Capital Rx

Pharmacy Provider Manual

December 1, 2022 | v4

Introduction

Welcome to the Capital Rx pharmacy provider network(s). Capital Rx is a pharmacy benefit manager that manages the pharmacy benefits and provides other services including reporting and clinical management for a number of client Plan Sponsors and their Members. Capital Rx networks support both national and regional clients and is committed to fostering a strong relationship with its provider pharmacies.

Please review this Provider Manual thoroughly as it is intended to outline certain policies, procedures, and other instructions necessary for its provider pharmacies to follow for participation in the provider network(s) ("Networks"). This Provider Manual, along with the base Agreement (into which this Provider Manual is incorporated) and any related amendment(s), addendum(s), exhibit(s), or other applicable documentation, governs the relationship between Capital Rx and you, the pharmacy provider (including as applicable any of the pharmacy locations affiliated with your chain code(s)) (hereinafter, "You", "Your", or "Pharmacy").

Please note that this Provider Manual is subject to change by Capital Rx and such changes are effective at the time of publication. This Provider Manual is not intended to address every issue or replace sound clinical professional judgment.

Thank you for your participation in Capital Rx's Networks. We appreciate the role you play in ensuring the health and safety of our Members.

Relevant Contacts

Pharmacy Help Desk Services

For Member eligibility and benefit plan information, claims processing, and payment/remittance questions please contact us by dialing the number located on the back of the member's ID card or by calling 888-832-2779.

Hours of operation: 24 hours a day 7 days a week including holidays

For pharmacy payment related questions, you may also reach out to ap@cap-rx.com.

For pharmacy remittance advice questions, you may also reach out to CapitalRx835@cap-rx.com.

Capital Rx Provider Relations Department

If you have feedback, issues or questions you would like to share with Capital Rx including feedback related to quality of care or services, or have questions related to your Agreement or credentialing, please contact Capital Rx at the mailing address or email address below.

228 Park Ave S. Suite 87234
New York, NY 10003
Email: Provider.Relations@cap-rx.com

Provider Forms and Documents
Pharmacy forms and documents are available online at: https://www.cap-rx.com/providers/pharmacist

Pharmacy Notifications and Communications
Capital Rx provides notifications and communications to its network pharmacies regarding updates to procedures, payer sheets, formularies, Manual, etc. via email. Pharmacies are required to update their information directly with NCPDP. Maintaining information about your pharmacy in NCPDP is vital.

To request copies of previous pharmacy communications, please contact Capital Rx Provider Relations at the following: **Email:** Provider.Relations@cap-rx.com

Pharmacy Audit Communications
In the event Pharmacy needs to contact the Capital Rx Audit Department, please contact Capital Rx at the mailing address or email address below.

228 Park Ave S. Suite 87234
New York, NY 10003
Email: Pharmacy_audit@cap-rx.com

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I. Definitions

The following definitions may be used in this Provider Manual and are derived from definitions in the Agreement, Plan Sponsor requirements, or applicable law or regulations.

1) **"Agreement"** means the contractual agreement to which Pharmacy and Capital Rx are parties that governs their relationship.
2) **"Affiliate"** means with respect to any person or entity, any other person or entity which directly or indirectly controls, is controlled by or is under common control with such person or entity.
3) **"Average Wholesale Price" or "AWP"** means the benchmark price established by a nationally available reporting service as selected by PBM based on the 11-digit National Drug Code ("NDC") of the Covered Medication dispensed by Pharmacy.
4) **"Brand Drug Product"** means a drug that is either a Multi- Source Brand or a Single-Source Brand and additionally not a DAW 5 Claim, and not a Specialty Drug.
5) **"Capital Rx"** shall mean Capital Rx, Inc. and Capital Rx IPA, LLC.
6) **"Centers for Medicare & Medicaid Services (CMS)"** is a federal agency within the United States Department of Health & Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program (SCHIP), and health insurance portability standards in addition to other responsibilities such as managing the administrative simplification standards from the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
7) **"Claim"** means and refers to Pharmacy's billing or invoicing following NCPDP standards for a single prescription for Covered Prescription Services dispensed to a Member enrolled with a Plan in accordance with the Agreement and this Provider Manual.
8) **"Claims Processor"** means Capital Rx or a third-party pharmacy claims processor with which Capital Rx may contract.
9) **"Clean Claim"** means and refers to a Claim prepared in the standard format promulgated by NCPDP which contains all of the information necessary for claim processing, that is compliant with all applicable legal requirements and regulations and it not found to be false, fraudulent, discrepant or otherwise ineligible by Capital Rx.
10) **"Co-payment" or "Cost Sharing Amount(s)"** means the amount Pharmacy shall collect from a Member for providing a Covered Prescription Service in accordance with the Member's Plan.
11) **"Compound Prescription"** means a prescription consisting of two or more ingredients, at least one of which is a prescription drug, and which is prepared by the pharmacist specifically for the Member according to the prescriber's directions. For the avoidance of doubt, the addition of only water and/or flavoring does not result in a Compound Prescription.
12) **"Covered Prescription Service(s)"** means the prescriptions and other products and services that may be dispensed or provided by Pharmacy to which a Member is entitled to receive in accordance with and subject to the terms and conditions of the Plan.
13) **"DAW 5 Claim"** means a Claim that is submitted with a dispense as written (DAW) code of 5, which indicates that a branded pharmaceutical product was dispensed in the same manner as a generic.
14) **"Drug"** means a pharmaceutical or pharmaceutical compound. This includes, without limitation, all products with a Medi-Span GPI-2 distinct from 97 or 94.
15) **"ePrescription"** means a prescription which is written and signed by a prescriber electronically and then transmitted electronically to the Member's pharmacy.
16) **"Formulary"** means the listing of drugs, pharmaceutical products, and devices that are covered by the applicable Plan that is developed and revised by Capital Rx which may be pursuant to direction of the applicable Plan.
17) **"Generic Drug Product"** means a drug that is either a Multi-Source Generic or a Single-Source Generic or a DAW 5 Claim and not a Specialty Drug.

18) **"Home Infusion"** (HI) Pharmacy is a Pharmacy-based, decentralized patient care organization with expertise in USP 797-compliant sterile drug compounding that provides care to patients with acute or chronic conditions generally pertaining to parenteral administration of drugs, biologics and nutritional formulae administered through catheters and/or needles in home and alternate sites. Extensive professional pharmacy services, care coordination, infusion nursing services, supplies and equipment are provided to optimize efficacy and compliance. For purposes of Medicare, PBM shall designate the pharmacies with a NCPDP primary provider Type Code "06" Home Infusion Therapy Provider as a Home Infusion pharmacy.
19) **"Indian Health Services, Tribal or Urban Indian Health, or I/T/U"** is a retail pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization or an urban Indian organization as defined in Section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603. These pharmacies are identified by a National Council for Prescription Drug Program's (NCPDP) dispenser type code of 8.
20) **"Long Term Care (LTC) Pharmacy"** is a pharmacy that dispenses medicinal preparations delivered to patients residing within an intermediate or skilled nursing facility, including intermediate care facilities for mentally retarded, hospice, assisted living facilities, group homes, and other forms of congregate living arrangements. For purposes of Medicare, "LTC Pharmacy" shall have the same meaning as the term "long term care network pharmacy" under 42 CFR § 423.100, as amended from time to time and Claims submitted with a patient residence code of 3 or 9 shall be deemed LTC Claims.
21) **"Mail Order Pharmacy"** is a pharmacy where pharmacists compound or dispense prescriptions or other medications in accordance with federal and state law, using common carriers to deliver the medications to patient or their caregivers. Mail order pharmacies counsel patients and caregivers (sometimes independent of the dispensing process) through telephone or email contact and provide other professional services associated with pharmaceutical care appropriate to the setting. Mail order pharmacies are licensed as a Mail Order Pharmacy in the state where they are located and may also be licensed or registered as nonresident pharmacies in other states.
22) **"Member"** means an individual who is enrolled with a Plan Sponsor that is entitled to receive Covered Prescription Services.
23) **"Multi-Source Brand"** means those Prescription Drug(s) identified as "O" by Medi-Span's Multi-Source Code indicator.
24) **"Multi-Source Generic"** means those Prescription Drug(s) identified as "Y" by Medi-Span's Multi-Source Code indicator.
25) **"NADAC"** means the National Average Drug Acquisition Cost list published by the Centers for Medicare and Medicaid Services (CMS).
26) **"NCPDP"** means the National Council of Prescription Drug Programs.
27) **"Network"** means Capital Rx's pharmacy participation network(s) designed to offer access to Covered Prescription Services to Members under Plans.
28) **"NPPES"** means National Plan and Provider Enrollment System.
29) **"OTC Drug"** means a Drug with a Medi-Span Rx-OTC Indicator Code of "O" or "P."
30) **"Pharmacy Reimbursement Rates"** means the agreed upon rates that Capital Rx has agreed to pay Pharmacy for the provision of, and payment for Covered Prescription Services.
31) **"Pharmacy Services Administration Organization (PSAO)"** means an administrator that contracts on behalf of a collective group of independent pharmacies. Independent pharmacies affiliated with a contracted PSAO provides services to Capital Rx through that delegated relationship.
32) **"Plan"** means the benefit to Members which may include, but is not limited to any Medicaid, Medicare Part D Plan, or other prescription drug plan, discount card programs and workers compensation programs that are operated, offered or provided by Capital Rx or Plan Sponsors that entitle Members to receive reimbursement for, or payment of Covered Prescription Services.
33) **"Plan Sponsor"** means, including, but not limited to, an employer, health insurer, managed care organization, union health and welfare trust, government agency or third party or pharmacy benefit administrator that operates, offers or provides the Plan(s) through PBM.

34) **"POS System"** means the online or real time (point-of-sale) telecommunication system used to communicate information including, but not limited to, Covered Prescription Services.
35) **"Prescription Drug"** means a pharmaceutical or pharmaceutical compound that under applicable law requires a prescription.
36) **"Provider Manual"** means but is not limited to the guidelines, policies and procedures regarding standards of practice, Plan specifications and additional terms and conditions to the Agreement to which Pharmacy is required to adhere. The Provider Manual is incorporated by reference into the Agreement.
37) **"Retail Pharmacy"** is a pharmacy where pharmacists store, prepare, and dispense medicinal preparations and/or prescriptions for a local patient population in accordance with federal and state law; counsel patients and caregivers (sometimes independent of the dispensing process); administer vaccinations; and provide other professional services associated with pharmaceutical care such as health screenings, consultative services with other health care providers, collaborative practice, disease state management, and education classes. A retail pharmacy does not self-identify with NCPDP as a Mail Order Pharmacy (dispenser type code of "5") or Specialty Pharmacy (dispenser type code of "15"). A retail pharmacy does not advertise itself as a Mail Order Pharmacy. The retail pharmacy represents that its primary method of dispensing or distributing Prescription Drugs, divides, or non-prescription drugs is not by mail or another common carrier.
38) **"Single-Source Brand"** means those Prescription Drug(s) identified as "M" or "N" by Medi-Span's Multi-Source Code and additionally as "B" or "T" by Medi-Span's Name Type Code.
39) **"Single-Source Generic"** mean those Prescription Drug(s) identified as "M" or "N" by Medi-Span's Multi-Source Code and additionally as "G" by Medi-Span's Name Type Code.
40) **"Specialty Drugs"** means Prescription Drugs that are typically used to treat chronic or complex conditions, and typically have one or more of several key characteristics, including frequent dosing adjustments and intensive clinical monitoring to decrease the potential for drug toxicity and increase the probability for beneficial treatment outcomes; intensive patient training and compliance assistance to facilitate therapeutic goals; limited or exclusive product availability and distribution (if a drug is only available through limited specialty pharmacy distribution it is always considered a Specialty Drug); specialized product handling and/or administration requirements; or costs $600 or more on a monthly basis. Specialty Drugs may be administered by any route of administration. Specialty Drugs include biosimilars. Specialty Drugs shall be deemed those drugs on the PBM's Specialty Drug List, and any added to the Specialty Drug List after the Effective Date.
41) **"Specialty Pharmacy"** is a pharmacy that (1) is licensed under Law, (2) dispenses Specialty Drugs to Members through the U.S. mail or a commercial carrier service, (3) dispenses generally low volume and high cost medicinal preparations to patients who are undergoing intensive therapies for illnesses that are generally chronic and complex; often these therapies require specialized delivery and administration and (4) has entered into an agreement with, or is an Affiliate of, Capital Rx in order to provide Covered Pharmaceuticals to Members. For purposes of this Agreement, a Retail Pharmacy is not a Specialty Pharmacy.
42) **"Usual and Customary" or "U&C"** means the lowest price Pharmacy would charge to a particular customer if such customer were paying cash for the identical Covered Prescription Services on the date dispensed. This includes any applicable discounts, including, but not limited to, advertised or sales prices, price matching, coupons, senior discounts, frequent shopper discounts, pharmacy provider's savings or discount programs with or without an enrollment fee, any program that offers medication at no cost (e.g. a U&C of $0.00 should be submitted) and other special discounts offered to attract customers. The PHARMACY is required to report an accurate U&C and must not underreport or conceal U&C for prescription services.
43) **"Vaccine"** means a Claim for a Covered Pharmaceutical that is a substance used to stimulate the production of antibodies and provide immunity against one or several diseases.
44) **"340B Drug Pricing Program"** means the program established under Section 340B of the Public Health Service Act that allows for drugs to be acquired at a reduced amount.

45) **"340B Covered Entity"** means the healthcare organization that is entitled to access the 340B Drug Pricing Program for itself or for pharmacies with which it may contract.
46) **"340B Pharmacy"** means a pharmacy that is entitled to access the 340B Drug Pricing Program through a contract with a 340B Covered Entity.

II. Provider Relations

1) Joining the Capital Rx Pharmacy Networks

In order to join the Capital Rx pharmacy network(s), please submit a request to the Capital Rx Provider Relations team at Provider.Relations@cap-rx.com.

Contracted pharmacies will be notified of changes to fee schedules and or contracting provisions either through updates to the provider manual or electronic communication, unless an alternative method is agreed upon.

2) PSAO Requirements

a) **PSAO Requirements**

Each PSAO attests that it has all necessary authority to enter into an agreement with Capital Rx on behalf of its participating pharmacies. Such participating pharmacies are therefore required to comply with any applicable terms or obligations in the agreement signed on their behalf by the PSAO. Each PSAO is required to routinely update the information regarding their participating pharmacy locations in the NCPDP database so as to ensure all pharmacies affiliated with the PSAO are credentialed and contracted as well as to ensure that the NCPDP database has complete and accurate information. PSAO understands that Capital Rx relies on the information in the NCPDP database and as such attests the information in the NCPDP database is accurate. In order to properly remove a pharmacy from affiliation with the PSAO, such pharmacy affiliation must be removed from the NCPDP database at the individual pharmacy level. PSAO is also responsible for ensuring the integrity of any data and reconciling such information with NCPDP as required. Upon reasonable request, PSAO and/or its participating pharmacies as applicable is/are required to respond to Capital Rx promptly upon receipt of a request for documentation necessary to support claims processing or credentialing initiatives. PSAOs are further required to share all relevant information upon request from Capital Rx.

Capital Rx and/or Plan Sponsors may immediately limit or exclude any pharmacy location affiliated with PSAO from participating in applicable network(s) under the terms and conditions of the Agreement. In addition, pharmacy locations affiliated with PSAO may be excluded from participating in applicable network(s) for reasons including: (i) the pharmacy location is a Mail Order Pharmacy or provides Covered Prescription Services in violation of the Agreement; (ii) the pharmacy location is independently contracted directly with Capital Rx; (iii) the pharmacy location has been identified as a 340B pharmacy and contracted independently Capital Rx as such; (iv) pharmacy location does not maintain a valid DEA License or had its DEA license revoked; (v) a pharmacy network is geographic-specific; (vi) the pharmacy location requires a Medicaid ID number for participation. In the event any pharmacy location is excluded for any of the aforementioned reasons, such pharmacy may contact Capital Rx directly for a contract per the contact information listed herein.

3) Credentialing

a) General Credentialing

Capital Rx has a credentialing program to ensure that the pharmacies that provide services to its Plans and Members are valid and properly licensed. Pharmacy is required to comply with Capital Rx's credentialing program requirements of which include:

i) Providing copies of all relevant licenses such as state pharmacy and DEA licenses and/or permits upon joining the Capital Rx Networks and thereafter providing updates to those licenses and/or permits as needed promptly (at least within 3 business days of any change to such licenses and/or permits);
ii) Provide a copy of the applicable certificate of insurance;
iii) Providing copies of relevant documentation or other information requested of it in a timely manner (typically within forty-eight (48) hours of request);
iv) Maintaining updated and accurate information in the NCPDP database;
v) Maintaining updated and accurate information in the NPPES database;
vi) Meeting all applicable standards of operation as required by law and/or regulations;
vii) Maintaining all applicable licenses and/or permits in good standing with federal, state and/or local agencies or authorities;
viii) Providing Capital Rx with prompt written notification (at least within seven (7) days) of the occurrence of any of the below:

- A license or permit of Pharmacy or any of its locations is likely to be suspended or revoked;
- Pharmacy or any of its locations is likely to be disciplined or receives notice or any situation, claim or proceeding that could lead to potential disciplinary action;
- Pharmacy, any of its locations or personnel is the subject of any disciplinary action including but not limited to disciplinary actions by any state or federal board of pharmacy, OIG, GSA or other law enforcement or regulatory body;
- Pharmacy or any of its locations receive a subpoena for records that are applicable to the services Pharmacy and its locations provide to Capital Rx;
- Pharmacy's records, systems or property are seized by law enforcement; or
- Pharmacy or any of its locations or personnel are the subject of any investigation.

**Note that Capital Rx may require enhanced credentialing based on Pharmacy's provider type, the services Pharmacy offers, pursuant to Client direction or legal requirements in which case Capital Rx will notify Pharmacy of such additional requirements it needs to complete.

Capital Rx may deny, terminate, suspend or revoke Pharmacy or any of its locations from any or all Networks as a result of Pharmacy's failure to comply with Capital Rx's credentialing program. In addition, if Capital Rx reasonably believes that Pharmacy or any of its locations or personnel has (i) engaged in any activity that poses a risk to the health, welfare or safety of a Member or the general public, (ii) engaged in behavior that suggests licenses and requirements for such licenses have not been properly maintained, or (iii) engaged in behavior that may reflect negatively on Pharmacy, its locations or personnel and their ability to provide services in accordance with the Agreement, Capital Rx shall have the right to immediately limit or suspend Pharmacy or any of its locations from any or all Networks.

Note that Capital Rx may require mail order/delivery pharmacies, specialty pharmacies, compounding pharmacies and home infusion pharmacies to complete additional credentialing which will be communicated to such pharmacies as applicable. These additional requirements may include accreditation with Verified Internet Pharmacy Practice Sites (VIPPS) (vipps.nadp.net) and/or URAC (urac.org). Additionally, Capital Rx reserves the right to require enhanced or additional credentialing for state, federal or other health plans.

Pharmacies are required to re-credential with Capital Rx every three (3) years or such lesser period time as determined by applicable by state or federal regulations.

Cultural Competency Training and Abuse, Neglect and Exploitation Training. Pharmacies are required to be aware of the cultural differences of our Members to promote the provision of services in a manner that addresses the diversity of the Member population and free of bias including, but not limited to, those with limited English proficiency, diverse cultural/ethnic backgrounds and mental and physical disabilities.

b) Pharmacies are also required to promote an environment free from discrimination based on gender, sexual orientation and/or gender identity. Pharmacies should be aware of any issues related to abuse, neglect, national origin and/or exploitation, and report any concerns to the appropriate state agency when warranted. **PSAO Credentialing**

If Pharmacy is a PSAO, Pharmacy attests/certifies that it has and maintains credentialing and compliance monitoring programs for itself and each of its affiliated pharmacies and that it and all pharmacies affiliated with it meet and will continue to comply with Capital Rx's credentialing program and compliance initiatives including ensuring that (i) all affiliated pharmacies update and maintain accurate pharmacy information in the NCPDP database, (ii) PSAO reviews and primary source verifies the DEA licenses and Pharmacy licenses, and verifies insurance coverage, exclusion and debarment information of its affiliated pharmacies as well as any disciplinary action imposed upon any of its affiliated pharmacies on a monthly basis and provide any relevant information to Capital Rx, (iii) any affiliated pharmacy, pharmacist, subcontractor or other personnel (including temporary personnel) that provides services to Members in the Capital Rx Networks have not been nor will be debarred, excluded or otherwise ineligible to participate in any federal, state or local government funded health care programs or convicted of a felony. If PSAO becomes aware that any affiliated pharmacy, pharmacist, subcontractor or other personnel (including temporary personnel) that provides services to Members in the Capital Rx Networks have been or are likely to be debarred, excluded or otherwise ineligible to participate in any federal, state or local government funded health care programs or convicted of a felony, PSAO shall immediately notify Capital Rx in writing and prevent such personnel or pharmacy location from providing services to Members. In such event, Capital Rx shall have the right to immediately terminate the applicable pharmacy location from the Capital Rx Networks whether or not the location itself or its personnel were or are the subject of the debarment, exclusion ineligibility or felony conviction. If PSAO itself is debarred, excluded or otherwise ineligible to participate in government funded programs or it has not complied with the actions required of it herein, Capital Rx shall have the right to take remedial actions it reasonably deems appropriate or immediately terminate the Agreement upon written notice to PSAO.

Capital Rx and/or its Clients shall have the right to monitor Pharmacy's credentialing program and may request access to Pharmacy's records to do so upon reasonable advance notice unless fraud is suspected. Pharmacy shall do its best to comply with such requests and promptly provide the information requested of it. In addition, Capital Rx and/or its Clients may verify the licenses or permits, insurance, exclusion/debarment status, or disciplinary actions of Pharmacy and/or its affiliated pharmacies and/or any applicable personnel which may include onsite visits to Pharmacy location(s).

In addition to the other requirements outlined herein, PSAO affiliated pharmacies are required to meet the following requirements:

i) Have and maintain proper licensing in the applicable state of residence;
ii) Have and maintain a DEA license;
iii) Have and maintain liability insurance at the minimum amounts below;
- $1,000,000 per occurrence
- $3,000,000 aggregate

iv) Not listed on any exclusion lists or databases including the lists found through the Office of Inspector General's (OIG), U.S. Department of Health and Human Services (HHS) List of Excluded Individuals/Entities (LEIE), General Serves Administration (GSA) System for Award Management (SAM) Excluded Parties Listing System (EPLS); this requirement applies to both the pharmacy owner and the pharmacy itself;
v) Not sanctioned or limited in any way that would prohibit the pharmacy location from fulfilling its obligations hereunder;
vi) Meets the obligations outlined in the Agreement for participation;
vii) Abides by the pharmacist-in-charge (PIC) and personnel requirements below:
- PIC has and maintains all appropriate licenses
- PIC and any pharmacist of other personnel are not listed on any exclusion lists or databases including the lists found through the OIG, HHS LEIE, GSA SAM EPLS
- PIC has and maintains the minimum insurance levels required by the applicable state
- PIC has not been restricted, sanctioned or otherwise limited within the most recent three-year period

Failure by PSAO or any of its affiliated pharmacies to comply with Capital Rx's credentialing program may result in termination or suspension of Pharmacy and/or any of its affiliated pharmacies from any or all Networks.

Pharmacy understands Capital Rx relies on the information about it's network pharmacy providers, as well at each Pharmacy location provided by NCDPD and directly to Capital Rx, therefore, network pharmacy provider:

- Agrees to update in a timely manner all information in NCPDP database whenever necessary as to ensure the information in the database is accurate as Capital Rx updates pharmacy provider profiles and may be displayed to members via on-line or paper directories.
- Information includes, but not limited to, changes in name, address, telephone number, email address, services, NPI, NCPDP, licensure information (e.g. State license, DEA registration), tax identification ID changes, Medicaid ID, provider affiliation, ownership information, provider dispensing type, certificate of insurance, cultural competency training indicator, FWA training indicator.

Pharmacies are also encouraged to update their information, including all taxonomy codes, on the National Plan and Provider Enrollment System (NPPES) as the following location: https://nppes.cms.hhs.gov. The information on MPPES including your pharmacy taxonomy information, may be used for network and contract validation by Capital Rx, Clients, and CMS.

4) Addition to Network

Pharmacies will not be added to Capital Rx's network until they have been properly credentialed. If Capital Rx receives notification from a PSAO/TPA of a new service relationship starting after the first of the month, the effective or start date will be the first of the following month. This includes updates to the service relationship ID in NCPDP.

5) Pharmacy Compliance

Capital Rx appreciates your participation in its Networks and in the role you play in providing services to our Members. In order to ensure that the pharmacy services you provide are compliant, please make sure

to abide by the terms of this Provider Manual and any changes made to it all of which are effective upon publication of such changes unless noted otherwise. In addition, Capital Rx requires its Pharmacy partners and their applicable personnel to be, and remain in, compliance with all applicable law and regulations including those outlined herein.

Please note that Pharmacy's participation in one (1) or more of Capital Rx's Networks shall not guarantee participation in any or all Networks. Capital Rx reserves the right to limit Pharmacy or any of Pharmacy's locations in any network in its sole discretion or pursuant to Client direction.

Capital Rx is reliant upon Pharmacy's participation in its networks and accordingly Pharmacy will not be allowed to opt out of any network without PBM's written consent (which will not be unreasonably withheld), unless applicable law requires Pharmacy to have the ability to opt out of individual networks.

Note that mail and specialty pharmacy partners may be subject to certain performance requirements as outlined in the applicable agreements. In the event an applicable pharmacy does not meet its performance requirements for the given time period, such pharmacy may be subject to certain corrective measures including remediation or corrective action plans to address such failings.

a) Prohibited Activities

In addition to any other prohibited activity listed in this Provider Manual or the Agreement, Pharmacy is prohibited from engaging in the following activities:

- Disclosing any confidential information to a Client or potential Client;
- Disparaging or disrupting the relationship between Capital Rx and any of its Clients or potential clients; or
- Soliciting a Member or Client to terminate its relationship with Capital Rx

In the event Pharmacy engages in any prohibited activity, Capital Rx shall have the right to take remedial actions including immediate termination of Pharmacy from any or all Network(s).

b) Drug Purchases and Transfers

Pharmacy is required to purchase covered drug products for any Claims submitted to Capital Rx from a NABP-VAWD (Verified–Accredited Wholesaler Distributors) licensed wholesaler as regulated by state and federal entities. This requirement includes the purchase of non-legend items (e.g. OTC, supplies). Pharmacy must be able to document the source is authorized to include federal/state licensure, oversight by regulatory agencies to include the Food and Drug Administration (FDA), DEA and ability to obtain pedigree information for drug products. Pharmacy is prohibited from entering into a captive pharmacy arrangement, whereby Pharmacy agrees to market and dispense drug products specifically for a manufacturer without disclosure to and written approval from Capital Rx. In addition, any inter-pharmacy transfers must be accurately and completely documented in a manner consistent with federal and/or state laws and industry standards.

A Pharmacy may transfer inventory to alleviate a temporary shortage or for the sale, transfer, merger or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets. On the day the drug products or medical supplies are transferred, a complete inventory must be taken which documents the drug name, dosage form, strength, NDC, lot number, quantity and date transferred. Additionally, documents must indicate

the supplier or manufacturer's name, address and registration number. All records involved in the transfer must be maintained and accessible for six (6) years.

In order to ensure Pharmacy is complying with these requirements, Capital Rx may request to review Pharmacy's relevant documentation and Pharmacy must promptly comply with any such requests.

c) Records

Pharmacy is required to keep and maintain in accordance with industry standards and practices, applicable law, boards of pharmacy requirements, Plan Sponsor and industry standards, and the Agreement and this Provider Manual accurate and complete records and accounts of all transactions including without limitation: patient records and information, data, prescription files, financial records, databases, daily Prescription logs, patient profiles, prescription hardcopies, prescriber information, signature/delivery logs, refill information, wholesaler/manufacturer/distributor/all other purchase invoices from a NABP accredited source, business records such as Fraud, Waste and Abuse training logs, LEIE/EPLS verifications, and other related and applicable files, and other related documents related to the provision of Covered Prescription Services. PHARMACY shall maintain all such Records for at least ten (10) ten years from the date the Covered Prescription Service is dispensed or longer if required by law.

Prescription Records shall include relevant information including the following:

i) Full name, address and date of birth of the applicable Member for whom the prescription was written;
ii) Full name, address, telephone number and any other required identifier for the prescriber;
iii) Name, strength, dosage form and quantity of the prescribed medication;
iv) Dosing directions (if a prescription contains ambiguous directions, Pharmacy personnel must clarify the directions and note the conversation to clarify);
v) Substitution instructions where applicable, or substitution requested by Member clearly noted;
vi) Refill instructions if applicable;
vii) Miscellaneous or other informational notes and all other data elements (e.g. Product Selection Code instructions) as required by applicable laws or regulations; and
viii) Complete documentation of items, quantities to be dispensed and directions for use for diabetic supplies and insulin.

Pharmacy is required to update, including any assignment of a new prescription number, prescription records annually or at such other frequency as required by applicable law. In addition, Pharmacy is encouraged to note as much information as possible on the prescription including detailing anything abnormal that occurred in dispensing so as to help provide answers to Auditors' questions or resolve discrepancies.

For prescriptions that have dosage or quantity changes, written documentation on the prescription, time-stamped electronic notations or a new hard copy prescription is required. For prescriptions on which the prescriber has written "as directed", information outlining at a minimum the maximum dose of medication taken per day or the exact instructions must be documented on the hard copy or noted electronically and viewable when requested. Note that only prescriber-generated prescriptions may be accepted by Capital Rx or the Auditors as post audit documentation for "as directed" prescriptions. If less medication is dispensed than what was ordered in the prescription, Pharmacy must document the reason for such decrease and, if more medication was dispensed than the total amount authorized by the prescription, the prescriber must authorize such increase.

ix) Any clarifications of missing or ambiguous information should be documented on the prescription or an electronically time-stamped note within the pharmacy system. This note shall include the prescriber or nurse authorizing the change, date of clarification and the initials or name of pharmacy representative making the notation.

x) Electronic prescription records should be readily retrievable and include the front and back (if applicable) images of the prescription. The hard copy shall be retained and retrieved if needed for audit.

d) Signature Log

Pharmacy is required to maintain a signature log that contains all of the customary information necessary for Capital Rx to confirm proper receipt of the Covered Prescription Services including but not limited to the prescription number for the underlying Covered Prescription Service, the date on which the Claim was approved, the date on which the prescription was dispensed, the product dispensed, Co-payment amounts, an authorization for release of information to Capital Rx and Plan Sponsor in order to process the Claim and the signature of the Member or authorized agent (where permitted by law) confirming receipt of the prescription. Pharmacy shall maintain the signature log for a period of not less than ten (10) years or such longer period of time as mandated by applicable law. If Pharmacy chooses to use an alternative method for documentation of receipt of Covered Prescription Services, Pharmacy shall provide sufficient information to Capital Rx whereby Capital Rx will determine in its sole discretion whether such alternative method is acceptable. Any such approval shall be obtained from Capital Rx in writing.

If a prescription is delivered to a home or business address, Pharmacy is required to obtain the signature of the Member or the Member's designee at the time of delivery. If the Member is sent a monthly billing statement, Pharmacy may insert a form listing the dates of fill and prescription numbers. The applicable Member or Member's authorized representative should be instructed to sign and return the form with payment. If Pharmacy is using mail services, Pharmacy is required to include information to document tracking of shipment, confirmation of delivery, or other proof of delivery.

All signature logs must be maintained in order by date as appropriate and readily accessible. An original or digital image of a signature log will suffice as evidence of receipt of goods.

e) Pharmacist Counseling

Pharmacy shall ensure that the Pharmacist are complying with any and all State and Federal laws or regulations on patient medication counseling including but not limited to the use of, side effects, disposal of expired, damaged, and unstable medications.

f) Pharmacy Storage and Mailing Conditions

Pharmacy shall take appropriate measures to ensure compliance with the guideline set forth by the USDA regarding medication's therapeutic integrity. Mail Order and Specialty Network Pharmacies shall also take appropriate measures and ensure that all temperature-sensitive Covered Prescription Services are dispensed directly to the Member or delivered under appropriate conditions to ensure stability and quality standards by overnight delivery to all locations within the United States.

g) Controlled Substances

Pharmacy shall be properly licensed prior to dispensing any controlled substances and follow any and all State and or Federal laws or regulations when dispensing controlled substances. Controlled substances that are shipped must also be done so in a secure manner to ensure proper delivery following any and all State and or Federal regulations.

h) Disaster Recovery Plan

Pharmacy shall have a disaster recovery plan consistent with the highest industry standards that enables Pharmacy to perform its duties, obligations, and services hereunder within forty-eight (48) hours of a disaster. In the event that it becomes impracticable, for reasons of a force majeure or otherwise, for Pharmacy to dispense Covered Prescription Services to Eligible Members as required hereunder, Pharmacy shall notify Capital Rx and use best efforts to have Covered Prescription Services dispensed from an alternate/backup pharmacy as detailed in Pharmacy's disaster recovery plan, subject to applicable laws and Plan requirements. Pharmacy shall furnish Capital Rx with a copy of its disaster recovery plan upon request and whenever changes are made to such disaster recovery plan.

i) Disposal of Hazardous waste/substances

Pharmacy shall dispose of hazardous waste/substances according to any and all State and Federal laws and regulations to prevent diversion and other abuses.

j) Pharmacy Physical Location

Pharmacy shall maintain a full array of different therapy classes of medications at all times for the applicable dispensing to members. Pharmacies must have the appropriate staff present when filling and dispensing any and all medications. Pharmacy shall maintain core hours of operations no less than 5 days a week. Notwithstanding the foregoing pharmacy shall comply with any and all State and or Federal laws or regulations regarding their physical pharmacy location

6) Applicable law and Regulations

Below are applicable law and regulations to which Pharmacy is required to adhere. Please note that this list is not all inclusive and Pharmacy is responsible for reviewing applicable state and federal law and regulations and making sure it, its pharmacists, and other personnel are in compliance with any such applicable laws or regulations.

a) **Fraud, Waste and Abuse (FWA):**
   i) **Fraud**: Knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program; or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program. (18 United States Code §1347).
   ii) **Waste**: Overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare Program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.
   iii) **Abuse**: Actions including those that may, directly or indirectly, result in unnecessary costs to the Medicare and Medicaid Programs, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud, because the

distinction between "fraud" and "abuse" depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors.

b) **Federal and State Anti- Kickback Statutes**

i) Examples of FWA (intended for educational purposes only and not intended to be an all-inclusive list):

- Examples of FWA by prescribers:
  (a) Illegal remuneration schemes in which a prescriber or Member is offered, paid, solicited or receives remuneration that is illegal to induce or reward them for inappropriate behavior;
  (b) Script mills in which a prescriber writes prescriptions that are not necessary including for people that are not the prescriber's patients;
  (c) Illegal usage of free samples in which samples are provided knowing that the prescriber will bill payers for the free samples.
- Examples by Members:
  (a) Member seeks, obtains and uses a Drug that poses more of a risk than a benefit to the Member;
  (b) Member alters the information on a valid prescription or writes an illegal prescription;
  (c) Member obtains a Drug but gives or sells that Drug to someone else.

c) In addition to the examples outlined above, below are some common examples of fraud, waste and abuse. The examples outlined herein are just for educational purposes and are not meant to list every example of fraud, waste or abuse. If Pharmacy engages in any of the activities outlined in these examples or in other fraud, waste or abuse activities, Pharmacy may be subject to remedial measures including audit, sanctions, suspension or termination from the Capital Rx Networks.

- Billing for a Brand Drug Product and dispensing a Generic Drug Product;
- Billing for a NDC other than what was dispensed;
- Overbilling of quantity prescribed;
- Billing multiple payers for the same Prescription;
- Inappropriate billing of compounded drugs;
- Submitting a dummy DEA/NPI or Invalid DEA/NPI number to obtain a paid response;
- Billing for a Brand Drug Product with Dispense as Written per the Prescriber (DAW 1) when a prescriber has not specified "Do Not Substitute" on the prescription or other inappropriate use of DAW codes;
- Billing for larger pack sizes of drug products supplied in unbreakable packages when one smaller pack size will meet the directions of the prescriber and remain within the benefit plan's maximum days' supply;
- Billing for more fills or refills than were authorized;
- Splitting prescriptions into multiple Claims to obtain multiple dispensing fees or undermine a prior authorization or quantity limits, etc.;
- Diluting the drug product provided to a Member;
- Acquiring prescription drugs on the black market and/or through black market sales;
- Colluding with a prescriber, wholesaler or others and kickback schemes
- Selling the same drug product twice (i.e. recycling pills);
- LTC Pharmacy billing for unused Covered Prescription Services and not applying credit to the applicable Member;
- Inappropriate, inaccurate or incomplete record-keeping practices related to billed prescriptions;
- Prospective billing;
- Phantom Claim billing (Claims for Covered Prescription Services not provided);

- Dispensing expired or adulterated prescription drug products;
- Forging or altering prescriptions;
- Refilling prescriptions erroneously;
- True out of pocket cost manipulation;
- Billing for prescriptions which are invalid due to invalid/illegal prescriber, forgery, or false or fictitious documents; and
- Billing for more medication or drug product than dispensed (i.e. pill shorting).

d) Capital Rx requires Pharmacy to report any actual, suspected or potential acts of fraud, waste or abuse to it as soon as possible. Capital Rx has a strict non-retaliation policy that protects anyone that reports fraud, waste or abuse to it in good faith.

In the event a potential fraud, waste or abuse or other compliance issue has been reported to Pharmacy, Pharmacy should begin an investigation as soon as possible (but not more than two (2) weeks) from the date the issue was reported or identified. If, after the investigation concluded, Pharmacy reasonably believes misconduct has occurred or potentially has occurred, Pharmacy shall notify Capital Rx immediately. Pharmacy shall not be retaliated against (as stated above) for such good faith report(s).

If Pharmacy provides services to a Medicare Part D or Medicaid Plan's Members, Pharmacy is responsible for (i) having and maintaining a program to prevent and control fraud, waste and abuse, (ii) facilitating compliance in its delivery of services through the Medicare Part D or Medicaid benefits (iii) ensuring that the fraud, waste and abuse certification program via NCPDP and its accompanying attestation are completed for Pharmacy and any affiliated pharmacies.

In the event Pharmacy, a pharmacist, or other personnel suspects a Member or Managed Care Organization is engaging in fraud or abuse, such Pharmacy, pharmacist or personnel must report this to the applicable federal or state agency and to Capital Rx.

In the event Pharmacy or a pharmacist, or other personnel suspects pharmacy location, pharmacist, or personnel is engaging in fraud, abuse or inappropriate billing practices, such Pharmacy, pharmacist or personnel must report this to the appropriate authority and to Capital Rx.

In addition to the reporting requirements listed herein, Pharmacy is required to cooperate and assist any federal or state agency tasked with identifying, investigating, sanctioning or prosecuting suspected fraud, waste or abuse. Pharmacy must provide original and/or copies of any and all information (including records) as requested by any such federal or state agency or investigating agency (free of charge) and shall allow such investigating entities access to its premises.

7) Fraud, Waste and Abuse Attestation and Training

Pharmacy is required to have and maintain a program to monitor and train its applicable personnel on compliance matters and fraud, waste and abuse. Such personnel must be trained upon hire and at least annually thereafter. Pharmacy is required to attest each year by December 31st that such training has occurred and that it is in compliance with all applicable law and regulations and other mandatory requirements related to guidance from government entities such as the Center for Medicare and Medicaid Services (CMS).

In addition, CMS has provided guidance within the Federal Register at 42 CFR Parts 422 and 423 and other agency guidance requiring Medicare Part D Plan Sponsors or their delegates, first tier, downstream or related entities to demonstrate compliance with the following if Pharmacy is in a Capital Rx Medicare Part D Network:

Pharmacy hereby verifies and certifies it has completed satisfactory annual Fraud, Waste and Abuse and general compliance training programs provided by CMS

In the event Pharmacy is a Pharmacy Services Administrative Organization (PSAO), Pharmacy shall comply with the attestation requirements herein by providing a single attestation on behalf of its entire membership of pharmacies.

8) Pharmacy and Pharmacy Personnel Exclusion

Pharmacy is required to ensure that none of its pharmacy locations, applicable pharmacists or other personnel, subcontracted delegates and/or other contractors are excluded from participation in federal or state health care programs such as Medicare Part D or Medicaid by reviewing exclusion lists maintained by the Office of Inspector General (OIG) U.S. Department of Health and Human Services (HHS), U.S. General Services Administration (GSA) System for Award Management (SAM), and any applicable state or Medicaid exclusion list. Pharmacy must review these lists upon hire of any applicable pharmacist, other personnel, subcontracted delegate and/or other contractor and monthly thereafter and as required by applicable law. Pharmacy attests that it performs these exclusion reviews upon hire and monthly thereafter and that no applicable pharmacist, other personnel, subcontracted delegate and/or other contractor is excluded.

9) Quality Related Issues and Requirements and Member Complaints

a) If Capital Rx identifies a quality related or service issue as a result of a member complaint, prescriber response, audit, call center discussion or through another avenue, and Capital Rx confirms that the issue occurred with the Pharmacy, Pharmacy will review the information with the Member, document such issue according to its own policies and procedures and report the issue to the appropriate government or regulatory authority as necessary (such as the Institute of Safe Medical Practices). If the issue was related to a paid Claim, Capital Rx reserves the right to reverse the Claim or recoup payment for the Claim.

b) Capital Rx wants to ensure that Members and/or prescribers have a mechanism to appeal denials and a Member (or their representative) or prescriber that wants to appeal a denial should follow the appeal information outlined in the appeal letter. In addition, if a Member submits a grievance or complaint to Capital Rx, a Plan or Pharmacy, Pharmacy shall fully cooperate with Capital Rx and/or the Plan in investigating and resolving the complaint or grievance in a timely manner. Such cooperation may include allowing Capital Rx or a Plan to visit the applicable Pharmacy location and submitting evidence of corrective actions and/or a corrective action plan.

c) In the event a dispensing error (including near misses) occurs, Pharmacy shall report such dispensing error to Capital Rx within twenty-four (24) hours of becoming aware of such error. The report must include all relevant information including any corrective actions taken as well as any known outcomes and any evidence requested of it regarding the corrective actions. Capital Rx reserves the right to take any remedial action it deems appropriate if Member health or safety was, is or may be in the future at risk as a result of such error.

10) Confidentiality

a) Pharmacy understands that the following items of Capital Rx are proprietary and confidential and therefore agrees to keep such items confidential unless prohibited by applicable law.
   i) The Agreement, any related Addenda, Exhibits and other related documentation including pricing;
   ii) Any and all methods of doing business, processes, procedures and programs;
   iii) Any and all symbols, logos, trademarks, trade names, Marks, patents, inventions, copyrights, copyrightable material, trade secrets, personnel information, operating manuals, memoranda, work marketing programs, plans and strategies, operating Agreements, financial

information and strategies, and computer software and other related materials developed or used by Capital Rx;

iv) If a switch operator is accessing any proprietary and/or confidential information of Capital Rx or Clients, Pharmacy shall restrict such switch operator from making any commercial use of that data.

b) Pharmacy shall allow Capital Rx and Plan Sponsors to use Pharmacy's name and information in directories and communications to Plans and Members.

11) HIPAA Compliance

Pharmacy shall ensure compliance with the requirements of the HIPAA Privacy Rule, the HIPAA Security Rule and the Health Information Technology for Economic and Clinical Health Act ("HITECH Act"), and any other applicable HIPAA Regulations in the performance of the Agreement.

Pharmacy will report, following discovery and without unreasonable delay, but in no event later than five (5) calendar days following discovery, any Breach or suspected Breach of Unsecured Protected Health Information as these terms are defined by HIPAA Rules. Upon Capital Rx's request, Pharmacy will perform a fact-based risk assessment, as required at 45 CFR 164.410, to determine whether there is a low probability of compromise of PHI resulting from a Breach. If notification to the media or DHHS is required pursuant to HIPAA Rules, Pharmacy shall be responsible for any and all costs relating to such notice. Pharmacy shall cooperate with Capital Rx in investigating the Breach and in meeting Capital Rx's contractual obligations and obligations under HIPAA Rules and any other security breach notification laws.

Pharmacy will further require any of its subcontractors and agents to provide reasonable assurance evidenced by a written contract that such subcontractor or agent will comply with the same privacy and security safeguard obligations applicable to Pharmacy.

12) Audit

a) Audit Generally

Capital Rx has an audit program in place to ensure that each Pharmacy and the claims submitted to it are proper, clean and in compliance with applicable law, regulations, the Agreement and this Provider Manual. Capital Rx's audit program is meant to monitor claim activity so as to detect and prevent fraud, waste and abuse and/or errors in billing. Accordingly, all claims submitted to Capital Rx are subject to audit and Capital Rx may observe and photograph as necessary applicable facility operations and conditions.

b) Capital Rx or its authorized agent, governmental agencies or their representatives, ("Auditor(s)"), shall have the right to audit Pharmacy's books, records, signature logs, files, purchase invoices from a NABP accredited wholesaler, distributor or manufacturer, drug pedigree information, drug utilization review reports, equipment, compliance documents or records, pharmacy policy and procedures, and the respective facilities of all transactions which relate to any aspect of Pharmacy's performance of the Agreement or requirements of law during normal business hours and typically with reasonable notice of at least thirty (30) days for onsite audits or such longer or shorter period of time as required by applicable law unless Capital Rx reasonably believes that Pharmacy has engaged in fraudulent, wasteful or abusive activities in which case Capital Rx may conduct an audit without notice to Pharmacy unless prohibited by applicable law. All distributor purchase summaries or invoices of each wholesaler/distributor must come directly from the wholesaler/distributor. Summaries or invoices received from the Pharmacy will not be accepted.

Audits may occur via a phone call, on-site visit, desktop audit or through a Client-directed, regulatory investigative and/or compliance review. An Auditor may request an extension of an audit in which case Pharmacy shall accommodate such extension.

In addition, Capital Rx shall have the right to perform a facility review with or without notice to ensure Pharmacy's location(s) are in compliance. Facility reviews may include but are not limited to review, as well as documentation of all applicable licensures, proof of identification of employees, compliance with all federal and/or state regulatory requirements, proof of compliance with return to stock policy (which must be fourteen (14) calendar days or fewer from the date Claims are submitted to Capital Rx) various other reviews and inquiries to assure that overall quality assurance measures are implemented.

Pharmacy shall cooperate with the Auditors and promptly provide access to all information or documents as requested by the Auditors in a safe and secure manner. The Auditors may reproduce any record at its own expense; however, no original copy may be removed from Pharmacy's facilities. The Auditor may report its audit findings to Clients, appropriate governmental entities, regulatory agencies and professional review and audit organizations. If Auditors are denied access to any requested audit documents, Capital Rx may request Pharmacy to reimburse it for the total amount previously paid for such questionable Claim(s) immediately.

Audits will be conducted in accordance with applicable laws and state regulatory guidelines. If additional language is required to be included in the Agreement or this Provider Manual by such applicable laws, such language shall be deemed included for the term of the Agreement and a period of five (5) years thereafter or such other time period in accordance with applicable law.

Pharmacy shall reimburse Capital Rx for any discrepant Claims found during an audit. Such audit recovery amounts may be deducted from future remittances to Pharmacy or Pharmacy shall have thirty (30) days from the date of the Final Audit Report to reimburse Capital Rx for such recovery amounts.

In addition and subject to applicable law, depending on the nature of the discrepancies discovered in an audit, Capital Rx reserves the right to assess a penalty equal to the entire amount of the Claim for each violation, suspend or terminate Pharmacy or any of its locations from any or all Network(s), suspend Claims payment to Pharmacy for an indefinite period of time on behalf of any or all Plan Sponsors (including but not limited to any government authority, direction by subpoena, non-response to an audit request) pending the outcome of an audit and/or reasonable belief that Pharmacy is engaged in fraudulent or illegal activity or pursue other disciplinary or remedial action it deems necessary in its sole discretion.

In the event Capital Rx determines in its sole discretion that the cumulative errors or discrepancies rise to the level of fraud, waste or abuse or negligence, Capital Rx shall have the right to use extrapolation where permitted by law in the audit subject to applicable law or government entity.

Below are some examples that Capital Rx may deem to rise to the level of fraud, waste or abuse or negligence. This list is not meant to be all inclusive and Capital Rx reserves the right to deem that other actions rise to the level of fraud, waste or abuse or negligence.

i) Billing for a Brand Drug Product and dispensing a Generic Drug Product;
ii) Billing of an NDC that is not what was dispensed;
iii) Overbilling of quantity prescribed;
iv) Undocumented substitution;
v) Non-covered item billed as covered;
vi) Duplicate Claim billed;
vii) Billing for more medication or drug product than dispensed (i.e., pill shorting);
viii) Submitting Claims for drug products that were not prescribed;
ix) Submitting dummy DEA/NPI or invalid DEA/NPI numbers to obtain a paid response;
x) Submitting claims for providers who have been sanctioned by CMS or who do not have a license to prescribe;

xi) Submitting Claims for more fills or refills than were authorized or illegal refill of a schedule II narcotic prescription;
xii) Billing for a Covered Prescription Service filled after the legal time limit has expired;
xiii) Billing for prescriptions which are invalid due to invalid/illegal prescriber, forgery, or false or fictitious documents including a provider who has lost his/her license to practice or does not have the proper credentials to prescribe;
xiv) Providing Covered Prescription services incorrectly based on the original order;
xv) Billing for Covered Prescription Services where a Member denies receiving the drug product(s) billed;
xvi) Billing for Covered Prescription Services where the prescriber denies prescribing the drug product(s) billed;
xvii) Covered Prescription Services returned to stock but not reversed;
xviii) Filling for prescriptions missing date written, or filled before date authorized;
xix) Filling for prescriptions missing prescriber signature;
xx) Filling for prescriptions missing any other information required by federal and/or state government authorities or law;
xxi) Filling for prescriptions that are illegal;

- Inappropriate, inaccurate or incomplete record-keeping practices related to billed prescriptions;
- Prescription splitting to obtain multiple dispensing fees or undermine prior authorization or quantity limits, etc.;
- Billing multiple lower strengths when one higher strength drug product is prescribed and available in the marketplace;
- Billing for a brand name Drug with DAW 1 when a Prescriber has not specified "Do Not Substitute" on the prescription, or other inappropriate use of DAW codes; and
- Billing where pharmacy has not collected or has forgiven the member copay.

c) **Onsite Audits**

i) For onsite audits, Pharmacy is required to:

- Have sufficient staff so as to be able to assist the Auditors in answering questions and/or gathering requested information;
- Not refuse an audit when the Auditors arrive at the prescheduled time and location;
- Provide the Auditors with a safe and secure space in which to work within the Pharmacy location that has the necessary elements the Auditors need (e.g., appropriate lighting, electrical outlets, etc.);
- Provide the Auditors with full access to all applicable records, files, logs and other relevant documentation as well as to the facilities themselves should the Auditors need to review any aspects of the facilities used to provide services to the Members (e.g., refrigeration, storage area, etc.);
- Provide the Auditors with the ability to observe the actual retrieval of the relevant records by Pharmacy personnel; and
- If applicable, provide the Auditors with a copy of any compound recipe identifying the ingredients used in a compounded prescription.

ii) For onsite audits, the Auditors:

- May request copies or take digital images of any of the applicable requested documents; and
- Will use reasonable efforts to minimize any disruption of Pharmacy's business while onsite.

iii) Reporting Procedure for onsite audits:

- Pharmacy will receive a written disclosure of preliminary audit findings following the conclusion of the onsite audit. Initial audit findings will be sent to pharmacy within thirty (30) days of the audit.
- Pharmacy or Pharmacy's locations shall have the opportunity to dispute the initial audit findings by filing an appeal within thirty (30) days, or within such other timeframe mandated by applicable law, from Pharmacy or Pharmacy location's receipt of the initial audit findings letter. Such appeal must be sent via certified mail or other method that evidences tracking (FedEx, UPS, etc.), to the attention of the Capital Rx Audit Manager, or as otherwise instructed in the initial audit findings letter. Upon extenuating circumstances, a request for an extension may be granted at the sole discretion of Capital Rx. Capital Rx must receive Pharmacy's request for an extension within the required thirty (30) day timeframe or such other timeframe listed in the initial audit findings letter. In the event Pharmacy does not submit an appeal within the timeframe allowed, Pharmacy shall be deemed to have accepted the audit findings in the initial audit findings letter and any discrepant Claims shall be subject to recoupment.
- Any prescription documentation Pharmacy submits after the audit has concluded must be original hard copies or other original documentation approved by Capital Rx as verbal orders will not be accepted by Capital Rx. The original documentation must be on the prescriber's letterhead, as outlined in the initial audit findings letter, if the documentation is to substantiate an order whereby a prescription order could not be located in the pharmacy.
- Capital Rx or its Auditors may contact patients to verify an order (a) has been requested by the patient and (b) picked up by the patient or its authorized caregiver. If prescription cannot be validated by the patient, the claim will be reversed. If the pharmacy cannot validate that payment of the copay has been made through credit card or cash receipts, then the prescription will be reversed.
- Capital Rx or the Auditors will send Pharmacy its final audit findings following the conclusion of the dispute period, in accordance with any applicable state law, and with consideration of any dispute that was filed timely. The final audit findings will state if and whether full or partial recoupment is necessary or if the findings are for educational purposes.

d) Audit Reporting and Dispute Process

With the exception of telephone/desk audits, the Auditors shall notify Pharmacy in writing of the audit findings based on the documentation provided to the Auditors ("Initial Audit Report"). Pharmacy shall have thirty (30) days, or such other amount of time as mandated by applicable law, from the date of the Initial Audit Report to provide supplemental information which shall be reviewed, and the Auditors shall determine whether such information is acceptable. Except for telephone/desk audits, based on Pharmacy's response to the Initial Audit Report, the Auditor's shall issue a Final Audit Report which shall include the final findings, remaining audit discrepancies, methods used to calculate such discrepancies, and any payments due to Capital Rx. In the event Capital Rx or the Auditors in their sole discretion finds that any errors or audit discrepancies are material, Pharmacy shall pay to Capital Rx all reasonable costs incurred in connection with the audit, including costs and expenses incurred to identify and correct such errors and/or discrepancies.

In the event pharmacy wishes to dispute the Final Audit Report it must be postmarked within thirty (30) days in writing to the following address with an electronic mail copy to pharmacy_audit@cap-rx.com:

Capital Rx LLC
ATTN: Pharmacy Audit Department

228 Park Ave. S, Suite 87234
New York, NY 10003

The letter should include pharmacy information, each claim in dispute with prescription number, date of fill, and supporting documentation to justify the disputed claims.

Note that if the pharmacy being audited is affiliated with a PSAO, Capital Rx may decide to notify the Pharmacy's PSAO of the audit findings.

e) Payment Withholding

In the event that Capital Rx suspects fraud, waste, or abuse ("FWA") by the Pharmacy, Capital Rx may suspend future payments to the respective Pharmacy until Capital Rx conducts and finalized its investigation.

13) Termination/Suspension

Capital Rx reserves the right to (i) immediately terminate or suspend the Agreement and/or any exhibit in place between Pharmacy and Capital Rx or (ii) immediately terminate or suspend Pharmacy or any of its individual locations from participation in its Networks pursuant to Client direction or specific network design, business needs or for cause including for any of the reasons listed below:

a. Engaging in actions, conduct or communication detrimental or disparaging to any or all Networks or Plans;
b. Engaging in actions that are reasonably believed to be fraudulent or in violation of any applicable federal, state or local law or regulation;
c. Rejecting Members at the point of sale for any non-clinical reason;
d. Implementing a block of any Plan or other systematic action that results in the blocking of a Plan and/or its Members;
e. Implementing any automated reversal process;
f. Attempting to redirect or steer Members to a different plan or other coverage including discount cards or other customer discount programs that would not result in a savings or benefit to the Member unless otherwise allowed by applicable law;
g. Attempting to steer a Client or Plan to terminate its relationship with Capital Rx or enter into a direct agreement;
h. Attempting to circumvent any security measure in place at the point of sale;
i. Losing any required licensure or insurance coverage;
j. Engaging in any action that disparages Capital Rx, any of its Clients or Members;
k. Providing any substandard, inferior or otherwise contaminated product or service to a Member;
l. Engaging in prohibited mail fulfillment;
m. Violating any term, condition or obligation contained in the Agreement and/or related Exhibits or other documentation including this Provider Manual;
n. Failure to maintain required credentialing information;
o. Acting in violation of any applicable federal, state and/or local law, regulation or rule including those related to the compounding, sale, dispensation, storage, packaging or use of any Drug Product, device, products or supplies dispensed to Members;
p. Being listed on the OIG or GSA exclusion lists or being sanctioned under or expelled from participation in the Medicare, Medicaid or other government programs;
q. Having any of its or its pharmacist's licenses or permits required to perform services under the Agreement suspended or revoked;

r. Affiliating (including without limitation gaining an ownership or controlling interest in the applicable pharmacy location, holding of the physical real estate of the applicable pharmacy location, establishing a consultant relationship with the applicable pharmacy location, or otherwise obscuring ownership links to the applicable pharmacy location) with a pharmacy that was terminated for any of the conditions outlined herein or due to fraud, waste and abuse.

In addition to the termination and suspension provisions outlined herein, Capital Rx reserves the right to terminate or suspend the Agreement, in accordance with the terms outlined in the particular Agreement by and between Pharmacy and Capital Rx, including any applicable notification time periods or such longer or shorter notification time periods as required by applicable Client, Plan, or law. If a particular Client, Plan or law requires a notification time period that is not the specific time period noted in the applicable Agreement, the Parties understand that the Agreement will not terminate until such other notification time period required by the Client, Plan or law has ended.

In the event Pharmacy and/or any of its pharmacy locations is terminated or suspended for cause pursuant to the terms herein or in the Agreement, such Pharmacy will be provided with written notice describing the reason(s) for such termination or suspension and an opportunity to appeal as outlined below. For purposes of clarity, the Parties understand that termination or suspension of Pharmacy shall not impact the obligations and rights of the Parties with respect to transactions that occurred prior to the effective date of termination or suspension.

If termination is to the entire Agreement and all Networks, Capital Rx shall make an accounting of all monies due to Pharmacy and owed from Pharmacy and shall provide such information to Pharmacy within sixty (60) sixty days following the termination effective date. Pharmacy and Capital Rx shall pay each other any required amounts due to the other within thirty (30) days of finalization and receipt of such accounting information.

Capital Rx reserves the right to notify Clients, Plan Sponsors and/or Members regarding any termination, suspension or revocation and Pharmacy agrees to cooperate with Capital Rx and/or Plan Sponsors including assisting with transferring prescriptions.

Notwithstanding anything to the contrary, Capital Rx reserves the right to create custom networks at any time during the term of the Agreement that may or may not include all or some of Pharmacy's locations. at any time during the term of the Agreement.

The termination or suspension of the Agreement or a Network as to any particular Pharmacy location shall not prevent the subsequent termination or suspension of the Agreement or a Network as to any other Pharmacy location or of the Agreement in its entirety.

In the event Pharmacy is terminated or suspended and wants to appeal the termination or suspension, such Pharmacy may submit an appeal or information outlined below or in the applicable termination or suspension letter it received.

a. In the event Pharmacy is subject to termination, suspension or corrective action related to licensure sanctions, or ongoing government/state disbarment lists, no appeal is allowed. Pharmacy may obtain and submit information related to the incident, but the termination, suspension or corrective action will remain in place as outlined in the applicable termination, suspension or corrective action letter received by Pharmacy. Once all sanctions or debarments have been lifted, Pharmacy may reapply for network inclusion.

b. In the event Pharmacy is terminated or suspended due to breach of Capital Rx's policies or procedures, Provider Manual or the Agreement, Pharmacy has the right to submit related information for Capital Rx's review rebutting claims of breach within thirty (30) calendar days (or such longer period of time mandated by applicable law) of receipt of the termination or suspension letter.

** Note that Capital Rx reserves the right to report any suspected fraud, waste or abuse to the applicable Client, Plan Sponsor and/or appropriate authority such as the NBI MEDIC, U.S. District Attorney's Office or Office of Inspector General, the appropriate State Board of Pharmacy, and/or State Department of Insurance.

14) Pharmacy Complaint Process

All Pharmacy complaints cam be submitted in writing or phoned in to Capital Rx. The following information must be included as part of the complaint:

1. Reason for the complaint and documentation to support the complaint
2. Pharmacy NCPDP or NPI number
3. Prescription number
4. Date of service
5. Disputed prescription claim payment date(s) if applicable

The Capital Rx Provider Relations team is responsible for working towards a resolution of your complaint. To file a complaint, please send it to Capital Rx Provider Relations Team at provider.relations@cap-rx.com or call the Pharmacy Help Desk at 888-832-2779.

15) Pharmacy Dispute Process

Pharmacy and Capital Rx agree that they will attempt in good faith to resolve any dispute that may directly or indirectly arise out of or relate to the Agreement or this Provider Manual. If they are unable to resolve such dispute within thirty (30) calendar days after initial notice, each Party may, by notice to the other, have such dispute referred to a senior officer of each Party. Such officer shall attempt to resolve the dispute by good faith negotiation within thirty (30) calendar days after receipt of such notice. If the designated officers are not able to resolve such dispute within such thirty (30) calendar-day period, then the dispute shall be submitted, upon the motion of either party, to arbitration to be conducted in accordance with the appropriate rules of the American Arbitration Association ("AAA") in New York. All such arbitration proceedings shall be administered by the AAA. The arbitration panel shall consist of three arbitrators. One arbitrator shall be appointed by each Party. The third arbitrator, who shall act as chairman of the arbitration panel, shall be appointed by the other two arbitrators. If any arbitration is commenced against any party hereto with respect to the subject matter contained in this Agreement, the Party prevailing in such arbitration shall be entitled, in addition to such other relief as may be granted in such proceeding, to a reasonable sum from the non-prevailing parties for attorney's fees, expenses, and costs in such arbitration, which sum shall be determined in such arbitration. The Parties agree that the decision of the arbitrators shall be final and binding as to each of them.

16) Rural Pharmacy Status

Capital Rx recognizes certain pharmacies as rural pharmacies if they are physically located more than fifteen (15) miles from another pharmacy's location, per the address on the NCPDP DataQ, irrespective of

city, county and state lines. If Pharmacy is deemed to be rural, such Pharmacy must notify Capital Rx within thirty (30) days of their qualification changes.

III. Claims Processing

1) Bank Identification Number and Processor Control Number (BIN/PCN)

PROCESSOR	BIN	PCN	LINE OF BUSINESS
Capital Rx	610852	CHM, CAPLRX, *varies	Commercial
Capital Rx	610770	CAPLRX, *varies	Commercial
Capital Rx	024730	GBHRX, *varies	Commercial
Capital Rx	610770	CRXMD, CRXMB, *varies	Medicare
Capital Rx	610744	CRXMC, *varies	Medicaid

** PCN can vary by client. Please refer to the member identification card when processing claims.

Capital Rx pharmacy payer sheets are located on the Pharmacist Resources page, https://www.cap-rx.com/providers/pharmacist

2) Claims Submission Generally

Pharmacies must follow all NCPDP processing standards when submitting or reversal Claims. Pharmacies shall accept valid prescriptions either by hard copy, fax, ePrescription, pharmacy to pharmacy transfers, or prescriber call, where allowed by state and federal guidelines. Capital Rx encourages pharmacies to submit Claims electronically, but if the POS System is not operating properly or Pharmacy is otherwise unable to submit Claims via the POS System, paper claims will be accepted. Claims may be submitted in the following standard formats:

a) POS System: NCPDP Version D.0 (or the most recent NCPDP standard);

b) Paper: Universal Claim Form (D.0 UCF). All paper Claims must be submitted on a Universal Claim Form (UCF, version PUCF_D02PT) to the following address unless otherwise noted on the Member's ID card or other Plan documentation provided by the Member. Information regarding the UCF is available at http://www.ncpdp.org/products.aspx

i) **Capital Rx**
Attn: Claims Department
228 Park Ave S, Suite 87234
New York, NY 10003

In addition, the Pharmacy is required to submit the appropriate PRC and PST code with each Claim in accordance with NCPDP standards and CMS requirements as applicable. Failure to do so may result in audit, recoupment of Claim payment or termination or suspension of the Agreement.

** Note that Pharmacy's acceptance of payment/reimbursement for a Claim is considered Pharmacy's consent and acceptance of the terms associated with such Claim including those outlined in the Agreement and this Provider Manual.

Claims Submission Medicare Part D

Per CMS requirements, and/or state regulatory requirements, Pharmacies must submit Claims to the Medicare Part D Sponsor or its intermediary whenever the ID card is presented or on file at the pharmacy, unless the Member expressly requests that a particular Claim not be submitted to the Medicare Part D Sponsor or its intermediary. Member may also present their ID card using an electronic device such as a phone or a tablet and may also have processing information included on an electronic prescription.

Unless a Medicare Member specifically requests that the claim not be submitted to their Medicare Plan, Network Pharmacy providers should refrain from collecting cash for claims that have, or could have been, adjudicated at POS and/or Medicare Part B copays that should be billed to Medicaid.

3) POS System

Capital Rx uses a POS System to adjudicate claims electronically and communicate certain information to Pharmacy location(s) real-time online. Pharmacy is encouraged to confirm their software vendor or proprietary system used by their location(s) are able to accept the messaging provided by the POS system. Below are examples of the type of Claims that can be adjudicated, and the type of information Capital Rx may communicate via the POS System.

a) **Claim types supported by the POS System**
   i) B1: Original Claims Adjudication - This transaction type captures and processes the Claim and returns the dollar amount allowed under the Plan's reimbursement formula. The B1 transaction is the prevalent transaction used by pharmacies.
   ii) B2: Claims Reversal - This transaction is used by a pharmacy to cancel a claim that was previously processed. To submit a reversal, a pharmacy must void a claim that has received a PAID status and select the REVERSAL (Void) option in its computer system.
   iii) B3: Claims Rebill - This transaction is used by the pharmacy to adjust and resubmit a claim that has received a PAID status. A "claim re-bill" voids the original claim and resubmits the claim within a single transaction. The B3 claim is identical in format to the B1 claim with the only difference being that the transaction code (Field # 1Vò3) is equal to B3.
   iv) E1: Eligibility inquiry – This transaction allows the pharmacy to determine eligibility.

** Note that for B2 Claims Reversal and B3 Claims Rebill, the Service Provider ID (NPI Number), prescription number, date of service (date the Claim was filled) and National Drug Code (NDC) must match the original paid Claim to be successfully transmitted.

b) **Communication types supported by the POS System**
   i) Plan eligibility (Note that Plan eligibility may change retroactively for government funded programs and due to updated Member information received by Capital Rx);
   ii) Drug coverage;
   iii) Dispensing limits; and
   iv) Pricing and payment information.

4) Required Data Elements

Capital Rx's payer specifications are required to be set up with Pharmacy's software vendor or proprietary software system to ensure access to required fields and to process Claims. Claims are not processed without all of the required or mandatory data elements. Required fields are noted in the POS system with a "R", Mandatory fields are noted in the POS system with a "M", and Qualified Requirement fields are noted with a "RW" in the POS System. Descriptions of these are below. Note that Required or Mandatory fields may or may not be used in the adjudication process and fields that are not required at this time may be required in the future. If data are submitted in fields not required for processing as indicated by the payer specifications, the data are subject to valid format/valid value checks. Failure to pass those checks could result in claim denials.

CODE	DESCRIPTION
M	**MANDATORY** Designated as MANDATORY in accordance with the NCPDP Telecommunication Implementation Guide Version D.0. The fields must be sent if the segment is required for the transaction.
R	**REQUIRED** Fields with this designation according to this program's specifications must be sent if the segment is required for the transaction.
RW	**QUALIFIED REQUIREMENT** "Required when" the situations designated have qualifications for usage ("Required if x," "Not required if y").

Capital Rx uses NCPDP-defined request formats or segments in the transaction types it implements. A list of those are below.

Segments supported for B1, B2 and B3 Transaction Types

TRANSACTION TYPE CODES			
Segment	**B1**	**B2**	**B3**
Header	M	M	M
Patient	S	S	S
Insurance	M	S	M
Claim	M	M	M
Pharmacy Provider	S	N	S
Prescriber	M	S	M
COB/Other Payments	S	N	S
Worker's Comp.	S	N	S
DUR/PPS	S	S	S
Pricing	M	S	M
Coupon	S	N	S

Compound	S	N	S
Prior Authorizations	S	N	S
Clinical	S	N	S
Facility	S	N	S

M = Mandatory **S = Situational** **N = Not Used**

5) Payer Specification

Capital Rx has included a list of transaction types and their field requirements in Appendix A – Plan D.0 Payer Specifications. These specifications outline the transaction types and their segments, fields, field requirement indicators (mandatory, situational, optional), and values supported by Capital Rx

6) Claim Processing Edits

Once Pharmacy submits a Claim through the POS System, the POS System returns a response indicating the outcome of the Claim processing. Below are the possible responses that may be returned via the POS System.

a) **PAID:** This message occurs when the Claim passes all edits.
b) **REJECTED (or DENIED):** This message occurs when the Claim fails an edit. Pharmacies requiring assistance should call the Pharmacy Support Center at 888-832-2779.
c) **Duplicate Response:** In addition to the messages below, the submitted Claim may be deemed a duplicate if Pharmacy tries to submit a Claim that has already been adjudicated with some or all of the information included with the previously submitted Claim. If there is an exact match on the fields below, the result will be a duplicate response and the POS System will return an NCPDP Error Code # 83 – Duplicate Paid Claim to indicate a possible suspected duplicate.
    i) Same Patient/Member
    ii) Same Service Provider ID
    iii) Same Date of Service
    iv) Same Product/Service ID
    v) Same Prescription/Service Reference Number
    vi) Same Fill Number

** Note that there may be instances in which Pharmacy sends a transaction request through the POS System and the request is received and processed, but, due to communication issues or interruptions, the response is not received by Pharmacy. In these instances, Pharmacy should resubmit the transaction request. The POS System responds with the same information as the first response, but the transaction response is marked as duplicate

Patient Residence Code (PRC) and Pharmacy Service Type (PST) Requirements

In conjunction with the requirements from NCPDP, Capital Rx requires that all claims are submitted to the POS system with a Patient Residence Code (PRC– D.0 field 3844X) and Pharmacy Service Type (PST – D.0 field 147-U7). Please ensure that accurate and appropriate information is submitted on every Claim because the PRC and PST information is reported to CMS. Failure to submit the correct PRC or PST code on a Claim may result in audit or recoupment of Claim payment.

If your pharmacy is contracted for more than one service, please ensure claims are submitted with the appropriate PRC and PST codes for the services provided.

Below are valid codes for claims submission:

Patient Residence Code (PRC)	PRC Description
00	Not Specified
01	Home
03	Nursing Facility/Long Term Care
04	Assisted Living Facility
06	Group Home
09	Intermediate Care/Mentally Retarded
11	Hospice

Pharmacy Service Type (PST)	PST Description
01	Community/Retail Pharmacy services
02	Compounding Pharmacy services
03	Home Infusion Therapy services
04	Institutional Pharmacy services
05	LTC Pharmacy services
06	Mail Order Pharmacy services
07	Managed Care Organization Pharmacy services
08	Specialty Care Pharmacy services
99	Other

Prescription Origin Code Claim Submission

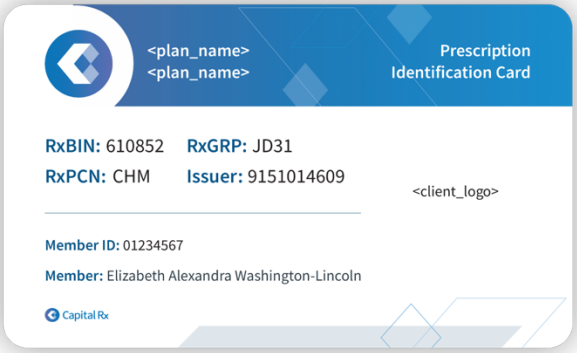
Pharmacies are required to submit the correct Prescription Origin Code in conformance with the NCPDP and PBM requirements. Please submit one of the following data elements within Prescription Origin Code (419-DJ):
1 = Written
2 = Telephone
3 = Electronic
4 = Facsimile (Fax)
5 = Transfer

Claims submitted for a Prescription missing one (1) of these values will reject with the following NCPDP Reject Code 33 — "MISSING INVALID PRESCRIPTION ORIGIN CODE". If such a rejection occurs, please resubmit the Claim with the appropriate value.

7) Program Setup

Below is a list of the values required to set up the Plan programs along with sample ID cards.

FIELDS			DESCRIPTION	COMMENTS
BIN #				
Processor Control # (PCN#)				
Group			Plan	
Provider ID #			NPI	10 bytes (numeric)
Cardholder ID #			Plan Assigned Number	Up to 20 bytes (numeric)
Prescriber ID #			NPI number	10 bytes (numeric); an algorithm validation will be performed to verify NPI is valid
Product Code	National Drug Code (NDC)	11 digits		



FRONT

BACK

Sample Identification Card

8) Service and Support

a) Online Certification

The Software Vendor/Certification Number (NCPDP Field # 11Ø-AK) of the Transaction Header Segment is required for claims submission under NCPDP Version D.0. Capital Rx certifies software vendors, not an individual pharmacy's computer system. Pharmacy should contact its vendor or Capital Rx to determine if the required certification has been obtained. Pharmacy should submit the value that is assigned to them when being certified.

9) Technical Problems

In the event the POS System is unavailable, Pharmacy will receive one of the messages below.

NCPDP	MESSAGE	EXPLANATION
90	Host hung up	Host disconnected before session completed.
92	System Unavailable/Host Unavailable	Processing host did not accept transaction or did not respond within time out period.
93	Planned unavailable	Transmission occurred during scheduled downtime. Scheduled downtime for file maintenance is typically Saturday, 11:00 p.m., ET–Sunday, 6:00 a.m., ET.
99	Host processing error	Do not retransmit claims.

Capital Rx encourages Pharmacy to have software that has the ability to submit backdated Claims.

If Pharmacy receives a message indicating that its own network is having problems communicating with Capital Rx or if Pharmacy is experiencing other technical difficulties connecting with Capital Rx's POS System, Pharmacy should follow the steps below:

a) Check the terminal and communication equipment to ensure that electrical power and telephone services are operational.
b) Call the telephone number that the modem is dialing and note the information heard (i.e., fast busy, steady busy, recorded message).
c) Contact the applicable software vendor if unable to access this information in the system
d) If Pharmacy has an internal technical staff, forward the problem to that department, then the internal technical staff should contact the Capital Rx Pharmacy Help Desk
e) If unable to resolve the problem after following the steps outlined above, directly contact the Pharmacy Help Desk at 888-832-2779.

10) Claim Timely Filing Requirements

Capital Rx encourages Pharmacy to submit Claims electronically. If a Claim is submitted outside of the timeframes listed, the Claim may be denied with a NCPDP error code 81 "Timely Filing Exceeded". In the event Pharmacy needs to submit Claim(s) outside of the timeframes, Pharmacy may contact Pharmacy Help Desk at 888-832-2779.

a) Initial Claim Submission

Initial Claims are to be submitted within thirty (30) days from the date of fill unless otherwise agreed to in writing between Pharmacy and Capital Rx or otherwise mandated by applicable law.

b) Reversals and Resubmissions

Claims reversals and resubmissions are to be submitted within thirty (30) days from the original date of fill unless otherwise agreed to in writing between Pharmacy and Capital Rx or otherwise mandated by applicable law.

If a prescription Claim is not picked up or received by the Member within fourteen (14) days after the initial Claim submission, it must be reversed.

c) **Refill Messages**
   i) DEA = 0: Original plus up to 99 refills within 366 days from the original date on which the prescription was written
   ii) DEA= 2: No refills
   iii) DEA = 3–5: Original plus 5 refills within 183 days from original date on which the prescription was written

11) Schedule II Drugs

According to the to the Comprehensive Addiction Recovery Act 2016 (CARA), Pharmacy may fill a partial fill of a Schedule II Prescription Drug under the circumstances outlined below:

a) The partial fill it is not prohibited by state law;

b) The prescription is written and filled in accordance with federal and state law;

c) The partial fill is requested by the Member or the practitioner who wrote the prescription; and

d) The total quantity dispensed of the sum of all partial fills does not exceed the total quantity prescribed.

Remaining portions of a partially filled prescription for a Schedule II controlled substance may be filled no later than thirty (30) days after the date on which the prescription was written. Per 21 CFR § 1306.11, Schedule II Prescription Drugs may not be dispensed without a prescriber's written prescription except in emergency situations or when dispensed directly by a prescriber other than a pharmacist to the end user of the Schedule II Prescription Drug. If partial fill was for an emergency oral Schedule II Prescription Drug, Pharmacy must fill the remaining amount within seventy-two (72) hours of the date of the first partial fill. Pharmacy must receive a new prescription to dispense any additional quantity after the seventy-two (72) hour window has expired.

In addition, Pharmacy must comply with applicable state and federal laws and regulations governing the dispensing (including partial dispensing) of Schedule II Prescription Drugs.

12) Generic Drug Programs

A Plan may have a mandatory Generic Drug program in place in which either:

a) Multi-Source Brand products submitted with a DAW code of '1,' Physician requested brand be dispensed (Physician writes "Dispense as Written" on the prescription when there is a generic equivalent available) may require a medical exception review to bypass the pricing. Member may have to pay the cost difference between the Brand Drug rate versus the Generic Drug rate, plan option; or

b) Multi-Source Brand products submitted with a DAW code of '2,' Member requests brand be dispensed. In addition, this scenario may require a prior authorization to bypass the pricing.

Member may have to pay the cost difference between the Brand Drug rate versus the Generic Drug rate, plan option.

** Note that exceptions to these programs may exist.

13) Dispensing Limits and Claim Restriction

A Plan may have certain dispensing limits or Claim restrictions in place that may result in point-of-sale rejections if Claims are submitted outside of such limits or restrictions. Please review the Claim reject responses and contact the Pharmacy Support Center (888) 832-2779as necessary.

a) Days' Supply

Plans determine their standard days' supply limits and may allow up to a one hundred two (102) retail day supply. Pharmacy must participate in the applicable extended day retail network in order to fill Claims with that retail day supply. Please contact the Pharmacy Support Center at (888) 832-2779if a days' supply rejection is received or contact the Pharmacy Relations team at Capital Rx to request a contract for participation.

b) Quantity, Dollar, Age and Other Limits

Plans determine their own quantity (minimum or maximum quantity limits, quantity per day and over time, maximum daily dose), dollar and age (minimum and maximum age), and other limits. Please refer to the rejection response received or contact the Pharmacy Support Center at (888) 832-2779if assistance is needed.

14) Reimbursement and Cost Sharing Amounts

a) Reimbursement Generally

Pharmacy's acceptance of a successfully adjudicated Claim constitutes its acknowledgment of participation in the applicable Network in which the Claim adjudicated and its acceptance of all corresponding terms and conditions, including the rates and reimbursements of Claims, for such Network. In addition, Pharmacy understands that Capital Rx may, at its option, decide to allow other pharmacy benefit or third-party administrators access to Capital Rx's networks and Pharmacy's acceptance of a successfully adjudicated Claim constitutes its acknowledgment and consent to participate in any such network. Capital Rx shall pay Pharmacy the Pharmacy Reimbursement Rates and Dispensing Fees as forth in the applicable Agreement, Network Exhibit, Provider Manual, or the on-line transaction response, less the applicable Cost Sharing Amount. Such Reimbursement Rates and Dispensing Fees may include compounding fees, Specialty Drug reimbursement or long-term care drug reimbursement and are subject to change or renegotiation between the Capital Rx and Pharmacy. Note that Pharmacy Reimbursement Rates and Dispensing Fees vary from Plan to Plan. The on-line transaction response pricing prevails, unless an overpayment is made to Pharmacy. Reimbursement is determined based on the NADAC price for the specific 11-digit NDC number for a particular Prescription Drug or, in the event there is no NADAC price for a Prescription Drug, the fallback logic pricing which may be AWP-based pricing, and paid at the lesser of: the Plan or Network specific Pharmacy Reimbursement Rates or other reference based or fallback logic pricing plus applicable Dispensing Fee, Pharmacy's submitted cost amount, or Pharmacy's U&C. The on-line transaction response pricing prevails, unless an overpayment is made to Pharmacy. Note that Capital Rx does not use any maximum allowable cost (MAC) pricing structures as part of its reimbursement models.

Capital Rx may make adjustments to recoup from Pharmacy overpayments made to Pharmacy or to address any errors in the POS System either via offsetting such overpayment amount from future payments to Pharmacy or requiring Pharmacy to remit payment to Capital Rx within thirty (30) days of notice of overpayment. Pharmacy acknowledges that it is obligated to review remittances received from Capital Rx to confirm accuracy and shall have thirty (30) days from receipt of a remittance to review and notify Capital Rx of any discrepancy. If Pharmacy does not notify Capital Rx of any discrepancy, Pharmacy will be deemed to have confirmed the accuracy of payments made by Capital Rx for Claims processed pursuant to such remittance.

Payment Rules under Medicare and Medicaid Programs

In accordance with requirements as set forth in 42 C.F.R §423.520(a)-§423.520(h) Pharmacy will be paid for Clean Claims as follows:

- For Medicare Part D, Clean Claims will be paid within fourteen (14) days after the date of receipt for electronic Claims and within thirty (30) days after receipt for paper Claims.
- Unless a particular state Medicaid agency requires a shorter time period, Medicaid Clean Claims will be paid within thirty (30) days of the Pharmacy's submission.

b) Electronic Fund Transfer (EFT)

For the pharmacy's convenience Capital Rx offers Electronic Fund Transfers. The pharmacy shall fill out the EFT form and provide the applicable documentation. Once the form has been completed and documents have been received by Capital Rx the EFT would be effective upon the next payment cycle.

c) Check Reissuance

Pharmacy paper checks are issued to the pharmacy mailing address registered with NCPDP. The cancelation of an issued check and reissuance of a replacement check is subject to a $10 per check fee (subject to change). Pharmacies are responsible with updating their mailing address with NCPDP of any address change. Pharmacies are subject to a $5 processing fee per check if pharmacy is requesting the replacement check to be issued to any address other than what is registered with NCPDP. A pharmacy must fill out the Check Reissue Request form located on the Capital Rx's website in order to receive a replacement check. A check must be outstanding for 30 days from the issue date before a reissuance request will be processed. Please allow up to three weeks for the original check to be cancelled and reissued. Check reissuance requests submitted in any manner other than the procedure described above may be subject to loss, processing delays, or rejection. To assure receipt by the proper department, the following email address should be used when submitting a check reissuance requests: ap@cap-rx.com.

d) Remittance Advice

For each check, Capital Rx provides an electronic remittance advice (ERA). Unless otherwise arranged with Capital Rx these reports are provided electronically through a Secure File Transfer Process (SFTP).

e) NADAC Unit Price Appeal

Capital Rx does not set the NADAC unit price. If the NADAC unit price is below the pharmacy acquisition cost, please follow the process CMS has set up for NADAC pricing concerns.

The NADAC Help Desk can be contacted through the following:
Toll-free phone: (855) 457-5264
Electronic mail: info@mslcrps.com
Facsimile: (844) 860-0236

f) **Cost Sharing Amounts**

Plans determine their own co-pay structure for all types of medications including by way of example only preferred Brand Drugs, non-preferred Brand Drug Products, Generic Drug Products, and Specialty Drugs. Please refer the Member to their own applicable Plan documentation, member portal, or the paid Claim response for applicable co-pay/Cost Sharing Amount information.

Notwithstanding anything to the contrary herein, PBM may include a Member service fee as an amount to be collected by the PHARMACY from the Member and remitted back to PBM on the applicable Claim(s). This fee does not impact the agreed upon Pharmacy Reimbursement Rate plus Dispensing Fee.

** Note that the Pharmacy Reimbursement Rate plus Dispensing Fee in addition to any Cost Sharing Amount for which a Member is responsible for based on their Plan, shall be considered full and final payment for the Covered Prescription Service rendered. Pharmacy may not seek any further payment from Member, Capital Rx, or Plan regardless of the payment amount or whether such amount is less than Pharmacy's U&C. Pharmacy may not waive the Cost Sharing amount unless approved by Capital Rx or allowed by applicable law.

15) Tax

In the event a tax obligation applies, Pharmacy shall pay such tax unless Capital Rx or the Plan is required to reimburse or pay the tax in which case Capital Rx or the Plan shall pay the tax on behalf of the Pharmacy. In the event the applicable tax obligation is imposed on Capital Rx or the Plan and the Pharmacy seeks reimbursement that includes the tax amount, the Pharmacy must submit the correct tax amount information in the applicable field during Claim submission.

16) Coordination of Benefits

In the event a Member has other insurance coverage, Capital Rx reserves the right to administer coordination of benefits (COB) in accordance with the Plan design and applicable law and regulations. Pharmacy is required to verify with Members whether or not they have other primary or secondary insurance. Refer to the online transaction response as applicable for COB processing. Note that COB processing requires that the Other Payer Amount Paid, Other Payer ID, Other Payer Date, and Other Payer Patient Responsibility be submitted on the Claim to the Plan. Pharmacy must also submit the other insurance carrier code when coordinating claims for payment with a primary payer. In the event PBM processes copay assistance programs, the maximum amount PBM shall reimburse Pharmacy shall be the maximum amount allowed for the applicable copayment. If the copay assistance program does not cover the member's full copay amount, such other amounts shall be collected from the member by Pharmacy.

The following COB Other Coverage Codes will be accepted:

a) 0 – Not Specified: Submit when the Member does not specify other coverage.
b) 1 – No Other Coverage: This code is used when no other coverage is available.
c) 2 – Other Coverage Exists: Payment Approved. OCC 2 is used when any positive amount of money is approved from another payer. Submit the amount approved from the primary payer.
d) 3 – Other Coverage Exists: Claim Rejected. OCC 3 is used when the Member has other coverage, and the Claim was rejected as not covered.

e) 4 – Other Coverage Exists: No Payment Approved. OCC 4 is used when a Member's other coverage is active and there was no payment amount approved from the other insurer (i.e., the Member has not met their deductible obligation, the total cost of the claim is less than the patient's cost share requirement). OCC 4 should also be used if the total cost of the Claim is less than the Member's other insurance co-pay requirement and the primary insurance plan made no payment.

** Note: OCC code value 8 – Claim Billing for Patient Financial Responsibility Only is not allowed.

17) Prior Authorization

Pharmacy is required to follow the prior authorization (PA) procedures detailed below. Such procedures may require Pharmacy to a help desk.

a) Clinical Prior Authorizations

The Capital Rx Clinical Call Center will receive Prior Authorization (PA) requests for products that have clinical edits for clients that use the Capital Rx adjudication platform. PA request(s) are made by the prescribing physician or the prescribing physician's agent. Requests may be initiated by telephone, fax, or mail.

b) Emergency Protocols

The Plan may pay for a 72-hour emergency supply of medications that require a clinical PA (formulary edits do not qualify) if a PA request has not been processed and it is after hours, a weekend, or a designated holiday. An example of when this may occur is when the prescriber is unavailable to provide sufficient information required to complete the prior authorization.

i) The appropriate PA process must be utilized during regular business hours. All of the following conditions must be met for an emergency supply:
- The participant is Plan-eligible on the date of service.
- The medication requires clinical PA (Formulary edits do not qualify).
- The medication is not an excluded product for the Plan.
- The days' supply for the emergency period does not exceed three days.

ii) Emergency Supply Override Process
- Claim denied for requiring a clinical PA. Non-formulary medications do not qualify.
- The dispensing pharmacist should determine if an immediate threat of severe adverse consequences exist should the patient not receive an emergency supply.
- In the dispensing pharmacist's judgment, if the dispensing of an emergency supply is warranted, determine the appropriate amount for a three-day supply. For unbreakable packages, the full package can be dispensed.

c) Preferred Drug List (PDL)/PA/Quantity/Duration Lists

i) All claims are interrogated against the Preferred Drug List (PDL), benefit requirements, and DUR criteria.

ii) All claims are interrogated for compliance with state and federal requirements.

iii) Prescriptions must be dispensed pursuant to the orders of a physician or legally authorized prescriber. Any subsequent refills may be dispensed not more than one year from the date the prescription was written (or earlier whenever legally dictated).

iv) Schedule 2 drugs (CIIs) may not be refilled; a new prescription is required for each fill.

v) Controlled drugs other than CIIs may be refilled, pursuant to the order of a physician or legally authorized prescriber, up to five refills or six months, whichever comes first.

vi) Non-controlled drugs may be refilled, pursuant to the order of a physician or legally authorized prescriber, up to one year.

18) Drug Utilization Review

Pharmacy is required to follow the drug utilization review (DUR) procedures detailed below and/or communicated to it. Such procedures may require Pharmacy to contact a help desk.

a) Prospective DUR Drug Utilization Review (PDUR)

PDUR Management tools help manage a patient's therapy before the medication is dispensed. PDUR encompasses the detection, evaluation, and counseling components of pre- dispensing drug therapy screening. Capital Rx performs an assessment of its UM programs (e.g., prior authorization, step therapy, quantity limit) and exceptions (e.g., formulary, tier), using evidence-based criteria, for medical necessity, efficiency and/or appropriateness of a drug prior to dispensing. This helps to address situations in which potential drug problems may exist. PDUR is performed prior to dispensing assists the pharmacists to ensure that their patients receive the appropriate medications.

Concurrent Drug Utilization (CDUR) management is embedded electronically in the Capital Rx clinical decision support tool and adjudication system, JUDI. Prescriptions are screened at the point of adjudication for any potential drug-therapy opportunities for improvement. The intention is to improve the health and safety outcomes for members in real time. If a problem is identified, a message is available for the pharmacy to view and address the potential issue(s).

Because the PDUR / CDUR system examines claims from all participating pharmacies, drugs that interact or are affected by previously dispensed medications can be detected. Capital Rx recognizes that the pharmacists use their education and professional judgments in all aspects of dispensing.

i) Drug Utilization Review Edits
The following CDUR edits will deny for the Plan:

- Early Refill (ER)
  (a) Early Refill Tolerance: 75–85%

  For non-controlled products, the system will automatically check for an increase in dose and when an increase in dosage is detected, the system will not deny the current claim for early refill.

  (b) The Call Center may assist in overriding this reject if one of the following circumstances exists:
    (i) Dosage/Therapy change has occurred
    (ii) Patient is no longer taking the original dosage
    (iii) Dosage Time/Frequency Change has occurred
    (iv) Two strengths of the same drug are used to make strength of that medication not currently manufactured
- Step Therapy
- Quantity Limits
- Therapeutic Appropriateness
  (a) Prior authorizations require a pharmacist to review a member's medical information to verify the requested medication is appropriate to treat the member's condition
  (b) If a medication is not appropriate, the pharmacist reviewing the case will contact the prescriber to address any concerns
- Generic use

(a) Formulary restrictions and prior authorizations help increase the use of generic medications

- Therapeutic interchange
  (a) Formulary restrictions and prior authorizations help increase the use of therapeutically appropriate substitutions
- Drug-disease contraindications
  (a) Prior authorizations require a pharmacist to review a member's medical information to verify the requested medication is appropriate to treat the member's condition
  (b) If a medication is not appropriate, the pharmacist reviewing the case will contact the prescriber to address any concerns
- Drug Dosage
  (a) Prior authorizations and quantity limits will require a pharmacist to review a member's medical information to verify the requested medication dose and quantity is appropriate to treat the member's condition
  (b) If a dosage or quantity is not appropriate, the pharmacist reviewing the case will contact the prescriber to address any concerns
- Duration of treatment
  (a) Medication approvals are granted for a time period defined in the prior authorization criteria. Extended treatment duration requires reapproval.
- Drug-age precautions
  (a) Age limits on access to drugs are driven by FDA recommendations
  (b) Medications with age restrictions are flagged
  (c) Min Age (in years): The patient filling the medication must be equal to or older than the number listed in the filled to fill the NDC
    (i) If the patient is younger than the Minimum Age listed for the NDC, when the claim processes, claim will reject
    (ii) Reject Code: R-60 Product/Service Not Covered for Patient Age
    (iii) Additional Message Info: "Field(s) possibly in error: 302-C2, 304-C4, 401-D1, 407-D7, 489-TE (Patient is too young.)"
  (d) Max Age (in years): The patient filling the medication must be younger than or equal to the number listed in the field to fill the NDC
    (i) If the patient is older than the Max age listed for the NDC, when the claim processes, claim will reject
    (ii) Reject Code: R-66 Patient Age Exceeds Maximum Age
    (iii) Additional Message Info: "Field(s) possibly in error: 302-C2, 303-C3, 304-C4, 306-C6 (Patient is too old.)"
  (e) Drug-gender precautions
    (i) When a member fills a medication that is limited to a Gender that does not match the member's gender, the claim should reject
      1. Reject Code: 61 Product/Service Not Covered for Patient Gender
    (ii) Medications with gender restrictions are flagged
  (f) Regulatory limitations
    (i) Limits are placed on medications in alignment with state and federal regulatory requirements, through the formulary and prior authorization criteria
    (ii) Non-FDA approved drugs are excluded during formulary development
  (g) Duplication of therapy
    (i) Duplicative drugs are drugs that share the same drug group, class, name, dosage form, and strength
  (h) Drug-drug or drug-allergy interaction

(i) Capital Rx will use Medi-Span's Drug Therapy Monitoring System (DTMS) to generate concurrent DUR screening results. Medi-Span will provide monthly updates to Capital Rx

(ii) Medi-span calculates persistence of ingredients in body and overlap in days supply to identify potential interactions

(iii) Soft reject for major and moderate interactions only
1. Reject CODE: 88 – "DUR Reject Error"
2. Additional Message Info: "Drug-drug interaction [interacting drug]"

(iv) To override a soft reject, pharmacist will be prompted to enter in one of the following in field 440-E5 Professional Service code:
1. MR (Medication Review) or
2. M0 (Prescriber consulted) or
3. P0 (patient consulted)

(v) Drug contains known allergens, drug-alcohol and drug-food interactions
1. Additional Message Info: "Drug contains known allergens"
2. Additional Message Info: "Potential alcohol interactions"
3. Additional Message Info: "Potential food interactions"

ii) CDUR Overrides

The following are the NCPDP interactive Professional Service, Result of Service, Reason for Service, and Submission Clarification codes. These codes may be used to override CDUR denials at the POS, if allowed.

Problem/Conflict Type: The following override codes may be used by providers in any condition where a provider level override is allowed for CDUR denials.

PROFESSIONAL SERVICE CODES ALLOWED FOR SUBMISSION	**All codes are allowed for all conflict types.**
PROFESSIONAL SERVICE CODE/DESCRIPTION	**Select one:** • AS/Patient Assessment • CC/Coordination of Care • DE/Dosing Evaluation/ Determination • FE/Formulary Enforcement • GP/Generic Product Selection • M0/Prescriber Consulted • MA/Medication Administration • MR/Medication Review • PH/Patient Medication History • PM/Patient • Monitoring • P0/Patient Consulted • PE/Patient Education/Instruction • PT/Perform Laboratory Test • RO/Physician Consulted Other Source • RT/Recommended Laboratory Tests • SC/Self CareConsultation • SW/Literature Search/Review • TC/Payer/Processor Consulted • TH/Therapeutic Product Interchange
RESULT OF SERVICE CODES ALLOWED FOR SUBMISSION	All codes are allowed for all conflict types.
RESULT OF SERVICE CODE/DESCRIPTION	**Select one:** • 1A/filled as is, false positive

	• 1B/filled prescription as is • 1C/filled, with different dose • 1D/filled, different direction • 1E/filled, with different drug • 1F/filled, different quantity • 1G/filled, Prescriber approved • 1H/brand, -to- generic change • 1J/Rx-to OTC change • 1K/filled, different dosage form • 2A/ prescription not filled • 2B/not filled – direction clarified • 3A/ recommendation accepted • 3B/ recommendation not accepted • 3C/discontinued drug • 3D/regimen changed • 3E/therapy changed • 3F/therapy chg – cost inc accepted • 3G/drug therapy • unchanged • 3H/follow-up report • 3J/Patient referral • 3K/instructions understood • 3M/compliance aid provided • 3N/medication administered
REASON FOR SERVICE CODE	• ER • DD • TD • SX
SUBMISSION CLARIFICATION CODE/DESCRIPTION (LISTED AS REFERENCE ONLY, NOT REQUIRED ON CLAIMS)	Select one: • 01/No Override • 02/Other Override • 03/Vacation supply • 04/Lost prescription • 05/Therapy change • 06/Starter Dose • 07/Medically necessary

All PDUR/CDUR alert messages appear at the end of the claim's adjudication transmission.

iii) Retro Drug Utilization Review (RDUR)

Capital Rx's RDUR management program reviews a member's therapy after they receive their medication. The logic identifies and profiles members, pharmacy providers, prescribers, and disease states. The purpose is to identify members and/or practitioners whose drug therapy regimens may not conform to best practices as determined by disease state guidelines. All standard retrospective DUR (RDUR) programs adhere to current standards of drug-based screening elements for medications that have limited clinical documentation supporting combination use, carry high-risk warnings for concomitant drug therapy, identify overuse, identify underuse or sub-therapeutic dosing of medication, suggest possible fraud, and abuse potential or offer other opportunities to improve patient care. Program-specific historical data are used to identify trends of interest and variables that can be used as reliable predictors of subsequent outcomes.

Paid pharmacy claims are retrospectively analyzed to identify members and providers that require intervention. Identified members and providers will receive a letter in the mail informing them of potential issues identified based on pharmacy claims data. Issues that are addressed include:

Underutilization: Identifies untreated members with qualified diagnoses and helps members start and stay on the right drugs to help improve adherence and close gaps in care (ex: prescribing statins for members with diabetes).

Overutilization: Identifies and reduces improper or unnecessary drug use, including potential misuse and abuse and off- label use (ex: short-acting Beta Antagonist (SABA) with no controller)

Clinical abuse or misuse: Identify and reduce improper medication use which can lead to member harm (ex: opioid use with benzodiazepine or skeletal muscle relaxant).

Drug-pregnancy precautions: Identify and reduce improper medication use in pregnant patients which can lead to harm (ex: avoiding certain medications in members taking prenatal vitamins)

Following implementation of each retrospective drug utilization management program, Capital Rx performs a follow-up evaluation to determine if the desired outcome was achieved. In cases where information is required from the prescriber, all requested information from the prescriber is limited to the member's clinical status at the time of the retrospective review determination.

Criteria are revised as therapeutic problems are identified and/or eliminated and new drug products are released. The program promotes therapeutic appropriateness of medications by checking for, but not limited to, early refills, brand versus generic utilization, drug-to-drug interactions, and therapeutic duplication. These RDUR edits detect potential adverse drug consequences of incorrect drug utilization. The RDUR system additionally detects excessive use of medication and insufficient daily doses. This RDUR edit detects errors in dosage and duration and also monitors member compliance. Clinical abuse/misuse can be determined so that remedial strategies can be introduced to improve quality of care and conserve program funds.

19) Consumer Safety

Capital Rx continually monitors FDA recall, market withdrawals, and other serious consumer safety notices and alerts. In the event of an FDA Class 1 recall, utilization reports are used to identify affected members who have received the product within the last 4-6 months (unless otherwise stated in the ship dates within the FDA recall alert) and these members are lettered.

1. In the event of a product recall, member-facing notifications will include the product's NDC, expiration date, and lot number. Further, if applicable, members will receive information regarding formulary alternatives for the recalled medication.
2. If required, impacted NDCs will be removed from adjudication to prevent recalled NDCs from being dispensed
    2.1. In these situations, the pharmacy will be notified of recalled and market withdrawal products via secondary messaging on the impacted NDCs
3. If the pharmacy is notified by the wholesaler or manufacturer of a recalled medication, it is the expectation that the pharmacy will follow internal processes to identify and assist patients and prescribers as required.

20) 340(B) Drug Program

Pharmacy shall promptly notify Capital Rx of its 340(B)-provider status in the event Pharmacy is or becomes a 340(B) provider and eligible to acquire Prescription Drugs from drug manufacturers or wholesalers at reduced prices for use by eligible Members under the Public Health Service Act, Section 340(B) program during the term in which it is a participating provider in Capital Rx's network(s). Accordingly, the Parties agree and acknowledge that Capital Rx shall be entitled to modify the pricing and reimbursement terms in its Agreement with Pharmacy to the extent that Pharmacy is able to acquire Prescription Drugs through the 340(B) program.

For all applicable 340B Drug Products, Pharmacy must identify 340(B) claims as follows: In the field 420-DK (Submission Clarification Code), a value of 20 indicates the Pharmacy has determined the drug products submitted to Capital Rx was purchased pursuant to rights available under Section 340B of the Public Health Act of 1992 including sub-ceiling purchases authorized by Section 340B (a) (10) and those made through the Prime Vendor Program (Section 340B (a) (8)).

If Pharmacy is made aware of the 340(B)-eligibility status after the claim has been adjudicated, Pharmacy must reverse the original claim and resubmit the claim with the correct Submission Clarification Code value of 20.

21) Compounded Drugs

Capital Rx seeks to ensure that the pharmacies that provide compounded drug services to its Members have the proper equipment, environment and abide by all applicable laws or regulations. Toward that end, Capital Rx may require Pharmacy to complete additional credentialing in order to provide compounded drug services. Such credentialing requirements may include: accreditation requirements, testing for stability and sterility, an ethics management compliance review to include business operations, compliance with Anti-Kickback and Stark law, federal/state pharmacy law, defined allowable sales and marketing conduct, and an onsite credentialing review. Evidence of unsafe compounding practices may be reported to the State Board of Pharmacy, Food and Drug Administration (FDA) or applicable regulatory agency.

Covered compounded drugs shall be reimbursed in accordance with a Pharmacy's submitted Claim information subject to any contractual or Plan requirements. The submitted Claim information that may be included in the determination of the Prescription Drug Compensation may include, but is not limited to: the final calculated allowable ingredient cost based on the combined price of the individual compounded drug ingredients and quantities in the compounded drug in addition to the total ingredient cost or U&C pricing submitted by the Pharmacy.

In addition, when covered by the Plan, the maximum reimbursement for the bulk chemical powders in compounded drugs containing raw ingredients packaged as bulk chemicals where an equivalent federal-legend drug is available in the marketplace will be the lesser of the Pharmacy's Prescription Drug Contracted Rate for each approved ingredient for the NDC utilized or for each approved ingredient based on the pricing of the equivalent federal-legend drug. All raw or bulk chemicals must be from FDA-registered chemical manufacturer facilities and wholesalers with distribution locations in the United States. Although required at this time, submitting the level of effort code may not result in any change in reimbursement on the compounded drug Claim.

In addition, Pharmacy shall adhere to the compounded drug guidelines outlined below:

a) Pharmacy shall not engage in price rolling practices. Price rolling is defined as the practice of submitting multiple Claims in order to obtain the highest reimbursement possible often by circumventing the standard Prior Authorization (PA) process. For example, the Pharmacy submits a Claim for a compounded drug and receives a rejection. At this point Pharmacy should seek a PA. If the Pharmacy instead decides to resubmit Claims of the same quantity but different U&C prices until a paid Claim response is received, the Pharmacy has engaged in price rolling.
b) Pharmacy may not attempt to attain reimbursement that is greater than the amount submitted when processing a Claim for a compounded drug. Pharmacy may not replace ingredients without authorization from the prescriber or new prescription. Compounded drug Claims should be submitted with the correct amount prescribed and with corresponding accurate quantities and days' supply calculations.
c) Any attempts to circumvent the PA process by altering the days' supply and keeping the same quantity or reducing the quantity and days' supply to receive a paid Claim are prohibited.
d) Pharmacy may not submit a Claim for a compounded drug that has an alternative commercially available equivalent Drug.
e) If Pharmacy uses tablets or capsules in a compounded drug (weight/weight compounds in which the weight of the tablet displaces the weight of the final product not applicable to other compounds such as weight/volume), Pharmacy must document the total weight of the tablets or capsules prior to adding them to the compound.
f) Note that reconstituted preparations such as powdered antibiotics mixed with water prior to dispensing are not considered compounded drugs.
g) Claims for single NDC pre-made compound or compound kits shall not be submitted as compounded drugs with a compound code.
h) Compounded drug claims must be submitted via the POS System using the appropriate compounding indicator code of "2" in field NCPDP D.0 406-D6 with each ingredient cost submitted by the particular quantity of the NDC and with the applicable Level of Effort (LOE) code in field 474-8E of the NCPDP D.0 format describing the amount of time/work required to produce the compounded drug.
i) Claims for compounded drugs may be subject to quantity limits, dollar thresholds or PA restrictions, or the exception process determined by the applicable Plan.
j) Pharmacy is responsible for using only approved ingredients in compounded drugs. Such ingredients need to be within accepted standards for strength, quantity and purity, and must have the appropriate labeling and packaging in accordance with good compounding practices, official standards and scientific information.
k) All federal legend drugs and raw or bulk chemicals submitted in the Claim for the compounded drug must be:
    i) Approved by the Food and Drug Administration (FDA) for safety and effectiveness;
    ii) Purchased from a FDA-registered wholesaler with distribution locations within the United States and point of origin from a FDA-registered manufacturer facility;
    iii) Available only by Prescription;
    iv) Used and sold in the United States; and
    v) Used for a medically accepted indication to treat a covered condition, illness or injury. Medically- accepted indication not only refers to the indication but also the route of administration of the compound.
l) Compounded drug exclusions include:
    i) Reconstitution of an oral antibiotic or similar product;
    ii) Raw bulk chemicals from a non-FDA registered manufacturer facility and wholesaler with locations within the US;
    iii) Charges for ancillary supplies, flavoring/sweeteners, equipment depreciation and/or labor are not eligible for reimbursement;
    iv) Ingredients with missing or invalid NDC numbers are not eligible for reimbursement;

v) Mixing of water or saline solution to another Federal Legend Drug; and
vi) Compounded drugs for office use by medical providers and not compounded for individual Members.

m) Multi-ingredient compounded drug Claim submission:
i) Applies to all BIN numbers
ii) Single-ingredient compound billing will not be accepted as a compounded drug (submit a compounding code indicator of "1" in NCPDP D.0 field 406-D6)
iii) Each individual ingredient should be represented by the NDC of the product(s) used and dispensed, including:
- The total quantity of each specific ingredient
- The cost of each individual ingredient with basis of cost determination
- Up to twenty-five (25) ingredients may be entered for each Compounded Drug Claim

iv) Submit the NDC number in the Claim segment as "0" (zero) and the Product/Service Identification qualifier should be submitted as "00" (two zero's). Use the correct NCPDP compound segment to identify each individual ingredient.

n) Submit a compound code of 2 (two) in field 406-D6 in accordance with NCPDP standards as defined in the payer sheets for Version D.0.

o) Submit the quantity dispensed as the total metric quantity of the finished compounded drug, including:

i) Sum of all individual ingredient costs as the Pharmacy's "Ingredient Cost Submitted" for the compounded drug Claim

ii) Submit the Pharmacy's U&C for the compounded drug Claim

p) The final cost (calculated total cost/ingredient cost submitted) should be no greater than the combined NADAC or fallback cost as applicable of all ingredients and the U&C.

EXAMPLES OF COMPOUNDED DRUG CODES AND DESCRIPTIONS		
11	Compounded drug does not contain an active pharmaceutical bulk powder ingredient or excipient	Magic Mouthwash, combinations of manufactured dermatological creams/ointments
12	Compounded drug contains at least 1 active pharmaceutical bulk powder ingredient	Simple suspensions, dermatological preparations
13	Compounded drug requires pH adjustment for stability, use of liposomal bases, troches, rapid dissolve tablets, suppositories, capsules (any route of administration)	Transmission occurred during scheduled downtime. Scheduled downtime for file maintenance is typically Saturday, 11:00 p.m., ET–Sunday, 6:00 a.m., ET.
14	Compounded drug contains hazardous/controlled substances	Do not retransmit claims.
15	Sterile compounded drug - must be compounded in a	Any sterile compounded drug

	<797> compliant environment and are dispensed as sterile finished preparation	

If a non-covered ingredient (such as bulk powders, invalid NDC's, plan exclusions, etc.) is submitted with a compounded Drug Claim, the Claim will reject and the POS System response will inform the Pharmacy which ingredients were rejected. Pharmacy may resubmit the and the compounded Drug Claim with a Submission Clarification code of "08". The resubmitted compounded Drug Claim will adjudicate and the applicable network (including Medicare Part D network) reimbursement will exclude the non-covered ingredients. Note that Pharmacy may not charge the Member more than the Cost-Sharing Amount provided by the POS System, including for non-covered ingredients.

Appendix A

Legal/Regulatory Specific Information

New York State Exhibit

The following State Exhibit sets forth certain state regulatory requirements that will apply only in the state of New York.

1) **Definitions for Purposes of this Exhibit**
   a) "Managed Care Organization" or "MCO" shall mean the person, natural or corporate, or any groups of such persons, certified under Public Health Law Article 44, who enter into an arrangement, agreement or plan or any combination of arrangements or plans which provide or offer, or which do provide or offer, a comprehensive health services plan.
   b) "Independent Practice Association" or "IPA" shall mean an entity formed for the limited purpose of arranging by contract for the delivery or provision of health services by individuals, entities and facilities licensed or certified to practice medicine and other health professions, and, as appropriate, ancillary medical services and equipment, by which arrangements such health care providers and suppliers will provide their services in accordance with and for such compensation as may be established by a contract between such entity and one or more MCOs.
   c) "IPA" may also include, for purposes of this Agreement, a pharmacy or laboratory with the legal authority to contract with other pharmacies or laboratories to arrange for or provide services to enrollees of a New York State MCO.
   d) "Provider" shall mean physicians, dentists, nurses, pharmacists and other health care professionals, pharmacies, hospitals and other entities engaged in the delivery of health care services which are licensed, registered and/or certified as required by applicable federal and state law.
2) **General Terms and Conditions**
   a) This Agreement is subject to the approval of the New York State Department of Health and if implemented prior to such approval, the Parties agree to incorporate into this Agreement any and all modifications required by the Department of Health ("DOH") for approval or, alternatively, to terminate this Agreement if so directed by the Department of Health, effective sixty (60) calendar days subsequent to notice, subject to Public Health Law §4403(6) (e). This Agreement is the sole agreement between the Parties regarding the arrangement established herein.
   b) Any material amendment to this Agreement is subject to the prior approval of the Department of Health, and any such amendment shall be submitted for approval at least thirty (30) calendar days, or ninety (90) calendar days if the amendment adds or materially changes a risk sharing arrangement that is subject to Department of Health review, in advance of anticipated execution. To the extent the MCO provides and arranges for the provision of comprehensive health care services to enrollees served by the Medical Assistance Program, the MCO shall notify and/or submit a copy of such material amendment to DOH or New York City, as may be required by the Medicaid managed care contract between the MCO and DOH (or New York City) and/or the Family Health Plus contract between the MCO and DOH.
   c) Assignment of an agreement between an MCO and (1) an IPA, (2) institutional network Provider, or (3) medical group Provider that serves five percent or more of the enrolled population in a county, or the assignment of an agreement between an IPA and (1) an institutional Provider or (2) medical group Provider that serves five percent or more of the enrolled population in a county, requires the prior approval of the Commissioner of Health.
   d) The Provider agrees, or if the Agreement is between the MCO and an IPA or between an IPA and an IPA, the IPA agrees and shall require the IPA's providers to agree, to comply fully and abide by

the rules, policies and procedures that the MCO (a) has established or will establish to meet general or specific obligations placed on the MCO by statute, regulation, or DOH or SID guidelines or policies and (b) has provided to the Provider at least thirty (30) calendar days in advance of implementation, including but not limited to:

i) quality improvement/management;
ii) utilization management, including but not limited to precertification procedures, referral process or protocols, and reporting of clinical encounter data;
iii) member grievances; and
iv) provider credentialing.

e) The Provider or, if the Agreement is between the MCO and an IPA, or between an IPA and an IPA, the IPA agrees, and shall require its Providers to agree, to not discriminate against an enrollee based on color, race, creed, age, gender, sexual orientation, disability, place of origin, source of payment or type of illness or condition.

f) If the Provider is a primary care practitioner, the Provider agrees to provide for twenty-four (24) hour coverage and back up coverage when the Provider is unavailable. The Provider may use a twenty-four (24) hour back-up call service provided appropriate personnel receive and respond to calls in a manner consistent with the scope of their practice.

g) The MCO or IPA which is a party to this Agreement agrees that nothing within this Agreement is intended to, or shall be deemed to, transfer liability for the MCO's or IPA's own acts or omissions, by indemnification or otherwise, to a Provider.

h) Notwithstanding any other provision of this Agreement, the parties shall comply with the provisions of the Managed Care Reform Act of 1996 (Chapter 705 of the Laws of 1996) Chapter 551 of the Laws of 2006, Chapter 451 of the Laws of 2007, Chapter 237 of the Laws of 2009, Chapter 297 of the Laws of 2012, Chapter 199 of the Laws of 2014, Part H, Chapter 60, of the Laws of 2014 and Chapter 6 of the Laws of 2015 with all amendments thereto.

i) To the extent the MCO enrolls individuals covered by the Medical Assistance Programs, this Agreement incorporates the pertinent MCO obligations under the Medicaid managed care contract between the MCO and DOH (or New York City) and/or the Family Health Plus contract between the MCO and DOH as if set forth fully herein, including:

i) The MCO will monitor the performance of the Provider or IPA under the Agreement, and will terminate the Agreement and/or impose other sanctions, if the Provider's or IPA's performance does not satisfy standards set forth in the Medicaid managed care contracts.
ii) The Provider or IPA/ACO agrees that the work it performs under the Agreement will conform to the terms of the Medicaid managed care contract between the MCO and DOH and that it will take corrective action if the MCO identifies deficiencies or areas of needed improvement in the Provider’s or IPA/ACO’s performance.
iii) The Provider or IPA agrees to be bound by the confidentiality requirements set forth in the Medicaid managed care contract between the MCO and DOH.
iv) The MCO and the Provider or IPA agree that a woman's enrollment in the MCO's Medicaid managed care product is sufficient to provide services to her newborn, unless the newborn is excluded from enrollment in Medicaid managed care or the MCO does not offer a Medicaid managed care product in the mother's county of fiscal responsibility.
v) The MCO shall not impose obligations and duties on the Provider or IPA that are inconsistent with the Medicaid managed care contracts, or that impair any rights accorded to DOH, the local Department of Social Services, or the United States Department of Health and Human Services.
vi) The Provider or IPA agrees to provide medical records to the MCO for purposes of determining newborn eligibility for Supplemental Security Income where the mother is a member of the MCO and for quality purposes at no cost to the MCO.
vii) The Provider or IPA agrees, pursuant to 31 U.S.C. § 1352 and CFR Part 93, that no federally appropriated funds have been paid or will be paid to any person by or on behalf of the MCO

for the purpose of influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of Congress, or an employee of a member of Congress in connection with the award of any federal loan, the entering into of any cooperative agreement, or the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement.

viii) If any funds other than federally appropriated funds have been paid or will be paid to any person for the purpose of influencing or attempting to influence an officer or employee of any agency, a member of Congress, an officer or employee of a member of Congress, in connection with the award of any federal contract, the making of any federal grant, the making of any federal loan, the entering of any cooperative agreement, or the extension, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative agreement, and the Agreement exceeds $100,000 the Provider or IPA shall complete and submit Standard Form LLL "Disclosure Form to Report Lobbying," in accordance with its instructions.

ix) The Provider agrees to disclose to MCO on an ongoing basis, any managing employee that has been convicted of a misdemeanor or felony related to the person's involvement in any program under Medicare, Medicaid or a Title XX services program (block grant programs).

x) The Provider agrees to monitor its employees and staff against the List of Excluded Individuals and Entities (LEIE) and excluded individuals, the Social Security Administration Death Master List, and the National Plan Provider Enumeration System (NPPES).

xi) The Provider agrees to disclose to MCO complete ownership, control, and relationship information.

xii) Provider agrees to obtain for MCO ownership information from any subcontractor with whom the provider has had a business transaction totaling more than $25,000, during the 12-month period ending on the date of the request made by SDOH, OMIG or DHHS. The information requested shall be provided to MCO within 35 days of such request.

j) Provider understands it is subject to the statutes, rules, regulations, and applicable Medicaid Updates of the Medicaid program and of DOH related to the furnishing of care, services or supplies provided directly by, or under the supervision of, or ordered, referred or prescribed by the subcontractor. This includes 18 NYCRR 515.2 except to the extent that any reference in the regulation establishing rates, fees, and claiming instructions will refer to the rates, fees and claiming instructions set by the MCO.

k) The parties to this Agreement agree to comply with all applicable requirements of the Federal Americans with Disabilities Act.

l) Provider agrees to comply with all applicable requirements of the Health Insurance Portability and Accountability Act, the HIV confidentiality requirements of Article 27-F of the Public Health Law, and Mental Hygiene Law § 33.13.

m) Compliance Program. Provider agrees that if it claims, orders, or is paid $500,000 or more per year from the Medical Assistance Program, including, in the aggregate, claims submitted to or paid directly by the Medical Assistance Program and/or claims submitted to or paid by any MCO under the Medicaid Managed Care Program, that it shall adopt and implement a compliance program which meets the requirements of New York State Social Services Law § 363-d(2) and 18 NYCRR § 521.3.

n) Compliance Program Certification. Provider agrees that if it is subject to the requirements of Section B (12) of this Appendix, it shall certify to DOH, using a form provided by OMIG on its website, within 30 days of entering into a Provider Agreement with the MCO, if they have not so certified within the past year that a compliance program meeting the requirements of 18 NYCRR §521.3 and Social Services Law § 363-d(2) is in place. The Provider shall recertify during the month of December each year thereafter using a form provided by OMIG on OMIG's website.

o) The Provider agrees to comply with all applicable requirements of the Health Insurance Portability and Accountability Act; the HIV confidentiality requirements of Article 27F of the Public Health Law and Mental Hygiene Law § 33.13.

3) **Payment/Risk Arrangements**

a) **Enrollee Non-liability**. Provider agrees that in no event, including, but not limited to, nonpayment by the MCO or IPA, insolvency of the MCO or IPA, or breach of this Agreement, shall Provider bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against a subscriber, an enrollee or person (other than the MCO or IPA) acting on his/her/their behalf, for services provided pursuant to the subscriber contract or Medicaid managed care contract or Family Health Plus contract and this Agreement, for the period covered by the paid enrollee premium. In addition, in the case of Medicaid managed care, Provider agrees that, during the time an enrollee is enrolled in the MCO, he/she/it will not bill the New York State Department of Health or the City of New York for Covered Prescription Services within the Medicaid managed care benefit package as set forth in the Agreement between the MCO and the New York State Department of Health. In the case of Family Health Plus, Provider agrees that, during the time an enrollee is enrolled in the MCO, he/she/it will not bill the New York State Department of Health for Covered Prescription Services within the Family Health Plus benefit package, as set forth in the Agreement between the MCO and the New York State Department of Health. This provision shall not prohibit the provider, unless the MCO is a managed long term care plan designated as a Program of All-Inclusive Care for the Elderly (PACE), from collecting copayments, coinsurance amounts, or permitted deductibles, as specifically provided in the evidence of coverage, or fees for uncovered services delivered on a fee-for-service basis to a covered person provided that Provider shall have advised the enrollee in writing that the service is uncovered and of the enrollee's liability therefore prior to providing the service. Where the Provider has not been given a list of services covered by the MCO, and/or Provider is uncertain as to whether a service is covered, the Provider shall make reasonable efforts to contact the MCO and obtain a coverage determination prior to advising an enrollee as to coverage and liability for payment and prior to providing the service. This provision shall survive termination of this Agreement for any reason, and shall supersede any oral or written agreement now existing or hereafter entered into between Provider and enrollee or person acting on his or her behalf.

b) **Coordination of Benefits (COB).** To the extent otherwise permitted in this Agreement, the Provider may participate in collection of COB on behalf of the MCO, with COB collectibles accruing to the MCO or to the provider. However, with respect to enrollees eligible for medical assistance, or participating in Child Health Plus or Family Health Plus, the Provider shall maintain and make available to the MCO records reflecting COB proceeds collected by the Provider or paid directly to enrollees by third party payers, and amounts thereof, and the MCO shall maintain or have immediate access to records concerning collection of COB proceeds.

c) If the Provider is a health care professional licensed, registered or certified under Title 8 of the Education Law, the MCO or the IPA must provide notice to the Provider at least ninety (90) calendar days prior to the effective date of any adverse reimbursement arrangement as required by Public Health Law § 4406-c (5- c). Adverse reimbursement change shall mean a proposed change that could reasonably be expected to have a negative impact on the aggregate level of payment to Provider. This provision does not apply if the reimbursement change is required by law, regulation or applicable regulatory authority; is required as a result of changes in fee schedules, reimbursement methodology or payment policies established by the American Medical Association current procedural terminology (CPT) codes, reporting guidelines and conventions; or such change is expressly provided for under the terms of this Agreement by the inclusion or reference to a specific fee or fee schedule, reimbursement methodology or payment policy indexing scheme.

d) The Parties agree to comply with and incorporate the requirements of Physician Incentive Plan (PIP) Regulations contained in 42 CFR §438.6(h), 42 CFR § 422.208, and 42 CFR § 422.210 into any

contracts between the contracting entity (Provider, IPA, hospital, etc.) and other persons/entities for the provision of services under this Agreement. No specific payment will be made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to an enrollee.

e) The Parties agree that a claim for home health care services following an inpatient hospital stay cannot be denied on the basis of medical necessity or a lack of prior authorization while a utilization review determination is pending if all necessary information was provided before a member's inpatient hospital discharge, consistent with Public Health Law § 4903.

f) The parties agree that, where required by Public Health Law §4903, a claim for certain continued, extended, or additional health care services cannot be denied on the basis of medical necessity or a lack of prior authorization while a utilization review determination is pending if all necessary information was provided within the required timeframes and under the circumstances described in Public Health Law §4903.

g) The parties agree to follow Section 3224-a of the Insurance Law providing timeframes for the submission and payment of Provider claims to the MCO.

h) The parties agree to follow Section 3224-b(b) of the Insurance Law prohibiting an MCO from initiating overpayment recovery efforts more than 24 months after the original payment was received by a health care Provider, except where: (1) the plan makes overpayment recovery efforts that are based on a reasonable belief of fraud or other intentional misconduct or abusive billing; (2) for the Medicaid Managed Care and Family Health Plus programs, the overpayment recovery period for such programs is six years from date payment was received by the health care Provider with written notice 30 days prior to engaging in overpayment recovery efforts. Such notice must state the patient's name, service date, payment amount, proposed adjustment, and a reasonably specific explanation of the proposed adjustment.

i) The parties agree to follow Section 3224-c of the Insurance Law providing that claims cannot be denied solely on the basis that the MCO has not received from the member information concerning other insurance coverage.

j) The parties agree that this contract does not waive, limit, disclaim, or in any way diminish the rights that any Provider may have pursuant to Section 3238 of the Insurance Law to the receipt of claims payment for services where preauthorization was required and received from the appropriate person or entity prior to the rendering of the service.

k) If applicable, the parties agree that for a contract involving Tier 2 or 3 arrangements as described in Section VII.B of the Guidelines, the contract must:
   i) Provide for the MCO's ongoing monitoring of Provider financial capacity and/or periodic Provider financial reporting to the MCO to support the transfer of risk to the Provider; and
   ii) Include a provision to address circumstance where the Provider's financial condition indicates an inability to continue accepting such risk; and
   iii) Address MCO monitoring of the financial security deposit, describing the method and frequency of monitoring and recourse for correcting underfunding of the deposit to be maintained by the MCO; and
   iv) Include a provision that the Provider will submit any additional documents or information related to its financial condition to the MCO, if requested by DOH.

l) If applicable, the parties agree that for any contract involving an MCO and IPA/ACO, the contract must include provisions whereby:
   i) The parties expressly agree to amend or terminate the contract at the direction of DOH (applies to Tier 1, Tier 2, and Tier 3);
   ii) The IPA/ACO will submit annual financial statements to the MCO, as well as any additional documents required by the MCO as necessary to assess the IPA/ACO's progress towards achieving value-based payment goals as specified in the Roadmap, and the MCO will notify DOH of any substantial change in the financial condition of the IPA/ACO (applies to Tier 2 and Tier 3); and

iii) The IPA/ACO will submit any additional documents or information related to its financial condition to the MCO, if requested by DOH (applies to Tier 2 and Tier 3); and

iv) The parties agree that all Provider contracts will contain provision prohibiting Providers, in the event of a default by the IPA/ACO, from demanding payment from the MCO for any covered services rendered to the MCO's enrollees for which payment was made by the MCO to the IPA/ACO pursuant to the risk agreement (applies to Tier 2 and Tier 3).

4) **Records Access**

a) Pursuant to appropriate consent/authorization by the enrollee, the Provider will make the enrollee's medical records and other personally identifiable information (including encounter data for government-sponsored programs) available to the MCO (and IPA if applicable), for purposes including preauthorization, concurrent review, quality assurance, and Provider claims processing, payment, member qualification for other government programs including, but not limited to, newborn eligibility for Supplemental Security Income, and for MCO/Manager analysis and recovery of overpayments due to fraud and abuse. The Provider will also make enrollee medical records available to the State for management audits, financial audits, program monitoring and evaluation, licensure or certification of facilities or individuals, and as otherwise required by state law. The Provider shall provide copies of such records to DOH at no cost. The Provider (or IPA if applicable) expressly acknowledges that he/she/it shall also provide to the MCO and the State (at no expense to the State), on request, all financial data and reports, and information concerning the appropriateness and quality of services provided, as required by law. These provisions shall survive termination of the contract for any reason.

b) When such records pertain to Medicaid or Family Health Plus reimbursable services the Provider agrees to disclose the nature and extent of services provided and to furnish records to DOH and/or the United States Department of Health and Human Services, the County Department of Social Services, the Comptroller of the State of New York, the Office of the Medicaid Inspector General, the New York State Attorney General, and the Comptroller General of the United States and their authorized representatives upon request. This provision shall survive the termination of this Agreement regardless of the reason.

c) The parties agree that medical records shall be retained for a period of six (6) years after the date of service, and in the case of a minor, for three (3) years after majority or six (6) years after the date of service, whichever is later, or for such longer period as specified elsewhere within this Agreement. This provision shall survive the termination of this Agreement regardless of the reason.

d) The MCO and the Provider agree that the MCO will obtain consent directly from enrollees at the time of enrollment or at the earliest opportunity, or that the Provider will obtain consent from enrollees at the time service is rendered or at the earliest opportunity, for disclosure of medical records to the MCO, to an IPA or to third parties. If the Agreement is between an MCO and an IPA, or between an IPA and an IPA, the IPA agrees to require the Providers with which it contracts to agree as provided above. If the Agreement is between an IPA and a Provider, the Provider agrees to obtain consent from the enrollee if the enrollee has not previously signed consent for disclosure of medical records.

5) **Termination and Transition**

a) Termination or non-renewal of an agreement between an MCO and an IPA, institutional network Provider, or medical group Provider that serves five percent or more of the enrolled population in a county, or the termination or non-renewal of an agreement between an IPA and an institutional Provider or medical group Provider that serves five percent or more of the enrolled population in a county, requires notice to the Commissioner of Health. Unless otherwise provided by statute or regulation, the effective date of termination shall not be less than forty-five (45) calendar days after receipt of notice by either Party, provided, however, that termination, by the MCO may be effected on less than forty-five (45) calendar days' notice provided the MCO demonstrates to DOH's satisfaction prior to termination that circumstances exist which threaten

imminent harm to enrollees or which result in Provider being legally unable to deliver the covered services and, therefore, justify or require immediate termination.

b) If this Agreement is between the MCO and a health care professional, the MCO shall provide to such health care professional a written explanation of the reasons for the proposed contract termination, other than non-renewal, and an opportunity for a review as required by state law. The MCO shall provide the health care professional sixty (60) calendar days' notice of its decision to not renew this Agreement.

c) If this Agreement is between an MCO and an IPA, and the Agreement does not provide for automatic assignment of the IPA's Provider contracts to the MCO upon termination of the MCO/IPA contract, in the event either Party gives notice of termination of the Agreement, the Parties agree, and the IPA's Providers agree, that the IPA Providers shall continue to provide care to the MCO's enrollees pursuant to the terms of this Agreement for one hundred eighty (180) calendar days following the effective date of termination, or until such time as the MCO makes other arrangements, whichever first occurs. This provision shall survive termination of this Agreement regardless of the reason for the termination.

d) **Continuation of Treatment.** The Provider agrees that in the event of MCO or IPA insolvency or termination of this contract for any reason, the Provider shall continue, until medically appropriate discharge or transfer, or completion of a course of treatment, whichever occurs first, to provide services pursuant to the subscriber contract, Medicaid managed care contract, or Family Health Plus contract, to an enrollee confined in an inpatient facility, provided the confinement or course of treatment was commenced during the paid premium period. For purposes of this clause, the term "Provider" shall include the IPA and the IPA's contracted Providers if this Agreement is between the MCO and an IPA. This provision shall survive termination of this Agreement.

e) Notwithstanding any other provision herein, to the extent that the Provider is providing health care services to enrollees under the Medicaid Program and/or Family Health Plus, the MCO or IPA retains the option to immediately terminate the Agreement when the Provider has been terminated or suspended from the Medicaid Program.

f) In the event of termination of this Agreement, the Provider agrees, and, where applicable, the IPA agrees to require all participating providers of its network to assist in the orderly transfer of enrollees to another provider.

6) **Arbitration**

a) To the extent that arbitration or alternative dispute resolution is authorized elsewhere in this Agreement, the Parties to this Agreement acknowledge that the Commissioner of Health is not bound by arbitration or mediation decisions. Arbitration or mediation shall occur within New York State, and the Commissioner of Health will be given notice of all issues going to arbitration or mediation, and copies of all decisions.

7) **IPA-Specific Provisions**

a) Any reference to IPA quality assurance (QA) activities within this Agreement is limited to the IPA's analysis of utilization patterns and quality of care on its own behalf and as a service to its contract Providers.

8) **New York State Medicaid Additional Terms**

a) **Cultural Competency Training:** Pharmacy is required to certify, on an annual basis, completion of State-approved cultural competence training curriculum, including training on the use of interpreters, for all Participating Providers' staff who have regular and substantial contact with Enrollees." Certification of such training should be kept on file and made available to Capital Rx, to be provided upon request to DOH.

North Carolina State Exhibit

The following State Exhibit sets forth certain state regulatory requirements that will apply only in the state of North Carolina.

1) **Claims Submission and Prompt Payment.** In order to receive payment, each PHARMACY must submit a Clean Claim to Claims Processor for each Covered Prescription Service dispensed via the POS System. PHARMACY is responsible for the payment of any and all transaction charges or fees associated with the transmission of claims or claim information to PBM. A Clean Claim must be submitted to Claims Processor within one hundred eighty (180) days after the date of service. If any Claim is rejected or if additional information is required for further processing by PBM or its Claims Processor, PHARMACY must resubmit the Claim within sixty (60) days of PHARMACY's receipt of such rejected Claim provided that the resubmitted Claim may only be processed and paid if it is a Clean Claim and subject to receipt of payment from the applicable Client. Unless otherwise agreed to by the PBM or Client, Claims submitted after the time periods set forth in this Section will not be eligible for payment. PBM will promptly pay Clean Claims in accordance with the Agreement and North Carolina General Statute 58-3-225.

2) **PHARMACY Administrative Duties and Records.** Pharmacy shall assure that administrative duties will be transitioned and that records will also be transitioned and readily available upon termination of the Agreement or insolvency, pursuant to Title 11 of the North Carolina Administrative Code Section 20.0202(5).

3) **Credentialing Verification and Sanction Program Compliance.** PHARMACY shall comply with PBM's and Client's credential verification and sanctions program, as applicable and pursuant to Title 11 of the North Carolina Administrative Code Section 20.0202(16). In addition, PHARMACY shall maintain licensure, accreditation and credentials sufficient to meet PBM's credential verification program requirements and to notify PBM of subsequent changes in status of any information relating to PHARMACY's professional credentials, as applicable and pursuant to Title 11 of the North Carolina Administrative Code Section 20.0202(6).

4) **PHARMACY Professional Liability Insurance.** PHARMACY shall maintain professional liability insurance coverage in an amount acceptable to PBM and notify the PBM of subsequent changes in status of professional liability insurance Title 11 of the North Carolina Administrative Code Section 20.0202(7).

5) **PHARMACY Professional and Ethical Responsibility.** Notwithstanding the requirements of PHARMACY to comply with PBM's and Client's applicable credential verification, sanctions, utilization management and quality management programs, such compliance shall not override the professional or ethical responsibility of PHARMACY or interfere with the PHARMACY's ability to provide information or assistance to customers.

6) **Assignment.** PHARMACY's duties and obligations under the Agreement shall not be assigned, delegated or transferred without the prior written consent of PBM. PHARMACY will notify the PBM, in writing, of any duties or obligations that are to be delegated or transferred before the delegation or transfer.

7) **Member Eligibility Verification.** PBM shall provide via the POS System the ability to verify Member eligibility, based on PBM's current information prior to rendering Covered Prescription Services.

8) **Data and Information to PHARMACY.** PBM will make available to PHARMACY information on performance feedback reports or information to the provider, if compensation is related to efficiency criteria, benefit exclusions; administrative and utilization management requirements; and credential verification, quality assessment and provider sanction programs, as applicable. Notification of changes in such requirements will be provided by PBM in a manner to allow PHARMACY to timely comply with such changes.

9) **Member Records.** PHARMACY shall maintain the confidentiality of Member's medical records, personal information and other health records as required by law, pursuant to Title 11 of the North Carolina Administrative Code Section 20.0202(11)(a).

10) **Member Billing.** To the extent applicable, when Covered Prescription Services are delivered on a prepaid basis under G.S. 58, Article 67, PHARMACY shall not bill any Member for Covered Prescription Services, except for specified Cost Sharing Amounts. However, PHARMACY and Member may agree to continue non-Covered Prescription Services at the Member's own expense, as long as the PHARMACY has notified the Member in advance that the PBM may not cover or continue to cover specific services and the Member chooses to receive the service. PHARMACY will not collect Cost Sharing Amounts for non-Covered Prescription Services.

11) **Prompt Claim Payments.**

a) As applicable, PBM shall pay claims and provide PHARMACY notices in accordance with Title 11 NCGS Section 58-3-225, including PBM shall within 30 calendar days after receipt of a claim, send by electronic or paper mail to the claimant: (1) Payment of the claim; (2) Notice of denial of the claim; (3) Notice that the proof of loss is inadequate or incomplete; (4) Notice that the claim is not submitted on the form required by the Benefit Plan, by the Agreement or by applicable law; (5) Notice that coordination of benefits information is needed in order to pay the claim; and (6) Notice that the claim is pending based on nonpayment of fees or premiums.

b) If PBM requests additional information from PHARMACY, including the information in subsection 10(A) above, and PBM does not receive such information within ninety (90) days of such request, PBM shall deny the claim and send the notice of denial to the claimant in accordance with subsection (c) of Title 11 NCGS Section 58-3-225. However, and as noted in the notice to claimant, PBM will reopen claim if the requested information is submitted to PBM within one (1) year after the date of the denial notice closing the claim.

c) Benefit Plan claim payments that are not made in accordance with Title 11 NCGS Section 58-3-225(c) shall bear interest at the annual percentage rate of eighteen percent (18%) beginning on the date following the day on which the claim should have been paid. However, such interest does not apply to claims for non-Covered Prescription Services nor to Cost Sharing Amounts.

d) PHARMACY shall submit claims within 180 days after the date of the provision of Covered Prescription Services to Member, except as allowed by Title 11 NCGS Section 58-3-225(f).

e) If a claim for which the claimant is a PHARMACY has not been paid or denied within sixty (60) days after receipt of the initial claim, PBM shall send a claim status report to Member. However, the claims status report is not required during the time PBM is awaiting information requested under subsection (B) of this Section 10. The report shall indicate that the claim is under review and PBM is communicating with PHARMACY to resolve the matter. While a claim remains unresolved, PBM

shall send a claim status report to the Member with a copy to PHARMACY thirty (30) days after the previous report was sent.

f) PBM may recover overpayments made to PHARMACY by making demands for refunds and by offsetting future payments in accordance with Title 11 NCGS Section 58-3-225(h), including providing at least a thirty (30) calendar days prior written notice to the PHARMACY before offsetting future payments or recovering overpayments.

g) PHARMACY shall maintain written or electronic records of its activities under and in accordance with Title 11 NCGS Section 58-3-225, including, records of when each claim was received, paid, denied, or pended, and PBM's review and handling of each claim.

12) **Amendments.** Any proposed amendments to the Agreement shall be in accordance with NCGS 58-50-271 to the PHARMACY Notice contact noted in the Agreement and shall be dated, labeled "Amendment", signed by PBM and include an effective date for the proposed amendment.

13) **Policies and Procedures.** PBM shall provide a copy of its applicable policies and procedures, including the PBM Benefit Manual to PHARMACY prior to execution of a new or amended agreement and annually to all participating pharmacies.

14) **North Carolina Governing Law.** The governing law for purposes of this Agreement with PHARMACY shall be the laws of North Carolina.

Appendix B

Medicare Part D

A. Excluded Drugs

a. Specific drug products or drug categories may be excluded from Part D coverage due to federal regulations such as the Social Security Act under Section 1927 (d)(2). These drugs are prohibited from coverage and are not appealable through a coverage determination process. Some examples, including but not limited to, are listed below:

i. Prescription vitamins and mineral products, with the exception of formulary prenatal vitamins and fluoride preparations.
ii. Agents when used for anorexia, weight loss, or weight gain; even if used for non-cosmetic purpose (i.e. morbid obesity).
iii. Agents when used to promote fertility
iv. Agents when used for cosmetic purposes or hair growth
v. Agents when used for the symptomatic relief of cough and colds
vi. Nonprescription or over-the-counter (OTC) drugs (with the exception of Insulin and associated medical supplies
vii. Drug Efficacy Study Implementation (DESI) drug products that are considered "Less-Than-Effective"
viii. Agents when used for the treatment of sexual or erectile dysfunction
ix. Covered outpatient Drug Products for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer as a condition of sale
x. End-Stage Renal Disease (ESRD) agents furnished to ESRD patients on dialysis
xi. Agents without New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) with the FDA.
xii. Any brand agent for which the manufacturer has not agreed to participate in the gap discount program (i.e. labeler code agreement).
xiii. Drug Products related to terminal illness furnished to Hospice patients
xiv. Compounded Drugs that contain at least one ingredient covered under Medicare Part B.
xv. Bulk ingredients/powders used in Compounded Drugs.
xvi. Self-administered oral anti-cancer agents with the same active ingredients and indications as chemotherapy agents administered as incident to a Prescriber's professional service.

B. Medicare Part A/B/D Coordination of Benefits (COB)

a. Coordination of benefit is a process to determine order of payment of claims when multiple payers for the same service exist. This process ensures that the primary payer adjudicates the initial claim and prevents duplication of payment between other secondary payer(s). CMS requires Medicare Plan Sponsors to perform coordination of benefits to ensure accurate payments between Medicare benefits such as Part A and Part B. For Part D, this provides a method to track and to calculate a member's true out-of-pocket (TrOOP) expenditures, which is a key information to administer Medicare coverage phases.

b. Pharmacies will receive claim messages indicating if other payer or other Medicare benefit exists. Pharmacies would have to bill to the primary payer or have to bill to the correct Medicare benefit. At times, a coverage determination may be needed to determine the indicated use so the correct Medicare benefit covers the product.

C. **Medicare Part D Clean Claim Determination**

a. All claims submitted by Pharmacies for Medicare Part D Drugs are submitted by applicable Medicare Part D Plan Sponsors to CMS as Prescription Drug Events (PDE). If CMS rejects or retro-actively denies a PDE because the PDE is not consistent with CMS instructions, guidance, regulations or applicable law, the underlying Claim may be deemed not a Clean Claim and may be tagged for correction by PBM on behalf of the Medicare Part D Sponsor to ensure the Member's TrOOP is correct. If a Medicare Part D Sponsor's PDE is not accepted by CMS due to any fault by Pharmacy, PBM reserves the right to recoup applicable amounts for the unaccepted PDE on behalf od the Medicare Part D Plan Sponsor.

D. **Medicare Part D Coverage Determination**

a. Coverage determination is a Medicare process of reviewing exception requests to determine coverage of drug products under the Part D benefit. Through the process, Medicare Plan Sponsors determine if the drug product is being used for medically accepted indications, if the drug is being used safely, if the drug is appropriately dosed, if member has had appropriate medications trials, or if coverage is under the appropriate Medicare benefit. A member, member's appointed or authorized representative, or prescriber may initiate a coverage determination.

b. If the Medicare Plan Sponsor approves a coverage determination request, the member, the member's appointed or authorized representative, and the prescriber will be notified of the approval and the approval will remain in effect at least until the end of the year. Members can obtain the drug product as long as the prescriber determines that it is clinically appropriate, safe, and continues to prescribe it.

c. If the Medicare Plan Sponsor denies a coverage determination request, the member, the member's appointed or authorized representative, and the prescriber will be notified of the denial and their appeal rights. Instructions on how to appeal a decision will be outlined in the notification.

E. **Permissible prescriber identifiers for Medicare Part D claims**

a. For Medicare Part D and Medicaid Claims:

1) Pharmacy must submit a Prescriber NPI on all Part D and Medicaid Claim submissions. Claim submissions without a Prescriber ID will result in a Claim rejection with code 25 — Missing/Invalid Prescriber ID.
2) Organizational NPIs should not be submitted.
3) NPI should be submitted using an individual NPI that is valid on the Date of Service (DOS) for the Claim.
4) Claims submitted without a valid individual Prescriber NPI will reject with NCPDP Reject Code 619 — Prescriber Type 1 NPI Required, or 56 — "NPI EXISTS. PRESCRIBER ID INVALID/NOT ALLOWED" and the corresponding NPI number may be provided for use when resubmitting the Claim.
5) Prescribers with a current exclusion list sanction (i.e. Office of Inspector General's (OIG) — U.S. Department of Health & Human Services (HHS) ~ List of Excluded Individuals/Entities (LEIE), as well as General Services Administration (GSA) — System for Award Management (SAM) ~ Excluded Parties Listing System (EPLS)) will be rejected.
6) Prescriptions written for controlled substances: PBM will reject Claims where the Prescriber being submitted on the Claim does not have the authority to write for the schedule Drug Product being prescribed.

7) Note that it is critical that you enter the correct Prescriber DEA and NPI numbers because PBM sends correspondence to providers based on pharmacy Claims. If incorrect provider information is given, privacy incidents and Member safety issues may occur.

F. Coverage Determination Timeframes

a. **Standard Coverage Determination**
A coverage decision is provided within seventy-two (72) hours of receipt of the request or for an exceptions request, 72 hours after receipt of the Prescriber supporting statement. If the Medicare Part D Sponsor has not provided an answer within 72 hours after receiving a request or for an exceptions request, 72 hours after receipt of the Prescriber's supporting statement, the request will be automatically forwarded to an independent organization called an Independent Review Entity (IRE) for review.

b. **Expedited Coverage Determination**
A coverage decision is provided no later than twenty-four (24) hours of receipt of the request or for an exceptions request, 24 hours after receipt of the Prescriber's supporting statement. If the Medicare Part D Sponsor has not provided an answer within 24 hours after receiving a request or for an exceptions request, 24 hours after receipt of the Prescriber's supporting statement, the request will be automatically forwarded to an independent organization called an Independent Review Entity (IRE) for review.

G. Claim Submissions/Adjustments

Pharmacies are required to:

a. submit Part D Covered Prescription Services to Medicare Drug Plan Members via the POS System; and
b. furnish Part D Covered Prescription Drugs in a manner that permits the Part D Sponsor to comply with Medicare laws and regulations.
c. Note that failure to submit all Part D Covered Prescription Services may impact Part D Sponsor's STAR ratings as well as individual Medicare Drug Plan Member's benefit calculations.
d. Medicare Part D Claim adjustments:
    i. Note that Pharmacies will be unable to reverse Medicare Part D Claims that PBM has reprocessed internally. Pharmacies attempting to submit reversal requests on such Claims that have been reprocessed by PBM will receive a NCPDP Rejection stating — "CLAIM NOT ELIGIBLE FOR REVERSAL. CONTACT HELP DESK FOR ASSISTANCE".
    ii. If there is a need to resubmit Claims due to incorrect Medicare Part D Low Income Subsidy (LIS) level, please contact the phone number of the back of the Member's ID card.
    iii. In the Medicare Prescription Drug Benefit Manual, Chapter 14, CMS acknowledged the use of free or discounted drug programs and indicated claims must be submitted by pharmacies to allow for accurate reporting of Medicare Drug Plan and Member paid amounts. Please review the Submission of Pharmacy's Cash Price as the U&C Price within that Provider Manual for additional information, and ensure that claims for $0 prescription drug costs are submitted, unless the Member specifically requests that the claim not be processed using his/her prescription drug benefit.
    iv. To the extent permitted by CMS, Pharmacy agrees to not collect Member Cost-Sharing due to the presumption of Medicaid entitlement due to institutional status of the Member. Pharmacy certifies that as a condition for reimbursement

from PBM for claims in which the Medicare Part D Cost-Sharing has been reduced or waived:

1. Long Term care (LTC) is defined as patient residence codes 03-Nursing Facility/LTC and 09-Intermediate Care facility/Mentally Disabled ONLY.
2. Pharmacy has not and will not collect Cost-Sharing Amounts from the Member or their representative who has paid on the Member's behalf; or Pharmacy has otherwise waived the same Cost-Sharing Amounts for the Member or their representative who has paid on the Member's behalf;
3. In the event Pharmacy did collect a cost sharing amount from the Member or their representative who paid on the Member's behalf, and also received reimbursement from PBM, Pharmacy is required to reimburse the Member or their representative within 45 days of receiving the refund.
4. Pharmacy shall hold the debt for the amounts incorrectly charged to Members;
5. The amounts reimbursed are appropriate, owed and payable in accordance with applicable federal and state requirements;
6. Pharmacy shall retain the appropriate documentation and records to establish these certifications, including for purposes of an audit.

H. **Coverage Limitations**

a. A Drug is a Medicare Part D Drug if it is used for a medically accepted indication as defined in the Medicare regulations and implementing guidance. This definition includes prescribed uses supported by a citation included or approved for inclusion in one (1) of the following two (2) compendia:
   i. American Hospital Formulary Service-Drug Information (AHFS-DI)
   ii. DRUGDEX Information System

b. If the Drug is to be used for cancer, this definition includes prescribed uses supported by a citation included or approved for inclusion in one (1) of the following compendia or resources:
   i. American Hospital Formulary Service-Drug Information (AHFS-DI)
   ii. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium • DRUGDEX Information System
   iii. Clinical Pharmacology
   iv. Lexi-Drugs
   v. One of the CMS approved peer reviewed literature sources

c. Based on the regulatory definitions, indications supported in peer reviewed medical literature are not "medically accepted" if they are not yet included, or approved for inclusion, in one of the compendia. Therefore, the use of a Drug Product for such indications would not meet the definition of a Medicare Part D Drug Product and the Drug Product would not be a Covered Prescription Service under the Benefit Plan, even if the Member's Prescriber states that the Drug Product is medically necessary.

d. The following additional coverage limitations may apply:
   i. Early refills for lost, stolen or destroyed Drug Products are not typically covered except during a declared "National Emergency."
   ii. Early refills for vacation supplies may be limited to a one (1) time fill of up to thirty-one (31) days per calendar year according to Benefit Plan.
   iii. Drug Products will not be covered if prescribed by Prescribers that are excluded from Medicare program participation (unless they have an approved waiver on file with the OIG. These occurrences are very rare).

iv. A Member may refill most Prescriptions when a minimum of seventy-five percent (75%) of the quantity is consumed based on the number of days supplied. This minimum quantity consumed amount is seventy percent (70%) for eye drops.

I. Medication Therapy Management (MTM)

Consistent with the Medicare Modernization Act (MMA) requirements for MTM, Medicare Part D Plan Sponsors provide MTM for eligible Members at no additional cost to the Members.
The MTM program is designed to ensure that medications are appropriately used to improve health outcomes and to reduce medication adverse events. A qualified health provider such as pharmacist performs this service.

a. MTM Eligibility

In order to qualify for these services, Medicare Plan Sponsors will identify these members based on their medical conditions, the number of medical conditions, the number of Part D medications, and the expected incurred annual cost of their Part D medications. Members part of a Drug Management Program (DMP) are considered as "at-risk beneficiaries (ARBs)" are also eligible for MTM. These measures may change annually based on Medicare guidance and will vary based on the Plan Sponsor. MTM criteria typically will be as follows, but specific details will be found on the member's Medicare Plan Sponsor's website.

- Member must have the specified minimum number of the following multiple chronic diseases
  - Alzheimer's Disease;
  - Chronic Heart Failure (CHF);
  - Diabetes;
  - Dyslipidemia;
  - End Stage Renal Disease (ESRD);
  - Hypertension
  - Respiratory diseases (such as Asthma, Chronic Obstructive Pulmonary disease (COPD), or Chronic Lung Disorders;
  - Bone Disease-arthritis (such as Osteoporosis, Osteoarthritis, or Rheumatoid Arthritis);
  - Mental Health (such as Depression, Schizophrenia, Bipolar disorder, or Chronic/Disabling Mental Health Conditions)
- Members must be taking a minimum of at least two to eight Part D medications
- Members are expected to meet or to exceed the annual Part D medication cost threshold. For calendar year 2022, the cost threshold is $4,696.
- Members that are part of a Drug Management Program (DMP) and are considered as "at-risk beneficiaries"

b. Scope of MTM Services

The scope of the MTM services will vary based on each Medicare Plan Sponsor, but at a minimum, will include all of the following as § 423.153(d)(1)(vii):

- Interventions for both members and prescribers
- An annual comprehensive medication review (CMR) with written summaries in CMS' Standardized Format under § 423.153(d)(1)(vii)(B) and (D)
- Quarterly targeted medication reviews (TMRs) with follow-up interventions when
- necessary as required at § 423.153(d)(1)(vii)(C).

- Information about safe disposal of prescription drugs that are controlled substances, drug take back programs, in-home disposal and cost-effective means to safely dispose of such drugs per § 423.153(d)(1)(vii)(E). This information must meet the criteria established in § 422.111(j).

c. **MTM Enrollment Process**
Eligible members are automatically identified for MTM based on their medication use and the Medicare Plan Sponsor's targeted conditions for the year. The MTM program is provided at no cost to eligible Medicare Part D members and they can opt-out at any time.

d. **MTM Reimbursement for Network Pharmacy Providers**
MTM contracting will vary based on each Medicare Plan Sponsor and how each is administering the MTM program. Reimbursements will be based on those contracts and whether or not network pharmacy providers are participating in those arrangements.

J. Medicare Part D Transition Policy

CMS requires Medicare Plan Sponsors to provide a temporary supply of some Part D drugs for certain members in order to avoid interruptions in drug therapy. Formulary Part D with coverage restrictions or non-formulary Part D drugs are eligible for transition. Members "new" to the Plan are eligible to receive transition supplies up to one month supply during the first ninety (90) days of initial membership. Existing members of a Plan will have transition benefits during the first ninety (90) calendar days of the year for any annual negative formulary changes that they utilize. If the prescription is for an unbreakable package, please refer to the Unbreakable Packages section. The prescription may be filled at a network pharmacy.

Notices for a transitional supply of a Drug will be provided to applicable Members and prescribers. These notices are sent by U.S. mail within three (3) business days of the temporary fill. It includes:

1. An explanation of the temporary nature of the transitional supply.
2. Instructions for working with the Plan and prescriber to identify appropriate formulary alternatives.
3. An explanation of the Member's right to request an exception.
4. A description of the procedures for requesting an exception.

Pharmacies may receive POS messaging for transition fill(s). After the transition supply ends, the Plan may require a coverage determination for continued coverage. Members are advised to discuss appropriate alternative therapies on the formulary with their prescriber. In the event there are no alternatives, the Member and prescriber may submit a coverage determination request. If an exception is approved, Members can obtain their drug for a specific period of time after their transition supply ends. The Plan may extend the transition supply period while the coverage determination is being processed and pursued.

Transition supply exceptions may also be allowed to address unplanned transitions such as due to hospital discharges or level-of-care changes. So as to allow time for Members to discuss alternative treatments with their prescriber or to pursue a coverage determination, Members may request a level of care transition supply up to the Plan's month supply. Some Plans may also allow transition supply for these "unplanned transitions" through the use of submission clarification codes at point of sale.

K. Medicare Part D Transitioning LTC Facility Residents

L. CMS requires Medicare Plan Sponsors to provide a temporary supply of some Part D drugs for members residing in Long Term Care facilities. Eligible members receive transition fill(s) up to one month supply at any time during the first ninety (90) days of initial membership for new Members or the first (90) days of the calendar year for existing Members. If the prescription is for an unbreakable package, please refer to the Unbreakable Packages section.

M. If the Member has been participating with the Plan for more than ninety (90) days and needs a Drug that is not on the formulary, has limited ability to acquire the Drug, or is pursuing a PA, the Plan may cover at least thirty-one (31) days or the Plan's month supply (whichever is greater) unless the prescription was written a shorter days' supply timeframe or the prescription is for an unbreakable package in which case please refer to the Unbreakable Packages section.

N. Transition supply exceptions may also be allowed to address unplanned transitions such as due to hospital discharges or level-of-care changes. So as to allow time for Members to discuss alternative treatments with their prescriber or to pursue a coverage determination, Members may request a level of care transition supply up to the Plan's month supply. Some Plans may also allow transition supply for these "unplanned transitions" through the use of submission clarification codes at point of sale.

O. **Unbreakable Packages Generally**

Drug Products in "unbreakable packages" must be dispensed in their original container/package and cannot be opened or broken. Please submit these Claims with a days' supply consistent with the dosing instructions on the Prescription and use the smallest package size when exceeding Plan Day Supply limitations. Note that Claims for Drug Products in unbreakable packages may be rejected if the days' supply submitted on the Claim is not consistent with dosing instructions or if it is not the smallest package size. Only the smallest and unbreakable package,will not be rejected if the days' supply is greater than Plan limitations.

If it's possible to submit a Claim with a smaller package size, the Claim may reject with "7X – Day's Supply > Plan Limitation." The Claim messaging will advise of next steps to process the Claim.

Unbreakable Packages Medicare Part D

Unbreakable package of transition eligible Part D Drug Products in its smallest packages that may be dispensed in excess of the limitations described in the "Medicare Part D transition policy" and the "Medicare Part D transitioning LTC facility residents" sections above. If the Member has remaining transition day supply, messaging may state "For CMS Transition, resubmit with remaining day supply of [#] or less." Resubmit the Claim with the smallest package size or fewest unbreakable packages that provides at least the transition day supply remaining.

P. **LTC Facility Information to be Provided Upon Termination**

In the event Pharmacy stops participating in an applicable network whether due to voluntary or involuntary termination or another reason, such Pharmacy is required to comply with the transition policies and procedures of applicable Plans. Pharmacy shall provide PBM with a list of LTC facilities to which it provides services for Members that are participating in Medicare Part D Plans no later than five (5) business days following the notice of termination. Such list shall include the Pharmacy Name, Pharmacy NCPDP number, Pharmacy Address, LTC Facility Name, LTC Facility Address and LTC Facility Phone Number along with a Member list by Facility, including each Member's Name, ID number and date of birth.

Q. **Short-Cycle-Dispensing (SCD) Processing for LTC**

CMS requires solid oral Brand Drugs to be dispensed in fourteen (14) days or less increments to Medicare Part D Members residing in LTC facilities. LTC Pharmacies may bill a short cycle claim for greater than a 14-day supply. However, you must dispense a short cycle prescription with a 14-day supply or less. This requirement is meant to reduce fraud, waste, and abuse by minimizing unused Drugs for the Medicare Part D program. Note that antibiotics in all forms, prepackaged Drugs and liquid Drugs formulations are exempt from this requirement. Member Cost-Sharing Amounts will be prorated based on the day supply.

When submitting Claims that are subject to the short-cycle regulations, providers must ensure that all of the following fields are submitted:

Pharmacy will receive one of the following rejection codes for Claims submitted with an invalid clarification code and special package indicator combination:

1. 597 — LTC dispensing type does not support packaging type
2. 613 — The packaging methodology or dispensing frequency is missing or inappropriate for LTC short-cycle
   The following fields must be completed on the Claim submission form:
   a. Patient qualification — patient residence
   b. Claim qualification — submission clarification code, special packaging type

The combination of values for these Claim qualifications are defined by CMS and NCPDP and are not user-definable. If an NCPDP defined combination is not submitted correctly by the pharmacy, the Claim will be rejected with the 613 code.

If the LTC Pharmacy has submitted the Claim according to the above guidelines and receives a 597 code, then the LTC Pharmacy may resubmit the Claim with Submission Clarification Code 21 and SPI 1 or 3 to bypass the edit.

When submitting Claims that are subject to the short-cycle regulations, providers must ensure that all of the following fields are submitted:

Short-Cycle-Dispensing (SCD) Fields		
NCPDP Field Name	**NCPDP Field ID**	**Appropriate value(s) for SCD claims**
Patient Residence	384-4X	3
Submission Clarification Code	420-DK	Several valid values
Level of Service	418-DI	7
Special Packaging Indicator	429-DT	Several valid values

Short-Cycle-Dispensing Matrix		
Submission Clarification Code 1 (420-DK)	**Submission Clarification Code 2 (420-DK)**	**Special packaging indicator (429-DT)**
14	21	1, 2, 3, 4, 5, 6, 7, OR 8
14	22	1, 2, 3, 4, 5, 6, 7, OR 8

14	23	1, 2, 3, 4, 5, 6, 7, OR 8
14	24	1, 2, 3, 4, 5, 6, 7, OR 8
14	25	1, 2, 3, 4, 5, 6, 7, OR 8
14	26	1, 2, 3, 4, 5, 6, 7, OR 8
14	27	1, 2, 3, 4, 5, 6, 7, OR 8
14	28	1, 2, 3, 4, 5, 6, 7, OR 8
14	29	1, 2, 3, 4, 5, 6, 7, OR 8
14	30	6, 7, OR 8
14	31	6, 7, OR 8
14	32	2, 3, 4, 5, 6, 7, OR 8
14	33	1, 2, 3, 4, 5, 6, 7, OR 8
14	34	1, 2, 3, 4, 5, 6, 7, OR 8
14	35	1, 2, 3, 4, 5, 6, 7, OR 8
14	36	1, 2, 3, 4, 5, 6, 7, OR 8
15	21	1, 2, 3, 4, 5, 6, 7, OR 8
15	22	1, 2, 3, 4, 5, 6, 7, OR 8
15	23	1, 2, 3, 4, 5, 6, 7, OR 8
15	24	1, 2, 3, 4, 5, 6, 7, OR 8
15	25	1, 2, 3, 4, 5, 6, 7, OR 8
15	26	1, 2, 3, 4, 5, 6, 7, OR 8
15	27	1, 2, 3, 4, 5, 6, 7, OR 8
15	28	1, 2, 3, 4, 5, 6, 7, OR 8
15	29	1, 2, 3, 4, 5, 6, 7, OR 8
15	30	6, 7, OR 8
15	31	6, 7, OR 8
15	32	2, 3, 4, 5, 6, 7, OR 8
15	33	1, 2, 3, 4, 5, 6, 7, OR 8
15	34	1, 2, 3, 4, 5, 6, 7, OR 8
15	35	1, 2, 3, 4, 5, 6, 7, OR 8
15	36	1, 2, 3, 4, 5, 6, 7, OR 8
17	21	1, 2, 3, 4, 5, 6, 7, OR 8

17	22	1, 2, 3, 4, 5, 6, 7, OR 8
17	23	1, 2, 3, 4, 5, 6, 7, OR 8
17	24	1, 2, 3, 4, 5, 6, 7, OR 8
17	25	1, 2, 3, 4, 5, 6, 7, OR 8
17	26	1, 2, 3, 4, 5, 6, 7, OR 8
17	27	1, 2, 3, 4, 5, 6, 7, OR 8
17	28	1, 2, 3, 4, 5, 6, 7, OR 8
17	29	1, 2, 3, 4, 5, 6, 7, OR 8
17	30	6, 7, OR 8
17	31	6, 7, OR 8
17	32	2, 3, 4, 5, 6, 7, OR 8
17	33	1, 2, 3, 4, 5, 6, 7, OR 8
17	34	1, 2, 3, 4, 5, 6, 7, OR 8
17	35	1, 2, 3, 4, 5, 6, 7, OR 8
17	36	1, 2, 3, 4, 5, 6, 7, OR 8
16		1, 2, 3, 4, 5, 6, 7, OR 8
18	16	1, 2, 3, 4, 5, 6, 7, OR 8
18	21	1, 2, 3, 4, 5, 6, 7, OR 8
18	22	1, 2, 3, 4, 5, 6, 7, OR 8
18	23	1, 2, 3, 4, 5, 6, 7, OR 8
18	24	1, 2, 3, 4, 5, 6, 7, OR 8
18	25	1, 2, 3, 4, 5, 6, 7, OR 8
18	26	1, 2, 3, 4, 5, 6, 7, OR 8
18	27	1, 2, 3, 4, 5, 6, 7, OR 8
18	28	1, 2, 3, 4, 5, 6, 7, OR 8
18	29	1, 2, 3, 4, 5, 6, 7, OR 8
18	30	6, 7, OR 8
18	31	6, 7, OR 8
18	32	2, 3, 4, 5, 6, 7, OR 8
18	33	1, 2, 3, 4, 5, 6, 7, OR 8
18	34	1, 2, 3, 4, 5, 6, 7, OR 8

18	35	1, 2, 3, 4, 5, 6, 7, OR 8
18	36	1, 2, 3, 4, 5, 6, 7, OR 8
22		1, 2, 3, 4, 5, 6, 7, OR 8
23		1, 2, 3, 4, 5, 6, 7, OR 8
24		1, 2, 3, 4, 5, 6, 7, OR 8
25		1, 2, 3, 4, 5, 6, 7, OR 8
26		1, 2, 3, 4, 5, 6, 7, OR 8
27		1, 2, 3, 4, 5, 6, 7, OR 8
28		1, 2, 3, 4, 5, 6, 7, OR 8
29		1, 2, 3, 4, 5, 6, 7, OR 8
30		6, 7, OR 8
31		6, 7, OR 8
32		2, 3, 4, 5, 6, 7, OR 8
33		1, 2, 3, 4, 5, 6, 7, OR 8
34		1, 2, 3, 4, 5, 6, 7, OR 8
35		1, 2, 3, 4, 5, 6, 7, OR 8

R. **Daily Cost Share (DCS)**

Claims that are submitted erroneously will be deemed non-Clean Claims and Pharmacy is responsible for all costs associated with such Claims. Pursuant to 42 CFR section 423.153(b)(4)(i), Medicare Part D Plans Sponsors are required to apply a DCS rate to certain covered Part D drugs when a network pharmacy dispenses for a supply less than the approved month's supply, if the drug is in the form of a solid oral dose and may be dispensed for less than the approved month's supply under applicable law, with some exceptions. Consequently, Medicare Part D Plan Sponsors may apply a prorated Cost Sharing Amount when the Drug meets the following condition:

- Does not have any of the listed daily cost share exclusions, and
- Is less than a month's supply, and
- Is a covered Part D drug, and
- Is a solid oral dose, and
- Has a member benefit copay design

Daily cost share will NOT be applied if any one of these exclusions exists:

- Non-part D drug
- Claim greater than or equal to a month's supply
- Antibiotics
- Compounds
- Vaccines

- Out of network claims
- Unbreakable products
- Member pays 100% of the cost of a claim
- Plan pays 100% of the cost of a claim

Some examples of where daily cost share logic may apply include, but not limited, to the following:

- Trial fills of less than a one (1) month supply
- Medication synchronization of Part D Drugs
- Long term care short cycle claim
- Opioid naïve 7 day supply or less claim
- Transition claims
- Emergency fills

Below are submitted clarification codes that may be used to override 'Refill Too Soon' rejections to synchronize fills related to DCS:

1. 47: Overrides Refill Too Soon for prorated Claims.
2. 48: Overrides the next Claim after the prorated Claim with a shortened supply to less days because of the prior Claim.
3. 61: Synchronization fill - A shortened days supply to align the dates of service across multiple medications.

S. Medicare Part D Notification of a Thirty (30) Day Negative Formulary Change

Notice of negative formulary changes will be available online and communicated to Pharmacies at least thirty (30) days prior to the removal or adverse change in the preferred or tiered Cost Sharing status of a Medicare Part D Drug. Due to FDA market withdrawals, notifications may or may not be retrospective. The notification will include the Drug name affected, information around whether the Drug is being removed from the formulary of just having an adverse change in tiered Cost Share status, along with reason(s) why the Drug is being removed or changing status and alternative Drugs available in the same therapeutic category, class or Cost-Sharing tier, and the anticipated Cost Share amount for the Drug. Information around how Members may obtain updated coverage determinations or exceptions will also be provided.

T. Medicare Part D Annual Notice of Change for Continuing Members

Applicable Members receive an Annual Notice of Change (ANOC) packet from their Medicare Part D Plan Sponsor each year typically in the fall. This packet identifies any benefit changes to take effect on January 1st of the upcoming benefit plan year. If applicable, Members be eligible for a transition fill(s) if they were using a drug with negative formulary changes or are new to the Plan. Please see the Transition Policy outlined in this Provider Manual.

U. Best Available Evidence (BAE)

1. **Non-LTC Pharmacies**

   In the event a Member has issues or questions their Cost Share Amount or states they are eligible for federal subsidy(ies) or help, such Member must provide valid supporting documentation in order to receive the lower Cost Share Amount. The following documents may be used as Best Available Evidence (BAE) to support the Member’s qualification for federal subsidy(ies):

   a. A copy of the beneficiary's Medicaid card that includes the beneficiary's name and an eligibility date during a month after June of the previous calendar year;

b. A copy of a state document that confirms active Medicaid status during a month after June of the previous calendar year;
c. A print out from the State electronic enrollment file showing Medicaid status during a month after June of the previous calendar year;
d. A screen print from the State's Medicaid systems showing Medicaid status during a month after June of the previous calendar year;
e. Other documentation provided by the State showing Medicaid status during a month after June of the previous calendar year; or,
f. For individuals who are not deemed eligible, but who apply and are found LIS eligible, a copy of the SSA award letter.

Accept any one of the following forms of evidence from beneficiaries or pharmacists to establish that a beneficiary is institutionalized and qualifies for zero cost-sharing:

g. A remittance from the facility showing Medicaid payment for a full calendar month for that individual during a month after June of the previous calendar year;
h. A copy of a state document that confirms Medicaid payment on behalf of the individual to the facility for a full calendar month after June of the previous calendar year; or
i. A screen print from the State's Medicaid systems showing that individual's institutional status based on at least a full calendar month stay for Medicaid payment purposes during a month after June of the previous calendar year.

If Pharmacy is provided with one of the documents listed above, Pharmacy shall contact the phone number of the back of the Member's ID card. If the documentation meets the BAE criteria, the Member's Cost Share Amount will be adjusted within forty-eight (48) to seventy-two (72) hours of receipt of BAE documentation. Pharmacy shall reprocess the Covered Prescription Service to capture the lower Cost Share amount. Please contact the phone number of the back of the Member's ID card with any questions related to this BAE process.

2. **LTC Providers Only**
In the event a Member has issues or questions their Cost Share Amount or states they are eligible for the institutional status zero (0) Cost Share Amount, such Member must provide valid supporting documentation in order to receive the zero (0) Cost Share amount. The following documents may be used as Best Available Evidence (BAE) to support the Member's institutional status and qualification for zero (0) Cost-Sharing:
a. A remittance from the facility showing Medicaid payment for a full calendar month for the beneficiary during a month after June 30 of the previous calendar year;
b. A copy of the state document that confirms Medicaid payment for a full calendar month for the beneficiary during a month after June 30 of the previous calendar year;
c. A screen print from the State's Medicaid systems showing the beneficiary's institutional status for at least a full calendar month stay for Medicaid payment purposes during a month after June 30 of the previous calendar year.

If a Member's subsidy level needs to be corrected utilizing BAE, Pharmacy must receive one (1) of the documents listed above from the Member and contact the phone number of the back of the Member's ID card.

If the documentation provided meets the criteria required for BAE, the Member's Cost Share will be adjusted between forty-eight (48) to seventy-two (72) hours of receipt of the documentation. Pharmacy must reprocess the Drug to get the lower Cost Share amount. Please contact the phone number of the back of the Member's ID card if assistance is needed.

V. Medicare Part D Home Delivery (Mail Order or Automatic Delivery)

1. Initial/New Prescriptions

Per guidance from CMS, if Pharmacy is contracted to provide mail order or other home delivery programs, Pharmacy is required to obtain the Member or the Member's authorized representative consent prior to delivery if the prescription was electronically transmitted directly to the Pharmacy and the Member has not previously received a Mail order or home delivery service with the Pharmacy.

If the prescription was submitted via paper by the Member or Member's authorized representative to the Pharmacy, separate consent is not required as the paper submission means the Member is choosing to have the Drug filled at the Pharmacy (i.e. submitted a paper prescription demonstrates consent).

Documentation showing the Member's or their authorized representative's consent to fill the prescription or a history of mail order or home delivery must be maintained by Pharmacy and made available to the PBM or Medicare Part D Sponsor upon request.

If the Pharmacy is dispensing Part B covered products to a Medicare Advantage Plan Member who also has Medicaid (a.k.a. traditional Medicaid (including SLMB+)), but that Member is not located in the same state as the Pharmacy, then the Part B copay may not be collected from the Member if they have qualifying Medicaid coverage for the product whether or not the Pharmacy is contracted with the Member's applicable Medicaid plan.

3. Refill Prescriptions

Per guidance from CMS, use of mail order or any auto-ship/auto-refill arrangements within Part D cannot be mandatory. If Pharmacy is contracted to provide mail order or other home delivery programs, Pharmacy is required to obtain the Member or the Member's authorized representative consent prior to delivery. Consent must be received from the Member after an initial fill of a new drug to activate auto-ship for any subsequent refills of that drug. Consent to auto-ship a specific drug may not be assumed or activated at the same time as an initial fill, allowing time for the Member to initiate therapy and determine whether treatment with the new drug is tolerated and to be continued. Consent to auto-ship a specific drug may not be assumed or activated at the same time as an initial fill o Pharmacy requires enrollees to opt-in to auto-ship refills on a drug-by-drug basis. A Member's voluntary selection of auto-ship for a specific drug implies a preference to have auto-shipped all refills authorized by the prescription order, unless or until they, their prescriber, or an authorized representative opts-out of that prescription (e.g., cancels auto-ship, cancels an order prior to shipping, or reports an order as unwanted after shipping). If a prescriber renews a prescription for an existing drug therapy, the auto-ship program may extend the previous Member consent to auto-ship the new prescription order and its authorized refills, unless instructed otherwise. Note that Members are allowed to opt-out of the auto-ship program at any time. For refills, Members are to receive a minimum of two shipping reminders, to include all relevant information, including the name of the drug, applicable Cost Sharing Amount and how to cancel the order prior to shipping. Pharmacy must promptly discontinue automatic deliveries after information becomes available from CMS, the Member, their prescriber, or an authorized representative that the Member has entered a skilled nursing facility or elected hospice coverage.

Documentation showing the Member's or their authorized representative's consent to fill the prescription or a history of mail order or home delivery must be maintained by Pharmacy and made available to the PBM or Medicare Part D Sponsor upon request.

W. **Dual Eligible Members Medicare Part B Cost Sharing and Prohibition of Balance Billing**

Those health plans that are Medicare Advantage Plans (a.k.a. MAPD or Part C) are insurance plans approved by CMS and administrated by private companies that take the place of and combine Medicare benefits from Parts A (hospital), B (medical), and D (prescription drug). Members that are Dual Eligible are Medicare beneficiaries who are also eligible for some level of Medicaid assistance. Most State Medicaid programs have a legal obligation to pay Medicare cost-sharing (deductible, copay or coinsurance) for these Dual Eligible individuals.

When Medicare providers try to bill Qualified Medicare Beneficiaries (QMBs) for Medicare cost share or copay amounts, such practice is called balance billing and is strictly prohibited by CMS. Note contracted Medicare physicians and pharmacies, including those providing services to MAPD Members (i.e. MAO, MAPD/Part C or Managed Care), are strictly prohibited from balance billing these Members. If the Member is QMB, the Medicare cost share is required to be submitted to Medicaid and the reimbursement amount must be accepted as payment in full regardless of the amount. Any Medicaid copays may be collected from the Member. Inability to submit a claim whether due to noncontracted status or systematic issues is not a valid reason to collect the Medicare cost share amounts from the applicable Member. In the event electronic secondary billing is not allowed for Medicare Advantage Members, please contact Medicaid to determine how to properly bill the Medicare cost share. Pharmacies who balance bill may be penalized (as established in Section 1902(n)(3)(C) of the Social Security Act) and/or terminated from the pharmacy network.

As many Medicaid agencies cover all or a portion of the Medicare cost share for Members that have full Medicaid even if they are not QMB, Pharmacy is advised to verify and coordinate Medicaid benefits appropriately. Pharmacies are required to bill Medicaid for the Medicare cost share if the Member has qualifying Medicaid coverage as well.

X. **Medicaid Dual Status Codes and Medicare Cost Share Coverage**

1. CMS 01 Partial Dual – QMB only (Qualified Medicare Beneficiary): Must bill Medicaid for Medicare copay – no exceptions. CMS strictly prohibits Balance Billing.
2. CMS 02 Full Dual – QMB+ (Qualified Medicare Beneficiary plus Full Medicaid): Must bill Medicaid for Medicare copay – no exceptions. CMS strictly prohibits Balance Billing.
3. CMS 03 Partial Dual – SLMB only (Specified Low Income Medicare Beneficiary): Medicare copay not covered by Medicaid; copay is Member responsibility.
4. CMS 04 Full Dual – SLMB+ (Specified Low Income Medicare Beneficiary plus Full Medicaid): Conditional – Verify Medicaid DME benefits and bill Medicaid for the Medicare copay when covered.
5. CMS 05 Partial Dual – QDWI (Qualified Disables and Working Individuals): Medicare copay not covered by Medicaid; copay is Member responsibility.
6. CMS 06 Partial Dual – QI (Qualified Individual): Medicare copay not covered by Medicaid; copay is Member responsibility.
7. CMS 08 Full Dual – Full Medicaid Benefit Dual Eligible: Conditional—Verify Medicaid DME benefits and bill Medicaid for the Medicare copay when covered.

   As a reminder, network providers shall comply with all state and federal laws and regulations.

Y. **Dual Eligible Members and Part B Drugs**

Some Medicare Part B covered drugs or diabetic supplies may be submitted via POS under the Medicare Part D BIN/PCN which will allow Pharmacy to identify Medicare Part B claims and Dual Eligible Members who have coverage for the Medicare Part B copay.

1. Benefit Stage Qualifier field (BSQ) will be populated with value 51 on the pricing segment response (D.0 Field #393-MV) when a Medicare Advantage Member receives a Medicare Part B covered service and CMS has notified the plan that QMB (Qualified Medicare Beneficiary) or full Medicaid coverage exists.
    i. When BSQ value 51 is present, the pharmacy must refrain from collecting the copay from the Member - otherwise known as "Balance Billing."
    ii. An additional alert may be provided via local claims messaging stating CMS Medicaid Status Code and partial or full Dual status (see chart on above): "Part B claim; If BSQ=51, bill Medicaid for copay. Balance Billing prohibited."
2. If a Member indicates they have QMB or full Medicaid coverage, but BSQ value is not 51, Pharmacy should contact the Member's State Medicaid or the number on the back of the Member's ID card to verify status.
3. Pharmacy should bill Medicaid for the remaining Medicare Part B copay or balance. If Medicaid imposes a Medicaid copay after they process the Medicare Part B secondary claim, the pharmacy may collect this amount from the Member.
4. Medicaid is always the payer of last resort and should never be billed as primary to circumvent coordination of benefits with the Medicare Advantage Plan.

Z. Medicare Supplier Number

Pursuant to 42 CFR § 424.57, Pharmacy is advised to obtain and maintain for each Pharmacy a Medicare Part B supplier number and update applicable information in the NCPDP database to capture the assigned numbers. PBM shall use the information in the NCPDP database to identify those pharmacies with Medicare Part B supplier numbers in the pharmacy network directories.

AA. Medicare Notice of Patient's Rights

Pharmacy is required to comply with all CMS regulations regarding the provision of written notices to Medicare Members. In order to indicate compliance, Pharmacy must:

1. Demonstrate and provide documentation that outlines the process by which each Member receives the communication entitled Notice of Patient Rights (CMS document 10147) during each rejection (rejection type 569);
2. Display the sign in the Pharmacy waiting area;
3. Notify a Member of a Claim rejection if the Member is not physically present at the Pharmacy and letting the Member know they can receive the Medicare Notice of Rights at the Pharmacy or through the mail.

BB. Compliance

All Medicare Plans (including MAO, MMP, MCO plans) are required to have a compliance plan that meets all applicable regulatory requirements (42 CFR Parts 422 and 423). Such compliance plan must be reasonably designed, implemented, and enforced to be effective in preventing, as well as detecting noncompliance with regulatory requirements. The plan must address program-specific requirements and address preventing/detecting potential criminal/fraudulent conduct. PBM has a compliance plan in place which aligns with Federal Sentencing Guidelines and supports the monitoring/detection of FWA (fraud, waste and abuse) within federal programs.

CC. Medicare Part D Specific Concurrent Drug Utilization Review (CDUR) Edits

In addition to CDUR edits previously outlined in the Drug Utilization Review section of the Provider Manual, CMS requires Plan Sponsors to implement several strategies to prevent and combat opioid overuse. These real-time safety edits occur at point of sale and engage patients and healthcare providers to address opioid overdose risks. Some members will be exempt from these

edits at point of sale if they have cancer, Sickle Cell Anemia, under hospice or palliative care, or reside in a long term care facility.

Medicare Part D Opioid Safety Edits	
90 Morphine Milligram Equivalent (MME) Care Coordination Edit	Point of sale care coordination safety edit that rejects opioid claims at ≥ 90 MME when a minimum number of opioid prescribers and pharmacy counts are met within a defined lookback period
Hard Opioid Edit	Point of sale care coordination safety edit that rejects opioid claims at specified MME that is at a minimum of 200 when a minimum number of opioid prescribers and pharmacy counts are met within a defined look back period
Opioid Naïve 7 Day Supply Edit	Point of sale safety edit that reject opioid day supply is greater than 7 for opioid naïve members
Duplicative Opioid Therapy	Point of sale safety edit that rejects long-acting opioid claim if filled within window of another long-acting opioid claim. Medicare Plan Sponsors can optionally implement duplicative short acting opioids
Concurrent use of Opioid and Benzodiazepine	Point of sale safety edit that rejects opioid claim if filled within a defined look back period of another benzodiazepine claim. Edit will also reject benzodiazepine claim if filled with a defined look back period of another opioid claim
Opioids with Acetaminophen greater than a 4000 mg Max Daily Dose	Point of sale safety edit that rejects claims with products containing APAP if cumulative daily dose is > 4000 mg per day
Concurrent use of Opioid and Medication Assisted Treatment (MAT)	Point of sale safety edit that rejects opioid claims after filling a MAT drug
Naloxone Co-prescribing Message	Point of sale messaging on any adjudicated paid opioid claim when opioid ≥ 50 MME

When these edits are triggered, a claim may reject and prompting prescribers and pharmacists to conduct additional safety review to determine if the enrollee's opioid use is appropriate and medically necessary. These edits may trigger during a member's transition period and multiple edits may be triggered concurrently.

Once the pharmacists have clinically reviewed the reject or performed care coordination activities, and determines that the dispensing of the medication is safe and medically necessary, the appropriate drug utilization review professional pharmacy service (DUR/PPS) override codes may be sent along the claim to bypass the reject. DUR/PPS service override codes are provided below for the corresponding edit.

If the pharmacist determines chooses not to dispense the opioid medication due to their clinical judgement, pharmacy must distribute a written copy of the standardized CMS pharmacy notice to the member ("Medicare Prescription Drug Coverage and Your Rights," CMS-10147, OMB Approval No. 0938-0975). This notice instructs members on how to contact their Plan and explains their right to obtain a coverage determination from the Plan, including information about the exceptions process.

Medicare Part D Opioid Safety Edits DUR/PPS Service Override Codes			
Opioid Edit	Reason for Service Code (439-E4)	Professional Service Code (440-E5)	Result of Service Code (441-E6)
90 Morphine Milligram Equivalent (MME) Care Coordination Edit	HC - High Cumulative Dose	CC Coordination of Care DP Dosage Evaluated DE Dosage Evaluation/Determination M0 Prescriber Consulted MR Medication Review R0 Pharmacist Consulted Othr	1A Dispensed As Is, False Positive 1B Dispensed Prescription As Is 1C Dispensed, With Different Dose 1D Dispensed, With Different Directions 1E Dispensed, With Different Drug 1F Dispensed, With Different Quantity 1G Dispensed, With Prescriber Approval 3D Regimen Changed 3E Therapy Changed 3G Drug Therapy Unchanged 4A Prescribed With Acknowledgments 4B Dispensed, Palliative Care 4C Dispensed, Hospice 4D Dispensed, Cancer Treatment 4E Dispensed, Chronic Pain 4F Dispensed, Exempt Per Prescriber 4G Dispensed, Surgery/Trauma 4H Dispensed, Hospital Admission/Discharge 4K Prescriber Exempt – Cancer/Palliative Care 4L Prescriber Exempt – Hospice
Hard Opioid Edit	HC - High Cumulative Dose	M0 Prescriber Consulted R0 Pharmacist Consulted Othr	4B Dispensed, Palliative Care 4C Dispensed, Hospice 4D Dispensed, Cancer Treatment 4K Prescriber Exempt – Cancer/Palliative Care 4L Prescriber Exempt – Hospice
		MR Medication Review	4D Dispensed, Cancer Treatment
Opioid Naïve 7 Day Supply Edit	MX - Excessive Duration Alert	M0 Prescriber Consulted R0 Pharmacist Consulted Othr	4B Dispensed, Palliative Care 4C Dispensed, Hospice 4D Dispensed, Cancer Treatment 4J Dispensed, Pt Not Opioid Naïve 4K Prescriber Exempt – Cancer/Palliative Care 4L Prescriber Exempt – Hospice
		MR Medication Review	4D Dispensed, Cancer Treatment 4J Dispensed, Pt Not Opioid Naïve
Duplicative Opioid Therapy	TD - Therapeutic Duplication	CC Coordination of Care DP Dosage Evaluated DE Dosage Evaluation/Determination M0 Prescriber Consulted MR Medication Review R0 Pharmacist Consulted Othr	1A Dispensed As Is, False Positive 1B Dispensed Prescription As Is 1C Dispensed, With Different Dose 1D Dispensed, With Different Directions 1E Dispensed, With Different Drug 1F Dispensed, With Different Quantity 1G Dispensed, With Prescriber Approval 3D Regimen Changed 3E Therapy Changed 3G Drug Therapy Unchanged 4A Prescribed With Acknowledgments 4B Dispensed, Palliative Care 4C Dispensed, Hospice 4D Dispensed, Cancer Treatment 4E Dispensed, Chronic Pain 4F Dispensed, Exempt Per Prescriber 4G Dispensed, Surgery/Trauma 4H Dispensed, Hospital Admission/Discharge 4K Prescriber Exempt – Cancer/Palliative Care 4L Prescriber Exempt – Hospice
Concurrent use of Opioid and Benzodiazepine	DD - Drug-Drug Interaction	CC Coordination of Care DP Dosage Evaluated DE Dosage Evaluation/Determination	1A Dispensed As Is, False Positive 1B Dispensed Prescription As Is 1C Dispensed, With Different Dose 1D Dispensed, With Different Directions

		M0 Prescriber Consulted MR Medication Review R0 Pharmacist Consulted Othr	1E Dispensed, With Different Drug 1F Dispensed, With Different Quantity 1G Dispensed, With Prescriber Approval 3D Regimen Changed 3E Therapy Changed 3G Drug Therapy Unchanged 4A Prescribed With Acknowledgments 4B Dispensed, Palliative Care 4C Dispensed, Hospice 4D Dispensed, Cancer Treatment 4E Dispensed, Chronic Pain 4F Dispensed, Exempt Per Prescriber 4G Dispensed, Surgery/Trauma 4H Dispensed, Hospital Admission/Discharge 4K Prescriber Exempt – Cancer/Palliative Care 4L Prescriber Exempt – Hospice
Opioids with Acetaminophen greater than a 4000 mg Max Daily Dose	HC - High Cumulative Dose	CC Coordination of Care DP Dosage Evaluated DE Dosage Evaluation/Determination M0 Prescriber Consulted MR Medication Review R0 Pharmacist Consulted Othr	1A Dispensed As Is, False Positive 1B Dispensed Prescription As Is 1C Dispensed, With Different Dose 1D Dispensed, With Different Directions 1E Dispensed, With Different Drug 1F Dispensed, With Different Quantity 1G Dispensed, With Prescriber Approval 3D Regimen Changed 3E Therapy Changed 3G Drug Therapy Unchanged 4A Prescribed With Acknowledgments 4B Dispensed, Palliative Care 4C Dispensed, Hospice 4D Dispensed, Cancer Treatment 4E Dispensed, Chronic Pain 4F Dispensed, Exempt Per Prescriber 4G Dispensed, Surgery/Trauma 4H Dispensed, Hospital Admission/Discharge 4K Prescriber Exempt – Cancer/Palliative Care 4L Prescriber Exempt – Hospice
Concurrent use of Opioid and Medication Assisted Treatment (MAT)	MC - Drug-Disease	CC Coordination of Care DP Dosage Evaluated DE Dosage Evaluation/Determination M0 Prescriber Consulted MR Medication Review R0 Pharmacist Consulted Othr	1A Dispensed As Is, False Positive 1B Dispensed Prescription As Is 1C Dispensed, With Different Dose 1D Dispensed, With Different Directions 1E Dispensed, With Different Drug 1F Dispensed, With Different Quantity 1G Dispensed, With Prescriber Approval 3D Regimen Changed 3E Therapy Changed 3G Drug Therapy Unchanged 4A Prescribed With Acknowledgments 4B Dispensed, Palliative Care 4C Dispensed, Hospice 4D Dispensed, Cancer Treatment 4E Dispensed, Chronic Pain 4F Dispensed, Exempt Per Prescriber 4G Dispensed, Surgery/Trauma 4H Dispensed, Hospital Admission/Discharge 4K Prescriber Exempt – Cancer/Palliative Care 4L Prescriber Exempt – Hospice

DD. Medicare Drug Management Program (DMP)

Beginning in 2022, Medicare Plan Sponsors are required to a Drug Management Program (DMP). The program identifies members that may be inappropriately using opioids based on a member's average daily morphine milligram equivalent (MME) for the past 6 months, number of unique opioid prescribers, number of unique dispensing pharmacies, or if a member has had an opioid related overdose.

Once at-risk members are identified, Medicare Plan Sponsors will work with the member's prescriber(s) to determine if limiting the member's access to specific frequently abused drugs (FAD's), such as opioid or benzodiazepine medication, is warranted. If a prescriber proceeds with case management, the member's access to FAD will be limited to the type of FAD, to the quantity or dose of the FAD, to specific prescribers of FAD, or to specific pharmacies. A prescriber may want to limit any number or any of these combinations.

Prescribers and members will be notified of the limit and the type of limit in advance. Pharmacies may receive the following rejects if a member is under a DMP. The member must fill their FAD as specified in their notice in order to be covered. If network pharmacies have any questions about rejected claims or issues due to DMP, please contact the pharmacy help desk number located on the Member ID card.

- 828 - Plan/Beneficiary Case Management Restriction In Place
- 943 - DUR Reject – Pharmacy Override Using DUR/PPS Not Allowed
- 979 - Patient Locked Into Specific Prescriber(s)
- 980 - Patient Locked Into Specific Pharmacy(s)