

Nascentia Health Plus

Policy and Procedure

Formulary Transition

I. Title

Formulary Transition

II. Section

MA-PD

III. Purpose

To provide an appropriate transition process for members prescribed Part D drugs that are not covered on the plan's Part D formulary.

IV. Policy

Implementation Statement: Nascentia Health Plus maintains within this transition policy a detailed explanation of how Nascentia Health Plus will process transition requests within the adjudication system; how the pharmacy is notified when transition medication is processed at the point of sale; description of edits and explanation of the process pharmacies follow to resolve transition medication edits at the point of sale.

Nascentia Health Plus implements and maintains an appropriate transition process, as approved by CMS and consistent with CMS rules and guidance (42 CFR §423.120(b)(3)). This process allows a meaningful transition for the following groups of Nascentia Health Plus Members whose current drug therapy may not be included on the Nascentia Health Plus Part D formulary:

- (a.) new members entering the Plan at the start of a contract year and/or following the annual coordinated election period;
- (b.) newly eligible Medicare Beneficiaries from other coverage;
- (c.) the transition of members who switch from one plan to another after the start of a contract year;
- (d.) current members affected by negative formulary changes across contract years;
- (e.) members residing in long-term care (LTC) facilities

Nascentia Health Plus submits a copy of its transition policy process to CMS.

This transition policy applies to Non-formulary Drugs, meaning:

- a) Part D drugs that are not on Nascentia Health Plus's formulary, and
- b) Part D Drugs that are on Nascentia Health Plus'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

The transition process allows for medical review of Non-formulary Drug requests, and when

appropriate, a process for switching new Nascentia Health Plus Members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

Nascentia Health Plus delegates formulary management to a contracted PBM whose P&T committee reviews procedures for coverage determination and exceptions, and, if appropriate, a process for switching new Members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

Nascentia Health Plus's delegated PBM Formulary Transition Policy and Formulary Transition SOP is attached below and included as part of this policy which further provides a detailed explanation of meeting each requirement.

Nascentia Health Plus will ensure its PBM has systems capabilities that allow it to provide a temporary supply of non-formulary Part D drugs to accommodate the immediate needs of a Member, as well as, to allow Nascentia Health Plus and/or the Member 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.

Nascentia Health Plus will ensure that the PBM Transition Fill (TF) processing and coding applies point-of-sale (POS) messaging to pharmacies and provides for at least a one-time, temporary 30-day fill, with multiple fills up to a cumulative 30-day supply allowed to accommodate fills for amounts less than prescribed, anytime during the first 90 days of a Member's enrollment in a plan, beginning on the Member's effective date of coverage.

Nascentia Health Plus will ensure that the cost-sharing tier for a temporary supply of drugs provided under this transition process will not exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible Members.

For non-LIS eligible Members:

- (a) Non-formulary Part D drugs transition supply will receive the same cost sharing that would apply for non-formulary drugs approved through a formulary exception in accordance with §423.578(b).
- (b) Formulary transition supply will receive the same cost sharing for a formulary drug subject to utilization management edits provided during the transition that would apply if the utilization management criteria are met.

Nascentia Health Plus will ensure that in the long-term care setting:

- (a) the transition policy will provide for at least a 30 day fill consistent with the applicable dispensing increment in the long-term care setting (unless the member presents with a prescription written for less), with refills provided if needed during the first 90 days of a member's enrollment in a plan, beginning on the member's effective date of coverage;
 - (b) after the transition period has expired or the days supply is exhausted, the
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transition policy will provide for at least a 31-day emergency supply of non-formulary Part D drugs (unless the member presents with a prescription written for less than the 31 days) while an exception or prior authorization determination is pending; and

- (c) for Members being admitted to or discharged from a LTC facility, early refill edits will not be used to limit appropriate and necessary access to their Part D benefit, and such Members will be allowed to access a refill upon admission or discharge.

Nascentia Health Plus will only apply the following utilization management edits during transition at point of sale (POS):

- (a) edits to determine Part A or B versus Part D coverage,
- (b) edits to prevent coverage of non-Part D drugs, and
- (c) edits to promote safe utilization of a Part D drug.

Step therapy and prior authorization edits will be coded to be resolved at POS.

Nascentia Health Plus will allow 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.

Nascentia Health Plus will apply its transition processes to a brand-new prescription for a Non-formulary Drug if a distinction cannot be made between a brand-new prescription for a Non-formulary Drug and an ongoing prescription for a Non-formulary Drug at POS.

Nascentia Health Plus will send written notices consistent with CMS transition requirements as outlined herein.

Nascentia Health Plus ensures that prior authorization or exceptions request forms are made available upon request to both Members and prescribing physicians via mail, fax, email, and are available on plan web sites.

Nascentia Health Plus will extend its transition policy across Contract Year should a Member enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.

Nascentia Health Plus will make general transition process information available to Members via the Medicare Prescription Drug Plan Finder link to its web site as well as in pre- and post-enrollment materials.

Nascentia Health Plus will provide a process for Members to receive necessary Part D drugs 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).

Nascentia Health Plus will implement the transition process for renewing Members whose drugs will be affected by negative formulary changes in the upcoming Contract Year. Nascentia Health Plus will offer its transition processes at the start of the new contract year and prior to the beginning of the Contract Year for effectuating a transition prior to the start of the new Contract Year.

Nascentia Health Plus will ensure that the PBM will maintain the ability to support routine and CMS-required reporting, as well as the ability to respond to ad hoc requests for:

- (a) denied claim reports; and
- (b) paid TF claim reports for new and renewing Members. It will also maintain the ability to support test TF claim processing in response to ad hoc requests and will regularly review and audit TF program data and system operations to monitor adherence with Part D Transition Fill requirements.

V. Audience

All Nascentia Health employees, students and volunteers.

VI. Relevant Legislation/Guidance

42 CFR §423.120(b)(3)

Chapter 6 of the Medicare Prescription Drug Benefit Manual

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PURPOSE

The purpose of this policy is to describe MedImpact's process for transition of care and ensure that continued drug coverage is provided to new and current Medicare-Medicaid Nascentia Health (MMP) 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).

1. Policy**1.1 Overview**

MedImpact supports Nascentia Health 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 Nascentia Health following the annual co-ordinated election period,
- (2) Newly eligible Medicare beneficiaries from other coverage,
- (3) Enrollees who switch from one Nascentia Health to another after the start of the contract year,
- (4) Current enrollees affected by negative formulary changes across contract years,
- (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) Drugs that are not on a Nascentia Health's formulary, and (2) Drugs that are on a Nascentia Health's formulary but require prior authorization or step therapy, or that have an approved quantity limit lower than the beneficiary's current dose, under a Nascentia Health'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 MMP Nascentia Health 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 Nascentia Health covers certain excluded drugs under an Enhanced or MMP benefit, those drugs should be treated the same as Part D drugs for the purposes of the transition process.

1.2 Transition of Care for State Covered Drugs

Nascentia Health have the option to apply transition of care logic to non-Part D drugs, drugs covered by the state. 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 Nascentia Health's transition policy requirements on an annual basis via the Implementation Questionnaire (IQ). The non-Part D drugs will be coded based on Nascentia Health's 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.

1.3 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 MMP Nascentia Health's formulary, it will effectuate a meaningful transition for: (1) new enrollees into prescription drug Nascentia Health following the annual co-ordinated election period, (2) newly eligible Medicare Medicaid beneficiaries from other coverage, (3) enrollees who switch from one Nascentia Health 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.

1.4 Transition Period

MedImpact allows Nascentia Health 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 Nascentia Health. The 90 days are calculated from the member's Nascentia Health start date. MedImpact will extend its transition policy across contract years should a beneficiary enroll in a Nascentia Health with an effective enrollment date of either November 1 or December 1 and need access to a transition supply. Nascentia Health 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, Nascentia Health have two options for setting the member's transition start date; utilizing MedImpact's system default logic or continue populating Segment code 5 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 Nascentia Health 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 Nascentia Health 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 Nascentia Health , MediImpact's default process will analyze the change in group number assignment to determine if it results in a new CMS contract and/or Nascentia Health 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
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member's transition start date will remain as is and will not be updated.

- If the change in group number resulted in a new Nascentia Health 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 Nascentia Health 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 Nascentia Health must effectuate transition for members that change either CMS contract or Nascentia Health, irrespective of whether or not the change resulted in a new Part D formulary assignment.

Nascentia Health who continue to utilize Segment 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.

Nascentia Health must place their members into a transition period by populating the appropriate Member Nascentia Health MMP Start Date in Segment Code 5 of the Type 24 File (Member Attribute Load File), or indicate a preference to utilize the Part D Transition of Care start date. If using the MMP start date indicated in Segment Code 5 of the Type 24 file, the transition period (90-day minimum) is then calculated from the Member Nascentia Health MMP Start Date with the Nascentia Health.

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.

Please see section 1.11 for specific information for the processing of non-formulary drugs in the Six Classes of Clinical Concern.

1.5 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 Nascentia Health 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 NCPDPreject and approval codes developed during the External Codes List (ECL) process. Pharmacy messages are modified based on industry standards.
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- c) **Edits During Transition:** MediImpact 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 drug. Step therapy and prior authorization edits must be resolved at point-of-sale.
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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).

- d) **Pharmacy Overrides at Point-Of-Sale:** During the member's transition period, all edits (with the exception of those outlined in section 1.5(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 1.8.

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

New York FIDA-IDD Nascentia Health s:

MedImpact will ensure that in outpatient settings, a temporary supply, consistent with 42 CFR §423.120(b)(3), when the Participant requests a refill of a non-formulary drug (including drugs that are on the FIDA-IDD Nascentia Health 's formulary but require Prior Authorization or step therapy under the FIDA-IDD Nascentia Health 's Utilization management rules) that otherwise meets the definition of a Part D drug during the first ninety (90) days following Enrollment in the FIDA-IDD Nascentia Health .

Medicare Part D and other state MMP Nascentia Health s:

Nascentia Health will ensure that in the outpatient 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 Nascentia Health 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 Nascentia Health , 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).

1.7 Transition Fills for New Members in the LTC Setting

New York FIDA-IDD Nascentia Health s:

MedImpact will ensure that in long-term care settings, a temporary supply of non-formulary drugs including drugs that are on the FIDA-IDD Nascentia Health 's formulary but require Prior Authorization or step therapy under the FIDA-IDD Nascentia Health 's Utilization management rules that otherwise meet the definition

of a Part D drug, consistent with 42 CFR §423.120(b)(3).

Medicare Part D and other state MMP Nascentia Health s:

Nascentia Health 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 Nascentia Health , beginning on the enrollee's effective date of coverage (2) after the transition period has expired, the transition policy provides for a 31-day 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.

1.8 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 1.5(c) of this policy. In this instance, the Nascentia Health does not need to enter a point-of-sale override.

1.9 Transition Across Contract Years

For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, the Nascentia Health 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 Nascentia Health year to the next. To accomplish this, POS

looks for claims in the member's claim history that were approved prior to January 1 of the new Nascentia Health 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 drug classification). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE drug classification).

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 Nascentia Health -year negative changes.

1.10 Transition Extension

Nascentia Health will make arrangements to continue to provide necessary 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 Nascentia Health or by MediImpact (if authorized by the Nascentia Health) in order to provide continued coverage of the transition drug(s).

1.11 Cost-sharing for Transition Supplies

MediImpact 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 Nascentia Health 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.

1.12 Six Classes of Clinical Concern

Per CMS guidance, members transitioning to a Nascentia Health 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 Nascentia Health 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 MMP Nascentia Health 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 transNascentia Health t rejection).
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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.

1.13 Member Notification

MedImpact provides Nascentia Health (via FTP) with two daily files called the Transition Notification "All" File and the Transition Notification "Print" file. The Transition Notification File, which contains claims data and other member information, provides Nascentia Health 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 with a 100 day period where the drug, transition type and applicable drug restrictions are the same.

Nascentia Health will send written notice 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 Nascentia Health is required to send notice with the first transition fill only. The notice must include (1) an exNascentia Health ation of the temporary nature of the transition supply an enrollee has received; (2) instructions for working with the Nascentia Health Nascentia Health and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the Nascentia Health 's formulary; (3) an exNascentia Health ation 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 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. Nascentia Health 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. Nascentia Health 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 Nascentia Health . Nascentia Health 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 Nascentia Health '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.

Nascentia Health will make their transition policy available to enrollees via link from Medicare Prescription Drug Nascentia Health Finder to Nascentia Health web site and include in pre-and post-enrollment marketing materials as directed by CMS.

1.14 Provider Notification

MedImpact provides Nascentia Health (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 Nascentia Health daily, as described above. The file/letter includes the following:

- Prescriber information
- Member information
- Transition claim details

Nascentia Health 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 Nascentia Health to utilize. The letter template provides physicians with formulary alternatives.

1.15 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 Nascentia Health and member cost sharing amounts on the Prescription Drug Event (PDE).

1.16 CMS Submission

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

1.17 Pharmacy and Therapeutics Committee Role

For MedImpact's standard formulary Nascentia Health 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.

1.18 Exception Process

MedImpact follows an overall transition Nascentia Health for MMP members; a component of which includes the exception process. MedImpact's exception process integrates with the overall transition Nascentia Health for these members in the following areas:

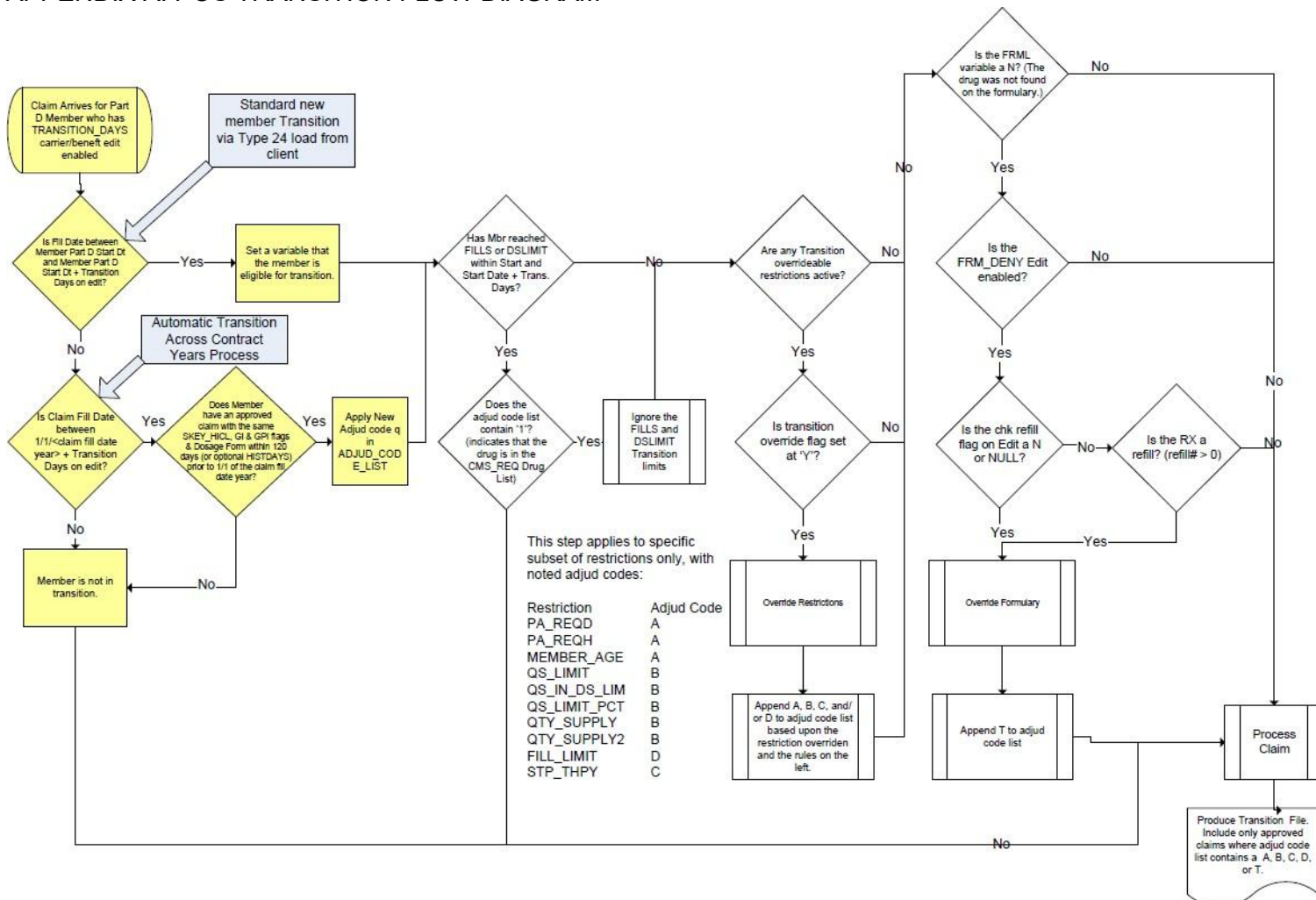
- 1) MediImpact's exception process complements other processes and strategies to support the overall transition Nascentia Health . The exception process follows the guidelines set forth by the transition Nascentia Health when applicable.
 - 2) When evaluating an exception request for transitioning members, the Nascentia Health '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 MMP Nascentia Health members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

Nascentia Health 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 Nascentia Health web sites.

APPENDIX A. POS TRANSITION FLOW DIAGRAM



1. Policy

1.1 Overview

MedImpact supports Nascentia Health Plus 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 Nascentia Health Plus following the annual coordinated election period;
- (2) Newly eligible Medicare beneficiaries from other coverage;
- (3) Enrollees who switch from one Nascentia Health Plus 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 Nascentia Health Plus's formulary, and (2) Part D drugs that are on a Nascentia Health Plus's formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary's current dose, under a Nascentia Health Plus'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 Nascentia Health Plus 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 Nascentia Health Plus 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

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 Nascentia Health Plus's formulary, it will effectuate a meaningful transition for: (1) new enrollees into prescription drug Nascentia Health Plus following the annual co-ordinated election period, (2) newly eligible Medicare beneficiaries from other coverage, (3) enrollees who switch from one Nascentia Health Plus 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 Nascentia Health Plus 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 Nascentia Health Plus. The 90 days are calculated from the Nascentia Health Plus start date. MedImpact will extend its transition policy across contract years should a beneficiary enroll in a Nascentia Health Plus with an effective enrollment date of either November 1 or December 1 and need access to a transition supply. Nascentia Health Plus 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, Nascentia Health Plus 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 Nascentia Health Plus 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 Nascentia Health Plus or that are re-enrolling but had a breakin 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 Nascentia Health Plus, MedImpact's default process will analyze the change in group number assignment to determine if it results in a new CMS contract and/or Nascentia Health Plus assignment.

- If the change in group number resulted in a new CMS contract assignment, the
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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 Nascentia Health Plus 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 Nascentia Health Plus 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 Nascentia Health Plus must effectuate transition for members that change either CMS contract or Nascentia Health Plus, irrespective of whether or not the change resulted in a new Part D formulary assignment.

Nascentia Health Plus 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. Nascentia Health Plus must place their members into a transition period by populating the appropriate Member Nascentia Health Plus 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 Nascentia Health Plus Part D Start Date with the Nascentia Health Plus.

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 Nascentia Health Plus 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 NCPDPreject 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).

- 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 Nascentia Health Plus 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 Nascentia Health Plus, 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 Nascentia Health Plus, 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 Nascentia Health Plus 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, the Nascentia Health Plus 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 Nascentia Health Plus 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 Nascentia Health Plus 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 Nascentia Health Plus-year negative changes.

1.8 Transition Extension

Nascentia Health Plus 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 Nascentia Health Plus or by MedImpact (if authorized by the Nascentia Health Plus 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 Nascentia Health Plus 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 Nascentia Health Plus 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 Nascentia Health Plus 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 Nascentia Health Plus 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 Nascentia Health Plus (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 Nascentia Health Plus 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.

Nascentia Health Plus 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 Nascentia Health Plus 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 Nascentia Health Plus and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the Nascentia Health Plus'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. Nascentia Health Plus 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. Nascentia Health Plus 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 Nascentia Health Plus. Nascentia Health Plus also have the option to contract with MedImpact's print vendor to receive the



Policy

Transition of Care Notification File and facilitate the fulfillment process of member notification on Nascentia Health Plus'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.

Nascentia Health Plus will make their transition policy available to enrollees via link from Medicare Prescription

Drug Nascentia Health Plus Finder to Nascentia Health Plus web site and include in pre- and post-enrollment marketing materials as directed by CMS.

MedImpact provides Nascentia Health Plus (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 Nascentia Health Plus daily, as described above. The file/letter includes the following:

- Prescriber information
- Member information
- Transition claim details

Nascentia Health Plus 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 Nascentia Health Plus 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 Nascentia Health Plus and member cost sharing amounts on the Prescription Drug Event (PDE).

1.13 CMS Submission

Nascentia Health Plus will submit a copy of its transition process policy to CMS.

1.14 Pharmacy and Therapeutics Committee Role

For MedImpact's standard formulary Nascentia Health Plus 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 steptherapy 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 Nascentia Health Plus for Medicare Part D members; a component of which includes the exception process. MedImpact's exception process integrates with the overall transition Nascentia Health Plus for these members in the following areas:

- 1) MedImpact's exception process complements other processes and strategies to support the overall transition Nascentia Health Plus. The exception process follows the guidelines set forth by the transition Nascentia Health Plus when applicable.
- 2) When evaluating an exception request for transitioning members, the Nascentia Health Plus's 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 Nascentia Health Plus membersto therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

Nascentia Health Plus 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 Nascentia Health Plus web sites.

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: <ul style="list-style-type: none"> • 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 Nascentia Health Plus. |
| Nascentia Health Plus | Medicare Part D Nascentia Health Plus Nascentia Health Plus 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 Nascentia Health Plus to ensure safe, efficacious and cost- |
|----|--|

APPENDIX B. POS TRANSITION FLOW DIAGRAM

