

EXHIBIT D

DRUG SERVICES

1. General Requirements

- a. All requirements in this Exhibit apply to all Covered Drugs regardless of the setting in which the drug is dispensed or administered the billing provider type, or how the CHC-MCO makes payment for the drug (pharmacy benefit and medical benefit).
- b. The amount, duration, and scope of Covered Drugs must be consistent with coverage under the Fee-for-Service (FFS) program. The CHC-MCO must cover all Covered Drugs listed on the CMS Quarterly Drug Information File when determined to be Medically Necessary, unless otherwise excluded from coverage. (See Section 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 Medical Assistance program, and sold or distributed by drug manufacturers that participate in the Medicaid Drug Rebate Program.
- c. The CHC-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 Drugs are the payment responsibility of the Participant's CHC-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 Drugs must be dispensed through CHC-MCO Network Providers. This includes Covered Drugs prescribed by both the CHC-MCO and the BH-MCO Providers.
- f. Under no circumstances will the CHC-MCO permit the therapeutic substitution of a drug by a pharmacist without explicit authorization from the licensed prescriber.
- g. All proposed Covered Drug policies, programs, and drug Utilization Management programs, such as but not limited to Prior Authorization, Step

Therapy, partial fills, specialty pharmacy, pill-splitting, mail order, 90-day supply programs, limited pharmacy networks, medication therapy management 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 CHC-MCO must include in its written policies and procedures an assurance that all requirements and conditions governing coverage and payment for Covered 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 Drug is provided as a 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 Medical Assistance FFS Program, when designated by the Department.
- i. The CHC-MCO must submit for review and approval a policy for each section of Exhibit D that includes the requirements in the respective section and the CHC-MCO’s procedures to demonstrate compliance.
- j. The CHC-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 Medical Assistance FFS Program when designated by the Department.
- k. The CHC-MCO must comply with Section 2117 of Article XXI of the Insurance Company Law of 1921, 40 P.S. § 991.2117 regarding continuity of care requirements and 28 Pa. Code Chapter 9. The CHC-MCO must also comply with the procedures outlined in Medical Assistance Bulletin # 99-03-13 and Medical Assistance Bulletin # 99-96-01. The CHC-MCO policy and procedures for continuity of care for 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 CHC-MCO will ensure no interruption in drug therapy and the course of treatment, and continued access to drugs that

the Participant was prescribed before enrolling in the CHC-MCO.

- I. The CHC-MCO must allow access to all new drugs approved by the Food and Drug Administration (FDA) and meet the definition of a Covered Drug either by addition to the Statewide PDL or MCO Formulary or through prior authorization, within 10 days from their availability in the marketplace.
- m. The CHC-MCO must comply with 1902(a)(85); Section 1004 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). The CHC-MCO will implement prospective safety edits on subsequent fills of opioid prescriptions, as specified by the state, which may include edits to address days' supply, early refills, duplicate fills, and quantity limitations for clinical appropriateness.

2. Coverage Exclusions

- a. In accordance with Section 1927 of the Social Security Act, 42 U.S.C.A. § 1396r-8, the CHC-MCO must exclude coverage for any drug marketed by a drug company (or labeler) that does not participate in the Medicaid Drug Rebate Program. The CHC-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 CHC-MCO may not provide coverage for Drug Efficacy Study Implementation (DESI) drugs under any circumstances.
- c. The CHC-MCO must exclude coverage of non-compensable drugs in accordance with 55 Pa. Code § 1121.54

3. Formularies and Preferred Drug Lists (PDLs)

- a. The CHC-MCO must utilize the Statewide PDL developed by the Department's Pharmacy and Therapeutics (P&T) Committee.

If the CHC-MCO fails to meet Statewide PDL quarterly compliance of 95% (excluding TPL) a financial sanction consistent with the difference in net cost using CHC-MCO actual compliance rate and the net cost if compliance rate was 95%. The minimum penalty of \$25,000 per quarter will be imposed. The CHC-MCO is responsible for submitting prior authorization approval and denial information in a format designated by the Department.

- b. The CHC-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 CHC-MCO must apply Statewide PDL prior authorization guidelines to all drugs and products included on the Statewide PDL. The CHC-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 CHC-MCOs may develop brand Medically Necessary prior authorization policies to determine whether a specific drug is Medically Necessary when both the brand and generic product of a specific drug are non-preferred on the Statewide PDL.

The CHC-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 CHC-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 CHC-MCO's P&T Committee, as defined in Section 6 of this Exhibit.

- e. The CHC-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 Section V. B.1., Prior Authorization of Services, and Exhibit E, Prior Authorization Guidelines for the CHC-MCO, and this Exhibit.
- f. The CHC-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. CHC-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 30 days before the effective date of the updated information.

- g. The CHC-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 CHC-MCO must submit written notification of any Formulary or PDL additions for drugs and products outside the scope of the Statewide PDL to the Department within fifteen (15) days of implementation.
- i. In addition to providing a link to the Statewide PDL on the CHC-MCO's website, the CHC-MCO must make available on the website in electronic format, information about its drug Formulary or PDL, listing which medications are covered, including both brand and generic names.

4 **Prior Authorization of Drugs**

- a. For Covered Drugs that require Prior Authorization (including Step Therapy) as a condition of coverage or payment:
 - i. The CHC-MCO must provide a response to the request for Prior Authorization by telephone or other telecommunication device to approve or deny the prescription within twenty-four (24) hours of the request; and
 - ii. If a Participant's prescription for a medication is not filled when a prescription is presented to the pharmacist due to a Prior Authorization requirement, the CHC-MCO must instruct the pharmacist to dispense either:
 - 1) A fifteen (15) day supply if the prescription qualifies as an Ongoing Medication.
 - 2) A seventy-two (72) hour supply of a new medication.
- b. For drugs not able to be divided and dispensed into individual doses, the CHC-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 Participant 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 Participant may be taking, would jeopardize the health or safety of the Participant. The CHC-MCO and/or its subcontractor must require that its participating dispensing Provider make good faith efforts to contact the prescriber.

- d. If the CHC-MCO denies the request for Prior Authorization, the CHC-MCO must issue a written denial notice to the Participant and the Provider, using the appropriate Drug Denial Notice template within twenty-four (24) hours of receiving the request for Prior Authorization. The specific reason(s) for denial must be included in the notice of decision. If additional information is required to approve the request, the specific documentation needed must be listed in the notice. If the requested drug is non-preferred/non-formulary and within the scope of the Statewide PDL or the CHC-MCO's Formulary, the CHC-MCO must list preferred alternatives appropriate for the beneficiary's diagnosis and clinical condition in the denial notice.
- e. If the CHC-MCO approves the request for prior authorization, the CHC-MCO must issue a written approval notice to Participant and Provider including the drug name and strength, effective and end dates of the approval within twenty-four (24) hours of receiving the request for prior authorization.
- f. If the Participant files a Grievance or DHS Fair Hearing request from a denial of an Ongoing Medication, the CHC-MCO must authorize the medication until the Grievance or DHS Fair Hearing request is resolved.
- g. When medication is authorized due to the obligation to cover pre-existing services while a Grievance or DHS Fair Hearing is pending, a request to refill that prescription, made after the Grievance or DHS Fair Hearing has been finally concluded in favor of the MCO, is not an Ongoing Medication.
- h. 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 Participant.
- i. When medication is authorized due to the CHC-MCO's obligation to continue services while a Participant's Grievance or Fair Hearing is pending, and the final binding decision is in favor of the CHC-MCO, a request for subsequent refill of the prescribed medication does not constitute an Ongoing Medication.
- j. The CHC-MCO guidelines to determine Medical Necessity of Covered Drugs outside the scope of the Statewide PDL cannot be more stringent than the FFS guidelines. The CHC-MCO must follow the Statewide PDL

Prior Authorization guidelines for drugs and products included on the Statewide PDL.

- k. The CHC-MCO must comply with the requirements of Section V. B. 1. Of the Agreement, Prior Authorization of Services, and Exhibit E, Prior Authorization Guidelines for CHC-MCOs, and receive written approval from the Department prior to implementation and annually thereafter. If a CHC-MCO covers a specific drug through both their medical and pharmacy benefits, the CHC-MCO must apply the same Department approved prior authorization guidelines to prior authorization requests.

5. Provider and Participant Notification

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

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

6. CHC-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, Medical Assistance Program Participants and other appropriate clinicians. Medical Assistance Program Participant representative membership must include the following:
 - i. One (1) physical health Participant representative. The physical health Participant representative must be a Participant enrolled in the CHC-

MCO, or a physician, a pharmacist, or a physical health Participant advocate designated by Participants enrolled in the CHC-MCO to represent them.

- ii. One (1) behavioral health Participant representative. The behavioral health Participant representative must be a Participant enrolled in the CHC-MCO, or a physician, a pharmacist, a behavioral health Participant advocate, or a family member designated by Participants enrolled in the CHC-MCO to represent them.
 - iii. One (1) LTSS Participant representative. The LTSS Participant representative must be a Participant enrolled in the CHC-MCO, or a physician, a pharmacist, a LTSS Participant advocate, or a family member designated by Participants enrolled in the CHC-MCO to represent them.
- b. The CHC-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 that of 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 CHC-MCO P&T Committee meeting must be posted for public view on the CHC-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 and Payment

- a. The CHC-MCO or Subcontractor must contract on an equal basis with any pharmacy qualified to participate in the Medical Assistance program that is willing to comply with the CHC-MCO's payment rates and terms and to adhere to quality standards established by the CHC-MCO as required by 62 P.S. § 449.
 - i. The provisions for any willing pharmacy apply if the CHC-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. CHC-MCOs are required to contract on an equal basis with any pharmacy qualified to participate in the Medical Assistance 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 CHC-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 CHC-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 CHC-MCO and any subcontractor must develop, implement, and maintain a process that ensures the amount paid to all network pharmacies reflects the pharmacy's acquisition cost for the ingredient, professional services, and cost to dispense the prescription to a Medicaid beneficiary. The CHC-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. The CHC-MCO must submit to the Department for review and approval the transparent pricing formula utilized in claims processing to determine the rates paid to pharmacies, with sufficient detail for the Department to assess compliance with Act 120 of 2020 and with the terms of this Agreement.
- c. The CHC-MCO or subcontractor must submit to the Department for review and approval all changes to the payment methodology, rates, and dispensing fees prior to implementation. This requirement applies to all changes being implemented by or on behalf of the CHC-MCO, whether through a direct or indirect subcontract.
- d. The CHC-MCO or subcontractor must report all changes to the payment methodology, rates, and dispensing fee in advance to network pharmacy providers.

- e. The CHC-MCO or subcontractor must report all changes to the maximum allowable cost rates in real-time to network pharmacy providers.
- f. (1) If a network pharmacy's claim is approved through the adjudication process, the CHC-MCO and any subcontractor may not retroactively deny or modify the payment unless any of the following:
 - i. The claim was fraudulent.
 - ii. The claim was duplicative of a previously paid claim.
 - iii. The pharmacy did not render the service.
- (2) Nothing in 7.e.(1) shall be construed to prohibit the modification of or recovery of an adjudicated claim that was determined to be an overpayment or underpayment resulting from audit, review, or investigation by a federal or state agency or CHC-MCO.
- g. The CHC-MCO and any subcontractor shall not charge a claim transmission/transaction fee to a network pharmacy.
- h. The CHC-MCO and any subcontractor shall use a PA MA specific processor Control Number (PCN) or PA MA specific Group number for drug claims. The PCN or group number and the Bank Identification Number (BIN) shall be submitted on the claim adjudication record.
- i. The CHC-MCO and any subcontractor shall not utilize an effective rate for reimbursement to a network pharmacy, including, but not limited to, generic effective rates, brand effective rates, dispensing fee effective rates, and direct and indirect remuneration fees. For the purposes of this Exhibit, an "effective rate contract" allows for adjustment of reimbursements over time so the overall reimbursement averages out to a guaranteed amount; the result is some claims are paid below the effective rate and others are paid above the effective rate. For the purposes of this Exhibit, "direct and indirect remuneration fees" are any fees charged by PBMs to pharmacies that are outside of administration fees and are generally collected after the point of sale.

8. Drug Rebate Program

- a. The CHC-MCO must report the necessary Drug Encounter Data in order for the Department to invoice drug manufacturers for rebates for all Covered Drugs. This includes physician-administered drugs, drugs dispensed by

340B covered entities or contract pharmacies, and drugs dispensed to Participants with private or public pharmacy coverage and CHC-MCO secondary coverage.

- b. The CHC-MCO must report all 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 CHC-MCO fails to submit Drug Encounter Data, then the Department shall impose a sanction of Twenty-Five Thousand Dollars (\$25,000.00) per quarter until the CHC-MCO is compliant.

The CHC-MCO or subcontractor may not negotiate rebates and discounts for Covered Drugs. The CHC-MCO or subcontractor may not negotiate rebates and discounts for non-drug products included on the Statewide PDL. If the CHC-MCO negotiates and collects its own rebates and discounts for non-drug products that are not included on the Statewide PDL, the CHC-MCO must report to the Department the full value of the rebates and discounts in a format designated by the Department. If the CHC-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 CHC-MCO's Participants back to the CHC-MCO. The subcontractor may not retain any portion of the rebates or discounts. The CHC-MCO must report the full value of the rebates and discounts to the Department in a format designated by the Department.

9. Drug Encounters

- a. The CHC-MCO shall submit all Drug Encounters to the Department within thirty (30) days (for NCPDP) and 90 days (for 837P and 837I) of the adjudication date of the claim to the CHC-MCO for payment.
- b. The CHC-MCO shall provide all Pharmacy Drug Encounter Data and supporting information as specified below for the Department to collect rebates through the Medicaid Drug Rebate Program and the Statewide PDL. For all Drug Encounter Data, including pharmacy point-of-sale (NCPDP), physician-administered drugs (837P), 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 or product dispensed.
 1. The CHC-MCO shall also include the HCPCS code associated with the NDC for all 837P and 837I Encounters where payment was made

- by the CHC-MCO based on the HCPCS code and HCPCS code units.
 - 2. The CHC-MCO shall also include the diagnosis codes associated with the NDC for all 837P and 837I Encounters where payment was made by the CHC-MCO based on the HCPCS code and HCPCS code units.
 - ii. Valid NDC units for the drug or product dispensed.
 - 1. The CHC-MCO shall also include the HCPCS units associated with the NDC for all 837P and 837I Encounters where payment was made by the CHC-MCO based on the HCPCS code and HCPCS code units.
 - iii. Actual paid amount by the CHC-MCO to the Provider for the drug dispensed.
 - iv. Actual TPL amount paid by the Participant's primary pharmacy coverage to the Provider for the drug dispensed.
 - v. Actual copayment paid by the Participant to the Provider for the drug dispensed.
 - vi. Actual dispensing fee paid by the CHC-MCO to the Provider for the drug dispensed.
 - vii. The billing Provider's:
 - 1. NPI and/or Medical Assistance Identification Number.
 - 2. Full address and phone number associated with the NPI.
 - viii. The prescribing Provider's:
 - 1. NPI and/or Medical Assistance Identification Number.
 - 2. 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 CHC-MCO, or the CHC-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 CHC-MCO shall edit and validate claim transaction submissions and

Drug Encounter Data for completeness and accuracy in accordance with claim standards such as NCPDP. The actual paid amount by the CHC-MCO to the dispensing Provider must be accurately submitted on each pharmacy Encounter to the Department.

- d. The CHC-MCO shall ensure that the NDC on all Drug Encounters is appropriate for the HCPCS code based on the NDC and units billed.
- e. The Department will review the Drug Encounters and remove applicable 340B covered entity Encounters from the drug rebate invoicing process.
- f. The CHC-MCO shall meet Drug Encounter Data accuracy requirements by submitting CHC-MCO paid pharmacy Encounters with no more than a three percent (3%) error rate, calculated for a month's worth of Encounter submissions. The Department will monitor the CHC-MCO's corrections to denied Encounters by random sampling performed quarterly and over the term of this Agreement. The CHC-MCO shall have corrected and resubmitted seventy-five percent (75%) of the denied Encounters for services covered under this Agreement included in the random sample within thirty (30) calendar days of denial.
- g. If the CHC-MCO fails to submit Drug Encounter data within timeframes specified, the Department shall assess civil monetary penalties upon the CHC-MCO. These penalties shall be Two Thousand Dollars (\$2,000.00) for each calendar day that the Drug Encounter Data is not submitted. The Department may waive these sanctions if it is determined that the CHC-MCO was not at fault for the late submission of the data.

10. Prospective Drug Utilization Review (Pro-DUR)

- a. The CHC-MCO must provide for a review of drug therapy before each prescription is filled or delivered to a Participant 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 CHC-MCO must provide for counseling of Participants receiving benefits from pharmacists in accordance with State Board of Pharmacy requirements.

11. Retrospective Drug Utilization Review (Retro-DUR)

- a. The CHC-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 Participants.

- b. The CHC-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 CHC-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 DUR Report

The CHC-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 healthcare delivery model that includes both a managed care and a Fee-for-Service delivery system. Each CHC-MCO that does not already include a PH-MCO representative and each 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 Medical Assistance Program Participants. 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 CHC-MCO may use a PBM to process prescription Claims only if the PBM Subcontract complies with the provisions in Section XII, Sub-contractual Relationships, Exhibit P: Required Contract Terms for Administrative Subcontractors, and has received advance written approval by the Department. The standards for Network composition and adequacy for Covered Drug services includes the requirements for any willing pharmacy as described above. The CHC-MCO must indicate the intent to use a PBM, identify the proposed PBM Subcontract and the ownership of the proposed PBM subcontractor.

The PBM subcontract must be submitted in unredacted format to the Department for review and written approval prior to implementation, prior to implementation of any changes, and annually thereafter. Changes that only impact non-Community HealthChoices lines of business do not need to be submitted for Department approval. The final Department-approved, fully executed, and unredacted CHC-MCO and PBM subcontract must be submitted to the Department.

If the PBM is owned wholly, in part, or by the same parent company as a CHC-MCO, retail pharmacy Provider, chain drug store or pharmaceutical manufacturer, the CHC-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 CHC-MCO must:

- a. Report the PBM's payment methodology, or methodologies for actual payment to all network pharmacy providers of covered 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. Submit unredacted PBM contracts with the CHC-MCO's network pharmacies upon request.
- c. Include on each drug encounter the PBM received amount (amount paid to the PBM by the CHC-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.

- d. Report any differences between the amount paid by the CHC-MCO to the PBM and the amount paid by the PBM to the providers of covered drugs as other fees.
- e. Report all PBM fees charged to the CHC-MCO and to the pharmacy provider, in a format designated by the Department.
- f. Submit a written description of the procedures that the CHC-MCO will put in place to monitor the PBM for compliance with the term and conditions of the Agreement related to covered drugs and actual payments to the providers of covered drugs.
- g. Upon request by the Department, conduct an independent audit of the PBM's transparent pricing arrangement in compliance with the provision in Exhibit O CHC Audit Clause.
- h. Ensure that the PBM is fully compliant with the requirements in Section V. T. Provider Dispute Resolution System.
- i. 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.
- j. Submit to the Department, prior to implementation, the CHC-MCO's policies and procedures relating to the resolution of PBM Provider pricing disputes.
 - i. The CHC-MCO must submit any changes to the policies and procedures to the Department for approval prior to implementation of the changes.
 - ii. The CHC-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 CHC zone. Unless otherwise required by law, the CHC-MCO may continue to operate under such existing policies and procedures until the Department approves the new or revised version.
- k. At a minimum, include in the CHC-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 CHC-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 CHC-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 CHC-MCO PBM Provider Pricing Dispute decisions to the PBM Provider, the PBM and the Department. If the dispute is denied by the CHC-MCO, the Provider Pricing Dispute decisions must include the specific rationale for the denial;
- I. Require the PBM and the PBM provider to abide by the final decision of the CHC-MCO. If the Provider Pricing Dispute is overturned by the CHC-MCO, adjustment must be made to the appealed claim and to future claims for the appealed drug. The PBM/CHC-MCO must update their payment methodology for the appealed drug; and
- m. 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 CHC-MCO and BH-MCO Interaction and Coordination of Drug Services

- a. BH-MCO prescribing Providers must comply with the CHC-MCO requirements for Utilization Management of behavioral health drugs.
- b. The BH-MCO will be required to issue an initial list of BH-MCO Providers to the CHC-MCO, and quarterly updates that include additions and terminations. Should the CHC-MCO receive a request to dispense medication prescribed by a BH Provider not listed on the BH-MCO's Provider file, the CHC-MCO must work through the appropriate BH-MCO to identify the Provider. The CHC-MCO is prohibited from denying prescribed medications solely on the basis that the BH-MCO Provider is not clearly identified on the BH-MCO Providerfile.
- c. Payment for inpatient pharmaceuticals during a BH admission is the responsibility of the BH-MCO and is included in the hospitalcharge.
- d. The CHC-MCO may deny payment of a Claim for a Covered Drug prescribed by a BH-MCO Provider only if one of the followingoccurs:
 - i. The drug is not being prescribed for the treatment of substance use disorder or mental illness and any side effects of psychopharmacological agents. Those drugs are to be prescribed by the CHC-MCO's PCP or specialists in the Participant's CHC-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 Participant may be taking would jeopardize the health and safety of the Participant.
- e. The CHC-MCO must receive written approval from the Department of the policies and procedures for the CHC-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. Comply with any CHC-BH MCO drug data exchange procedures

specified by the Department.

- iii. Timely resolve disputes which arise from the payment for or use of drugs, including a mechanism for timely, impartial mediation when resolution between the CHC-MCO and BH-MCO does not occur.
- iv. Share independently developed Quality Management/Utilization Management information related to drug services, as applicable.
- v. 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 Participants associated with specific drugs.