

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner

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

No. 12-061-BC

/

Issued and entered
this 16th day of January 2013
by R. Kevin Clinton
Commissioner

ORDER ISSUING DETERMINATION REPORT

I

BACKGROUND

Pursuant to Public Act 350 of 1980, as amended (Act), being MCLA 550.1101 et seq.; MSA 24.660 (101) et seq., the Commissioner of the Office of Financial and Insurance Regulation (Commissioner) issued Order No. 12-034-BC on August 1, 2012, giving notice to Blue Cross and Blue Shield of Michigan (BCBSM), and to each person who requested a copy of such notice, of his intent to make a determination with respect to the pharmacy provider class plan for calendar years 2010 and 2011.

II

FINDINGS OF FACT AND CONCLUSIONS OF LAW

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

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

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

III

ORDER

Therefore, it is ORDERED that:

1. The attached pharmacy provider class plan determination report shall be incorporated by reference as part of this order and shall serve as the Commissioner's determination with respect to the pharmacy provider class plan for the calendar years 2010 and 2011.
2. Pursuant to Section 510(2) of the Act, the Commissioner shall notify BCBSM and each person who has requested a copy of such determination by certified or registered mail.
3. Pursuant to Section 515(1) and (2), any appeal must be filed within 30 days of the date of this determination report. The request for an appeal shall identify the issue or issues involved and how the person is aggrieved.

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



R. Kevin Clinton
Commissioner

EXECUTIVE SUMMARY

Pursuant to Public Act 350 of 1980, this report provides a review and determination of whether the arrangements Blue Cross and Blue Shield of Michigan (BCBSM) has established with health care providers have substantially achieved the access, quality of care, and cost goals set forth in the Nonprofit Health Care Corporation Reform Act for calendar years 2010 and 2011. The statutory goals specify that these arrangements, known as provider class plans, must assure subscribers reasonable access to, and reasonable cost and quality of, health care services covered under BCBSM's certificates.

The analysis and determination of goal performance is based on BCBSM's 2009-2010 pharmacy provider class plan annual report, additional data requested of BCBSM, and information on file with respect to this provider class plan. This material was supplemented as necessary by data from published sources. The determination report analyzes the level of achievement for each goal separately and discusses interaction and balance among the goals.

Access Goal

Achievement of the access goal requires BCBSM to be able to assure that, in any given area of the state, a BCBSM member has reasonable access to pharmacy services whenever necessary. In analyzing BCBSM's performance on the access goal, consideration was given to the formal participation rates of pharmacy providers. The number of pharmacy providers participating with BCBSM in most Michigan regions is at an acceptable level. BCBSM also demonstrated a commitment to service through the availability of easily accessible electronic publications and tools and effective provider servicing. Based on these facts, it is determined that BCBSM met the access goal during 2010 and 2011.

Quality of Care Goal

The quality of care goal requires BCBSM to assure that providers meet and abide by reasonable standards of health care quality. To achieve this goal, BCBSM must show that it makes providers aware of practice guidelines and protocols for pharmacy services, that it verifies that providers adhere to such guidelines and that it maintains effective methods of communication with its providers. During calendar years 2010 and 2011, BCBSM continued to ensure that its qualification standards for participation were met by pharmacy providers. BCBSM also conducted utilization review audits to ensure that the services rendered to BCBSM patients were medically necessary and appropriately administered, and had an established appeal process to deal with provider disputes. BCBSM kept the lines of communication open with pharmacy providers with regular meetings of the Pharmacy Advisory Committee as well as regular communications with providers through its monthly publication of the *Record*, provider manuals and appeal processes. Based on the information analyzed during this review, it is determined that BCBSM met the quality of care goal stated in the Act for the calendar years 2010 and 2011. BCBSM is encouraged to continue meeting regularly with the MPA to address its concerns regarding an updated provider manual as the provider manual is rather outdated in comparison to those available

to other provider classes. BCBSM is also encouraged to obtain reports from its pharmacy benefit manager with respect to many of BCBSM's initiatives so BCBSM knows whether such initiatives are achieving desired results.

Cost Goal

The cost goal requires that the arrangements BCBSM maintains with each provider class will assure a rate of change in the total corporation payment per member that is not higher than the compound rate of inflation and real economic growth. Achievement of the cost goal is measured by application of the cost formula specified in the Act, which is estimated to be 1.4% for the period under review. As the rate of change in the total corporation payment per member for the pharmacy provider class has been calculated to be an increase of 42.3% over the two years being reviewed, BCBSM did not meet the cost goal stated in the Act for 2010 and 2011.

Overall Balance of Goals

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



RICK SYNDER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
R. KEVIN CLINTON, COMMISSIONER

STEVE ARWOOD
ACTING DIRECTOR

**Blue Cross and Blue Shield of Michigan's
Pharmacy Provider Class Plan
for calendar years 2010 and 2011**

**A Determination Report issued by
Commissioner R. Kevin Clinton**

January 2013

PHARMACY
PROVIDER CLASS PLAN
DETERMINATION REPORT

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Introduction

The purpose of this report is to determine whether Blue Cross and Blue Shield of Michigan (BCBSM) met the access, quality of care, and cost goals outlined in the Nonprofit Health Care Corporation Reform Act, MCLA 550.1101 et seq. (Act), with respect to the pharmacy provider class plan for the calendar years 2010 and 2011.

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

Provider Class Plans - Legal Background

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

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

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

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

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

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

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

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

Overview of the Pharmacy Provider Class Plan

The pharmacy provider class for BCBSM covers prescriptions dispensed by pharmacies such as FDA-approved drugs; state controlled drugs; injectable insulin; disposable syringes and needles when dispensed with a drug; select over the counter drugs and compound drugs containing at least one "FDA-approved" drug. BCBSM's mail order drug program is offered to customers as an option under their prescription drug coverage and covers up to a 90-day supply of prescription drugs. Under the pharmacy provider class, retail pharmacies can administer select vaccinations to members under their medical benefits. Specialty pharmacies dispense specialty drugs directly to members and patient-specific specialty drugs to physicians to be administered to their patients. Lastly, anti-hemophilia factors can be dispensed with a patient specific prescription to a member or health care practitioner's office under the member's medical benefit.

For the period 2010-2011, payments to pharmacy providers represented an average of 70% of the total benefit payments made to health care providers on behalf of BCBSM members. In 2011, payments to retail pharmacies comprised 64.2% of the total pharmacy payout, payments to mail order pharmacies comprised 34.9% of the total pharmacy payout, with the remaining 0.9% of the payout made to specialty pharmacies. BCBSM states that 6.8% of all pharmacy payments made were associated with BCBSM's traditional program and 93.2% of payments were associated with BCBSM's PPO program.

For the purpose of provider class plan reviews by the Office of Financial and Insurance Regulation (OFIR), paid claims data are categorized by nine geographic regions. A map, which depicts these geographic regions, is included in Attachment A.

BCBSM's qualification standards for all pharmacies include:

- Current registration with the Drug Enforcement Agency (DEA)
- Have sufficient liability insurance as required by BCBSM
- All employed, associated or contracted personnel are licensed or certified, supervised (as required by state law), and qualified by education, training and experienced to perform their professional duties and act within the scope of their licensure or certification
- Dispense prescription drugs with pharmacist professional judgment and comply with all applicable state, local and federal laws and regulations
- Comply with BCBSM utilization management programs
- Have no history of inappropriate utilization or practice patterns as identified through proven subscriber complaints, peer review and utilization management
- Have no history of fraudulent or illegal activities

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There are also additional standards specific to each type of pharmacy program. BCBSM states it may deny participation to pharmacies that do not meet or maintain its qualification standards.

All retail pharmacies are required to be licensed in Michigan as a pharmacy and use best efforts to obtain or to assist members in obtaining prescribed medications, including high cost/high tech covered services not routinely stocked by the pharmacy. Participating retail pharmacies that wish to administer selected vaccines under the Vaccine Affiliation Agreement are required to register all immunizations with the state of Michigan's vaccine registry.

In order to participate as a mail order pharmacy, the pharmacy is required to meet additional standards which include, but are not limited to, licensure as a pharmacy in the state in which the pharmacy is located.

BCBSM states that additional standards for formal participation as a specialty pharmacy include, but are not limited to:

- Have current licenses and/or permits required by local, state or federal authorities to dispense specialty drugs and ancillary products
- Accredited by a nationally recognized accrediting body accepted by BCBSM
- Maintain a comprehensive quality assurance or quality improvement program
- Maintain documentation of applicable state and federal inspections

Additional standards for formal participation as a hemophilia provider include, but are not limited to:

- Have the capability to distribute factor throughout the state of Michigan
- Have all current licenses or permits required by local, state or federal authorities applicable to dispensing specialty drugs and ancillary products
- Possess current wholesale or distribution licenses and registrations to service BCBSM practitioners
- Accredited by at least one national accreditation organization approved by BCBSM or recognized as a Hemophilia Treatment Center receiving 340B status of the Public Health Service Act
- Maintain a physical location on an appropriate site in Michigan, as determined by BCBSM, where the provider conducts business as a supplier of home hemophilia therapy

Although the Act requires BCBSM to only report information pertaining to BCBSM's traditional benefit program, BCBSM has reported information pertaining to its PPO and point of service (POS) programs for the pharmacy provider class because it is unable to

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separate traditional membership from PPO and POS membership for the pharmacy provider class.

Reimbursement to retail (chain and independent) pharmacies includes the sum of drug product cost and dispensing fee, minus member liability, plus any applicable incentives. Vaccines reimbursement is the sum of the drug product cost plus an administration fee. No dispensing fee or incentive is paid to the pharmacy.

Mail order pharmacies are reimbursed at the lowest of the maximum allowable cost (MAC) payment level, the discounted average wholesale price, or the submitted ingredient cost, plus the dispensing fee and any sales tax, if applicable, minus any member liability.

Specialty pharmacies were reimbursed for covered drugs dispensed to members and providers according to the following:

- The drug product cost for drugs dispensed to a member and billed to BCBSM under the member's pharmacy benefit are reimbursed at the average wholesale price minus a negotiated percentage and any member liability. No dispensing fee or incentive was paid. Reimbursement included the cost of any ancillary products or services provided by the specialty pharmacy.
- The drug product cost for drugs dispensed to a physician and billed to BCBSM under the member's medical benefit are reimbursed at the average sale price plus a negotiated percentage minus any member liability. No dispensing fee or incentive was paid. If no average sale price was available for a covered drug, BCBSM reimbursed the discounted average wholesale price less a negotiated percentage until an average sale price became available.

The drug product cost for hemophilia factors dispensed to a member or physician and billed to BCBSM under the member's medical benefit was reimbursed at the average wholesale price minus any member liability. No dispensing fee or incentive was paid. Reimbursement included the cost of any ancillary products or services provided by the hemophilia provider.

During the review period, pharmacy providers could participate with BCBSM only under its formal participation program. A formally participating provider has signed an agreement to accept BCBSM reimbursement as payment in full, excluding applicable co-payments or deductibles, for all covered services rendered to BCBSM members by the provider. Members who receive covered drugs from a nonparticipating pharmacy in the United States are directly reimbursed at 75% (100% for emergency pharmacy services) of the pharmacy's charge minus the member's copay amount. For covered drugs obtained from

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a nonparticipating pharmacy outside the United States, BCBSM reimburses the member for the drug product cost and dispensing fee, minus the member's copay amount.

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

Access:

- To provide direct reimbursement to participating providers who provide covered drugs and high-quality services to BCBSM members.
- To communicate with participating providers about coverage determinations, billing, benefits, provider appeals processes, BCBSM's record keeping requirements and the participation agreement and its administration.

Quality of Care:

- To ensure provision of quality care to BCBSM subscribers through the application of participation qualifications and performance standards as a basis for pharmacy participation.
- Meet with the Pharmacy Advisory Committee on an ongoing basis
- Meet with specialty liaison societies to discuss issues of interest and concern, as necessary
- Maintain and update, as necessary, an appeals process that allows participating providers to appeal individual claims disputes and disputes regarding utilization review audits

Cost:

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

History of the Pharmacy Provider Class Plan

BCBSM had an existing reimbursement arrangement with pharmacists in effect when the Act took effect on August 27, 1985. BCBSM first filed the pharmacists' provider class plan with OFIR pursuant to Section 506(1) of the Act on August 17, 1987. Section 506(2) states:

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

Section 506(2) further states:

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

Since the pharmacists' provider class plan met the filing requirements of Section 506 of the Act stated above, OFIR notified BCBSM by letter on September 3, 1987 that the pharmacies' provider class plan was placed into effect and retained for the commissioner's records pursuant to Section 506(4).

On November 5, 1987, BCBSM amended all of its provider class plans, including the pharmacists' plan, to include an appeal process for utilization review audits performed by the corporation. This amendment to the pharmacists' provider class plan was made by BCBSM in accordance with Section 508(1) of the Act.

Prior to December 9, 1993, the name of this provider class plan was the pharmacists' provider class plan. BCBSM renamed the plan to the pharmacy provider class plan inasmuch as the provider contract is between BCBSM and the pharmacy, not BCBSM and the individual pharmacists. Other changes to the plan filed on December 9, 1993 included changes to the reimbursement methodology, the participation agreement and the addition of a mail order pharmacy participation agreement.

The pharmacy provider class plan was modified by BCBSM on February 23, 1995, November 4, 1996, and December 26, 1997. The various modifications BCBSM made to the plan included the implementation of a participation contract for mail order providers, and changes in the reimbursement methodology used to pay pharmacy providers and the appeal process available to non-hospital, non-physician providers.

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BCBSM also modified the pharmacy provider class plan on August 30, 2005. BCBSM updated its language regarding reimbursement, and reformatted the provider class plan to reflect the current mail order pharmacy program.

On September 25, 2006, BCBSM modified the pharmacy provider class plan to include an updated provider contract for mail order services and to recognize specialty pharmacies as providers. Lastly, on July 10, 2008, BCBSM revised the provider class plan to recognize hemophilia providers as part of the pharmacy provider class. In September 2010, BCBSM revised the pharmacy provider class plan to include the vaccine affiliation agreement and the revised pharmacy benefit manager master agreement. The plan was revised to reflect that pharmacies can bill BCBSM for select vaccines under the member's medical benefits. The pharmacy benefit manager master agreement was updated with respect to the mail order drug program. The updated agreement replaced the 2000 pharmacy benefit manager master agreement and was effective January 1, 2010. BCBSM also modified its provider class plan on June 13, 2012 to reflect updates to the Affinity pharmacy provider contracts to indicate that BCBSM for contraceptive medications that are mandated under the Patient Protection and Affordable Care Act. BCBSM notes that its traditional and PPO pharmacy programs account for 33.8% and 66.2% of BCBSM's total pharmacy payout, respectively.

Review Process

On August 1, 2012, the Commissioner issued Order No. 12-034-BC, which provided written notice to BCBSM, health care providers, and other interested parties of his intent to make a determination with respect to the pharmacy provider class plan for the calendar years 2010 and 2011. Order No. 12-034-BC also called for any person with comments on matters concerning the provider class plan to submit such comments to OFIR in accordance with Section 505(2) of the Act. Section 505(2) requires the Commissioner to establish and implement procedures whereby any person may offer advice and consultation on the development, modification, implementation, or review of a provider class plan. Requests for testimony on BCBSM's pharmacy provider class plan were sent to all those on OFIR's interested persons list for the pharmacy provider class and posted on OFIR's website, providing interested parties three months to prepare and submit testimony.

Summary of Testimony and Input:

Testimony with respect to the pharmacy provider class plan was received only from the Michigan Pharmacists Association (MPA). MPA states that while it acknowledges that most pharmacies accept BCBSM, not all do, so MPA recommends that BCBSM identify in a detailed level exactly what the pharmacy participation level is. Also, since BCBSM differentiates pharmacy practice providers, MPA believes BCBSM should provide a

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detailed report identifying pharmacy participation levels based upon BCBSM specified pharmacy provider types.

A review of a detailed report would identify concerns pertaining to pharmacy access on a number of levels. BCBSM has several beneficiary mandates (mail order mandates and specialty pharmacy mandates) that restrict access to particular pharmacy providers. BCBSM has a specific designated specialty pharmacy agreement which has resulted in locking out all specialty pharmacies with the exception of one major provider for medications supplied under the medical benefit. If BCBSM policies allow pharmacies to dispense medications under the medical benefit, then appropriate access to pharmacy providers should be required instead of a restriction. Restriction in the specialty pharmacy program does not provide open access and, therefore, negates BCBSM comments that they have "almost 100 percent participation" under access. BCBSM similarly mandates member use of a mail-order program.

MPA states BCBSM maintains several different pharmacy networks based upon its multi-level provider agreement types (e.g. traditional, preferred). Historically, pharmacies have had the opportunity to choose to participate in either network or both. BCBSM has been limiting pharmacy participation in the networks, no longer allowing the option for the pharmacy to participate in one or more of the networks, thereby restricting provider access for members. MPA would like to see BCBSM report on a detailed level the percentage of pharmacy participation and access based upon the specific type of pharmacy provider network. MPA believes that if BCBSM had one pharmacy participation contract, without separate amendments based upon geography, sub-classification of provider type and class, then the reporting level identified in its annual report could be allowed on an aggregate level. MPA notes that provides a separate dispensing fee for certain counties and believes that pharmacy provider participation levels should be evaluated based upon this geographic reimbursement difference as well.

MPA states that BCBSM indicated its desire to develop a strong relationship with participating providers and maintaining effective relations with them through communications, an appeal process and the Pharmacy Advisory Committee (PAC) meetings. MPA states it appreciates the opportunity to participate in PAC, however, lately pharmacy provider participation does little to ensure effective relations with pharmacy providers and appropriate communication. BCBSM should invite more providers to attend PAC meetings to ensure the best opportunity for collaboration and to effectively communicate information.

BCBSM established a Pharmacy Advisory Subcommittee following responses made during the 2009 Pharmacy Provider Class Review to address several issues that had been identified. To date, the Pharmacy Advisory Subcommittee has not yet completed several of the items that were open for discussion. MPA states that for the past several years

providers have been requesting an updated copy of the BCBSM Guide for Pharmacists. In reality, BCBSM has not updated its policy manual since 1997 even though many of its policies have changed. Pharmacy providers do, however, have access to annually updated pharmacy provider manuals from all other health insurers, both statewide and nationally. Yet, BCBSM not only does not have a current pharmacy provider manual in print, there is also not a copy available online. Many providers are simply at the will of BCBSM for imposing policies that providers cannot readily access.

BCBSM identifies that audits are a quality control element to assist with maintaining quality of care. MPA recognizes the importance of audits and their intended purpose to identify fraud. MPA believes, however, that BCBSM's auditing practices are merely a tool to find ways to not pay pharmacies. Despite the establishment of the PAC subcommittee after the last review of the pharmacy provider class plan, no significant changes have resulted. The following list provides examples of BCBSM's unfair practices:

- BCBSM is interpreting the Public Health Code to its benefit, rather than the standard of practice that is recognized throughout the State Of Michigan
- BCBSM does not accept an affidavit of the prescriber that the prescription was a valid prescription and interpreted correctly by the pharmacist
- Audits are not conducted on the whole book of business but rather, targeted audits on specific drugs (i.e. high cost drugs)
- Audits identifying prescribers who fail to comply with the proper prescribing requirement and elements results in monetary recoupment only to the pharmacy and not to the prescriber that initiated and authorized the prescription. No action is taken by BCBSM against these prescribers, despite three of the top nine pharmacy audit findings being the result of actions the prescriber failed to perform.

MPA is concerned over the actions of BCBSM in the handling of medications it has identified as "specialty drugs". The specialty drug classification is one of BCBSM's own classifications. Specialty drugs are not defined federally or by the state of Michigan. BCBSM continues to move a number of drugs into its specialty drug classification, thereby restricting access of the medications at the patient's local pharmacy. BCBSM policy allows local pharmacies to dispense the medication but many pharmacies do not due to BCBSM's inadequate pricing. In many instances, the reimbursement is significantly below the cost of purchasing the medication.

MPA states it also has concerns pertaining to quality of care for members in long-term care (LTC) facilities and appropriate handling of prior authorization requests for needed medications. BCBSM does not accept prior authorizations that are signed by the doctor and faxed by the LTC pharmacy fax machine; BCBSM indicates that the fax must come from the physicians fax machine. The requirement by BCBSM for the prior authorization

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be sent to the physician and not the pharmacy does not improve quality of care. Asking pharmacy providers who already have a valid order to dispense medications and a valid signed prior authorization to send the form back to the doctor to fax into BCBSM is an unnecessary process and does not provide quality of care to members. MPA believes pharmacy providers should be allowed to assist the prescriber in obtaining needed prior authorization on behalf of patients. Pharmacy providers assist BCBSM every day by contacting prescribers and obtaining correct valid orders if a prescription has missing elements, prescription medications are not the correct dosing for the patient and obtaining valid covered alternatives when a prescribed medication is not covered; yet, BCBSM will not allow LTC pharmacy providers to assist their patients, in a facility where quality of care is particularly critical to more fragile and medically-compromised patients. BCBSM will not allow pharmacists to verbally initiate a prior authorization or will not accept a pharmacist's signature on the prior authorization even if the pharmacist has been delegated authority by the prescriber (even though other health plans do). BCBSM does allow its pharmacy benefit manager (PBM) the ability to contact physicians to authorize medication changes for its members and allows the PBM to fax these physician-signed orders from the PBM fax directly to the pharmacy. BCBSM has set the precedent for allowing faxed orders to be received from their PBM and not from the prescriber, so why not accept them from the LTC pharmacy?

MPA states that BCBSM has not been responsive to developments in the marketplace, particularly related to timely maximum allowable cost (MAC) pricing updates and addressing needed pricing strategies related to drug product shortages. BCBSM is responsive to pricing changes when it is to its benefit (MAC decreases) but it is extremely slow in addressing pricing changes that benefit the pharmacy provider (MAC increases). Pharmacies are required to provide BCBSM with invoicing information for each MAC price adjustment when the pharmacy has identified that BCBSM is paying under market price and request a reimbursement re-evaluation or review. BCBSM identifies the invoicing as a necessary step because it was not aware of the price increase. BCBSM does not, however, ask pharmacies for copies of invoices before it lowers the price of reimbursement to a pharmacy. MPA has serious concerns over how BCBSM can be aware of a price decrease but not a price increase. MPA believes BCBSM should be updating its reimbursement fees for pharmacy providers on a daily basis, which would resolve the issue of untimely price updates.

MPA states that over the past several years, BCBSM has made changes to reimbursement for pharmacy services, resulting in decreased reimbursement to pharmacies. The pharmacy dispensing fee has not been increased over the past several years to account for the increasing cost of pharmacist-provided services and should be evaluated to include the cost of point-of-sale transaction fees and the cost of the e-prescribing fee.

Discussion of Goals Achievement/Findings and Conclusions

Access Goal:

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

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

The following information, supplied to OFIR in December 2012 by BCBSM, shows the number of Michigan participating pharmacies and membership by geographic region for calendar years 2011:

**Pharmacy Provider Class Plan
Formal Participation Rates**

	2011		
	No. of Par Providers	Total Providers	Par Rate %
Region 1	1,189	1,203	99.4%
Region 2	128	128	100%
Region 3	145	148	98%
Region 4	97	97	100%
Region 5	217	218	99.5%
Region 6	257	257	100%
Region 7	170	170	100%
Region 8	123	123	100%
Region 9	79	79	100%
Statewide	2,405	2,423	99.2%

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In its annual report, BCBSM inaccurately reported the data associated with its formal participation rates. The above chart accurately represents BCBSM's 2011 participation levels. BCBSM indicates it maintained an overall participation rate of 99.7% with fourteen pharmacy providers not participating in regions one (southeast Michigan), three in region three (Flint area) and one in region five (southwest Michigan). Thus, BCBSM actual statewide formal participation rate was 99.2% during 2010 and 2011. BCBSM believes, based upon National Council for Prescription Drug Programs Information (a national organization of pharmacy payers, providers and vendors), the non-participating pharmacies in these regions are independent pharmacies. BCBSM states it does not inquire as to the reasons these pharmacies do not participate so it is not able to speculate as to the specific reasons these pharmacies remain non-participating.

BCBSM states it did not deny participation to any provider who met its qualification standards for participation. BCBSM was unable to identify where these pharmacies were located and whether the pharmacies were chain or independent pharmacies because its source database reflects up-to-date information and information cannot be queried from previous time periods. Overall, this data shows that overall there were 19 more available pharmacy locations for BCBSM members to get their prescription medication than there were during the 2009 review of this provider class plan.

The above participation rates do not include pharmacy providers such as inpatient hospital pharmacies, nuclear pharmacies, prison pharmacies, veterinary hospital pharmacies, clinic pharmacies associated with other insurers, compounding pharmacies or physician dispensaries.

Based on comments from MPA, BCBSM was requested to provide information regarding the number of pharmacies participating in both the traditional and preferred networks. During the review period, 2,403 pharmacies participated in BCBSM's traditional pharmacy network and 2,405 participated in BCBSM's Preferred pharmacy network, demonstrating there is very little difference in the participation levels between the two programs.

BCBSM's mail order drug program provides an additional source of access to BCBSM members. Eligible members may use mail order drugs to obtain almost any drug covered under the members' drug plan. Mail service is most often used and most beneficial for obtaining drugs prescribed on a long-term basis for chronic conditions like high blood pressure, high cholesterol, heart disease and diabetes. Eligible members can obtain up to a 90-day supply of prescription drugs by mail.

BCBSM states the type of medication needs determines which mail order vendor the member must use to obtain the medication. Specialty drugs used to treat complex conditions must be ordered through Walgreen Specialty Pharmacy. Specialty drugs are prescription medications that require special handling, administration, or monitoring. They

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are used to treat complex, chronic and often costly conditions like asthma, multiple sclerosis, cancer, organ transplants, rheumatoid arthritis, HIV/AIDS and infertility. All other medications should be ordered through Medco, BCBSM's mail order pharmacy.

MPA states that "specialty drugs" are not defined by the state or federal government but rather is a drug classification set forth by BCBSM. BCBSM acknowledges that there is no single federal, state or industry definition of specialty drugs. BCBSM defines specialty drugs as medications that: 1) treat rare or complex diseases; 2) have limited distribution; 3) require clinical monitoring; 4) are injected or infused (excluding insulin type products); 5) require special handling; and 6) are extremely expensive.

BCBSM states it implemented the specialty pharmacy program to ensure that our members have access to specialty drugs at a competitive price. When BCBSM implemented the specialty drug program, a corporate decision was made to include retail pharmacies in the program. Retail pharmacies are not required to dispense specialty medications and many retail pharmacies have the option to either dispense the specialty drug or send the member to another participating retail pharmacy or to BCBSM's specialty vendor. Because BCBSM does not separately contract with retail pharmacies for specialty drugs, BCBSM states it does not have data on the number and location of retail pharmacies that choose to dispense specialty drugs.

BCBSM states it allows all participating Michigan network retail pharmacies to dispense specialty medications at its specialty contracted rates, provided they have access to the medications. BCBSM states it contracts with a specific specialty pharmacy in order to assure access to all specialty medications, including limited distribution products. Limited distribution specialty medications are restricted by the Food and Drug Administration (FDA) or by the manufacturer as to which pharmacies have access and can dispense these medications.

BCBSM contracts with Medco to manage its mail order program. Medco recently merged with Express Scripts. BCBSM's mail order provider is required to comply with all applicable legal and regulatory requirements governing its mail order operations, including licensure, Drug Enforcement Agency registration, sufficient liability insurance, fiscal soundness and the absence of inappropriate utilization practices, fraud and illegal activities.

Eligible members may use the mail order program to obtain almost any drug covered under BCBSM's prescription drug plans. Mail service is most often used and most beneficial for obtaining drugs prescribed on a long-term basis for chronic conditions like high blood pressure, high cholesterol, heart disease, or stomach disorders. Eligible members can obtain up to a 90-day supply of prescription drugs by mail.

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BCBSM's goal is to make it easy for providers to work with BCBSM by providing them with the tools and information needed to render quality care using the best available technologies. One way BCBSM believes it meets this goal is by having a payment policy that provides incentives for high-quality and cost-effective care. BCBSM's reimbursement policies for its traditional, preferred, mail order and specialty prescription drug programs are described on page 3-5 of this report.

BCBSM states it provides the following resources, discussed more fully in the quality of care section of this report, to communicate with and educate pharmacists:

- The Pharmacy Advisory Committee (PAC) is committed to providing ongoing support to the retail pharmacy committee.
- The *Record*, a monthly BCBSM publication that communicates current information regarding billing guidelines, policy changes and other administrative issues.
- The *Guide for Pharmacists*, which provides information on how to do business with BCBSM.
- The liaison process, which provides a forum in which specialty societies can bring issues of concern to BCBSM's attention as necessary. The process can include meetings with specialty societies as well as contact with BCBSM representatives by telephone or e-mail.

The Pharmacy Services Clinical Help Desk also interfaces with external providers (pharmacy and physician callers). The Medco/Express Scripts Pharmacy Help Desk assists pharmacy callers with issues related to routine point of service (POS) messages such as refill too soon or concurrent drug interactions (DUR). Escalated pharmacy provider inquiries are transferred to BCBSM's Pharmacy Clinical Help Desk. This resource also interfaces with physicians regarding prior authorizations. Routine pharmacy inquiries relating to benefit, eligibility or copay questions are directed to the Provider Inquiry department.

BCBSM has a variety of initiatives that are designed to help control costs and reduce member out-of-pocket expenses. BCBSM's website www.bcbsm.com link offers both provider and member access to these initiatives for patient participation and/or education. These initiatives include:

- Brand to Alternate Generic Interchange
- Dose Optimization
- Generic Copay Holiday

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- Generic Copay Waiver
- Off-Label/High-Cost Specialty Review Program
- Preferred Therapy
- Quantity Limits

Many of the above initiatives are discussed in the quality of care section of this determination report. BCBSM states in addition to these pharmacy initiatives, the www.bcbsm.com member portal has several sections available to pharmacy members including Prescription Drugs, Helping Members Save Money and Member Forms. The Prescription Drug section includes approved drug lists (formularies), medication guides, pharmacy initiatives and descriptions of the 90-day retail pharmacy, mail order and specialty drug programs. The section labeled *Helping Members Save Money* gives a description of and a link to the generic drug program and it also provides members with information on prescription drug discounts. The *Member Forms* section provides members with Mail Order Program request forms as well as Pay Subscriber forms. Each of the areas of the member portal provides members with greater access to benefit information and educational documentation.

Over the years, BCBSM has built a multi-faceted approach to electronic prescribing, including collaboration efforts with the Southeast Michigan e-Prescribing (eRx) Initiative (SEMI) and the BCBSM eRx program.

SEMI was created in 2005 by BCBSM, Health Alliance Plan, Medco Health Solutions (now Express Scripts), the United Auto Workers and Ford, General Motors and Chrysler. The program offers financial incentives to physicians who implement e-prescribing with one of the SEMI-approved e-technology vendors and who exhibit sustained use of the tool. Providers must participate in BCBSM's PPO network, be located in southeast Michigan and practice in the specialties of primary care, family practice, Ob-Gyn or internal medicine. Currently, more than 7,600 physicians participate in the SEMI initiative. Current statistics for eRx show almost 11 million prescriptions generated since the program began in 2007 and over 2 million prescriptions generated in 2011 through the BCBSM program. A positive sign of the program's implementation is that current monthly prescription volume for the past several months has shown over one million electronic prescriptions per month generated using e-Prescribing technology.

BCBSM states an important feature of this technology is improved patient safety by alerting physicians to the risks related to drug interventions, medication allergy alerts, patient prescriptions histories, formulary alerts and other potential medication problems at the point of prescribing. Statistics show that a physician will alter the prescription 41% of the time when presented with a severe or moderate drug-to-drug alert or a medication allergy alert.

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Out of the 29,000 physicians who formally participate with BCBSM, 8,526 physicians are eRx-enabled. About 29% of BCBSM's network physicians have e-prescribing technology available to them through the combined impact of SEMI and eRx, a 61% increase over the 2009 rate.

BCBSM states it was recognized in 2010 as a leader in promoting the use of electronic prescriptions and Michigan was the only state in the nation to finish in the top 10 in all three subcategories of e-prescribing measured for the award (prescription benefit, medication history and prescription routing). According to Surescripts®, the nation's largest e-prescription network, Michigan ranked third in the nation for the number of e-prescriptions filled.

Findings and Conclusions - Access

In order to achieve compliance with the access goal, BCBSM needs to be able to assure that in any given area of the state a member has reasonable access to certificate-covered pharmacy services. During the 2-year period under review, BCBSM participated with 99.2% of Michigan retail pharmacies. Access to BCBSM participating providers actually increased during the period under review as a result with 19 additional locations throughout the state. As such, it is evident that BCBSM members had no difficulty obtaining reasonable access to retail pharmacy services, including vaccinations. BCBSM members were also able to obtain prescription medications through BCBSM's mail order pharmacy or its specialty vendor. Based on the information analyzed during this review, it is therefore determined that BCBSM met the access goal stated in the Act for calendar years 2010 and 2011.

Quality of Care Goal:

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

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

BCBSM's approach to achieving its quality of care objectives for the pharmacy provider class include ensuring BCBSM members receive quality care by requiring participating providers to meet BCBSM's qualifications and performance standards; maintaining quality controls through documentation guidelines, drug utilization review initiatives and audits; implementing quality management initiatives that promote safety, improve member compliance and ensure the delivery of high quality health care; and developing strong relationships with participating providers by offering them various avenues to receive information and to voice concerns requiring benefit coverage and/or claims disputes.

To ensure acceptable levels of care are provided by pharmacies providers, BCBSM requires that these providers meet the participation qualifications and performance standards listed on pages 3 and 4 of this report. BCBSM states that provider qualification status is continually monitored to ensure subscriber access to competent providers who are not involved in fraud or illegal activities.

BCBSM states pharmacy providers must maintain documentation for all claims based on BCBSM guidelines. The guidelines ensure the appropriate medically necessary prescription drug information is included before a prescription is filled. Documentation must be legible, dated, signed with professional credentials noted and prepared as soon as possible after the service is performed. Documentation guidelines for specific types of service are included in the *Guide for Pharmacists*. General requirements include patient name, drug name, dosage, quantity and refill instructions; dispense as written instructions; physician signature; the DEA number of the physician writing the prescription; physician NPI number, the date of the prescription and any other information as required by the state of Michigan and federal rules and regulations. Topics detailed in the manual include member eligibility requirements, benefits and exclusions, criteria and guidelines for services, documentation guidelines, claim submission information, utilization management and sections describing how to obtain information from BCBSM's provider inquiry department and claims appeals processes.

MPA has expressed concern of BCBSM's failure to update BCBSM's pharmacy provider manual as well as the lack of an online version of the pharmacy provider manual. MPA notes that BCBSM has an online provider manual for every other provider class plan but the pharmacy provider class plan. BCBSM has indicated that there is only a hard copy of the *Guide for Pharmacists* available to pharmacies. This manual is provided to newly-credentialed and newly-participating BCBSM pharmacies. BCBSM states that currently participating pharmacies that are not able to locate their copy of the manual can request that another copy be sent to them. Review of the Pharmacy Advisory Committee (PAC) minutes reveal that this matter has been a continual topic of discussion at PAC meetings with the latest meeting minutes from January 2012 indicating that a pharmacy secure portal website is under development. The plan is to have pharmacies with a PIN number to be able to access this portal for access to the pharmacy manual, Fax Blasts, *Record* articles,

the Medicare Part D Guide, Prior Authorization and Step Therapy Medication Request forms and information on fraud, waste and abuse.

BCBSM contends that because web-DENIS is primarily devoted to providing BCBSM member medical benefit information to participating BCBSM providers, most pharmacies do not have access to this website. While some pharmacies may have access due to their participation in a medical benefit (e.g. DME services), web-DENIS is an inappropriate location to house the manual because the majority of pharmacy providers do not have a need to access the medical benefit and patient information housed on that website.

BCBSM states that it communicates information to pharmacies via the manual, its edition of *The Record*, and fax blast communications. Pertinent updates and important new information are disseminated via fax blast communications in order to ensure timely review by pharmacy providers.

BCBSM managed drug utilization through prospective, concurrent and retrospective drug utilization initiatives. These initiatives are designed to identify and avoid adverse drug interactions, inappropriate dosing regimens, use for unproven indications, and potential medication overuse before, during and subsequent to the prescription being dispensed.

BCBSM provides intervention in prescribing medication before a prescription is ever dispensed through the management of a drug formulary. The BCBSM drug formulary is a list of FDA-approved prescription drugs the BCBSM/BCN Pharmacy and Therapeutics Committee have determined to be high quality and cost effective for patient care based on scientific evidence of safety and efficacy. The preferred agents on the formulary are selected based on clinical effectiveness, safety and the relative costs of medications in the same therapeutic class. The formulary represents the clinical judgment of Michigan physicians, pharmacists and other experts in the diagnosis and treatment of disease and promotion of health. Providers can easily access BCBSM formulary information through electronic prescribing programs, ePocrates (web-based formulary tool) and BCBSM's corporate website at bcbsm.com.

BCBSM utilizes the Medco/Express Scripts drug claim processing system for claims processed in Michigan. Express Scripts is an online prescription drug processing system that links pharmacy and health plan submitted medical claims. The online concurrent review system examines prescriptions for drug interactions and duplications such as drug-to-disease interactions, drug-to-drug interactions, drug-to-age precautions, minimum-maximum dosage precautions, pregnancy drug alerts, therapeutic duplications, ingredient duplications and early refills.

BCBSM states that through an innovative program between BCBSM and Medco, BCBSM Care Management Nurses are provided with access to BCBSM members' updated

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medication profile to better address therapeutic issues and medication adherence during chronic disease management discussions. If the member has questions about their medication regimen (including safety, appropriate use or cost), the Care Management Nurse may transfer the member to a Therapeutic Resource Center Clinical Pharmacist to further address any questions the member may have about their medications.

BCBSM's Pharmacy and Therapeutics Committee is comprised of 15 members with a quorum consisting of at least eight members, one of which shall include a practicing physician and one of which shall include a practicing pharmacist. Currently there are 10 physicians (four are BCBSM/BCN employees), two practicing pharmacists, two BCBSM/BCN Pharmacy Directors and one consumer advocate. All committee members, except the consumer advocate, have voting privileges. Neither the northern portion of the Lower Peninsula or the Upper Peninsula is represented on the committee at this time, but BCBSM does not believe the practice of evidence-based medicine varies significantly by regions in Michigan. The current members of BCBSM's Pharmacy and Therapeutics Committee reside primarily in West Michigan, Mid-Michigan, and Southeast Michigan.

The formulary selected by BCBSM's Pharmacy and Therapeutics Committee is based on clinical effectiveness, safety and cost. BCBSM states the formulary represents the clinical judgment of Michigan physicians, pharmacists and other experts in the diagnosis and treatment of disease and promotion of health. The committee considers the therapeutic advantages in terms of safety and efficacy when selecting formulary drugs and when reviewing placement of formulary drugs into formulary tiers.

BCBSM also monitors the use of certain medications to ensure members receive the most appropriate and cost-effective drug therapy under the Step Therapy, Prior Authorization, Preferred Therapy, Off-Label/High Cost Specialty, and Quantity Limits programs. Step Therapy is an automated claim edit program that requires use of a more cost-effective alternative (as approved by the BCBSM/BCN Pharmacy and Therapeutics Committee) before use of the more expensive non-preferred drug. If the claims system detects an approved claim for the preferred alternative, the non-preferred drug may process without requiring prior authorization. If there is no claim for the alternative required drug, the physician must seek approval for use and provide clinical justification as to why the preferred alternative is not clinically appropriate. BCBSM performed 1,988 therapeutic reviews of prescription claims under this program during 2010. The review resulted in 635 prescriptions not being approved. In 2011, BCBSM performed 12,617 reviews of prescription claims, with 228 prescriptions not being approved.

Prior authorization is a program where certain clinical criteria must be met before select drugs are covered. The criteria for authorization is based on current medical information, recommendations of the BCBSM Pharmacy and Therapeutics Committee, a group of physicians, pharmacists and other experts. During 2010, there were 4,382 therapeutic

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reviews of prescription drug claims, with 2,016 not being approved. In 2011, 5,475 reviews were completed, with BCBSM not approving 888 prescriptions. The Off Label/High Cost Specialty review functions as a prior authorization program specifically targeting drugs known to be prescribed for off-label use (e.g. growth hormone) or new, higher cost specialty drugs with very specific approved indications for use.

The Preferred Therapy Program is a limited step therapy program that targets "me too" branded drugs (e.g. isomers, extended release) that provide little therapeutic efficacy or safety over available generic alternatives. These types of drugs are commonly developed by the pharmaceutical manufacturers to extend revenue for the original brand name drug once it is available as a generic.

The Quantity Limits initiative is a program that manages the dispensing of targeted drugs in quantities consistent with FDA approved labeling or published clinical criteria to assure appropriate and safe use. The initiative targets select drug classes and limits the quantity of prescription drugs dispensed to the manufacturer recommended dosing guidelines or those published in national guidelines. All limits are approved by the BCBSM/BCN Pharmacy and Therapeutics Committee. The first time a member's prescription is filled for a targeted drug, the pharmacist will fill the prescription for the quantity limit allowed for that drug by BCBSM. For quantities greater than the recommended amount, the physician is required to call BCBSM and provide evidence of medical necessity. BCBSM states this initiative helps to ensure that patients use medication appropriately. During 2010, there were 191 quantity limit prescription claims reviewed of which 102 were not approved. In 2011, there were 13,427 quantity limit prescription claims reviewed of which 487 were not approved.

BCBSM states it continues its commitment to "best in class" quality management through the implementation of several innovative programs geared toward better quality care through patient compliance and the effective and safe dispensing of medications.

BCBSM developed a multi-disciplinary workgroup including representatives from BCBSM's Corporate Financial Investigations (CFI), Pharmacy, Medical Affairs, Legal, Value Partnerships and Case Management divisions to oversee the appropriate prescribing, dispensing and utilization of controlled substances and compounds. The workgroups review utilization data and identifies areas for further investigation, intervention or medical policy. Through the CFI division, some data analyses are presented to local and federal law enforcement to support investigations. Medical policies were drafted and approved through the BCBSM/BCN Pharmacy and Therapeutics Committee to support appropriate and safe use of opioids for non-cancer pain and compounded drug prescriptions.

BCBSM identified opportunities to improve the quality and cost-effectiveness of prescription medications through several physician and member-directed initiatives. The

pharmacy initiatives identified during the two year period under review are intended to provide members with the safest, most therapeutically effective and most cost-efficient medications possible. These initiatives are designed to help manage rising costs while delivering a level of safety and quality:

The *Dose Optimization* (Dosing, Optimally, Simply, Effectively) initiative was implemented in September 2007. The initiative is a physician-directed initiative that encourages improved patient compliance and optimization of therapeutic outcomes, by assisting patients in converting from multiple-tablet dosing to more consolidated dosing. As part of this initiative BCBSM works with the member's physician to switch the member to a more cost-effective and consolidated daily dose of the same drug. Select drug classes were targeted and the first time a member's prescription is filled for the targeted drug, BCBSM contacts the member's physician to recommend the simplest regimen. The program covers drugs such as Benicar, Caduet, Cymbalta, Effexor, Zoloft, Lipitor, Crestor, Prilosec and Prevacid. Adjusting a multiple dose regimen can improve patient adherence to the regimen and reduce costs. BCBSM states it is not able to provide how many prescriptions were converted from a multiple dose regimen to a single dose regimen during the two year period under review because it had changed pharmacy benefit managers and Medco, at that time, did not have the reporting capabilities to provide this information. BCBSM states that Medco will start reporting this information in 2012.

The *Brand-to-Alternative Generic Interchange* is a physician-directed initiative that encourages the replacement of brand name drugs with less costly generic alternatives. When a drug is part of this initiative, BCBSM works with the member's physician to encourage a less costly generic alternative that is as equally effective to the brand name drug.

During the two year period under review, BCBSM mailed copay waiver letters to members identified as receiving targeted brand-name drugs as an incentive to switch to a generic prescription drug or therapeutic equivalent. BCBSM also provides physicians with educational materials to share with their patients that describe the safety and effectiveness of generic drugs.

BCBSM states it continues to heighten awareness of the quality, value and safety of generic drugs through education and the "Generic Drugs: The Unadvertised Brand" Campaign. The best health outcomes occur when prescription drug therapies are prescribed and dispensed by well-informed physicians and pharmacists and taken by well-informed patients. Facts and cost savings related to generic drugs are made available through the www.theunadvertisedbrand.com website; the Top 10 Facts on Generic Drug brochure, generic pricing comparison cards, generic copay waivers and the generic copay holiday program.

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During the two year period under review, BCBSM states it changed pharmacy benefit managers. BCBSM converted from MedImpact to Medco (now merged with Express Scripts). As a result, BCBSM did not receive reports to be able to identify how many incentive letters were mailed to members encouraging them to switch to generic drugs or how many brand name drug prescriptions were successfully switched to a generic drug during the review period.

The drug utilization review team of clinical pharmacists communicates with prescribing physicians to discuss issues identified through claims analysis. Currently all academic detailing activity is being conducted through the Physician Group Incentive Program (PGIP), a physician group program designed to use incentives to improve patient care. BCBSM is working with 40 physician organizations on multiple initiatives including generic prescribing and specialty drug use. Each of the physician organizations has a primary representative of whom half are clinical pharmacists. The academic message is delivered by the pharmacy representatives to their respective physician population.

The PGIP organization provides quarterly performance reports to physician organizations. In addition, BCBSM pharmacy staff meets with the physician organization representative in person or by phone and hold quarterly group meetings with representatives from each physician organization, with two sessions specifically related to pharmacy initiatives. BCBSM also prepares academic fact sheets to educate physicians on target therapeutic categories which are distributed by the pharmacy representatives to the physician organizations. Eight fact sheets have been prepared and distributed during the two year period under review. The fact sheets included information on Long Acting Opioid Analgesics for the management of chronic pain, Imitrex (generic version), Evidence Based Treatment for Fibromyalgia, Fibrate Facts Cozaar and Hyzaar (generic version), COPD Exacerbations: Closing the Gaps in Care, the \$4 Show Your Card and Proton pump inhibitors.

Evidence based care reporting is also an important tool used to identify patients not receiving standard of care treatments for chronic conditions. The PGIP organization seeks to close gaps in care through the integration of medical and pharmacy data and the application of this information to nationally accepted guidelines.

BCBSM states it evaluated medical necessity and the quality of care provided to BBSM members through an external audit process. The audit process is not just designed to recover overpayments, but also allows BCBSM to validate that contractual agreements were met and high quality care was given to members.

During audits, BCBSM's auditors reviewed records to ensure compliance with documentation guidelines. BCBSM also compares information in providers' medical and financial records with information reported on claims. Providers were typically selected for

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review based on referrals and risk indicators which include pharmacy income level, generic dispensing rates, DAW rate, average quantity per prescription, and average cost per prescription.

BCBSM states there is only one purpose for its auditing process – the detection of fraud. A sound audit program fulfills several functions, including:

- Verifying that pharmacies are compliant with BCBSM's billing requirements.
- Meeting terms of BCBSM's customer contracts that require BCBSM to audit three to five percent of its pharmacy network each year for program compliance.
- Complying with requirements from the Centers for Medicare and Medicaid Services to monitor program compliance and detect fraud, waste and abuse for Medicare claims.

BCBSM conducted 91 field audits and nine desk audits in 2010 and 101 field audits and 12 desk audits in 2011 to recover overpayments made in error. The initial savings identified were approximately \$4.2 million in 2010 and \$34.4 million in 2011. Amounts recovered totaled approximately \$844,100 for 2010 and \$650,500 in 2011, with potential additional recoveries of \$26,000 for 2010 and \$1.6 million for 2011. BCBSM states the top audit findings were as follows:

- Prescription not signed by a physician
- Acquisition cost overstated for a compound claim
- Medication billed, not verified as dispensed by signature log
- Pharmacy improperly cut quantity dispensed resulting in an increased number of refills
- The DEA number is not accurate for prescribing physician
- Order not signed by a licensed prescriber
- The common indicator was reported incorrectly
- Dispensed quantity exceeds quantity prescribed
- Written prescription not dated by prescribing physician

A summary of BCBSM's audit activity for the pharmacy class is listed below.

Audit Performance 2010-2011

	2010	2011
Number of audits	100	113
Initial identified savings	\$4,188,130	\$3,150,678
Finalized recoveries	\$844,076	\$651,539
Pending recoveries	\$26,371	\$1,645,159
Referred to Corporate Financial Investigation	2	1

BCBSM states that all three of the pharmacies referred to BCBSM's Corporate Financial Investigations department related to suspicious or anomalous billing.

BCBSM states it created an alliance with Michigan's pharmacy regulatory agency and the Institute for Safe Medication Practices (ISMP) to promote the ISMP medication safety self-assessment survey tool. The tool is designed to assess the safety of medication practices in the pharmacy, identify opportunities for improvement and compare a pharmacy's experience with the aggregate experiences of demographically similar community pharmacies around the nation. The ultimate goal is to make them aware of best practices. The survey assesses staff competency, education, quality processes and risk management. During this review period, a total of 1,784 pharmacies, comprising 75% of BCBSM participating pharmacies, completed the self-assessment survey.

Another measure of BCBSM's achievement of the quality of care goal includes BCBSM's ability to effectively communicate with providers. Given that the quality of care goal defined in the Act requires that "providers meet and abide by reasonable standards of health care quality," it is necessary for providers to be made aware of BCBSM's standards, for BCBSM to verify that its providers adhere to such standards and that BCBSM is responsive to provider inquiries, input, and appeals, as all of these factors impact the quality of pharmacy services given to BCBSM members.

BCBSM states that it maintains open communications with pharmacy providers through its monthly publications, provider manuals, regular meetings of the Pharmacy Advisory Committee and its formal appeal process. All participating pharmacy providers currently receive BCBSM's monthly publication, the *Record*. This publication contains current information pertinent to the timely and efficient servicing of BCBSM members, such as policy changes, group-specific benefit changes, patient education and other provider-specific issues. BCBSM states the issues discussed in this publication are those that often impact providers' practice patterns and the achievement of utilization performance standards. BCBSM also has provider service representatives that are available through the Pharmacy Services Clinical help desk as well as a web site devoted to providers that provides information on benefits, eligibility, and contact numbers. The site also contains a

hyperlink to the Michigan Health and Safety Coalition (MHSC). MHSC is a collaborative quality improvement initiative focused on improving patient safety in Michigan.

The Pharmacy Advisory Committee (PAC) is a collaborative council made up of representatives of the Michigan Pharmacists Association, BCBSM, BCN and providers from both independent and chain pharmacies. The committee meets quarterly, offering pharmacists the opportunity to discuss issues with BCBSM on a regular basis. The purpose of BCBSM/BCN's Pharmacy and Therapeutics Committee is to evaluate the clinical use of drugs, determine the appropriate formulary placement of drugs, ensure that the formulary is appropriately revised to adapt to both the number and types of drugs on the market, and advise in the development of policies for managing drug use, drug administration, and the formulary system. Topics discussed during the two year period under review include the development of a controlled substance committee, group updates, vaccine program update, audit of the vaccine program, MAC pricing, Medicare Part D updates, compound drug edits, pharmacy audit updates, fraud/waste/abuse training, proposed provider class plan changes, health care reform and limit removal, Allegra OTC product and update of the pharmacy secure portal website.

MPA expressed concern that the Pharmacy Advisory Subcommittee that was established after the 2009 review of the pharmacy provider class plan has yet to complete many of the items that have been brought to the table, particularly a new provider manual. BCBSM acknowledges that as a result of several high-priority projects, the completion of several outstanding items has been necessarily delayed. This "to do list" was on the PAC committees November 27, 2012 agenda.

PAC currently has a total of 29 members with 15 chain pharmacy representatives, 7 independent pharmacy members, six BCBSM/BCN representatives and one member from MPA. BCBSM states that the 23 non-BCBSM/BCN members represent a variety of pharmacy types and services provided to BCBSM's commercial/Medicare members that include, but are not limited to retail, 90 day, long term care, specialty, compounding and home infusion providers. BCBSM states that many of the PAC committee members represent numerous pharmacies in various regions of Michigan. This occurs because a single member who represents chain pharmacies will serve as representation for multiple locations throughout the state.

BCBSM also maintains a provider appeal process for pharmacy providers. The purpose of the appeal process is to resolve claim or audit disagreements. Pharmacies are informed of the appeal process through the *Record*. Information about the appeals process is also included in the *Guide* and both the Traditional Rx Pharmacy Participation Agreement.

There are many different levels of the appeals process. The provider starts with a routine inquiry to BCBSM and can follow with a written complaint asking for a reconsideration

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review. If the provider is not satisfied with the reconsideration, he or she may submit a written request for a Managerial-Level Conference (MCL). During this conference, BCBSM and the provider discuss the dispute in an informal setting and explore possible resolutions of the dispute.

If the provider is dissatisfied with the MCL review, the provider can continue with BCBSM's appeal process, appeal to OFIR, initiate legal action, or if medical necessity issues are in dispute, request an external peer review for medical necessity issues. It is understood and agreed that BCBSM and the provider will each pay a prorated share of the total cost of the arbitration proceeding, based on the percentage approval or denial rate in relation to the total number of cases reviewed. The decision of the external review organization on medical necessity disputes is final and binding on both the provider and BCBSM.

Providers that go through BCBSM's appeals process and remain dissatisfied can appeal to OFIR for an informal review and determination. If the provider remains dissatisfied, they can move to a contested case hearing pursuant to Section 550.1404(6) of the Act. Contested case hearing decisions are subject to appeal in the circuit court. At any time after the written complaint or reconsideration review and informal managerial conference steps, the provider may appeal to OFIR or initiate legal action to resolve the issue.

BCBSM states there were two requests for review and determinations received by OFIR from pharmacies during the two year period under review. OFIR has reviewed and issued review and determinations on both cases. BCBSM states approximately 90% of all pharmacy appeals are settled through BCBSM's reconsideration and managerial level conference appeal steps.

Findings and Conclusions - Quality of Care

In order to meet the quality of care goal, the provider class plan must assure that "providers will meet and abide by reasonable standards of health care quality." During calendar years 2010 and 2011, BCBSM continued to monitor pharmacists' qualification standards, implemented and maintained a variety of drug utilization review programs, quality control standards and utilization management initiatives. BCBSM kept the lines of communication open with pharmacy providers with regular meetings of the Pharmacy Advisory Committee as well as regular communications with providers through its monthly publication of the *Record*, provider manuals and appeal processes. Based on the information analyzed during this review, it is determined that BCBSM met the quality of care goal stated in the Act for the calendar years 2010 and 2011. BCBSM is encouraged to continue meeting regularly with the MPA to address its concerns regarding an updated provider manual as the provider manual is rather outdated in comparison to those available to other provider classes. BCBSM is also encouraged to obtain reports from its pharmacy benefit manager

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with respect to many of BCBSM's initiatives so BCBSM knows whether such initiatives are achieving desired results.

Cost Goal:

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

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

The rate of change in the total corporation payment per member for the pharmacy provider class for calendar years 2010 and 2011 shall not exceed 1.4%.

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

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

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

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

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

Given the January 2011 population data obtained from population reports published by the Bureau of Census, as obtained to OFIR from the U. S. Census Bureau (www.census.gov/popest/national/NA-EST2011-01.xls), and economic statistics for the GNP and implicit GNP price deflator from the U. S. Department of Commerce, Bureau of Economic Analysis as published in July 2012 by the Federal Research Bank of St. Louis (research.stlouisfed.org/fred2/data/GNPC96.txt and research.stlouisfed.org/fred2/)

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data/GNPDEF.txt) and economic statistics for the GNP and implicit GNP price deflator published in the July 2012 edition of "Economic Indicators" prepared for the Joint Economic Committee, by the Council of Economic Advisers (www.gpoaccess.gov/indicators/index.html) the following calculations have been derived:

I = Inflation as defined in the cost goal formula:

% change in implicit GNP price deflator

2011	1.6
2012	2.4

2 yr. average 2.0

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

% change in per capita GNP in constant dollars

2008	(1.2)
2009	(4.4)
2010	2.4
2011	1.0

4 yr. average (.6)

Using the latest population and economic statistics available, the cost goal for the period under review is estimated to be 1.4%, as shown below:

Inflation = 2.0

Real Economic Growth = (.6)

$$\frac{[(100 + 2.0) \times (100 + (.6))]}{100} - 100 = 1.4\%$$

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

As stated in Section 504(2)(e) of the Act, the "[R]ate of change in the total corporation payment per member to each provider class' means the arithmetic average of the percentage changes in the corporation payment per member for that provider class over the 2 years immediately preceding the commissioner's determination." The cost and membership data for the pharmacy provider class plan for the calendar years 2010 and 2011, as filed with OFIR by BCBSM, are presented below on a combined basis as well as broken down by retail and mail order payments. Cost data reflect claims incurred in the calendar year and paid through February 28th of the following year.

Total Retail and Mail Order Pharmacy Payment Experience

BCBSM Retail and Mail Order Payments	2009	2010	2011	Average Yearly Rate of Change
Total Payments	\$1,419,742,759	\$2,776,455,821	\$2,621,355,535	
Payments/1000 Members	\$ 813,896.28	\$1,623,369.09	\$1,380,221.61	
Rate of Change (%)		99.5%	(15.0)%	42.3%
Total Prescriptions	19,669,339	29,776,717	27,656,319	
Prescriptions/1000 Members	11,276	17,410	14,561	
Rate of Change (%)		544.0%	(16.4)%	263.8%
Payment/Script	\$72.18	\$93.24	\$94.78	
Rate of Change (%)		29.2%	1.7%	15.5%
Total Members	1,744,378	1,710,305	1,899,228	

Although payments per member decreased 15% during 2011, the two year average percent change increased 42.3%. Since the experience for retail and mail order pharmacy payments was dramatically different, it warrants examining retail and mail order data separately.

During the review period, as shown below, retail pharmacy utilization decreased an average of 14%. BCBSM's average payment per prescription increased an average of 3.4% and utilization decreased 16.9% in the retail setting. A 30 day supply of medication is typically dispensed per prescription in the retail setting, although members with the Rx-90 rider can receive up to a 90-day supply for certain medications. BCBSM states the Rx-90 rider is not available to members with traditional prescription coverage as the traditional individual and group membership account for less than two percent of BCBSM's pharmacy membership which would make the administrative costs associated with adding such a

rider disproportionately high. BCBSM states that all new pharmacy products are based on the Preferred Rx certificate as it is more competitively priced and provides greater access to members. Rider Rx-90 is offered with all preferred prescription PPO products.

Total Utilization and Payment Experience – Retail Claims

BCBSM Retail Pharmacy Data	2009	2010	2011	Average Yearly Rate of Change
Total Payments	\$1,138,153,569	\$1,285,889,910	\$1,227,683,992	
Payments/1000 Members	\$652,470	\$751,848	\$646,413	
Rate of Change (%)		15.2%	(14.0)%	0.6%
Total Scripts	17,705,779	19,359,141	17,871,312	
Per 1,000 members	10,150.20	11,319.12	9,409.79	
Rate of Change (%)		11.5%	(16.9)%	(2.7)%
Payment/Script	\$64.28	\$66.42	\$68.70	
Rate of Change (%)		3.3%	3.4%	3.4%
Total Members	1,744,378	1,710,305	1,899,225	4.6%

Decreased use was the driver of a 15.8% decrease in mail order payments per 1,000 members, where a 90-day supply of medication is typically dispensed per prescription. Utilization declined by 15.4% while the average payment per prescription decreased by 0.3% as noted in the chart below. BCBSM attributes declining use to a number of factors, including the availability of the Rx-90 rider, which allows up to a 90-day supply of medication to be dispensed by a retail pharmacy; higher cost-sharing requirements which disproportionately impacted mail order prescriptions; and the availability of some high use drugs such as Prilosec, Claritin and Zyrtec over the counter.

BCBSM notes that in 2010, approximately 220,000 members were added for several large self-funded customer groups that required mandatory mail order use. The mandatory use of mail order use caused a "spike" in the payments from 2009 to 2010. This increase magnified the 2011 two year average payment trend. BCBSM notes that the large self-funded customer groups that began requiring mandatory mail order use were not new BCBSM but rather existing groups, thus even though there was an increase in payments during the two year period under review, membership remained constant. Further, the payment per 1,000 members then actually decreased 15.8% during the 2010 to 2011 reporting period. BCBSM contends this indicates stabilization in its membership's use of mail order pharmacies.

Most BCBSM members have a mail order pharmacy option "MOPD-2x", which is a rider allowing the member to receive up to a 90-day supply of most medications via mail order for two standard retail copayments. This eliminates one standard retail copayment, resulting in a net savings to the member. For this reason, MOPD-2x may become more

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attractive to the member for chronic medications as member cost-share increases. This is typically coupled with an analogous 90-day retail option (RX 90-2x) that also provides the member a 90-day supply of medications from participating 90-day retail pharmacies for two times their standard retail copay.

From a plan/group perspective, MOPD-2x becomes less cost-effective with higher member copayments because the loss of one copayment may be greater than the savings (i.e., deeper discounts from AWP and no dispensing fees) achieved at mail order or through the 90-day retail network. As such, BCBSM states it is in the process of developing different mail order and 90-day retail copay options that still provide member incentives (lower copayments) to use mail order or 90-day retail pharmacies for their maintenance drugs while preserving the group savings associated with the more favorable reimbursement rates associated with mail order and 90-day retail pharmacy claims.

Total Utilization and Payment Experience - Mail Order Claims

BCBSM Mail Order Pharmacy Data	2009	2010	2011	Average Yearly Rate of Change
Total Payments	\$281,589,190	\$1,490,565,911	\$1,393,671,542	
Payments/1000 Members	\$161,426.70	\$871,520.52	\$733,810.66	
Rate of Change (%)		439.9%	(15.8)%	212.1%
Total Prescriptions	1,963,560	10,417,576	9,784,007	
Per 1,000 members	1,125.65	6,091.06	5,151.58	
Rate of Change (%)		441.1%	(15.4)%	212.9%
Payment/Prescription	\$143.41	\$143.08	\$142.44	
Rate of Change (%)		(0.2)%	(0.4)%	(0.3)%
Total Members	1,744,378	1,710,305	1,899,225	4.6%

* Although mail order payment per prescription appears higher than retail payment per prescription, mail order represents up to a 90-day supply while many drugs obtained through retail pharmacies have a maximum supply of 34 days.

For specialty pharmacy claims, payments per 1,000 members increased 22.6% between 2010 and 2011 as more physicians shifted to using the BCBSM vendor for drugs administered in the office instead of purchasing these drugs themselves. Prior to the specialty pharmacy program, physicians purchased drugs directly and stocked them in the office until needed. The physician billed the member's medical coverage for the drug at the time it was administered. Now the specialty pharmacy provider can dispense the drug to the physician and bills the member's medical coverage.

The current two year average percent change for specialty pharmaceuticals, as shown in the table below, increased 26.1 percent. Top specialty drugs include Incivek (used to treat chronic hepatitis C), Humira (used to treat rheumatoid arthritis) and Gilenya (used to treat

multiple sclerosis). In 2011, 17.6% of total pharmacy costs among Express Scripts plan sponsors were for specialty medications. The real growth in specialty drug costs is somewhat hidden, however, because approximately 47% of overall specialty medication costs are billed under a member's medical benefits. In oncology, 78% are billed under a member's medical benefits¹

**Specialty Pharmacy Claims – Medical Benefit
 2010-2011**

	2009	2010	2011
Total Payments	\$ 15,571,094.00	\$16,126,358.00	\$22,052,208.00
Payments per 1000 members	\$ 5,985.85	\$ 7,753.46	\$ 9,504.25
% change		30%	23%
Members	2,601,316	2,079,893	2,320,247

Hemophilia refers to a group of bleeding disorders in which it takes a long time for the blood to clot. In July 2008 BCBSM began participating with some specialty pharmacies with locations in Michigan to supply anti-hemophilia factors and supplies to members diagnosed with the condition. Reimbursement is covered under the member's medical/surgical benefits.

Payments per 1,000 members for hemophilia decreased 20.2% between 2010 and 2011; however they increased substantially between 2010 and 2009. This volatility can be explained by the "starting up" of the program in July 2008. As more physicians shift to using the BCBSM specialty vendor for hemophilia drugs administered in the office, BCBSM anticipates the trend will become more stable.

¹ 2011 Express Scripts Trend Report-available at <http://digital.turn-page.com/ii/69012/0> (accessed by BCBSM on July 17, 2012).

**Hemophilia Claims
 2010-2011**

	2008-2009*	2010	2011
Total Payments	\$ 3,776,190.00	\$35,075,413.00	\$25,719,334.00
Payments per 1000 members	\$1,452	\$14,634	\$11,678
% change		908.1%	-20.2%
Members	2,601,316	2,396,894	2,202,461

*Hemophilia program began in July 2008

BCBSM groups drugs by therapeutic classes. A therapeutic class is a grouping of drugs that are prescribed to treat similar illnesses or diseases, such as anti-arthritic drugs, anti-ulcer drugs and diabetic therapies. BCBSM notes there is a miscellaneous class, which represents drugs that do not have a disease-specific therapeutic category. The majority of drugs in the miscellaneous class are treatments for multiple sclerosis, Alzheimer's disease, osteoporosis, organ transplant rejection and erectile dysfunction. BCBSM states that during the two year period under review, drugs in the miscellaneous category had a combined payment of \$900 million, representing 10.7% of BCBSM's combined retail and mail order pharmacy payments. This therapeutic category typically includes many new therapies and as a result, these drugs are usually very expensive.

BCBSM also includes a category entitled "All Others" which represented a significant payout of both retail and mail order pharmacy payments. This category includes anticoagulants such as Plavix; anti-anxiety and antipsychotics such as Abilify; antivirals such as Valtrex; topical local anesthetics such as the Lidoderm patch; non-narcotic analgesics such as Celebrex and Ibuprofen; central nervous system stimulants such as Provigil; ADHD drugs such as Adderall XR, oral contraceptives and antibiotics.

BCBSM's retail pharmacy trend is illustrated below. Antineoplastic drugs, miscellaneous drugs, anti-ulcer drugs, anti-arthritic drugs and narcotic analgesics had the most significant impact on its retail pharmacy trend. Antineoplastics are drugs that control or kill neoplastic cells and are used in chemotherapy to kill cancer cells. Miscellaneous drugs used in the treatment of arthritis had the largest effect on prescription drug trends among the top therapeutic categories. Payments per 1,000 members increased an average of 17.5% and 4.8%, respectively, primarily the result of higher average payment per prescriptions. Average payment per prescription increased 18.8% for antineoplastics and 16.1% for miscellaneous drugs. As baby boomers age, the shifting demographics contributed to the increase in drugs associated with aging, such as cancer fighting medications and medications used to treat bone and joint disorders.

Anti-arthritics and narcotic analgesics were the top drivers of cost growth as a result of significant increases in payment per prescription (anti-arthritics) and increased use in the

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average prescription per member (narcotic analgesics). Payment per prescription grew an average of 7.5% for anti-arthritic drugs and 12.3% for narcotic analgesics. Use increased 7.3% for narcotic analgesics; however anti-arthritic drug use decreased 4.8%.

Newer biological therapies were the top drugs by payment within the miscellaneous and anti-arthritic classes. Biologicals are a class of medications produced through the use of recombinant DNA technology. These drugs are typically injected by the patient at home. The cost of each drug can vary between \$10,000 to \$25,000 per year or more depending on each patient's dosage and treatment regimen.

The top drugs by payments for BCBSM within these classes were Copaxone, a multiple sclerosis treatment, Cialis, which is used to treat erectile dysfunction, and Forteo, which is used to treat osteoporosis. BCBSM's 2011 payment per retail prescription averaged \$5,389 for Copaxone, \$1,407 for Forteo, with Cialis the least costly drug at \$173 per prescription.

BCBSM states that four drugs, Lipitor, Humira, Enbrel and Copaxone were the top drivers of higher retail pharmacy costs. Two lipotropics, Adderall and generic heparin, along with generic Zyrtec had the biggest impact on lowering pharmacy costs due to a decline in the average number per prescriptions.

**Retail Pharmacy Trends by Top Therapeutic Classes
2009-2011**

Therapeutic Class	Two Year Average Rate of Change			Three Year Payout	% of Total Payout	Percent Contribution to Trend
	Payments/ 1000 Members	Scripts Per 1000 Member	Payment/ Script			
Miscellaneous	4.8%	(9.6)%	16.1%	\$442,188,247	12.1%	89.4%
Psychostimulants/ Antidepressants	(3.5)%	(4.5)%	(5.3)%	\$220,351,710	6.0%	(92.9)%
Anti-arthritics	7.5%	(4.9)%	13.2%	\$262,923,027	7.2%	81.5%
Lipotropics	(5.6)%	(8.1)%	3.1%	\$209,914,501	5.7%	(49.6)%
Anti-ulcer preps	(25.5)%	(11.3)%	(16.4)%	\$163,744,635	4.5%	(203.5)%
Diabetic Therapy	5.3%	(5.5)%	11.9%	\$209,674,501	5.7%	47.7%
Bronchial Dilators	5.1%	(5.1)%	10.8%	\$185,631,319	5.1%	39.5%
Narcotic Analgesics	12.3%	7.3%	2.8%	\$182,517,081	5.0%	69.6%
Antineoplastics	17.5%	(1.8)%	18.8%	\$164,594,265	4.5%	104.7%
Other hypotensives	(8.2)%	(5.6)%	(3.6)%	\$108,670,626	2.9%	(39.7)%
All Others	0.8%	(1.1)%	2.0%	1,503,517,559	41.2%	53.4%
Total	0.6%	(2.7)%	3.4%	\$3,6541,727,471	100.0%	100.0%

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BCBSM states utilization increased substantially for all of the top ten mail order therapeutic categories as illustrated in the table below. Average payment per prescription decreased less than one percent for all mail order prescriptions, however; among the top ten therapeutic classes, average payment increased 407.1% for anti-arthritics, 285.9% for drugs in the miscellaneous category, and 260.4% for psychostimulants-antidepressants. The overall volatility between the therapeutic classes caused the average payment per prescription to increase 212.1%.

BCBSM states the top contributors to the trend due to significant increases in use were medications for lipotropic and diabetic therapy. Payment per prescription grew an average of 173.6% for lipotropic drugs and 232.4% for drugs associated with diabetes. Use increased substantially in both of these categories, increasing 237.1% for lipotropic drugs and 225.6% for diabetic therapy. Payments for drugs in the miscellaneous class increased 285.9%, entirely due to increase use. Drugs associated with multiple sclerosis, Alzheimer's disease, osteoporosis and enlarged prostate were the largest contributors to the miscellaneous category.

There is no question that the approximately 220,000 members from several large self-funded customer groups that began requiring mandatory mail order use caused a significant spike in use and payments from 2009 to 2010 which magnified the two year average payment trend.

**Mail Order Pharmacy Trends by Top Therapeutic Classes
 2009-2011**

Therapeutic Class	Two Year Average Rate of Change			Three Year Payout	% of Total Payout	Percent Contribution to Trend
	Payments/ 1000 Members	Scripts Per/1000s Members	Payment/ Script			
Lipotropics	173.6%	237.1%	(8.7)%	\$457,844,829	13.5%	16.5%
Diabetic Therapy	232.4%	225.6%	4.5%	\$417,482,899	12.3%	16.1%
Other Hypotensives	177.8%	223.2%	(13.8)%	\$245,729,517	7.3%	9.4%
Miscellaneous	285.9%	186.0%	15.8%	\$312,150,997	9.2%	13.6%
Anti-Ulcer Preps	45.5%	42.8%	(3.6)%	\$98,251,738	2.9%	2.4%
Bronchial Dilators	218.8%	206.0%	7.8%	\$237,331,618	70%	9.0%
Anticoagulants	288.8%	205.2%	11.7%	\$198,342,732	5.9%	7.4%
Other Cardio Preps	179.1%	225.4%	(11.1)%	\$154,633,313	4.6%	5.8%
Psychostimulants/ Antidepressants	260.4%	270.5%	(2.8)%	\$149,760,773	4.4%	6.1%
Anti-arthritics	407.1%	205.0%	43.2%	\$123,741,096	3.7%	5.4%
All Others	404.3%	25.7%	(10.9)%	989,475,958	29.2%	12.7%
Total	212.0%	212.8%	(0.3)%	\$3,384,745,470	100.0%	100.0%

BCBSM states drugs with patent protection and extensive marketing continue to demand high prices. During the two year period under review, fewer new blockbuster drugs came into the market. In therapy classes where there are multiple treatment options, competition has increased between brand name drugs and between brand name drugs and generic drugs. Formularies and tiered copayment options create incentives for members to take generic medications or lower cost brand-name drugs. Once drugs lose patent protection and generic competition starts, it is typical for brand name drug sales to decline as health payers adjust their formularies to require patients to switch to the lower costing generic medication.

BCBSM states that in 2009 and 2010, loss of patent exclusivity for several major blockbuster medications, including Prevacid (heart burn and acid reflux), Imitrex (migraines), Lipitor (cholesterol lowering), Protonix (antacid) and Flomax (enlarged prostate) had a positive impact on the 2010 prescription drug trend, allowing price stability. When a brand name drug loses its patent, both the price of the drug and the dollar value of its sales each tend to drop about 80% over the next year, as competition opens to a host of generic drug makers. As generic drugs cost less than brand name drugs, the dispensing rate of generic drugs increases contributing to a slower spending growth.

As described in the quality of care section of this determination report, therapeutic interchange refers to substituting a brand name drug for a less costly therapeutic alternative. Therapeutic alternatives produce comparable therapeutic effects although they are not the same chemical compounds. Therapeutic interchanges must be approved by the prescribing physician before they are implemented.

BCBSM states that many employers have adopted pharmacy benefit designs that require their employees to pay higher copayments for brand-name drugs than for generic drugs. For some brand name or single source medications there is often no lower cost generic or therapeutic substitute available. BCBSM's Corporate Trend Report reveals that use and cost trends are impacted when members with higher out-of-pocket costs consume fewer services and choose less costly alternatives when they do seek all types of services, including prescription drugs. National data reveals a similar trend. An analysis released in September 2011 by the Generic Pharmaceutical Association shows the use of generic prescription drugs in the United States saved consumers and the health care system over \$900 billion from 2001-2010. In 2010 alone, generic drug savings amounted to nearly \$158 billion or an average of three million dollars per week. The savings that come with the use of generic drugs provide a winning solution to consumers that need to decrease their health care costs. Generic pharmaceuticals represent 78% of the prescriptions dispensed in the United States, but they only amount to 25% of the total drug spending²

² www.gphaonline.org/media/press-release/2011/new-study-finds-use-generic-prescription-drugs-saved-consumers-and-us-heal

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BCBSM implemented a variety of initiatives to enhance its pharmacy products. These initiatives are part of the basic pharmacy benefits and apply to all customer groups unless they choose to opt out. BCBSM states these initiatives focus on:

- Encouraging prescribing of select over-the-counter drugs, generic drugs and generic alternatives to expensive brand name drugs
- Using dose optimization to improve patient compliance and reduce costs
- Ensuring prescribing is consistent with FDA recommendations for certain therapeutic classes
- Requiring medical necessity review of off-label use of targeted drugs.

Several of these initiatives, including the Dose Optimization, Brand to Alternate Generic Interchange, Generic Copay Waiver and Quantity Limits programs were described in the quality of care section of this determination report. Additional BCBSM initiatives include the Generic Copay Holiday Program and the Off-Label Coverage Initiative. These initiatives are clinically sound and provide value by lowering out-of-pocket costs for members and holding down benefit costs for customer groups. A current targeted drug list for each of these initiatives is maintained at bcbsm.com.

Approximately 15% of customers have “opted out” of BCBSM’s pharmacy initiatives. Most of these groups are large, self-funded customers or union groups that have negotiated contracts prohibiting pharmacy cost management programs. BCBSM states that customer groups may not opt-out of our off-label/high cost specialty prior authorization review program.

The Generic Copay Holiday Initiative waives the copayment for three retail or three mail order prescriptions when the member switches from a targeted drug to a generic equivalent.

BCBSM’s Off-Label Coverage Initiative requires medical necessity approval for specific drugs prescribed for uses other than those approved by the FDA. The member’s physician must obtain approval of medical necessity for the member to receive the targeted drugs. Drugs which may be prescribed for uses other than those approved by the FDA include human growth hormone, FDA approved for documented growth hormone deficiency but may be prescribed for off-label use for anti-aging or athletic enhancement; human chorionic gonadotropin, FDA approved for infertility but may be prescribed for off-label use for weight loss; and anabolic steroids, FDA approved for the treatment of anemias caused by deficient red cell production. Acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs often respond to anabolic steroids. Anabolic steroids may also be prescribed for off-label use for anti-aging and athletic enhancement.

BCBSM states membership declined an average of 4.8% or approximately 97,000 members. In 2011, 27% of members were 25 years of age and younger, while 39% of

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members were age 56 years and older. Twenty six percent of members were between the ages of 36-55 years of age and older. BCBSM states that prescription drug use and the use of multiple prescription drugs tend to increase with age. According to data reported by the Center for Disease Control, 65% of people ages 45-64 and 90% of adults 65 years old and older take at least one prescription medication. In each age group women were more likely than men to use prescription drugs.

Members over the age of 45 accounted for 68% of payments and 66% of prescriptions in 2011. While 21% percent of the membership was over age 65, these members accounted for 19% of payments and 18% of prescriptions, with payment per prescription averaging \$90.49. Members aged 56 to 65 were the second most costly per prescription segment, accounting for 27% of payments and 26% of prescriptions.

Average payment per prescription increased by age category and ranged from a low of \$78 dollars for members from birth to age 25 to a high of almost \$103 for members over age 65. Growth hormones and ataractics (drugs associated with having a soothing or calming effect on mood, thought or behavior) were the top two therapeutic drug classes for members aged 0-25. Lipotropic and diabetic therapy drugs were the top two classes for members older than 65.

BCBSM states that female members accounted for 58% of prescription drug use and 53% of payments for the mail order and retail programs combined. Payment per prescription averaged approximately \$96 for males and \$80 for females in 2011.

MPA indicated in its written testimony that BCBSM has separate dispensing fees for certain counties. BCBSM states its traditional pharmacy contract provides for the same dispensing fee regardless of the county of where the pharmacy is located. BCBSM's Preferred Rx contract, on the other hand, provides for higher dispensing fees in the more rural areas of the state. Because pharmacies in these less-populated areas do not process the same volume of prescriptions as those in suburban or urban areas of the state, they are unable to spread dispensing costs over a large number of prescriptions. To account for this disparity, pharmacies in counties other than Wayne, Oakland, Macomb, Washtenaw, Genesee, Kent, Ingham, Saginaw and Kalamazoo counties receive a dispensing fee that is 40 cents per prescription higher than pharmacies in the counties identified in this paragraph.

MPA alleged that BCBSM is quick to decrease MAC pricing when acquisition costs decrease but is slow to increase MAC pricing when acquisition costs increase. BCBSM states MAC prices are established using the best available market intelligence and that there is an established process for pharmacies to dispute these prices. This process requires that a pharmacy provide BCBSM with a purchase invoice demonstrating that the product is not available at the established MAC price. Once this information is received, action is taken to adjust the pricing. As the update process may not commence until this

information is received, delays in the submission of documentation may lead to an increased time between the initial notice and updates to the list.

BCBSM states that prior to September 2012, BCBSM updated the MAC list on a monthly basis. These updates include price increases, price decreases, as well as the addition or removal of drugs from the MAC list. As of September 2012, BCBSM has dedicated a company resource to ensure bi-weekly updating of the MAC list. While BCBSM strives to keep the list as up-to-date as possible, BCBSM's Pharmacy Advisory Committee is allowed 3-7 days to review all proposed changes. Additionally, the system dictates that all potential changes require a 7-10 day lead time for implementation. BCBSM states that any delays in updates to the MAC list are the result of these review provisions and technical limitations.

BCBSM was asked whether it was to be considering an increase to its current dispensing fees. BCBSM states its pharmacy reimbursement rates are under continuous review to ensure that rates are competitive and equitable to pharmacy providers through periodic benchmarking studies. These benchmarking studies analyze the cost-to-dispense with respect to the pharmacy's total reimbursement for both brand and generic drugs, accounting for discounts to AWP and dispensing fees as well as incentives. BCBSM states it last performed such a study in 2010. Further studies are planned for 2013 as BCBSM continues to strive to maintain the current level of pharmacy enrollment as a percentage of overall medical membership.

Findings and Conclusions - Cost

Based on the cost information analyzed during this review, it is determined that BCBSM did not meet the cost goal stated in the Act for the pharmacy provider class during the two year period under review. This decision is based on the fact that the rate of change in the total corporation payment per member to the pharmacy provider class has been calculated to be a increase of 42.3% during the two years being reviewed and therefore exceeded the compound rate of inflation and real economic growth of 1.4%.

There are, however, factors that impact BCBSM's ability to contain costs and use within the constraints of the cost goal specified in the Act. Prominent factors include an aging baby boomer generation and the overall health status of Michigan residents. Cutting edge technologies in medical diagnosis and treatment along with significant advances in the development of prescription drugs used to treat chronic illness have enabled Michigan residents to live longer lives. This increased longevity also increases the likelihood for Michigan residents to develop chronic conditions which require ongoing care, particularly prescription medications.

Another significant factor affecting cost performance during this particular two year review period includes the approximately 220,000 members from several large self-funded customer groups who were required to begin mandatory mail order use caused a

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significant spike in use and payments from 2009 to 2010 which magnified the two year average payment trend.

Because of this, it is not necessary to require that a change to the current pharmacy provider class plan be filed pursuant to Section 511 of the Act. BCBSM is encouraged to continue its efforts to find new, innovative programs that instill responsible cost controls so that all the goals and objectives of the corporation can be achieved.

Determination Summary

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



ATTACHMENT A

