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	Chapter 6 Medicare Prescription Drug Benefit Manual
	Medicare Marketing Guidelines
	Transition of Care Notification File
	Implementation Questionnaire (IQ)
480-PD-1007	Medicare Part D Coverage Determinations
(GD)Guide=Overview | (PL)Policy=Rule | (PD)Procedure=Action | (FD)Flow Diagram=Visual (WI)Work Instruction=Details | (FM)Form=Predefined | (RD)Reference Document=Supporting	

REQUIRED APPROVALS (Process Owner and management approval required)	
Approvers	**Title**
Toni Adepoju	Program Manager
Tine MacLochlainn	Manager Medicare Programs and Services
Susan Scott	Director GPS
Carrie Armstrong	VP, Government Programs Services

Approvals: Time-stamped approvals are recorded electronically and stored via Compliance 360 (C360). Process Management inserts the Approval Audit Record into document before it is finalized and published. Annual Review Approval Audit Records to indicate no process changes of current version were necessary are inserted on last page.

Approver Name	Job Title	Approval Date	Title	Process Document Number	Version	EffectiveDate
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DOCUMENT DEFINITIONS (When using definition in document Capitalize First Word)	
Word/Term	**Definition**
	See Appendix A

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PURPOSE	The purpose of this policy is to describe MedImpact's 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 in a manner that is timely, accurate and compliant with all relevant CMS guidance and requirements as per 42 CFR §423.120(b)(3). Scope: This policy is necessary with respect to: (1) new enrollees into prescription drug plans following the annual co-ordinated 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. Applicable personnel in Government Programs, Health Services and Operations follow this policy. This document is intended to describe processes necessary to meet regulatory requirements as of the effective date above.

1. Policy

1.1 Overview

MedImpact supports Plans 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.

MedImpact 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 a Plan 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.

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1.2 Transition Population

MedImpact 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 co-ordinated 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 Plans 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. MedImpact 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. Plans 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, Plans have 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 for Plans that do not utilize the 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 the health plan 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.

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- 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.

MedImpact's default logic aligns with guidance issued by CMS stating Plans 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.

Plans who continue to utilize Segment Code 05 of the Type 24 for setting member's transition start date are ultimately responsible for indicating which of their members should be in a transition period. Plans must place their 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 then calculated from the Member plan Part D Start Date with the plan.

MedImpact 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 non-formulary drug and an ongoing prescription for a non-formulary drug at the point-of-sale.

1.4 Implementation Statement

a) 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 the plan 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.

b) Pharmacy Notification at Point-Of-Sale: MedImpact 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.

c) Edits During Transition: MedImpact 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.

MedImpact 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).

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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

MedImpact 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 the Part D Sponsor 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

MedImpact 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, the Plan does not need to enter a point-of-sale override.

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For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, the Sponsor 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

Sponsor 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 the Plan or by MedImpact (if authorized by the Plan to do so) in order to provide continued coverage of the transition drug(s).

1.9 Cost-sharing for Transition Supplies

MedImpact 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 non-formulary 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 as long as the drug remains on formulary. 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

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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 Plans (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 Plans 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.

Sponsor will send written notice consistent with CMS transition requirements via U.S. first class mail to 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 the Plan. Plans also have the option to contract with MedImpact's print vendor to receive the Transition of Care Notification File and facilitate the fulfillment process of member notification on Plan's behalf.

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.

Sponsor will make their transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to sponsor web site and include in pre-and post-enrollment marketing materials as

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directed by CMS.

MedImpact provides plans (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

Plans are given the option to use MedImpact's preferred print vendor to mail the Prescriber Transition letters or to mail the notification on their own. 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 Plan and member cost sharing amounts on the Prescription Drug Event (PDE).

1.13 CMS Submission

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

1.14 Pharmacy and Therapeutics Committee Role

For MedImpact's standard formulary Plans only, 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 Plan's exception evaluation process considers the clinical aspects of the drug, including any risks involved in

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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.

Sponsor 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 plan web sites.

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APPENDIX A. GLOSSARY

Term	Description
CMS	Centers for Medicare and Medicaid Services – The agency within the US Federal Government that is charged with the execution and maintenance of the law defining the prescription drug program for senior citizens, the disabled, and the infirm.
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	An 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 Changes	Level of care changes include the following changes from one treatment setting to another: • Enter LTC facility from hospitals or other settings; • Leave LTC facility and return to the community; • Discharge from a hospital to a home; • End a skilled nursing facility stay covered under Medicare Part A (including pharmacy charges), and revert to coverage under Part D; • Revert from hospice status to standard Medicare Part A and B benefits; and • Discharge from a psychiatric hospital with medication regimens that are highly individualized.
LTC	Long Term Care
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.
Plan	Medicare Part D Plan Sponsors who are MedImpact clients.
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.

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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-

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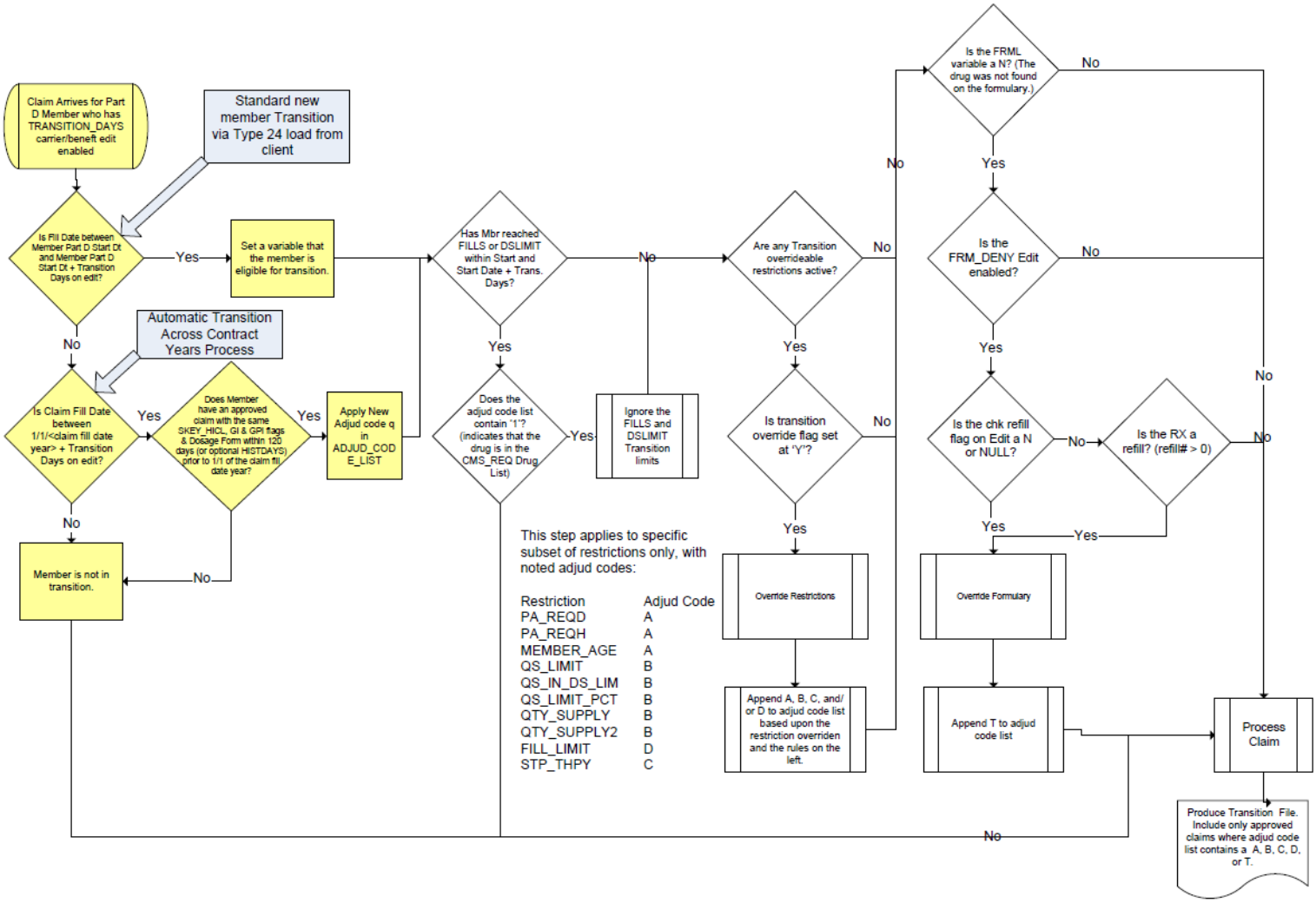
APPENDIX B. POS TRANSITION FLOW DIAGRAM



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Departmental Leader	Carrie Armstrong, VP Government Program Services
Process Owner	Toni Adepoju, Program Manager
Add'l Responsible Party ***(optional)***	Tine MacLochlainn, Manager, Medicare Programs and Services

RELATED EXTERNAL REFERENCES (Use of Links to external references requires additional maintenance of document to ensure accuracy – Use this sparingly)	
Name	**Link**

CHANGE HISTORY / VERSION CONTROL	
Version	**Comments**
	Versions 5.0 through 14.0 retained in C360 Process Library; prior versions retained by Department outside of C360.
15.0	Updated by Shaahida Williams per the CMS 2022 Transition Attestation
16.0	Updated by Shaahida Williams per the CMS 2023 Transition Attestation
17.0	Updated by S. Williams per the CMS 2024 Transition Attestation
18.0	Updated/reviewed T. MacLochlainn 5/2024
18.0	Updated Section 1.10 added phrase "as long as the drug remains on formulary" Toni Adepoju 5/2024
19.0	Reviewed with no content changes (T. Oluwatoni 5/2026)

*no document content/process updates made***:** Audit Record inserted by Process Management before document is finalized and published.

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