

**McLAREN HEALTH PLAN
POLICY & PROCEDURE MANUAL**

Initial Approval Date: 1/1/2022
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Review Cycle: annual

SCOPE

McLaren Health Plan

SUBJECT

Pharmacy Transition Policy – Medicare Part D

POLICY NUMBER

RX-MED-D-011

SECTION

Medicare Pharmacy

AUTHORIZED BY

Pharmacy & Therapeutics Committee

PURPOSE

- McLaren Health Plan (MHP) provides Medicare Advantage Prescription Drug (MAPD) plans, individual and/or employer group, per annual contracts with the Centers for Medicare and Medicaid Services (CMS).
- This policy shall pertain to the MAPD plans and their respective products e.g., HMO, HMO-POS, and PPO, as applicable.
- This policy ensures MHP complies with all applicable state and federal laws and regulations, including, but not limited to, those pertaining to the Medicare Advantage (MA) and MAPD programs and provides direction and processes regarding implementation of CMS rules and regulations.
- MHP delegates certain Part D functions to our Pharmacy Benefit Manager (PBM), MedImpact Health Systems. This includes administering transition of care claims appropriately as directed by the CMS guidance. MHP will utilize MedImpact's process based on their policy titled "Transition Process Requirements for Medicare Part D" (910-PL-1013), which is detailed below.
- The purpose of this policy is to describe the process for transition and ensure that continued drug coverage is provided to new and current Part D members. The transition process allows for a temporary supply of drugs and sufficient time for members to work with their health care providers to select a therapeutically appropriate formulary alternative, or to request a formulary exception based on medical necessity. Transition processes will be administered by MedImpact, and overseen by MHP, in a manner that is timely, accurate and compliant with all relevant CMS guidance and requirements as per 42 CFR §423.120(b)(3).

DEFINITIONS:

Term	Definition
Centers for Medicare & Medicaid Services (CMS)	The federal agency that runs the Medicare program. In addition, CMS works with the states to run the Medicaid program. CMS works to ensure that the beneficiaries in these programs can receive high quality health care.
Pharmacy Benefit Manager (PBM)	The contracted vendor selected to administer prescription drug claims for the pharmacy portion of the benefit.

Medicare Advantage (MA)	A Medicare program that gives more choices among health plans for Medicare Parts A and B benefits.
Medicare Advantage Organization (MAO)	A public or private entity organized and licensed by a state as a risk-bearing entity that is certified by CMS as meeting MA contract requirements.
Prescription Drug (PD)/Part D Plan (PDP)	A private Medicare plan offering Part D (prescription drug) coverage.
Emergency Supply	An Emergency Supply is defined by CMS as a one-time transition fill that is necessary with respect to members that are outside of their initial 90-day transition period and that are in the LTC setting.
FTP	File Transfer Protocol – One of the methods used by MedImpact and its clients to transfer electronic files via the Internet. The first two bits of the file indicate the type of file.
HICL	A First Data Bank (FDB) data warehouse term that is an alpha-numeric code used to describe drugs ingredients. The HICL codes have been sequenced according to an ingredient sequence table. The HICL sequence table establishes relative importance to each ingredient, relative to other ingredients. The relative importance of an ingredient is based on its clinical and therapeutic use. The most important ingredients are sequenced first and the least significant are sequenced last.
Level of Care Change	Level of care changes include the following changes from one treatment setting to another: <input type="checkbox"/> Enter LTC facility from hospitals or other settings; <input type="checkbox"/> Leave LTC facility and return to the community; <input type="checkbox"/> Discharge from a hospital to a home; <input type="checkbox"/> End a skilled nursing facility stay covered under Medicare Part A (including pharmacy charges), and revert to coverage under Part D; <input type="checkbox"/> Revert from hospice status to standard Medicare Part A and B benefits; and <input type="checkbox"/> Discharge from a psychiatric hospital with medication regimens that are highly individualized.
LTC	Long Term Care
NCPDP	A 7-digit number assigned to a pharmacy by the National Council for Prescription Drug Programs (NCPDP), with the first 2 identifying the state and the last 5 identifying the pharmacy.
NSDE	The FDA's Comprehensive NDC Structured Product Labeling Data Elements file. This file is used to provide structured product labeling of Brand and Generic drugs.
PA	Prior Authorization - The process undertaken to make a benefit determination that is made prior to the intended delivery of the healthcare service, treatment or supply under review (e.g., a Pre-Service Claim). Prior Authorization includes requests for coverage

	determination for medications that are designated on the client part D formulary as “Prior Authorization Required”, “Step Therapy”, “Quantity Restrictions” or for requests for exception for non-formulary medications or co-insurance amount.
PDE	Prescription Drug Event. File that reports all claims transactions to CMS for inclusion in the annual financial reconciliation between CMS and the Plans.
POS	The acronym given to MedImpact’s point-of-sale prescription transaction processing computer system. Also indicates that the actual retail transaction occurs when the claim is submitted electronically by the pharmacy.
P&T Committee	Pharmacy & Therapeutics Committee – An independent group of external & internal health care practitioners that are responsible for evaluating the efficacy, safety and cost effectiveness of medications to determine potential additions, subtractions and other changes to a formulary.
UM	Utilization Management – A set of guidelines that can be applied independently or jointly that otherwise restrict access to the dispensing or consumption of prescription drugs. The four basic restrictions are prior authorization (PA), quantity limits (QL), step therapy (ST) and tier placement. UM is a tool used by health plans to ensure safe, efficacious and cost effectiveness.

POLICY STATEMENT:

1.1 Overview

MedImpact supports MHP in administering a transition process that is in compliance with the established CMS transition requirements.

This policy is necessary with respect to:

- (1) New enrollees into prescription drug plans following the annual coordinated election period;
- (2) Newly eligible Medicare beneficiaries from other coverage ;
- (3) Enrollees who switch from one plan to another after the start of a contract year;
- (4) Current enrollees affected by negative formulary changes across contract years; and
- (5) Enrollees residing in long-term care (LTC) facilities.

MHP will ensure that its transition policy will apply to non-formulary drugs, meaning both (1) Part D drugs that are not on a plan’s formulary, and (2) Part D drugs that are on a plan’s formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary’s current dose, under a plan’s utilization management rules. MedImpact will ensure that its policy addresses procedures for medical review of non-formulary drug requests, and when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

Also, in accordance with CMS requirements, MedImpact ensures that drugs excluded from Part D coverage due to Medicare statute are not eligible to be filled through the transition process. However, to the extent that MHP covers certain excluded drugs under an Enhanced benefit, those drugs should be treated the same as Part D drugs for the purposes of the transition process.

1.2 Transition Population

MHP will maintain an appropriate transition process consistent with 42 CFR §423.120(b)(3) that includes a written description of how, for enrollees whose current drug therapies may not be included in their new Part D plan's formulary, it will effectuate a meaningful transition for: (1) new enrollees into prescription drug plans following the annual coordinated election period, (2) newly eligible Medicare beneficiaries from other coverage, (3) enrollees who switch from one plan to another after the start of a contract year, (4) current enrollees affected by negative formulary changes across contract years, (5) enrollees residing in long-term care (LTC) facilities.

1.3 Transition Period

MedImpact allows MHP to choose the number of transition days offered under their transition policy. CMS requires a minimum of 90 days from the start of coverage under a new plan. The 90 days are calculated from the plan start date. MHP will extend its transition policy across contract years should a beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply. MHP may choose to enhance their transition policy to provide coverage beyond the CMS minimum requirements.

With the exception of MedImpact's "Transition Across Calendar Years" processes described later in this policy, MHP has two options for setting the member's transition start date; utilizing MedImpact's system default logic or continue populating Segment Code 05 of the Type 24 file.

MedImpact's default process for setting the transition start date will work with MedImpact's Type 23 (member record layout) file, or equivalent file type if not utilizing a Type 23. Whenever the Type 23 loads or its equivalent file loads, the transition start date default process will run simultaneously and analyze the member's group number assignment and the member's effective date within that group.

- For members that are new to MHP or that are re-enrolling but had a break in coverage, MedImpact's default process will set the transition start date to match the member's effective date within the group.
- For existing (non-new) members that are assigned to a new group within the same health plan, MedImpact's default process will analyze the change in group number assignment to determine if it results in a new CMS contract and/or plan assignment.
 - If the change in group number resulted in a new CMS contract assignment, the member's transition start date will be updated to mirror the effective date of the group change.
 - If the change in group number did not result in a new CMS contract assignment, the member's transition start date will remain as is and will not be updated.
 - If the change in group number resulted in a new plan assignment and new formulary ID, the member's transition start date will be updated to mirror the effective date of the group change.

- If the change in group number did not result in a new plan assignment or new formulary ID, the member's transition start date will remain as is and will not be updated.

MHP's default logic aligns with guidance issued by CMS stating that a plan must effectuate transition for members that change either CMS contract or plan, irrespective of whether or not the change resulted in a new Part D formulary assignment.

When utilizing Segment Code 05 of the Type 24 for setting member's transition start date, MHP is responsible for indicating which of their members should be in a transition period. MHP will place members into a transition period by populating the appropriate Member plan Part D Start Date in Segment Code 05 of the Type 24 File (Member Attribute Load File). The transition period (90-day minimum) is calculated from the Member plan Part D Start Date with the plan.

MHP will ensure that it will apply all transition processes to a brand-new prescription for a non-formulary drug if it cannot make the distinction between a brand-new prescription for a nonformulary drug and an ongoing prescription for a non-formulary drug at the point-of-sale.

1.4 Implementation Statement

- Claims Adjudication System:** MedImpact has systems capabilities that allow MedImpact to provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to allow MHP and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.
- Pharmacy Notification at Point-Of-Sale:** MHP utilizes the current NCPDP Telecommunication Standard to provide POS messaging. MedImpact reviews NCPDP reject and approval codes developed during the External Codes List (ECL) process. Pharmacy messages are modified based on industry standards.
- Edits During Transition:** MHP will only apply the following utilization management edits during transition at point-of-sale: edits to determine Part A or B versus Part D coverage, edits to prevent coverage of non-Part D drugs, and edits to promote safe utilization of a Part D drug. Step therapy and prior authorization edits must be resolved at point-of-sale.

MHP will ensure that the transition policy provides refills for transition prescriptions dispensed for less than the written amount due to quantity limit safety edits or drug utilization edits that are based on approved product labeling.

As outlined in 42 CFR §423.153(b), MedImpact has implemented Point-of-Sale (POS) PA edits to determine whether a drug is covered under Medicare Parts A or B as prescribed and administered, is being used for a Part D medically accepted indication or is a drug or drug class or its medical use that is excluded from coverage or otherwise

restricted under Part D (Transmucosal Immediate Release Fentanyl (TIRF) and Cialis drugs as an example).

- d) Pharmacy Overrides at Point-Of-Sale:** During the member's transition period, all edits (with the exception of those outlined in section 1.4(c)) associated with non-formulary drugs are automatically overridden at the point-of-sale. Pharmacies can also contact MedImpact's Pharmacy Help Desk directly for immediate assistance with point-of-sale overrides. MedImpact can also accommodate overrides at point-of-sale for emergency fills as described in section 1.7.

Please see section 1.10 for specific information for the processing of non-formulary drugs in the Six Classes of Clinical Concern.

1.5 Transition Fills for New Members in the Outpatient (Retail) Setting

MHP will ensure that in the retail setting, the transition policy provides for a one-time temporary fill of at least a month's supply of medication (unless the enrollee presents with a prescription written for less than a month's supply in which case MHP must allow multiple fills to provide up to a total of a month's supply of medication) anytime during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage. If a brand medication is being filled under transition, the previous claim must also be brand (based on Comprehensive NDC SPL Data Elements File [NSDE] marketing status). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE marketing status).

1.6 Transition Fills for New Members in the LTC Setting

MHP will ensure that in the long-term care setting: (1) the transition policy provides for a one time temporary fill of at least a month's supply (unless the enrollee presents with a prescription written for less) which should be dispensed incrementally as applicable under 42 CFR §423.154 and with multiple fills provided if needed during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage (2) after the transition period has expired, the transition policy provides for a 31-day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days) while an exception or prior authorization is requested and (3) for enrollees being admitted to or discharged from a LTC facility, early refill edits are not used to limit appropriate and necessary access to their Part D benefit, and such enrollees are allowed to access a refill upon admission or discharge.

1.7 Emergency Supplies and Level of Care Changes for Current Members

An Emergency Supply is defined by CMS as a one-time fill of a non-formulary drug that is necessary with respect to current members in the LTC setting. Current members that are in need of a one-time Emergency Fill or that are prescribed a non-formulary drug as a result of a level of care change can be placed in transition via an NCPDP pharmacy submission clarification code. MedImpact can also accommodate a one-time fill in these scenarios via a manual override at point-of-sale.

Upon receiving an LTC claim transaction where the pharmacy submitted a Submission Clarification Code (SCC) value of “18”, which indicates that the claim transaction is for a new dispensing of medication due to the patient’s admission or readmission into an LTC facility, MedImpact’s claims adjudication system will recognize the current member as being eligible to receive transition supplies and will only apply the point-of-sale edits described in section 1.4(c) of this policy. In this instance, MHP does not need to enter a point-of-sale override.

For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, MHP will effectuate a meaningful transition by either: (1) providing a transition process at the start of the new contract year or (2) effectuating a transition prior to the start of the new contract year.

POS logic is able to accommodate option 1 by allowing current members to access transition supplies at the point-of-sale when their claims history from the previous calendar year contains an approved claim for the same drug that the member is attempting to fill through transition and the drug is considered a negative change from one plan year to the next. To accomplish this, POS looks for Part D claims in the member’s claim history that were approved prior to January 1 of the new plan year, and that have the same HICL value as the transition claim. Additionally, if a brand medication is being filled under transition, the previous claim must also be brand (based on NSDE marketing status). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE marketing status).

Negative changes are changes to a formulary that result in a potential reduction in benefit to members. These changes can be associated to removing the covered Part D drug from the formulary, changing its preferred or tiered cost-sharing status, or adding utilization management. The transition across contract year process is applicable to all drugs associated to mid-year and across plan-year negative changes.

1.8 Transition Extension

MHP will make arrangements to continue to provide necessary Part D drugs to enrollees via an extension of the transition period, on a case-by-case basis, to the extent that their exception requests or appeals have not been processed by the end of the minimum transition period and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request). On a case-by-case basis, point-of-sale overrides can also be entered by MHP or by MedImpact (if authorized by MHP to do so) in order to provide continued coverage of the transition drug(s).

1.9 Cost-sharing for Transition Supplies

MHP will ensure that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS enrollees, a sponsor must charge the

same cost sharing for non-formulary Part D drugs provided during the transition that would apply for nonformulary drugs approved through a formulary exception in accordance with 42 CFR §423.578(b) and the same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply if the utilization management criteria are met.

1.10 Six Classes of Clinical Concern

Per CMS guidance, members transitioning to a plan while taking a drug within the six classes of clinical concern must be granted continued coverage of therapy for the duration of treatment, up to the full duration of active enrollment in the plan. Utilization management restrictions (PA and/or Step Therapy), which may apply to new members naïve to therapy, are not applied to those members transitioning to the Medicare Part D plan on agents within these key categories. The six classes include:

- 1) Antidepressant;
- 2) Antipsychotic;
- 3) Anticonvulsant;
- 4) Antineoplastic;
- 5) Antiretroviral; and
- 6) Immunosuppressant (for prophylaxis of organ transplant rejection).

For new members, protected class drug logic will always override transition logic to process the claim. Additionally for new members, a 120-day transition period from their member start date is provided.

1.11 Member Notification

MedImpact provides MHP (via FTP) with two daily files called the Transition Notification “All” File and the Transition Notification “Print” file. The Transition Notification “All” File, which contains claims data and other member information, provides MHP with all of the information needed to contact members and providers regarding transition fills. The Transition Notification “Print” File includes necessary member and claims data needed to produce member notices. This file was created to allow the ability to produce one transition notice per member within a 100-day period where the drug, transition type and applicable drug restrictions are the same.

MHP will send written notice consistent with CMS transition requirements via U.S. first class mail to an enrollee within three business days of adjudication of the temporary transition fill. If the enrollee completes his or her transition supply in several fills, the sponsor is required to send notice with the first transition fill only. The notice must include (1) an explanation of the temporary nature of the transition supply an enrollee has received; (2) instructions for working with the plan sponsor and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the plan's formulary; (3) an explanation of the enrollee's right to request a formulary exception; and (4) a description of the procedures for requesting a formulary exception. For long-term care residents dispensed multiple supplies of a Part D

drug in increments of 14-days-or-less, consistent with the requirements under 42 CFR 423.154(a)(1)(i), the written notice must be provided within 3 business days after adjudication of the first temporary fill. Sponsor will use the CMS model Transition Notice via the file-and-use process or submit a non-model Transition Notice to CMS for marketing review subject to a 45-day review. Sponsor will ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice.

Providing written notification to the member and/or provider in accordance with CMS requirements is ultimately the responsibility of MHP. MHP will contract with MedImpact's print vendor to receive the Transition of Care Notification File and facilitate the fulfillment process of member notification on MHP's behalf. Copies of all notifications will be sent to MHP via secure FTP.

MedImpact and MedImpact's print vendor adhere to all CMS Marketing Guidelines as set forth in Chapter 2 of the Medicare Prescription Drug Benefit Manual.

MHP will make their transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to MHP's web sites and include in pre-and post-enrollment marketing materials as directed by CMS.

MedImpact provides MHP (via FTP) with a file to assist in producing a Prescriber Transition Notification letter to be mailed to the prescriber at the same time the transition letter is mailed to the member. This information is obtained from the existing Transition Notification Files that are sent to plans daily, as described above. The file/letter includes the following:

- Prescriber information
- Member information
- Transition claim details

MHP will use MedImpact's preferred print vendor to mail the Prescriber Transition letters. MedImpact has created a Prescriber Transition Notification letter template and a File Specification document for plans to utilize. The letter template provides physicians with formulary alternatives.

1.12 PDE Reporting

Since this is a CMS required process, any drugs dispensed that qualify under the transition period are reported as covered Part D drugs with appropriate MHP and member cost sharing amounts on the Prescription Drug Event (PDE).

1.13 CMS Submission

MHP will submit a copy of its transition process policy to CMS.

1.14 Pharmacy and Therapeutics Committee Role

The MedImpact Pharmacy and Therapeutics Committee (P&T) maintains a role in the transition process in the following areas:

- 1) The MedImpact P&T committee reviews and recommends all MedImpact formulary step therapy and prior authorization guidelines for clinical considerations; and
- 2) The MedImpact P&T committee reviews and recommends procedures for medical review of non-formulary drug requests, including the MedImpact exception process.

1.15 Exception Process

MedImpact follows an overall transition plan for Medicare Part D members; a component of which includes the exception process. MedImpact's exception process integrates with the overall transition plan for these members in the following areas:

- 1) MedImpact's exception process complements other processes and strategies to support the overall transition plan. The exception process follows the guidelines set forth by the transition plan when applicable.
- 2) When evaluating an exception request for transitioning members, the MHP exception evaluation process considers the clinical aspects of the drug, including any risks involved in switching, when evaluating an exception request for transitioning members.
- 3) The exception policy includes a process for switching new Medicare Part D plan members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

MHP will make available prior authorization or exceptions request forms upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on MHP web sites.

1.16 Transition of Care for State Covered Drugs

MHP has the option to apply transition of care logic to non-Part D drugs, drugs covered by the state in a member covered by both Medicare and Medicaid. The logic is similar to the Part D functionality and allows new enrollees a transition fill for a defined period of time (e.g., 90 day minimum) for a specific day supply limit (e.g., 90 day supply) for a specific list of drugs. MedImpact obtains plans' transition policy requirements on an annual basis via the Implementation Questionnaire (IQ). The non-Part D drugs will be coded based on plan selection on the annual IQ. These transition claims are also included in the daily notification files used for member and prescriber letter generation. Additionally, individual state requirements for transition time periods are reviewed and implemented if different.

REGULATIONS AND STANDARDS:

- [Federal Register, Vol. 76, No. 73, Part II, p. 21526](#)
- 42 CFR [§423.120\(b\)\(3\)](#), [§423.153\(b\)](#), [§423.154](#)
- [Chapter 6 Medicare Prescription Drug Benefit Manual](#)
- [Medicare Marketing Guidelines](#)
- PBM Implementation Questionnaire(IQ)
- Medicare Part D Coverage Determination documentation
- PBM Transition Policy Documents 910-PL-1013 v.18

REVIEW CYCLE:

This policy will be reviewed and revised as needed to incorporate changes in applicable laws, regulations, and other program requirements; however, review will occur no less than on an annual basis.

Review Date	Revised Date	Effective Date
05/2021		1/1/2022
05/2022	05/2022	1/1/2023
05/2023	05/2023	1/1/2024
05/2024	05/2024	1/1/2025
05/2025	05/2025	1/1/2026