PHARMACY

The MCO shall cover all medically necessary prescription medicines on the Covered Drug List (CDL). The MCO may also cover additional pharmacy benefits, such as vaccines, diabetic supplies, and compounded drugs.

The MCO shall not cover the following excluded drugs:

- Agents when used for anorexia, weight loss, or weight gain, except orlistat.
- Agents when used to promote fertility, except vaginal progesterone when used for high-risk pregnancy to prevent premature births.
- Agents when used for symptomatic relief of cough and colds, except for antihistamine and antihistamine/decongestant combination products.

The MCO shall cover the following drugs, with restrictions:

- Agents used for cosmetic purposes or hair growth only when medical necessity has been determined.
- Select drugs for erectile dysfunction, except when used for the treatment of conditions or indications other than erectile dysfunction as approved by the FDA.

The MCO shall notify LDH prior to implementing or changing any prescription limits. The MCO shall cover a minimum of four prescriptions per calendar month if prescribed for the enrollee. However, it may not enact prescription limits more stringent than those in the Louisiana Medicaid State Plan. If prescription limits are enacted, the MCO shall have Point of Sale (POS) override capabilities when a greater number of prescriptions per calendar month are determined to be medically necessary by the prescriber.

Except for the use of LDH-approved generic drug substitution of branded drugs, under no circumstances shall the MCO permit the therapeutic substitution of a prescribed drug without a prescriber's authorization.

Covered Drug List

In accordance with 42 C.F.R. § 438.3, the MCO shall maintain a Covered Drug List (CDL) which includes all outpatient drugs for which the manufacturer has entered into a federal rebate agreement and meet the standards in Section 1927 of the Social Security Act.

The CDL shall include all drugs deemed medically necessary for enrollees under the age of 21.

The CDL shall exclude only those drugs or drug categories permitted for exclusion under Section 1927(d) of the Social Security Act, with exceptions listed in the State Plan. MCOs may cover compounded drugs, diabetic supplies, and rebate eligible OTCs as a regular pharmacy benefit (not value added). MCOs may cover additional drugs as a value added benefit. MCOs shall cover, at a minimum, all vaccines and administration covered by FFS for adults and make them payable in the same program types.

The CDL shall be updated at least weekly using a national drug database.

When drugs (OTC or legend) are being covered as a pharmacy benefit and offered as a value-added benefit, pharmacy encounters shall indicate such in the Character 1: Submission type (Q, F, or V) of the 4-character prefix on the ICN of the Rx encounter.

The MCO may apply Point of Sale safety and utilization edits that align with FDA indications.

Self-administered drugs dispensed by a pharmacy, including specialty pharmacies, shall be covered as a pharmacy benefit unless otherwise approved by LDH.

The medications listed in the U.S. Preventive Services Task Force (USPSTF) A and B Recommendations shall be payable as a pharmacy benefit and exempt from copay. Corresponding age limits may be applied.

Physician-administered drugs that are not listed on the FFS fee schedule but for which the manufacturer has signed a federal rebate agreement shall be covered as either a pharmacy benefit or a medical benefit. If the physician administered drug is not on the FFS fee schedule, but the MCO covers as a medical benefit, then reimbursement shall be set as a minimum by the current FFS reimbursement methodology in the State Plan.

The medications listed in the U.S. Preventive Services Task Force (USPSTF) A and B Recommendations shall be payable as a pharmacy benefit and exempt from copay. Corresponding age limits may be applied.

Preferred Drug List

A subset of the CDL shall be the Preferred Drug List (PDL). The PDL is established by LDH and indicates the preferred and non-preferred status of covered drugs.

The PDL shall be maintained by LDH and made available on the LDH website [link]. The MCO shall make the PDL available to its providers and enrollees through electronic prescribing tools and a static link on the MCO website to the PDL maintained on the LDH website.

LDH shall provide the MCO with a list of drugs included on the PDL by NDC number after each FFS Pharmaceutical and Therapeutics Committee (P&T) meeting and upon the Secretary's approval of P&T recommendations. Changes shall be implemented January 1 and July 1 after the P&T meeting, unless otherwise directed by LDH. LDH shall provide the MCO at least 30 days written notice prior to the implementation date of any changes to the list of drugs included on the PDL.

LDH shall monitor the rate of MCO compliance with the PDL. Compliance rate shall be defined as the number of preferred prescriptions paid (drugs classified with PA Indicators 1 & 3) divided by total prescriptions paid for drugs in therapeutic classes listed on the PDL (drugs classified with PA Indicators 1-4). The MCO shall achieve at least a 92% overall compliance rate and at least a 92% compliance rate for each medication on the brand-over-generic list provided by LDH (calculated as brand/(brand + generic)). The PDL compliance rate shall be calculated at the sole determination of LDH. Failure to meet both of these standards may result in monetary penalties as set forth in the Contract.

New drugs entering the marketplace in the PDL therapeutic classes shall be added as non-preferred until P&T reviews the drug, unless otherwise directed by LDH.

If a branded product with generic available is preferred on the PDL, the MCO shall not require the prescriber to indicate in writing that the branded product is medically necessary. The MCO shall reimburse

for a brand name drug at a brand reimbursement when the brand drug is preferred. POS denial messaging for the generic entity shall indicate that the brand name is preferred.

The fiscal intermediary will post weekly drug file data for the MCO. The MCO shall have three business days after receipt of file to download and implement drug prior authorization status, for drugs covered as an outpatient pharmacy benefit.

There shall be a mandatory generic substitution for all drugs, when a generic is available, unless the brand is justified with applicable dispense as written (DAW) codes or the brand is preferred.

Claims for multi-source "Brand Name Products" that are not included in the PDL/NPDL process (drugs not listed on the Preferred Drug List on the static link), will not be subject to prior authorization. Since the manufacturers of these brand name products have signed the federal rebate agreement, these drugs must have a potential payable status. In consideration of the mandatory generic substitution, we are requiring the MCO/PBMs to allow DAW codes "1", "8" and "9" for brand name processing. We would expect these codes to accommodate the filling of a brand name product without use of prior authorization. Preferred brand over generic drugs should process with DAW 9. Brand name medically necessary from prescriber should process with a DAW 1. If the pharmacy is billing the brand because the generic is not on the market then the claim should process with a DAW 8. Denials of brand drugs (unless the Brand is a preferred drug—in or out of the process) should deny with an error code stating "generic substitution required", mapped to NCPDP 22 (M/I Dispense as written (DAW)/Product selection code).

Manufacturer-Derived Revenue

The MCO shall not negotiate, pursue collection of, or collect Manufacturer-Derived Revenue for prescribed drugs.

The MCO shall diligently and in good faith negotiate, maximize, and pursue collection of all Manufacturer-Derived Revenue for diabetic supplies on behalf of LDH.

The MCO shall report all Manufacturer-Derived Revenue the MCO receives, including any future Manufacturer-Derived Revenue, related to any covered drug or diabetic supply provided under the Contract, according to the Financial Reporting Guide. This provision survives termination of the contract between LDH and the MCO. The MCO shall report all Manufacturer-Derived Revenue received on claims incurred prior to the termination of the contract until one hundred percent (100 percent) of earned Manufacturer-Derived Revenues specific to the contract between LDH and the MCO are paid.

Within ten (10) business days of LDH's request, the MCO shall provide LDH with unredacted copies of or access to all books, records, and Manufacturer-Derived Revenue agreements with pharmaceutical and diabetic supply manufacturers, intermediaries, subcontractors, wholesalers, or other third parties related to the Contract. This provision applies to the MCO as well as all subcontractors. All such information shall be kept confidential by LDH and shall be exempt from disclosure under the Louisiana Public Records Law.

Within ten (10) business days of LDH's request, the MCO shall provide LDH an itemized report of all Manufacturer-Derived Revenue amounts received by the MCO and its subcontractors, if applicable, within a specified time period. This report must itemize Manufacturer-Derived Revenue by National Drug Code number and manufacturer, indicate amounts paid to the MCO, and indicate the time frames when the

Manufacturer-Derived Revenue was received by the MCO or its subcontractors. The report must also indicate when the Manufacturer-Derived Revenue was paid to the MCO by the PBM, if applicable.

Hepatitis C Project

The MCO shall follow the PDL preferred/non-preferred status and criteria. The MCO PBM shall program denials of 340B claims for all Hepatitis C direct acting anti-viral (DAA) agents. The denials shall be based on the 340B pharmacy list provided by LDH quarterly.

Behavioral Health Specific Pharmacy Policies and Procedures

The MCO shall develop LDH approved policies and procedures that meet or exceed the following requirements:

- The MCO or its subcontractor(s) shall contract with the psychiatric facilities and residential substance use facilities so that the plans are notified upon patient admission and upon patient planned discharge from the psychiatric facility or residential substance use facilities. Prior to discharge the MCO shall be informed of the enrollee's discharge medications. The MCO shall then be responsible to override or allow all behavioral health discharge medications to be dispensed by overriding prior authorization restrictions for a ninety (90) day period. This includes, but is not limited to, naloxone, Suboxone, and long-acting injectable anti-psychotics.
- If the MCO is not notified prior to the discharge and the enrollee presents at the pharmacy with a medication issued at the time of discharge, the MCO shall provide a prior authorization override for a ninety (90) day period from the date of discharge as long as the enrollee presents the prescription within ninety (90) days of being discharged from a psychiatric and/or residential substance use facility.
- The MCO shall have a specific Suboxone, Subutex and methadone management program and approach, which shall be approved by LDH. The policy and procedure must be in accordance with current state and federal statutes in collaboration with the State Opioid Treatment Authority/LDH.
- The MCO shall have a LDH approved pharmacy management program and approach to stimulant prescribing for children under age 6, and persons age 18 or older.
- The MCO shall have a LDH approved program and approach for the prescribing of antipsychotic medications to persons under 18 years of age.
- The MCO shall use encounter, beneficiary, and prescription data to compare Medicaid physician, medical psychologist or psychiatric specialist APRN's prescribing practices to nationally recognized, standardized guidelines, including but not limited to, American Psychiatric Association Guidelines, American Academy of Pediatrics Guidelines, American Academy of Child, and Adolescent Psychiatry Practice Parameters.

Brand Name and Generic Drugs

Claims for multi-source "Brand Name Products" that are not included in the PDL/NPDL process (i.e., drugs not listed on the Preferred Drug List on the static link), shall not be subject to prior authorization. Since the manufacturers of these brand name products have signed the federal rebate agreement, these drugs must have a potential payable status. In consideration of the mandatory generic substitution, LDH requires the MCOs/PBMs to allow dispense as written (DAW) codes "1", "5", "8", and "9" for brand name processing. LDH expects the following codes to accommodate the filling of a brand name product without use of prior authorization:

- DAW "1": Brand name medically necessary from prescriber.
- DAW "5": Substitution allowed-brand drug dispensed as a generic (should be allowed when the brand drug is less expensive for 340B providers).
- DAW "8": Substitution allowed, generic drug not available in marketplace.
- DAW "9": Preferred brand over generic drugs.

Denials of brand drugs (unless the brand is a preferred drug—in or out of the process) should deny with an error code stating "generic substitution required", mapped to NCPDP 22 (M/I Dispense as written (DAW)/Product selection code).

Drug Utilization Review Program

The MCO shall maintain a Drug Utilization Review (DUR) program in accordance with the Contract and the CMS Managed Care Final Rule (CMS-2390-F). The Prospective DUR Program, Retrospective DUR Program, and Educational DUR Program standards implemented by the MCO shall be consistent with the standards established by LDH in the Contract. The MCOs and Medicaid FFS will implement new and revised DUR criteria as voted on by the Medicaid DUR Board. LDH will send the MCO the approved new and revised MCO-specific DUR criteria, and the MCO shall implement within the time period established by LDH. DUR initiatives directed by LDH shall be implemented as directed or with written LDH approval of alternative programming reaching the same outcomes. DUR initiatives not or incorrectly implemented may result in monetary penalties.

Any revisions to the MCO's DUR policy, procedures, or standards shall be approved by LDH prior to implementation. At a minimum, the MCO DUR programs shall include all Medicaid DUR Board initiatives and shall submit any new initiatives to LDH that it would like to include on the Medicaid DUR Board agenda at least 45 days in advance of the DUR Board meeting.

The MCO shall provide a detailed description of its DUR program annually to LDH to comply with CMS DUR annual reporting requirements as per the Managed Care Final Rule. The annual report to the state will be due six weeks after LDH sends the CMS template to the MCOs. The MCO shall be responsible for developing responses to any questions posed by CMS on the annual report and for coordinating its response through LDH. MCOs are required to program their claims processing systems to capture claim level data that is required by CMS for incorporation into the DUR Annual Report.

The MCO DUR program shall contain the following components:

Prospective DUR Program

The MCO shall provide for a review of drug therapy at Point of Sale (POS) before each prescription is given to the enrollee. Screening should be performed for potential drug problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, duration of therapy, and clinical misuse. The following parameters should be screened at POS. Inappropriate therapy should trigger edits and each edit should have its own separate denial code and description including, but not limited to: early refill, duration of therapy, therapeutic duplication, pregnancy precaution, quantity limit (excluding opioids), quantity limit for long-acting opioids, quantity limit for short-acting opioids, diagnosis code required on selected agents, drug interactions, age limit, and dose limits. Reporting capabilities shall exist for these denial codes. The MCOs shall align their coding of NCPDP compliant POS edits and overrides with LDH. Prior authorization is not an acceptable method to override certain POS edits.

Pharmacy claims processing shall be capable of capturing diagnosis codes at the POS and utilizing codes in the adjudication process at POS. Denial of pharmacy claims could be triggered by an inappropriate diagnosis code or the absence of a diagnosis code.

The MCO shall allow pharmacist overrides on selected POS denials as instructed by LDH. Pharmacist overrides shall utilize NCPDP established standards.

The MCO should ensure the pharmacist offers to counsel the patient or caregiver. A log of receipt of prescription and the offer to counsel by the pharmacist shall be incorporated into MCO policy.

The MCOs shall follow prospective safety edits for opioids including early, duplicate and quantity limits, as specified by the state, to comply with the SUPPORT Act.

The MCOs shall follow maximum daily morphine milligram equivalents (MME) prospective safety edits, as specified by the state, to comply with the SUPPORT Act.

The MCOs shall follow the State's clinical authorization criteria for monitoring and managing the appropriate use of antipsychotic medications by children enrolled under the State plan, in order to comply with the SUPPORT Act.

Early refill edit on controlled drugs shall be set at 90% used.

Each inappropriate therapy edit identified through the Prospective DUR Program shall be coded with an individual denial description, which shall be reported separately.

Some DUR prospective criteria will allow for a soft edit or a pharmacist override. MCOs shall align National Council for Prescription Drug Programs (NCPDP) compliant POS edits and overrides. When the pharmacist receives a prospective DUR alert message that requires a pharmacist's review, the MCO POS system shall have the capability to allow the pharmacist to override the alert using the appropriate NCPDP "conflict, intervention and outcome" codes or other NCPDP compliant PA/MC[1] override. POS overrides shall be implemented upon LDH direction. The MCO shall identify the top 10 pharmacies that have the most edit overrides and report them on the revised monthly DUR report (RX162).

[1] Indicates that the use of the drug may be inappropriate in light of a specific medical condition that the patient has. Information about the specific medical condition was provided by the prescriber, patient, or pharmacist.

Denial of pharmacy claims could be triggered by an inappropriate diagnosis code or the absence of a diagnosis code, depending on the Medicaid DUR Board approved criteria. Diagnosis codes shall be supplied by the prescriber on the prescription or transmitted verbally from the prescriber's office to the pharmacist. The pharmacist shall enter the diagnosis code at POS in NCPDP field 424-DO (diagnosis code).

MCO reporting, in accordance with the new CMS Managed Care Final Rule, shall include but not be limited to, the following:

Top drug claims data reviewed by the DUR Board (See Tables ~~1~~ in MCO~~FFS~~ DUR Annual Report [link]):

1. Top 10 prior authorization (PA) requests by drug name;
2. Top 10 PA requests by drug class;
3. Top five claim denial reasons other than eligibility (e.g., quantity limits, early refill, PA, therapeutic duplications, age limits);
4. Top 10 drug names by amount paid;
5. From data in number 4, a determination of the percentage of total drug expenditures;
6. Top 10 drug names by claim count; and
7. From data in number 6, a determination of the percentage of total claims represented by the top 10 drugs.

The MCO shall comply with all final reporting requirements and/or templates produced by CMS.

Retrospective DUR Program

The MCO, in conjunction with LDH, shall provide for the ongoing periodic examination of claims data to identify patterns of gross overuse, abuse, potential fraud, and inappropriate or medically unnecessary care among prescribers, pharmacists, or enrollees.

Claims review must be assessed against predetermined standards while monitoring for therapeutic appropriateness. Prescribers and pharmacists should be contacted via an electronic portal or other electronic means if possible. Facsimile and mail will suffice in some instances.

Retrospective DUR initiatives shall be implemented monthly as directed by LDH. The MCOs shall follow retrospective automated claim reviews of opioid and benzodiazepines concurrent fill reviews and opioid and antipsychotic concurrent fill reviews on an annual basis, in order to comply with the SUPPORT Act. Additional retrospective DUR initiatives may be implemented by the MCO when previously approved by LDH.

At a minimum, the MCO shall implement all of the DUR Board approved retrospective initiatives. An implementation timeline for retrospective interventions will be coordinated through LDH. Retrospective interventions are defined as communication from the MCO through intervention letters to the provider when DUR criteria are met.

Intervention letters, including enrollee profiles, shall be sent to selected prescribers and/or pharmacy providers and include the following:

- Cover sheet (template will be provided by LDH);
- Response sheet (template will be provided by LDH);

- ❖ Additional enclosures, if applicable (examples include recommendations and supportive clinical guidelines if not included in cover sheet); and
- ❖ Enrollee profile with at least nine months of historical data. In order to display drug utilization patterns, the MCO or its PBM shall generate enrollee profiles, which shall be approved by LDH and sent to the prescriber and/or pharmacy provider.
    - o Enrollee profiles shall be composed of the following elements:
        - Enrollee information – name, Medicaid ID, date of birth, and gender – should be included in the header on every page;
        - Prescription claim information, including drug name; National Drug Code (NDC); prescription number; diagnosis (if provided); date of service; quantity dispensed; days' supply; pharmacy information such as name, address, and National Provider Identifier (NPI) number; and prescriber information (name, address, NPI);
        - Physician administered drugs (currently optional); and
        - Exception criteria and description should be displayed at the beginning of the enrollee profile (e.g., 1-Famotidine: exceeds maximum recommended dose (80 mg/day); 2-Contraindication: dorzolamide/timolol ophthalmic for patient with asthma; 3-Possibility of patient non-compliance with anti-diabetes therapy).
    - ~~o Enrollee profiles shall exclude line items that contain any substance use disorder (SUD) diagnosis, drugs, and providers (such as clinicians, prescribers, and facilities) who solely treat SUD. See Code of Federal Regulations, Title 42, Chapter I, Subchapter A, Part 1 [link].~~

To determine if intervention letters are necessary, the MCO shall have a clinician, or a team of clinicians, evaluate the enrollee profile before sending the intervention letter. Clinicians shall be pharmacists, nurses, or physicians. The clinician must be familiar with current clinical guidelines. The purpose is to send only meaningful information to the prescriber/pharmacist that will enable them to improve the enrollee's care.

The MCO shall track and report prescriber/pharmacist responses to intervention letters through standing reporting established by LDH. Reporting shall include, but not be limited to, the following for the DUR annual report to CMS:

- ❖ Retrospective DUR Educational Outreach Summary. Rank of the top 10 interventions: number of hits (numerator)/number of claims (denominator). This is a year-end summary report on RetroDUR screening and educational interventions. The year-end summary reports should be limited to the top 10 problems with the largest number of exceptions including the results of RetroDUR screening and interventions.
- ❖ Summary of Medicaid DUR Board Activities. LDH or its fiscal intermediary will supply this information to the MCO for inclusion in its CMS annual report. Separately, the MCO shall include additional MCO-initiated activities which have been approved by LDH.
- ❖ Generic Drug Substitution Policies. The description of policies that may affect generic utilization percentage.
- ❖ Generic Drug Utilization Data. This includes the number of generic claims, total number of claims, and generic utilization percentage. CMS has developed an extract file from the Medicaid Drug Rebate Program Drug Product Data File identifying each NDC along with sourcing status of each drug: S (Single Source), N (Non-Innovator Multiple-Source), or I (Innovator Multiple-Source). This

file will be made available by CMS to facilitate consistent reporting across states with this data request.

- Innovative Practices. Describe in detailed narrative form any innovative practices that are believed to have improved the administration of the MCO's DUR program, the appropriateness of prescription drug use, and/or have helped to control costs (i.e., disease management, academic detailing, automated prior authorizations, continuing education programs).
- E-Prescribing Activity Summary. Describe all development and implementation plans/accomplishments in the area of e-prescribing.
- Executive Summary.

Within the LDH standing report, retrospective intervention reporting shall also include but not be limited to the following for the Medicaid DUR Board (six months after the intervention letter is sent):

- Number of enrollee profiles reviewed. This is the number of enrollee profiles reviewed by the clinician. One enrollee profile is one enrollee; one enrollee profile can have more than one intervention.
- Number of enrollee profiles with intervention letters issued. More than one provider can get a letter for the same enrollee; one letter can address more than one intervention.
- Number of responses and response rate.

Educational DUR Program

The MCO shall provide active and ongoing educational outreach programs to educate and inform prescribers and pharmacists on common drug therapy programs with the aim of improving prescribing and/or dispensing practices. The frequency of patterns of abuse and gross overutilization or inappropriate or unnecessary care among prescribers, pharmacists and recipients should be identified.

MCOs should educate prescribers, pharmacists, and enrollees on therapeutic appropriateness when overutilization or underutilization occurs. LDH expects the MCOs to use current clinical guidelines and national recommendations to alert prescribers and pharmacists of pertinent clinical data. Clinical outcomes shall be monitored by the MCO and reported to LDH on a periodic basis established by the Department.

Lock-In Program

The MCO shall refer to the Contract for lock-in program requirements and the **Marketing and Member Education Companion Guide** for lock-in letter templates.

Medication Therapy Management

General Requirements

The MCO shall have established a medication therapy management (MTM) program that:

- Is comprehensive and patient-centered;
- Is designed to increase medication adherence;

- Is designed to ensure that medications are appropriately used to optimize therapeutic outcomes through improved medication use;
- Is designed to reduce the risk of adverse events from medication therapy;
- May be administered by a pharmacist or other qualified providers, such as physicians, nurse practitioners, physician assistants, or nurses;
- Shall be developed in cooperation with licensed and practicing pharmacists and physicians; and
- Shall include coordination between the MCO, the enrollee, the pharmacist and the prescriber using various means of communication.

To assess the enrollee's medication therapy, the MTM program shall include an interactive comprehensive medication review (CMR), which includes enrollee discussion and prescriber intervention if needed. This results in the creation of a written summary and is followed by frequent monitoring with further interventions as needed.

The MCO shall ensure that all requirements are met regardless of whether the MCO utilizes a contractor for MTM services. The MCO and its contractor, if applicable, shall not limit the MTM services provided for enrollees meeting MTM criteria. MTM criteria must be approved by LDH pharmacy staff. MTM shall be executed as specified herein and as directed by LDH.

Enrollment

The MCO shall enroll targeted enrollees in an opt-out method of enrollment only. This means enrollees may choose to opt-out of the program if desired at any time.

The MCO shall auto-enroll the targeted enrollees each year when they meet the eligibility criteria, and they are considered enrolled in the MTM program unless the enrollee declines enrollment. The enrolled may refuse or decline individual services without having to disenroll from the MTM program.

Targeted Enrollees

The MTM program may include enrollees with multiple chronic diseases or any specific chronic disease. If the MTM program is designed to target individual specific chronic diseases, then the program shall include at least three of the following:

- Behavioral health (such as Alzheimer's disease, bipolar disorder, depression, schizophrenia, or other chronic/disabling mental health conditions);
- Bone disease-arthritis (such as osteoporosis, osteoarthritis, or rheumatoid arthritis);
- Cardiovascular disease (such as dyslipidemia, heart failure, or hypertension);
- Diabetes;
- End-stage renal disease (ESRD);
- Hepatitis C infection;
- Respiratory disease (such as asthma, chronic obstructive pulmonary disease (COPD), or chronic lung disorders); and
- Substance use disorder.

The MCO should also offer MTM services to an expanded population of enrollees who do not meet the eligibility criteria but would benefit from MTM services. The MCO shall also leverage effective MTM to

improve safety (e.g., increase adherence to medications, reduce the use of high-risk medications, and address issues of overutilization).

Required MTM Services

The MCO shall offer a minimum level of MTM services to each enrollee in the program that includes all of the following:

- Interventions for both enrollees and prescribers, as needed; and
- An annual Comprehensive Medication Review (CMR) with written summaries created in a standardized format approved by LDH; and
- Targeted Medication Reviews (TMRs), when needed, with follow-up interventions when necessary.

Comprehensive Medication Review

Comprehensive Medication Review (CMR) is a systematic process of:

- Collecting patient-specific information;
- Assessing medication therapies to identify medication-related problems;
- Developing a prioritized list of medication-related problems; and
- Creating a plan to resolve them with the patient, caregiver and/or prescriber.

The MCO shall offer a CMR to all enrollees in the MTM program at least annually.

The MCO shall offer to provide a CMR to newly targeted enrollees as soon as possible after enrollment into the MTM program, but no later than 60 days after being enrolled in the MTM program.

The enrollee's CMR shall be conducted using an interactive, person-to-person review (including prescriptions, over-the-counter medications, herbal therapies and dietary supplements) performed by a pharmacist or other qualified provider, and may result in a recommended medication action plan.

A written summary of the results of the review shall be provided to the targeted individual(s) in a standardized format approved by LDH and shall include the following:

- Any concerns the enrollee may have regarding their drug therapy;
- Purpose and instructions for use of the enrollee's medications; and
- Personal medication list (including prescription, non-prescription drugs, and supplements) which will aid in assessing medication therapy and engaging the enrollee in management of his or her drug therapy.

The MCO shall encourage enrollees to take their action plan and personal medication list from their CMR to any medical encounter (e.g., physician visit, pharmacy, or hospital admission). This summary shall serve as a valuable tool to share information across providers and help reduce duplicate therapy and drug-drug interactions.

Targeted Medication Review

The MCO shall perform Targeted Medication Reviews (TMRs) when needed to address potential or specific medication-related problems, to assess any transition of care the enrollee may have experienced, or to monitor new, unresolved, or continued medication therapies. The findings of the TMR shall then be reviewed to determine if a follow-up intervention is needed for the enrollee or the prescriber. The MCO may determine how to tailor the follow-up intervention based on the specific needs or medication use issues of the enrollee. For example, these interventions may be person-to-person or telephonic.

Outcomes Measurement

The MCO shall have a process in place to measure, analyze, and report the outcomes of their MTM program. This process shall include whether the goals of therapy have been reached and shall capture drug therapy recommendations and resolutions made as a result of MTM recommendations. A recommendation is defined as a suggestion to take a specific course of action related to the enrollee's drug therapy. Examples of drug therapy problem recommendations made as a result of MTM services and recommendations include, but are not limited to:

- Needs additional therapy;
- Unnecessary drug therapy;
- Dosage too high;
- Dosage too low;
- Adverse drug reaction;
- Medication non-adherence;
- Initiate drug;
- Change drug (such as product in different therapeutic class, dose, dosage form, quantity, or interval);
- Discontinue or substitute drug (such as discontinue drug, generic substitution, therapeutic substitution, or formulary substitution); or
- Medication adherence.

Quarterly Reporting Requirements

Reporting is an important factor in determining the effectiveness of an MTM program. The MCO shall document interventions, contact attempts, number of enrollees enrolled, and other associated parameters. Report requirements include, but are not limited to the following:

- Enrollee enrollment parameters;
- Number of contact encounters and contact-related outcomes;
- Number of MTM interventions, both telephonic and face-to-face;
- Number of comprehensive medication reviews;
- Number of drug therapy problems identified, such as potential drug-drug interactions, adverse events, or the simplification of a complex regimen with the same therapeutic benefit; and
- Number of drug therapy problems resolved, such as modifications to drug dose, form, or frequency or changes in drug regimen due to identification of potential adverse event or interaction.

- If specific disease states are targeted, the MCO shall include the following:
- Number of drug-related parameters improved, such as improved adherence in disease-specific medication regimen, modifications in drug therapy to reflect appropriate current treatment guidelines, or disease-related laboratory test monitoring;
- Percentage of the MCO's enrollee population with each targeted disease state that received MTM services; and
- An example of a positive outcome demonstrated by MTM interventions for each targeted disease state. Examples include improvement in blood pressure measurements, A1C levels, LDL levels, etc.

This information shall be submitted to LDH on a quarterly basis, by the 30th day of the month following the end of the reporting period.

Mosquito Repellent Coverage

The MCO shall cover mosquito repellant as a pharmacy benefit to decrease the risk of exposure to the Zika virus.

Coverage must be provided for enrollees who are:

- Pregnant; or
- Of childbearing age (women and men ages 14-44) who are trying to conceive.

One bottle of mosquito repellent every rolling 30 days will be allowed. A prescription will be required to cover one of the following products:

Product Name	Ounces	Bill As	UPC	"NDC"
Cutter Backwoods 25% Spray	6 oz.	170 g	71121962805	71121-0962-80
Cutter Skinsations 7% Spray	6 oz.	177 mL	16500540106	16500-0540-10
OFF! Family Care 15% Spray	2.5 oz.	71 g	46500018428	46500-0710-37
OFF! Deep Woods Dry 25% Spray	4 oz.	113 g	46500717642	46500-0717-64
OFF! Deep Woods 25% Spray	6 oz.	170 g	46500018428	46500-0018-42
OFF! Active 15% Spray	6 oz.	170 g	46500018107	46500-0018-10
Repel Sportsmen 25% Spray	6.5 oz.	184 g	11423941375	11423-0941-37
Repel Sportsmen Max 40% Spray	6.5 oz.	184 g	11423003387	11423-0003-38
Natrapel 20% Picaridin	5 oz.	177 mL	44224068781	44224-0068-78
Sawyer Insect Repellent 20% Picaridin	4 oz.	118 mL	50716005448	50716-0005-44

Opioid Prescription Policy

The MCO shall have an opioid prescription policy that includes the following:

- Acute Pain
    - 7-day quantity limit for opioid-naïve enrollees or Morphine Milligram Equivalent (MME) limit of 90 milligram per day, whichever is less. Opioid-naïve enrollees are enrollees with no opioid claims in the most current 90 days.
- Chronic Pain

- Morphine Milligram Equivalent (MME) limit of 90 milligram per day for all opioid prescriptions.

❖ Exemptions that bypass opioid quantity limits shall include:

DIAGNOSIS DESCRIPTION	CODE
Cancer	C00.* – C96.*
Palliative Care	Z51.5
Burn of second or third degree of head, face and neck	T20.2* – T20.3*
Corrosion of second or third degree of head, face and neck	T20.6* – T20.7*
Burn of second or third degree of trunk	T21.2* – T21.3*
Corrosion of second or third degree of trunk	T21.6* – T21.7*
Burn of second or third degree of shoulder and upper limb, except wrist and hand	T22.2* – T22.3*
Corrosion of second or third degree of shoulder and upper limb, except wrist and hand	T22.6* – T22.7*
Burn of second or third degree of wrist and hand	T23.2* – T23.3*
Corrosion of second or third degree of wrist and hand	T23.6* – T23.7*
Burn of second or third degree of lower limb, except ankle and foot	T24.2* – T24.3*
Corrosion of second or third degree of lower limb, except ankle and foot	T24.6* – T24.7*
Burn of second or third degree of ankle and foot	T25.2* – T25.3*
Corrosion of second or third degree of ankle and foot	T25.6* – T25.7*
Hb-SS disease with crisis	D57.0
Hb-SS disease with crisis, unspecified	D57.00
Hb-SS disease with acute chest syndrome	D57.01
Hb-SS disease with splenic sequestration	D57.02
Sickle-cell/Hb-C disease with crisis	D57.21
Sickle-cell/Hb-C disease with acute chest syndrome	D57.211
Sickle-cell/Hb-C disease with splenic sequestration	D57.212
Sickle-cell/Hb-C disease with splenic sequestration	D57.219
Sickle-cell thalassemia with crisis	D57.41
Sickle-cell thalassemia with acute chest syndrome	D57.411
Sickle-cell thalassemia with splenic sequestration	D57.412
Sickle-cell thalassemia with crisis, unspecified	D57.419
Other sickle-cell disorders with crisis	D57.81
Other sickle-cell disorders with acute chest syndrome	D57.811
Other sickle-cell disorders with splenic sequestration	D57.812
Other sickle-cell disorders with crisis, unspecified	D57.819

Clotting Factor

The MCO shall follow the FFS reimbursement methodology for clotting factor products in the Louisiana Medicaid State Plan, effective October 1, 2023, contingent on CMS approval and as directed by LDH. Clotting factor products will be identified by LDH. Clotting factor products administered in an outpatient setting shall only be reimbursed as a pharmacy benefit, not as a medical/professional benefit.

Pharmacy Copayment

Copayment Threshold

The MCO must have a Point of Sale edit that will apply a per-enrollee maximum monthly copayment and turn off cost sharing when maximum copayments are met.

All copay exemptions shall be applied. The fiscal intermediary provides a monthly report to the MCOs with the per-enrollee maximum monthly copayment. This will eliminate all of the risk for enrollees to exceed the 5 percent aggregate family limit.

Exemptions for Preventive Medications

To be in compliance with the Affordable Care Act (ACA) requirements related to coverage of preventive medications, medications listed in the U.S. Preventive Services Task Force (USPSTF) A and B Recommendations should be reimbursable and exempt from pharmacy copayments. Corresponding age limits may be applied.

Prior Authorization

MCO prior authorization (PA) criteria shall align with FFS for drugs on the Single PDL that were filled in an outpatient pharmacy setting. LDH intends to align FFS and MCO criteria for drugs not on the Single PDL over time through the DUR board. The MCO shall have input on PA criteria development and representation on the DUR board. The MCO shall have a PA process that complies with 42 C.F.R. § 438.3(s)(6) and the following requirements.

- The MCO shall allow prescribers, and may allow pharmacies at the MCO's discretion, to submit PA requests by phone, fax or an automated process.
- The MCO shall provide access to a toll-free call center for prescribers to call to request PA for non-preferred drugs or drugs that are subject to clinical edits. If the MCO or its pharmacy benefit manager operates a separate call center for PA requests, it will be subject to the provider call center standards and monetary penalties set forth in the Contract.
- PA requests shall be approved or denied within 24 hours of receipt, seven days a week. The MCO shall notify the requesting practitioner of the approval or disapproval of the request within 24 hours. Denials of prior authorization requests or offering of an alternative medication shall be provided to the prescriber and enrollee in writing. PA denials may be appealed in accordance with the Contract.

Consistent with the requirements of Section 1927 of the Social Security Act, LDH will hold MCOs to a 99.5% compliance rate with the 24-hour PA resolution requirement. If an MCO is reporting less than 99.5% compliance on the RX055 report, justification shall be included with the report in the notes section.

The MCO shall have an automated process that allows the pharmacy to dispense without PA up to a 72-hour emergency supply of a product or full unbreakable package. At a minimum, the MCO shall allow two emergency supply fills per prescription. The MCO shall reimburse the pharmacy for both the ingredient and the dispensing fee for both fills. Emergency fills may be included in a post payment review to identify misuse.

The MCO shall prior authorize drugs with a non-preferred status on the PDL.

The MCO shall not prior authorize drugs with a preferred status on the PDL, except to align with FFS clinical edits.

For self-administered drugs, the MCO shall not prior authorize drugs not on the PDL, except to align with FFS clinical edits or as otherwise directed by LDH.

The MCO may prior authorize drugs when safety and utilization edits are exceeded when approved by LDH, except for drugs used for the treatment and prevention of HIV/AIDS. Drug utilization edits aligned through DUR initiatives shall be adhered to; however, safety and utilization edits outside of DUR initiatives may be aligned with FDA indications.

MCO prior authorization criteria and/or step therapy related to the preference of one agent over another agent within a therapeutic class listed on the PDL shall not be more restrictive than FFS.

Prior authorization and/or step therapy shall not be applied to preferred agents listed on the PDL in a manner that would disadvantage the selection of the preferred agents over other agents within the therapeutic class.

Prior authorization and/or other safety edits are allowed on physician-administered drugs.

If a PA is requested for a narrow therapeutic index (NTI) drug, every effort should be made to verify if the enrollee is currently on a specific brand/generic, then the PA shall be approved for the corresponding product. NTI drugs include: Aminophylline, Carbamazepine, Cyclosporine, Digoxin, Disopyramide, Ethosuximide, Flecainide, L-Thyroxine, Lithium, Phenytoin, Theophylline, Thyroid, Valproic Acid, and Warfarin.

Prior authorization shall not require more than two failures of preferred products.

The MCO shall override PA for selected drug products or devices at LDH's discretion, including but not limited to certain DUR initiatives.

The MCO shall not require PA for drugs with FDA indication for emergency contraception.

The MCO shall not require PA for a dosage change for any medications (including long-acting injectable antipsychotics) and other medication assisted treatment (including dosages of buprenorphine or buprenorphine/naloxone) that have been previously authorized and/or approved by the MCO, as long as the newly prescribed dose is within established FDA guidelines for that medication.

The MCO shall not penalize the prescriber or enrollee, financially or otherwise, for PA requests or other inquiries regarding prescribed medications.

An enrollee receiving a prescription drug that was on the PDL and was removed from the PDL or changed from preferred to non-preferred status shall be allowed to continue to receive that prescription drug for

at least 60 days after notification. The MCO shall have 30 days after receipt of the NDC list to send out notifications of negative changes to prescribers and enrollees. Brand/generic preference changes of the same drug entity do not constitute a negative PDL change.

When a prescriber is requesting brand name medication that has a generic equivalent, the MCO can encourage a prescriber to complete the FDA Medwatch form. A Medwatch form shall not be required or considered in the PA approval/denial determination of a brand drug.

Prior authorization shall not be utilized to prefer a B-rated generic drug over an A-rated generic.

The statewide universal prior authorization form shall be posted and utilized as specified in Act 423 of the 2018 Louisiana Regular Session. In order to obtain necessary information for prior authorization processing, the following therapeutic drug classes may be considered specialty for prior authorization purposes only: Hepatitis C Direct Acting Antiviral Agents (as directed by LDH), Spinraza®, Aduhelm®, and Synagis®. MCOs shall utilize the LDH form and criteria for these specialty classes filled in the outpatient pharmacy setting.

The MCO shall adhere to the provisions of La. R.S. 46:153.3(C)(1) which exempt HIV/AIDS drugs from the prior authorization process.

340B Policy for Claim Level Indicators

The MCO is required to submit drug-related encounter data to LDH for the purposes of collecting federal Medicaid rebates. Louisiana Medicaid must prevent duplicate discounts against drug manufacturers when 340B covered entities dispense drugs purchased through the 340B Discount Program. Federal Medicaid rebates are not allowed on 340B discount drug utilization.

340B is a federal program administered by the Health Resources and Services Administration (HRSA). HRSA's Office of Pharmacy Affairs (OPA) maintains a searchable database of all healthcare providers enrolled as 340B covered entities. Medicaid and Managed Care Medicaid claims billed by 340B covered entities that self-attest to HRSA that their Medicaid populations are carved into their 340B programs are removed from Federal Medicaid Rebate invoicing. This means the provider attests that their Medicaid claims are all 340B discount stock and are not eligible for Federal Rebate collection. Louisiana Medicaid requires a claim-level indicator be used by the billing provider in order to denote a drug claim's status as 340B. Due to the cost to charge methodology, outpatient hospital claims are excluded from the claim level indicator requirement.

MCOs should include the following requirements in contracts with 340B covered entities.

- Pharmacy 340B Drug Claims:
  - NCPDP: Bill value of "20" in the Submission Clarification Code field (420-DK).
  - NCPDP: Bill value of "08" in the Basis of Cost Determination field (423-DN).
- Outpatient/Professional Services 340B Drug Claims:
  - CMS 1450/UB04: Enter UD Modifier immediately following drug HCPCS/CPT code in field 44. For example, HCPCS J1111 billed as J1111UD.
  - CMS 1500: Enter HCPCS code in field 24C followed by the UD Modifier. 837I: Loop 2400 SV2 can send up to four modifiers SV202-3, SV202-4, SV202-5, and SV202-6.

- 837I: Loop 2400 SV2 can send up to four modifiers SV202-3, SV202-4, SV202-5, and SV202-6
- 837P: Loop 2400 SV1 can send up to four modifiers in SV101-3, SV101-4, SV101-5, and SV101-6.

The MCO shall deny claims at Point of Sale (POS) from 340B carved-in pharmacies that have missing or invalid claim level indicators. The MCO shall require submission of the UD modifier on 340B outpatient/professional services drug claims. Encounters shall follow requirements in the **Batch Pharmacy Encounters Companion Guide**.

Hepatitis C Virus Direct-Acting Antiviral (DAA) Agents

The MCO shall deny claims at POS for hepatitis C direct-acting antiviral agents from 340B pharmacies carved-in to Medicaid. Claims for hepatitis C direct-acting antiviral agents from 340B carve-out pharmacies are not subject to this limitation and shall process as usual.

Vaccines for Adults

The MCO shall allow 340B pharmacies carved-in to Medicaid to bill vaccines and administration for adults (19 years and older) at POS as a pharmacy benefit. Claim level indicators should not be required on claims for vaccines. Vaccines are not 340B or rebate eligible.

Inpatient 340B Drug Claims

Drugs are not billed separately from the per-diem inpatient rate. Per HRSA guidelines, 340B stock must not be dispensed in an inpatient setting.

340B Exclusion

Only providers registered as 340B covered entities and listed on the HRSA Medicaid Exclusion File may bill drug stock purchased through 340B with these indicators. The indicator is meant to denote that the specific drug billed on the claim was obtained through the 340B discount program by the billing provider.

These modifiers should not be used by providers that are not registered 340B covered entities, or by covered entities that are not listed on the Exclusion File because they have attested that they do not use 340B drug stock for their Medicaid beneficiaries.

340B contract pharmacies are not permitted to bill 340B stock to Medicaid FFS or MCOs in Louisiana.

The MCO should deny claims at POS if the 340B indicators are on the claim, but the pharmacy is not listed in the Medicaid Exclusion File. The pharmacy should be directed to fill the claim with regular pharmacy stock with the denial.

Claims with these modifiers will be excluded from federal Medicaid rebate invoicing only when billed by 340B covered entities listed on the Medicaid Exclusion file as using their 340B drug stock for Medicaid beneficiaries.

Emergencies

In the event of an emergency, as defined by LDH, LDH shall have the authority to require the MCOs to implement any necessary configuration modifications to pharmacy requirements within 72 hours of notification. Within 24 hours from LDH's request, the MCO shall alter or remove Point of Sale, prior authorization, or other pharmacy requirements as determined by LDH, in a manner that may be statewide or limited to certain zip codes or parishes.

For an emergency, specific changes shall be determined by LDH and may include:

- Point of Sale edits: This may include, but is not limited to, altering early refill and refill too soon edits to an educational alert (message to pharmacy only, no denial at Point of Sale) as well as altering early refill and refill too soon edits set to deny so that they return an override code to be utilized by the pharmacy if needed to bypass the edit, without the requirement of a phone call to the help desk.
- Prior authorization requirements: This may include, but is not limited to, altering prior authorization denials to an educational alert (message to pharmacy only, no denial at Point of Sale) as well as extending the expiration date of currently approved prior authorizations to a date requested by LDH.
- Quantity limitations: This may include, but is not limited to, allowing dispensing of a 90 day supply for medications specified by LDH.
- Copays: This may include, but is not limited to, waiving member copays for pharmacy claims, which shall be added back to the pharmacy reimbursement.
- Signatures: This may include, but is not limited to, removing the requirement of a signature for pick-up or delivery.
- Lock-in restrictions: This may include, but is not limited to, removing pharmacy lock-in restrictions or both pharmacy and prescriber lock-in restrictions including on a case-by-case basis.
- Any other change deemed necessary by LDH to respond to the emergency and protect enrollee health.