Puerto Rico Pharmacy Network Provider Manual

Table of Contents

Section 1. Introduction

MC-Rx is a pharmacy benefit manager (PBM) with headquarters in Caguas, Puerto Rico. Established in 1998, MC-Rx's mission is to provide unique, tailored, flexible, and comprehensive pharmacy administration programs for corporations, managed care organizations, employee benefit managers, Employer Group Waiver Plans, governmental healthcare organizations, and other entities.

In 2009, MC-Rx became the first Puerto Rican PBM to attain the URAC Pharmacy Benefit Management Accreditation. Since then, MC-Rx has consistently complied with URAC standards, which help promote healthcare quality through its accreditation and certification programs. This accreditation reaffirms MC-Rx's commitment to the highest quality and safety standards in healthcare services.

In May of 2018, MC-Rx successfully partnered with ProCare Rx; a partnership that provides additional benefits such as a state-of-the-art claims adjudication system, proprietary client service programs, sound technological tools and applications, and a deeper understanding of the Commercial, Medicare, and Medicaid lines of business from the mainland's perspective.

MC-Rx provides pharmacy benefit design and management services, administration of pharmacy networks, and a sophisticated, state-of-the-art claims processing system. Programs such as formulary design and formulary management strategies, drug utilization review, clinical service initiatives, healthcare management programs, rebate administration, and value-based contracting allow MC-Rx to partner with its clients to effectively manage the cost of providing prescription benefits to their

members.

This Pharmacy Provider Manual provides a summary of MC-Rx's policies and procedures and establishes the quality of service standards expected from participating Pharmacy Network providers. It is also intended to serve as a working tool to guide Pharmacy staff through day-to-day transactions - such as claims processing and prior-authorizations management - and provides important information to better understand the processes related to these operations.

Section 2. General Information

2.1. About the Pharmacy Providers Manual

The purpose of the Pharmacy Provider Manual ("Manual") is to explain MC-Rx's administrative and compliance policies and procedures with respect to its Pharmacy Network. MC-Rx will update this Manual as necessary, at its sole discretion, but at least once a year. This version of the Manual supersedes all previous versions of the Manual. MC-Rx posts the most current version of the Manual at www.mc-rx.com.

Between revisions, MC-Rx will keep Pharmacy Participants posted with relevant instructions, notices, information, and supplements or changes to this Manual to promote high quality and a consistent standard of care. Communications will be sent to the Pharmacy email address and/or fax number listed on file. This is one more reason to keep your records with MC-Rx up to date. All communications will also be available on our website at

www.mc-rx.com, and all updated instructions or procedures communicated by this means will supersede instructions or procedures listed in the Manual.

This Manual applies to all lines of business, including, but not limited to Medicare, Medicaid, and commercial business.

Information included in the Manual is considered proprietary and is intended for use only by duly credentialed MC-Rx Pharmacy Network providers. Providers cannot copy, reproduce, distribute, or share information included in the manual except as authorized by the provider agreement.

Appendixes included in this Manual as references are substantially representative of the forms detailed throughout, and may be updated or modified by MC-Rx at its sole discretion, without the need to revise the representative form as attached hereto.

2.2. Contact Us

Your partnership in delivering pharmaceutical care within our Pharmacy Network is highly valued. Please send questions, suggestions regarding the performance of the organization, or other information regarding the MC-Rx Pharmacy Providers Manual to:

MC-Rx
Attention: Pharmacy Services Manager
Call Box 4908
Caguas, Puerto Rico 00726

Section 3. Contact Information

3.1. MC-Rx Offices

Location: **Road #1, Km. 33.3, Bo. Bairoa, Angora Industrial Park, Lot #4, Caguas, Puerto Rico 00725**

Mailing Address: **P.O. Box 4908, Caguas, Puerto Rico 00726**

Telephone: **787-286-6032**

Website: **www.mc-rx.com**

Georgia Headquarter:

Location: **1267 Professional Pkwy, Gainesville, GA 30507**

Mailing Address: **1267 Professional Pkwy, Gainesville, GA 30507**

Telephone: **1-800-377-1037**

Website: **www.procarerx.com**

3.2. PR- Pharmacy Network (Credentialing and Re-credentialing)

Office Hours: **Monday – Friday 8:00 a.m. – 5:00 p.m.**

Telephone: **787-286-6032, ext. 3147**

Fax: **787-653-2856**

Email: **PharmacyContracting@mc-rx.com**

MC-Rx's Pharmacy Network provides pharmacies with administrative support to ensure compliance with applicable policies, regulations and laws, and contractual agreements. This is a continuous, collaborative process that

promotes sound business practice and ensures the utmost quality service standards for members.

The Pharmacy Network support staff will assist you with questions regarding Pharmacy Network contracts, requirements for becoming a Pharmacy Network member (Credentialing), and Re-credentialing process, among other Pharmacy Network issues.

3.3. Pharmacy Services Call Center

Office Hours: **24 hours / 7 days a week**

Telephone: **1-888-311-6001/1-866-411-6001**

Fax: **787-653-2814**

MC-Rx's Pharmacy Services Call Center – the Pharmacy Call Center – is staffed with knowledgeable, fully-bilingual pharmacy technicians to effectively assist during your call. The Call Center Support Representatives will assist with information regarding a member's benefit plan (eligibility, co-payments, deductibles, or co-insurance), or call to clarify alert messages, or confirm if a physician is a participant provider, among other important information to help during the processing of a claim. Keep these numbers at hand for assistance with your day-to-day claims management needs.

3.4. Prior Authorization (PA) Call Center

Office Hours: **24 hours / 7 days a week**

Telephone: **1-866-999-6221 / 1-866-989-6221**

There are designated fax numbers per plan sponsor. Note that these numbers are to be used for clients' lines of business in which MC-Rx is the designated PBM.

FOR THESE CLIENTS	USE THIS FAX
MAPFRE, AMGEN, BMS, WALMART, CONWASTE	1 (866) 245-5057
ADAP HIAP	1 (866) 785-0069

3.5. Benefit Integrity Program

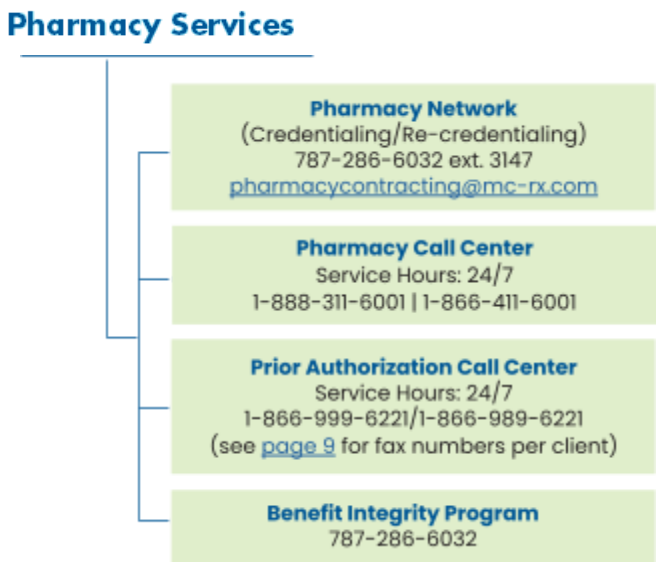
Office Hours: **Monday – Friday 8:00 a.m. – 5:00 p.m.**

Telephone: **787-286-6032**

FWA Hotline: **787-286-6032, ext. 3800**

FWA Email: compliance@mc-rx.com

Fax: **787-653-2846**



Section 4. Defined Terms

The following terms and definitions are used throughout this document and are derived from the Puerto Rico Pharmacy Law, the Pharmacy Services Agreement, CMS regulations, MC-Rx Policies and Procedures for Pharmacy Network Members, and other program documents. These definitions provide relevant background information when reading the Manual.

Average Wholesale Price or AWP

As used in the Pharmacy Network Services Agreement (PNSA), AWP or Average Wholesale Price refers to the price defined and distributed by **Medi-Span**, **First Data Bank (FDB),** or other nationally recognized database. The price is based on the **National Drug Code (NDC)** number of the dispensed medication.

Carrier/Organization

The insurance company, insurer and insurance carrier. Refer to the Client.

Claim

Invoice and/or electronic claim issued by the Participating Pharmacy and submitted to MC-Rx acting as the pharmacy benefit manager for its clients. The claim contains information on the medications dispensed to a member under the pharmacy benefits services coverage.

Client

Any entity that receives pharmacy benefit management services from MC-Rx, and on behalf of whom MC-Rx will process claims from the Participating Pharmacy.

CMS

Stands for Centers for Medicare and Medicaid Services. A federal agency within the United States Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid, the Children's Health Insurance Program (CHIP)

Coordination of Benefits (COB)

Coordination of benefits between two drug benefit plans, whether they are private or a mix of public and private coverage.

Copayment

That portion of the total charge for each covered medication that a member is required to pay to the pharmacy in accordance with that member's drug benefit plan, whether designated as a copayment or deductible.

Covered Medication

Prescription drugs, supplies, and other items prescribed by an authorized, licensed practitioner that are covered by a drug benefit plan.

Credentialing and Re-credentialing

Refers to the processes through which the pharmacy benefit manager validates the credentials of pharmacies and any person with an ownership, controlling interest, or

managing employees within their networks. This is a necessary measure to ensure they are in good standing with all applicable state and federal laws and meet quality performance standards.

Dispensing Fee

The amount established by the Client as payment per claim that has been dispatched by the Participating Pharmacy.

Dispensing of Medications

The act of delivery of any medication and professional counseling, including but not limited to, the contents, therapeutic value, uses and risks of the same. It also includes the interpretation of the prescription and the composition or preparation, packing, and labeling of the medication; this act will be done by a duly licensed pharmacist.

Good Pharmacy Practices

Minimum requirements that every Participating Pharmacy must comply with in order to ensure efficiency, quality, and safety in the services rendered. Considers all the accreditation and licenses requirements, as well as the physical facilities of the establishment, materials, reference books, and equipment.

Maximum Allowable Cost (MAC List)

List of commercially available generic drugs and their associated prices maintained by MC-Rx that will be reimbursed to Participating Pharmacy for dispensing services provided to Eligible Members.

Medication

Any drug, chemical product, or pharmaceutical preparation of animal or vegetable

origin, of simple or compound formulation, for internal or external use in an adequate dosage form to be dispatched and administered to humans. The same is understood to be used to cure, diagnose, prevent, or alleviate diseases.

Member, Beneficiary, or Subscriber

An individual and his/her dependents who are entitled to the Pharmacy Benefits Services as defined in the Pharmacy Benefits Services Coverage.

Participating Pharmacy Provider or Participating Pharmacy

A group of pharmacies that have contracted with MC-Rx to provide covered products and services to members. In this Manual, the terms Pharmacy Provider, Pharmacy Network, Pharmacy Network Provider and Participating Pharmacy Provider are equivalent.

Pharmacy Benefit Manager

The party responsible for administering the drug benefit plan details with the client on behalf of the drug benefit plan members.

Pharmacy Benefit Services Coverage

A pharmacy benefit insurance program developed by a client for each of its members.

Pharmacy Network Services Agreement

Refers to the contract document including its attachments and the Pharmacy Provider Manual that contains the mutual covenants between MC-Rx and the Participating Pharmacy.

Prescriber

A physician, dentist, podiatrist, or veterinarian authorized to practice in Puerto Rico, who issues the prescription or prescription for dispensing medication to a patient with whom he or she maintains a valid professional relationship.

Prescription or Medical Prescription

Original written order, issued and signed by a doctor such as the doctor, dentist, podiatrist or when it is for use in animals, by a veterinarian, in the normal course and legal exercise of their profession in Puerto Rico, so that certain medications or devices are dispensed in compliance with the provisions of this Act. It will be mandatory for the physician who issues said order, to fulfill the professional responsibility of a true doctor-patient relationship.

Signature Registry or Signature Log

Form used to log services rendered to eligible members. The eligible member, or his/her representative, registers his/her signature and writes down the number of a second identification document with a photograph.

Telepharmacy

The practice of Telepharmacy is governed by the respective state's definition of "practice of pharmacy" unless the governing state specifically provides an exception and in which the exception will govern. Electronic transaction data in lieu of physical pharmacy records may be accepted or in accordance with state law.

Universal Claims Form (UCF)

Form universally accepted and used to provide information on a medical

prescription that has been processed for a subscriber or eligible member, and to attest that the subscriber or eligible member has received the prescribed medications in accordance with the pharmacy benefits services coverage.

Section 5. MC-Rx Pharmacy Network Providers

Credentialing and re-credentialing initiatives exist to ensure that participating pharmacies are in good standing with all applicable state and federal laws and meet quality performance standards. The applicant pharmacy must comply with the credentialing and re-credentialing requirements established by MC-Rx, and agrees to provide MC-Rx with documentation and other relevant information that may be required in association with such procedures.

MC-Rx's Pharmacy Network provides participating pharmacies with the administrative support to ensure compliance with applicable policies, regulations and laws, and contractual agreements. This is a continuous, collaborative process that promotes sound business practices and ensures the utmost quality service standards for members.

The Pharmacy Network support staff will assist participating pharmacies with matters regarding pharmacy network agreements, requisites for becoming a Pharmacy Network member (Credentialing), and maintaining such membership (Re-credentialing process).

5.1. Pharmacy Enrollment and Participation

Pharmacies willing to participate in the MC-Rx Pharmacy Network may

contact MC-Rx at 787-286-6032, ext. 3147. During this call, applicants should be prepared to provide the pharmacy name, corresponding NABP number, contact name, business address, telephone number, fax number and email address. Following this initial contact, the Pharmacy Network support staff will send the applicant the Pharmacy Credential Application form to initiate the credentialing process.

5.2. Pharmacy Credentialing Application

The applicant is required to complete, sign, and return the Pharmacy Credential Application form to the Pharmacy Network (pharmacycontracting@mc-rx.com; fax 787-653-2856).

The application contains a list of pharmacy-specific data and documentation required to submit along with the application form, such as:

- Pharmacy profile information (NABP Number, NPI Number, NABP Number, others)
- Pharmacy hours of operation
- Pharmacy services provided
- Druggist liability insurance
- Pharmacy required licenses
    - Department of Health Pharmacy License
    - Controlled Substances Licensing (ASSMCA, DEA)
    - Biological Products License
- Pharmacists and Pharmacy Technicians
    - Pharmacy Board of Puerto Rico License
    - Continuing Education Registration Certification
    - Pharmacy Technician Certifications

Requirements are specific and may vary some for retail, chain, and specialty pharmacies.

The applicant will complete the application process in full, including the submission of all required documentation, within 180 days from the date on the Pharmacy Credential Application form. If the applicant does not meet this term, he/she will be required to complete a new Pharmacy Credential Application form.

5.3. Credentialing Standards

MC-Rx has a standardized process for pharmacy credentialing. All applicants are subject to a review and verification process of all submitted documentation. For the Department of Health Pharmacy License and for the DEA License, MC-Rx will perform a primary source verification with the corresponding agencies.

MC-Rx has the right to determine whether an applicant meets and maintains the appropriate credentialing standards to participate as a provider in the MC-Rx Pharmacy Network, and to adjust its credentialing standards and policies without notice.

5.3.1. Licensure

The applicant must meet all standards of operation as described in Federal, State, and local laws. The applicant must furnish copies of Federal, State, and local licenses and/or business permits as required by applicable law when applying for enrollment as a provider in the MC-Rx Pharmacy Network. The applicant must be in

good standing with these licenses and/or permits at all times.

Once credentialed to participate in the MC-Rx Pharmacy Network, the provider must notify MC-Rx immediately in writing if its licenses and/or permits are canceled, revoked, suspended, or otherwise terminated. Failure to immediately notify MC-Rx in writing of any such action may result in immediate termination from the Pharmacy Network. Moreover, failure to maintain the appropriate licenses and/or permits will result in immediate termination from the MC-Rx Pharmacy Network.

Furthermore, the Participating Pharmacies are responsible for ensuring that its pharmacists and pharmacy technicians comply with all professional credentials and with good pharmacy practices. MC-Rx shall not be liable for claims arising from violations of such practices.

5.3.2. Insurance

When applying for enrollment as a provider in the MC-Rx Pharmacy Network, applicants must furnish copies of policies for general and professional liability insurance, including malpractice and **druggist liability, at a minimum amount of $500,000.00 or greater**, if otherwise required by Law. The applicant must maintain these policies in amounts necessary to ensure that the provider and any of its personnel are insured against any claims for damages arising from the provision of pharmacy services at all times.

Once credentialed to participate in the MC-Rx Pharmacy Network, the provider must notify MC-Rx immediately in writing if its insurance is canceled, suspended, or otherwise terminated. Failure to immediately notify MC-Rx in writing of any such termination of insurance coverage may result in immediate termination from the pharmacy network. Additionally, failure to maintain the minimum coverage will result in immediate termination from the pharmacy network.

5.3.3. Drug Enforcement Agency Controlled Substance Registration Certificate

The applicant must furnish a copy of Drug Enforcement Agency (DEA) Controlled Substance Registration Certificate as required by applicable law when applying for enrollment as a provider in the MC-Rx Pharmacy Network. The applicant must keep registration in good standing at all times.

Once credentialed, the provider must notify MC-Rx immediately in writing if the DEA registration certificate is canceled, revoked, suspended, or otherwise terminated. Failure to immediately notify MC-Rx in writing of any such action may result in immediate termination from the pharmacy network. Furthermore, failure to maintain the DEA registration certificate may result in immediate termination from the MC-Rx Pharmacy Network.

Section 6. Pharmacy Inspections

Once all documentation has been submitted and MC-Rx confirms that pharmacy credentials are in good standing, a Pharmacy Credentialing Specialist will schedule an onsite visit to inspect the pharmacy facilities. This visit will be scheduled within fifteen (15) working days after MC-Rx has received and reviewed all required documentation.

During the visit, MC-Rx's staff will evaluate that the pharmacy has in place the operational structure needed to provide a high quality of service, including, but not limited to:

- The quality, safety, and distribution of the pharmacy's drug inventory
  - Reasonable availability and variety of pharmaceutical products
  - No expired drugs on shelf
  - Refrigerator temperature register
  - "No food" sign on refrigerator used for biological products
  - Area to prepare compounds and infusions therapies
  - Controlled substances CII adequate storage
- Pharmacy service hours, pharmacy staff, and work shifts
- Existing equipment (telephone, fax machine, computer, paper shredder, refrigerator for biological drugs, permanent and automatic electric generator, etc.)
- Access to an Online Claims Operating System
- Signature registry log
- Pharmacy staff (Pharmacists and Technicians) licenses and other pharmacy certifications are displayed

- Adequate access, including parking facilities for handicapped persons
- Waiting area for customers
- Internal policies and procedures for the adequate handling of PHI, disposition of expired medications, among others

After the inspection is completed and the pharmacy complies with all requirements, the Pharmacy Credentialing Specialist will provide orientation to the new pharmacy, which includes a Welcome Package containing all necessary documentation on updates of network activities, changes to fee schedules, benefit, eligibility, formulary, dispute, appeals on the Pharmacy Manual.

6.1. Contracting Terms

After inspection, MC-Rx will send a Pharmacy Network Services Agreement and applicable addendums to those applicants who have complied with all established credentialing requirements and criteria.

The Agreement between MC-Rx and a Participating Pharmacy will be valid for the period of time established and agreed upon between the parties. The Agreement will continue to renew for a similar term as long as the Participant Pharmacy complies with all credentialing requirements and with all laws and regulations established by the Commonwealth of Puerto Rico.

6.2. Pharmacy Network Participation

Applicants become eligible to participate in the MC-Rx networks once the Pharmacy Network Services Agreement is fully executed by both parties. A fully

signed copy of the Pharmacy Network Services Agreement will be sent to the Pharmacy Provider.

All Pharmacies are expected to adhere to the Service Agreement terms. Failure to comply could result in the termination of the Agreement by MC-Rx.

6.2.1 Chain Pharmacies

The execution of a Service Agreement means that all pharmacy locations active at the time the Agreement, and included in the Agreement, are accepted as Participating Pharmacies. Additional pharmacies opened or in operation after the execution date of the Agreement are not covered by the Agreement and are not automatically considered a Participating Pharmacy Provider.

Participating Chain Pharmacy shall notify MC-Rx of all new pharmacy locations as they become available at least sixty (60) days prior to the opening or initiation of operations. Provided that said pharmacy is properly licensed and meets all MC-Rx credentialing requirements, MC-Rx will include the new pharmacy store as a Participating Pharmacy Provider. MC-Rx shall promptly notify Participating Pharmacy in writing of its decision.

6.3. Re-Credentialing

Through the Re-credentialing process, MC-Rx validates that a Participating Pharmacy Provider continues to comply with all requirements stated in the

MC-Rx Pharmacy Network Services Agreement, and operates in accordance with applicable law and contractual obligations.

As a member of the MC-Rx's Pharmacy Network, providers have the responsibility to keep track of the validity of its pharmacy's licenses, permits and certifications. Copies of current documentation must be submitted to MC-Rx's Pharmacy Network to maintain an updated record. [P&P] The Pharmacy Network maintains a year-round monitoring program to identify licenses, permits, and certifications coming up for renewal.

Sixty (60) days prior to the expiration date, MC-Rx will send a written notice indicating which credentials need to be resubmitted to MC-Rx (1st notice). Pharmacy can submit requested documentation by fax (787-653-2856), by e-mail (pharmacycontracting@mc-rx.com) or by mail (MC-Rx, Pharmacy Network, P.O. Box 4908, Caguas, Puerto Rico 00726).

- Pharmacy has sixty (60) calendar days from the date of the written communication (1st notice) to submit the requested documents.
- Reminders will be sent thirty (30) calendar days (2nd notice) and fifteen (15) calendar days (final notice) after to those pharmacies that have not yet submitted the requested credentials.
- If renewal of any of the required documentation is underway, the provider will submit valid evidence of the renewal process. The final and official document will be sent to MC-Rx once the renewal process is completed.
- Non-compliant Pharmacy Providers may be subject to contract termination. A notice of termination will be sent to the pharmacy and to the plan sponsor 30 days before termination is effective. The notice of

termination will convey a requirement for the implementation of a transition process for members.

Section 7. Participating Pharmacy Providers Responsibilities

7.1. Advertising and Promotions

Without the prior written consent of MC-Rx, the pharmacy provider must not use words, symbols, trademarks, or service marks which MC-Rx uses in advertising or promotional materials or otherwise. The provider must not advertise or publicly display that it is a member pharmacy without the prior written consent of MC-Rx. Providers must immediately cease any and all usage of such immediately upon termination of the agreement.

MC-Rx will not advertise or use any trademarks, service marks, or symbols pertaining to a pharmacy network provider without a prior written consent. However, MC-Rx may list providers by name, address, and telephone number for each of its locations in applicable directories, brochures, or other publications for distribution and/or use by MC-Rx's clients or potential clients.

7.2. License Requirements

The Participating Pharmacy and all its employees shall maintain and comply with all licenses required by the Department of Health of the Commonwealth of Puerto Rico, and of the Federal Drug Enforcement Administration, and with any other federal or state agency that governs and regulates the operation of such establishments.

7.3. Reporting of Investigations and Disciplinary Actions

The Pharmacy Provider must notify MC-Rx immediately in writing if its license(s) and/or permit(s) have been suspended or revoked, or are in jeopardy of being suspended or revoked for any reason. The provider must also notify MC-Rx immediately in writing if it receives notice of any proceedings that may lead to disciplinary actions, or if any disciplinary actions are taken against the provider or any of its personnel, including actions by Boards of Pharmacy, the Office of Inspector General (OIG), or other regulatory bodies. Failure to immediately notify MC-Rx in writing of any such investigations or disciplinary actions may result in immediate termination as a provider.

7.4. Changes in Pharmacy Profile

Changes in pharmacy's contact information (address, telephone, fax, e-mails, owner, etc.) should be communicated in writing to MC-Rx's Pharmacy Network. You can request a Pharmacy Profile Update Form by calling 787-286-6032, ext. 3147, or by visiting www.mc-rx.com.

7.4.1 Update Information with NABP

MC-Rx's claim adjudication system incorporates NABP's updates monthly, which include changes to a Participating Pharmacy address, phone number, Pharmacy Chain/PSAO affiliation, and the addition of new pharmacies.

To ensure the integrity of MC-Rx's data, it is the Provider's

responsibility to contact NAPB whenever their information changes. In the event of a conflict between the Pharmacy's information on file and the NABP database, or missing information, MC-Rx may rely on the information on file with NABP regarding the Pharmacy, including for purposes of directories and payments.

7.4.2. Changes in Documentation and Other Information

Provider must notify MC-Rx in writing, **within 10 calendar days**, of any changes in the documentation and other information provided to MC-Rx in connection with any credentialing or re-credentialing initiatives.

7.4.3. Ownership or Control Changes of a Pharmacy Provider

Participating Providers **must immediately notify MC-Rx** in the event of a change of ownership or control.

7.5. Quality Standards

The Participating Pharmacy shall comply with all quality care standards established upon pharmacy practice by regulating organizations. The Participating Pharmacy agrees to offer pharmaceutical services, which include but are not limited to:

- Maintain an adequate inventory of medications
- Reasonable waiting times for the dispensing of medications to Eligible Members
- Offer proper and adequate orientation on the use of medications, including drug interaction profiles

7.5.1. Quality Assurance Programs

MC-Rx highly values and encourages medication safety practices and requires Participating Providers to develop and maintain Quality Assurance (QA) Programs to ensure that services rendered are appropriate, effective and efficient, and result in an improved quality of care for our client's members.

MC-Rx expects Participating Pharmacy Providers to establish policies to:

- Confirm the authenticity of the prescription order
- Reasonably verify the identities of the member, the prescriber, and the caregiver, when applicable.
- Ensure environmental standards that preserve the integrity of the medications while they are stored and shipped
- Ensure proper accounting of controlled substances

QA Programs should provide a structured, systematic process to continuously improve quality of services. It should establish procedures to uncover potential risks while promoting ways to reduce susceptibility to errors, and should include internal medication error identification and reduction methods to ensure proper dispensing of medications - correct drug, dosage, quantity, and treatment directions to the correct eligible member.

Pharmacists are responsible for applying their professional judgment regarding the appropriate drug use.

MC-Rx keeps a registry of pharmacies that have been identified as a potential safety risk for members. These pharmacies will be evaluated by the MC-Rx Quality Assurance Committee for corrective action plans and/or other decisions deemed necessary.

7.6. Pharmacy Good Practices

Participating Pharmacy Providers are responsible for confirming that pharmacists employed by them comply with all professional requirements to exercise their profession and with Good Pharmacy Practices. MC-Rx will not be responsible for claims arising from violations to these standards.

7.7. Code of Conduct & Ethics

The Participating Pharmacy must comply with all applicable laws, regulations, and instructions, which includes having compliance policies and procedures in place and a standard of conduct and ethics that is disseminated among the pharmacy staff.

7.8. Privileged Health Information

Pharmacy Network members shall keep all subscribers or eligible members' medical records in strict confidentiality and will disclose such records only:

- As established in the Service Agreement contract
- If subject to applicable laws and regulations, particularly those contained in the HIPAA Law, or to orders of any legal court

- To another provider who will provide healthcare services to the eligible member
- If the insured member consents in writing

7.9. Confidentiality and Proprietary Rights

All eligible persons' information related to Prescription Drug Benefits and other records identifying eligible persons, shall be treated by the provider as confidential and proprietary. The provider shall comply with all applicable federal and state privacy laws and regulations, including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Health Information Technology for Economic and Clinical Health Act (HITECH), and the implementing regulations thereunder, and may be amended from time to time.

The provider shall not use eligible persons' information for competitive purposes, nor provide such information to others for provider's pecuniary gain. Further, this information shall not be given to any third party, except to the extent that disclosure may be required pursuant to law, or may be permitted by the plan sponsor or by MC-Rx.

All materials relating to pricing, contracts, programs, services, business practices and procedures of MC-Rx are proprietary and confidential. The provider must maintain the confidential nature of such materials. The provider acknowledges that any unauthorized disclosure or use of information or data obtained from or provided by MC-Rx would cause MC-Rx immediate and irreparable injury or loss that cannot be fully remedied by monetary damages.

Accordingly, if a provider should fail to abide by these provisions, MC-Rx is entitled to seek and obtain injunctive relief, monetary remedies, or other such damages as available by law against the provider.

7.10. Court Orders, Subpoenas or Governmental Requests

If MC-Rx receives a court order, subpoena or governmental request relating to a participating provider, MC-Rx may comply with such order, subpoena or request, and the Participating Pharmacy must indemnify and hold MC-Rx harmless for, from, and against any and all costs (including reasonable attorney's fees and costs), losses, damages, or other expenses MC-Rx may incur in connection with responding to such order, subpoena, or request.

7.11. Non Discrimination

MC-Rx requires that its Pharmacy Providers render its services to eligible members under the terms of the contract agreement, without establishing conditions that discriminate or have the effect of discriminating against or among the eligible members.

Pharmacy Providers must comply with applicable federal civil rights laws and will not discriminate against any insured member, exclude people, or treat them differently by reason or the basis of race, color, national origin, age, disability, ethnicity, gender, marital status, sexual orientation, or sex.

Notwithstanding any provision to the contrary, a Participating Pharmacy

Provider may withhold prescription services to an Eligible Member if the Eligible Member fails to pay for services rendered (e.g. deductibles, co-payments); or requests a quantity of medications in excess of prescribed quantities or refill limitations.

7.12. Pharmacy Hours and Conditions

The Participating Pharmacy shall provide its services to the eligible members for a minimum of six (6) days a week and ten (10) hours per day, excluding Sundays.

Other service hour requirements apply to pharmacies in Diagnosis and Treatment Center (CDT) and Specialty Pharmacies.

7.13. Failures in the Communication System

The Participating Pharmacy shall provide services to the Eligible Member at all times during Participating Pharmacy's business hours. In the event that interruptions or failures in communication arise, or if there are failures in the electronic eligibility verification system, the Participating Pharmacy shall take all necessary and reasonable steps to ensure that services to the Eligible Members are not affected (e.g. contact MC-Rx's Pharmacy Providers Call Center to verify the eligibility of a member and coverage). During such events, MC-Rx will reimburse Participating Pharmacy for all Claims approved by MC-Rx's Pharmacy Providers Call Center.

7.14. Eligibility Verification and Identification

The Participating Pharmacy shall be responsible to provide to the Eligible Member those medications as prescribed by the Authorized Physician in accordance with the applicable Pharmacy Benefits Services Coverage of the corresponding Client, and in accordance with the provisions of the Agreement.

As part of said responsibilities, the Participating Pharmacy shall verify the eligibility of the member by means of a personal computer (PC) through the mechanisms of electronic transmission. If for any reason, the Pharmacy is unable to verify such eligibility via electronic transmission, it shall use commercially reasonable efforts to confirm such eligibility by contacting MC-Rx's Pharmacy Providers Call Center.

MC-Rx shall not be responsible for any claim arising during the validity of the Agreement or after its termination if a Participating Pharmacy does not verify the eligibility of a member or the coverage of a certain medication, and renders services to a person that does not have the right to pharmacy services as provided in the Pharmacy Benefits Coverage of the corresponding client.

The Participating Pharmacy shall further verify the identity of the Eligible Member through the use of an identification document with photograph, as well as verifying the signature of the Eligible Member against the signature that appears on the identification card issued by the Client.

7.15. Claims

The Pharmacy Provider shall submit its claims for the reimbursement of

payments for medications and dispensing fee through the use of a personal computer and using the mechanisms of electronic transmission. In case the Participating Pharmacy is unable, for any reason, to invoice through electronic transmission, it shall submit to MC-Rx all the information related to the services rendered using the Universal Claims Form (UCF).

Such information shall be submitted no later than sixty (60) days from the date on which the services were rendered. Those claims submitted subsequent to sixty (60) days after the services were rendered to the Eligible Member shall not be paid by MC-Rx.

7.16. Medications Not Covered

The Participating Pharmacy shall inform the Eligible Member if a medication requested by him/her is not included in the Pharmacy Benefits Service Coverage, and therefore is not covered by the Client.

CMS establishes specific procedures on how to handle member communications when an MPD prescription cannot be filled (Coverage Determination Process). Please refer to section 18.2 of this Manual.

7.17. Deductible, Copayment

It shall be the sole responsibility of the Participating Pharmacy to notify the Eligible Member of the total amount of the deductible payment or copayment

as indicated by the electronic claims transmissions system prior to dispensing the medication. The Pharmacy shall only charge the Eligible Member the amount that corresponds to the deductible payment or copayment, according to the Pharmacy Benefit Services Coverage of the particular Client. The amounts corresponding to the payment of the deductible or copayment shall be part of the compensation received by the Participating Pharmacies for the services rendered to the Eligible Member.

The Participating Pharmacy shall be responsible, and shall hold MC-Rx harmless, for any claim or action whatsoever, that arises from, or related to, any request of deductible payment or copayment to the Member that exceeds the amount stated in the Pharmacy Benefits Services Coverage. MC-Rx shall not be liable to the Participating Pharmacy for any claim or action whatsoever, filed during the validity or after the termination of the Agreement by an Eligible Member for the collection of any amount paid in excess of the amount stipulated in the contract signed between the Eligible Member and the Client.

7.18. Signature Registry

The Participating Pharmacy must maintain a Signature Registry for Eligible Members in accordance with the specifications and instructions stated in the Agreement and in this Manual.

The signature registry will be:

- Kept daily for each day in which services are rendered to Eligible Members

- Filed in ascending order of date and prescription number per calendar year
- Certified: the administrator, owner, authorized or legal representative of the Participating Pharmacy must certify with its signature that the Participating Pharmacy offered such services and that the Signature Registry is correct

The Participating Pharmacy that submits its claims using the Point of Sale equipment shall have the option of not keeping the Transaction Receipt that the system produces with the prescription if it has completed the Registry of Signatures. In the event the parties hereto mutually agree upon the implementation of an electronic signature tracking system, the Participating Pharmacy will no longer be required to keep and/or maintain the Signature Registry.

If the Eligible Member cannot sign at the time he/she is receiving the service, the identity and signature of his/her tutor or representative shall be obtained and verified by means of an identification card with photograph. The Eligible Member's tutor or representative shall indicate his/her relationship with the Eligible Member.

MC-Rx will not honor the payment of any service to the Participating Pharmacy for which no signature or second identification of the Eligible Member or his/her representative exists in the Signature Registry.

7.19. Record Retention

Pharmacy Network members shall maintain record of services rendered to Eligible Members. The Pharmacy will retain original prescriptions, the transaction receipt, and the Signature Registry of Eligible Members for a seven (7) year period after the dispensing date of the medication, or as required by applicable laws.

For Government Health Plan and Medicare Part D claims, ten (10) years document retention is mandated by CMS (Centers for Medicare and Medicaid).

Section 8. Termination of Agreement

8.1. No Cause Termination

Both MC-Rx and the Pharmacy Provider may terminate the Agreement at any time without cause by providing at least a **thirty (30)-day** prior written notice of its intention to terminate the Agreement.

8.2. Termination for Breach

If there is any material default by either party in the performance of the terms and conditions of the Services Agreement, the non-defaulting party may terminate the Agreement upon thirty (30) day prior written notice to the other party, provided, however, that the defaulting party has not cured such default prior to the end of such thirty (30) calendar day period.

The Participating Pharmacy may terminate the Agreement upon sixty (60) days prior written notice to MC-Rx due to MC-Rx's failure to pay on behalf of its Clients the claims received from Participating Pharmacies and all other

required fees, costs, and charges within the time period specified in the Agreement, unless full payment of the outstanding amount is received by the Participating Pharmacy within thirty (30) days from the date of written notice of non-payment.

8.3. Immediate Suspension or Termination

Notwithstanding the above, the Agreement may be immediately terminated or suspended by MC-Rx in the event of any of the following:

- Pharmacy breaches any representation or warranty of Pharmacy under the Agreement;
- Pharmacy fails to maintain appropriate licensure, registration, certification, and/or good standing as required under the Agreement and/or Law
- Pharmacy's hereunder required insurance is canceled, lapsed, terminated, or otherwise suspended without replacement coverage;
- Pharmacy is indicted or convicted of a felony, fraud, and/or submission of false claim information;
- Pharmacy fails to cooperate with MC-Rx in resolving member complaints or grievances;
- Pharmacy is listed in the OIG/SAM Exclusion List, the CMS Preclusion List, or is sanctioned under or expelled from participation in the Medicare, Medicaid, or other government programs;
- Pharmacy fails to satisfy any or all of the credentialing requirement of MC-Rx;
- Pharmacy is guilty of any conduct tending to injure the business reputation of MC-Rx;

- Pharmacy makes an assignment for the benefit of its creditors, becomes unable to pay debts when due, files a petition of bankruptcy, whether voluntary or involuntary, and/or a receiver or trustee is appointed for the transfer or sale of a material portion of Pharmacy's assets; and/or
- MC-Rx or a Plan determines that the health, safety, or welfare of Members is jeopardized by continuation of the Agreement.
- Pharmacies that incur fraud, waste, and/or abuse investigations will be highlighted as a high priority and will be conducted in an expedited manner and will be inactivated immediately.
- The Quality Assurance Committee (QAC) will be consulted no later than two (2) business days upon receipt of the information. The committee will take the determination based on the findings of the investigation.

If the Pharmacy does not agree with the termination of services determination, it can appeal the decision within (10) days of the termination notice. To do so, the Pharmacy must submit a written notice explaining the reasons why the deactivation should not take place and documentation that significantly supports the request.

The Pharmacy will receive MC-Rx's final determination within five (5) to seven (7) business days. If MC-Rx requires additional time to reach a decision, the Pharmacy will be informed of when a final determination is expected. MC-Rx could request the development and implementation of a corrective action plan as a condition to consider the reactivation of the Pharmacy.

8.4. Specific Network Termination

A Pharmacy may be excluded from participating in a network with respect to any specific plan. A written notice will be sent to the Pharmacy thirty (30) calendar days (or longer period as required by applicable Law) prior to the inactivation date.

8.5. Termination Due to Claims Processing Volume

MC-Rx maintains an ongoing monitoring of claims processing volume. Pharmacies who have not processed claims in a two (2) week period, will be sent a 30-day Notice of Termination. Upon receipt, the Pharmacy may contact MC-Rx to provide an update on the status of the business.

If no response is received from the Pharmacy, or if Pharmacy informs of closure of business, MC-Rx will inform Plan Sponsors of the inactivation of the Pharmacy by the end of the thirty (30) day period and will provide data needed to implement a transition process that will ensure continued service to members.

8.6. Termination Due to Closure of Business

Participating Pharmacy Providers decide to cancel the Service Agreement with MC-Rx due to closure of business, the Pharmacy must notify MC-Rx in writing at least thirty (30) calendar days in advance of the closing date.

The closure of a pharmacy conveys a transition process to ensure uninterrupted service to beneficiaries. MC-Rx will identify participating pharmacies nearest to the location of the closing pharmacy and will provide

Plan Sponsors with a list of members who have pending prescription refills at the closing pharmacy.

8.7. Effect of Termination

Notwithstanding the termination, suspension, and/or breach of the Agreement, the contracting parties shall continue to be responsible for all obligations that may have arisen under this Agreement during the time the Agreement was in force. The parties will cooperate in good faith to promptly resolve any outstanding financial, administrative, or Member service issues upon termination of this Agreement.

Section 9. Payment Guidelines

9.1. Pricing Benchmark: Average Wholesale Price (AWP)

MC-Rx uses the Average Wholesale Price or AWP as its drug pricing benchmark. AWP drug prices are defined and published by third parties [Medi-Span and First Data Bank (FDB) are the most widely used]. This price is based on the National Drug Code (NDC) number of the dispensed medication. AWP prices are updated in MC-Rx's claim processing system no less than once a week to reflect the most current AWP pricing.

In the event that MC-Rx determines to use another recognized source for AWP pricing, or another benchmark other than AWP, MC-Rx will provide Pharmacy Providers a ten (10) day notice of such change.

9.2. Maximum Allowable Cost (MAC) List

The term Maximum Allowable Cost List, or MAC List, refers to the list of generic drugs commercially available and their associated prices. The MAC list is maintained by MC-Rx, and the prices on such a list determine amounts to be reimbursed to Participating Pharmacy for dispensing services provided to Eligible Members.

Federal regulations require the disclosure and review standards for prices of prescribed drugs included in the Medicare MAC list. See section 18.8 for more information.

9.3. Claims Payment

Claims that comply with all requirements set forth in the Agreement are paid within thirty (30) calendar days after the receipt of the claim, unless otherwise required by law.

- Reimbursement payments for commercial and government segments are processed twice a month.
- Reimbursement payments for the Medicare segment are processed weekly.

During the first month of each year, MC-Rx will distribute its Pharmacy Providers an itinerary of payment dates for each cycle during the year.

MC-Rx pays the Participating Pharmacy according to the agreed upon rates subject to the terms and conditions of the Participating Pharmacy Network Agreement. The deductibles, applicable co-insurance, and processing fee will

be deducted from such compensation.

The Participating Pharmacy will not be entitled to claim any reimbursements other than those indicated in the compensation attachments of the Agreement.

Providers will receive payments through electronic funds transfer. If Pharmacy provider chooses an electronic funds transfer, an EFT Payment Request form must be completed and returned to MC-Rx by email to: financeservices@mc-rx.com, by fax (787-653-2850) or by mail at Call Box 4908, Caguas, Puerto Rico 00726. Allow up to twenty (20) calendar days for enrollment to be processed. To obtain an EFT Payment Request form you may visit www.mc-rx.com Pharmacy Section, Pharmacy Forms.

9.4. Remittance Advice

MC-Rx provides a remittance advice report with each payment showing a record of all claims submitted, processed, and paid in each processing cycle. Providers are urged to review remittance advice when received to verify accuracy.

Any claim payment not disputed within six (6) months of receipt of Provider's remittance advice is deemed to be confirmed as accurate by the Provider.

9.5. Claims Payment Adjustments

MC-Rx will accept requests for investigations on the status of claims if the request is made within six (6) months from the date of which the service was rendered. MC-Rx is responsible for investigating any remittance advice

dispute or adjustment only if properly notified in the manner and timeframe specified herein.

9.5.1. Unpaid Claims

In the event a Pharmacy Provider identifies an unpaid claim, it will contact the Pharmacy Call Center to communicate such occurrence and request a review of the alleged unpaid claim.

9.5.2. MAC Price Reimbursement Disagreements

If a Pharmacy Provider disagrees with the adjudicated MAC price reimbursed for a drug, it can request a MAC price review.

MC-Rx has developed the MAC Price Review application, a tool that allows Pharmacy Providers to submit and track the status of a submitted request. A step-by-step guide on how to register and use the MAC Price Review application is available at www.mc-rx.com.

MC-Rx is responsible for investigating all pricing review requests only if properly notified in the manner and timeframe specified herein. Pharmacy will be notified of the result of the evaluation through an email originated by the MAC Price Review application.

MC-Rx will accept requests for reviews submitted within sixty (60) days of the service date for commercial lines of business, and up to ninety (90) days after the service date for Medicare and Medicaid

business lines.

Pharmacies can only submit one appeal per prescription and/or drug. Questions regarding a denial decision can be sent to MC-Rx by email (MACappealsupport@mc-rx.com) or by contacting the Pharmacy Providers Call Center.

9.5.3. Disputed Claims

In the event a Network Pharmacy Provider seeks to dispute a claim due to an alleged error, miscalculation, discrepancy, or other matter associated with the accuracy of a claim, the Network Pharmacy Provider must complete a Disputed Claims form. Pharmacy will provide Pharmacy NABP number, Eligible Person ID number, Prescription number, date of fill, and details as to why adjustment is needed (e.g. wrong NDC submitted, wrong NPI submitted, wrong quantity submitted, etc.). The completed form, along with the required support documentation, should be sent by email (pharmacyadjudication@mc-rx.com) or by fax (787-653-2814). MC-Rx will accept requests for disputed claims, if the request is made within ninety (90) days from the date on which the service was rendered.

The Disputed Claims forms are available at www.mc-rx.com.

Section 10. Provider Complaints and Grievances

Pharmacy Providers' complaints or grievances are means of continually improving the quality of our services. Participant Providers can visit the Pharmacy Services section in MC-Rx's web page (www.mc-rx.com) to complete and submit a complaint form.

This process applies to the expression of dissatisfaction about a matter related to MC-Rx other than a determination of medical necessity for a service. A complaint does not include a matter of misunderstanding or misinformation that can be promptly resolved. Grievances are an expression or dissatisfaction about matters such as, but not limited to, the quality of services provided by an MC-Rx staff member.

All complaints received will be handled in a timely manner. Response times range from 72 hours to ten (10) working days, depending on the nature and complexity of the reported situation.

Section 11. Communications to Pharmacy Network Providers

MC-Rx will keep Participating Pharmacies posted with relevant instructions, notices, information regarding network activities, member eligibility and benefits, formulary inclusions and exclusions, online processing procedures, changes in fee schedules, Medicare Part D program information, dispute and appeal processes, and fraud, waste and abuse regulations, among other information or changes to this Manual to promote high quality and consistent standard of care. Communications will be sent to the Pharmacy email address and/or fax number listed on file. This is one more reason to keep your records with MC-Rx up to date. All communications will also be available at www.mc-rx.com, and all updated instructions or procedures

communicated by this means will supersede instructions or procedures listed in the Manual.

11.1. Drug Recall and Safety Alert Notices

Pharmacies are notified of recalled medications from a variety of sources including drug manufacturers, drug wholesalers, and government agencies such as the Food and Drug Administration. MC-Rx also keeps Participating Pharmacies posted with FDA-issued drug recalls and safety alert notices which include recommendations and instructions to follow for each particular issue.

Participating Pharmacies are expected to have policies and procedures in place to outline steps on how to manage drug recalls and safety alert notices. Some steps for pharmacies to consider are:

- After finding out about recalls, pharmacists should remove the affected medications from their inventory and relay the news of recalls to customers who come in to fill a prescription.
- The pharmacy wholesalers and/or manufacturers typically send out a list of drugs and their lot numbers when products have been recalled; these should always be checked carefully by pharmacists.
- Recalls are often announced via television news shows and other media outlets. Pharmacy staff should be trained and prepared to handle incoming members who visit the pharmacy to return recalled products.
- If the pharmacy has dispensed the drug in the past, it should go through its prescription records for the relevant time period to identify any customers

to whom the medication was dispensed. Notify the physicians of these customers and keep a record of the notifications. The practitioners can then get in touch with their patients from there.

Section 12. Concurrent Drug Utilization Review (cDUR) Edits

To detect and address clinical quality and safety issues, certain concurrent drug utilization reviews (cDURs) are applied at the time the prescription is being dispensed.

Concurrent DUR edits identify at the dispensing point of service, potential conflicts such as duplicate therapies, age or gender related contraindications, overutilization or underutilization, drug-drug interactions, incorrect drug dosage or duration of drug therapy, drug-allergy contraindications, among others.
There are two types of concurrent DUR edits: hard and soft. These edits or alert messages are associated with the level of severity.

Dispensing Pharmacists must always exercise their clinical knowledge, expertise and judgment in reviewing and overriding warning messages if deemed medically appropriate.

- Concurrent hard edits, e.g., the claim is stopped and blocked and cannot be hastily overridden by the pharmacy.
- Concurrent soft edits can be overridden by the pharmacy and are provided mainly as a message to the pharmacy.

Refer to Section 17 of this Manual for a description on how to manage claims

associated with concurrent DUR edits.

Section 13. Clinical Drug Utilization Edits (DUE)

Drug utilization edits (DUE), also known as drug management tools (DMT), are mechanisms designed to optimize patient outcomes and ensure the use of the most appropriate medications while reducing waste, error, and unnecessary prescription drug use and cost.

The members of the Pharmacy and Therapeutic Committee (P&T) are responsible for developing, evaluating, and updating the criteria for all drug management tools. This ongoing process is based on the latest scientific data available and the current standards of medical practice, with the sole purpose of promoting safe and effective medication use.

The most commonly used drug management tools are Prior Authorization (PA), Step Therapies (ST), Specialty Limit (SL), Quantity Limit (QL) and Age Limit (AL).

13.1. Prior Authorization

Prior-Authorization (PA) is a drug utilization tool employed by direct-based healthcare organizations that requires compliance with certain clinical-based criteria before a medication is approved. The prior-authorization process guarantees the appropriate delivery of medications, while reducing errors and expenses, and encouraging an adequate use of prescribed medications.

For example, prior-authorization criteria requires the patient's diagnosis and recent lab tests. The patient's diagnosis enables confirmation of the

medication being prescribed according to its FDA-approved indication or clinical treatment guidelines recommendations.

Refer to Section 15 of this Manual for a description on how to manage claims that require a prior authorization.

13.2. Step Therapy

The Step Therapy edit requires the use of a first-line medication recommended by treatment clinical guidelines before using a second-line medication. If the desired therapeutic benefit is not achieved with the first-line medication, then the second-line medication may be approved.

Refer to Section 16 of this Manual for a description on how to manage claims that are subject to a step therapy edit.

13.3. Age Limits

The edit ensures that the prescribed medication is used as approved by the FDA. For example, in the case of a medication indicated for use in patients over 18 years of age, the age limit edit helps protect and prevent morbidity and mortality associated with its use in a patient under 18 years of age.

13.4. Medical Specialty Limits

Some medications require a prescription from a certain medical specialist. In general, these are specialty drugs that need a high level of experience and monitoring by a physician specialized in certain health conditions. Examples:

chemotherapies, biological agents, among others.

13.5. Quantity Limits

The Quantity Limit (QL) edit limits the amount to be dispensed of a certain drug. The quantity limit is based on the maximum effective dose approved by the FDA and on evidence from clinical trials. A QL edit prevents problems related to drug misuse, abuse, or waste. For example, the use of higher than recommended doses which may pose a potential harm to a member's health. QLs can also be applied to prevent inappropriate use of medications with unproven long-term benefits.

Section 14. Pharmacy Claims Processing

14.1. Eligibility and Pharmacy Benefit Information

MC-Rx will provide the Participating Pharmacy with subscriber enrollment and pharmacy benefit services coverage of its clients including, but not necessarily limited to, member co-payment, deductible limits, covered drugs, days' supply, and participating physicians (including any updates, deletions, or additions to the foregoing as changes occur).

This information will be available to the Participating Pharmacy at the time of dispensing through the electronic claims transmission systems maintained between MC-Rx, its designated processor, and the Participating Pharmacy. The Pharmacy will use this information to determine the members' eligibility and pharmacy benefit services coverage at the time of dispensing the medications.

14.2. Processing Fee

As established in the agreement, the Participating Pharmacy will pay MC-Rx a processing fee for each claim processed through electronic transmission. The processing fee shall be deducted from the claims reimbursement amount.

14.3. Personal Computer

The Participating Pharmacy shall have a personal computer to process claims and to verify the eligibility and identity of an Eligible Member.

14.4. Protecting Privileged Health Information

Participating Pharmacies shall always keep in mind that sending protected health information (PHI) to an incorrect entity constitutes a breach of federal HIPAA laws.

MC-Rx reiterates that, as a covered entity, the Pharmacy is responsible for verifying the fax number being used before transmitting PHI. Fax numbers are constantly changing and using fax numbers obtained on the internet or in a telephone book, is not recommended. Double-checking that the correct fax number has been entered before initiating a fax transmission is forcefully recommended.

14.5. Eligibility Verification

Before processing a claim, the Participating Pharmacy shall take steps to gather information that will allow confirming a member being eligible for a

particular plan benefit.

The Pharmacy staff shall request the plan member to present a member identification (ID) card of the pharmacy benefit or healthcare plan AND a valid identification. The cardholders' identification number and date of birth shall be confirmed before claim processing. The member identification (ID) card presented must be the most current card issued to the plan member.

The plan member's eligibility can be confirmed through the online Claims Processing System or by calling MC-Rx's Pharmacy Call Center at 1-888-311-6001 or 1-866-411-6001.

14.6. Professional Judgment

The Pharmacy is required to deliver pharmacy services under the direct supervision of a licensed pharmacist and according to prescriber instructions in accordance with applicable law. The Pharmacy must exercise professional judgment at all times in rendering pharmacy services to an eligible plan member. Moreover, the Pharmacy may refuse to deliver pharmacy services to an eligible plan member based on their professional judgment.

14.7. Electronic Prescriptions

The Pharmacy Law of Puerto Rico (Act No. 247 of September 3, 2004) was amended with Act No. 138 on November 16, 2009 to allow the release of electronic prescriptions without a handwritten signed prescription.

Electronic prescribing is defined as electronic generation and transmission of a prescription from the prescriber to a pharmacy freely selected by the member, through a system that authenticates the electronic signature of the prescriber and safeguards the security of the transmission in accordance with the applicable standards, laws, and regulations. Electronic prescriptions require the same elements as an ordinary written prescription, and some other additional elements (see Electronic Prescriptions, page 48).

For purposes of this Act, a prescription that is generated and transmitted electronically is also known as an electronic prescription and constitutes an original order and, therefore, an order with handwritten signature will not be required. This Act came into effect 30 days after the adoption of Regulation No. 142 of August 9, 2010, which incorporated the new provisions to the Pharmacy Regulation.

Participating pharmacies must transmit transactions electronically in accordance with standards established by the National Council for Prescription Drug Programs (NCPDP). In addition, you must comply with electronic prescribing standards, security, and transmission of electronic prescribing as defined by CMS when receiving or transmitting electronic prescriptions or prescription-related information.

14.8. Online Adjudication System

The Pharmacy Provider is required to submit all claims in an accurate and complete mode online using the current NABP approved format.

The online adjudication system allows for claims processing in real time, 24 hours a day, 365 days a year. See following table for input codes needed for online adjudication process.

Input Code for Online Adjudication	MCRx
MC-Rx Bin Number **	010868
Pharmacy ID Number (Qualifier 01)**	NPI #
Member ID Field **	See member's card
Date of Birth**	MM/DD/YYYY
Telecommunication Standard	NABP Version D.O.
Prescriber Information **	NPI#

** Required Fields

Pharmacy Providers must consult with their software vendors to ensure proper system configuration.

14.9. Processing Claims Manually

If for any reason the pharmacy is unable to process claims electronically, it should submit all information related to services rendered using a **Universal Claim Form (UCF)**.

The completed UCF, as well as the electronic claim, should be submitted to MC-Rx no later than sixty (60) days after rendering services to the Plan Member. Please be aware that manual claims require prior authorization by MC-Rx. You may request authorization for a manual claim by calling the Pharmacy Call Center.

You may obtain a UCF at www.mc-rx.com or by calling MC-Rx's Pharmacy Call Center at 1-888-311-6001 or 1-866-411-6001.

14.10. Coordination of Benefits

The coordination of benefits (COB) allows an insured person to use two health plans with pharmacy benefits – a primary plan and a secondary plan – for one same prescription.

14.10.1. How will I know that the person has two health plans with pharmacy benefits?

- The insured member informs you, or
- The online claims adjudication system alerts you that the insured member has an alternate health plan.

14.10.2. How should I process a claim with COB?

- First, process the claim to the insured's primary plan. The primary plan informs the amount it will pay for the claim and member's copay / coinsurance.
- Second, process the claim to the insured's secondary plan (BIN#, PCN and Group) using the same information submitted to the primary plan - prescription number, dispensing date, NDC, quantity to be dispensed, days' supply and refills.

  Allowed values in the "Other Coverage Codes" field may vary by client. The following are some of the allowed values in this field:

Other Allowed Coverage Codes	
3	Other Coverage Billed - claim not covered
8	Claim is billing for patient financial responsibility only (Copay / Coinsurance)

The Pharmacy Provider should consult with its software provider to ensure the proper system configuration to allow for the processing of COB claims.

14.11. Processing a Compound

MC-Rx administers pharmacy benefits on behalf of many different plan sponsors. Each individual health insurance plan determines its benefit plan design, such as the specific drugs/ingredients covered, cost-sharing, and day supply limitations, among other benefit characteristics.

Pharmacy Providers are expected to observe applicable state and federal laws, CMS policies, professional standards, and FDA communications when preparing and dispensing compound drugs. For instance, the Medicare Advantage and the Medicare Prescription Drug Benefit Programs (42 CFR 423.120) clearly state that for any non-Part D ingredient of the Part D compound, pharmacies must not do balance billing to charge the member the cost of ingredients not covered in the compound.

A compound drug claim contains a Drug Product which is weighed or

measured by a licensed pharmacist who combines, mixes, and/or alters ingredients to create a medication for a covered person for which a commercial Drug Product is not available. This excludes reconstitution and/or dilution of a Drug Product according to manufacturer guidelines. Sweeteners and flavorings are also excluded.

When processing compounds with multiple ingredients, the pharmacy has the option of offering the insured client the dispensing of those ingredients of the compound covered by the plan.
When applicable, entering option 8 in the "Submission Clarification Code" field on the online claims adjudication system, will allow the pharmacy to process a claim for a compound when at least one of the ingredients is a covered drug.

For additional information, please refer to the following descriptions and information on the fields used for billing compounds with multiple ingredients.

CLAIM SEGMENT FIELDS NCPDP FIELD	FIELD NAME	COMMENTS/VALUES
4Ø6-D6	COMPOUND CODE	Use '**2**' if the product is a compound. The Compound Segment is also required if a compound code of 2 is submitted.
436-E1	PRODUCT/SERVICE ID QUALIFIER	00 = Not specified required with use of the Compound Segment
4Ø7-D7	PRODUCT/SERVICE ID	NDC Number. Submit 'Ø' to identify the claim as a multi-ingredient compound.

CLAIM SEGMENT FIELDS NCPDP FIELD	FIELD NAME	COMMENTS/VALUES
442-E7	QUANTITY DISPENSED	Of entire product – quantity of the final compounded product dispensed
42Ø-DK	SUBMISSION CLARIFICATION CODE	**The value is "8" (eight).** A value of "8" allows a compound claim to continue processing if at least one ingredient is covered
45Ø-EF	COMPOUND DOSAGE FORM DESCRIPTION CODE	Dosage form of the complete compound mixture. One occurrence per claim.
451-EG	COMPOUND DISPENSING UNIT FORM INDICATOR	Describes the units' form of the entire compound. One occurrence per claim.
447-EC	COMPOUND INGREDIENT COMPONENT COUNT	Maximum **10** ingredients
49Ø-UE	COMPOUND INGREDIENT BASIS OF COST DETERMINATION	Required if needed for receiver claim determination when multiple products are billed. [Ea. 01 = AWP; 02 = Local Wholesaler, etc.]
Updates to these instructions may be communicated to Pharmacy Providers from time to time. Refer to Pharmacy Communications section in this Manual.		

14.12. Flex 90™ Program

The Flex 90™ program allows the health plan member to receive a 90-day supply of maintenance drugs.

The member's participation in this program can be optional or mandatory, as defined by the plan benefit design. The number of refills allowed is also determined by the plan benefit design, and may vary from one plan to the

other.

Prescriptions for the Flex-90™ program are acceptable in any of the following forms:

- **30-day supply and X refills** – X equals the number of refills needed to complete a 90-day supply. The maximum number of refills allowed is five (5); this is the initial prescription fill plus five refills. Medicare allows a maximum of eleven (11) refills.
- **90-day supply and X refills** – the maximum number of refills allowed is one (1); this is the initial prescription fill plus one refill. The maximum number of refills for Medicare is three (3).

Section 15. Processing Claims for Drugs that Require Prior Authorizations

To ensure effective and timely evaluation of each PA request, the Pharmacy Provider must submit all required and relevant-to-the-case documentation.

15.1. Steps to Effectively Manage a Prior Authorization Claim

- Check that the prescription is complete and meets all legal requirements (e.g. patient information, date, instructions to pharmacist, directions to patient, diagnosis, etc.).
- Provide all relevant information and documentation, including the patient's name, cardholder member ID, age, weight, etc. In some cases, additional information may be required to perform an evaluation.

ALERT MESSAGE →	PA
DOCUMENTATION REQUIRED TO	Submit patient's diagnosis

PERFORM EVALUATION

- Complete the Prior Authorization Request Form. To obtain a **PA Request Form**, call our Pharmacy Provider Call Center or visit www.mc-rx.com.
- Submit the PA Request Form and other documentation to the Prior Authorization Call Center corresponding fax number (refer to page 9 for fax numbers per plan sponsor).
- MC-Rx will notify the pharmacy of the determination of the case in writing. Response times vary from one client to another.

15.2. Incomplete Prior Authorization Requests

If the Pharmacy does not submit all required documentation, MC-Rx will send the Pharmacy a written notice indicating the request is incomplete.

The Pharmacy will then have 24 hours to complete and submit to MC-Rx the missing information. If the requested documentation is not received within the 24-hour period, MC-Rx will send the Pharmacy a notice stating that the case has been closed due to incomplete information.

15.3. Pharmacy PA Status Tool

The Pharmacy PA Status Tool, available at www.mc-rx.com, allows Pharmacy Providers access to REAL-TIME STATUS of PA applications submitted to MC-Rx through fax. The tool also provides Pharmacy Providers a confirmation of the receipt of the pre-authorization documents sent by fax. This, rather than having to call MC-Rx to confirm the receipt.

Pharmacy Providers may contact the PA Call Center to request a User's Guide to register and use the PA Status Tool.

Section 16. Processing Claims for Drugs that Require Step Therapy

The **Step Therapy** approach requires the use of a first-line medication recommended by treatment clinical guidelines before using a second-line medication. If the desired therapeutic benefit is not achieved with the first-line medication, then the second-line medication may be approved.

16.1. Steps to Effectively Manage a Step Therapy Claim

- The use of the first-line medication may or may not be identified automatically by the online Claims Processing System.

ALERT MESSAGE →	**Step Therapy (e.g.: "Use Omeprazole first")**
DOCUMENTATION REQUIRED TO →PERFORM EVALUATION	Submit evidence of prior use of first-line drugs (e.g.: pharmacy drug profile, letter form physician, etc.)

- If the use of the first-line medication is not shown on the online claims processing system, there are other methods to prove the use of first-line medications, such as:
  - A letter from the physician certifying the previous use of first-line medications
  - The patient's medication profile provided by the pharmacy

  - Evidence provided by the patient that proves prior use of first-line medications under another health plan contract number or group
- Complete the Prior Authorization Request Form. To obtain a PA Request Form, call our Pharmacy Providers Call Center or visit www.mc-rx.com.
- Submit the PA Request Form and supporting documentation, if applicable, to the Prior Authorization Call Center corresponding fax (refer to page 9 for fax numbers information).

Section 17. Claim Processing Alert Messages

MC-Rx's Online Adjudication System has the capability of issuing alert messages when interactions are detected. Pharmacy staff should be aware of these messages and should know where to look to find them in the online claims system.

Alert messages are associated with the following levels of severity:

- **Severe (Major)** – interactions that are well documented and have the potential to cause harm, or that occur with a low incidence but have the potential to cause serious adverse effects.
- **Moderate** – these interactions are associated with a lower probability of causing damage and are not as well documented.
- **Minor** – these interactions can occur, but are less significant because the available data is poor and conflicting. Minor interactions are associated with a limited risk or no clear risk to the patient.
- **None** – there are no known interactions. The Pharmacist must decide how to handle the event according to the level of severity of the interaction, and should always document the actions taken.

- **Severe (Major) or Moderate Severity** – the Pharmacist must contact the physician to discuss alternatives, such as a change of the prescribed medication, discontinuation of one of the drugs related to the interaction for a short period of time, dose adjustment of one or both drugs, or a change in the time of the day in which the drugs are administered, among other measures.
- **Minor Severity** – the Pharmacist may choose to counsel the patient about the potential for interactions and advise him/her to contact their physician if a problem arises.

17.1. Potentially Severe Drug – Drug Interactions

17.1.1. Code 88 – Drug-to-Drug Interactions

The online adjudication system is programmed to detect potentially severe drug-to-drug (DD) interactions for certain drug combinations.

What to do?

A rejection code 88: "Drug-Drug Interaction use DUR/PPS coding" indicates a potentially severe drug-drug interaction has been detected and the claim has been rejected.

The online adjudication system provides a means to override a "drug-drug interaction" rejection. The process, however, will only be used if and when the prescribing physician or the pharmacist, based on their clinical judgment, determine and document that the rejected drug poses no danger to the health of the patient and,

therefore, the prescription can be filled as ordered.

The Pharmacist must document on the prescription or in the member's electronic record, the intervention performed to support the drug-drug interaction override. This process is subject to audit.

Drug to Drug Interaction – Accepted Values		
Conflict Code	**DUR/PPS Intervention Code**	**DUR/PPS Outcome Code**
• Reason for the service = **DD** (for Drug to Drug Interaction)	• Professional Service Codes o **M0** = Prescriber Consulted o **P0** = Patient Consulted o **SC** = Self-Care Consultation o **SW** = Literature Search / Review	• Outcome Service Codes **o 1A** = Filled As Is, False Positive **o 1B** = Filled Prescription As Is o **1D** = Different Directions **o 1F** = Different Quantity o **1G** = Filled, Prescriber Approved

17.2. Common Rejection Alert Messages

17.2.1. Code 70 - NDC Not Covered, Generic Substitute Required for Payment

The plan benefit design may be Generic Mandatory. If you are processing a claim for an original (brand) medication, this rejection code indicates that it must be substituted with a generic version in order to obtain payment ("Generic Subst. Required for Payment").

- Private/commercial sector plan - verify the member's coverage; it may indicate Generic Mandatory.
- Government related program - verify if the medication is

included in formulary and if it has been prescribed by an authorized physician. If so, the alert means that the medication prescribed has a generic substitute and that the original (brand) product is not covered by the plan.

17.2.2. Code 70 - Plan Exclusion

The medication being claimed may be excluded or limited to a medical specialty.

What to do?

- Private/commercial sector plan - verify the member's coverage; the medication may be excluded or limited to a medical specialty.
- Government related program - verify if the medication is included in formulary and if it has been prescribed by an authorized physician.

17.2.3. Code 78 – Cost Exceeds Maximum

The cost of the submitted claim is greater than the predefined dollar amount established by the health plan (e.g. $75, $500, $1,000, etc.).

What to do?

- Review data entry for possible error in the drug quantity or cost. Modify information, if necessary.
- If information entered is correct, complete a **Prior**

Authorization Request Form and submit it along with the prescription to the Prior Authorization Call Center (refer to page 8 for fax numbers information).

17.2.4. Code 76 - Maximum Days' Supply

The days' supply or the quantity of medication in the submitted claim are greater than those covered by the health plan. The maximum days' supply varies according to the plan pharmacy benefit design. For example, some plans have different maximum days' supply for maintenance and acute medications.

What to do?

If you need assistance, call the Pharmacy Network Call Center.

17.2.5. Code 77 - Discontinued NDC Number/Service ID

The claimed drug has an inactive NDC number.

What to do?

The online claim adjudication system does not accept claims for drugs with inactive NDC numbers. A rejection for this medication does not mean that the medication is not covered by the plan, but that it must be processed with an active NDC number.

Call your supplier for information on available alternatives for inactive NDC numbers.

17.2.6. Code 79 - DUR Reject Error Refill Too Soon

Prescription is refilled sooner than appropriate with respect to quantity and directions for use.

What to do?

Review data entry for possible error in the drug quantity or cost. Modify information, if necessary.

Some plan sponsors allow pharmacy staff to enter an override code due to an upcoming trip/vacation. In such cases, Pharmacy must submit the prescription, along with evidence of the upcoming trip to the Prior Authorization Center (refer to page 8 of this Manual for fax numbers).

17.2.7. Code 88 - DUR Reject Error High Dose Alert

Dose exceeds the daily maximum recommended dose.

What to do?

Pharmacists must exercise their clinical judgment and/or contact the prescriber to document that the prescribed dose does not pose a risk to the member and that dispensing is appropriate.

The Pharmacist must always document the intervention that supports the override on the prescription or in the member's electronic record. This process is subject to review during a pharmacy audit process.

Reason for Service Code	Service Code	Result of the Service Code
HD	M0 / MR / R0 / SC / SW	1B or 1G
EX	M0 or MR	1B or 1G
ER	M0 or MR	1B or 1G
HC	M0 or MR	1B or 1G

HC	High cumulative dose MME
HD	High Dose - The prescribed dose is higher than the maximum dose.
EX	Excessive Quantity - The amount processed exceeds the quantity limits for the period for which prescribed. Note: Use for opioids MME
ER	Overuse for opioids MME
M0	The physician has been consulted and has provided approval for the dispensing of interacting drugs.
MR	The pharmacist has determined, based on an evaluation of the drugs, that the interaction can be voided or replaced.
R0	Pharmacist consulted other source
SC	Self-care consultation
SW	Literature self/review
1B	Fill Prescription as is – The Pharmacist has evaluated the therapeutic alert and has determined that such alert is not relevant, and proceeds to fill the prescription as originally written.
1G	Filled with Prescriber Approval - The Pharmacist evaluated the therapeutic alert and fills the prescription after consulting with the prescriber and obtaining his/her approval.

17.2.8. Code 88 - Duplicate Therapy-Use PPS Code

Members have been prescribed multiple therapies from the same therapeutic category.

ALERT MESSAGE ⟶	**Duplicate Therapy (e.g.: Enalapril y Remipril)**

DOCUMENTATION REQUIRED TO PERFORM EVALUATION	Submit a justification to support medical use of both drugs concurrently

What to do?

For this soft edit, the Pharmacist will evaluate the claim or consult the prescriber to determine if the therapy is appropriate. If so, the Pharmacist may use a combination of DUR Service Override Codes to continue the claim process.

The pharmacist must document the intervention performed, either on the back of the prescription or in the member's electronic file to support the service edit used.

Reason for Service Code	Service Code	Result of the Service Code
TD	M0 or MR	1B or 1G
ID	M0 or MR	1B or 1G

TD	Therapeutic Duplication – Code indicates duplicity or therapy between two or more drugs.
ID	Ingredient Duplication
M0	The physician has been consulted and has provided approval for the dispensing of interacting drugs.
MR	The pharmacist has determined, based on an evaluation of the drugs, that the interaction can be voided or replaced.
1B	Fill Prescription as is – The Pharmacist has evaluated the therapeutic alert and has determined that such alert is not relevant, and proceeds to fill the prescription as originally written.

1G	Filled with Prescriber Approval - The Pharmacist evaluated the therapeutic alert and fill the prescription after consulting with the prescriber and obtaining his/her approval.

17.3. Strategy to Combat Opioid Crisis

MC-Rx administers pharmacy benefits on behalf of many different plan sponsors. Each individual health insurance plan determines its benefit plan design, such as the specific drugs/ingredients covered, cost sharing, and days' supply limitations, among other benefit characteristics.

While most beneficiaries utilize, and clinicians prescribe opioids in ways that are medically appropriate, opioid overutilization is nonetheless a significant concern for the healthcare industry. MC-Rx is helping plan sponsors identify individuals who are at risk for opioid abuse.

These strategies, which help plan sponsors prevent and combat prescription opioid overuse through improved concurrent drug utilization review (DUR), include initiatives with new opioid users (opioid naïve), chronic opioid users, and those with potentially problematic concurrent medication use.

Section 18. Medicare Part D Compliance Requirements

18.1. Pharmacy Compliance

CMS requires all entities that contract with MC-Rx or an MC-Rx subsidiary, including pharmacies, to meet Medicare compliance program training requirements. These requirements include review and adherence to MC-Rx's

compliance policies and procedures.

MC-Rx's general compliance and Fraud, Waste and Abuse (FWA) requirements for contracted pharmacy providers include, but are not limited to:

- Monitoring and auditing the compliance of subcontractors that deliver services or support related to administrative or health care services provided to a member of a Medicare Prescription Drug Plan.
- Obtaining approval from MC-Rx for relationships with downstream entities. MC-Rx must notify CMS of any location outside of the United States or a United States territory that receives, processes, transfers, stores, or accesses Medicare member protected health information (PHI) in oral, written, or electronic form.
- Having policies and procedures in place for preventing, detecting, correcting, and reporting FWA, including, but not limited to:
    - Requiring employees and subcontractors to report suspected and/or detected FWA
    - Safeguarding MC-Rxs' confidential and proprietary information
    - Providing accurate and timely information/data in the regular course of business
- Cooperating fully with any investigation of alleged, suspected or detected violation of the manual, MC-Rx policies and procedures, applicable state or federal laws, or regulations and/or remedial actions.
- Publicizing disciplinary standards to employees and subcontractors.

18.2. Coverage Determination

As established by CMS under 42 CFR 423.128(b)(7)(iii) and 423.562(a)(3), Participating Pharmacies are required to provide beneficiaries with a written copy of the standardized pharmacy notice (CMS-10147) when the member's prescription cannot be filled under the Part D benefit and the issue cannot be resolved at the Point-of-Service. The notice instructs the member on how to contact their plan and explains the member's right to receive, upon request, a coverage determination (including a detailed written decision) from the Part D plan sponsor regarding his or her Part D prescription drug benefits, including information about the exceptions process.

18.3. Medicare Transition

CMS requires an appropriate transition process to provide covered persons with a temporary supply of prescription drugs in certain circumstances, including, but not limited to:

- Current drug therapies not included in their new Medicare Part D Benefit Sponsor's Drug Formulary.
- Current drug therapies are subject to certain limits such as a prior authorization (PA), step therapy (ST), and/or quantity limits (QL).

The transition process promotes continuity of care and avoids interruptions in drug therapy while a switch to a therapeutically equivalent drug or the completion of a coverage determination, or an exception request to maintain coverage of an existing drug based on medical necessity reasons, can be effectuated.

Claims for products covered under transition are identified with a special alert message. As a Pharmacy Provider, we expect you to provide the member information and orientation whenever a transition supply is filled by the Pharmacy.

The online claims processing and adjudication system provides automatic adjudication for drugs that comply with transition requirements

If the **transition is not related** to non-formulary drugs or to drugs that require prior authorization or are subject to step therapy or quantity limits, the pharmacy will receive a warning message.

The pharmacy should provide the member with information on the number of supply days and explain that this is a one-time supply for the transition process only.

The transition process does NOT apply to drugs in the following categories excluded by CMS.

- Non-prescription medications ("OTC" - over the counter)
- Vitamins (except prenatal and fluoride preparations)
- Medications for anorexia, weight gain, or reduction
- Drugs to promote fertility
- Drugs for cosmetic purposes
- Drugs to promote hair growth
- Cold and cough relief medications

- Covered medications for which the manufacturer requires the purchase of a test or monitoring service exclusively provided by the same manufacturer as a condition of sale
- Drugs used to treat sexual or erectile dysfunction

  Note: These medications meet the definition of drugs under Part D when they are prescribed for any indication approved by the FDA other than erectile dysfunction.
- Drugs that have not completed efficacy trials as required by the FDA (DESI Drugs)
- Brand drugs whose manufacturers have not signed an agreement with CMS

18.4. Exclusion Lists

Pharmacy Providers are required to have policies and procedures in place for the periodic review of their personnel in the exclusion lists required by CMS:

- **Office of Inspector General of the U.S. Health and Human Services (HHS-OIG)** at https://oig.hhs.gov/exclusions/exclusions_list.asp
- **U.S. General Services Administration (GSA)** at https://www.sam.gov/SAM/pages/public/searchRecords/search.jsf

Pharmacies must check these lists for each new hire **within 90 days prior to the hire date and then monthly thereafter**, to ensure that its employees are not included in such lists, and therefore, unable to work with federal programs. The Pharmacy must keep records to evidence that the monthly revisions were duly performed. Such records must be available to MC-Rx when requested.

If an employee is indeed listed in either exclusion lists, he/she shall be removed immediately from any direct or indirect activity related to any federal healthcare programs, such as Medicare and Medicaid, and the pharmacy must take the necessary corrective actions.

18.5. CMS Preclusion Lists

Starting in 2019, CMS requires Medicare plan sponsors to remove any contracted provider included in the Preclusion List from their network as soon as possible. This requirement also applies to Medicare Part D plans, which are also expected to remove any precluded pharmacy from their network as soon as possible. In the event that your pharmacy is listed in CMS Preclusion List, MC-Rx will notify you in writing the actions to be taken.

18.6. Conflict of Interest

The Pharmacy Provider must assure that those employees responsible for the administration or dispensing of medications under Medicare Part D do not have any conflict of interest whatsoever for administering or dispensing medications for Medicare Part D.

18.7. Code of Conduct & Ethics

Pharmacy Providers must comply with all applicable Medicare laws and regulations, and CMS instructions, which include having compliance policies and procedures in place, and a standard of conduct and ethics disseminated upon the pharmacy staff.

MC-Rx too has developed a Code of Conducts and Ethics in compliance with these statutes. This document is available at our website www.mc-rx.com.

18.8. MPD MAC Pricing

Federal regulations establish the disclosure and review standards for prices of prescribed drugs included in the Medicare MAC list.

In compliance with CMS requirements established in 42 CFR § 423.505(b)(21), MC- Rx reviews and updates MAC prices periodically; such updates are made available to pharmacies for review in advance of their use. MC-Rx has developed an online tool that will provide Participating Pharmacies with access to updated pricing information for Medicare Part D covered drugs. Visit www.mc-rx.com to register and review the Medicare Part D MAC price list.

18.9. Vaccines Administration

Since January 1st, 2008, the Medicare Part D program covers the cost associated with the administration of certain vaccines. As a result, the member has a variety of options to receive services associated with the purchase and administration of vaccines.

- **Option 1: Pharmacy dispatches and administers the vaccine**

  The member buys the vaccine at a pharmacy and the vaccine is administered by duly authorized healthcare professionals at the dispensing pharmacy. To do so, the pharmacy must have duly authorized healthcare professionals to administer such vaccines. The pharmacy will electronically process, in a single transaction, the costs associated with the vaccine and its administration.

Pharmacies interested in participating in the Vaccine Administration Network need to submit evidence of compliance with all required credentials of healthcare professionals who will administer vaccines at the pharmacy facilities and a duly completed and signed Compensation Attachment Form (MC-Rx Compensation Attachment-/ Medicare Part D Vaccine Administration).

For more information on how to become a Vaccine Administration Pharmacy Provider, or vaccines claim processing requirements, contact MC-Rx's Pharmacy Network.

- **Option 2: Pharmacy only dispatches the vaccine**

  In this case, either the Pharmacy does not have authorized healthcare professionals to administer vaccines or the member prefers to buy the vaccine at the Pharmacy and have the vaccine administered by a healthcare professional at another facility.

  Thus, the pharmacy will process only the cost of the vaccine. The member will pay the administration costs to the healthcare provider and afterwards submit a reimbursement request to the health insurance plan.

Section 19. Benefit Integrity Program

MC-Rx has adopted a comprehensive Benefit Integrity Program (the Program) in compliance with Federal and local regulatory requirements. The Program aims at

preventing, detecting, correcting, and reporting Fraud, Waste and Abuse (FWA) as well as ensuring compliance with regulatory and contractual requirements by network pharmacies to guarantee integrity in the benefits administered by MC-Rx. This is accomplished through the implementation and continuous assessment of a set of guidelines that seek to:

- Reduce fraud, waste and abuse
- Improve quality of service
- Ensure compliance at the pharmacy operations
- Educate involved parties and stakeholders on FWA topics
- Reduce financial burdens caused by potential FWA and billing inaccuracies
- Among others

At the very core of this Program is MC-Rx's commitment with ethical and lawful activities throughout all our business endeavors. To this end, the Program shall serve our network pharmacies as a guide to assist them in preventing, detecting, investigating, and helping correct potential misconducts and billing inaccuracies.
MC-Rx fulfills its fiduciary, contractual, and regulatory obligations to uphold quality of care and discourage the submission of false and inaccurate claims, as described in this Program, through two (2) main approaches:

- Pharmacy Audits
- Fraud, Waste and Abuse (FWA) Monitoring and Investigations

Please be advised that the **Benefit Integrity Program Handbook** (the **Handbook**) is available to you at your request. You may request it by sending an email to pharmacycontracting@mc-rx.com. Participating Pharmacy agrees to comply with

the Benefit Integrity Program Handbook which is incorporated herein by reference. The Handbook provides information on:

- Fraud, Waste and Abuse (FWA) - including applicable federal laws and common FWA schemes
- Pharmacy Audits Program - including detailed information on audit guidelines
- Guidelines for the Proper Billing/Adjudication and Dispensing of Drugs
- Among others

The **Benefit Integrity Program** is reviewed on a regular basis and updated as necessary, so we encourage you to continuously review the Benefit Integrity Program Handbook to ensure compliance and maintain up-to-date information.

19.1. Fraud, Waste and Abuse

MC-Rx is committed to upholding the highest standards of honesty and integrity in all business activities. That is why we believe that it is in the best interest of our network pharmacies to implement measures that will help them prevent fraud, waste and abuse – which can have a detrimental impact on the quality of healthcare and associated costs.

MC-Rx has designed specific activities – in addition to routine monitoring – to support the detection, prevention, and reporting of fraud, waste and abuse. As part of these activities, all network pharmacies are required to immediately report any suspicion of fraud, waste and abuse. Internal and external reporting mechanisms are available to anyone who suspects fraud, waste or abuse within MC-Rx or its network.

The guidelines described in the **Benefit Integrity Program Handbook** (available in your **Provider Portal**) have been developed in an effort to prevent fraud, waste and abuse and are focused on network pharmacies that provide services to the clients we serve, with special emphasis on government-funded programs such as Medicare Part D and Medicaid.

We strongly encourage you to carefully review the **Handbook** to learn more about fraud, waste and abuse, including:

- Definitions
- Federal Anti-FWA Laws
- Exclusions Lists
- Common FWA Schemes
- Prevention of FWA
- Identification and investigation of FWA
- Acting upon FWA
- Reporting Suspicions of FWA
- FWA Education

19.2. Pharmacy Audits Program

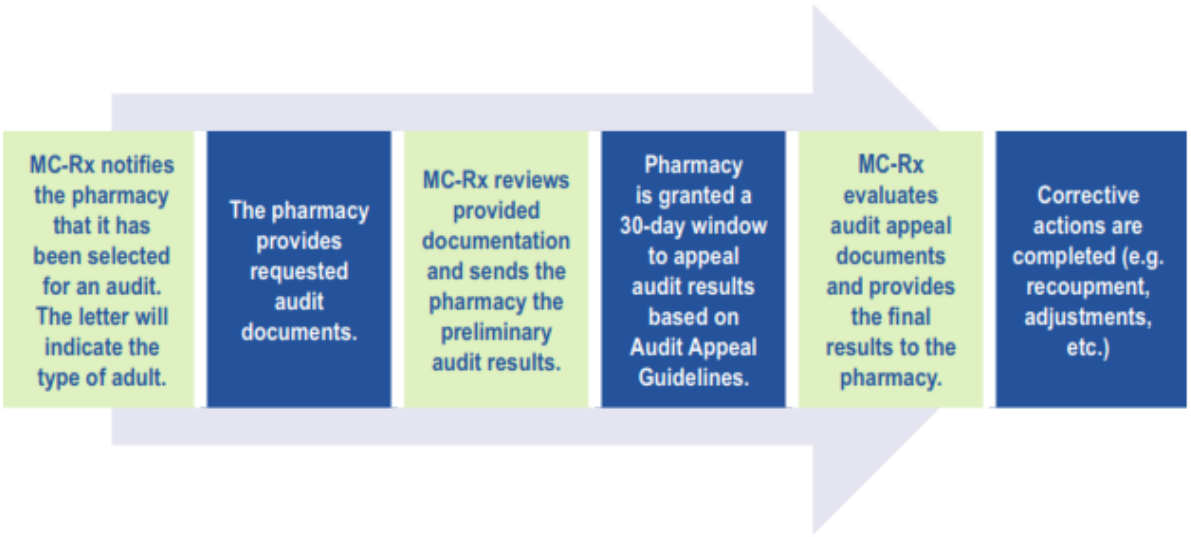
The main objective of MC-Rx's Pharmacy Audit Program is to ensure compliance with applicable Federal and local laws and regulations, as well as contractual terms between MC-Rx and participating pharmacies. In addition, the program seeks to deter, identify and detect potential fraud, waste and abuse, ensure the validity and accuracy of the claims processed and invoiced

to our customers and to CMS, and educate participating pharmacies on related topics. Audits may be conducted either remotely (desktop) or physically (onsite) always following MC-Rx's pharmacy audit guidelines.

Pharmacies are identified for an audit process either randomly or based on, but not limited to, one or more of the criteria listed below:

- Apparent aberrant utilization and/or billing patterns
- Suspected wrongdoings or suspicious activities
- Referrals received by MC-Rx's Special Investigations Unit (SIU)
- Alerts obtained from the MEDIC (Medicare Drug Benefit Integrity Contractor) and/or any other agency
- Fraud prevention and detection advisory opinions, alerts, bulletins, etc., distributed by the United States Department of Health and Human Services (HHS-OIG)
- Time since last audit
- Any other mechanisms that may trigger participating pharmacies to be audited

The following chart provides a high-level overview of MC-Rx's pharmacy audit process:



We strongly encourage you to carefully review the **Handbook** to learn more about MC-Rx's Pharmacy Audit Program, including:

- Audit Process
- Types of Audits
- Audit Notifications
- Documentation Submission Standards
- Preliminary Audit Results
- Pharmacy Audit Appeal Guidelines
- Final Audit Results
- Claims Adjustment and/or Recoupment Process
- Corrective Actions

19.3. Guidelines for the Proper Billing/Adjudication and Dispensing of Drugs

19.3.1. Prescription Requirements

All prescriptions must comply with the provisions stated in Puerto Rico's Pharmacy Law No. 247 of September 3, 2004. Among other elements, prescriptions must include the following:

- Patient's name
- Patient's address
- Prescription date
- Drug name, strength and dosage form
- Drug quantity
- Directions for use
  - "Use as Directed" will not be accepted
  - For sliding scale dosing, the maximum daily dosage must be documented
- Prescriber's signature
- Prescriber's state license number and NPI
- Prescriber's DEA license number – in case of controlled substances
- Date of pick-up or delivery

According to Puerto Rico's Pharmacy Law, pharmacists may complete missing information by consulting with the prescriber or the patient and annotating it on the back of the prescription. In order for these annotations to be accepted, they must include the date and time stamp of the intervention, and the pharmacist's

initials/signature.

Prescriptions that do not reflect information required by law will be considered "incomplete" and will be reported as an audit finding.

19.3.2. Bioequivalent and Biosimilar Medications Exchange

- **Bioequivalent:** Pharmacists must offer all patients the exchange of brand drugs for bioequivalent drugs whenever applicable, as required by the Puerto Rico's Pharmacy Law. Prescriptions must show a valid signature from the patient authorizing the exchange. The pharmacy must ensure that all product exchanges are made in accordance with FDA guidelines.
- **Interchangeable Biosimilar Substitution**
  - An interchangeable biosimilar may be substituted at the pharmacy for the reference product if it has been approved as interchangeable for the prescribed biologic product and has been included in the Purple Book.
  - The FDA considers an unbranded biologic to be equivalent to its brand name biologic. As such, the FDA considers that it is the same product, under the same BLA license (Biologics License Application).
  - The product may be interchanged by the pharmacy when the prescriber has NOT indicated "Do not Substitute or DAW" in the prescription.
  - If the prescriber has documented "Do not Substitute or DAW"

in the prescription, the pharmacy must submit the claim using DAW code 1.

- The pharmacist must notify the patient that the product has been substituted for an interchangeable product; the patient has the right to refuse the substitution of the biologic product if he/she decides so.
- If the patient refuses the substitution, the pharmacy must submit the claim using DAW code 2 and document the patient's decision either on the back of the prescription or the electronic system.
- The pharmacist who performs the substitution, or his/her designated individual, must notify the prescriber of the specific product that was dispensed to the patient, including the product name and its manufacturer. This notification must occur within two (2) days after dispensing the medication and may be done either through phone, fax, electronic transmission, or any other means of communication.

19.3.3. Validity of Prescriptions

Prescriptions for non-controlled medications are valid for twelve (12) months (365 days) from the date of issue, as stated in Puerto Rico's Law No. 189 from November 20, 2014. This also applies to refills of the same prescription, to the maximum of refills approved by the member's coverage, except for prescriptions issued by physicians

licensed to practice in the United States, which may be refilled in Puerto Rico within a period of three (3) months, including the day in which the prescription was issued.

Validity of prescriptions for controlled substances is subject to the provisions of Puerto Rico's Law No. 4 from June 23, 1971, as amended, known as the Controlled Substances Law of Puerto Rico, as well as Title 21 Code of Federal Regulations, Part 1306.

19.3.4. Directions for Use

All prescriptions must contain valid directions for use. In cases where the prescriber indicates "use as directed", the pharmacist will be responsible for contacting the prescriber to clarify the directions for use. This clarification must be annotated on the back of the prescription or in the patient's electronic record with a date and time stamp. In order for this annotation to be accepted, it must include an explanation of the prescriber's instructions, the date and time stamp of the intervention, and pharmacist's initials/signature.

19.3.5. Calculation of Day's Supply

Pharmacies must ensure the appropriate calculation and submission of the correct days' supply for all medications, including drops, inhalers, liquids, injectable products, insulins, etc. For your reference, we have included below additional descriptions and conversion tables. This information must not be considered

exhaustive and the Pharmacist is expected to apply their clinical judgment, directions for use, package sizes and product stability when making these calculations. "Use as Directed" or "As needed" will not be accepted for the calculation of days' supply, unless there is a clarification made according to the previous section (Directions for Use). Claims with discrepancies in quantities and/or days' supply will be subject to recoupment of the amount paid for these. In some cases, day's supply miscalculations may lead to unauthorized early refills; these refills may also be subject to recoupment.

- **Ophthalmic Drops** - Ophthalmic drops must be calculated based on a 1:20 ratio (20 drops per mL), unless the product provides for a more specific drops/mL ratio on its package.

Standard Duration of Ophthalmic Drops								
Presentation	One (1) drop/day		Two (2) drops/day		Three(3) Drops/day		Four (4) drops day	
	1 eye	2 eyes	1 eye	2 eyes	1 eye	2 eyes	1 eye	2 eyes
2.5 mL	50 days	25 days	25 days	12 days	16 days	8 days	12 days	6 days
5 mL	100 days	50 days	50 days	25 days	33 days	16 days	25 days	12 days
10 mL	200 days	100 days	100 days	50 days	66 days	33 days	50 days	25 days
15 mL	300 days	150 days	150 days	75 days	100 days	50 days	75 days	37 days

- **Insulin** - Days' supply and quantities for insulin products must be calculated to accurately show the prescribed directions for use, units per mL and manufacturer's guidelines (e.g. storage and stability) of the product. For sliding scale dosing, the days' supply must be calculated based on the maximum daily dosage per the

prescribed range. If the range is not provided, the Pharmacist must consult directly with the prescriber to obtain the sliding scale range. This intervention must be documented following the guidelines described in the previous section (Directions for Use).

- **Inhalers** - Days' supply calculations for inhaler products must be made in accordance with directions of use and metered actuations described in the product's package. In some cases, the days' supply may exceed certain benefit design limits (e.g. claims that exceed 30 days). In such cases, MC-Rx instructs the pharmacy to (1) evaluate the feasibility of providing a smaller package size if available (e.g. topical products), (2) call our Pharmacy Help Desk to request administrative overrides that would allow the claims to adjudicate beyond the benefit design limit, or (3) submit the claim for the days' supply instructed in the rejection message but ensuring that no upcoming refills are paid too early.
- **Other Unbreakable Products** - It is MC-Rx's policy that all products must be billed according to prescriber directions for use, product package sizes, and manufacturer's guidelines (e.g. storage and stability). In some cases, because of their "unbreakable package" nature, the days' supply may exceed certain benefit design limits (e.g. claims that exceed 30 days). In such cases, MC-Rx instructs the pharmacy to: (1) evaluate the feasibility of providing a smaller package size if available (e.g. topical products), (2) call our Pharmacy Help Desk to request

administrative overrides that would allow the claims to adjudicate beyond the benefit design limit, or (3) submit the claim for the days' supply instructed in the rejection message but ensuring that no upcoming refills are paid too early. This would ensure appropriate utilization and integrity of the benefit, thus reducing potential waste. Some of these products include:

- Inhalers
- Injectable products
- Insulin
- Some topical products
- Otic/Ophthalmic drops

19.3.6. Prescription Splitting and Partial Fills

As opposed to partial fills, splitting a 30-day prescription into separate supplies is not allowed and may be considered a potential FWA scheme. Whenever a prescription is split, the remaining quantities must not be billed to the plan.

- **Example 1:** The physician prescribed 30 tablets for 30 days. The pharmacy billed 15 tablets for 15 days and instructed the patient to come back to the pharmacy in 15 days to obtain the remainder. This is unacceptable.
- **Example 2:** The physician prescribed 60 tablets for 30 days. The plan rejected the claim with a "15-day limitation". The pharmacy bills 30 tablets for 15 days. The remaining 15-day supply cannot be billed to the plan as a refill. In this case, the

patient would need a new prescription.

- **Example 3:** The physician prescribed 30 tablets for 30 days. The patient asked the pharmacy to fill only a 15-day supply since they would go back to the pharmacy to get the remaining 15-day supply. The remainder must not be billed to the plan and the patient would need a new prescription. Contrary to prescription splitting, a "Partial Fill" is defined by NCPDP as an optional claim billing process for when a prescription cannot be filled for the full quantity ordered due to insufficient inventory on-hand at the dispensing pharmacy. In these cases, the pharmacy must identify the claim as a partial fill using the applicable NCPDP fields in the claims processing system.

19.3.7. Compounds Processing

Compound claims selected for audit must contain the appropriate compound worksheet/log identifying the products used for such compounds, including NDCs and quantities.

Also, this worksheet will be used to evaluate the Level of Effort (LOE) billed by the pharmacy in order to determine whether the LOE is appropriate based on the complexity of the compound. Claims whose information does not match that in the worksheet, or the LOE does not match the documented complexity of the compound, will be subject to corrective actions, including recoupment.

19.3.8. Signature/Delivery Logs

Participating pharmacies must maintain a signature or delivery registry log for each medication dispensed or delivered. The signature log must contain, at least, the following information:

- Patient's name and ID number
- Proxy's name and ID number (if applicable)
- Date of fill
- Rx number
- Patient's/Proxy's signature
- Date of pick-up or delivery

Both electronic and manual signature logs are acceptable. In order to ensure proper validation of the person picking up the prescription and prevent potential FWA, the following forms of identification will be considered valid: driver's license, passport, or electoral ID card.

19.3.9. Prescription Origin Code

Pharmacies must submit an accurate and valid prescription origin code for each claim submitted to MC-Rx:

- 1 = written
- 2 = telephone
- 3 = electronic
- 4 = facsimile

19.3.10. Electronic Prescriptions

Generally, electronic prescriptions must comply with the same elements as an ordinary written prescription. In addition, electronic

prescriptions must comply with the following:

- Origin Code "3" must be used for all electronic prescriptions.
- Prescribers' phone number and unique e-prescription network ID, also known as SPI number, must be documented in the electronic prescription.
- For electronically prescribed controlled substances, the pharmacy must retain digital signatures and verify the DEA registration of a prescriber on any suspected fraudulent prescription. The pharmacy and prescriber's software must be certified as DEA compliant with established rules for e-prescribed controlled substances effective June 1, 2010.

19.3.11. Prescription Transfers

The transfer of a non-controlled medication requires the following information in writing by the pharmacist receiving the transferred prescription, according to federal guidelines:

- Origin Code "5" must be used for all transferred prescriptions.
- The word "transfer" must be written on the front of the prescription.
- Prescription must contain all elements described above.
- The date of issuance of the original prescription must be registered.
- The original number of refills authorized on the original prescription must be registered.

- Number of valid refills remaining and dates and locations of previous refills must be registered.
- Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred and originally filled must be registered.
- The name of the pharmacist transferring the prescription must be documented.

19.3.12. Undelivered/Unpicked Medications

Participating pharmacies must ensure that prescriptions that have not been delivered or picked up by the patient during the last 14 days are returned to stock and claims are reversed accordingly.

Section 20. MC-Rx Online

Visit our webpage www.mc-rx.com for valuable information and materials.

Circular Letters are readily available for day–to–day reference

- Benefit Integrity Program Handbook
- FWA General Compliance Training Course
- FWA Training Attestation
- MAC Price Review Tool & Users Guide
- Medicare Part D MAC Pricing Tool & Users Guide
- Code of Ethics and Conduct
- Disclosure Statement
- Most frequently used forms – complete online or download
  - Pharmacy Profile Information Update

- Prior Authorization Request
- MAC Price Review Request
- Universal Claim Form (UCF)
- Request to Dispute a Claim
- Electronic Funds Transfer (EFT)
- CMS Notice 10147 Medicare Prescription Drug Coverage and your Rights