirming diagnoses and providing information to guide the treatment of diseases. Effective September 1, 2009, BCBSM applied PPO fees to Traditional clinical labs, eliminating the 5 percent fee differential between products. This change resulted in administrative efficiencies for BCBSM and cost savings for BCBSM customers. BCBSM no longer needs to update and communicate to providers two separate fee schedules. Cost savings are achieved by eliminating the higher Traditional fees.

ACCESS GOAL PERFORMANCE

“There will be an appropriate number of providers throughout this state to assure the availability of certificate-covered health care services to each subscriber.”

Objectives

- ◆ 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 participating agreement and its administration
- ◆ Maintain and periodically update a printed or website directory of participating providers

Performance

The access goal for clinical laboratories was met during the review period. There was an appropriate number of participating laboratories throughout the state to assure the availability of certificate-covered health care services to each subscriber.

Table 5
Clinical Laboratories Provider Class
2007-2009 Access

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

The following factors impacted access performance:

Participation Rates

Formal participation rates exceeded 94 percent during the reporting period.

Participation Policies

Clinical laboratories only participated on a formal basis.

Contract Issues

BCBSM revised the contract to reflect the provider class plan updates implemented on July 1, 2009. The revisions related to BCBSM qualification standards and reimbursement methodology and impacted Addendums B and C of the contract.

Provider Communications

BCBSM's channels of communication helped establish and maintain a good rapport with participating providers.

Publications and Services

BCBSM publishes *The Record*, a monthly source of information that communicates billing, reimbursement, group-specific benefit changes, and day-to-day business information from BCBSM. *The Record* is distributed to providers electronically via 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 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 offers providers the options of speaking with provider service representatives, writing to our 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.

BCBSM provides members with access to a searchable on-line provider directory at bcbsm.com. Members can search for participating laboratory providers by network affiliation, languages spoken, office hours and location at bcbsm.com.

Inquiry Systems

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 over the world wide web. 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 code levels 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 providers to obtain needed information from BCBSM is CAREN⁺. This integrated voice response system receives 5 million calls from providers each year and provides information on eligibility, benefits, deductibles and copayments.

Strategies and Initiatives

BCBSM's Value Partnerships strategy is a fundamental approach to doing business that fosters an ongoing commitment to excellent performance and dialogue with providers. To better serve our 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

Value Partnerships initiatives implemented during the reporting period that pertain to the access goal included:

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

Unique Access Issues

Laboratory services are also available and reported under the hospital, MD, DO and ambulatory surgery facilities provider class plans. Rapid advances in automated technology have yielded instrumentation that is easy to operate, producing high-quality test results. These advancements enable physicians to conduct diagnostic laboratory tests in the office or ASF while the patient is being seen.

QUALITY OF CARE GOAL PERFORMANCE

“Providers will meet and abide by reasonable standards of health care quality.”

Objectives

- ◆ 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 or disputes regarding utilization review audits

Performance

The quality of care goal for clinical laboratories was met during the reporting period. BCBSM took steps to ensure that clinical laboratories met and abided by reasonable standards of health care quality.

The following factors impacted quality of care performance:

Qualifications

To be reimbursed for covered lab 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. In addition, testing personnel must be qualified and equipment must be adequately maintained. Laboratories must have quality standards in place to ensure that covered services are properly performed and appropriate for their intended purpose.

Provider Relations

Clinical laboratories routinely received *The Record*, which provided information regarding billing practices, changes in reimbursement policies and other administrative issues that allowed them to render appropriate care to BCBSM members.

BCBSM's formal appeals process provided clinical laboratories with a mechanism for appealing audit or claims payment decisions. In 2009, there was one new lab request for determination received from the Office of Financial and Insurance Regulation and one lab decision made by OFIR. At year end, four lab cases remained pending from 2008.

Quality Controls

Utilization review audits 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 cases, audits result 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 department.

During this reporting period, primary audit findings for clinical laboratories pertained to diagnosis codes not payable with the billed procedure codes.

The following table provides 2008 - 2009 audit activity.

Table 6
Clinical Laboratory Audit Results
2008-2009

	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 Corporate Financial Investigation	0	0

BCBSM Member-Focused Quality Initiatives

BCBSM 2009 quality initiatives included the patient-centered medical home program and the Healthcare Advisor resource.

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. 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 percent, resulting in national savings of \$67 billion per year and improved care quality.⁸

In addition to the patient-centered medical home, BCBSM gives members access to a variety of on-line 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 MI 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 & 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.
- *Medication Advisor* provides side-by-side comparisons of drugs, helping members consider your 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.

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.

⁸ "BCBSM launches nation's largest program for Patient-Centered Medical Home," [Blues News Direct](#), April 22, 2009.

CONCLUSION

Cost Goal

With an average increase of 8.6 percent in payments per 1000 members, BCBSM did not achieve the cost goal of 1.3 percent. The lab cost trend growth was entirely due to increased use of services. Services per 1000 members grew an average of 21.8 percent while payment per service declined 11 percent during the reporting period.

Access Goal

BCBSM met the access goal by exceeding 94 percent participation among available clinical laboratory providers in the state of Michigan. Additionally, BCBSM demonstrated a commitment to excellent service through easily accessible electronic publications and tools, effective provider servicing and training opportunities. BCBSM implemented a new, electronic provider enrollment and credentialing system during the reporting system and expanded electronic funds transfer to all professional providers, including clinical labs.

Quality of Care Goal

BCBSM met the quality of care by ensuring providers met and abided by reasonable standards of health care quality. Providers were required to be certified and compliant with the federal Clinical Laboratories Improvement Amendments. The provider class plan was updated in 2009 requiring participating labs to be licensed as a clinical laboratory in the state of Michigan, in accordance with a recent change in the Michigan Public Health Code.

Clinical laboratory audits were conducted to ensure that benefits were paid appropriately based on medical necessity, compliance with BCBSM program policies, coding standards, documentation, and accuracy of billing.

BCBSM implemented a number of member-focused initiatives, including the patient centered medical home and member access to on-line tools via bcbsm.com to promote patient-engagement and improving the value of care provided.

APPENDIX A

Overview of Public Act 350

This section briefly describes the provider class plan annual reporting requirements mandated under Public Act 350.

Annual reporting requirements

The provider class plan annual reports are submitted pursuant to section 517 of PA 350, which requires BCBSM to submit to the Commissioner an annual report for each provider class that shows the level of BCBSM's achievement of the goals provided in section 504.

PA 350 Goals

The term "goals", used in section 517 above, refers to specific cost, access and quality goals described in section 504. This section states:

"A health care corporation shall, with respect to providers, contract with or enter into a reimbursement arrangement to assure subscribers reasonable access to, and reasonable cost and quality of health care services in accordance with the following goals:

Cost Goal

"Providers 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." This is expressed by the following formula:

$$\left[\frac{((100 + I) \times (100 + REG))}{100} \right] - 100$$

Access Goal

"There will be an appropriate number of providers throughout this state to assure the availability of certificate-covered health care services to each subscriber."

Quality of Health Care Goal

"Providers will meet and abide by reasonable standards of health care quality."

Cost Goal Calculation

P.A. 350 Cost Goal Formula

The P.A. 350 cost goal formula , as stated in the Act is:

$$\frac{((100 + I) \times (100 + \text{REG}))}{100} - 100$$

Goal Calculations

<u>Year of Determination</u>	<u>2010</u>
I (CY 2007 - 2008)	1.324%
REG (CY 2008 - 2005)	-0.004%

Applying these indices into the formula, the cost goal becomes:

$$\frac{((100 + I\%) \times (100 + \text{REG}\%))}{100} - 100 = \mathbf{1.320\%}$$

PA 350 Cost Goal Assumptions

Year	Population (1)	Real GNP (2)	Per Capita GNP	Implicit GNP Price Deflator (3)	Percent Change	
					PC GNP	IPD
2005	295,507,000	\$ 12,825,600,000,000	\$ 43,402.02	101.31		
2006	298,217,000	\$ 13,129,500,000,000	\$ 44,026.67	104.22	1.439%	2.872%
2007	300,913,000	\$ 13,563,300,000,000	\$ 45,073.83	107.07	2.378%	2.735%
2008	303,598,000	\$ 13,240,500,000,000	\$ 43,611.95	109.17	-3.243%	1.961%
2009	305,529,000	\$ 13,246,000,000,000	\$ 43,354.31	109.92	-0.591%	0.687%

(1) Population projections based on 2000 census released May 11, 2004
[www.census.gov/ipc/www/usinterimproj/usproj_detail_file RTT](http://www.census.gov/ipc/www/usinterimproj/usproj_detail_file_RTT) (Total Resident Population)

(2) <http://research.stlouisfed.org/fred2/series/GNPC96/downloaddata?cid=106>

(3) <http://research.stlouisfed.org/fred2/series/GNPDEF/downloaddata?cid=21>

Definitions

Section 504 of the Act also provides the following definitions for terms used in the cost goal calculation:

“Gross Domestic Product (GDP) in constant dollars’ means that term as defined and annually published by the United States Department of Commerce, Bureau of Economic Analysis.”

“Implicit price deflator for gross national product’ means that term as defined and annually published by the United States Department of Commerce, Bureau of Economic Analysis.”

“Inflation’ (I) means the arithmetic average of the percentage changes in the implicit price deflator for gross national product over the 2 calendar years immediately preceding the year in which the commissioner's determination is being made.”

“Compound rate of inflation and real economic growth’ means the ratio of the quantity 100 plus inflation multiplied by the quantity 100 plus real economic growth to 100; minus 100.”

“Rate 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.”

“Real economic growth’ (REG) means the arithmetic average of the percentage changes in the per capita gross national product in constant dollars over the 4 calendar years immediately preceding the year in which the commissioner's determination is being made.”

Determination Process

Under PA 350, the commissioner is required to consider information presented in the annual report, as well as all other relevant factors that might affect the performance of a particular provider class, in making a determination with respect to that class.

Section 509 of the Act outlines factors that should be considered by the commissioner to “determine if the health care corporation has substantially achieved the goals of a corporation as provided in section 504 and achieved the objectives contained in the provider class plan.” Many of these factors are beyond BCBSM's direct control and may adversely impact the cost and use of health care services for a particular provider class. Specifically, section 509(4) states:

The commissioner shall consider all of the following in making a determination...:

(a) Annual reports transmitted pursuant to section 517.

(b) The overall balance of the goals provided in section 504, achieved by the health care corporation under the plan. The commissioner shall give weight to each of the goals provided in section 504, shall not focus on one goal independently of the other goals of the corporation, and

shall assure that no portion of the corporation's fair share of reasonable costs to the provider are borne by other health care purchasers.

(c) Information submitted or obtained for the record concerning:

- ◆ Demographic trends;*
- ◆ Epidemiological trends;*
- ◆ Long-term economic trends, including changes in prices of goods and services purchased by a provider class not already reflected in the calculation in section 504(2)(d);*
- ◆ Sudden changes in circumstances;*
- ◆ Administrative agency or judicial actions;*
- ◆ Changes in health care practices and technology; and,*
- ◆ Changes in benefits that affect the ability of the health care corporation to reasonably achieve the goals provided in section 504.*

(d) Health care legislation of this state or of the federal government. As used in this subdivision, 'health care legislation' does not include Act No. 218 of the Public Acts of 1956, as amended, being sections 500.100 to 500.8302 of the Michigan Compiled Laws.

(e) Comments received from an individual provider of the appropriate provider group, or from an organization or association that represents the appropriate provider class, and comments received pursuant to section 505(2).

After considering the information and factors described in section 509(4), the goals of a health care corporation as provided in sections 504, and the objectives contained in the provider class plan, the commissioner shall determine one of the following [as stated under section 510(1)]:

(a) That the provider class plan achieves the goals of the corporation as provided in section 504.

(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 or submitted to support a determination that the failure to achieve one or more of the goals was reasonable due to factors listed in section 509(4).

(c) That a provider class plan does not substantially achieve one or more of the goals of the corporation as provided in section 504.

A determination made by the commissioner under section 510 1(a) or 1(b) would require no further action by the corporation. Upon a 511(1)(c) determination by the commissioner, under section 511, the corporation:

(1) Within 6 months or a period determined by the commissioner..., shall transmit to the commissioner a provider class plan that substantially achieves the goals, achieves the objectives, and substantially overcomes the deficiencies enumerated in the findings made by the commissioner pursuant to section 510(2). In developing a provider class plan under this subsection, the corporation shall obtain advice and consultation from providers in the provider class and subscribers, using procedures established pursuant to section 505.

If after 6 months or a period determined by the commissioner..., the health care corporation has failed to act pursuant to subsection (1), the commissioner shall prepare a provider class plan..., for that provider class.

The findings of the commissioner may be disputed by any party through an appeals process available under section 515 of PA 350.

APPENDIX B

Technical Notes

The data indices presented in the 2007, 2008 and 2009 databases and analyzed in the annual reports reflect a defined subset of BCBSM claims experience. The data specifications and collection methodologies are discussed in the following sections.

Data Elements and Collection

The basic statistics analyzed for each provider class are total payments and utilization, from which an average price per utilization unit is derived. These data were collected from BCBSM data files that are based on claims submitted to the Corporation and approved for payment to the provider or in some cases, the subscriber.

The data collection period captures health care services incurred during specific twelve-month calendar years and paid through fourteen months. For example, the 2009 dataset includes all services incurred between 1/1/09 and 12/31/09, and paid from 1/1/09 through 2/28/10. It is reasonable to expect that for any provider class a significant percent of total experience is captured.

Participation rates are based on providers who sign a BCBSM participation agreement and the total number of licensed providers registered with BCBSM.

Scope of the Data

Provider Class Accountability

PA 350 requires BCBSM to report its Traditional line of business for the purposes of provider class accountability. However, for the ancillary provider classes, including pharmacy, managed care experience is included. BCBSM membership systems capture members' product line information only once, reflecting the member's MD/medical-surgical coverage (e.g., a member with managed care pharmacy coverage but traditional MD/medical-surgical coverage is considered a traditional member).

Underwritten groups and administrative services contracts are included. For ancillary provider classes, complementary claims and membership data is included. The data excludes the Federal Employee Program and non-Michigan liability such as claims paid through the Inter-Plan Teleprocessing System for out-of-state Blue members. Claims incurred out-of-state by BCBSM members are also excluded.

Blue Care Network data are excluded from the reporting requirements referred to in PA 350 Section 502(a) (11) and the HMO Act.

Regional Experience

Regions selected for analysis are compatible with Michigan Metropolitan Statistical Areas (MSAs) and provide an acceptable basis for analysis of access as well as of provider practice patterns.

The data cover total Traditional business, divided into nine regions. Regions one through nine represent groups of Michigan counties. Michigan claims experience with unidentified zip codes was allocated among the nine regions according to the distribution of data with identifiable zip codes.

Membership

This report includes all BCBSM Traditional members residing in Michigan.

The regions used for analysis pertain to the location where services were delivered. For example, region one experience represents payments to region one providers for services rendered to BCBSM members regardless of residency. This is because subscribers who live in one region may receive services in another region because they reside near a border or want services from a provider in another region.

Methodology to Calculate Percent Average Contribution to Trend

The percent average contribution to trend illustrates each component's share of the change in the cost trend (e.g., total payment per 1000 members). The percent average contribution to trend is calculated as follows using payments per 1000 members for three consecutive years. Table B1 is provided for illustration purposes.

Step 1: Calculate the contribution to trend for each two-year period using payments per 1000 (PPT) members as follows: $(\text{Year 2 PPT} - \text{Year 1 PPT}) / \text{Year 1 Total PPT}$.

Step 2: Calculate the average annual contribution to trend for the two time periods.

Step 3: Calculate the percent contribution to trend by dividing the average annual contribution to trend by total average annual contribution to trend.

Table B1
Percent Contribution to Trend Example

Major Diagnostic Category	Payments/1000 Members			Step 1 Contribution to Trend		Step 2 Avg. Annual Cont. to Trend	Step 3 Percent Cont. to Trend
	2007	2006	2005	2006-2007	2005-2006		
Musculoskeletal	\$ 12,339.00	\$ 10,557.00	\$ 8,332.00	9%	14%	12%	78%
Digestive	\$ 6,528.00	\$ 6,332.00	\$ 6,001.00	1%	2%	2%	10%
Other	\$ 2,127.00	\$ 1,998.00	\$ 1,572.00	1%	3%	2%	11%
TOTAL	\$ 20,994.00	\$ 18,887.00	\$ 15,905.00	11%	19%	15%	100%
Percent Change	11%	19%	NA				

APPENDIX C

Supporting Tables

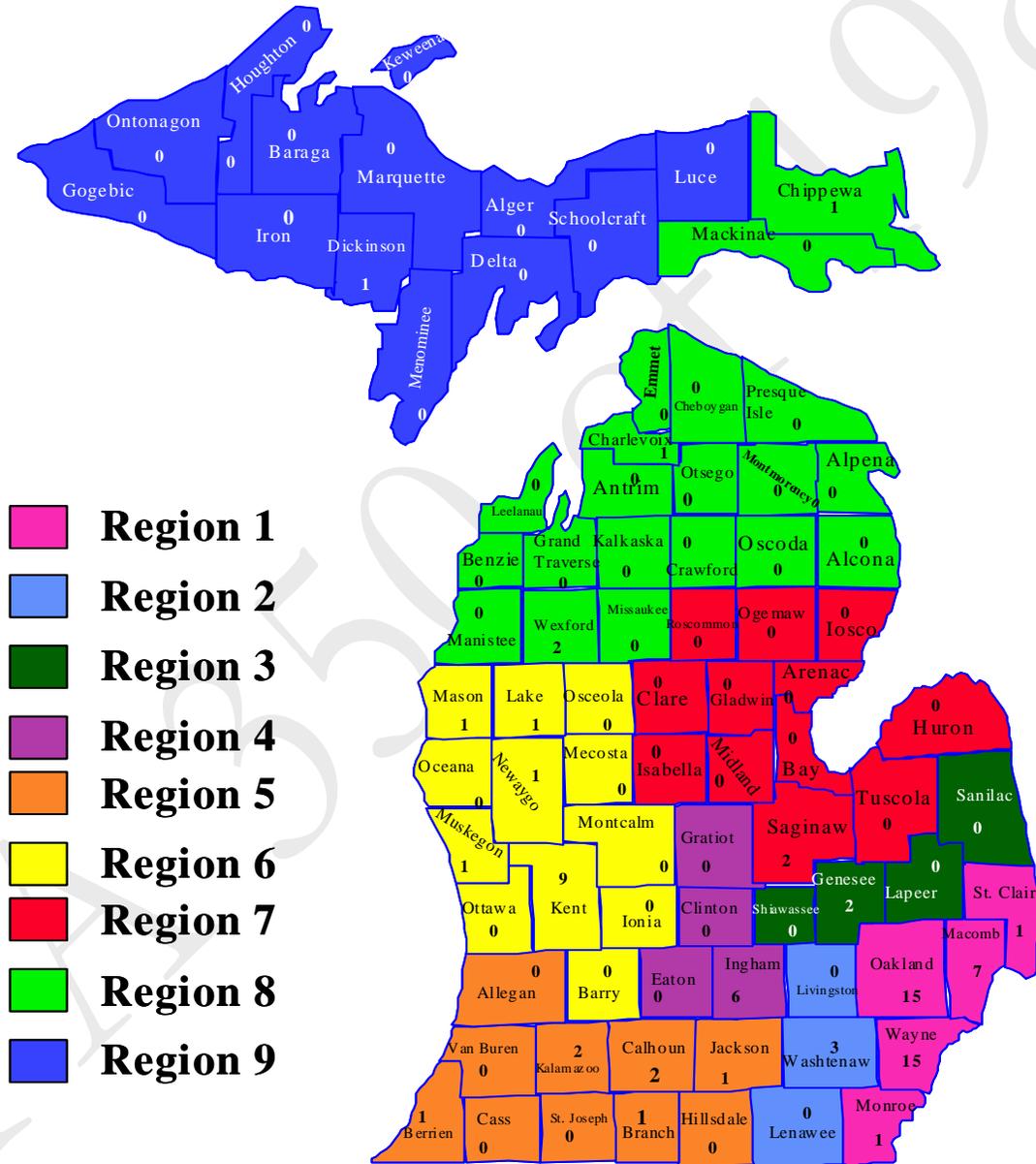
Procedure Code	Description	2009 Payments	2009 Services
80061	LIPID PANEL	\$ 357,456	36,239
85025	BLD CT; HG/PLTLT CT AUTO/COMPLT WBC	\$ 158,710	24,440
80053	COMPREHENSIVE METABOLIC PANEL (DO NOT USE W/ 80048, 80076)	\$ 241,821	18,496
84443	THYROID STIM HORMONE	\$ 228,121	18,358
80050	GENERAL HEALTH PANEL	\$ 422,529	13,743
84450	TRANSFERASE; ASPARTATE AMINO	\$ 11,882	13,049
83036	HGB; GLYCATED	\$ 108,940	13,048
84460	TRANSFERASE; ALANINE AMINO	\$ 11,677	12,884
84439	THYROXINE; FREE	\$ 85,692	12,408
82565	CREATININE; BLD	\$ 10,828	10,983
84153	PROSTATE SPEC ANTIG	\$ 162,533	10,410
88305	LEVEL IV-SURG PATH GROSS/MICRO EXAM	\$ 971,975	10,091
84520	UREA NITRO; QUAN	\$ 8,795	9,509
G0145	Screening cytopathol,cerv/vag,in fluid,auto thin layer prep,scr w/phys cell sel	\$ 350,574	9,473
82306	CALCIFEDIOL	\$ 224,439	8,988
84550	URIC ACID; BLD	\$ 8,363	8,480
81001	UA DIP STICK/TABLET; AUTO W/MICRO	\$ 22,496	8,370
82947	GLU; QUAN	\$ 7,552	7,951
80051	ELECTROLYTE PANEL INCL: CO2(82374), CHLORIDE(82435), POTAS(84132), SODIUM(84295)	\$ 23,110	6,196
87086	CULT BACTERIAL URIN; QUAN COLONY CT	\$ 37,830	5,997
82550	CREATINE KINASE; TOT	\$ 5,517	5,673
80048	BASIC METABOLIC PANEL (DO NOT USE W/ 80053)	\$ 43,211	5,521
G0123	Screening cytopathology,cerv/vag,in fluid,auto thin layer prep,cytotech+phys scr	\$ 148,513	5,333
84100	PHOSPHORUS INORGANIC	\$ 5,091	5,036
83615	LACTATE DEHYDROGENASE	\$ 4,889	5,028
Top 25 Procedures Subtotal		\$ 3,662,543	285,704
Total All Procedures		\$ 6,628,309	564,291
Top 25 Procedures % of Total		55.3%	50.6%

Procedure Code	Description	2008 Payments	2008 Services
80061	LIPID PANEL	\$ 449,760	36,887
85025	BLD CT; HG/PLTLT CT AUTO/COMPLT WBC	\$ 189,249	25,586
80053	COMPREHENSIVE METABOLIC PANEL (DO NOT USE W/ 80048, 80076)	\$ 297,700	18,775
84443	THYROID STIM HORMONE	\$ 275,855	18,583
84450	TRANSFERASE; ASPARTATE AMINO	\$ 15,093	13,374
84460	TRANSFERASE; ALANINE AMINO	\$ 14,979	13,232
80050	GENERAL HEALTH PANEL	\$ 483,554	13,136
83036	HGB; GLYCATED	\$ 126,026	12,877
84439	THYROXINE; FREE	\$ 102,000	12,206
88305	LEVEL IV-SURG PATH GROSS/MICRO EXAM	\$ 1,088,867	10,843
82565	CREATININE; BLD	\$ 12,469	10,677
84153	PROSTATE SPEC ANTIG	\$ 196,656	10,342
84520	UREA NITRO; QUAN	\$ 11,157	9,528
84550	URIC ACID; BLD	\$ 10,699	9,074
81001	UA DIP STICK/TABLET; AUTO W/MICRO	\$ 26,734	8,538
82947	GLU; QUAN	\$ 8,788	8,263
G0123	Screening cytopathology,cerv/vag,in fluid,auto thin layer prep,cytotech+phys scr	\$ 193,415	7,087
87086	CULT BACTERIAL URIN; QUAN COLONY CT	\$ 47,879	6,518
80051	ELECTROLYTE PANEL INCL: CO2(82374), CHLORIDE(82435), POTAS(84132), SODIUM(84295)	\$ 28,982	6,409
G0145	Screening cytopathol,cerv/vag,in fluid,auto thin layer prep,scr w/phys cell sel	\$ 234,548	6,402
82550	CREATINE KINASE; TOT	\$ 6,778	5,856
84100	PHOSPHORUS INORGANIC	\$ 6,939	5,732
83615	LACTATE DEHYDROGENASE	\$ 6,626	5,656
82306	CALCIFEDIOL	\$ 168,777	5,376
87070	CULT BACTERIAL DEFINIT; OTHER SOURC	\$ 38,783	5,217
Top 25 Procedures Subtotal		\$ 4,042,313	286,174
Total All Procedures		\$ 7,414,602	551,191
Top 25 Procedures % of Total		54.5%	51.9%

Procedure Code	Description	2007 Payments	2007 Services
80061	LIPID PANEL	\$ 544,897	38,666
85025	BLD CT; HG/PLTCT AUTO/COMPLT WBC	\$ 226,746	26,405
80053	COMPREHENSIVE METABOLIC PANEL (DO NOT USE W/ 80048, 80076)	\$ 350,172	19,512
84443	THYROID STIM HORMONE	\$ 325,954	18,506
84450	TRANSFERASE; ASPARTATE AMINO	\$ 18,855	14,469
84460	TRANSFERASE; ALANINE AMINO	\$ 18,527	14,221
83036	HGB; GLYCATED	\$ 144,679	13,114
80050	GENERAL HEALTH PANEL	\$ 545,778	12,866
84439	THYROXINE; FREE	\$ 118,557	12,055
88305	LEVEL IV-SURG PATH GROSS/MICRO EXAM	\$ 1,359,866	11,756
82565	CREATININE; BLD	\$ 15,532	11,556
84153	PROSTATE SPEC ANTIG	\$ 227,013	10,677
84520	UREA NITRO; QUAN	\$ 13,794	10,237
84550	URIC ACID; BLD	\$ 13,255	9,912
G0123	Screening cytopathology,cerv/vag,in fluid,auto thin layer prep,cytotech+phys scr	\$ 261,014	9,509
82947	GLU; QUAN	\$ 11,234	8,918
81001	UA DIP STICK/TABLET; AUTO W/MICRO	\$ 30,416	8,422
80051	ELECTROLYTE PANEL INCL: CO2(82374), CHLORIDE(82435), POTAS(84132), SODIUM(84295)	\$ 34,823	6,744
82550	CREATINE KINASE; TOT	\$ 8,595	6,510
83615	LACTATE DEHYDROGENASE	\$ 8,614	6,426
87086	CULT BACTERIAL URIN; QUAN COLONY CT	\$ 53,150	6,277
84100	PHOSPHORUS INORGANIC	\$ 8,280	6,125
G0145	Screening cytopathol,cerv/vag,in fluid,auto thin layer prep,scr w/phys cell sel	\$ 200,330	5,501
85610	PROTHROMBIN TIME	\$ 25,003	5,487
80048	BASIC METABOLIC PANEL (DO NOT USE W/ 80053)	\$ 57,738	5,453
Top 25 Procedures Subtotal		\$ 4,622,822	299,324
Total All Procedures		\$ 8,323,943	561,008
Top 25 Procedures % of Total		55.5%	53.4%

APPENDIX D

2009 Participating Clinical Laboratories by County and Region



Participation Agreements (Attached)

PA 350 of 1980



A nonprofit corporation and independent licensee
of the Blue Cross and Blue Shield Association

Clinical Laboratories Provider Class Plan

Table of Contents

TABLE OF CONTENTS 1

PROVIDER CLASS 2

Definition 2

Scope of Services 2

PA 350 GOALS AND OBJECTIVES 3

Cost Goal..... 3

Access Goal 4

Quality of Care Goal..... 4

BCBSM POLICIES AND PROGRAMS 5

Provider Participation 5

Provider Programs..... 6

Reimbursement Policies 7

CLINICAL LABORATORY PARTICIPATION AGREEMENT 9

Provider Class

A provider class includes health care facilities or health care professionals who have a contract or reimbursement arrangement with Blue Cross Blue Cross Blue Shield of Michigan to render services to BCBSM's members. Qualification standards and the services for which reimbursement is made may differ for the types of providers within a provider class.

Definition

The clinical laboratories provider class is composed of freestanding clinical laboratories that are certified by and comply with the Clinical Laboratory Improvement Amendments (CLIA).

Covered Services

Clinical laboratories are reimbursed for a variety of services that BCBSM considers them qualified and licensed to perform in accordance with benefits covered by member certificates.

PA 350 Goals and Objectives

Provider class plans are developed and maintained pursuant to section 504 of PA 350, which requires BCBSM to provide subscribers reasonable cost, access to, and quality of health care services in accordance with the following goals and objectives.

Cost Goal

“Providers 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.” The goal is derived through the following formula:

$$\left(\frac{(100 + I) * (100 + REG)}{100} \right) - 100$$

Where “I” means the arithmetic average of the percentage changes in the implicit price deflator for gross domestic product over the 2 calendar years immediately preceding the year in which the commissioner's determination is being made; and,

Where ”REG” means the arithmetic average of the percentage changes in the per capita gross domestic product in constant dollars over the 4 calendar years immediately preceding the year in which the commissioner's determination is being made.

Objectives

- ◆ Strive toward meeting the cost goal within the confines of Michigan and national health care market conditions
- ◆ Provide equitable reimbursement to participating providers through the reimbursement methodology outlined in the participating agreement

Access Goal

“There will be an appropriate number of providers throughout this state to assure the availability of certificate-covered health care services to each subscriber.”

Objectives

- ◆ 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 participating agreement and its administration
- ◆ Maintain and periodically update a printed or Web site directory of participating providers

Quality of Care Goal

“Providers will meet and abide by reasonable standards of health care quality.”

Objectives

- ◆ 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 or disputes regarding utilization review audits

BCBSM Policies and Programs

BCBSM maintains a comprehensive set of policies and programs that affect its relationship with health care providers. These policies and programs are designed to help BCBSM meet the PA 350 goals and objectives by limiting cost, maintaining accessibility, and ensuring quality of health care services to its members. To that extent, the following policies and programs may, individually or in combination, affect achievement of one or more of the PA 350 goals. BCBSM annually reports its performance against the goals and objectives for each provider class plan.

Provider Participation

Providers may formally participate with BCBSM or, with respect to some provider classes, providers may participate on a per-claim basis. To formally participate, providers must sign a participation agreement with BCBSM that applies to all covered services the provider renders to BCBSM members. To participate on a per-claim basis, providers must indicate on the claim form that they are participating for the services reported.

Participation Policy

Clinical laboratories may only participate on a formal basis with BCBSM. Their participation agreement requires them to do many things, such as meet BCBSM's qualification standards, abide by BCBSM policies and accept BCBSM's payment as payment in full for all covered services, except for copayments and deductibles identified in members' certificates.

Covered services rendered by clinical labs that do not participate are payable to the member. A current list of participating laboratories is available on the BCBSM Web site.

Qualification Standards

BCBSM offers all qualified clinical laboratories the opportunity to participate. Standards for formal participation may include, but are not limited to:

- ◆ Certification and compliance with the Clinical Laboratory Improvement Amendments (CLIA) as to all covered services performed for members and billed to BCBSM
- ◆ Licensed by the state of Michigan
- ◆ Availability of qualified testing personnel and adequately maintained equipment to properly perform covered services for members
- ◆ Establishment and maintenance of quality standards to ensure that covered services are properly performed and appropriate for the purpose intended
- ◆ No ownership by any professional health care provider licensed to order laboratory services other than a pathologist, except as permitted by state or federal law

- ◆ Absence of inappropriate practice patterns as identified through proven member complaints, medical necessity audits and peer review
- ◆ Absence of fraud or other illegal activities

Departicipation Policy

A departicipation policy allows BCBSM to departicipate a provider after review and recommendation for departicipation by the BCBSM Audit and Investigations Subcommittee. This policy is described further in Article VI of the Clinical Laboratory Provider Participation Agreement.

Member Sanctions

BCBSM will not apply any sanction to members receiving services from departicipated providers unless it is authorized to do so by an amendment to PA 350 or other appropriate authority.

Provider Programs

BCBSM strives to ensure that members receive appropriate and quality care through a combination of provider communications, education, and quality assurance programs.

Utilization Management Initiatives

BCBSM works to ensure that only medically necessary services are delivered to members through utilization management and quality assessment programs.

Communications and Education

BCBSM provides the following resources to communicate with and educate clinical laboratories:

- ◆ *The Record*, a monthly BCBSM publication that communicates current information regarding billing guidelines, policy changes and other administrative issues
- ◆ The BCBSM Web site and an online manual that provide information on how to do business with BCBSM including billing, benefits, provider appeals processes, managed care, BCBSM's record keeping requirements, the Clinical Laboratory Participation Agreement and its administration. BCBSM maintains and updates the Web site and this manual as necessary.
- ◆ The liaison process that provides a forum in which specialty societies can bring issues of concern to BCBSM's attention. The process can include meetings with specialty societies as well as contact with BCBSM representatives by telephone or email.

Performance Monitoring

- ◆ Utilization review audits, when conducted, serve as a check and balance to ensure that services were medically necessary and paid within the scope of members' benefits.

- ◆ Suspected fraudulent activity, reported to BCBSM by providers, members or BCBSM staff, is referred to Corporate and Financial Investigations for further investigation. If fraud or illegal activities are confirmed, BCBSM will report such providers to the Michigan Department of Labor and Economic Growth.

Appeals Process

BCBSM's appeals process allows providers the right to appeal adverse claim decisions and utilization review audit determinations. The process is described in Addendum G of the Clinical Laboratory Provider Participation Agreement.

Reimbursement Policies

BCBSM reimburses participating clinical laboratory providers for covered services deemed medically necessary by BCBSM. Addendum A of the attached Clinical Laboratory Participation Agreement describes determination of medical necessity.

Reimbursement Methods

BCBSM will pay the lower of the provider's billed charge or BCBSM's maximum payment for covered clinical laboratory services less any deductible or copayment that is the member's responsibility.

Billed Charge

The billed charge refers to the actual charge indicated on the claim form submitted by the provider.

Maximum Payment Level

Part of the Maximum Payment Schedule is based on the Resource Based Relative Value Scale developed by the Centers for Medicare and Medicaid Services, in which services are ranked according to the resource costs needed to provide them. The resource costs of the RBRVS system include physician time, training, skill, risk, procedure complexity, practice overhead and professional liability insurance. Values are assigned to each service in relation to the comparative value of all other services. The relative values are then multiplied by a BCBSM-conversion factor to determine overall payment levels.

Other factors that may be used in setting maximum payment levels include comparison to similar services, corporate medical policy decisions, analysis of historical charge data and geographic anomalies. BCBSM may give individual consideration to services involving complex treatment or unusual clinical circumstances in determining a payment that exceeds the maximum payment level. BCBSM may adjust maximum payment levels based on factors such as site of care or BCBSM payment policy.

Fees for non-Relative Value Unit-based clinical laboratory services will be based on a BCBSM factor applied to Medicare rates.

BCBSM reviews relative values and reimbursement levels periodically and may adjust them as necessary.

Hold Harmless Provisions

Participating clinical laboratories agree to accept BCBSM's payment as payment in full for covered services. Member copayments or deductibles are subtracted from BCBSM's payment before the provider is reimbursed and are the member's responsibility. As outlined in Addendum D of the Clinical Laboratory Participation Agreement, a participating clinical laboratory must hold members harmless from the following:

- ◆ Balance billing for covered services
- ◆ Liability for services that are not covered because they are not medically necessary or are experimental, unless the member agrees in writing to pay for the services before they are provided
- ◆ Liability for covered services provided but not billed to BCBSM within a prescribed time frame

**Clinical Laboratory Participation Agreement
(Attached)**

PA 350 of 1980

BLUE CROSS BLUE SHIELD OF MICHIGAN
CLINICAL LABORATORY PARTICIPATING AGREEMENT

This Agreement by and between Blue Cross Blue Shield of Michigan (BCBSM), a nonprofit health care corporation, and the undersigned Laboratory (Provider), a clinical laboratory duly certified or licensed under applicable federal or state law to conduct business. Pursuant to this Agreement, BCBSM and Provider agree as follows:

ARTICLE 1
DEFINITIONS

For purposes of this Agreement, defined terms are:

- 1.1 **"Agreement"** means this written Agreement between BCBSM and Provider which designates Provider as eligible to provide Covered Services and incorporates by reference any Provider Manuals, and other BCBSM written or web-based manuals.
- 1.2 **"Certificate"** means benefit plan descriptions under the sponsorship of BCBSM, or certificates and riders issued by BCBSM, or under its sponsorship, or Member's coverage documents or benefits provided pursuant to contracts issued by other Blue Cross or Blue Shield (BCBS) Plans, administered through reciprocity of benefit agreements or other Inter-Plan Arrangements such as BlueCard. "Certificate" does not include benefits provided pursuant to automobile or workers' compensation insurance coverage.

For purposes of this definition, "sponsorship" includes:

- a. Self-funded administrative accounts of BCBSM for which BCBSM provides any one or more of the following administrative services: utilization management, quality assessments, reviews, audits, claims processing systems or a cash flow methodology.
- b. Self-funded administrative service accounts for which another Plan is Control Plan and BCBSM is a participating plan and for which BCBSM or the Control Plan assumes the risk of reimbursing Provider for Covered Services in the event the account becomes insolvent.

For purposes of this definition, "sponsorship" does not include Health Maintenance Organizations (HMOs) or benefit plans owned, controlled or operated in whole or part by BCBSM or its subsidiaries, or by other BCBS Plans or their subsidiaries.

- 1.3 **"Clean Claim"** means a claim that (i) identifies the provider that provided the service sufficiently to verify the affiliation status and includes any identifying numbers; (ii) sufficiently identifies that patient is a BCBS Member; (iii) lists the date and place of service; (iv) is a claim for Covered Services for an eligible individual; (v) if necessary, substantiates the Medical Necessity and appropriateness of the service provided; (vi) if prior authorization is required for certain patient services, contains information sufficient to establish that prior authorization was obtained; (vii) identifies the service rendered using an accepted system

- of procedure or service coding adopted and published by BCBSM; (viii) includes additional documentation based upon services rendered as reasonably required by BCBSM.
- 1.4 **"Copayment"** means the portion of BCBSM's approved amount that the Member must pay for Covered Services under the terms of a Certificate. This does not include a Deductible.
- 1.5 **"Covered Services"** means those health care services which are (i) identified as payable in Certificate(s), (ii) Medically Necessary as defined in such Certificates, (iii) ordered by a health care provider licensed or legally authorized to order such services and (iv) performed by a clinical laboratory licensed and CLIA certified to perform such services.
- 1.6 **"Deductible"** means the portion of BCBSM's approved amount a Member must pay for Covered Services under a Certificate before benefits are payable. This does not include a Copayment.
- 1.7 **"HCPCS"** means the Healthcare Common Procedure Coding System.
- 1.8 **"Medical Necessity"** shall be defined as set forth in Addendum A.
- 1.9 **"Member"** means the person eligible to receive Covered Services on the date the Covered Services were rendered.
- 1.10 **"Physician"** means a doctor of medicine or osteopathy who is licensed or legally authorized to practice in the state of Michigan.
- 1.11 **"Provider Manual"** means a working document, including but not limited to, BCBSM published bulletins and provider notices, that provide specific guidelines and direction by which Provider may meet their contractual responsibility as described in this Agreement. Provider Manuals are published on web-DENIS.
- 1.12 **"Qualification Standards"** are those standards set forth in Addendum B.
- 1.13 **"Reimbursement Methodology"** means the methodology by which BCBSM determines the amount of payment due Provider for Covered Services.

ARTICLE 2 PROVIDER RESPONSIBILITIES

- 2.1 **Maintain Qualification Standards.** Provider will have and maintain the appropriate CLIA certification or licensure under applicable federal or state laws to conduct business and has met all applicable BCBSM Qualifications Standards as set forth in Addendum B.
- 2.2 **Services to Members.** Provider, within the limitations of its certification under CLIA or state licensure laws, will provide Covered Services to Members as set forth in Certificates.
- 2.3 **Notice of Adverse Actions.** Provider shall promptly notify BCBSM of any action, determination, or circumstance involving Provider which affects or may affect the provision of Covered Services. Such circumstances shall include, without limitation, the following:

- a. Plea of guilty or nolo contendere or conviction or placement in a diversion program for any crimes related to the payment or provision of health care;
 - b. Censure, reprimand, resolution, suspension, revocation, or reduction to probationary status of Provider's license or CLIA certification.
- 2.4 **Subcontracting.** Provider shall disclose upon request to BCBSM whether any Covered Services provided under this Agreement are subcontracted. Any subcontract for the provision of Covered Services shall be subject to the terms and conditions of this Agreement.
- 2.5 **Accept BCBSM Payment as Payment in Full.** Except for Copayments and Deductibles specified in Members' Certificates, Provider will accept BCBSM's approved amount as full payment for Covered Services and agrees not to collect any further payment from any Member, except as set forth in Addendum "D." Provider also agrees to accept, as payment in full for Covered Services, except for applicable Copayments and Deductibles, BCBSM's approved amount for Members covered under any of BCBSM's laboratory programs or any BCBS laboratory program if Provider provides Covered Services to such Member. Provider will not collect deposits from Members. Deposit is defined as an amount in excess of a Copayment or Deductible which is collected on or prior to the date of service.
- 2.6 **Release of Records.** BCBSM represents that BCBSM Members, by contract, have authorized Provider to release to BCBSM information and records, including but not limited to all medical, hospital and other information relating to their care and treatment. Provider will release patient information and records requested by BCBSM to enable it to process claims and for pre-or post-payment review of medical records and equipment, lawsuits, coordination of benefits, as related to claims filed.
- 2.7 **Claims Submission.** Unless otherwise prohibited by federal or state law, Provider will submit Clean Claims for all Covered Services to BCBSM within one hundred eighty (180) days of the date of service.
- 2.8 **Provider Obligations.** Provider at all times during the term of this Agreement shall:
- a. **Cost Sharing Waivers.** Not waive Copayments and/or Deductibles that are the responsibility of the Member, except for hardship cases that are documented in the Member's record or where reasonable collection efforts have failed.
 - b. **Adherence to BCBSM Quality and Utilization Management Policies.** Adhere to all quality management, utilization management and reimbursement policies and procedures of BCBSM regarding precertification, case management, disease management, retrospective profiling, credentialing or privileging specific to particular procedures, billing limitations or other programs which may be in effect at the time the Covered Service is provided and submit reports, including lab value data, as requested by BCBSM.
 - c. **Laboratory Changes.** Notify BCBSM within thirty (30) days of changes in Provider's business including changes in ownership, name, tax identification number, location, phone number, business structure, licensure, CLIA certification, accreditation, National Provider Identifier or CLIA number. Prior notice of such changes does not guarantee continued participation under this Agreement;

- d. **Coordination of Benefits.** Provide Covered Services to Members even though there might be coverage by another party under workers' compensation, occupational disease, or other statute. Provider shall bill the appropriate responsible party for Covered Services and shall provide information to BCBSM regarding the applicability of such statutory coverage;

Request information from Members regarding other payors that may be primarily responsible for Members' Covered Services, pursue payment from such other responsible payors, and shall bill BCBSM only for Covered Services not paid by the primary payors. All payments received from primary payors for Covered Services shall be promptly credited against or deducted from amounts otherwise payable by BCBSM for such services. Except where BCBSM payment is secondary to Medicare, BCBSM's secondary coverage will be limited to the difference, if any, between the maximum amount BCBSM would have paid less the amount paid by the primary carrier. If the primary carrier's payment exceeds the BCBSM maximum payment amount, no secondary payment will be made by BCBSM. Provider agrees to submit claims to the primary payors before submitting them to BCBSM;
 - e. **Medical Records.** Develop and utilize accurate medical, appointment, financial and billing records of all matters relating to obligations under this Agreement and provide them to BCBSM upon request;
 - f. **Member Eligibility.** Verify Member eligibility contemporaneous with the rendering of services. BCBSM will provide systems and/or methods for verification of eligibility and benefit coverage for Members. This is furnished as a service and not as a guarantee of payment;
 - g. **Discrimination.** Not discriminate against Members based upon race, color, age, gender, marital status, religion, national origin, or sexual orientation nor may Provider refuse to render Covered Services to Members based upon BCBSM's payment level, benefit or reimbursement policies.
- 2.9 **Audits and Recovery.** Provider agrees that BCBSM may photocopy, review and audit Provider as set forth in Addendum F and BCBSM has the right of recovery of any overpayments as set forth in Addendum E.
- 2.10 **Successor's Obligations.** Provider will require any prospective successor to its interest to assume liability for any amounts for which Provider is indebted to BCBSM. Assumption of liability shall be a condition for approval of any successor as a participating provider. Assumption of liability shall not release Provider from the indebtedness unless an agreement to that effect is entered into between BCBSM, Provider, and any prospective successor, or if the successor is a participating provider and expressly agrees to assume Provider's liabilities to BCBSM or BCBS.
- 2.11 **Provider Directories.** Provider agrees to the publication of Provider's name, address and telephone number in any participating provider directories published by BCBSM or BCBS.

**ARTICLE 3
BCBSM RESPONSIBILITIES**

- 3.1 **Direct Payment.** BCBSM or its representative, will make payment directly to Provider for Covered Services except for Copayments and Deductibles that are the responsibility of the Member.
- 3.2 **Claims Processing.** BCBSM will process Provider's Clean Claims submitted in accordance with this Agreement in a timely fashion.
- 3.3 **BCBSM Reimbursement.** BCBSM will pay Provider for Covered Services in accordance with the Reimbursement Methodology set forth in Addendum C.
- 3.4 **Provider Manuals and Bulletins.** BCBSM will, without charge, supply Provider with BCBSM guidelines and administrative information concerning billing requirements, benefits, utilization management and such other information as may be reasonably necessary for Provider to deliver Covered Services to Members and be paid. As available, BCBSM may provide such information through electronic means via web-DENIS or the Internet.
- 3.5 **Confidentiality.** BCBSM will maintain the confidentiality of Member information and records in accordance with applicable federal and state laws as set forth in Addendum G.

**ARTICLE 4
PROVIDER ACKNOWLEDGMENT OF BCBSM
SERVICE MARK LICENSEE STATUS**

- 4.1 BLUE CROSS®, BLUE SHIELD®, and the Cross and Shield symbols (Marks) are registered service marks of the Blue Cross and Blue Shield Association. Other than the placement of small signs on its premises indicating participation in BCBSM programs, Provider shall not use, display or publish the Marks without BCBSM's written approval.
- 4.2 Provider hereby expressly acknowledges his/her understanding that this Agreement constitutes a contract between Provider and BCBSM and that BCBSM is an independent corporation operating under a license from the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans, (the Association) permitting BCBSM to use the Blue Cross and Blue Shield Service Marks in the state of Michigan, and that BCBSM is not contracting as the agent of the Association. Provider further acknowledges and agrees that it has not entered into this Agreement based upon representations by any person other than BCBSM and that no person, entity, or organization other than BCBSM shall be held accountable or liable to Provider for any of BCBSM's obligations to Provider created under this Agreement. This paragraph shall not create any additional obligations whatsoever on the part of BCBSM other than those obligations created under other provisions of this Agreement.

ARTICLE 5 CLAIM DISPUTES AND APPEALS

Provider may appeal claim and audit determinations through the BCBSM appeal process as set forth in the Provider Manual or other sources as published by BCBSM which may be amended from time to time. Provider agrees to abide by this appeal process.

ARTICLE 6 GENERAL PROVISIONS

- 6.1 **Term.** This Agreement will become effective on the date indicated on the Signature Document.
- 6.2 **Termination.** This Agreement may be terminated as follows:
- a. by either party, with or without cause, upon sixty (60) days written notice to the other party;
 - b. immediately by either party where there is a material breach of this Agreement by a party which is not cured within twenty (20) business days of written notice from the other party;
 - c. by BCBSM, immediately and without notice, if: (i) Provider is censured, placed on probation, or has its CLIA certification or license suspended, revoked, or nullified, or (ii) an officer, director, owner or principal of Provider or Provider commits civil fraud, or is convicted of, or pleads to a health care related misdemeanor or a felony, including any "plea bargain," reducing a felony to a misdemeanor; (iii) Provider fails to meet the Qualification Standards; or (iv) Provider is excluded, expelled or suspended from Medicare or Medicaid Programs (Title XVIII or XIV of the Social Security Act);
 - d. by either party upon thirty (30) days, upon the filing of any involuntary or voluntary proceeding in bankruptcy against either party, insolvency of any party, upon the appointment of a receiver of any party, or any other similar proceeding if such proceedings are not dismissed or withdrawn within sixty (60) days;
 - e. by either party immediately if Provider ceases doing business or providing laboratory services;
 - f. by Provider immediately if BCBSM is not able to meet its financial obligations to Provider for a period of fifteen (15) consecutive days and Provider provides at least thirty (30) days prior written notification of such termination;
 - g. by BCBSM immediately, at its option, if there is change in the ownership of Provider; and
 - h. by BCBSM immediately if termination of this Agreement is ordered by the State Insurance Commissioner.

- 6.3 **Existing Obligations.** Termination of this Agreement shall not affect any obligations of the Parties under this Agreement prior to the date of termination including, but not limited to, completion of all medical records and cooperation with BCBSM with respect to any actions arising out of this Agreement filed against BCBSM after the effective date of termination. This Agreement shall remain in effect for the resolution of all matters pending on the date of termination. BCBSM's obligation to reimburse Provider for any Covered Services will be limited to those provided through the date of termination. BCBSM's right of audit and recovery from Provider as set forth in Article 2, Section 2.9, shall survive the termination of this Agreement.
- 6.4 **Relationship of Parties.** It is expressly understood that Provider is an independent contractor. BCBSM shall not be responsible to withhold or cause to withhold any federal, state or local taxes, including FICA from any amounts paid to Provider. The responsibility for the payment of taxes shall be that of the Provider.
- 6.5 **Assignment.** This Agreement shall be binding and shall inure to the benefit of the successors and assigns of BCBSM. BCBSM may assign any right, power, duty or obligation under this Agreement. Provider shall not assign any right, power, duty, or obligation hereunder without the prior written consent of BCBSM.
- 6.6 **Amendment.** BCBSM may unilaterally amend this Agreement by providing ninety (90) days prior notice, written or electronic, of such amendment. Electronic notice shall include, but not be limited to, publication on web-DENIS. Provider's signature is not required to make the amendment effective. However, should Provider no longer wish to continue its participation in the network because of an amendment, then Provider may terminate this Agreement by providing forty-five (45) days written notice to BCBSM.
- 6.7 **Waiver.** No waiver of any provision of this Agreement shall be valid unless in writing and signed by the parties. Failure to enforce any provision of this Agreement by either party shall not be construed as a waiver of any breach of this Agreement or of any provisions of this Agreement.
- 6.8 **Scope and Effect.** This Agreement constitutes the entire Agreement between the parties and supersedes any and all prior agreements or representations oral or written as to matters contained herein, and supersedes any agreements between Provider and BCBSM which conflict with the terms and conditions of this Agreement.
- 6.9 **Severability.** In the event any portion of this Agreement is declared null and void by statute or ruling of court of competent jurisdiction or BCBSM's regulator, the remaining provisions of the Agreement will remain in full force and effect
- 6.10 **Notices.** Unless otherwise indicated in this Agreement, notification required by this Agreement shall be sent by first class United States mail addressed as follows:

If to Provider:

A current address on
BCBSM Provider File

If to BCBSM:

Provider Enrollment, and Data Management
Blue Cross Blue Shield of Michigan
Mail Code B443
600 E. Lafayette Blvd.
Detroit, Michigan 48226-2998

- 6.11 **Third Party Rights.** This Agreement is intended solely for the benefit of the parties and confers no rights of any kind on any third party and may not be enforced except by the parties hereto.
- 6.12 **Provider Information.** BCBSM may disclose Provider specific information as follows:
- a. pursuant to any federal, state or local statute or regulation;
 - b. to customers for purpose of audit and health plan administration so long as the customer agrees to restrict its use to these purposes; and
 - c. for purposes of public reporting of benchmarks in utilization management and quality assessment initiatives, including publication in databases for use with all consumer driven health care products, or other similar BCBS business purposes.
 - d. For civil and criminal investigation, prosecution or litigation to the appropriate law enforcement authorities or in response to appropriate legal processes.
- 6.13 **Member Discussions.** Notwithstanding any other provision in this Agreement and regardless of any benefit or coverage exclusions or limitations in Member's Certificates, Provider's representatives shall not be prohibited from discussing fully with a Member any issues related to the Member's health including recommended treatments, treatment alternatives, treatment risks and the consequences of any benefit coverage or payment decisions made by BCBSM or any other entity. Nothing in this Agreement shall prohibit Provider's representatives from disclosing to the Member the general methodology by which Provider is compensated under this Agreement, provided the specific terms of the compensation arrangement are not mentioned to the Member. BCBSM shall not refuse to allow or to continue the participation of any otherwise eligible Provider, or refuse to compensate Provider in connection with services rendered solely because Provider has in good faith communicated with one or more of its current, former or prospective Members regarding the provisions, terms or requirements of a Certificate as they relate to the health needs of such Member.
- 6.14 **Compliance With Laws.** Both parties will comply with all federal, state and local laws ordinances, rules and regulations applicable to its activities and obligations under this Agreement.
- 6.15 **Governing Law.** This Agreement, except as governed by CLIA or other federal law, will be governed and construed according to the laws of the state of Michigan.

SIGNATURE DOCUMENT ATTACHED AND MADE A PART HEREOF.

ADDENDA

- A. Medical Necessity Criteria
- B. Qualification Standards
- C. Reimbursement Methodology
- D. Services For Which Provider May Bill Member
- E. Service Reporting and Claims Overpayment Policy
- F. Audit and Recovery Policy
- G. Confidentiality Policy

MEDICAL NECESSITY CRITERIA

"Medically Necessary" or "Medical Necessity" shall mean health care services that a provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- a. In accordance with generally accepted standards of medical practice;
- b. Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and
- c. Not primarily for the convenience of the Member, Provider, or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of physicians practicing in relevant clinical areas and any other relevant factors.

QUALIFICATION STANDARDS

In order to participate with BCBSM, Provider must have all of the following standards in effect at all times during the term of the Agreement:

1. Certification and compliance with the Clinical Laboratory Improvement Amendments (CLIA) as to all Covered Services performed for Members and billed to BCBSM and, if applicable, be licensed and comply with any state law which may be enacted to supersede CLIA in accordance with the provisions contained therein.
2. Availability of qualified testing personnel and adequately maintained equipment to properly perform Covered Services for Members.
3. The establishment and maintenance of quality standards to ensure that Covered Services are properly performed and appropriate for the purpose intended.
4. Have and maintain a license as a clinical laboratory as required by the state of Michigan in accordance with PA368 of 1978 or other applicable state licensure laws if not doing business in Michigan.
5. Absence of inappropriate practice patterns as identified through proven Member complaints, Medical Necessity audits and peer review.
6. Absence of fraud or other illegal activities.

REIMBURSEMENT METHODOLOGY

For each Covered Service performed, BCBSM will pay the lesser of billed charges or the published maximum screen as set forth in BCBSM's Maximum Payment Schedule less any Deductible and/or Copayment for which the Member is responsible. The Maximum Payment Schedule is based, in part, on a system of the ranking of relative values of all medical and surgical procedures and services which are revealed by BCBSM as a regular business activity. Relative values are multiplied by a BCBSM specific conversion factor to determine price per procedure. These factors vary by year. Nationally imposed charges to the nomenclature and national coding system (HCPCS) for procedural codes, and correction of typographical errors may result in immediate modifications to the Maximum Payment Schedules without prior notice.

BCBSM will make the Payment Schedule available to Provider via web-DENIS or other electronic means. Fees for non-Relative Value Unit-based clinical laboratory services will be the Medicare fee multiplied by a BCBSM specific factor.

Fees for multichannel codes are individually priced and are subject to the BCBSM physician fee update.

BCBSM will review reimbursement levels at least every twelve (12) months to determine if modifications are necessary. BCBSM does not warrant or guarantee that the review process will result in increased reimbursement.

SERVICES FOR WHICH PROVIDER MAY BILL MEMBER

Provider may bill Member for:

1. Non-Covered Services unless the service has been deemed a non-Covered Service solely as a result of a determination by a BCBSM Physician or professional provider that the service was:
 - Medically Unnecessary,
 - denied as an overpayment, or
 - not eligible for payment to Provider as determined by BCBSM based upon BCBSM's credentialing, privileging, payment, reimbursement or other applicable published policy for the particular service rendered, in which case Provider assumes full financial responsibility for the denied claims. BCBSM will endeavor to apply like medical specialties to the claims review process.

Provider, however, may bill the Member for claims denied as Medically Unnecessary only as stated in paragraph 2, below;

2. Services determined by a BCBSM Physician to be Medically Unnecessary, if the Member specifically agrees in writing in advance of receiving such services as follows:
 - a. The Member acknowledges that BCBSM will not make payment for the specific service to be rendered because it is deemed Medically Unnecessary.
 - b. The Member consents to the receipt of such services.
 - c. The Member assumes financial responsibility for such services.
 - d. Provider provides an estimate cost to the Member for such services.
3. Covered Services denied by BCBSM as untimely billed, if both of the following requirements are met:
 - a. Provider documents that a claim was not submitted to BCBSM within one hundred eighty (180) days of performance of such services because a Member failed to provide proper identifying information; and
 - b. Provider submits a claim to BCBSM for payment consideration within three (3) months after obtaining the necessary information.

SERVICE REPORTING AND CLAIMS OVERPAYMENT POLICY

I. Service Reporting

Provider will furnish a claim or a report to BCBSM in the form BCBSM specifies and furnish any additional information BCBSM may reasonably request to process or review the claim. All services shall be reported without charge, with complete and accurate information, including diagnosis, and procedure codes approved by BCBSM, license number of prescribing physician/provider, and such other information as may be required or published by BCBSM to adjudicate claims.

II. Overpayments

Provider shall promptly report overpayments to BCBSM discovered by Provider and agrees BCBSM will be permitted to deduct overpayments (whether discovered by Provider or BCBSM) from future BCBSM payments, along with an explanation of the action taken. In audit refund recovery situations, where Provider appeals the BCBSM determination, BCBSM will defer deduction of overpayments until the determination, or the last unappealed determination, whichever occurs first. Audit refund recoveries and other overpayment obligations which cannot be fully repaid over the course of one (1) month, will bear interest at the BCBSM prevailing rate, until fully repaid. Provider agrees that filing an appeal tolls the applicable Statute of Limitations that may apply to BCBSM actions relating to the overpayment or recovery.

AUDIT AND RECOVERY POLICY

I. Records

BCBSM or its designees shall have access to the Member's medical records or other pertinent records of Provider to verify Medical Necessity and appropriateness of payment and may inspect and photocopy the records. BCBSM will reimburse Provider for the reasonable copying expense incurred by Provider where Provider copies records requested by BCBSM in connection with BCBSM audit activities.

Provider shall prepare and maintain all appropriate records on all Members receiving services, and shall prepare, keep and maintain records in accordance with BCBSM's existing record keeping and documentation requirements and standards previously communicated to Provider by BCBSM, and any requirements subsequently developed which are communicated to Provider prior to their implementation, and as required by law.

II. Scope of Audits

Audits may consist of, but are not necessarily limited to, verifications of services provided, Medical Necessity of services provided, and appropriateness of procedure codes reported to BCBSM for services rendered.

III. Time

BCBSM may conduct on-site audits during Provider's regular business hours. BCBSM's inspection, audit and photocopying or duplication shall be allowed during regular business hours, upon reasonable notice of dates and time.

IV. Recovery

BCBSM shall have the right to recover amounts paid for services not meeting applicable benefit criteria or not Medically Necessary as determined by BCBSM under Addendum A. BCBSM shall have the right to recover amounts for services not meeting the applicable benefit, reimbursement or Medical Necessity criteria established by BCBSM overpayments, services not documented in Provider's records, any services not received by Member, non-Covered Services or for services furnished when Provider license or CLIA certification was lapsed, restricted, revoked or suspended. BCBSM will not utilize statistical sampling methodologies to extrapolate refund requests on Medical Necessity issues identified through sampling. BCBSM may extrapolate refund recoveries from statistically valid samples involving issues other than Medical Necessity, including but not limited to, procedure code billing errors.

BCBSM shall have the right to initiate recovery of amounts paid for services up to two (2) years from the date of payment, except in instances of fraud, as to which there will be no time limit on recoveries.

CONFIDENTIALITY POLICY

The purpose of BCBSM's Confidentiality Policy is to provide for the protection of the privacy of Members, and the confidentiality of personal data, and personal information.

BCBSM's Policy sets forth the guidelines conforming to MCLA 550.1101 et seq. which requires BCBSM's Board of Directors to establish and make public the policy of the Corporation regarding the protection of the privacy of Members and the confidentiality of personal data.

In adopting this policy, BCBSM acknowledges the rights of its Members to know that personal data and personal information acquired by BCBSM will be treated with respect and with reasonable care to ensure confidentiality; to know that it will not be shared with others except for legitimate business purposes or in accordance with a Member's specific consent or specific statutory authority.

The term personal data refers to a document incorporating medical or surgical history, care, treatment or service; or any similar record, including an automated or computer accessible record relative to a Member, which is maintained or stored by a health care corporation.

The term personal information refers to a document or any similar record relative to a Member, including an automated or computer accessible record, containing information such as an address, age/birth date, Coordination of Benefits data, which is maintained or stored by a health care corporation.

BCBSM will collect and maintain necessary Member personal data and take reasonable care to secure these records from unauthorized access and disclosure and collect only the personal data necessary to review and pay claims for health care operations, treatment and research. BCBSM will identify routine uses of Member personal data and notify Members regarding these uses.

Enrollment applications, claim forms and other communications will contain the Member's consent to release data and information that is necessary for review and payment of claims. These forms will also advise the members of their rights under this policy.

Upon specific request, a Member will be notified regarding the actual release of personal data. BCBSM will disclose personal data as permitted by the Health Insurance Portability and Accountability Act of 1996, Public Act 104-191 and the regulations promulgated under the Act and in accordance with PA 350 of 1980. Members may authorize the release of their personal information to a specific person.

BCBSM will release required data pursuant to any federal, state or local statute or regulation.

For civil and criminal investigation, prosecution or litigation, BCBSM will release requested data to the appropriate law enforcement authorities or in response to appropriate legal process.



A nonprofit corporation and independent licensee
of the Blue Cross and Blue Shield Association

Clinical Laboratories Provider Class Plan

Table of Contents

TABLE OF CONTENTS 1

PROVIDER CLASS 2

Definition 2

Scope of Services 2

PA 350 GOALS AND OBJECTIVES 3

Cost Goal..... 3

Access Goal 4

Quality of Care Goal..... 4

BCBSM POLICIES AND PROGRAMS 5

Provider Participation 5

Provider Programs..... 6

Reimbursement Policies 7

CLINICAL LABORATORY PARTICIPATION AGREEMENT 9

Provider Class

A provider class includes health care facilities or health care professionals who have a contract or reimbursement arrangement with Blue Cross Blue Cross Blue Shield of Michigan to render services to BCBSM's members. Qualification standards and the services for which reimbursement is made may differ for the types of providers within a provider class.

Definition

The clinical laboratories provider class is composed of freestanding clinical laboratories that are certified by and comply with the Clinical Laboratory Improvement Amendments (CLIA).

Covered Services

Clinical laboratories are reimbursed for a variety of services that BCBSM considers them qualified and licensed to perform in accordance with benefits covered by member certificates.

PA 350 Goals and Objectives

Provider class plans are developed and maintained pursuant to section 504 of PA 350, which requires BCBSM to provide subscribers reasonable cost, access to, and quality of health care services in accordance with the following goals and objectives.

Cost Goal

“Providers 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.” The goal is derived through the following formula:

$$\left(\frac{(100 + I) * (100 + REG)}{100} \right) - 100$$

Where “I” means the arithmetic average of the percentage changes in the implicit price deflator for gross domestic product over the 2 calendar years immediately preceding the year in which the commissioner's determination is being made; and,

Where ”REG” means the arithmetic average of the percentage changes in the per capita gross domestic product in constant dollars over the 4 calendar years immediately preceding the year in which the commissioner's determination is being made.

Objectives

- ◆ Strive toward meeting the cost goal within the confines of Michigan and national health care market conditions
- ◆ Provide equitable reimbursement to participating providers through the reimbursement methodology outlined in the participating agreement

Access Goal

“There will be an appropriate number of providers throughout this state to assure the availability of certificate-covered health care services to each subscriber.”

Objectives

- ◆ 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 participating agreement and its administration
- ◆ Maintain and periodically update a printed or Web site directory of participating providers

Quality of Care Goal

“Providers will meet and abide by reasonable standards of health care quality.”

Objectives

- ◆ 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 or disputes regarding utilization review audits

BCBSM Policies and Programs

BCBSM maintains a comprehensive set of policies and programs that affect its relationship with health care providers. These policies and programs are designed to help BCBSM meet the PA 350 goals and objectives by limiting cost, maintaining accessibility, and ensuring quality of health care services to its members. To that extent, the following policies and programs may, individually or in combination, affect achievement of one or more of the PA 350 goals. BCBSM annually reports its performance against the goals and objectives for each provider class plan.

Provider Participation

Providers may formally participate with BCBSM or, with respect to some provider classes, providers may participate on a per-claim basis. To formally participate, providers must sign a participation agreement with BCBSM that applies to all covered services the provider renders to BCBSM members. To participate on a per-claim basis, providers must indicate on the claim form that they are participating for the services reported.

Participation Policy

Clinical laboratories may only participate on a formal basis with BCBSM. Their participation agreement requires them to do many things, such as meet BCBSM's qualification standards, abide by BCBSM policies and accept BCBSM's payment as payment in full for all covered services, except for copayments and deductibles identified in members' certificates.

Covered services rendered by clinical labs that do not participate are payable to the member. A current list of participating laboratories is available on the BCBSM Web site.

Qualification Standards

BCBSM offers all qualified clinical laboratories the opportunity to participate. Standards for formal participation may include, but are not limited to:

- ◆ Certification and compliance with the Clinical Laboratory Improvement Amendments (CLIA) as to all covered services performed for members and billed to BCBSM or, if applicable, be licensed and comply with any state law which may be enacted to supersede CLIA
- ◆ Availability of qualified testing personnel and adequately maintained equipment to properly perform covered services for members
- ◆ Establishment and maintenance of quality standards to ensure that covered services are properly performed and appropriate for the purpose intended
- ◆ No ownership by any professional health care provider licensed to order laboratory services other than a pathologist, except as permitted by state or federal law

- ◆ Absence of inappropriate practice patterns as identified through proven member complaints, medical necessity audits and peer review
- ◆ Absence of fraud or other illegal activities

Departicipation Policy

A departicipation policy allows BCBSM to departicipate a provider after review and recommendation for departicipation by the BCBSM Audit and Investigations Subcommittee. This policy is described further in Article VI of the Clinical Laboratory Provider Participation Agreement.

Member Sanctions

BCBSM will not apply any sanction to members receiving services from departicipated providers unless it is authorized to do so by an amendment to PA 350 or other appropriate authority.

Provider Programs

BCBSM strives to ensure that members receive appropriate and quality care through a combination of provider communications, education, and quality assurance programs.

Utilization Management Initiatives

BCBSM works to ensure that only medically necessary services are delivered to members through utilization management and quality assessment programs.

Communications and Education

BCBSM provides the following resources to communicate with and educate clinical laboratories:

- ◆ *The Record*, a monthly BCBSM publication that communicates current information regarding billing guidelines, policy changes and other administrative issues
- ◆ The BCBSM Web site and an online manual that provide information on how to do business with BCBSM including billing, benefits, provider appeals processes, managed care, BCBSM's record keeping requirements, the Clinical Laboratory Participation Agreement and its administration. BCBSM maintains and updates the Web site and this manual as necessary.
- ◆ The liaison process that provides a forum in which specialty societies can bring issues of concern to BCBSM's attention. The process can include meetings with specialty societies as well as contact with BCBSM representatives by telephone or email.

Performance Monitoring

- ◆ Utilization review audits, when conducted, serve as a check and balance to ensure that services were medically necessary and paid within the scope of members' benefits.

- ◆ Suspected fraudulent activity, reported to BCBSM by providers, members or BCBSM staff, is referred to Corporate and Financial Investigations for further investigation. If fraud or illegal activities are confirmed, BCBSM will report such providers to the Michigan Department of Labor and Economic Growth.

Appeals Process

BCBSM's appeals process allows providers the right to appeal adverse claim decisions and utilization review audit determinations. The process is described in Addendum G of the Clinical Laboratory Provider Participation Agreement.

Reimbursement Policies

BCBSM reimburses participating clinical laboratory providers for covered services deemed medically necessary by BCBSM. Addendum A of the attached Clinical Laboratory Participation Agreement describes determination of medical necessity.

Reimbursement Methods

BCBSM will pay the lower of the provider's billed charge or BCBSM's maximum payment for covered clinical laboratory services less any deductible or copayment that is the member's responsibility.

Billed Charge

The billed charge refers to the actual charge indicated on the claim form submitted by the provider.

Maximum Payment Level

Part of the Maximum Payment Schedule is based on the Resource Based Relative Value Scale developed by the Centers for Medicare and Medicaid Services, in which services are ranked according to the resource costs needed to provide them. The resource costs of the RBRVS system include physician time, training, skill, risk, procedure complexity, practice overhead and professional liability insurance. Values are assigned to each service in relation to the comparative value of all other services. The relative values are then multiplied by a BCBSM-conversion factor to determine overall payment levels.

Other factors that may be used in setting maximum payment levels include comparison to similar services, corporate medical policy decisions, analysis of historical charge data and geographic anomalies. BCBSM may give individual consideration to services involving complex treatment or unusual clinical circumstances in determining a payment that exceeds the maximum payment level. BCBSM may adjust maximum payment levels based on factors such as site of care or BCBSM payment policy.

Fees for non-Relative Value Unit-based clinical laboratory services will be based on the Medicare fee schedule plus a percentage set by BCBSM.

Fees for multichannel codes are individually priced and are subject to the physician fee update.

BCBSM reviews relative values and reimbursement levels periodically and may adjust them as necessary.

Hold Harmless Provisions

Participating clinical laboratories agree to accept BCBSM's payment as payment in full for covered services. Member copayments or deductibles are subtracted from BCBSM's payment before the provider is reimbursed and are the member's responsibility. As outlined in Addendum D of the Clinical Laboratory Participation Agreement, a participating clinical laboratory must hold members harmless from the following:

- ◆ Balance billing for covered services
- ◆ Liability for services that are not covered because they are not medically necessary or are experimental, unless the member agrees in writing to pay for the services before they are provided
- ◆ Liability for covered services provided but not billed to BCBSM within a prescribed time frame

**Clinical Laboratory Participation Agreement
(Attached)**

PA 350 of 1980

**BLUE CROSS BLUE SHIELD OF MICHIGAN
CLINICAL LABORATORY PARTICIPATING AGREEMENT**

This Agreement by and between Blue Cross Blue Shield of Michigan (BCBSM), whose address is 600 Lafayette East, Detroit, Michigan 48226, and the undersigned Laboratory (Laboratory), a clinical laboratory provider duly certified or licensed under applicable federal or state law, which has executed and returned to BCBSM the attached Signature Document acknowledging receipt of this Agreement and to be bound by its terms and conditions.

**ARTICLE I
DEFINITIONS**

For purposes of this Agreement, defined terms are:

- 1.1. **"Agreement"** means this Agreement, and all exhibits and Addenda attached hereto, or other documents specifically referenced and incorporated herein.
- 1.2. **"Alternative Delivery System"** means any preferred provider organization, health maintenance organization, point of service or any other than traditional delivery systems owned, controlled, administered or operated, in whole or in part, by BCBSM, its subsidiaries, or by any other Blue Cross and/or Blue Shield (BCBS) Plan.
- 1.3. **"BCBS Plans"** means organizations which are licensed by the Blue Cross and Blue Shield Association to use the Blue Cross and/or Blue Shield names and service marks. Unless otherwise specified, the term BCBS Plans includes BCBSM.
- 1.4. **"Certificate"** means benefit plan descriptions under the sponsorship of BCBSM or other BCBS Plans, or certificates and riders issued by or under their sponsorship, or arrangements with any employer group, including any self-funded plan, where BCBSM or other BCBS Plans administer benefits; however, "sponsorship" does not include any Alternative Delivery System(s).
- 1.5. **"Covered Services"** means those clinical laboratory services which are listed or provided for in Certificates, which are Medically Necessary (Medical Necessity) as set forth in Addendum "A" and which are within Laboratory's scope of certification under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) or state licensure laws, whichever may be applicable at the time such Services are rendered.
- 1.6. **"Member"** means a person entitled to receive Covered Services pursuant to Certificates.
- 1.7. **"Out-of-Panel Services"** means clinical laboratory services provided to a member of an Alternative Delivery System by a clinical laboratory which is not an approved panel provider of such Alternative Delivery System at the time such Services are provided.
- 1.8. **"Qualification Standards"** means those criteria established by BCBSM which are used to determine Laboratory's eligibility to become or remain a participating clinical laboratory provider.
- 1.9. **"Reimbursement Policies"** means the policies by which BCBSM determines the amount of payment due Laboratory for Covered Services.

**ARTICLE II
LABORATORY RESPONSIBILITIES**

- 2.1. **Services to Members.** Laboratory, within the limitations of its certification under CLIA or state licensure laws, will provide Covered Services to Members based on BCBSM medical necessity criteria as set forth in Addendum A, and as governed by this Agreement and all other BCBSM policies in effect on the dates Covered Services are provided.
- 2.2. **Qualification Standards.** Laboratory will comply with the Qualification Standards established by BCBSM and agrees that BCBSM has sole discretion to amend and modify these Qualification Standards from time to time, provided BCBSM will not implement any changes in the Qualification Standards without sixty (60) days prior written notice to Laboratory. The current Qualification Standards are set forth in Addendum B.
- 2.3. **Eligibility and Benefit Verification.** Before billing a Member directly for any services, Laboratory will first verify the Member's eligibility and coverage through such processes as BCBSM shall establish from time to time.
- 2.4. **Reimbursement for Services.** Except for applicable copays and deductibles, Laboratory agrees to accept as full payment:
 - a. for Covered Services, the amount reimbursed by BCBSM pursuant to Section 3.4. and BCBSM's Reimbursement Policies (Addendum C) of this Agreement; and
 - b. for any Out-of-Panel Services, the amount paid by the Alternative Delivery System according to its reimbursement policies, including any provider sanctions.

Laboratory also agrees not to collect any additional payment from any Members except as set forth in Addendum D, or from any members of Alternative Delivery Systems except as may be provided in their standard reimbursement policies or contractual arrangements with their members.

- 2.5. **Claims Submission.** Laboratory will submit acceptable claims for Covered Services and for services provided to members of Alternative Delivery Systems directly to BCBSM using BCBSM approved claim forms, direct data entry systems, tape-to-tape systems or such other methods as BCBSM may approve from time to time. An acceptable claim is one which complies with the requirements stated in published BCBSM administrative manuals or additional published guidelines and criteria.

All claims for Covered Services shall be submitted within one hundred eighty (180) days of the date(s) of service. Claims submitted more than one hundred eighty (180) days after the date(s) of service, shall not be entitled to reimbursement from either BCBSM or a Member except as set forth in Addendum D. Laboratory will submit claims and report overpayments in accordance with the Service Reporting and Claims Overpayment Policy attached as Addendum E.

HOWEVER, NOTWITHSTANDING ANYTHING CONTAINED IN THIS AGREEMENT TO THE CONTRARY, BCBSM WILL NOT REIMBURSE LABORATORY FOR ANY COVERED SERVICES REQUESTED OR ORDERED BY ANY PROFESSIONAL HEALTH CARE PROVIDER LICENSED TO ORDER LABORATORY SERVICES, EXCEPT A PATHOLOGIST, WHO HAS ANY OWNERSHIP AND/OR FINANCIAL INTEREST IN LABORATORY WHICH IS IN VIOLATION OF ANY STATE OR FEDERAL

LAW. BCBSM SHALL HAVE THE RIGHT TO RECOVER FROM LABORATORY ANY AMOUNTS PAID FOR SUCH SERVICES, INCLUDING THE RIGHT OF SET OFF AGAINST ANY AMOUNTS THEN OWING TO LABORATORY.

- 2.6. **Utilization and Quality Programs.** Laboratory will adhere to BCBSM's policies and procedures regarding utilization review, quality assessment, precertification and case management, or other programs established or modified by BCBSM, and will retain records as set forth in BCBSM administrative policy. BCBSM agrees to furnish Laboratory with necessary information to enable Laboratories to adhere to BCBSM policies and procedures.
- 2.7. **BCBSM Access to Records and Equipment.** Laboratory will allow BCBSM access to information related to any Covered Services provided pursuant to this Agreement including, but not limited to, BCBSM patient and financial records, equipment, reagents, controls, quality control charts, maintenance charts, procedure manuals, worksheets and requisitions to determine: (i) the appropriateness of its benefit payments; (ii) the eligibility of Members; (iii) continued compliance with Qualification Standards; (iv) verification of the uniformity of patient charges.
- 2.8. **Confidentiality.** Laboratory will maintain the confidentiality of the medical records and related information of Members as required by law.
- 2.9. **Record Retention.** Laboratory will prepare and maintain all appropriate medical and financial records related to Covered Services provided to Members as required by BCBSM published policies and procedures and as required by law.
- 2.10. **Audits and Recovery.** Laboratory agrees that BCBSM may photocopy, review and audit Laboratory's records to determine, but not necessarily limited to, verification of services provided, the Medical Necessity of services provided, and the appropriateness of procedure codes reported to BCBSM and to obtain recoveries based on such audits as set forth in Addendum F.
- 2.11. **Laboratory Changes.** Laboratory will notify BCBSM, in writing, at least thirty (30) days prior to implementation of major changes such as, but not limited to changes in: (i) name; (ii) location; (iii) ownership; (iv) licensure; (v) certification; (vi) changes in federal tax identification numbers, and (vii) National Provider Identification Number (NPI). Such prior notification of changes is required so that BCBSM may determine Laboratory's continued compliance with Qualification Standards and contractual obligations; however, prior notification of such major changes does not ensure continued participation and will require specific BCBSM approval for continued participation by Laboratory.

Laboratory will also notify BCBSM of any actions, policies, determinations, or other developments which may have an impact on the provision of services to Members including, but not limited, to any: (i) action against any of its licenses, certification or accreditation; and (ii) legal action against Laboratory, or any of its owners, officers, directors or employees which affects this Agreement such as for professional negligence, fraud, violation of any law, or against any license.

- 2.12. **Successor's Obligations.** Laboratory will require any prospective successor to its interest to assume liability for any amounts for which Laboratory is indebted to BCBSM. Such assumption of liability shall be a condition for approval of any such successor as a participating provider. Such assumption of liability shall not release Laboratory from the indebtedness unless an agreement to that effect is entered into between BCBSM,

Laboratory, and any prospective successor, or the successor is a participating provider and expressly agrees to assume Laboratory's liabilities to BCBSM.

- 2.13. **Compliance-Laws/Standards of Practice.** Laboratory will provide Covered Services in a manner which complies with (i) all applicable federal, state and local laws, rules and regulations, and (ii) the standards of professional conduct and practice prevailing in the applicable community during this Agreement.
- 2.14. **Provider Directories.** Laboratory agrees that BCBSM will have the right to publish Laboratory's name, address and telephone number in any participating provider directories published by BCBSM.

ARTICLE III BCBSM RESPONSIBILITIES

- 3.1. **General.** BCBSM's payment obligations pursuant to this Agreement will be limited to Covered Services provided by Laboratory in accordance with the terms and conditions contained herein. Neither BCBSM, nor any member of an Alternative Delivery System shall have any obligation to reimburse Laboratory pursuant to this Agreement for any Out-of-Panel Services provided to any such member, such reimbursement will be only pursuant to the reimbursement policies of the Alternative Delivery System in effect at the time such services are rendered, including any provider sanctions.
- 3.2. **Eligibility and Benefit Verification.** BCBSM will provide Laboratory with a system and/or method, in accordance with Article II, Section 2.3, to promptly verify eligibility and benefit coverages of Members; provided that any such verification by BCBSM will be given as a service and not as a guarantee of payment.
- 3.3. **Claims Processing.** BCBSM will process claims submitted by Laboratory for Covered Services provided to Members in a timely fashion and in accordance with the terms and conditions contained in this Agreement.
- 3.4. **BCBSM Reimbursement.** Pursuant to the terms and conditions contained in this Agreement, BCBSM will, where applicable, make direct payment to Laboratory for Covered Services provided to Members. BCBSM will have no obligation to provide Laboratory with prior notice of routine adjustments in procedure code reimbursement levels made in the normal course of its operations. In the case of other changes in its Reimbursement Policies for Clinical Laboratories, BCBSM will provide Laboratory with ninety (90) days prior written notification. The current Reimbursement Policies are set forth in Addendum C.

The exclusions and limitations set forth in Section 3.1. of this Article, regarding reimbursement for Out-of-Panel Services provided by Laboratory to members of Alternative Delivery Systems are also applicable to this Section.

- 3.5. **Administrative Manuals and Bulletins.** BCBSM will provide, at no charge to Laboratory, web access to any administrative manual, Maximum Payment Schedules, publications and such other information and documentation as shall be necessary for Laboratory to properly provide and be reimbursed for Covered Services provided to Members pursuant to this Agreement.

- 3.6. **Appeals Process.** BCBSM will provide a reconsideration appeals process for Laboratory, as set forth in Addendum G, if Laboratory disagrees with any claim adjudication or audit determination made by BCBSM.
- 3.7. **BCBSM Audits and Recovery.** BCBSM will have the right of recovery of any overpayments in accordance with Addendum E and of any amounts identified in audit(s) conducted by BCBSM as set forth in Addendum F.
- 3.8. **Confidentiality.** BCBSM shall maintain the confidentiality of Members' and Laboratory's records and information of a confidential or sensitive nature in accordance with applicable state and federal law and as set forth in Addendum H.

ARTICLE IV LABORATORY ADVISORY COMMITTEE

BCBSM will establish an advisory committee comprised of representatives of the independent clinical laboratories subject to this Agreement. The members of the committee will be designated by BCBSM in a manner to provide a representative cross section of such laboratories. BCBSM will convene the advisory committee when necessary to obtain advice and consultation on the following matters related to this Agreement, including but not limited to: (i) proposed modifications or amendments; (ii) provider class plan modifications, (iii) administrative issues; and (iv) reimbursement issues.

ARTICLE V LABORATORY ACKNOWLEDGMENT OF BCBSM SERVICE MARK LICENSEE STATUS

- 5.1 This contract is between Laboratory and BCBSM, an independent corporation licensed by the Blue Cross and Blue Shield Association (BCBSA) to use the Blue Cross and Blue Shield names and service marks in Michigan. However, BCBSM is not an agent of BCBSA and, by accepting this contract, Laboratory agrees that it made this contract based only on what it was told by BCBSM or its agents. Only BCBSM has an obligation to Laboratory under this contract and no other obligations are created or implied by this language.

ARTICLE VI GENERAL PROVISIONS

- 6.1. **Term.** The term of this Agreement shall begin on the date BCBSM receives the Signature Document from Laboratory, executed by an authorized representative of Laboratory, and shall continue until terminated as provided herein below.
- 6.2. **Termination.** This Agreement may be terminated as follows:
 - a. by either party, with or without cause, upon sixty (60) days written notice to the other party;
 - b. immediately by either party where there is a material breach of this Agreement by a party which is not cured within twenty (20) business days of written notice from the other party;
 - c. by BCBSM, automatically and without notice, if: (i) Laboratory is censured, placed on probation, or has its certification or license suspended, revoked, or

nullified, or (ii) an officer, director, owner or principal of Laboratory or Laboratory commits civil fraud, or is convicted of, or pleads to a health care related misdemeanor or a felony, including any "plea bargain," reducing a felony to a misdemeanor; or (iii) Laboratory is excluded, expelled or suspended from Medicare or Medicaid Programs (Title XVIII or XIV of the Social Security Act);

- d. by either party, upon the filing of any involuntary or voluntary proceeding in bankruptcy against either party, insolvency of any party, upon the appointment of a receiver of any party, or any other similar proceeding if such proceedings are not dismissed or withdrawn within sixty (60) days;
- e. by either party immediately if Laboratory ceases doing business or providing laboratory services;
- f. by Laboratory if BCBSM is not able to meet its financial obligations to Laboratory for a period of fifteen (15) consecutive days and Laboratory provides at least thirty (30) days prior written notification of such termination;
- g. by BCBSM, at its option, if there is a significant change in the ownership of Laboratory; and
- h. by BCBSM if termination of this Agreement is ordered by the State Insurance Commissioner.

6.3. **Existing Obligations.** Termination of this Agreement shall not affect any obligations of the Parties under this Agreement prior to the date of termination including, but not limited to, completion of all medical records and cooperation with BCBSM with respect to any actions arising out of this Agreement filed against BCBSM after the effective date of termination. This Agreement shall remain in effect for the resolution of all matters pending on the date of termination. BCBSM's obligation to reimburse Laboratory for any Covered Services will be limited to those provided through the date of termination.

6.4. **Right of Recovery.** The expiration or termination of this Agreement or any changes as provided in this Agreement shall not terminate or otherwise limit BCBSM's right of recovery from Laboratory as set forth in Article III, Section 3.7., or based upon any audit conducted pursuant to Article II, Section 2.10. of this Agreement. Such rights of BCBSM shall survive the termination of this Agreement.

6.5. **Nondiscrimination.** Laboratory will not discriminate because of age, sex, race, religion, color, or national origin, in any area of Laboratory's operations, including but not limited to employment, patient care, and clinical staff training and selection. Any violation of this provision by Laboratory shall constitute a material breach and give BCBSM the right to immediately terminate this Agreement as provided in Article VI.2.b.

6.6. **Relationship of Parties.** BCBSM and Laboratory are independent entities. Nothing in the Agreement shall be construed or be deemed to create a relationship of employer and employee, or principal and agent, or any relationship other than that of independent parties contracting with each other for the sole purpose of carrying out the provisions of this Agreement.

6.7. **Assignment.** Any assignment of this Agreement by either party without the prior authorized written consent of the other party will be null and void.

- 6.8. **Amendment.** This Agreement may be altered, amended, or modified at any time, but only by the prior authorized written consent of the parties; however, BCBSM shall have the right to unilaterally amend this agreement upon giving not less than sixty (60) days prior written notice to Laboratory as provided in Section 6.12 below or, at BCBSM's discretion, by publication in the appropriate provider publication, e.g. *The Record*.
- 6.9. **Waiver.** No waiver of any of the provisions of this Agreement shall be valid unless in writing and signed by the authorized representative of the party against whom such a waiver is being sought. Any waiver of one or more of the provisions of this Agreement or failure to enforce the Agreement by either of the parties hereto shall not be construed as a waiver of any subsequent breach of this Agreement or any of its provisions.
- 6.10. **Scope and Effect.** This Agreement shall supersede any and all prior agreements and understandings between the parties, whether written or oral, regarding the matters herein, and shall constitute the entire agreement and understanding between the parties and binding upon their respective representatives, successors and assignees.
- 6.11. **Severability.** If any provision of the Agreement is deemed or rendered invalid or unenforceable, the remaining provisions of the Agreement shall remain in full force and effect; unless any such invalidity or unenforceability has the effect of materially changing the obligations of either party, as in the judgment of the party affected, (i) will cause it serious financial hardship, or (ii) cause it to be in violation of its corporate Articles of Incorporation or Bylaws, in which event such party shall have the right to terminate this Agreement upon thirty (30) days prior written notice to the other party.
- 6.12. **Notices.** Unless otherwise provided in this Agreement, any notice required or permitted under this Agreement shall be given in writing and sent to the other party by hand-delivery, or postage pre-paid regular mail at the following address or such other address as a party may designate from time to time.

If to Laboratory:

Current address shown on
BCBSM Clinical Laboratory File

If to BCBSM:

Provider Enrollment, MC B43
Blue Cross Blue Shield of Michigan
600 Lafayette East
Detroit, Michigan 48226-2998

- 6.13. **Third Party Rights.** This Agreement is intended solely for the benefit of the parties and confers no rights of any kind on any third party and may not be enforced except by the parties hereto.
- 6.14. **Governing Law.** This Agreement, except as governed by CLIA or other federal law, will be governed and construed according to the laws of the State of Michigan.

SIGNATURE DOCUMENT ATTACHED AND MADE A PART HEREOF.

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ADDENDA

- A. Medical Necessity Criteria
- B. Qualification Standards
- C. Reimbursement Policies
- D. Services For Which Laboratory May Bill Member
- E. Service Reporting and Claims Overpayments
- F. Audit and Recovery Policy
- G. Disputes and Appeals
- H. Confidentiality Policy

MEDICAL NECESSITY CRITERIA

Medical Necessity or Medically Necessary is determined by physicians. For purposes of payment by BCBSM, Medical Necessity or Medically Necessary means a determination by physicians for BCBSM based upon criteria and guidelines developed by physicians for BCBSM acting for the appropriate professional provider group and/or medical specialty, or, in the absence of such criteria and guidelines, based upon physician review, in accordance with accepted medical standards and practices, that the service:

is accepted as necessary and appropriate for the patient's condition and is not mainly for the convenience of the member or physician; and in the case of diagnostic testing, the tests are essential to and are used in the diagnosis and/or management of the patient's condition.

QUALIFICATION STANDARDS

In order to participate with BCBSM, Laboratory must have all of the following standards in effect at all times during the term of the Agreement:

1. Certification and compliance with the Clinical Laboratory Improvement Amendments (CLIA) as to all Covered Services performed for Members and billed to BCBSM or, if applicable, be licensed and comply with any state law which may be enacted to supersede CLIA in accordance with the provisions contained therein.
2. Availability of qualified testing personnel and adequately maintained equipment to properly perform Covered Services for Members.
3. The establishment and maintenance of quality standards to ensure that Covered Services are properly performed and appropriate for the purpose intended.
4. No ownership by any professional health care provider licensed to order laboratory services other than a pathologist except as permitted by state or federal law.
5. Absence of inappropriate practice patterns as identified through proven Member complaints, medical necessity audits and peer review.
6. Absence of fraud or other illegal activities.

REIMBURSEMENT POLICIES

For Covered Services performed by Laboratory, BCBSM will pay the lesser of billed charges or the amount indicated in the BCBSM Maximum Payment Schedule (the "Schedule") less any deductible and/or copayment amount for which the Member is responsible. The billed charge refers to the actual charge indicated on the claim form submitted by Laboratory. Part of the Schedule is based on the Resource Based Relative Value Scale (RBRVS) developed by the Centers for Medicare and Medicaid Services (CMS), in which services are ranked according to the resource costs needed to provide them. The resource costs of the RBRVS system include physician time, training, skill, risk, procedure complexity, practice overhead and professional liability insurance. Values are assigned to each service in relation to the comparative value of all other services. The relative values are then multiplied by a BCBSM conversion factor to determine overall payment levels.

Other factors that may be used in setting maximum payment levels include comparison to similar services, corporate medical policy decisions, analysis of historical charge data and geographic anomalies. BCBSM may give individual consideration to services involving complex treatment or unusual clinical circumstances in determining a payment that exceeds the maximum payment level. BCBSM may adjust maximum payment levels based on factors such as site of care or BCBSM payment policy.

Fees for non-Relative Value Unit-based clinical laboratory services will be based on the Medicare fee schedule plus a percentage set by BCBSM.

Fees for multichannel codes are individually priced and are subject to the physician fee update.

BCBSM reviews relative values and reimbursement levels periodically and may adjust them as deemed necessary by BCBSM. A review does not guarantee that any relative values or maximum payment levels will be increased.

Notice required under Section 3.4 and Addendum C of this Agreement will be (i) by mail, or (ii) published in the Schedule, or, (iii) at BCBSM's option, in the appropriate BCBSM provider publication (e.g., *The Record*, *web-DENIS*, etc.).

SERVICES FOR WHICH LABORATORY MAY BILL MEMBER

Laboratory may bill Member for:

1. Services which are not Covered Services, unless the service has been deemed to be noncovered solely as a result of a retrospective determination by a BCBSM medical consultant that the service was not Medically Necessary, in which case Laboratory assumes full financial responsibility for the denied claims. BCBSM will endeavor to apply like medical specialties to the claims review process. Laboratory may bill the Member for claims denied as not Medically Necessary only as stated in paragraph 2. below;
2. Any service so determined by a BCBSM medical consultant to be not Medically Necessary, where the Member acknowledges that BCBSM will not make payment for the service, and the member, prior to the receipt of any such service, has assumed financial responsibility for the service in writing, either to Laboratory or to the ordering health care provider.
3. Covered Services denied by BCBSM as untimely billed, if all of the following requirements are met:
 - a. Laboratory documents that a claim was not submitted to BCBSM within one hundred eighty (180) days of performance of such services because either a Member failed to provide proper identifying information, or the ordering health care provider refused to provide the appropriate information, such as diagnosis codes, required for Laboratory to properly bill and obtain reimbursement from BCBSM..
 - b. Laboratory submits a claim to BCBSM for payment consideration within three (3) months after obtaining the necessary information.

SERVICE REPORTING AND CLAIMS OVERPAYMENT POLICY

I. Service Reporting

Laboratory will report services to BCBSM in the form BCBSM specifies and furnish any additional information BCBSM may reasonably request to process or review the claim. All services shall be reported without charge, with complete and accurate information, including diagnosis, with HCPCS procedure codes approved by BCBSM, Laboratory's assigned Provider Identification Number (PIN), license number of prescribing physician/provider, and such other information as may be required by BCBSM to adjudicate claims.

Laboratory will use the Clinical Laboratory PIN assigned by BCBSM for billing of Covered Services.

Laboratory agrees to use reasonable efforts to cooperate with and assist BCBSM in coordinating benefits with other sources of coverage for Covered Services by requesting information from Members, including but not limited to information pertaining to workers' compensation, other group health insurance, third-party liability and other coverages. Laboratory further agrees to identify those members with Medicare coverage and to bill BCBSM or Medicare consistent with applicable federal and state laws and regulations. When Laboratory is aware the patient has primary coverage with another third-party payer or entity, Laboratory agrees to submit the claim to that party before submitting a claim for the services to BCBSM. BCBSM's secondary coverage will be limited to the difference, if any, between the maximum amount BCBSM would have otherwise paid less the amount paid by the primary carrier. If the primary carrier's payment exceeds the BCBSM maximum payment, no secondary coverage will be provided by BCBSM.

II. Overpayments

Laboratory shall report overpayments to BCBSM due to Laboratory's billing errors or BCBSM payment errors within thirty (30) days after discovery, and agrees BCBSM will be permitted to deduct overpayments (whether discovered by Laboratory or BCBSM) from any payments then or thereafter due Laboratory under any BCBSM program, along with an explanation of the action taken. In audit refund recovery situations, where Laboratory appeals the BCBSM determination, BCBSM will defer deduction of overpayments until the determination, or the last unappealed determination, whichever occurs first. Audit refund recoveries and other overpayment obligations which cannot be fully repaid over the course of one (1) month, will bear interest at the BCBSM prevailing rate, until fully repaid.

AUDIT AND RECOVERY POLICY

I. Records

BCBSM shall have access to the Member's medical records or other pertinent records of Laboratory to verify Medical Necessity and appropriateness of payment and may inspect and photocopy the records. BCBSM will reimburse Laboratory for the reasonable copying expense incurred by Laboratory where Laboratory copies records requested by BCBSM in connection with BCBSM audit activities.

Laboratory shall prepare and maintain all appropriate records on all Members receiving services, and shall prepare, keep and maintain records in accordance with BCBSM's existing record keeping and documentation requirements and standards previously communicated to Laboratories by BCBSM, and any requirements subsequently developed which are communicated to Laboratory prior to their implementation, and as required by law.

II. Scope of Audits

Audits may consist of, but are not necessarily limited to, verifications of services provided, Medical Necessity of services provided, and appropriateness of procedure codes reported to BCBSM for services rendered.

III. Time

BCBSM may conduct on-site audits during Laboratory's regular business hours. BCBSM's inspection, audit and photocopying or duplication shall be allowed during regular business hours, upon reasonable notice of dates and time.

IV. Recovery

BCBSM shall have the right to recover amounts paid for services not meeting applicable benefit criteria or not Medically Necessary. BCBSM will not utilize statistical sampling methodologies to extrapolate refund requests on Medical Necessity issues identified through sampling. BCBSM may extrapolate refund recoveries from statistically valid samples involving issues other than Medical Necessity, including but not limited to, procedure code billing errors.

BCBSM shall have the right to initiate recovery of amounts paid for services up to two (2) years from the date of payment, except in instances of fraud, as to which there will be no time limit on recoveries.

**DISPUTES AND APPEALS
APPEALS PROCESS FOR INDIVIDUAL CLAIMS DISPUTES AND UTILIZATION REVIEW
AUDIT DETERMINATIONS**

ROUTINE INQUIRY PROCEDURES AND/OR AUDIT DETERMINATION

Laboratory must complete BCBSM's routine status inquiry, telephone (optional) and written inquiry procedures (for individual claims disputes), or receive an audit determination before beginning the appeals process.

WRITTEN COMPLAINT / RECONSIDERATION REVIEW

Within 30 days of completing BCBSM's routine written inquiry procedures, or within 30 days of receiving BCBSM's written audit determination, Laboratory shall begin the appeals process by submitting a Written Complaint and/or a request for a Reconsideration of the Audit Determination. The Written Complaint/Reconsideration Review request should be mailed to:

For **individual claims** disputes:

Blue Cross and Blue Shield of Michigan
Provider Appeals Unit MC 2005
Mail Code 2005
600 Lafayette East
Detroit, MI 48226-2998

For disputes regarding **professional provider utilization review audit results**:

Blue Cross Blue Shield of Michigan
Manager, Professional Utilization Review MC J103
600 Lafayette East
Detroit, MI 48226-2998

A request for a Reconsideration Review must include the following:

- Area of dispute;
- Reason for disagreement;
- Any additional supportive documentation;
- and, Copies of medical records (if not previously submitted).

Within 30 days of receipt of the request for Written Complaint/Reconsideration Review, BCBSM shall provide in writing a specific explanation of all of the reasons for its action that form the basis of Laboratory's complaint and/or the results of the Reconsideration Review.

MANAGERIAL-LEVEL REVIEW CONFERENCE

If Laboratory is dissatisfied with the determination of the Written Complaint/Reconsideration Review, Laboratory may submit a written request for a Managerial-Level Review Conference. The purpose of the Conference is to discuss the dispute in an informal setting, and to explore possible resolution of the dispute. The written request for this Conference must be submitted within 60 days after the receipt of the determination letter from the Written Complaint or Reconsideration Review. If the dispute involves issues of a medical nature, a BCBSM medical consultant may participate in the Conference. If the dispute is non-medical in nature, other appropriate BCBSM personnel will attend. Laboratory or its representative will normally be in attendance to present their case. The conference can be held by telephone if Laboratory prefers. The request for a Conference shall be submitted in writing to BCBSM:

For Conferences regarding **individual claims** disputes:

Blue Cross Blue Shield of Michigan
Conference Coordination Unit
Mail Code 2027
600 Lafayette East
Detroit, MI 48226-2998

For Conferences regarding **professional utilization review audit results** disputes:

Blue Cross Blue Shield of Michigan
Manager, Professional Utilization Review MC J103
600 Lafayette East
Detroit, MI 48226-2998

A request for a Managerial-Level Review Conference must include the following:

- Area of dispute;
- Reason for disagreement;
- Any additional supportive documentation;
- and, Copies of medical records (if not previously submitted).

BCBSM will both schedule the Conference and communicate the results to Laboratory in writing within 30 days of the request for the Conference. The determination(s) of a Managerial-Level Review Conference delineate the following, as appropriate:

- 1) The proposed resolution;
- 2) The facts, along with supporting documentation, on which the proposed resolution was based.
- 3) The specific section or sections of the law, certificate, contract or other written policy or document on which the proposed resolution is based;
- 4) A statement describing the status of each claim involved in the dispute; and

5) If the determination is not in concurrence with the Professional appeal, a statement explaining Laboratory's right to appeal the matter to the Michigan Insurance Bureau with 120 days after receipt of BCBSM's written response to the Conference, as well as Laboratory's option to request External Peer Review (Medical Necessity issues only), request a review by the BCBSM Internal Review Committee/Provider Relations Committee (administrative, billing and coding issues only), or initiate an action in the appropriate State Court.

EXTERNAL PEER REVIEW

For disputes involving **issues of Medical Necessity** that are resultant from medical record reviews, Laboratory may submit a written request for an External Peer Review if dissatisfied with the previous level of appeal. Within 30 days of the Managerial-Level Review Conference determination, Laboratory can request a review by an external peer review organization to review the medical record(s) in dispute. Laboratory will normally be notified of the determination(s) made by the review organization within 60 days of submission of the records to the peer review organization. Such determination will be binding upon the provider and BCBSM.

If BCBSM's findings are upheld on appeal, Laboratory will pay the review costs associated with the appeal. If BCBSM's findings are reversed by the external peer review organization, BCBSM will pay the review costs associated with the appeal. If BCBSM's findings are partially upheld and partially reversed, the parties will share in the review costs associated with the appeal, in proportion to the results as measured in findings upheld or reversed.

This appeal step ends the appeal process for all Medical Necessity issues arising from any medical record review and operates as a waiver of Laboratory's right to appeal any Medical Necessity issues to the Insurance Bureau or to initiate an action on those issues in a state court.

The **Professional** request for External Peer Review for a dispute regarding medical record audit results shall be mailed to:

Blue Cross Blue Shield of Michigan
Manager, Professional Utilization Review MC J103
600 Lafayette East
Detroit, MI 48226-2998

For **Individual Claims** disputes, a request for External Peer Review shall be mailed to:

Blue Cross Blue Shield of Michigan
Conference Coordination Unit
Mail Code 2027
600 Lafayette East
Detroit, MI 48226-2998

INTERNAL REVIEW COMMITTEE

For disputes involving **Administrative and/or Billing & Coding issues**, Laboratory may submit a written request for a review by the BCBSM Internal Review Committee (IRC) which is composed of 3 members of BCBSM senior management. The request for an IRC hearing shall

specify the reasons why the BCBSM policy(ies) in dispute is inappropriate or has been wrongly applied, and shall be submitted in writing within 30 days of receipt of BCBSM's response to the Managerial-Level Review Conference. Within 60 days of the request, a meeting will be held. Laboratory, or its representative and upon Laboratory's written request, may be present at this hearing. BCBSM will communicate the determination of the Committee within 30 days of the meeting date.

The request for a IRC hearing should be mailed to:

Blue Cross Blue Shield of Michigan
Director, Utilization Management MC J423
600 Lafayette East
Detroit, MI 48226-2998

If Laboratory is dissatisfied with the determination of the Internal Review Committee, it may appeal the determination to either the Provider Relations Committee (a sub-committee of BCBSM's Board of Directors) or directly to the Michigan Insurance Bureau; or initiate an action in an appropriate state court.

PROVIDER RELATIONS COMMITTEE

If dissatisfied with the decision of the IRC, Laboratory may, within 30 days of receipt of the IRC determination, submit a written request for a review to the Provider Relations Committee (PRC); a sub-committee of the BCBSM Board of Directors composed of BCBSM participating professionals, community leaders and BCBSM senior management. BCBSM will acknowledge the receipt of the request and will schedule a meeting with the PRC within 90 days. Laboratory must represent itself at this level of appeal and an advanced position statement is required. The determination of the PRC may or may not be rendered on the day of the hearing. The PRC's mandate is to render a determination within a reasonable time; however these decisions will normally be rendered within 30 days of the date of the hearing. As such, BCBSM will communicate in writing the determination of the PRC within 30 days of the PRC's determination.

The request for a PRC hearing should be mailed to:

Blue Cross Blue Shield of Michigan
Director, Utilization Management MC J423
600 Lafayette East
Detroit, MI 48226-2998

If Laboratory is dissatisfied with the determination of the Provider Relations Committee, it may appeal the determination to the Michigan Insurance Bureau, or initiate an action in an appropriate state court.

MICHIGAN INSURANCE BUREAU

Informal Review & Determination

If Laboratory is dissatisfied with BCBSM's response to either the Managerial-Level Review Conference, the Internal Review Committee review, or the Provider Relations Committee review, and if Laboratory believes that BCBSM has violated a provision of either Section 402 or 403 of P.A. 350, Laboratory shall have the right to submit a request to the Michigan Insurance Bureau for an Informal Review & Determination (IR&D).

The request shall be submitted within 120 days of receipt of BCBSM's determination and must specify which provisions of P.A. 350 Sections 402(1) and 403 BCBSM has violated. The request shall be mailed to:

Commissioner of Insurance
Michigan Insurance Bureau
Post Office Box 30200
Lansing, Michigan 48909

The Informal Review and Determination may take place through submission of written position papers or through the scheduling of an informal meeting at the offices of the Insurance Bureau. Within 10 days of the receipt of position papers or the adjournment of the informal meeting, the Insurance Bureau shall issue its determination.

Contested Case Hearing

If dissatisfied with the Insurance Bureau's determination, either Laboratory or BCBSM may ask the Insurance Commissioner to have the matter heard by an Administrative Law Judge as a Contested Case under the Michigan Administrative Procedures Act. A Contested Case must be requested in writing within 60 days after the Insurance Bureau's Determination is mailed, and shall be mailed to the Insurance Bureau at the same address found in the prior step.

CIVIL COURT REVIEW

Either Laboratory or BCBSM may appeal the Contested Case result to the Ingham County Circuit Court.

STATE COURT SYSTEM

Also, as noted above, at any time after the completion of the Written Complaint/Reconsideration Review and Management Review Conference steps, Laboratory may attempt to resolve the dispute by initiating an action in the appropriate state court.

CONFIDENTIALITY POLICY

The purpose of BCBSM's Confidentiality Policy is to provide for the protection of the privacy of Members, and the confidentiality of personal data, personal information, and Laboratory financial data and information.

BCBSM's Policy sets forth the guidelines conforming to MCLA 550.1101 et seq which requires BCBSM's Board of Directors to establish and make public the policy of the Corporation regarding the protection of the privacy of Members and the confidentiality of personal data.

In adopting this policy, BCBSM acknowledges the rights of its Members to know that personal data and personal information acquired by BCBSM will be treated with respect and with reasonable care to ensure confidentiality; to know that it will not be shared with others except for legitimate business purposes or in accordance with a Member's specific consent or specific statutory authority.

The term personal data refers to a document incorporating medical or surgical history, care, treatment or service; or any similar record, including an automated or computer accessible record relative to a Member, which is maintained or stored by a health care corporation.

The term personal information refers to a document or any similar record relative to a Member, including an automated or computer accessible record, containing information such as an address, age/birth date, Coordination of Benefits data, which is maintained or stored by a health care corporation.

The term Laboratory financial data and information refers to a document or other record, limited to automated or computer record, containing paid claims data, including utilization and payment information. BCBSM will maintain Laboratory financial data and information as confidential.

BCBSM will collect and maintain necessary Member personal data and take reasonable care to secure these records from unauthorized access and disclosure.

Records containing personal data will be used to verify eligibility and properly adjudicate claims. For coordinated benefits, BCBSM will release applicable data to other insurance carriers to determine appropriate liability.

Enrollment applications, claim forms and other communications to Members will notify Members of these routine uses and contain the Member's consent to release data for these purposes. These forms will also advise the Members of their rights under this policy.

Upon request, a Member will be notified regarding the actual release of personal data.

BCBSM will not release Member-specific personal data except on a legitimate need-to-know basis or where the Member has given specific authorization. Data released with the Member's specific authorization will be subject to the condition that the person receiving the data will not release it further unless the Member executes in writing another prior and specific informed consent authorizing the additional release. Where protected by specific statutory authority, Member-specific data will not be released without appropriate authorization.

Experience rated and ASC customers and hospitals may obtain personal data and Laboratory financial data for auditing and other purposes provided that claims of identifiable Members are protected in accordance with any specific statutory authority. For these requests, the recipients of the data will enter into a confidentiality and indemnification agreement with BCBSM to ensure confidentiality and to hold BCBSM harmless from any resultant claims or litigation.

Parties acting as agents to accounts and facilities will be required to sign third-party agreements with BCBSM and the recipient of the data prohibiting the use, retention or release of data for other purposes or to other parties than those stated in the agreement.

Data released under this policy will be subject to the condition that the person to whom the disclosure is made will protect and use the data only as authorized by this policy.

BCBSM will release required data pursuant to any federal, state or local statute or regulation.

For civil and criminal investigation, prosecution or litigation, BCBSM will release requested data to the appropriate law enforcement authorities or in response to appropriate legal process.

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