December 4, 2015

The Honorable Edward J. Kaseymeyer
Chair
Senate Budget & Taxation Committee
3 West Miller Senate Office Bldg.
Annapolis, MD 21401-1991

The Honorable Maggie McIntosh
Chair
House Appropriations Committee
121 House Office Bldg.
Annapolis, MD 21401-1991

The Honorable Thomas M. Middleton
Chair
Senate Finance Committee
3 East Miller Senate Office Bldg.
Annapolis, MD 21401-1991

The Honorable Peter A. Hammen
Chair
House Health and Government Operations Committee
241 House Office Bldg.
Annapolis, MD 21401-1991

Re: HB 1290 (Ch. 309 of the Acts of 2015) – Report on DHMH’s Plan to Ensure That Medical Assistance Program Recipients Enrolled in Managed Care Organizations Have Reasonable Access To Pharmacy Services

Dear Chairmen Kaseymeyer, Middleton, McIntosh and Hammen:

In keeping with the requirements of HB 1290 (Ch. 309 of the Acts of 2015) – Medicaid Managed Care Organizations – Pharmacy Networks – Plan, enclosed is the Department of Health and Mental Hygiene’s report on the Department’s plan to ensure MCO enrollees have reasonable access to pharmacy services in the event an MCO makes changes to its pharmacy network that reduce the number of providers or alters the location of services provided. This report also addresses network adequacy generally, as well as how the Department uses geographic standards to ensure access to pharmacy services in urban, rural, and suburban areas of the State.

Thank you for your consideration of this information. If you have questions or need more information on the subjects included in this report, please contact Allison Taylor, Director of Governmental Affairs at (410) 767-6480.

Sincerely,

Van T. Mitchell
Secretary

Enclosure
cc:  Shannon McMahon
     Tricia Roddy
     Susan Tucker
     Jill Spector
     Rosemary Murphey
     Alyssa Brown
     Allison Taylor
Ensuring Maryland Medical Assistance Program Recipients Enrolled in Managed Care Organizations Have Reasonable Access to Pharmacy Services

Submitted by the Department of Health and Mental Hygiene

As Required by HB 1290 (Ch. 309 of the Acts of 2015)
Introduction

Following a proposal by one of the Maryland Medicaid managed care organizations (MCOs) to remove certain providers from its pharmacy network in the spring of 2015, the General Assembly requested additional information regarding the Department’s approach to monitoring network adequacy. Pursuant to HB 1290 (Chapter 309 of the Acts of 2015), the Department of Health and Mental Hygiene (the Department) submits this report regarding the Department’s plan to ensure MCO enrollees have reasonable access to pharmacy services in the event an MCO makes changes to its pharmacy network that reduce the number of providers or alter the location of services provided. This report also addresses network adequacy generally as well as how the Department uses geographic standards to ensure access to pharmacy services in urban, rural, and suburban areas of the State.

Background

The Maryland Medicaid Program serves approximately 1.2 million low-income Marylanders. More than 80 percent of Maryland Medicaid recipients receive their care through HealthChoice, Maryland’s statewide mandatory managed care program implemented in 1997 under authority of Section 1115 of the Social Security Act. The HealthChoice program seeks to improve access and quality of care to recipients by providing comprehensive, patient-focused, coordinated care. Eligible Medicaid participants enroll in an MCO of their choice and select a primary care provider (PCP) to oversee their medical care. MCOs receive a capitation payment in exchange for providing care to their enrollees.

While not required by the Centers for Medicare & Medicaid Services (CMS), Maryland, like all other states, has elected to cover pharmacy services as part of its Medicaid benefit package. Each of the eight MCOs that participate in the HealthChoice program is responsible for managing its provider networks in order to ensure their enrollees receive high quality, cost effective, and efficient care, including pharmacy services. Based on preliminary estimates, the Department anticipates that pharmacy costs attributable to the HealthChoice program exceeded $448 million for calendar year (CY) 2014.

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1 UnitedHealthcare initially proposed and subsequently made substantial modifications to its plan to remove certain community pharmacies from its network. The Department notes that, despite concerns raised by stakeholders, UnitedHealthcare’s network would have continued to meet the Department’s network adequacy requirements had the MCO moved forward with its original proposal.

2 This estimate is based on figures included in the preliminary CY 2014 HealthChoice Financial Monitoring Report (HFMR). Note that this estimate includes expenses for substance use disorder (SUD) medications, estimated to exceed $23 million. SUD medications were carved out of the MCO benefit package effective January 1, 2015. Not including SUD medications, preliminary estimates indicate CY14 HealthChoice spending for pharmacy costs will be approximately $425 million.
**Current Network Adequacy Requirements**

Network adequacy requirements for Medicaid managed care programs are governed generally by 42 C.F.R. § 438.206 and § 438.207. States have considerable latitude in the standards they establish for their plans. Maryland has elected to develop access standards that limit the distance enrollees should have to travel to access services. Specifically, under COMAR 10.09.66.06, MCOs must maintain a pharmacy network sufficient to meet the following geographic requirements:

1. In urban areas, pharmacies shall be within 10 miles of each enrollee’s residence;
2. In rural areas, pharmacies shall be within 30 miles of each enrollee’s residence; and
3. In suburban areas, pharmacies shall be within 20 miles of each enrollee’s residence.

The Department may in its discretion approve an MCO’s network that does not meet these requirements if special circumstances exist which, considered along with the overall strength of the MCO’s network, establish that the network will still enhance recipients’ overall access to quality health care services in the area to be served. The Department has not exercised this option with respect to the pharmacy networks of any of the eight MCOs currently serving the HealthChoice Program.

In 2014, the Department began assessing network adequacy based solely on a geographic distance-based standard. Previously, the Department assessed network adequacy using both geographic distance- and time-based standards. Unlike distance-based standards, time-based standards were unreliable and difficult to apply consistently. Adopting a strictly distance-based standard has permitted the Department to assess accessibility using a uniform standard that is not impacted by unpredictable variables such as fluctuations in traffic volume, mode of transit used, weather conditions, and road accessibility. Other states have also elected to implement distance-based standards.

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3. In addition to the geographic access standards, MCOs must meet additional standards regarding access to somatic providers, including the local access area enrollee-to-provider ratios specified in COMAR 10.09.66.05 and specialty provider network requirements specified in COMAR 10.09.66.05-1. Appointment wait-time standards for clinical care are specified in COMAR 10.09.66.07.

4. These geographic requirements also apply to primary care, OB/GYN, and diagnostic laboratory and X-ray providers. For purposes of MCO geographical access standards, the “urban” enrollment area includes Baltimore City. “Rural” enrollment areas include Allegany, Calvert, Caroline, Cecil, Charles, Dorchester, Frederick, Garrett, Kent, Queen Anne’s, Saint Mary’s, Somerset, Talbot, Washington, Wicomico, and Worcester counties. “Suburban” enrollment areas include Anne Arundel, Baltimore, Carroll, Harford, Howard, Montgomery, and Prince George’s counties.

5. *E.g.*, Texas (all clients must have access to a minimum of one network pharmacy within 15 miles of the client’s residence and with 24-hour coverage within 75 miles of the client’s residence); Indiana (members shall have access to primary care within a maximum of 30 miles of the member’s residence and at least two providers of each specialty type within 60 miles of member’s residence); Missouri
Maryland’s Approach to Monitoring Network Adequacy and Access

The Department engages in a broad variety of activities to monitor network adequacy and access that begin the moment an MCO applies to participate in the HealthChoice program and continue over time. When an MCO fails to meet the established network requirements, the Department can exercise its sanction authority to bring the MCO back into compliance. The Department’s quality assurance strategy is designed to ensure HealthChoice enrollees receive high quality care without creating an undue administrative burden for the MCOs. Efforts to explore new ways to assess the performance of the MCOs and hold them accountable for their performance are ongoing.

MCOs seeking to join the HealthChoice program undergo a rigorous review process. This review includes an assessment by the Department of the adequacy of its provider network, including its pharmacies. Beginning in CY 2013, the Department amended COMAR to require all MCOs participating in HealthChoice to obtain National Committee for Quality Assurance (NCQA) accreditation by January 1, 2015. New plans joining the HealthChoice program must obtain NCQA accreditation within two years of the date they begin providing HealthChoice services.\(^6\) Organizations obtaining NCQA accreditation must undergo comprehensive review and are subject to annual reporting requirements. As of July 2015, 20 states, including Maryland, mandate NCQA accreditation for their Medicaid Managed Care plans.\(^7\) All eight HealthChoice MCOs are currently engaged in the NCQA accreditation process. One MCO, Jai Medical Systems, has achieved an "Excellent" rating, the highest accreditation standard.

Any changes to an MCO’s network are subject to the scrutiny of the Department. The Department monitors provider participation among primary and specialty care providers through quarterly reports prepared by the Hilltop Institute at University of Maryland, Baltimore County. The Department is also in the process of amending COMAR 10.09.65.17B to require MCOs to provide the Department with at least 90 days notice prior to eliminating any provider.\(^8\) Increasing the current notice requirement from 30 days to 90 days will enable the Department to thoroughly reassess the adequacy of the MCO’s network in light of the changes and, in the case of termination of a primary care provider (PCP) or other substantial changes, to provide adequate notice to the affected members to ensure continuity of care is not compromised.

\(^6\) COMAR 10.09.64.08.


\(^8\) 42 Md. Reg. 1236 (September 2015), available at http://www.dsd.state.md.us/MDR/4219.pdf. The Department estimates these changes will be effective in February 2016.
Federal law also supports states in their efforts to hold MCOs accountable for the adequacy of their networks over time. 42 C.F.R. § 438.202(a) requires each state contracting with an MCO to have a written strategy for assessing and improving the quality of managed care services. The cornerstone of the Department’s comprehensive strategy for monitoring the HealthChoice program is its Medicaid Quality Strategy. Subject to comprehensive revision every five years and re-assessed annually, the Quality Strategy incorporates feedback from stakeholders solicited during a public comment period as well as input from the MCOs. The Quality Strategy encompasses a wide scope of activities, including:

- System Performance Review (SPR) to assess the structure, process, and outcome of each MCO’s internal quality assurance programs;
- Administration of the annual Consumer Assessment of Healthcare Providers Systems (CAHPS) survey for Medicaid Plans;
- Collection of Healthcare Effectiveness and Data Information Set (HEDIS) measures;
- Performance Improvement Projects (PIPs) selected by the Department to significantly improve quality, access, or timeliness of service delivery; and
- Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) medical record review

Although many components of the Quality Strategy can be leveraged to ensure access to pharmacy services is maintained, two of the most crucial components are the Systems Performance Reviews (SPRs) and CAHPS surveys.

As a condition of participating in the HealthChoice program, MCOs must participate in SPRs conducted by the Department’s designated External Quality Review Organization (EQRO). The SPR assesses quality of care provided to HealthChoice enrollees by assessing MCOs’ minimum compliance rate across eleven performance standards, including availability and accessibility of services. In response to concerns about MCOs’ ability to meet pharmacy access needs and provide services in the event of an emergency, an assessment of the MCOs’ Disaster Recovery Plans has also been incorporated into the SPR. MCOs that fail to meet the acceptable compliance threshold for a given performance standard must develop a Corrective Action Plan (CAP). MCOs subject to a CAP have their progress assessed annually.

The CAHPS survey is another mechanism the Department uses to assess consumer satisfaction with the care received through the HealthChoice program. The CAHPS survey is distributed to a random selection of recipients enrolled in the program and includes measures related to access to care. Composite results to some questions included on the survey are incorporated into the annual Consumer Report Card (CRC), which is shared publicly on the websites of the

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9 The current Medicaid Quality Strategy can be accessed online: https://mmcp.dhmh.maryland.gov/healthchoice/SitePages/HealthChoice%20Quality%20Assurance%20Activities.aspx.

10 COMAR 10.09.65.03.
Department and the Maryland Health Connection. The CRC is also included with enrollment materials provided to all new recipients. Since performance on the CRC can influence consumer plan selection and impact plan enrollment, MCOs have an added incentive to perform well on access to care measures.

Additionally, the Department has conducted a series of evaluations of the HealthChoice program since its inception in 1997. The annual HealthChoice Evaluation examines the progress made with respect to meeting the programs core goals of expanding coverage, improving access to and quality of care, and providing recipients with an appropriate medical home. Five comprehensive evaluations of the program have been conducted to date as part of the State’s 1115 waiver renewals. Between waiver renewals, the Department completes an annual evaluation for HealthChoice stakeholders. The next comprehensive evaluation will be completed in early 2016 as part of the Department’s renewal of its 1115 waiver.

The mechanisms described above are valuable tools to ensure MCOs comply with network adequacy requirements each year. The Department also believes that it is important to maintain open channels of communication for feedback from consumers and providers to ensure emerging issues are proactively addressed. Maintenance of the HealthChoice hotline, accessible through a toll-free number, enables the Department to identify and track questions and complaints regarding access to care in real time. Complaints are logged and addressed as they are received. Grievance and appeal procedures serve as a further safeguard for identifying and remedying access to care issues faced by recipients.11

Simply monitoring MCO compliance is not sufficient. Through its sanction authority, the Department has a variety of methods through which to address issues that arise when an MCO fails to meet network adequacy requirements. Remedies include:

- Requiring the MCO to develop a CAP to address the issue;
- Levying fines, withholding capitation payments or other financial sanctions;
- Freezing auto-assignment or enrollment;
- Permitting enrollees to annually change to a new MCO voluntarily; or
- In the case of significant issues, terminating the MCOs contract and ending its participation in the HealthChoice Program.

Network Adequacy and Proposed Rule CMS-2390-P

CMS issued Proposed Rule CMS-2390-P on June 1, 2015.12 The first major overhaul to managed care regulations in more than a decade, the Proposed Rule includes a broad array of changes to

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11 COMAR 10.09.72.

12 Medicaid and Children’s Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability, 80 Fed. Reg. 31097 (proposed June 1, 2015), available at
the existing regulations governing the Medicaid and Children’s Health Insurance Program (CHIP) Programs. In the preamble to the Proposed Rule, CMS asserted its desire to establish minimum standards in terms of network adequacy to provide a more uniform approach across the states. Proposed 42 C.F.R. § 438.68 would require states to develop “time and distance standards” for specific types of providers, including pharmacies, although states would be permitted to vary time and distance standards by provider type and geographic area. The Proposed Rule would continue to permit states to seek exceptions from these network adequacy standards. States are also encouraged to take into account factors such as the number of providers not accepting new Medicaid patients when assessing network adequacy.

The Department submitted formal comments on the Proposed Rule on July 27, 2015. Based on its past experience using time-based standards for determining network adequacy and recognizing the shortcomings of this method of assessment, the Department advocated for the continued ability of states to implement a distance-based standard.

At the time of this report, the Proposed Rule has not yet been enacted and CMS’ timeline for moving forward with the proposed network adequacy provisions are unclear. For these reasons, the Department believes it would be premature to make amendments to its existing network adequacy requirements, but is taking several new steps to assure and monitor access to services provided by the HealthChoice MCOs.

**Immediate Actions: Implementing New Strategies to Monitor Access**

With federal regulatory changes on the horizon, the Department is continuing to monitor network adequacy through its existing strategies while also implementing new initiatives to assure access to care for Medicaid recipients.

**PCP Monitoring:** A key goal of the HealthChoice program is to improve access to care by assigning recipients to a PCP who serves as their health home. To assess how recipients use their PCPs, the Department has begun collecting monthly PCP assignment data from the MCOs. The Department will use the information compiled to gain further insight into how program recipients access and utilize care. Once a baseline of performance has been established, future initiatives may focus on incentivizing improvements in use of primary care, for example, through the implementation of a value-based purchasing measure.

**Secret Shopping:** The Department is also piloting a “Secret Shopper” initiative to verify the accuracy each MCO’s primary care provider directory. Future iterations of the initiative may extend to other provider types—including verifying directory entries for specialists and pharmacies.

**Notice Requirements:** As noted above, the Department has also implemented changes to require MCOs to provide the Department with at least 90 days notice prior to making provider network changes.

**Recommendations and Next Steps**

The Department believes that the newly implemented efforts to monitor networks through secret shopping, additional notice requirements and enhanced reporting of PCP networks are important first steps in advance of the imminent federal regulations to define and monitor network adequacy.

*Limited Pharmacy Networks Reduce Costs without Compromising Access to Care*

The Department continues to believe that encouraging MCOs to utilize pharmacy benefit managers (PBMs) to limit their pharmacy networks represents an effective strategy for achieving substantial savings without jeopardizing access to needed medications and services. The adoption of an “any willing provider” (AWP) law that requires MCOs to contract with any willing pharmacy provider has been proposed as one mechanism for improving access to care for HealthChoice recipients. The Department opposes this approach.

Studies show that permitting insurers to work with PBMs to limit or restrict their pharmacy networks results in financial savings without compromising access to care, while implementing AWP laws has been shown to increase pharmacy costs. The Federal Trade Commission has consistently advised against AWP laws on the grounds that they reduce competition and threaten the effectiveness of selective contracting with pharmacies as a tool for lowering costs.

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When MCOs engage in selective contracting to limit their pharmacy network, providers have significant incentives to compete, resulting in lower costs to the MCO, and by extension, the State. Absent the promise of exclusivity, MCOs’ bargaining power is diluted and providers have little incentive to offer discounts to MCOs resulting in higher costs.\textsuperscript{16} These increased costs are eventually passed on to the Department in the form of increased capitation rates paid by the State to the MCOs. Notably, the Department’s existing network adequacy requirements serve as a critical safeguard for Medicaid recipients, effectively acting as guardrails to ensure no MCO restricts its network to the point that the ability of enrollees to access care is compromised.

The Department provided estimates regarding the savings attributable to the use of limited pharmacy networks by the MCOs through the legislative fiscal note process for HB 1290 (establishing more restrictive geographic standards) and a related bill, HB 1291 (requiring MCOs to cover pharmacy services from AWP), during the 2015 session of the General Assembly. In the absence of specific information from the MCOs regarding their individual pharmacy networks, the Department assumed that all of the MCOs utilized limited pharmacy networks—resulting in an estimated $67 million (total funds) in savings to the Department in fiscal year (FY) 2016.\textsuperscript{17}

The Department has since gathered additional information from the MCOs. While all eight MCOs use PBMs, only half appear to use limited pharmacy networks. Even those MCOs that use selective contracting to create a limited pharmacy network include a combination of chain and independent pharmacies. Based on preliminary HFMR spending estimates in CY14, the four MCOs currently utilizing a PBM to develop a limited pharmacy network represent approximately 64% of the total cost of the HealthChoice pharmacy program, suggesting that as much as $42.9 million of the potential savings have already been realized. It is possible that additional savings could be realized if all MCOs utilized PBMs that also establish limited pharmacy networks.

\textit{Encouraging the Use of Mail Order Pharmacies}

Many Medicaid recipients use prescription medications on a regular basis to manage chronic conditions. For those with limited mobility due to health conditions or limited access to

\begin{itemize}
\item \textsuperscript{16} The Department recognizes that the bargaining power of MCOs with smaller numbers of enrollees and proportionally lower demand for prescription medications may be more limited than that of their larger peers.
\item \textsuperscript{17} The Department adopted the methodology used in a recent study to estimate savings. The Menges Group, \textit{Medicaid Pharmacy Savings Opportunities: National and State-Specific Estimates} (2013), available at: https://www.themengesgroup.com/upload_file/final_medicaid_savings_report_menges_group_may_2013.pdf
\end{itemize}
transportation, refilling prescriptions in a timely fashion can sometimes prove challenging. Mail order pharmacies give recipients the additional option to fill prescriptions without a trip to a traditional brick and mortar location. Dispensing medications through a single mail order pharmacy may increase medication compliance rates, improve health outcomes, and help identify potential drug interactions that might be missed when an enrollee uses multiple pharmacies.\(^{18}\) Studies also suggest use of mail order pharmacies is associated with lower costs and improved efficiency.\(^{19}\)

Mail order pharmacies are not included when the Department assesses the adequacy of an MCO’s pharmacy network. However, under COMAR 10.09.67.04, MCOs have the discretion to implement programs to encourage recipients to obtain specialty drugs through mail order pharmacy services. A specialty drug is defined as:

1. A prescription drug that:
   1. Is prescribed for an individual with a complex, chronic or rare medical condition;
   2. Costs $600 or more for up to a 30-day supply;
   3. Is not typically stocked at retail pharmacies; and
   4. Requires a difficult or unusual process of delivery to the patient in the preparation, handling storage, inventory or distribution of the drug; or 
2. Requires enhanced patient education, management, or support, beyond those required for traditional dispensing, before or after administration of the drug.

An enrollee may opt-out of receiving specialty drugs from a mail order pharmacy at any time. The enrollee must expressly request all other uses of mail order pharmacy services.

At the time of this report, six of the eight MCOs include a mail order option in their pharmacy networks. Of the MCOs that provide a mail order pharmacy benefit, four MCOs allow enrollees to use mail order pharmacies to fill all prescription types, while the other two limit access to

\(^{18}\) See, e.g., Julie A. Schmittdiel, PhD, et al., Safety and Effectiveness of Mail Order Pharmacy Use in Diabetes, 19 AM J MANAG CARE 882-87 (2013) (finding that mail order pharmacy use is not associated with adverse outcomes in most diabetes patients, and is associated with lower emergency department use); Julie A. Schmittdiel, PhD, et al., The Comparative Effectiveness of Mail Order Pharmacy Use vs. Local Pharmacy Use on LDL-C Control in New Statin Users, 26 J. GEN. INTERN. MED. 1396-1402 (2011) (finding that mail order pharmacy use was positively associated with LDL-C control in new statin users); O. Kenrik Duru, MD, MSHS, et al., Mail-Order Pharmacy Use and Adherence to Diabetes-Related Medications, 16 AM. J. MANAG. CARE 33-40 (2010) (finding that when compared with patients who obtained medication refills at local pharmacies, patients who received them by mail were more likely to have good adherence).

\(^{19}\) The Lewin Group, Mail-Service Pharmacy Savings and the Cost of Proposed Limitations in Medicare and the Commercial Sector (September 2006), available at: http://amcp.org/WorkArea/DownloadAsset.aspx?id=12048
mail order pharmacy services to specialty drugs. Two MCOs do not use mail order pharmacies in any fashion. This suggests that the potential access and financial benefits of mail order pharmacies have not yet been fully realized.

Opportunities for Savings

Looking ahead, the Department believes there may be additional opportunities to improve access to care while maximizing savings. As part of broader austerity measures, MCO capitation rates have been reduced. Given these fiscal constraints, MCOs are incentivized now more than ever to use their PBMs as utilization management entities. There exists an opportunity for four more MCOs to better manage cost and care through the implementation of more cost effective pharmacy networks and mail order pharmacies. It is the Department’s recommendation that the MCOs’ continue to have the latitude to make adjustments to their pharmacy networks within the boundaries of the Department’s established network adequacy guidelines, and that they be encouraged to contract with PBMs that are equipped to implement strategies such as mail order pharmacy for members.

Conclusion

The Department’s robust quality assurance program is designed to assure that the one million low-income Marylanders currently enrolled in HealthChoice are able to access care appropriately. Safeguards, such as regular SPRs and the annual HealthChoice evaluation, enable the Department to monitor MCO compliance with network adequacy requirements over time, while the HealthChoice hotline and pending regulations updating network change notice requirements permit the Department to react quickly to circumstances that might compromise access to care as they arise. While federal changes to network adequacy are imminent, the Department is implementing new monitoring strategies for MCOs, including secret shopping, monitoring of PCP assignment data, and a requirement for the Department to be notified 90 days prior to any network changes. However, with federal changes on the horizon, it is premature to make changes to existing network adequacy regulations. Moving forward, MCOs should be encouraged to contract with PBMs that are equipped to manage the needs of their patients while also monitoring costs. The opportunity for MCOs to use mail order pharmacy should also be explored.