

## EXHIBIT BBB

### OUTPATIENT DRUG SERVICES

#### 1. General Requirements

- a. All requirements in this Exhibit apply to all Covered Outpatient Drugs regardless of the setting in which the drug is dispensed or administered and regardless of the billing provider type.
- b. The amount, duration, and scope of Covered Outpatient Drugs must be consistent with coverage under the Fee-for-Service (FFS) program. The PH-MCO must cover all Covered Outpatient Drugs listed on the Center for Medicare and Medicaid Services (CMS) Quarterly Drug Information File when determined to be Medically Necessary, unless otherwise excluded from coverage. (See 2. Coverage Exclusions below for exclusions.) This includes brand name and generic drugs, and over-the-counter drugs (OTCs), prescribed by licensed providers enrolled in the MA program, and sold or distributed by drug manufacturers that participate in the Medicaid Drug Rebate Program.
- c. The PH-MCO must provide coverage for all medically accepted indications, as described in Section 1927(k)(6) of the Social Security Act, 42 U.S.C.A. 1396r-8(k)(6). This includes any use which is approved under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. 301 et seq. or whose use is supported by the nationally recognized pharmacy compendia, or peer-reviewed medical literature.
- d. Unless financial responsibility is otherwise assigned, all Covered Outpatient Drugs are the payment responsibility of the Member's PH-MCO. The only exception is that the behavioral health managed care organization (BH-MCO) is responsible for the payment of methadone when used in the treatment of substance abuse disorders and when prescribed and dispensed by BH-MCO service Providers.
- e. All Covered Outpatient Drugs must be dispensed through PH-MCO Network Providers. This includes Covered Outpatient Drugs prescribed by both the PH-MCO and the BH-MCO Providers.
- f. Under no circumstances will the PH-MCO permit the therapeutic substitution of an outpatient drug by a pharmacist without explicit authorization from the licensed prescriber.
- g. All proposed pharmacy policies, programs and drug utilization management programs, such as prior authorization, step therapy, partial fills, specialty pharmacy, pill-splitting, mail order, 90day supply programs, etc. must be submitted to the Department for review and written approval prior to implementation, prior to implementation of any changes, and annually thereafter.

- h. The PH-MCO must include in its written policies and procedures an assurance that all requirements and conditions governing coverage and payment for Covered Outpatient Drugs, such as, but not limited to, prior authorization (including step therapy), medical necessity guidelines, age edits, drug rebate encounter submission, reporting, notices of decision, etc. will,
  - i. Apply, regardless of whether the Covered Outpatient Drug is provided as an outpatient drug benefit or as a “medical benefit” incident to a medical service and billed by the prescribing Provider using codes such as the Healthcare Common Procedure Coding System (HCPCS).
  - ii. Ensure access for all medically accepted indications as documented by package labeling, nationally recognized pharmacy compendia, peer-reviewed medical literature, Statewide Preferred Drug List (PDL) prior authorization guidelines, if applicable, and FFS guidelines to determine medical necessity of drugs that require prior authorization in the MA FFS Program, when designated by the Department.
- i. The PH-MCO must submit for review and approval a policy for each section of Exhibit BBB that includes the requirements in the respective section and the PH-MCO’s procedures to demonstrate compliance.
- j. The PH-MCO must agree to adopt the same requirements for prior authorization and some or all of the same guidelines to determine medical necessity of selected drugs or classes of drugs as those adopted by the MA FFS Program when designated by the Department.
- k. The PH-MCO must comply with Section 2117 of Article XXI of the Insurance Company Law of 1921, as amended, 40 P.S. 991.2117 regarding continuity of care requirements and 28 PA Code Ch. 9. The PH-MCO must also comply with the procedures outlined in MA Bulletin 99-03-13 and MA Bulletin # 99-96-01. The PH-MCO policy and procedures for continuity of care for outpatient drugs, and all subsequent changes to the Department-approved policy and procedures, must be submitted to the Department for review and approval prior to implementation. The policy and procedures must address how the PH-MCO will ensure no interruption in drug therapy and the course of treatment, and continued access to outpatient drugs that the Member was prescribed before enrolling in the PH-MCO.
- l. The PH-MCO must allow access to all new drugs approved by the Food and Drug Administration (FDA) and meet the definition of a Covered Outpatient Drug either by addition to the Statewide PDL or MCO Formulary for drugs and products not included in the Statewide PDL, or through prior authorization, within ten (10) days from their availability in the marketplace.

## **2. Coverage Exclusions**

- a. In accordance with Section 1927 of the Social Security Act, 42 U.S.C.A. 1396r-8, the PH-MCO must exclude coverage for any drug marketed by a drug company (or labeler) who does not participate in the Medicaid Drug Rebate Program. The PH-MCO is not permitted to provide coverage for any drug product, brand name or generic, legend or non-legend, sold or distributed by a company that did not sign an agreement with the federal government to provide rebates to the Medicaid agency. This requirement does not apply to vaccines, compounding materials, certain vitamins and minerals or diabetic supplies.
- b. The PH-MCO must not provide coverage for Drug Efficacy Study Implementation (DESI) drugs under any circumstances.
- c. The PH-MCO must exclude coverage of noncompensable drugs in accordance with 55 PA Code §1121.54.

### **3. Formularies and Preferred Drug Lists (PDLs)**

- a. The PH-MCO must utilize the Statewide PDL developed by the Department's Pharmacy and Therapeutics (P&T) Committee.  
If the PH-MCO fails to meet Statewide PDL quarterly compliance of 95% (excluding TPL) a financial sanction consistent with the difference in net cost using PH-MCO actual compliance rate and the net cost if compliance rate was 95%. The minimum penalty of \$25,000 per quarter will be imposed.
- b. The PH-MCO must implement use of the Statewide PDL, any changes to the Statewide PDL, the Statewide PDL prior authorization guidelines, and any changes to the Statewide PDL prior authorization guidelines on the effective date provided by the Department.
- c. The PH-MCO must apply Statewide PDL prior authorization guidelines to all drugs and products included on the Statewide PDL. The PH-MCO may not impose additional prior authorization requirements for drugs and products included on the Statewide PDL. Quantity limits can be no more restrictive than the Department's quantity limits.

The PH-MCO must submit the policies, procedures, and guidelines to determine medical necessity of drugs included on the Statewide PDL to the Department. Submissions must occur prior to the effective date of the changes as determined by the Department and at least annually.

- d. The PH-MCO may use a Formulary or PDL to manage MA covered drugs and products that are outside the scope of the Statewide PDL as long as the Department has prior approved it and the Formulary or PDL meets the clinical needs of the MA population.

The Formulary or PDL must be developed and reviewed at least annually by the PH-MCO's P&T Committee, as defined in Section 6 of this Exhibit.

- e. The PH-MCO must allow access to all non-formulary or non-preferred drugs that are included in the CMS Quarterly Drug Information File, other than those excluded from coverage by the Department, when determined to be Medically Necessary through a process such as Prior Authorization (including Step Therapy), in accordance with Prior Authorization of Services Section V. B.1. and Exhibit H, Prior Authorization Guidelines for Participating Managed Care Organizations in the HealthChoices Program, and this Exhibit.
- f. The PH-MCO must receive written approval from the Department of the Formulary or PDL, the list of specialty drugs, quantity limits, age edits, and the policies, procedures and guidelines to determine medical necessity of drugs and products not included on the Statewide PDL that require prior authorization, including drugs that require step therapy and drugs that are designated as non-formulary or non-preferred, prior to implementation of the Formulary or PDL, the designation of specialty, and the requirements. PH-MCOs may add drugs to the specialty drug list that are in therapeutic classes already included on the specialty drug list prior to receiving approval from the Department. However, these additions must be included in the specialty drug designations submitted to the Department for written approval. Submissions for annual reviews must occur at least thirty (30) days before effective date of the updated information.
- g. The PH-MCO must submit all Formulary or PDL deletions for drugs and products outside the scope of the Statewide PDL to the Department for review and written approval prior to implementation.
- h. The PH-MCO must submit written notification of any Formulary or PDL additions for drugs outside the scope of the statewide PDL to the Department within fifteen (15) days of implementation.
- i. The PH-MCO must make available on the website in a machine readable file and format, information about its drug formulary or PDL, listing which medications are covered, including both brand and generic names.

#### **4. Prior Authorization of Outpatient Drugs**

- a. For Covered Outpatient Drugs that require Prior Authorization (including step therapy) as a condition of coverage or payment:
  - i. The PH-MCO must provide a response to the request for prior authorization by telephone or other telecommunication device indicating approval or denial of the prescription within twenty-four (24) hours of the request, and

- ii. If a Member's prescription for a medication is not filled when a prescription is presented to the pharmacist due to a Prior Authorization requirement, the PH-MCO must instruct the pharmacist to dispense either a:
  - Fifteen (15) day supply if the prescription qualifies as an Ongoing Medication, unless the PH-MCO or its designated subcontractor issued a proper written notice of benefit reduction or termination at least ten (10) days prior to the end of the period for which the medication was previously authorized and a Grievance or DHS Fair Hearing request has not been filed, or
  - A seventy-two (72) hour supply of a new medication.
- b. For drugs not able to be divided and dispensed into individual doses, the PH-MCO must instruct the pharmacist to dispense the smallest amount that will provide at least a seventy-two (72) hour or fifteen (15) day supply, whichever is applicable.
- c. The requirement that the Member be given at least a seventy-two (72) hour supply for a new medication or a fifteen (15) day supply for an Ongoing Medication does not apply when a pharmacist determines that the taking of the prescribed medication, either alone or along with other medication that the Member may be taking, would jeopardize the health or safety of the Member.
- d. In such an event, the PH-MCO and/or its subcontractor must require that its participating dispensing Provider make good faith efforts to contact the prescriber.
- e. If the PH-MCO denies the request for prior authorization, the PH-MCO must issue a written denial notice, using the appropriate Outpatient Drug Denial Notice template within twenty-four (24) hours of receiving the request for prior authorization.
- f. If the Member files a Grievance or DHS Fair Hearing request from a denial of an Ongoing Medication, the PH-MCO must authorize the medication until the Grievance or DHS Fair Hearing request is resolved.
- g. Requests for prior authorization will not be denied for lack of medical necessity unless a physician reviews the request for a medical necessity determination. Such a request for prior authorization must be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the Member.
- h. In addition, for children under the age of twenty-one (21), requests for service will not be denied for lack of medical necessity unless a physician or other health care professional with appropriate clinical expertise in treating the

Member's condition or disease determines:

- i. That the prescriber did not make a good faith effort to submit a complete request, or
  - ii. That the service or item is not medically necessary, after making a reasonable effort to consult with the prescriber. The reasonable effort to consult must be documented in writing.
- i. When medication is authorized due to the PH-MCO's obligation to continue services while a Member's Grievance or Fair Hearing is pending, and the final binding decision is in favor of the PH-MCO, a request for subsequent refill of the prescribed medication does not constitute an Ongoing Medication.
  - j. The PH-MCO guidelines to determine medical necessity of Covered Outpatient Drugs outside the scope of the Statewide PDL cannot be more stringent than the FFS guidelines. The PH-MCO must follow the Statewide PDL Prior Authorization guidelines for drugs and products included on the Statewide PDL.
  - k. The PH-MCO must comply with the requirements for Prior Authorization of Services, Section V. B. 1. and Exhibit H, Prior Authorization Guidelines for Participating Managed Care Organizations in the HealthChoices Program, and receive written approval from the Department prior to implementation and annually thereafter.

## **5. Provider and Member Notification**

The PH-MCO must have policies and procedures for notification to Providers and Members of changes to the Statewide PDL or MCO Formulary used by the PH-MCO for drugs and products outside the scope of the Statewide PDL, Prior Authorization requirements and other requirements for Covered Outpatient Drugs such as, but not limited to, specialty program requirements.

- a. Written notification for changes to requirements must be provided to all affected Providers and Members at least thirty (30) days prior to the effective date of the change.
- b. The PH-MCO must provide all other Providers and Members written notification of changes to the requirements upon request.
- c. The PH-MCO also must generally notify Providers and Members of changes through Member and Provider newsletters, its web site, or other regularly published media of general distribution.
- d. Member notices must be submitted to the Department for review and approval

prior to mailing.

## **6. PH-MCO Pharmacy & Therapeutics (P&T) Committee**

- a. The P&T Committee membership must include physicians, including a minimum of two (2) behavioral health physicians, pharmacists, MA program consumers and other appropriate clinicians. MA program consumer representative membership must include the following:
  - i. One (1) physical health consumer representative. The physical health consumer representative must be a consumer enrolled in the PH-MCO, or a physician, a pharmacist, or a physical health consumer advocate designated by consumers enrolled in the PH-MCO to represent them.
  - ii. One (1) behavioral health consumer representative. The behavioral health consumer representative must be a consumer enrolled in the PH-MCO, or a physician, a pharmacist, a behavioral health consumer advocate, or a family member designated by consumers enrolled in the PH-MCO to represent them.
- b. The PH-MCO must submit a P&T Committee membership list for Department review and approval upon request.
- c. When the P&T Committee addresses specific drugs or entire drug classes requiring medical expertise beyond the P&T Committee membership, specialists with knowledge appropriate to the drug(s) or class of drugs being addressed must be added as non-voting, ad hoc members.
- d. The minutes from each PH-MCO P&T Committee meeting must be posted for public view on the PH-MCO's website within thirty (30) days of the date of the meeting at which the minutes are approved. Minutes will include vote totals.

## **7. Pharmacy Provider Network**

- a. The PH-MCO or Subcontractor must contract on an equal basis with any pharmacy qualified to participate in the MA Program that is willing to comply with the PH-MCO's payment rates and terms and to adhere to quality standards established by the PH-MCO as required by 62 P.S. 449.
  - i. The provisions for any willing pharmacy apply if the PH-MCO or Subcontractor enters into agreements with specific pharmacies to provide defined drugs or services such as but not limited to, specialty, mail order, and 90-day supplies. PH-MCOs are required to contract on an equal basis with any pharmacy qualified to participate in the MA program that is willing to accept the same payment rate(s) and comply with the same terms and conditions for quality standards and reporting.

- ii. Subcontracts and agreements with specific pharmacies contracted to provide defined drugs or services must be submitted to the Department for advance written approval. Any changes to subcontracts or agreements must also be submitted to the Department for advance written approval.
  - iii. The PH-MCO must submit annually the list of specific pharmacies contracted to provide defined drugs or services, and a list of the drugs or services each pharmacy is contracted to provide, to the Department for review and written approval. Submissions for annual reviews must occur at least thirty (30) days before the effective date of the updated information.
  - iv. The PH-MCO must notify the Department on an ongoing basis of the following: (1) specific pharmacies that are no longer contracted to provide defined drugs or services and the reason why, (2) pharmacies that request contracting to provide defined drugs or services but are not admitted into the specific pharmacy network and the reason why, (3) any pharmacies that are only contracted to provide a limited scope of defined drugs or services and the reason why.
- b. The PH-MCO must develop, implement, and maintain a process that ensures the amount paid to all network pharmacies reflects the pharmacy's acquisition cost, professional services and cost to dispense the prescription to a Medicaid beneficiary. The PH-MCO must submit to the Department the policies and procedures for development of network pharmacy payment methodology including the process to ensure that brand and generic payment rates reflect the pharmacy's acquisition cost (from a readily available distributor doing business in Pennsylvania) and the professional dispensing fee accurately reflects the pharmacist's professional services and cost to dispense the prescription to a Medicaid beneficiary.
  - c. The PH-MCO or subcontractor must submit to the Department for review and approval all changes to the payment methodology prior to implementation.
  - d. The PH-MCO or subcontractor must report all changes to the payment methodology and rates, including but not limited to the maximum allowable cost rates, to network pharmacy providers.
  - e. If a network pharmacy's claim is approved through the adjudication process, the PH-MCO and any subcontractor will not retroactively deny or modify the reimbursement unless the claim was fraudulent, the network pharmacy was reimbursed for the claim previously, or the services reimbursed were not rendered by the network pharmacy.
  - f. The PH-MCO and any subcontractor will not charge a fee related to a network pharmacy's claim unless the amount of the fee is disclosed and applied at the time of claim adjudication.

## **8. Drug Rebate Program**

Under the provisions of Section 1927 of the Social Security Act 42 U.S.C.A. 1396r-8, drug companies that wish to have their products covered through the

MA Program (both FFS and managed care) must sign an agreement with the federal government to provide rebates to the State. The Affordable Care Act (ACA) provides for federal drug rebates for drugs paid for by the PH-MCOs.

- a. In order to ensure full compliance with the provisions of the ACA, PH-MCOs must report the necessary Outpatient Drug Encounter Data in order for the Department to invoice drug manufacturers for rebates for all Covered Outpatient Drugs. This includes physician-administered drugs, drugs dispensed by 340B covered entities or contract Pharmacies, and drugs dispensed to PH-MCO Members with private or public pharmacy coverage and the PH-MCO provided secondary coverage.
- b. The PH-MCO must report all outpatient drug information, including National Drug Codes (NDCs) and accurate NDC units for all drug claim types, NCPDP, 837 Professional, 837 Institutional, etc. as designated by the Department.

If the PH-MCO fails to submit Outpatient Drug Encounter Data when invoiced to manufacturers for rebate, at least 90% are collectable within 90 calendar days of invoicing by the Commonwealth a sanction of \$25,000 per quarter shall be imposed until the PH-MCO reaches the 90% threshold.

The PH-MCO or subcontractor may not negotiate rebates and discounts for Covered Outpatient Drugs. The PH-MCO or subcontractor may not negotiate its own rebates and discounts for non-drug products included on the Statewide PDL. If the PH-MCO negotiates and collects its own rebates and discounts for non-drug products that are not included on the Statewide PDL, the PH-MCO must report to the Department the full value of the rebates and discounts in a format designated by the Department. If the PH-MCO assigns responsibility for negotiating and/or collecting the rebates and discounts for non-drug products not included on the Statewide PDL to a subcontractor, the subcontractor must pass the full value of all rebates and discounts on drugs dispensed to the PH-MCO's Members back to the PH-MCO. The subcontractor may not retain any portion of the rebates or discounts. The PH-MCO must report the full value of all the rebates and discounts to the Department in a format designated by the Department.

The PH-MCO or subcontractor may negotiate outcomes-based contracts for Covered Outpatient Drugs. The PH-MCO must submit the contract to DHS for review and approval prior to implementation and report to the Department the full value of the financial impact of the outcomes-based contract in a format designated by the Department.

## **9. Outpatient Drug Encounters**

- a. The PH-MCO shall submit all Outpatient Drug Encounters to the Department within 30 days (for NCPDP) and 90 days (for 837P and 837I) of the adjudication date of the claim to the MCO for payment.
- b. The PH-MCO shall provide all Outpatient Drug Encounter data and supporting information as specified by the Department to collect rebates through the

Medicaid Drug Rebate Program and the Statewide PDL. For all Outpatient Drug Encounter data including pharmacy point-of-sale (NCPDP), physician-administered drugs (837P), outpatient hospital drugs (837I), and drugs dispensed by 340B covered entities and contract pharmacies, the following data elements are required:

- i. Valid NDC for the drug dispensed.
  - The PH-MCO shall also include the HCPCS code associated with the NDC for all 837P and 837I encounters where payment was made by the MCO based on the HCPCS code and HCPCS code units.
  - The PH-MCO shall also include the diagnosis codes associated with the NDC for all 837P and 837I encounters where payment was made by the PH-MCO based on the HCPCS code and HCPCS code units.
- ii. Valid NDC units for the drug dispensed
  - The PH-MCO shall also include the HCPCS units associated with the NDC for all 837P and 837I encounters where payment was made by the PH-MCO based on the HCPCS code and HCPCS code units.
- iii. Actual paid amount by the PH-MCO, or the PH-MCO's PBM, to the provider for the drug dispensed.
- iv. Actual TPL amount paid by the Member's primary pharmacy coverage to the provider for the drug dispensed.
- v. Actual copayment paid by the Member to the provider for the drug dispensed.
- vi. Actual dispensing fee paid by the PH-MCO, or the PH-MCO's PBM, to the provider for the drug dispensed.
- vii. The billing provider's:
  - NPI and/or Medical Assistance Identification Number
  - Full address and phone number associated with the NPI
- viii. The prescribing provider's:
  - NPI and/or Medical Assistance Identification Number
  - Full address and phone number associated with the NPI
- ix. The date of service for the dispensing of the drug by the billing provider.

- x. The date of payment by the PH-MCO, or the PH-MCO's PBM, to the provider for the drug.
- xi. Any other data elements identified by the Department to invoice for drug rebates.
- c. The PH-MCO shall edit and validate claim transaction submissions and Outpatient Drug Encounter data for completeness and accuracy in accordance with claim standards such as NCPDP. The actual paid amount by the PH-MCO, or the PH-MCO's PBM, to the dispensing provider must be accurately submitted on each Outpatient Drug Encounter to the Department.
- d. The PH-MCO shall ensure that the NDC on all Outpatient Drug Encounters is appropriate for the HCPCS code based on the NDC and units billed. The NDC must represent a drug that was available to the prescriber in an outpatient setting for administration.
- e. The Department will review the Outpatient Drug Encounters and remove applicable 340B covered entity encounters from the drug rebate invoicing process.
- f. The PH-MCO shall meet Outpatient Drug Encounter Data accuracy requirements by submitting PH-MCO paid Outpatient Drug Encounters with no more than a 3% error rate, calculated for a month's worth of Encounter submissions. The Department will monitor the PH-MCO's corrections to denied Encounters by random sampling performed quarterly and over the term of this Agreement. The PH-MCO shall have corrected and resubmitted 75% of the denied Encounters for services covered under this Agreement included in the random sample within 30 calendar days of denial.
- g. If the PH-MCO fails to submit Outpatient Drug Encounter data within timeframes specified, the Department shall assess civil monetary penalties upon the PH-MCO. These penalties shall be \$2,000 for each calendar day that the Outpatient Drug Encounter data is not submitted. The Department may waive these sanctions if it is determined that the PH-MCO was not at fault for the late submission of the data.

#### **10. Prospective Drug Utilization Review (Pro-DUR)**

- a. The PH-MCO must provide for a review of drug therapy before each prescription is filled or delivered to a Member at the point-of-sale or point-of-distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions and clinical abuse/misuse.

- b. The PH-MCO must provide for counseling of Members receiving benefits from pharmacists in accordance with State Board of Pharmacy requirements.

#### **11. Retrospective Drug Utilization Review (Retro-DUR)**

- a. The PH-MCO must, through its drug claims processing and information retrieval system, examine claims data and other records to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists and Members.
- b. The PH-MCO shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using nationally recognized compendia and peer reviewed medical literature) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care.
- c. The PH-MCO shall provide for active and ongoing educational outreach programs to educate practitioners on common drug therapy problems aimed at improving prescribing or dispensing practices.

#### **12. Annual Drug Utilization Review (DUR) Report**

The PH-MCO must submit an annual report on the operation of its Pennsylvania Medicaid Drug Utilization Review (DUR) program in a format designated by the Department. The format of the report will include a description of the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of the DUR program.

#### **13. Drug Utilization Review Board (DUR Board)**

The Department maintains a DUR Board that reflects the structure of the health care delivery model that includes both a managed care and a fee-for-service delivery system. Each PH-MCO and BH-MCO is required to include a representative to serve as a member of the DUR Board. The DUR Board is a standing advisory committee that recommends the application of predetermined standards related to Pro-DUR, Retro-DUR, and related administrative and educational interventions designed to protect the health and safety of the MA program recipients. The Board reviews and evaluates pharmacy claims data and prescribing practices for efficacy, safety, and quality against predetermined standards using nationally recognized drug compendia and peer reviewed medical literature as a source. The Board recommends appropriate utilization controls and protocols including prior authorization, automated prior authorization, system edits, guidelines to determine medical necessity, generic substitution, and quantity limits

for individual medications or for therapeutic categories.

#### **14. Pharmacy Benefit Manager (PBM)**

The PH-MCO may use a PBM to process prescription Claims only if the PBM Subcontract complies with the provisions in Section XII: Subcontractual Relationships, and has received advance written approval by the Department. The standards for Network composition and adequacy for outpatient drug services includes the requirements for any willing pharmacy as described above. The PH-MCO must indicate the intent to use a PBM, and identify the proposed PBM Subcontract, the PH-MCO's payment methodology or methodologies (ingredient cost and dispensing fee) for payment to the PBM Subcontractor, the PBM's payment methodology or methodologies (ingredient cost and dispensing fee) for actual payment to the providers of covered outpatient drugs, and the ownership of the proposed PBM subcontractor. If the PBM is owned wholly, in part, or by the same parent company as a PH-MCO, retail pharmacy Provider, chain drug store or pharmaceutical manufacturer, the PH-MCO must submit a written description of the assurances and procedures that will be put in place under the proposed PBM Subcontract, such as an independent audit, to assure confidentiality of proprietary information. These assurances and procedures must be submitted and receive advance written approval by the Department prior to initiating the PBM Subcontract. The Department will allow the continued operation of existing PBM Subcontracts while the Department is reviewing new contracts.

The PH-MCO must:

- a. Report the PBM's payment methodology, or methodologies for actual payment to all network pharmacy providers of covered outpatient drugs, including community pharmacies, long-term care pharmacies, network pharmacies contracted to provide specialty drugs, and dispensing prescribers for existing PBM Subcontractors and new PBM Subcontractors.
- b. Include on each outpatient drug encounter the PBM received amount (amount paid to the PBM by the PH-MCO [ingredient cost and dispensing fee]) and the provider received amount (the actual amount paid by the PBM [ingredient cost and dispensing fee] to the dispensing pharmacy or prescribing provider).
- c. Report differences between the amount paid by the PH-MCO to the PBM and the amount paid by the PBM to the providers of covered outpatient drugs as administrative fees.
- d. Report all PBM administrative fees, including the differences in amounts paid as described in d. above, in a format designated by the Department.
- e. Submit a written description of the procedures that the PH-MCO will put in place to monitor the PBM for compliance with the term and conditions of the Agreement related to covered outpatient drugs and actual payments to the providers of covered outpatient drugs.

- f. Upon request by the Department, conduct an independent audit of the PBM's transparent pricing arrangement in compliance with the provision in Exhibit WW HealthChoices Audit Clause.
- g. Ensure that the PBM is fully compliant with the requirements in Section V. K. Provider Dispute Resolution System.
- h. Develop, implement, and maintain a Second Level PBM Provider Pricing Dispute Resolution Process that provides for settlement of a PBM network Provider's pricing dispute with the PBM, on the condition that the PBM's network Provider exhausted all of its remedies against the PBM.
- i. Submit to the Department, prior to implementation, the PH-MCO's policies and procedures relating to the resolution of PBM Provider pricing disputes.
  - i. The PH-MCO must submit any changes to the policies and procedures to the Department for approval prior to implementation of the changes.
  - ii. The PH-MCO's submission of new or revised policies and procedures for review and approval by the Department shall not act to void any existing policies and procedures that have been prior approved by the Department for operation in a HC Zone. Unless otherwise required by law, the PH-MCO may continue to operate under such existing policies and procedures until the Department approves the new or revised version.
- j. At a minimum, include in the PH-MCO's Second Level PBM Provider Pricing Dispute Resolution policies and procedures the following:
  - i. The process for submission and settlement of Second Level PBM Provider Pricing Disputes;
  - ii. A requirement that the PBM Provider must exhaust all of its remedies against the PBM before requesting a PH-MCO Second Level PBM Provider Pricing Dispute Resolution;
  - iii. Acceptance and usage of the Department's definition/delineation of Provider Disputes;
  - iv. Timeframes for submission and resolution of Second Level PBM Provider Pricing Disputes;
  - v. Processes to ensure equal treatment of all PBM providers in the resolution of pricing disputes.
  - vi. Process to ensure the paid amount reflects the pharmacy's drug acquisition cost, professional services, and cost to dispense the prescription to an MA beneficiary.

- vii. A requirement for both the PBM Provider and the PBM to provide documentation supporting each entity's position(s) related to the pricing dispute;
- viii. Designation of PH-MCO staff responsible for resolution of the PBM Provider Pricing Dispute who have:
  - The knowledge and expertise to address and resolve PBM Provider Pricing Disputes;
  - Access to data and documentation of the informal resolution of the PBM Provider Dispute and the formal PBM Provider Appeal and decisions necessary to assist in making decisions; and
- ix. Mechanisms and time-frames for reporting PH-MCO PBM Provider Pricing Dispute decisions to the PBM Provider, the PBM and the Department. If the dispute is denied by the PH-MCO, the Provider Pricing Dispute decisions must include the specific rationale for the denial;
- k. Require the PBM and the PBM provider to abide by the final decision of the PH-MCO. If the Provider Pricing Dispute is overturned by the PH-MCO, adjustment must be made to the appealed claim and to future claims for the appealed drug. The PBM/PH-MCO must update their payment methodology for the appealed drug; and
- l. Require the PBM to inform all PBM providers of the process and conditions to request a Second Level PBM Provider Pricing Dispute.

**15. Requirements For PH-MCO and BH-MCO Interaction and Coordination of Outpatient Drug Services**

- a. BH-MCO prescribing Providers must comply with the PH-MCO requirements for utilization management of outpatient behavioral health drugs.
- b. The BH-MCO will be required to issue an initial list of BH-MCO Providers to the PH-MCO, and quarterly updates that include additions and terminations. Should the PH-MCO receive a request to dispense medication prescribed by a BH Provider not listed on the BH-MCO's Provider file, the PH-MCO must work through the appropriate BH-MCO to identify the Provider. The PH-MCO is prohibited from denying prescribed medications solely on the basis that the BH-MCO Provider is not clearly identified on the BH-MCO Provider file.
- c. Payment for inpatient pharmaceuticals during a BH admission is the responsibility of the BH-MCO and is included in the hospital charge.

- d. The PH-MCO may deny payment of a claim for a Covered Outpatient Drug prescribed by a BH-MCO Provider only if one of the following occurs:
  - i. The drug is not being prescribed for the treatment of substance abuse/dependency/ addiction or mental illness and any side effects of psychopharmacological agents. Those drugs are to be prescribed by the PH-MCO's PCP or specialists in the Member's PH-MCO Network.
  - ii. The prescription has been identified as a case of Fraud, Abuse, or gross overuse, or the dispensing pharmacist determined that taking the medication either alone or along with other medications that the Member may be taking, would jeopardize the health and safety of the Member.
- e. The PH-MCO must receive written approval from the Department of the policies and procedures for the PH-MCO and BH-MCO to:
  - i. When deemed advisable, require consultation between practitioners before prescribing medication, and sharing complete, up-to-date medication records.
  - ii. Timely resolve disputes which arise from the payment for or use of drugs, including a mechanism for timely, impartial mediation when resolution between the PH-MCO and BH-MCO does not occur.
  - iii. Share independently developed Quality Management/Utilization Management information related to outpatient drug services, as applicable.
  - iv. Collaborate in adhering to a drug utilization review program approved by the Department. Collaborate in identifying and reducing the frequency of patterns of Fraud, Abuse, gross overuse, inappropriate or medically unnecessary care among physicians, pharmacists and Members associated with specific drugs.
- f. The PH-MCO must send data files, via the Department's file transfer protocol (FTP), containing records of detailed outpatient drug services as provided to individual enrollees of the BH-MCOs contracted with the Department. The PH-MCO must adhere to the file delivery schedule established at the implementation of the data exchange process or notify the Department in advance of schedule changes. Files must be sent directly to the Department for distribution by the Department.