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PHARMACY MANUAL INTRODUCTION

The Pharmacy Manual (Pharmacy Manual may also be referred to in the Participating Provider Agreement as Provider Portal) outlines the policies, procedures, and regulations for Pharmacies participating in the EnvisionRx Network. This Manual provides information that Pharmacies in the Network must follow in addition to the provisions included in the Participating Provider Agreement (PPA). Pharmacies can reference the Pharmacy Manual and utilize the information to ensure the quality service to Members. Pharmacies participating in the Network are obligated to review the Pharmacy Manual regularly and ensure compliance of Pharmacy staff members.

We thank you for continued cooperation and participation in our Network.

GENERAL INFORMATION

EnvisionRx is a Pharmacy Benefits Manager (PBM) with headquarters located in Twinsburg, OH.

This Pharmacy Manual, including our policies, procedures and regulations, is designed to offer Pharmacies, with important information regarding program requirements and operational procedures. Pharmacies that sign our PPA are contractually bound to comply with the terms as it is incorporated into and a part of your PPA. All Pharmacies are expected to adhere to the PPA terms. Failure to comply may result in the termination of your PPA by EnvisionRx.

EnvisionRx credentials potential pharmacies prior to their acceptance in any EnvisionRx Network. EnvisionRx monitors the credentials of its Pharmacies in accordance with EnvisionRx policies, acceptable industry standards and/or as mandated by law. Pharmacies must respond promptly to provide EnvisionRx with any requested documentation necessary to in order to maintain its participation status in the network.

Depending on the line of business, certain sections of the Pharmacy Manual will apply (i.e. Medicare, HMA, Exchange). Capitalized terms used in the Pharmacy Manual but not defined herein shall have the same meaning as set forth in the PPA. This Pharmacy Manual supersedes and replaces all previous versions of the Pharmacy Manual. EnvisionsRx does not require Pharmacy or PSAO approval prior to revising or modifying the Pharmacy Manual. Pharmacy shall also mean PSAO contracting on behalf of Pharmacy (as applicable).

EnvisionRx receives all Pharmacy information updates through National Council for Prescription Drug Programs (NCPDP). To make updates to information including address, email, fax number, phone number, chain/PSAO affiliation, payment center, and other important information to NCPDP, visit NCPDP’s website at online.ncpdp.org. It is the responsibility of the Pharmacy to provide timely updates to NCPDP to ensure that EnvisionRx has the most accurate and updated data.

EnvisionRx reserves the right to update this document from time to time.

PROPRIETARY AND CONFIDENTIAL

The information contained in this Pharmacy Manual is privileged and confidential property of EnvisionRx and is for business purposes only. The Pharmacy Manual is not nor should it be considered legal, compliance, medical/health, or financial advice. The Pharmacy Manual cannot be copied, reproduced, transmitted or otherwise used or disclosed in any form without the written approval of EnvisionRx or as authorized in the PPA.
ADVERTISING REQUESTS
Pharmacies are expressly denied any rights to use the EnvisionRx name, likeness, logo, service marks, or trademarks in any advertisement, promotion, or otherwise without prior, written consent from EnvisionRx. Note Envision Rx will not approve any advertisement or promotional materials that is designed to waive or discount participant Cost Share (copayments, coinsurances or deductibles). The Pharmacy will immediately discontinue use of approved advertisement, promotion or otherwise if suspended or terminated from the Pharmacy Network.

CONTACT INFORMATION / WHERE TO GET HELP
The Pharmacy Help Desk is available 24 hours a day, 7 days a week, 365 days per year including holidays, at: 800-361-4542 (TTY Users may call 711). Pharmacies may also reference the phone number provided in the claim response messaging or on the back of the Member ID card. Below is the contact information for each department and the types of inquires they are responsible for. For questions on topics that are not listed below, please contact our Pharmacy Help Desk. If a Pharmacy has suggestions as to how EnvisionRx can better serve our Members, they can complete the Pharmacy Satisfaction Survey.

<table>
<thead>
<tr>
<th>Department</th>
<th>Inquiry Type</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Payables</td>
<td>Payments, electronic funds transfer (EFT) and electronic remittance advice (ERA)</td>
<td>Email: <a href="mailto:pharmacyaccountingissues@envisionrx.com">pharmacyaccountingissues@envisionrx.com</a></td>
</tr>
<tr>
<td>Compliance and Fraud Waste and Abuse Hotline</td>
<td>Report suspected fraud, waste and abuse and other compliance related issues</td>
<td>Phone: 1-866-417-3069 Online: myethicsline.envisionrx.com</td>
</tr>
<tr>
<td>MAC</td>
<td>MAC drug pricing</td>
<td>Email: <a href="mailto:MAC@envisionrx.com">MAC@envisionrx.com</a></td>
</tr>
<tr>
<td>Network Compliance</td>
<td>Pharmacy enrollment, credentialing, recredentialing, and change of ownership</td>
<td>Email: <a href="mailto:providerenrollment@envisionrx.com">providerenrollment@envisionrx.com</a></td>
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<tr>
<td>Pharmacy Audits and Fraud, Waste, and Abuse</td>
<td>Ongoing audits, audit appeal, suspensions</td>
<td>Email: <a href="mailto:pharmacyaudits@envisionrx.com">pharmacyaudits@envisionrx.com</a> Fax: 844-236-3021</td>
</tr>
<tr>
<td>Pharmacy Help Desk</td>
<td>Billing/payment, formulary, disputes and appeals, Member eligibility, plan benefits, Pharmacy Network issues, and prior authorizations, dispute resolution, coverage determinations</td>
<td>Phone: 800-361-4542 TTY: 711</td>
</tr>
<tr>
<td>Provider Relations</td>
<td>Pharmacy contracting, contract status, AWP drug pricing questions</td>
<td>Email: <a href="mailto:pharmacycontracting@envisionrx.com">pharmacycontracting@envisionrx.com</a></td>
</tr>
</tbody>
</table>

PRICING AND REIMBURSEMENT QUESTIONS
In order for the Pharmacy Help Desk to review claim information, pharmacies will need provide their NCPDP number, prescription number, date of service, NDC number of the drug, quantity dispensed and the amount due. The representative will record the details and forward the disputed Claim over to the appropriate department for review and follow up.

Please be advised that if a Pharmacy submits a Claim to EnvisionRx, even if Pharmacy is not currently contracted at the time of service for a program, the acceptance for reimbursement constitutes acceptance of the rates for that program. EnvisionRx contracts for rebates and provides the discount price to compare with the Usual and Customary price. The lower of the two prices is sent back to the Pharmacy as the amount to be paid to the Pharmacy.
In the event that EnvisionRx determines that your Pharmacy was overpaid or underpaid for a prescription, the adjusted amount will be applied to your next reimbursement cycle. The Pharmacy must continue to dispense prescriptions to Members in good faith during and subsequent to any pricing and reimbursement. Pharmacies must refrain from making disparaging comments to Members about EnvisionRx or about Member’s Plan Sponsor.

MAXIMUM ALLOWABLE COST (MAC)

MAC LISTS
MAC pricing lists will be reviewed and updated at least every seven (7) business days to reflect changes in pricing data. If there is a conflict with EnvisionRx’s standard for updating the MAC price lists and an applicable state law or regulation, EnvisionRx will follow the stricter provision.

MAXIMUM ALLOWABLE COST APPEALS
Pharmacies must provide the information below to ensure requests can be reviewed without any disruption: Rx BIN, Group ID, Rx Number, Date of Fill, NDC, Drug and Strength, Quantity Dispensed, NCPDP Number, Acquisition Cost and Contact Name and Number.

Upon receipt of the required Claim information, the MAC department will complete market research utilizing nationally recognized wholesalers to determine the independent Pharmacy purchasing price. This price will be compared to the current MAC price to determine if an adjustment is needed. If an update in price be needed, EnvisionRx will update the MAC price within five (5) business days. If an appeal price is deemed valid and supported by market research, a response back to the Pharmacy will include the reason for denial and if necessary based on the appeal, the NDC for the lower cost product which substantiates the MAC price. Appeals will be responded to within seven (7) business days. If there is a conflict between EnvisionRx’s standards for addressing MAC appeals and an applicable state law or regulation, Envision will follow the stricter provision.

VACCINES

The purpose of the EnvisionRx Pharmacy Vaccine Program is to provide a range of vaccines that may be appropriately administered in the Pharmacy setting. The fee schedule is listed at the Generic Product Indicator (GPI) level, allowing Pharmacies the flexibility to purchase various NDCs within that GPI. EnvisionRx may modify the list of GPIs below from time to time to accommodate industry availability. Pharmacies are eligible to receive a vaccine administration fee for the list of GPI’s below.

State laws may vary regarding administration of some vaccines in a retail setting or by a pharmacist. Pharmacies are required to know and comply with your state’s regulations regarding the administration of vaccines by your Pharmacy.

RETAIL VACCINE PROCESSING INSTRUCTIONS
In order for Pharmacies to be reimbursed correctly, Claims should be submitted with the NDC code. Pharmacies must submit quantity dispensed (i.e. one vial is submitted as quantity 1, regardless of mL dose) in the “Metric Decimal or Quantity Dispensed” field which appears as FIELD # 442-E7 on the Payer Sheet. Pharmacies must submit “MA” in the “Pro Svc Code, Professional Service Code” field which appears as FIELD # 440-E5 on the Payer Sheet. The administration fee must be entered in the ”Incent Amt Sub, Incentive Amount Submitted” field which appears as FIELD # 438-E3 on the Payer Sheet.
In order to receive a vaccine under this program, Members should present their Member ID Card to the pharmacist. The BIN/PCN will be the same as submitted for Commercial, Medicare, or Medicaid Claims. The Pharmacy is contractually obligated to collect any applicable copays or Cost Sharing. Please note that not all Plan Sponsors participate in this program.

**Vaccine Program List**

<table>
<thead>
<tr>
<th>GPI</th>
<th>Name</th>
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</thead>
<tbody>
<tr>
<td><strong>Influenza Vaccines</strong></td>
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<tr>
<td>1710002021E620</td>
<td>Afluria Preservative Free</td>
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<tr>
<td>17100020201800</td>
<td>Afluria</td>
</tr>
<tr>
<td>1710002046E620</td>
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<tr>
<td>1710002086E520</td>
<td>Flublok Quadrivalent Preservative Free</td>
</tr>
<tr>
<td>1710002082E620</td>
<td>Flucelvax Quadrivalent</td>
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<tr>
<td>17100020821800</td>
<td>Flucelvax Quadrivalent</td>
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<tr>
<td>17100020541800</td>
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<td>1710002023E620</td>
<td>Fluzone HD Preservative Free</td>
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<tr>
<td>17100020251820</td>
<td>Fluzone Quadrivalent INJ 2018-2019</td>
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<tr>
<td>1710002025E620</td>
<td>Flu, Flulaval, Fluzone, &amp; Fluarix Quadrivalent Preservative Free</td>
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<tr>
<td>17100020251800</td>
<td>Flulaval &amp; Fluzone Quadrivalent</td>
</tr>
<tr>
<td>1710002025E610</td>
<td>Fluzone Quadrivalent Pediatric dose Preservative Free</td>
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<td><strong>Additional Vaccines</strong></td>
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<td>17100095401920</td>
<td>Shingrix</td>
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<tr>
<td>18990002201805</td>
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</table>
NETWORK APPLICATION AND CREDENTIALING GUIDELINES

APPLYING FOR PARTICIPATION
To apply to become a Pharmacy in our Network, please fill out the application Provider Credentialing and Verification to the Participating Provider Agreement located on our website. Once you submit the application, we will initiate the enrollment process. Please allow up to forty five (45) business days for your application to be processed.

CREDENTIALING GUIDELINES
EnvisionRx credentials and continually monitors the credentials of all participating Pharmacies prior to and after inclusion into the EnvisionRx Network. Pharmacies are required to meet conditions of participation set forth by EnvisionRx and adhere to governmental regulations and standards. The credentialing process includes, but is not limited to, a review of the following:

1. Minimum Credentialing Requirements for Independent Pharmacies:
   - Current DEA
   - Current State License(s)
   - Current Professional Liability Insurance of $1,000,000 per occurrence/$3,000,000 aggregate or an equivalent Umbrella policy
   - No sanctions per the Office of Inspector General (OIG) List of Excluded Individuals/Entities (LEIE)
   - No sanctions per any Office of Medicaid Inspector General in any state
   - No sanctions per the General Service Administration’s (GSA) System for Award Management (SAM)
   - Additional information as determined by EnvisionRx

2. PSAOs and Chains must attest to, and be able to provide for all or a sample of pharmacies upon entrance and when requested:
   - Verification of credentialing program for itself and each of its member pharmacies
   - Copy of credentialing policy for itself and each of its member pharmacies
   - All requirements listed above in number 1
   - If PSAO cannot attest, each Pharmacy will be recognized as an Independent Pharmacy and will adhere to the same Credentialing standards as an Independent (see above for Independent Credentialing Standards)

EnvisionRx uses primary-source verification during its review of the pharmacy license and DEA registration. For additional information, please refer to the Envision Credentialing and Re-Credentialing FAQ located on the EnvisionRx website.

QUARTERLY PROVIDER CREDENTIALING AUDITS
EnvisionRx audits the credentials of its Pharmacies on a quarterly basis. We may contact your Pharmacy to request proof of insurance coverage or additional copies of your Pharmacy’s other credentials. The required documents must be faxed or emailed the same business day of the request, unless another timeframe is noted in the communication or in your PPA.

If your Pharmacy is contacted during an EnvisionRx quarterly credentialing check, we thank you for your anticipated cooperation in providing the required information.
PROVIDER AND MEMBER SERVICE STANDARDS

NON-DISCRIMINATION CLAUSE
The Pharmacy must not discriminate against Members on a basis of age, sex, race, disability, ethnic group, national origin, sexual orientation, medical condition, religion, family or marital status, source of payment or reimbursement rate, enrollment in a plan, or any other characteristics or basis protected by law.

PROVIDER NETWORK – ACCESSIBILITY
Pharmacies shall ensure that Members receive equal treatment, access, and rights without regard to race, color, national origin or Limited English Proficiency (LEP). Pharmacies shall provide or arrange language assistance (i.e. interpreters and/or language appropriate written materials) to person with LEP. All Pharmacies in the EnvisionRx Network must be compliant with applicable access standards related to the Americans with Disabilities Act of 1990 (or its successor).

Nothing in the Agreement shall restrict the Pharmacy from informing, nor penalize Pharmacy for informing, a Member of any differential between the negotiated price of, or Cost Share for, the Covered Drug to the Member and a lower price the Member would pay for the Covered Drug if the Member obtained the drug without using health insurance coverage.

PHARMACY COMMUNICATIONS
All Pharmacies within the EnvisionRx Network shall have a standard format method for receiving communications for continuing participation requirements, notifications of Network activities, and/or federal and state mandates. Email is the preferred method for Pharmacy communications by EnvisionRx. Pharmacies will be notified of any communications via email or fax.

NON-PREFERRED VS. PREFERRED STATUS
Pharmacies that currently have “preferred or non-preferred” status in an EnvisionRx Network may lose that status if they change their current contract status with EnvisionRx (i.e. changing PSAO affiliation, contracting independently, no longer contracted, etc.).

QUALITY ASSURANCE
Pharmacy agrees to use commercially reasonable efforts to promptly respond to, resolve, and remedy any problems that may arise and cooperate with Network to investigate and resolve any complaints from Members. Pharmacy agrees to use best efforts to immediately respond to, resolve, and remedy all Member grievances presented by the Network within five (5) business days and restore goodwill to Members to the Network’s, Plan Sponsor’s or Program Sponsor’s satisfaction. The Pharmacy will exercise professional judgment in the provision of Covered Drugs to Members, and will counsel Members on their drug therapy as indicated. Pharmacies will refrain from making disparaging comments to Members about EnvisionRx, Plan Sponsors or Program Sponsors. Pharmacies will educate its pharmacists and other employees who have contact with the Members on these topics. No provision of this Pharmacy Manual shall be construed to require any pharmacist or Pharmacy to dispense any Covered Drugs to any Member if, in the pharmacist’s reasonable professional judgement, such Covered Drug should not be dispensed to such Member.
COMPLIANCE WITH LAWS
The Pharmacy must comply with all applicable laws, regulations and guidelines (formal or informal) in performing the Pharmacy services, including but not limited to: the Anti-Kickback Statute, the False Claims Act, the Affordable Care Act, and HIPAA.

INVESTIGATIONS AND DISCIPLINARY ACTIONS
The Pharmacy must immediately notify EnvisionRx if its license or permit is suspended or revoked; if any disciplinary action has been taken against the Pharmacy or the Pharmacy’s personnel by any regulatory body or law enforcement; or there is a seizure by law enforcement of any Pharmacy property (i.e. prescription records, accounts, computers).

CHANGE OF INFORMATION
Unless otherwise specified, the Pharmacy must update NCPDP and notify EnvisionRx in writing within thirty (30) days of any changes in documentation or other information provided to EnvisionRx in connection with enrolling as a Pharmacy in the network. The Pharmacy must update NCPDP within fourteen (14) business days of a change of ownership. Upon a change of ownership, the Pharmacy is required to contact Network Compliance to determine if they are subject to recredentialing.

EXCLUDED PARTIES
The Pharmacy is required to check the HHS OIG List of Excluded Individuals and Entities (LEIE), and the System for Award Management (SAM) Excluded Parties Lists System prior to the hiring (and monthly thereafter) of any new employee, temporary employee, volunteer, consultant, governing body member, or subcontractor, to ensure that it does not employ or contract with a person or entity who is excluded from participating in any federal or federally funded health care program. If any person or entity employed by or under contract with the Pharmacy is found on the OIG LEIE, CMS Preclusion List, GSA/SAM or any Medicaid exclusion lists, the Pharmacy must immediately notify the Network and refund the Network any reimbursements made to the Pharmacy for any Claims submitted to Network by the excluded person or entity within ten (10) business days.

FRAUD, WASTE AND ABUSE TRAINING
CMS requires all Pharmacies to conduct both General Compliance and Fraud, Waste and Abuse training for their personnel (i.e. employees, contracted staff and vendors) who are engaged in providing Medicare services. This training must be provided within ninety (90) days of contracting with EnvisionRx and annually thereafter. The Pharmacy must be able to demonstrate that its employees have satisfied these training requirements and must retain proof of such training for ten (10) years. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications from the employees taking and completing the training. Upon reasonable request by EnvisionRx, your Pharmacy must be willing to offer written attestation to its compliance of this section.

SUSPENSIONS AND TERMINATIONS
EnvisionRx will monitor and suspend a Pharmacy from participation in its Network if the Pharmacy has been identified or under review for engaging in any behavior or practice that:
1. Poses a significant risk to the health, welfare, or safety of any Member; or
2. Promotes or commits fraud, waste, or abuse; or
3. Commits an act, omission or material breach that is contrary to the criteria set forth in the PPA and the Pharmacy Manual.
In addition, EnvisionRx reserves the right to immediately suspend a Pharmacy upon becoming aware that the Pharmacy has been investigated, within the past five (5) years, or is currently under investigation by a federal or state governmental agency or regulatory body.

The following practices may constitute a breach of the PPA and may result in claims chargeback, suspension and termination from the Network, or other rights and remedies that may be available to EnvisionRx under the Agreement, or at law, or equity:

- Sharing ownership, partial ownership, officers, affiliates, principals or other relationships with Pharmacies previously suspended or terminated from network;
- Shipping medications or supplies to members without their consent or initiation
- Shipping to states where Pharmacy is not licensed
- Obtaining prescriptions through the use of telemarketing companies or services
- Submitting a large number of test claims
- Promoting drugs to patients, direct or indirectly, without prior relationship to patient
- Not collecting copayments (Cost Share) at time of service
- Utilizing secondary payer coupons or copayment cards that are not recognized or sponsored by pharmaceutical manufacturers or offered through a recognized or verifiable patient assistance program operated by an independent charity in compliance with the OIG 2014 Special Advisory Bulletin
- Using pharmaceutical manufacturer copayment cards or coupons for Part D or other federally-funded health program covered medications
- Not cooperating or providing access to books, records or the facility during an onsite audit
- Lack of pharmacist presence during hours of operation
- Adjudicating components of a compound drug as separate ingredients, single-NDC claims
- Adjudicating claims for compound drugs in which the ingredients are not supported by a medically acceptable indication through the same administration route for the condition being treated
- Adjudicating claims for compound drugs in which the same or similar formulation is available on the market
- Finding inventory shortages upon invoice reconciliation when comparing Pharmacy drug utilization and purchase invoice records
- Insufficient records of inventory transfer(s) from/to commonly owned Pharmacy location
- Insufficient records of inventory transfer(s) from/to another Pharmacy (ex. sale, merger, etc.)
- Omitting information or providing inaccurate data on the credentialing or recredentialing application
- Failure to respond to recredentialing request or audit
- Failure to complete and attest to the annual Medicare Part D FWA Training and general Compliance Trainings
- Refusing to service a member due to reimbursement rates

If a Pharmacy is being investigated for any reason, EnvisionRx reserves the right to suspend the Pharmacy, until the investigation is complete. Once the investigation is complete, the Pharmacy will either be reinstated or terminated from participating in the Network. Unless otherwise specified by law, any Claims processed by the Pharmacy that are determined as invalid or ineligible Claims, if applicable, are subject to be recouped by Network. This includes the entire Claim, including any dispensing fee(s).

EnvisionRx may temporarily withhold payment or cancel checks, in whole or in part, and/or prevent claims adjudication during the suspension period.
EnvisionRx’s remedies under this section include termination of the Pharmacy from the Network. These termination rights are in addition to any and all other rights and remedies that may be available to EnvisionRx under the Agreement, or at law, or equity.

Pharmacy may submit an appeal of the suspension or termination to EnvisionRx by writing to the address provided in the Agreement notice within fourteen (14) days of receipt of such notice. The written appeal submitted by the Pharmacy must include supporting documents in order to be considered for reinstatement into the Network.

PROCESSING A CLAIM

BIN NUMBER AND PCN INFORMATION
Current BIN and PCN numbers are located on the EnvisionRx website at: https://www.envisionrx.com/PrescribersAndProviders/Pharmacies#ProcessingInformation. PCN numbers must be entered with all capital letters. Please see the Medicare Part D Payer Sheet for more information regarding Part D BIN requirements.

 ELECTRONIC CLAIMS TRANSMISSIONS REQUIREMENT
Pharmacy shall submit online Claims to EnvisionRx via Network’s System in NCPDP format, within three (3) days of compounding or dispensing a Covered Drug to a Member in order to receive payment. Pharmacy shall bill Network using the 11 digit National Drug Code (NDC) number for the drug dispensed. The Pharmacy must submit its Usual and Customary Price (U&C) and submitted ingredient cost as part of the pricing information submitted for each prescription. EnvisionRx shall not be liable for any transmission charges for Claims data.

The Pharmacy shall submit the Claim to EnvisionRx or its designated processor and include the following information:

i. the Member’s name;
ii. identification number;
iii. group number (for Member under a group plan contract);
iv. service date;
v. Pharmacy NCPDP or NPI number with service provider qualifier;
vi. prescription number;
vii. NDC number;
viii. quantity dispensed;
ix. prescribed days’ supply;
x. prescribing practitioner’s DEA or NPI number and prescribing provider qualifier;
xii. Average Wholesale Price (AWP), Wholesale Acquisition Cost (WAC), or such other pricing methodology as has been adopted by the industry;
xii. dispensing fee as described in the Plan Sheets attached to the Agreement; and
xiii. copayments, deductibles or coinsurance collected from Member.

Pharmacy acknowledges and agrees the prescribing practitioner’s NPI must be submitted for all Medicare Claims.

EnvisionRx requires all Pharmacies to be Health Insurance Portability and Accountability Act (HIPAA) compliant with all electronic Claim transactions utilizing the NCPDP version D.0 Telecommunication Standard format.
EnvisionRx recognizes “Dispense As Written” (DAW) Codes 0, 1, 2, 3, 4, 5, 7, and 9 only. The DAW field drives reimbursement of the prescription and the Member copayment. This field must be populated correctly; the DAW data entered by the Pharmacy may be subject to retrospective review. For formulary mandated drugs, DAW code 9 must be submitted.

1. **ONLINE SYSTEM DOWN-TIME TRANSMISSION PROCEDURES**
   In the event a party’s Claims adjudication System is unavailable, the Pharmacy should attempt to resubmit the Claim no later than thirty (30) days of the date the prescription was filled.

2. **CLAIMS REVERSALS AND CLAIM ADJUSTMENTS**
   If a Pharmacy needs to resubmit a Claim previously processed through the System, the original Claim must first be reversed prior to the Claim resubmission. Reversals must be made within sixty (60) days from the date the Pharmacy ran the Claim through the System. Once a reversal is submitted and accepted, an adjusted Claim may be transmitted. For prescriptions billed to EnvisionRx that are not picked up by the Member, EnvisionRx requires Pharmacies to reverse the Claim via the System within fourteen (14) days from the date the prescription was filled. EnvisionRx reserves the right to audit for prescriptions that were not picked up by the Member to ensure appropriate Claim reversals. Pharmacies may need to contact their online Systems software vendor for information on how to submit a Claim reversal.

Pharmacies unable to reverse Claims over sixty (60) days from the date of service via the System should contact the Pharmacy Help Desk.

**ACCURATE CLAIM SUBMISSION AND PRESCRIPTION RECORD**

1. **Submission of Accurate Claims**
   a. Claims in which the accurate days' supply is modified in order to obtain a paid Claim are considered recoverable, depending on plan benefit limitations.
   b. Claims should be billed with quantity and days' supply consistently matching the directions for use and within plan benefit limitations. If the directions for use are not specific, such as “use as directed” or “apply to affected area”, clarification must be obtained from prescriber and documented accordingly on the prescription hard copy or the Pharmacy’s electronic record system.
   c. Ensure the max daily dose (MDD) is present on use as directed (UAD) and sliding scale instructed prescriptions to avoid discrepancies and chargebacks.
   d. Smaller package size should be billed if it meets the prescriber directions and remains within the maximum days' supply limitation set up by the plan.
   e. Splitting prescription (lowering prescribed quantity) to bypass adjudication messages indicating requirement for prior authorizations or outreach to the Pharmacy Help Desk is not allowed, and will be subject to audit chargebacks.
   f. The NDC number of the dispensed drug, matching the package size, must be billed to accurately reflect the dispensed product. Billing of similar NDC is not allowed and will be subjected to audit
chargebacks, according to audit findings. Wholesaler invoices and other drug related records should outline NDCs and drug names to be considered valid.

g. The dispensing Pharmacy NPI number must be used for claims submission, unless otherwise authorized in writing by EnvisionRx. Utilizing another Pharmacy NPI number for submission of claims is subject to audit review and chargebacks.

h. Claims adjudicated with incorrect prescriber NPI or identifiers, or incorrect origin codes, will be subject to adjustment or reversal if the adjustment results in claim rejection.

i. A pre-printed substitution drug is not valid without a new prescription or a properly documented verbal authorization from prescriber.

2. **Standards for Ophthalmic and Otic Drops:** Unless indicated otherwise by manufacturer:
   a. Solutions - 20 drops/mL
   b. Suspensions - 15 drops/mL

3. **Topical Products, Drops, Inhalers:** When calculable directions are not specified, the smallest commercially available package size should be dispensed. If a larger amount is required, the frequency and surface area (for topical products) or maximum daily dose documentation is required on the prescription at the time of dispensing.

4. **Return to Stock:** Billed Claims must be reversed after fourteen (14) days if prescription is not picked up or received by the patient. Receipt of medications post fourteen (14) days of billing is subject to audit chargebacks.

5. **Override and DUR Codes:** All NCPDP override DUR coding should accurately reflect the reason for the DUR override. If the Pharmacy utilizes an override code in order to obtain a paid Claim (i.e. 1B for “clarified with prescriber”) the interaction must be documented on the prescription or in the Pharmacy System with traceable time stamps. Lack of supporting documentation is subject to audit chargebacks. Dispensing pharmacists should review DUR codes based on their clinical judgement, expertise and using applicable direction from governing organizations (i.e. Centers for Medicare and Medicaid Services). A Therapeutic Duplication (TD) message or edit requires a review of the patient's utilization history within the previous thirty (30) days, as it indicates an attempt to fill a medication within the same drug class. There may be claims from other pharmacies. In these circumstances, it is expected that the Pharmacy seek clarification about therapy from either the Member or the prescriber. If a clarification effort is made then the pharmacist should document information obtained from clarification and utilized to make a clinical decision. The pharmacist may override the rejection, if any, by using applicable Reason, Professional and Result codes.

6. **Telephoned Prescriptions:** Called-in prescriptions or verbal authorizations/clarifications added to any prescription must be documented with date and name of caller. Missing information is subject to audit chargebacks.

7. **Signature Log Requirement:** Electronic or manual signature should be recorded at time of pick-up or delivery by the Member or designated Member representative. The record should include the date of pick-up or delivery and prescription number. For deliveries, the date delivered cannot be pre-printed by the Pharmacy.
8. **Prescriptions Delivered by common carrier (Mail, FedEx, UPS etc.):** For delivery logs, a tracking number alone is not considered a valid proof of Member receipt. The tracking number must be accompanied by Member signature or tracking detail from carrier showing medication was delivered.

   a. **Auto-ship requirements:** A pharmacy that is mailing prescription drugs must obtain the Member’s (or Member’s authorized representative) authorization prior to the delivery of medication. This requirement applies to both new prescriptions and refills. Such confirmation is unnecessary when the beneficiary personally initiates the refill or new prescription request (i.e. by mailing prescription to the Pharmacy). Pharmacies are required to keep documentation related to authorization for delivery on file for audit purposes.

9. **Long Term Care Pharmacy Considerations:**
   a. Orders must indicate the time frame for which they are valid. Original orders without indication of number of refills are invalid if billed outside of the time frame indicated on the prescription.
   
   b. Facility nursing staff call in notes, refill stickers or electronic refill requests are only valid to show intent to refill and not considered to be a valid order.
   
   c. Prescription delivery should not take place before the date of service billed and no later than the following day.
   
   d. Additional documentation may be required from the Pharmacy depending on the circumstance, such as medication administration records (MARs).
   
   e. MARs are not considered valid proof of delivery, but may be requested from time to time to assure patient utilization of medication.

10. **Initiated Prescriptions:** Pharmacy shall not deliver Covered Drugs to a Member without the Member’s consent prior to each delivery. Additionally, Pharmacy agrees that it will not bill for reimbursement for Member’s Covered Drug prescriptions until and unless the Member has received such prescriptions.

11. **Identification Cards:** All information to process a Claim is included on the Member ID Card. The Pharmacy is required to process the Claim using the Member information unless the Member expressly requests that a Claim not be submitted to the insurer. The Member ID is typically a unique number containing alpha characters. EnvisionRx also utilizes a relationship designation which may or may not be printed on the card.

    The card normally contains the following information when issued by EnvisionRx:
    
    a. The Member’s name on the card with a Member ID consisting of up to 15 characters which may be alpha numeric but does not contain Member’s Social Security Number.
    
    b. The family Member card will either list the Member’s full name with no dependents or the Member’s last name with dependents. The relationship code for the dependents may or may not be listed on the card. The Member cardholder will have “01” as the person code, spouses will have “02”, and other dependents may be listed by first name on the card and use the person codes “03”, “04” etc., respectively.
    
    c. The toll-free number listed on the back of the Member ID card is the contact number for the Pharmacy Help Desk.
Please verify the ID number on the Member’s prescription card before transmitting a Claim in order to avoid a rejection, subsequent adjustment, or the processing of the Claim incorrectly under another Member’s eligibility.

In order to process a Claim, the entire Member number, including the two digit person code, must be submitted for each Claim.

12. Compound Prescriptions
   a. **Compound Prescription Definition:** means a prescription for medication which would require the dispensing pharmacist to produce an extemporaneously produced mixture containing at least one Covered Drug that is a Federal Legend drug, the end product of which is not available in an equivalent commercial form and the Member had an inadequate response or inability to tolerate all commercially available therapeutic alternatives to treat the condition for which the Compound Prescription has been requested. A prescription will not be considered a Compound Prescription if the medication is reconstituted, if the only ingredient added to the prescription medication is water, alcohol or a sodium chloride solution or the compounded product includes any product which has been removed from the market for safety reasons. Compound Prescription means any Claim in which a Compound Drug is adjudicated.

   b. **Compound Prescription Claim Submission:** Compound Prescription Claims should be submitted by entering compounding indicator “2” and listing all the NDC’s ingredients in the compound, the quantity used for each NDC and the submitted ingredient cost for each NDC. Your Pharmacy will be reimbursed for Compound Prescriptions based on covered ingredients. Your Pharmacy will not be reimbursed for the non-covered ingredients (i.e. water, alcohol, or sodium chloride solution). Your Pharmacy will be reimbursed the lesser of the Pharmacy’s U&C or ingredient cost plus a dispensing fee, minus the Member Cost Share (copayment, coinsurance or deductible). Ingredient cost is based on Medi-Span’s Average Wholesale Prices (AWP) as reflected in the System at the time the prescription was filled, minus the discount reflected in the PPA.

      i. Compound logs must be in accordance to Chapter 795 of the United States Pharmacopeia (USP 795) for non-sterile products and Chapter 797 of the United States Pharmacopeia (USP 797) for sterile products as well as applicable state law or regulation. When sending documentation include the master formula. The billing log or detail will not be considered in lieu of compound log.

      ii. The amount billed for each component must correspond to the amount dispensed to the patient/ amount used in the compound. Quantities billed in excess to make up to the entire package size are considered excessive and will be subject to chargeback.

      iii. The NDC numbers billed must correspond to the NDC numbers dispensed. Pharmacies billing for an NDC not used in the actual compound are subject to chargebacks.

      iv. Manipulation of rejected Claims in order to obtain paid Claims by excluding covered NDCs from Claim submission, misrepresenting U&C and others are not acceptable practices and will result in audit recoveries. Pharmacy must not modify the quantity or chemical entity of each individual component in order to obtain Claim reimbursement. Pharmacy should not manipulate the compound indicator or pricing to bypass utilization management edits (i.e. Max Dollar or Max Quantity). Such findings are subject to audit chargeback and other corrective actions.
v. EnvisionRx does not permit substitution for compounds without a new prescription or a properly documented verbal authorization from prescriber. EnvisionRx does not consider compounded medication as a generic drug for the purposes of any applicable state generic substitution law or regulation.

vi. If requested by EnvisionRx, Pharmacy must provide clinical evidence for utilization of each chemical entity within the compound with literature on file supporting the therapeutic value. The chemical entities submitted in the Compound Drug Claim fields should be used for a medically accepted indication to treat a covered condition, illness and injury, applicable to the compound route of administration.

vii. Compound products should be billed and dispensed as a final compounded product. Therefore, billing each ingredient as single source drug for a drug meant to be used as a Compounded Drug constitutes inappropriate billing and is subject to chargebacks.

viii. Compound products should be billed and dispensed based on an individualized prescription and treatment plan for identified Members. Pharmacies may not produce, distribute, or accept pre-printed or pre-populated prescriptions for compound products.

**REIMBURSEMENT AND COST SHARE**

For each Covered Drug dispensed at a Pharmacy location, Network will pay Pharmacy the lesser of the negotiated rate plus dispensing fee as set forth in the PPA or U&C.

EnvisionRx will deduct the Member Cost Share (copayments, coinsurances, and deductibles) from the Pharmacy’s reimbursement. The Pharmacy must collect the full amount of the Member’s Cost Share as determined by the EnvisionRx Network System at point-of-sale. Copayments, coinsurances or deductibles are not eligible to be discounted or excused/waived at any time. The Pharmacy may not collect copayments, coinsurances and deductibles that exceed the Pharmacy’s U&C. Payments received from programs other than verifiable charitable foundations or manufacturer sponsored or recognized program are considered discounted/waived which is prohibited.

**EDITS**

**FRAUD WASTE AND ABUSE EDITS**

Plan Sponsors may choose to apply edits for Fraud, Waste and Abuse purposes. These edits typically fall under 2 categories:

1. Max Quantity Limits – maximum quantity of medication that can be dispensed over a specific period of time at the applicable copayment, coinsurance, or deductible.
2. Max Dollar Limits – maximum amount of money that a Plan Sponsor will pay for Claims within a specific time period.

Both edits listed above are designed to confirm the Pharmacy is dispensing the appropriate dose/quantity based on the prescriber’s directions. The examples below are potential rejection messages Pharmacies may receive:

- Reject 76: Plan limitations exceeded – MH
- Reject 76: Potential FWA please call 1-866-417-3069
Upon calling the number listed in the rejected Claim messaging, the Pharmacy is required to confirm the drug name, dosage form, strength and directions from the prescriber. An override may be placed in Network’s System for the Claim to be resubmitted.

**DRUG UTILIZATION REVIEW (DUR) EDITS**

Claims may reject based on Medi-Span DUR edits in the following categories: Therapeutic Duplication, Drug-Drug Interaction, Ingredient Duplication, Drug Age Precaution, and High Dose. The Plan Sponsor selects soft or hard rejections to be applied to these DUR edits.

Pharmacies can override soft rejections, by populating NCPDP standard service codes in the fields below

1. Professional Service Code NCPDP field = 44Ø-E5.

The DUR conflict code should be the deciding factor on which combination of service codes are submitted to override the rejection.

<table>
<thead>
<tr>
<th>DUR Conflict Code</th>
<th>Description</th>
<th>Prof Service Code</th>
<th>Reason for Service Code</th>
<th>Result of Service Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>TD</td>
<td>Therapeutic Duplication</td>
<td>MR</td>
<td>TD</td>
<td>1B</td>
</tr>
<tr>
<td>DD</td>
<td>Drug-Drug Interaction</td>
<td>MR</td>
<td>DD</td>
<td>1B</td>
</tr>
<tr>
<td>ID</td>
<td>Ingredient Duplication</td>
<td>MR</td>
<td>ID</td>
<td>1B</td>
</tr>
<tr>
<td>PA</td>
<td>Drug Age Precaution</td>
<td>MR</td>
<td>PA</td>
<td>1B</td>
</tr>
<tr>
<td>HD</td>
<td>High Dose</td>
<td>MR</td>
<td>HD</td>
<td>1B</td>
</tr>
</tbody>
</table>

**Drug-Drug Interaction: Reject 88:**
- Use DD, MO/MR, 1B/1G. For >1 alert use 00000000003

**Dose Check-High Dose Interaction: Reject 88:**
- Use HD, DE/MO/MR, 1B/1G. For >1 alert use 00000000003

**Drug-Age Interaction: Reject 88:**
- Use PA, MO/MR, 1B/1G. For >1 alert use 00000000003

**Drug-Sex Interaction: Reject 88:**
- Use SX, MO/MR, 1B/1G. For >1 alert use 00000000003

**Duplicate Drug: Reject 88:**
- Use ID, MO/MR, 1B/1G. For >1 alert use 00000000003

**Duplicate Therapy: Reject 88:**
- Use TD, MO/MR, 1B/1G. For >1 alert use 00000000003

All NCPDP override DUR coding should accurately reflect the reason for DUR override. If the Pharmacy utilizes an override code in order to obtain a paid Claim, the interaction (or rationale) for approval must be documented on the prescription or in the Pharmacy System with traceable time stamps. For example, for override code 1B (“clarified with prescriber”) a record should be made to support clarification and interaction. Lack of supporting documentation is subject to audit chargebacks.
POINT OF SALE (POS) OPIOID PATIENT SAFETY EDITS

POS opioid patient safety edits are enforced for Medicare Part D claims processed by EnvisionRx. The following edits have been established to assist Pharmacies in managing and resolving opioid safety rejections for Members using high opioid doses or opioid combinations, increasing risk of adverse events. Documentation is needed to support use and EnvisionRx encourages Pharmacies to verify coordination of care when more than one prescriber is involved. EnvisionRx further encourages the downward titration of opioids and efforts to lessen member dependence on opioids whenever possible.

Seven Day Supply Limit for Initial Opioid Fills (Opioid Naïve). POS edit limiting opioid analgesic prescriptions to a seven day supply for Members considered to be opioid naïve.

<table>
<thead>
<tr>
<th>Reject Code</th>
<th>925</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reject Message</td>
<td>Member is opioid naïve: Seven day supply allowed; call for override assistance or PA request. Enter codes ID applicable – reason code = MX, prof. code = M0/MR, result code = 4C(hospice)/4D(cancer)/4J(not opioid naïve)</td>
</tr>
<tr>
<td>Resolution</td>
<td>Decrease prescription quantity and day supply to seven days or less and resubmit the claim</td>
</tr>
</tbody>
</table>
| Resolution Alternatives | Service codes may only be used when the following apply:  
- Member is being actively managed by hospice  
- Member’s opioid is for “active” cancer pain  
- Member has an opioid Claim within the last 120 days |
| Reason for Service Code | MX: Excessive duration |
| Professional Service Code | M0: Prescriber consulted; MR: Medication review |
| Result of Service Code | 4C: Dispensed, hospice; 4D: Dispensed, cancer treatment; 4J: Dispensed, patient not opioid naïve |

Cumulative Daily 200 Morphine Milligram Equivalence (MME). POS edits requiring prescriber attestation to ensure Member safety when the cumulative daily MME reaches 200 mg or greater.

<table>
<thead>
<tr>
<th>Reject Code</th>
<th>88</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reject Message</td>
<td>200 milligram Morphine equivalent limit: PA required</td>
</tr>
<tr>
<td>Resolution</td>
<td>Member or Member’s representative must submit a coverage determination request to EnvisionRx for review.</td>
</tr>
</tbody>
</table>

Care Coordination Edit (90 MME). POS edit requiring prescriber attestation to ensure Member safety when the cumulative daily MME reaches 90 mg or greater.

<table>
<thead>
<tr>
<th>Reject Code</th>
<th>88</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reject Message</td>
<td>90 mg Morphine equivalence limit: consult prescriber and enter DUR codes if appropriate or PA required</td>
</tr>
<tr>
<td>Resolution</td>
<td>Service codes may be entered after the dispensing Pharmacy verifies through prescriber consultation that meeting or exceeding 90 MME for the given member is intended and safe.</td>
</tr>
<tr>
<td>Resolution Alternatives</td>
<td>If the dispensing Pharmacy is unable to verify opioid safety with the prescriber or deems the situation clinically inappropriate, the Member or Member’s representative may submit a coverage determination request to EnvisionRx for review.</td>
</tr>
<tr>
<td>Reason for Service Code</td>
<td>DR: Dose range conflict</td>
</tr>
<tr>
<td>Professional Service Code</td>
<td>M0: Prescriber consulted</td>
</tr>
<tr>
<td>Result of Service Code</td>
<td>1G: Filled with prescriber approval; 4C: Dispensed, hospice; 4D: Dispensed, cancer treatment</td>
</tr>
</tbody>
</table>
Duplicate Extended-Release/Long-Acting (ER/LA) Opioid Therapy. POS edit requiring a safety review by the dispensing Pharmacy when a Member is concurrently utilizing more than one extended release/long-acting (ER/LA) opioid analgesic.

<table>
<thead>
<tr>
<th>Reject Code</th>
<th>88</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reject Message</td>
<td>Multiple ER/LA opioid use: review opioid history and enter DUR codes if safe to use &gt;1 ER/LA opioid</td>
</tr>
<tr>
<td>Resolution</td>
<td>Dispensing Pharmacy should enter applicable service codes after verifying it is safe and appropriate to utilize more than one extended release opioid analgesic.</td>
</tr>
<tr>
<td>Reason for Service Code</td>
<td>SD: Suboptimal drug/indication</td>
</tr>
<tr>
<td>Professional Service Code</td>
<td>MØ: Prescriber consulted; MR: Medication review</td>
</tr>
<tr>
<td>Result of Service Code</td>
<td>1B: Filled prescription as-is; 1G: Filled with prescriber approval; 4C: Dispensed, hospice; 4D: Dispensed, cancer treatment</td>
</tr>
</tbody>
</table>

Concurrent Opioid and Benzodiazepine Use. POS edit requiring a safety review by the dispensing Pharmacy when a Member is utilizing an opioid analgesic in combination with a benzodiazepine.

<table>
<thead>
<tr>
<th>Reject Code</th>
<th>88</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reject Message</td>
<td>Additive toxicity alert: review history of benzodiazepine use; enter DUR codes is safe and appropriate</td>
</tr>
<tr>
<td>Reject Message</td>
<td>Additive toxicity alert: review history of opioid use; enter DUR codes is safe and appropriate</td>
</tr>
<tr>
<td>Resolution</td>
<td>Service codes may be entered only after verifying that it is safe and appropriate for the Member to use opioid analgesics along with benzodiazepines.</td>
</tr>
<tr>
<td>Reason for Service Code</td>
<td>AT: Additive toxicity</td>
</tr>
<tr>
<td>Professional Service Code</td>
<td>MØ: Prescriber consulted; MR: Medication review</td>
</tr>
<tr>
<td>Result of Service Code</td>
<td>1B: Filled prescription as-is; 1G: Filled with prescriber approval; 4C: Dispensed, hospice; 4D: Dispensed, cancer treatment</td>
</tr>
</tbody>
</table>

Concurrent Opioid and Buprenorphine Use. POS edit requiring a safety review by the dispensing Pharmacy when a Member is utilizing an opioid analgesic in combination with a buprenorphine product indicated only for the treatment of opioid dependence.

<table>
<thead>
<tr>
<th>Reject Code</th>
<th>88</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reject Message</td>
<td>Opioid dependence treatment alert: enter DUR codes if appropriate to use opioids with Buprenorphine</td>
</tr>
<tr>
<td>Resolution</td>
<td>Service codes may be entered only after verifying it is appropriate for the Member to utilize an opioid analgesic in the presence of opioid dependence treatment with Buprenorphine.</td>
</tr>
<tr>
<td>Reason for Service Code</td>
<td>DC: Drug-disease (inferred)</td>
</tr>
<tr>
<td>Professional Service Code</td>
<td>MØ: Prescriber consulted; MR: Medication review</td>
</tr>
<tr>
<td>Result of Service Code</td>
<td>1B: Filled prescription as-is; 1G: Filled with prescriber approval; 4C: Dispensed, hospice; 4D: Dispensed, cancer treatment</td>
</tr>
</tbody>
</table>
COORDINATION OF BENEFITS (COB)

Coordination of Benefits establishes the order in which Plan Sponsors pay Claims when more than one plan exists. When more than one Plan Sponsor is involved, the following will apply to Claim submission:

1. Accepted Values:
   - 00 – Not specified
   - 01 – No other coverage identified
   - 02 – Other coverage exists, payment collected
   - 03 – Other coverage exists, this Claim not covered
   - 04 – Other coverage exists, payment not collected
   - 08 – Claim is billing for copay

2. When the COB field (308-C8) is populated, the Pharmacy must submit the appropriate values in the fields below:
   - 431-DV: OPA*required for Government COB Processing only
   - 430-DU: Gross Amount Due (OPPRA)
   - 352-NQ: PRA (OPPRA)

AUDIT GUIDELINES

INTRODUCTION

In accordance with the PPA, EnvisionRx has the right to audit Pharmacies in the EnvisionRx Pharmacy Network. These guidelines will provide Pharmacies with an overview of network compliance and Pharmacy audit procedures.

Audit results are regularly reviewed by the EnvisionRx Pharmacy Audit and Fraud, Waste, and Abuse and Network Compliance Departments. Evidence of discrepancies may result in payment chargebacks, referrals to state/federal investigative agencies impact on participation in the Network, or other corrective action. The information provided within these guidelines may not be specific to your Pharmacy. Please refer to your PPA or PSAO/Chain PPA for specific information related to your Pharmacy. Federal, state, or local law, regulation or guidance varies and may supersede these audit guidelines. If a conflict occurs between an applicable law, regulation or guidance, to the extent permissible, the audit will follow the stricter provision.

TYPES OF AUDITS

EnvisionRx may conduct a desk audit, on-site audit, or investigational audit of a Pharmacy. Nothing prohibits EnvisionRx from conducting an audit that does not follow these audit guidelines as long as such audit is in compliance with applicable federal, state, or local law, regulation or guidance.

1. Desk Audits: Desk audits are generated according to proprietary algorithms flagging Pharmacy data, and performed on a random basis for verification of Pharmacy compliance. Audits are communicated in writing via email or fax requesting documentation to confirm billing practices and Member receipt. Medicare and/or Medicaid Plan Sponsor-requested desk audits follow stricter guidelines and require short turnaround times.
2. **Onsite Audits**: Onsite audits are audits conducted at a Pharmacy's physical location. EnvisionRx generally notifies Pharmacies in advance, via U.S.P.S., to schedule the on-site audit, however written notification is not mandatory for this type of audit to occur. Prescription hard copies and signature logs should be made readily available for the auditor. The Pharmacy is provided a parameter of fill dates and prescription numbers prior to the onsite audit. Pharmacy practices classified as unprofessional or unsafe during the onsite audit may result in actions taken against the Pharmacy up to and including termination of the Pharmacy contract, issuance of corrective actions and/or Network reporting to applicable regulatory agencies.

3. **Investigational Audits**: Investigational audits are more extensive and detailed in scope in comparison with desk or onsite audits. Additional documentation may be requested from the Pharmacy beyond the standard request for copies of prescriptions and delivery logs. The time frame for reviewing documentation may be extended depending on the nature of the investigation.

**REQUESTED DOCUMENTATION AND RECORDS**
The Pharmacy must provide EnvisionRx, Plan Sponsors, governmental agencies, and their authorized agents and representatives, with copies of any and all records necessary to determine compliance with applicable law, regulation or guidance and the PPA. Records subject to audit include, but are not limited to, the following:

1. Prescription hard copy (front and back)
   a. LTC: Physician's order sheet for date of service
   b. The Pharmacy must include the Vaccination Administration Record (VAR) if the requested copy is a vaccine prescription and the vaccine was both dispensed and administered at your location
2. Prescription label
3. Signature log (or valid proof of delivery)
4. Compound log
   a. Include the record for master preparation if the medication is compounded or compounded in bulk (i.e. for multiple patients from same formula)
5. Manufacturer, wholesaler, and distributor invoices and pedigrees
6. Any other documentation required by applicable federal, state or local law, regulation or guidance

**TYPICAL AUDIT PROTOCOL AND APPEALS PROCESS**
EnvisionRx provides the following claims audit protocol and appeals process:
- The Pharmacy is given thirty (30) calendar days to respond to the audit request.
- If any discrepancies are identified, the initial findings will be sent to the Pharmacy.
- The discrepancy letter provides an explanation of the identified discrepancy and acceptable appeal documentation. Pharmacies are given thirty (30) days to submit an appeal.
- Upon completion of the appeal review, a decision letter is sent to the Pharmacy with the final findings.

Time frame allowances described above will be shortened for investigative reviews, Plan Sponsor requests, CMS requests, or audits initiated as a result of Member complaint.

EnvisionRx has the right to off-set for any amounts due where permissible by applicable law or regulation.
**WHOLESALE, MANUFACTURER AND DISTRIBUTOR INVOICES: REQUIREMENTS AND AUDITS**

Pharmacies must provide wholesaler, manufacturers and distributor invoices as requested by EnvisionRx. It is the responsibility of the Pharmacy to ensure all wholesalers, manufacturers and distributors utilized to provide Covered Drugs to Members are lawfully licensed to do so. Covered Drug products in this context include OTC items and supplies.

In order to source medication inventory from another licensed Pharmacy, the following requisites must be met:

1. The supplying Pharmacy must be licensed as a wholesaler unless otherwise specified in applicable law.
2. The Pharmacy must maintain documentation about the sourced medication. This documentation must include, at minimum, the following items: medication name and strength; medication NDC; lot number; exact quantities purchased; date of purchase; proof of financial transactions between both Pharmacies.

In order to transfer medication inventory from another licensed Pharmacy, the following requisites must be met:

1. The Pharmacy must maintain documentation about the medication transfer. This documentation must include, at minimum, the following items: medication name and strength; medication NDC; lot number; exact quantities purchased; date of purchase; proof of financial transactions between both Pharmacies.
2. Unless otherwise specified in the PPA or applicable law, if the transfer is related to the sale, merger or inventory consolidation, then the Pharmacy must conduct a full inventory while documenting the items listed above.

Important points to remember:

- Pharmacy must be able to provide, upon request, the pedigree information for dispensed drug products.
- All wholesaler/distributor invoices or purchase summaries must be submitted directly from the wholesaler.
- Documentation received from the Pharmacy will not be accepted for audit consideration.
- Pharmacy must provide comprehensive drug utilization report upon request; this report includes all payers for the NDCs requested (PHI should be redacted). A denial of this request constitutes a denial of access to records.

**FREQUENTLY ASKED AUDIT QUESTIONS**

Please contact the Pharmacy Audits and Fraud, Waste, and Abuse Department regarding the information below.

1. **What happens if a partial or illegible communication is received by the Pharmacy?**
   a. Include the Pharmacy’s NABP or NPI and the Audit Ref# (if legible) in the subject line of e-mail or fax cover page
   b. Describe any decipherable information on the letter and the issue

2. **What type of documentation may be requested for a desk audit?**
   a. Copy of the audit request letter with QR code (two-dimensional bar code).
   b. Copy of the original prescription (front and back)
   i. LTC Pharmacy: Physician’s order sheet for date of service or interim order. Medication Administration Records (MAR) are not acceptable proof of the prescriber order.
   ii. Include the Vaccine Administration Record (VAR) if the prescription is for a vaccine
   c. Rx label: Copy of the label placed on the dispensed medication for the requested date of service
   d. Copy of the signature log sheet (pickup or delivery) for verification
   e. Compound log (if compounded medication)
3. **How does the Pharmacy submit requested documentation?**
   a. Use the bar coded audit request letter or most recent letter as the cover page of audit response
   b. Submit requested documentation
   c. If you don’t have secure e-mail, you can send a request to us advising of such and we can setup a secure link for document submission

4. **How do I address questions regarding an audit, including audit status?**
   a. Submit all questions and/or concerns in writing using bar coded audit letter

5. **What happens if my initial audit response is not received?**
   a. Locate fax confirmation or email communication
   b. Resubmit initial audit response along with fax confirmation or e-mail communications related to previous submission
   c. Upon evaluation of documentation, audit will be placed back for initial review.

6. **How do I update the Pharmacy contact for audit communications?**
   a. Audit communications can be sent via email or fax. They cannot be sent via multiple mechanisms. We can accommodate up to two email addresses.
   b. It is the Pharmacy’s responsibility to advise the Pharmacy Audits and Fraud, Waste, and Abuse and Network Compliance Departments of any change to the contact information on file.

7. **How do I appeal audit findings?**
   a. Each discrepancy and decision letter contains a discrepancy table
   b. The discrepancy table includes a description of the discrepancy noted and the acceptable documentation for appeal
   c. Once all required appeal documentation is gathered, submit once within the thirty (30) days’ time frame given (might vary for investigational audits). Use the discrepancy letter as the cover page to properly route to the audit.
   d. All appeals must be sent via encrypted email or fax

8. **Can I request an extension to respond to the audit or to appeal the initial audit findings?**
   a. Audit extensions are considered on a case by case basis. All requests for audit extensions are handled in writing only via email or fax

9. **Can I still appeal if the initial audit response was not submitted?**
   a. Yes, gather requested documentation and submit your appeal
   b. Use the discrepancy letter with the QR code (two-dimensional bar code) as your cover page

10. **Can my Pharmacy obtain a list with the prescriptions that will be reviewed during the onsite audit?**
    a. No, EnvisionRx does not provide a list with the exact prescription numbers prior to the audit. This is part of the procedure to maintain the integrity of the onsite visit. However, a parameter of fill dates and prescription numbers are provided in advance.
    b. Pharmacy will have opportunity to provide additional documentation during the appeal phase.

11. **What happens if the tracking number is too old to retrieve from the mail courier website?**
a. Contact your account representative at the mail courier to provide date and time of successful delivery. Excel files with pertinent tracking information are acceptable if coming directly from the carrier account representative.

b. Alternatively, a Member attestation acknowledging delivery is acceptable.

c. Providing only a tracking number does not confirm Member receipt.

**ACCEPTABLE AUDIT APPEALS**

All audit discrepancy and decision letters will provide the reason a Claim has failed audit. The following chart provides the audit discrepancy codes and descriptions, and acceptable or required documentation to appeal a Claim marked as discrepant on an audit:

<table>
<thead>
<tr>
<th>CODE</th>
<th>Description</th>
<th>Explanation</th>
<th>Required Documents for Appeals</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFX</td>
<td>Cut Fax Header</td>
<td>Fax header removed from Rx document that would authenticate the origin submitted on claim as &quot;Fax&quot;.</td>
<td>Prescriber statement*</td>
</tr>
<tr>
<td>CIN</td>
<td>Clinically Inappropriate</td>
<td>Billed claim goes against current accepted medical literature; without documentation of prescriber interaction and authorization.</td>
<td>Pharmacy and/or prescriber must provide current clinical literature validating the use of this drug and/or dose as prescribed.</td>
</tr>
<tr>
<td>COM</td>
<td>Missing or Incomplete Compound Log</td>
<td>Compound log not submitted or missing required elements.</td>
<td>Date and time stamped compound log with all required elements according to USP 795.</td>
</tr>
<tr>
<td>CPD</td>
<td>Compound Incorrectly billed</td>
<td>A compounded prescription is billed incorrectly resulting in overpayment, or claim is billed with an NDC number that was not used in the actual compound.</td>
<td>Compound logs with new elements other than what was initially submitted must contain verifiable date and time stamp or other traceable information to be considered.</td>
</tr>
<tr>
<td>DAW</td>
<td>Incorrect DAW Code</td>
<td>DAW billed must be documented on the prescription hard copy.</td>
<td>Date and time stamped note in patient profile that documents patient's preference (electronically captured documentation) or medical record that supports prescriber's preference.</td>
</tr>
<tr>
<td>DEA</td>
<td>DEA Number Not Documented on Prescription</td>
<td>The hard copy prescription does not contain a DEA number (CII-CV drugs only).</td>
<td>No post audit documentation accepted. Federal regulations require the prescriber's DEA number as part of the prescription hard copy PRIOR to dispensing.</td>
</tr>
<tr>
<td>DPU</td>
<td>Delayed Pick-up from billed Date of Service</td>
<td>Prescriptions billed and not picked up or delivered within 14 days from date of service should be reversed. No post audit documentation accepted.</td>
<td>No post audit documentation accepted.</td>
</tr>
<tr>
<td>EXC</td>
<td>Excessive Quantity Billed/Overfilled</td>
<td>The quantity billed exceeds amount authorized by the prescriber or the quantity billed would last greater than the days' supply limit of the plan.</td>
<td>Prescriber statement* acceptable in cases of quantity billed that exceeds amount authorized by prescriber.</td>
</tr>
<tr>
<td>EXP</td>
<td>Expired Prescription</td>
<td>Prescription is filled greater than timeframe allowed by state and/or federal regulation.</td>
<td>Copy of the state or federal regulation defining the valid length of time the prescription can be filled.</td>
</tr>
<tr>
<td>IDS</td>
<td>Incorrect Days' Supply</td>
<td>The days' supply billed is not consistent with the quantity and directions described by prescriber.</td>
<td>No post audit documentation accepted.</td>
</tr>
<tr>
<td>INV</td>
<td>Invalid Prescription</td>
<td>Prescription does not conform to all applicable regulatory requirements.</td>
<td>Prescriber statement*. No post audit documentation accepted for CII-CV.</td>
</tr>
<tr>
<td>IOC</td>
<td>Incorrect Origin Code</td>
<td>Origin code submitted differs from the hard copy prescription.</td>
<td>No post audit documentation accepted; informational citation.</td>
</tr>
<tr>
<td>IPO</td>
<td>Invalid Physician's Order</td>
<td>Physician’s order is not valid for the billed date of service.</td>
<td>Copy of physician's order or interim order that authorized the date of service billed.</td>
</tr>
<tr>
<td>ISH</td>
<td>Drug Invoice Shortage</td>
<td>Pharmacy billed for a higher quantity of drugs compared to amount purchased.</td>
<td>Invoice data submitted by the wholesaler(s) reported on the signed 'Pharmacy Attestation of Wholesalers'.</td>
</tr>
<tr>
<td>CODE</td>
<td>Description</td>
<td>Explanation</td>
<td>Required Documents for Appeals</td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
<td>-------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>ITX</td>
<td>Incomplete Transfer Information</td>
<td>Prescription does not have complete transfer information.</td>
<td>Prescriber statement*. No post audit documentation accepted for CII-CV.</td>
</tr>
<tr>
<td>LAB</td>
<td>Missing or Incomplete Rx label</td>
<td>Rx label not received or does not conform to regulatory requirements.</td>
<td>A computer generated label or sticker with all defined Rx elements for requested date of service.</td>
</tr>
<tr>
<td>MDP</td>
<td>Member Denies Prescription</td>
<td>Member denied receiving the prescription or knowing the pharmacy.</td>
<td>Member statement** and member’s explanation to justify initial claim(s) denied.</td>
</tr>
<tr>
<td>MDR</td>
<td>Member Denies Ordering/Requesting Prescription Received</td>
<td>Member denied ordering or requesting prescription billed to member’s benefit.</td>
<td>Member statement** with explanation of initial denial, AND, pharmacy’s call log recordings, or printout from the pharmacy system with date and time stamp or other traceable information.</td>
</tr>
<tr>
<td>MLL</td>
<td>Mis-labeled</td>
<td>Label discrepancy in which Rx directions are not accurately described on Rx label provided to patient.</td>
<td>If therapeutic impact, include incident report that documented the error in a timely manner and proof that the prescriber and patient were notified.</td>
</tr>
<tr>
<td>MSL</td>
<td>Missing Signature Log or Delivery Manifest</td>
<td>Signature log or proof of receipt by member not received.</td>
<td>Member statement** or facility statement*** confirming medication was received, OR signature captured electronically.</td>
</tr>
<tr>
<td>MSP</td>
<td>Missing Prescription</td>
<td>Copy of prescription cannot be found in documentation submitted.</td>
<td>Prescriber statement* or original prescription hard copy (front and back). Telephoned or called in prescription hard copies are not accepted during the appeal phase.</td>
</tr>
<tr>
<td>N</td>
<td>No Standing Discrepancy</td>
<td>No discrepancies encountered.</td>
<td>Not applicable</td>
</tr>
<tr>
<td>NPD</td>
<td>Not Part D</td>
<td>Claim not covered under Medicare Part D.</td>
<td>Will be specified depending on error.</td>
</tr>
<tr>
<td>NRS</td>
<td>No Response to Audit Request</td>
<td>Pharmacy failed to respond to audit request.</td>
<td>Original prescription hard copy (front and back) or prescriber statement*, Rx label, signature log and compound log (if applicable).</td>
</tr>
<tr>
<td>OTH</td>
<td>Other</td>
<td>Will be described depending on the error.</td>
<td>Will be specified depending on the error.</td>
</tr>
<tr>
<td>OTH2</td>
<td>Other</td>
<td>Will be described depending on the error.</td>
<td>Will be specified depending on the error.</td>
</tr>
<tr>
<td>PDP</td>
<td>Prescriber Denies Prescription</td>
<td>Prescriber denied authorizing prescriptions billed under his/her name.</td>
<td>Prescriber statement* with explanation to justify initial prescription denial and medical record to support prescriber statement.</td>
</tr>
<tr>
<td>PUMP</td>
<td>Drug infused using implantable pump for Part D plan</td>
<td>Drugs infused using implantable pump should be billed to Part B.</td>
<td>Pharmacy may provide records showing type of insulin pump used by member.</td>
</tr>
<tr>
<td>RMA</td>
<td>Risk Management Authorization</td>
<td>No risk management authorization number recorded on prescription to authorize dispensing.</td>
<td>Original documentation or an archived profile note in the pharmacy system with time and date stamp that documents the date and RMA number.</td>
</tr>
<tr>
<td>RTS</td>
<td>Refill Too Soon</td>
<td>Refill too soon based on submission of correct days’ supply.</td>
<td>No post audit documentation accepted.</td>
</tr>
<tr>
<td>SPL</td>
<td>Split quantity</td>
<td>Quantity billed is less than prescribed, resulting in frequent fills and dispensing fees and/or circumventing plan limitations.</td>
<td>No post audit documentation accepted.</td>
</tr>
<tr>
<td>SUP</td>
<td>Supervising MD Missing</td>
<td>Supervising MD name not on prescription hard copy written by mid-level practitioner.</td>
<td>Prescriber statement* from supervising MD. No post audit documentation accepted for CII-CV.</td>
</tr>
<tr>
<td>UAD</td>
<td>&quot;Use As directed&quot;! No Directions Documented</td>
<td>Prescription hard copy missing specific, calculable directions.</td>
<td>Prescriber statement* containing one of the following specified directions 1.) Surface area and frequency or 2.) Maximum daily dose.</td>
</tr>
<tr>
<td>URF</td>
<td>Unauthorized Refills Billed</td>
<td>Refills for adjudicated claim are not specified on the prescription hard copy.</td>
<td>Prescriber statement* that indicates refill was authorized PRIOR to dispensing date.</td>
</tr>
<tr>
<td>WDD</td>
<td>Wrong Drug Dispensed or Billed</td>
<td>Pharmacy billed a different medication than the one ordered by the prescriber, with no documentation on prescription hard copy or member profile.</td>
<td>Prescriber statement* to verify authorized change. Appeal documentation accepted for substitution due to therapeutic exchange only.</td>
</tr>
<tr>
<td>CODE</td>
<td>Description</td>
<td>Explanation</td>
<td>Required Documents for Appeals</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>------------------------------------------------</td>
</tr>
<tr>
<td>WMB</td>
<td>Wrong Member Billed</td>
<td>The member identified on the prescription hard copy is not the member identified on the paid claim.</td>
<td>No post audit documentation accepted.</td>
</tr>
<tr>
<td>WPS</td>
<td>Wrong Prescriber Submitted</td>
<td>Incorrect prescriber submitted for claim adjudication or inappropriate use of prescriber ID.</td>
<td>If the correct prescriber has been sanctioned or otherwise excluded by payor, claim will be reversed. No post audit documentation accepted.</td>
</tr>
<tr>
<td>WSL</td>
<td>Wrong Signature Log</td>
<td>Signature log copy submitted is for a different date of service or different medication.</td>
<td>Signature log/Electronically captured signature for requested Date of Service, Member statement** or facility statement*** confirming medication was received.</td>
</tr>
<tr>
<td>XDEA</td>
<td>XDEA Number Missing</td>
<td>No XDEA number on Suboxone or Subutex prescription hard copy that is required for opioid dependence treatment.</td>
<td>No post audit documentation accepted.</td>
</tr>
</tbody>
</table>

*Prescriber Statement must be legible, written on the prescriber's letterhead or on a pre-printed blank prescription showing a fax header from the prescriber's office or an office stamp. The statement MUST include the following: 1) prescriber's full address and telephone number, 2) patient's name and date of birth, 3) medication, 4) strength and dosage form, 5) directions for use, 6) quantity prescribed, 7) refills (if any), 8) written or authorized date, 9) DAW indicator and 10) prescriber's handwritten signature.

**Member statement must be legible and include the following: 1) patient’s full name and address, 2) telephone number or contact information, 3) prescription number(s), 4) medication(s) and strength(s), 5) date(s) of service and 6) patient’s signature.

***Facility statement must be legible and include the following: 1) patient's name, 2) date of service, 3) prescription number(s), 4) medication(s) and strength(s), 5) quantity of medication delivered, 6) date of delivery, and 7) signature of staff who accepted delivery.

**DEFINITIONS**

- **Abuse** – intentional over-utilization or improper use of a drug that can result in potential Member harm and unnecessary costs.
- **Appeal** – opportunity to dispute findings of an audit.
- **Audit** – process of reviewing billed Claims according to prescription records, inventory records and signature logs.
- **Claims adjudication** – billing entered by the Pharmacy according to the several elements on a prescription and the drug dispensed.
- **Discrepancy** – an identified inaccuracy in a billed Claim according to submitted documentation. May or may not have financial impact.
- **Fraud** – intentional misrepresentation of a Claim or service billed but not rendered.
- **Informational Citation** – an identified discrepancy that does not have financial impact.
- **PDE** – prescription drug event submitted to CMS for Medicare Part D.
- **Waste** – billing a quantity above the plan benefit structure allowance according to days’ supply.

**MEDICARE PART D**

The Medicare Part D program has some unique requirements. Below is a summary of each requirement.

**MEDICARE COVERAGE GAP DISCOUNT PROGRAM**

The Affordable Care Act includes provisions to close the Medicare Part D prescription drug coverage gap (also known as the “donut hole”) to make prescription drugs more affordable for people with Medicare. The first step in closing the
coverage gap was the mailing of the one-time $250 rebate check to most people who reached the coverage gap in 2010.

People with Medicare who have Part D coverage, but do not receive extra help (the low-income subsidy), will receive a 50% discount under the Medicare Coverage Gap Discount Program on “applicable” drugs at the point of sale and a 7% increase in coverage for all other covered Part D drugs (i.e. generic drugs and supplies associated with the delivery of insulin) while they are in the coverage gap. Prescription drug coverage has continuously increased for all Covered Drugs in the coverage gap so the amount people pay during the gap will continue to decrease until it reaches 25% in 2020.

WHAT ARE “APPLICABLE” DRUGS?
Applicable drugs are Part D prescription drugs approved under new drug applications (NDAs) or licensed under biologics license applications (BLAs). These are generally covered brand-name Part D drugs including insulin and Part D vaccines. Applicable drugs also include Part D prescription drugs that are commonly considered generic drugs, but actually have been FDA approved under NDAs. These drugs must be covered by a signed discount agreement to be covered under Part D. Only those applicable drugs that are covered under a signed manufacturer discount agreement with the Centers for Medicare & Medicaid Services (CMS) are covered under Part D.

All other covered Part D drugs (i.e. generic drugs approved under abbreviated new drug applications (ANDAs) and supplies associated with the delivery of insulin) may continue to be covered by Part D plans irrespective of a signed manufacturer agreement. In addition, to be considered an applicable drug, drugs approved under ANDAs, BLAs and NDAs must all be properly listed with the FDA to process under Medicare Part D guidelines.

HOW WILL THE MEDICARE COVERAGE GAP DISCOUNT PROGRAM WORK?
Drug manufacturers must sign agreements with CMS to participate in the Medicare Coverage Gap Discount Program. The agreement specifies that all of the manufacturers’ applicable BLA and NDA drugs will automatically be discounted by 50% at the point of sale for non-LIS Member’ coverage gap Claims. The discount does not include the cost of the dispensing fee. The full cost of the drug will count as out-of-pocket spending for the purposes of reaching catastrophic coverage.

Example: A Member reaches their coverage gap. They go to their Pharmacy to fill a prescription for an applicable drug. The price for the drug is $60 and the dispensing fee is $2. Once the 50% discount is applied, the cost of the drug is $30. The $2 dispensing fee is added to the $30 discounted amount. The Member will pay $32 for their prescription, but the entire $62 (both the amount the Member and the manufacturer pay) is counted as out-of-pocket spending and will help the Member reach the end of the coverage gap.

If a drug manufacturer does not sign a discount agreement with CMS, their applicable drugs will not be covered under Part D, and Part D Plan Sponsors will not be allowed to grant an exception or provide a transition fill for such drugs. Members may still buy the drug at its full price, but the cost will not count towards the progression through the coverage gap. Medicare Part D Plan Sponsors will review coverage gap Claims to determine the Member’s eligibility and if the drugs are eligible for the discount.

HOW WILL MY PHARMACY KNOW WHICH MANUFACTURERS HAVE SIGNED A COVERAGE GAP DISCOUNT PROGRAM AGREEMENT WITH CMS?
CMS publishes a listing of companies that have signed an agreement along with the associated five-digit labeler codes on its Web site. The listing of labeler codes and manufacturers can be found on the CMS website at:
www.cms.gov/PrescriptionDrugCovGenIn. Select “Part D Information for Pharmaceutical Manufacturers” on the left hand side of the page.

MEDICARE AUDIT AND RECORD RETENTION REQUIREMENTS
Pharmacies and their downstream contracted entities must comply with Medicare laws, and, regulations and CMS instructions and guidelines. CMS requires that records be maintained for a period of ten (10) years from the final date of the contract between CMS and the Plan Sponsor or the date of audit completion, whichever is later. The Pharmacy agrees to make its books and other records available in accordance with section 42 CFR 423.505(e)(2) and 42 CFR 423.505(i)(2), which generally states that CMS may inspect, evaluate and audit any books, contracts, records, including medical records and documentation related to CMS’ contract with the Plan Sponsors. Pharmacies are responsible for notifying EnvisionRx of Pharmacy closures, acquisitions and mergers. Once EnvisionRx has been notified of a pharmacy closure, acquisition or merger, an attestation will be sent to the Pharmacy to attest to the status of the prescription records.

REJECTIONS
Pharmacies will receive rejections for Claims on drugs with the following rejection message if they are not properly listed with the FDA (ANDA, BLA, NDA drugs) or they are properly listed with the FDA but they are not contracted with CMS for participation in the Coverage Gap Discount Program (BLA/NDA drugs):

1. **Reject 70-PM Excludes**: NDC not FDA listed (ANDA drugs) or not CMS contracted (BLA/NDA drugs). Based on guidance from CMS, EnvisionRx utilizes the FDA’s Comprehensive NDC Structured Product Labeling Data Element File (NSDE) to determine if a drug is considered a valid Part D drug eligible for coverage under the Medicare Part D Program. Below are the steps in determining if a drug is eligible for coverage under Medicare Part D:

   - Determine if the drug product is approved by the FDA. In order to verify the approval status of drug products, verification at the NDC level of all NDCs must be confirmed. This is done through matching the specific NDC against the FDA’s NSDE file.

   - If a drug product is not correctly listed in the FDA’s NSDE file, EnvisionRx is not able to determine that the drug product is approved by the FDA and the reject messaging listed above will be received by the Pharmacy. For everything properly listed, step 2 is followed.

2. **Determine if the Drug Product is Licensed Under an ANDA, NDA or BLA**

   - CMS provides guidance regarding administration of the coverage gap discount program. Specifically, drugs that have been approved by the FDA under a New Drug Application (NDA) or Biological License Application (BLA) are considered applicable drugs for the coverage gap discount program. All other Part D drugs (drugs approved under an ANDA, compounds, syringes, and other medical supplies associated with the delivery of insulin) are eligible for coverage under Medicare Part D.

   - If the drug product is licensed under an ANDA (these are typically generic products) or is one of the other non-applicable drug products (i.e. insulin syringes), the product is eligible for coverage under Medicare Part D. If the drug product is licensed under an NDA or BLA, step 3 is followed.
3. **Determine if the Drug Product is Made by a Manufacturer who has a Signed Agreement with CMS to Provide the 50% Coverage Gap Discount**

- All manufacturers of applicable drugs must have signed agreements with CMS in order to be considered covered Part D drugs. If the manufacturers did not sign agreements with CMS to provide the coverage gap discount, those drugs are NOT eligible for coverage under any phase of the Medicare Part D benefit. CMS maintains a list of manufacturers that have signed agreements and their applicable labeler codes. This list is then used to verify that drugs properly listed in the FDA NDC Directory with an application type of NDA or BLA is a drug product that is made by a participating manufacturer and therefore considered a valid Part D Drug if the drug is on the Part D Plan’s Formulary.

*If the drug product is licensed under an NDA or BLA but the manufacturer is not considered a participating manufacturer, then the drug product is not eligible for coverage under Medicare Part D and the reject message stated above will be received by the Pharmacy.*

4. **Reject 70-PM Excludes; NDC not FDA Listed (ANDA drugs) or Not CMS Contracted (BLA/NDA drugs)**

It is our recommendation to try to fill the prescription with another NDC for the product. Oftentimes, an alternative manufacturer is listed appropriately in the FDA’s NSDE file. If a prescription is filled with an NDC properly listed in the FDA’s NSDE file the Claim will pay. Please contact the number provided in the rejected Claim messaging, if assistance is needed in identifying an NDC that is properly listed with the FDA.

Pharmacies should contact the physician for a generic or a branded alternative produced by a participating manufacturer if they receive this rejection when filling for brand medications.¹

**PART D UNIQUE BIN REQUIREMENTS**

CMS requires that Claims for the Medicare Part D program be submitted through a unique BIN/PCN combination. This is to ensure that (1) Pharmacies can routinely identify situations in which they are billing a Part D Claim and (2) that payers secondary to Part D can properly coordinate benefits on Part D Claims. EnvisionRx has a dedicated BIN/PCN for Medicare Part D Claims 012312/PARTD. In the event a Claim is submitted for medications that are eligible for Medicare Part B coverage for MA-PD Plan Sponsors, Pharmacies will receive the following reject message:

 Reject 01: FORCEREJCODE: 01 Invalid BIN. Medicare Part B Drugs must be submitted to BIN/PCN: 009893 / ROIRX

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¹ **Resources/Further Information:**
- FDA NDC Directory FAQs [http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm](http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm)
Claims should then be re-submitted using the same Member identification number to the 009893 BIN.2

**TRANSITION REQUIREMENTS**

Medicare Part D requires that a transition process be maintained with respect to: (1) the transition of new Members into prescription drug plans following the annual coordinated election period; (2) the transition of newly eligible Medicare Members from other coverage into a Part D plan; (3) the transition of Members who switch from one Part D plan to another after the start of the contract year; (4) new Members residing in long term care (LTC) facilities; (5) current Members affected by negative formulary changes from one contract year to the next; (6) Members who request an exception but there is a failure to issue a timely decision on the request by the end of the transition period; (7) Members who remain in the same plan for the new plan year and are on a drug that was the result of an exception that was granted in the previous plan year; (8) current Members experiencing a level of care change; (9) current Members entering the LTC setting from other care settings; and (10) current Members in a LTC setting requiring an emergency supply of a non-formulary drug.

The transition process requirements are applicable to both non-formulary formulary drugs with utilization management edits, meaning both: (1) Part D Covered Drugs that are not on the applicable Plan Sponsor formulary, and (2) Part D Covered Drugs that are on the applicable Plan Sponsor formulary but require prior authorization or step therapy under Plan Sponsor's utilization management rules.

The EnvisionRx online System will automatically provide up to a temporary thirty (30) day fill in the retail setting (unless the Member presents a prescription written for less than thirty (30) days, in which case EnvisionRx will allow multiple fills to provide up to a total of thirty (30) days of medication) anytime within the first ninety (90) days of the Member’s enrollment in a plan, beginning on the Member’s effective date of coverage with the Plan Sponsor.

To the extent that a Member is outside their ninety (90) day transition period, EnvisionRx will still provide an emergency supply of Part D covered non-formulary medications (including Part D Covered Drugs that are on a Plan Sponsor's formulary that would otherwise require prior authorization or step therapy under Plan Sponsor’s utilization management rules). This will occur on a case by case basis, when it has been identified that the Member’s exception request or appeal has not been completed by the end of the transition period.

In the long term care (LTC) setting, the EnvisionRx online System will automatically provide up to a ninety-eight (98) day supply of medications eligible for transition fills (unless the Member presents with a prescription written for less than thirty-one (31) days), with multiple refills as necessary, during the first ninety (90) days of a beneficiary’s enrollment in a plan, beginning on the Member’s effective date of coverage. Pharmacies are required to place a service location code of 0 or 1 on the Claim and a patient residence code of 03 for NCPDP D.0 submissions in order for the automatic LTC transition process to work correctly. Members in assisted living facilities are able to obtain up to a thirty-one (31) day transition fill (instead of thirty (30)) when Pharmacy Network providers submit a patient residence code of 04 on a NCPDP D.0 Claim.

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In the LTC setting, after the ninety (90) day transition period has expired, EnvisionRx will still provide a thirty-one (31) day emergency supply of Part D covered non-formulary medications, as well as Part D Covered Drugs that are on a Plan Sponsor’s formulary that would otherwise require prior authorization or step therapy under a Plan Sponsor’s utilization management rules (unless the Member presents with a prescription written for less than thirty-one (31) days), while an exception or prior authorization is requested or when it has been identified that the Member’s exception request or appeal has not been completed by the end of the transition period.

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

In the event a prescription is for a pack size that due to dosing requirements exceeds the thirty (30) day transition fill rule (i.e. eye drops or insulin) and the pack size cannot be broken to provide only the thirty (30) day supply, Pharmacies may obtain a manual transition override.³

**MEDICARE PRESCRIPTION DRUG COVERAGE AND YOUR RIGHTS – REVISED GUIDANCE FOR DISTRIBUTION OF STANDARDIZED PHARMACY NOTICE (CMS-10147)**

As required by CMS guidelines, Medicare Part D Network Pharmacies (including Mail-Order and Specialty Pharmacies) are required to distribute a written copy of the standardized Pharmacy Notice when the Member’s prescription cannot be covered (“filled”) under the Medicare Part D benefit and the issue cannot be resolved at point of sale. The Pharmacy Notice instructs Members about their right to contact their Part D Plan Sponsor to request a coverage determination, including an exception. This is a standardized Pharmacy Notice, the content of which may not be altered. The Office of Management and Budget (OMB) control number must be displayed in the upper right corner of the notice. The fields for the Member’s name, drug and prescription number are optional and may be populated by the Pharmacy. A logo is not required but Pharmacies may place their logo in the space above the optional fields for the Member’s name, drug and prescription number.

Printing the Pharmacy Notice on prescription label stock or an integrated prescription receipt is permitted, so long as the Pharmacy Notice is provided to the Member in at least 12-point font. Electronic distribution of the Pharmacy Notice is permitted if the Member or the Member’s appointed representative has provided an e-mail address or fax number and has indicated a preference for that method of communication.

**MAIL ORDER PHARMACIES**

If a prescription is not covered (“filled”) under the Medicare Part D program as described above, the Mail Order Pharmacy must distribute the standardized Pharmacy Notice to the Member. The Mail Order Pharmacy has the option of working with the Plan Sponsor and prescriber to resolve the matter and provide the needed medication or an appropriate substitute. If the matter cannot be resolved and the Pharmacy cannot fill the prescription, the Pharmacy Notice must be provided to the Member via the Member’s preferred method of communication (fax, email, or first class

Reminder of the Part D Transition Policy
(mail) as expeditiously as the Member’s health condition requires, but no later than seventy two (72) hours from the Pharmacy’s receipt of the original transaction response indicating the Claim is not covered by Medicare Part D.

**HOME INFUSION PHARMACIES**

If a prescription cannot be covered (“filled”) under the Medicare Part D program as described above, the home infusion Pharmacy must distribute the standardized Pharmacy Notice to the Member either electronically, by fax, in-person, or by first class mail. The home infusion Pharmacy has the option of working with the plan and the prescriber to resolve the matter and provide the needed medication or an appropriate substitute. If the Pharmacy cannot fill the prescription, the Pharmacy Notice must be provided to the Member expeditiously as the Member’s health condition requires. However, no later than seventy two (72) hours from the Pharmacy’s receipt of the original transaction response indicating the Claim is not covered by Medicare Part D. For Member brought on service by the home infusion Pharmacy, the Pharmacy can also choose to deliver the Pharmacy Notice in person with delivery of home infusion drugs or through an infusion nurse if the next scheduled visit is within seventy two (72) hours of the receipt of the transaction code indicating the Claim cannot be covered by Medicare Part D.

**HOME INFUSION PHARMACY NPPES REGISTRATION**

Pharmacies must maintain the CMS required specialty registration and identification as a home infusion provider through National Plan & Provider Enumeration System (NPPES). Failure to maintain such self-reported registration and identification may result in reimbursement withholds or reductions and/or recovery of paid Claims amounts by Network on behalf of its Plan Sponsors, unless or until all Pharmacy primary and additional specialty(ies) registration requirements have been met.

**NOTE:** Network reserves the right to audit Claims and related documentation of Pharmacy on behalf of its Plan Sponsors to ensure compliance with the PPA as a home infusion Pharmacy.

**PHARMACIES SERVICING LONG TERM CARE FACILITIES**

Given the uniqueness of the long term care (LTC) setting, there is typically no point of sale encounter between the Pharmacy and the Member (LTC resident) and, therefore, no practical means for the Pharmacy to provide the Pharmacy Notice directly to the Member. If there is an issue with a prescription, CMS expects the pharmacist to contact the prescriber or appropriate staff personnel at the LTC facility to resolve the matter. This ensures the Member receives the necessary medication or an appropriate substitute, obviating the need to deliver the Pharmacy Notice. If the Pharmacy must fax or otherwise deliver the Pharmacy Notice to the Member, the Member’s representative, prescriber or an appropriate staff person at the LTC facility must receive the Pharmacy Notice expeditiously as the Member’s health condition requires. However, no later than seventy two (72) hours from the Pharmacy’s receipt of the original transaction response indicating the Claim is not covered by Part D.

**NOTE:** If the Member is a self-pay resident, and the Pharmacy cannot fill the prescription under the Part D benefit, the Pharmacy must, upon receipt of the transaction response, fax, or otherwise deliver the Pharmacy Notice to the Member, the Member’s representative, prescriber or an appropriate staff person at the LTC facility. After distribution of the Pharmacy Notice, the LTC Pharmacy should continue to work with prescriber or facility to resolve the matter and ensure the resident receives the needed medication or an appropriate substitute.  

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4 Resources/Additional Information: NCPDP website  
http://www.NCPDP.org/  
Medicare Prescription Drug Coverage and Your Rights
EnvisionRx will provide Pharmacies a primary reject code for the following reasons:

1. Reject 70: Non Formulary Medications
2. Reject 75: Prior Authorization or Step Therapy Required
3. Reject 9G: Quantity Dispensed Exceeds Maximum Allowed

In addition, EnvisionRx will transmit a secondary Reject Code 569. Per NCPDP, this rejection code is defined as: “Provide Beneficiary with CMS Notice of Appeal Rights”. This secondary reject code will notify Pharmacies that a Pharmacy Notice is required to be distributed to the Member.

The Notice of Appeal Reject Code will not be returned in circumstances where transition coverage would not apply, such as:

1. The Claim does not contain all necessary data elements for adjudication
2. The drug in question is an over-the-counter (OTC) medication that is not covered by Plan Sponsor
3. The prescription is written by a sanctioned provider who has been excluded from participation in the Medicare Program
4. The drug is not listed on the participating CMS Manufacturer Labeler Code List
5. The drug is not listed on the Food and Drug Administration (FDA) Electronic List-NDC Structured Product Labeling Data Elements File (NSDE)
6. The Claim rejects for a refill too soon/early refill edit
7. The drug in question is not covered by the Part D plan benefit, but is covered by a co-administered insured benefit managed by a single processor. In this scenario, the Pharmacy submits a single Claim transaction for the drug and drug is covered by the co-administered insured benefit after being rejected by Part D and processed in accordance with the benefits offered by the supplemental payer.
8. The drug is excluded from coverage under Medicare Part D (i.e. drugs used for cosmetic purposes, drugs used for weight loss or gain, drugs used to promote fertility, drugs used for the symptomatic relief of cough & cold symptoms, prescription vitamins or mineral products except for prenatal vitamins or fluoride preparations, or drugs used to treat erectile dysfunction)
9. The drug requires a Medicare Part B vs. Medicare Part D determination

Additional copies of the Medicare Prescription Drug Coverage and Your Rights Standardized Pharmacy Notice are available from the Network Compliance Department as well as the CMS website.5

**HOSPICE MEDICATIONS**

CMS requires that Part D Plan Sponsors ensure that Part D does not pay for drugs and biologics that may be covered under the Medicare Part A per-diem payment to a hospice program. As specified in Section 1861(dd) of the Social

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5 **Resources/Additional Information:**

Medicare Prescription Drug Coverage and Your Rights

Security Act and in federal regulations at 42 CFR 418, the hospice provider is responsible for covering all drugs or biologics for the palliation and management of the terminal and related conditions.

Please note CMS’ position is stated in the 1983 Hospice Final Rule, which implemented the hospice benefit.

CMS interpreted related conditions broadly, and wrote that hospices are required to cover virtually all the palliative care needed by terminally ill patients (48 FR 56010). Drugs for the palliation and management of the terminal illness and related conditions are the responsibility of the hospice, and as CMS has noted in rulemaking, at the end of life, most conditions are related.

When a Plan Sponsor receives a transaction reply report (TRR) showing a Member has elected hospice, they must have controls in place in order to comply with this requirement. Plan Sponsors are encouraged to place beneficiary-level PA requirements on four categories of prescription drugs, including:

1. Analgesics
2. Antinauseants (Antiemetics)
3. Laxatives
4. Antianxiety Drugs

EnvisionRx requires Member level prior authorization for the above four categories of medications for all Members who have elected hospice coverage as identified via Medicare eligibility data.

Pharmacies will receive rejections on drugs previously covered under the Part D benefit. Reject messaging will state: “Member in hospice, bill hospice provider. PA req for Part D drug unrelated to the terminal illness & related conditions. To req PA or if hospice has ended” Pharmacies should call the phone number listed in the reject messaging in order to obtain PA or if hospice has ended.

Once the edits are in place for current Member, EnvisionRx will notify all Pharmacies with prior Claims for the Member to request the Claims be reversed and billed to the hospice provider. EnvisionRx will send the hospice provider contact information to the Pharmacy if available.  

**PreSCRIBER VErIFICATION**

CMS guidance specifies the NPI is intended to uniquely identify a health care provider in standard transactions, such as health care Claims. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires that covered entities use NPIs in standard transactions by the specified compliance dates. The NPI is the only health care provider identifier that covered entities may use to identify health care providers.

Type I (Individual) NPIs must be submitted on Claims. As per this requirement, any Type 2 (Organizational) NPI submitted by the Pharmacy will be rejected at point of sale with a force Reject Code 619. EnvisionRx will only accept Claims for a valid Type I Prescriber NPI.

EnvisionRx subscribes to a service that maintains Prescriber NPI, DEA numbers, and the scope of practice with respect to authority to prescribe controlled substances. This database is updated bi-weekly. Electronic Claims will reject if the prescriber is not found within the database or their DEA or NPI is expired or invalid.

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CMS allows rejections on these Claims as long as they can be resolved at point of sale. Pharmacies receiving a Reject 619 (Rejection 619: Prescriber Type 1 NPI Required; Effective 5.6.2013 a valid Individual Prescriber NPI is required on all Claims. Organizational NPIs no longer permitted), should follow the steps below and attempt to obtain a paid Claim:

Verify that the correct prescriber NPI/DEA number has been entered on the Claim.
- Correct the number and resubmit the Claim. If previously submitted with an incorrect NPI/DEA number.
- If the Claim is still rejecting, verify the NPI/DEA submitted does not belong to an organization. Correct the number and resubmit the Claim if this occurs.

If Pharmacy submitted the correct prescriber NPI/DEA number on the Claim and the NPI is not a Type II
- Verify the physician name is spelled correctly.
- Verify the physician address and phone number are entered correctly.

**LONG TERM CARE PHARMACY (LTC)**
Pharmacies have up to ninety (90) days from the date of dispensing to submit a Claim for reimbursement if they are located in, or have a contract with, an LTC facility.

**SHORT CYCLE DISPENSING**
Pursuant to CMS 42 CFR 423.154, to the extent that long term care (LTC) Pharmacies dispense Oral Solid Brands to Members residing in long term care facilities, LTC Pharmacy shall dispense only Short Cycle Drug Doses of an Oral Solid Brand, regardless if the Oral Solid Brand is written for an amount exceeding a fourteen (14) day supply by a prescriber.

“Oral Solid Brand” or “Oral Solid Brand Name Maintenance Covered Product” means a brand name prescription drug that is a prescription product as defined in CMS 42 CFR 423.4. Excluded from the definition of Oral Solid Brand name prescription drugs as defined at CMS 42 CFR 423.154(b) include prescription drugs such as, but not limited to, solid oral doses of antibiotics and solid oral doses of prescription drugs that are dispensed in their original container as indicated in the Food and Drug Administration Prescribing Information or are customarily dispensed in their original packaging (i.e., oral contraceptives).

Pharmacies may receive rejections on drugs you believe are generic. The excerpt below is from the Medicare Prescription Drug Benefit Manual explaining when Medicare considers a drug a generic medication under the Medicare Part D program.

“… (f)or a purpose of Part D, what determines whether a drug is a generic drug is the type of application on file for that product with the Food and Drug Administration (FDA). If a drug product approval is based upon an abbreviated new drug application (ANDA), that drug is therefore a generic drug.” (42 CFR 423.4)

Pharmacies receiving Claim rejections can verify the drug application type on file with the FDA by referencing the following links: [http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm](http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm) or [http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm](http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm)
As set forth in the CMS requirement, announced changes to the Drug Data Processing System (DDPS) for the purpose of using prescription drug event (PDE) data as a vehicle for meeting the regulatory reporting requirements described at 42 CFR 423.154(a)(2). Health care providers (i.e. hospitals) must require certain non-covered individual health care providers who are prescribers to obtain and disclose a NPI. Sponsors must report only a Type 1 (individual) NPI on the PDE record.

CMS requires the PDE detail record layout to include Pharmacy Service Type (147-U7), Patient Residence (384-4X), and Submission Clarification Code (420-DK). The field’s Definitions and Values included in the PDE detail record layout are listed below. For Claims where the Patient Residence is 03 (Nursing Facility), the Submission Clarification Code (SCC), if applicable, must also be valid.

<table>
<thead>
<tr>
<th>FIELD NAME</th>
<th>DEFINITION / VALUES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Service Type</td>
<td>The type of service being performed by a Pharmacy when different contractual terms exist between a payer and the Pharmacy, or when benefits are based upon the type of service performed. 01 – Community/Retail Pharmacy Services 02 – Compounding Pharmacy Services 03 – Home Infusion Therapy Provider Services 04 – Institutional Pharmacy Services 05 – Long Term Care Pharmacy Services 06 – Mail Order Pharmacy Services 07 – Managed Care Organization Pharmacy Services 08 – Specialty Care Pharmacy Services 99 – Other</td>
</tr>
<tr>
<td>Patient Residence</td>
<td>Code identifying the patient’s place of residence. 00 – Not specified, other patient residence not identified below 01 – Home Community/Retail Pharmacy Services 03 – Nursing Facility 04 – Assisted Living Facility 06 – Group Home 09 – Intermediate Care Facility/Mentally 11 - Hospice</td>
</tr>
<tr>
<td>Submission Clarification Code</td>
<td>Code indicating they the pharmacist is clarifying the submission. 16 – Long Term Care (LTC) emergency box or automated dispensing machine 21 – LTC dispensing, 14 days or less not applicable 22 – LTC dispensing, 7 day supply 23 – LTC dispensing, 4 days 24 – LTC dispensing, 3 day 25 – LTC dispensing, 2 day 26 – LTC dispensing, 1 days 27 – LTC dispensing, 4 day, then 3 day supply 28 – LTC dispensing, 2 day, then 3 day supply 29 – LTC dispensing, daily during the week then multiple days for weekend 30 – LTC dispensing, per shift 31 – LTC dispensing, per med pass 32 – LTC dispensing, PRN on demand 33 – LTC dispensing, other 7 day or less cycle</td>
</tr>
</tbody>
</table>
THING FOR CODING PATIENT RESIDENCE AND PHARMACY SERVICE TYPE ON CLAIM TRANSACTIONS

CMS requires a valid Patient Residence and Pharmacy Service Type on all Medicare Part D Claims. All Retail and Mail Order Pharmacies must include a valid Patient Residence code on all Part D Claims transactions. If the patient residence is unknown, the Pharmacy may default to a Patient Residence of 01 (Home). Long term care, home infusion, and specialty Pharmacies should be able to reliably report on all Claims since they deliver to the Member residence. In the event a transaction has a missing or invalid code, the Claim may be rejected at point-of-sale.

<table>
<thead>
<tr>
<th>Valid Patient Residence Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>00 – Not specified other patient residence not identified below</td>
</tr>
<tr>
<td>01 – Home</td>
</tr>
<tr>
<td>03 – Nursing Facility</td>
</tr>
<tr>
<td>04 – Assisted Living Facility</td>
</tr>
<tr>
<td>06 – Group Home</td>
</tr>
<tr>
<td>09 – Intermediate Care Facility/Mentally Retarded</td>
</tr>
<tr>
<td>11 – Hospice</td>
</tr>
</tbody>
</table>

All Pharmacies are expected to understand and correctly apply the appropriate (i.e. non-default) Pharmacy service code to include on all Part D Claims.

<table>
<thead>
<tr>
<th>Valid Patient Residence Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 – Community/Retail Pharmacy Services</td>
</tr>
<tr>
<td>02 – Compounding Pharmacy Services</td>
</tr>
<tr>
<td>03 – Home Infusion Therapy Provider Services</td>
</tr>
<tr>
<td>04 – Institutional Pharmacy Services</td>
</tr>
<tr>
<td>05 – Long Term Care Pharmacy Services</td>
</tr>
<tr>
<td>06 – Mail Order Pharmacy Services</td>
</tr>
<tr>
<td>07 – Managed Care Organization Pharmacy Services</td>
</tr>
<tr>
<td>08 – Specialty Care Pharmacy Services</td>
</tr>
<tr>
<td>99 - Other</td>
</tr>
</tbody>
</table>

*Network reserves the right to audit Claims on behalf of its Plan Sponsors. Failure by Pharmacy to submit Claims with proper submission codes may result in reimbursement withholds or reductions and/or recovery of paid Claims amounts, unless or until all correct submission code requirements have been met.

DAILY COST SHARING REQUIREMENTS

Certain prescriptions that are dispensed by a Pharmacy for less than a thirty (30) days' supply may have an applicable daily Cost Sharing rate attached in accordance with 42 C.F.R. § 423.153(b)(4)(i). This requirement provides Part D Members, in consultation with their prescribers, the option of shorter days' supplies of initial fills of new prescriptions without the disincentive of the Member paying a full month's co-payment or coinsurance. Prescribers are expected to
be particularly supportive of this prescribing option when the prescription is for a drug that has significant side effects, is frequently poorly tolerated, and when less than a month’s supply of the prescription is clinically appropriate. In addition, it would allow the Member the ability to synchronize their prescriptions in consultation with their pharmacists without having to pay a full month’s Cost Share when less than a month’s supply of medication(s) is dispensed during the synchronization process until all medications are on the same thirty (30) or more days refill schedule. CMS intends to include language in future Medicare & You and Part D Evidence of Coverage (EOC) documents on the availability of daily Cost Sharing rates, and on how beneficiaries should consider taking advantage of them. Please note the daily Cost Sharing requirements do not address how Pharmacy dispensing fees are negotiated, calculated or paid. There is no necessary connection between daily Cost Sharing amounts charged to beneficiaries and how dispensing fees are paid to Pharmacies.  

**ADDITIONAL MEDICARE PART D REQUIREMENTS**

1. **True Out Of Pocket ("TrOOP"):** Pharmacies must process TrOOP expenses as required by CMS. Pricing information is communicated back to the Pharmacy via the online System.

2. **Cost Sharing:** Pharmacies must charge and apply the correct Member Cost Share amount, including that which applies to the Member qualifying for the low-income subsidy. Cost Share amounts are communicated back to the Pharmacy via the online System. Pharmacy must also, if expressly requested by the Part D Member, agree to not submit the Claim to the payer.

3. **Pricing Differential:** A Pharmacy must inform a Medicare Part D Member at the point of sale (or at the point of delivery) of the lowest priced, generically equivalent drug (if applicable for the Member’s prescription), and an associated differential in price. (Member’s copayments are typically based on whether a generic, preferred brand or non-preferred brand is dispensed.) Prescription drug costs can be managed efficiently through the following actions:

   - **Generic Drug Substitution** – Dispense FDA-approved generic equivalent drugs whenever possible and in accordance with federal and state laws. Contact the prescriber, if necessary, in order to dispense a generic equivalent drug. Certain drugs with documented dosing problems should not be dispensed generically unless requested by the prescriber.
   - **Prescription Drug List Compliance** – If a generic equivalent drug cannot be substituted, contact the prescriber to determine if a drug from the Prescription Drug List can be dispensed as an alternative. Claims messaging typically provides the preferred drug alternative.
   - **Prescriber “Dispense as Written” Prescription (DAW1)** – If a prescription specifies “Dispense as Written,” Pharmacy should contact the prescriber to determine if a generic equivalent or drug from the Prescription Drug List can be dispensed as an alternative.

4. **Compliance:** Pharmacies are required to fill prescriptions, provide reporting, and provide all services required to support the Medicare Prescription Drug Benefit Program, and abide by all applicable federal and state laws and regulations and CMS instructions.

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7 **Resources/Additional Information:**
CMS Memorandum on 2014 Requirements for Coding Patient Residence and Pharmacy Service Type on Claims dated June 20, 2013, available at [www.envisionrx.com](http://www.envisionrx.com)
5. **Home Infusion Pharmacies**

   *All home infusion Pharmacies shall, at a minimum, meet the following requirements:*

   (i) Are capable of delivering home-infused drugs in a form that can be administered in a clinically appropriate fashion.

   (ii) Are capable of providing infusible Part D drugs for both short-term acute care and long-term chronic care therapies.

   (iii) Ensure that the professional services and ancillary supplies necessary for home infusion therapy are in place before dispensing Part D home infusion drugs.

   (iv) Provide delivery of home infusion drugs within twenty-four (24) hours of discharge from an acute care setting, or later if so prescribed.

   in accordance with CMS § 423.120 Access to Covered Part D Drugs. “

6. **e-Prescribing:** If a Pharmacy transmits and/or receives prescriptions and prescription related information using electronic media for Part D Covered Drugs for Part D eligible individuals, the Pharmacy must comply with all e-prescribing standards, using current NCPDP standards.

7. **Minimum Standards:** Pharmacy is required to comply with the applicable minimum standards for pharmacy practice as established by the state in which the Pharmacy is located.

8. **Payment of Clean Claims:** In accordance with 42 CFR 423.520, Pharmacies are reimbursed within fourteen (14) days of submission date for all clean Claims submitted via the online System, and within thirty (30) days for other Claims (i.e. rejected or disputed Claims).

**STATE SPECIFIC PROVISIONS**

**NEW HAMPSHIRE - MEDICAID LINE OF BUSINESS**

Pharmacies must comply with the following provisions in connection with the New Hampshire Medicaid Care Management Program. Said provisions are subject to DHHS’ approval and revisions.

**Pharmacy’s Licensure and Enrollment.** Pharmacy represents and agrees that it is licensed and/or certified in accordance with the laws of the State of New Hampshire, and Pharmacy is not excluded from participation in federal health care programs or under sanction or exclusion from participation in the New Hampshire state Medicaid program. Pharmacy further represents and agrees that it is enrolled as a New Hampshire Medicaid provider. Pharmacy agrees to notify Network immediately should Pharmacy be excluded from participation in federal health care programs or be sanctioned or excluded from the New Hampshire state Medicaid program.

I. **Pharmacy’s Acceptance of – and Compliance with – all Eligibility and Reporting Requirements.** Pharmacy represents and agrees that it is in compliance with all federal and state eligibility criteria, reporting requirements, and any other applicable rules and regulations related to the New Hampshire state Medicaid program.
II. Pharmacy’s Acceptance of – and Compliance with – Federal and State Statutes and Regulations. Pursuant to 42 CFR 438.6, 42 CFR 438.100(a)(2) and 42 CFR 438.100(d), Pharmacy agrees to adhere to all applicable federal and state laws, including the following without limitation:

A. Pharmacy shall ensure that at a minimum, conflict of interest safeguards equal to federal safeguards (as set forth at 41 USC 423, section 27) are in place (as set forth in Social Security Act, Section 1923(d)(3)).

B. Pharmacy shall comply with the following Federal and State Medicaid Statutes, Regulations, and Policies:

i. Medicare: Title XVIII of the Social Security Act, as amended; 42 U.S.C.A. §1395 et seq.

ii. Related rules: Title 42 Chapter IV

iii. Medicaid: Title XIX of the Social Security Act, as amended; 42 U.S.C.A. §1396 et seq. (specific to managed care: §§ 1902(a)(4), 1903(m), 1905(t), and 1932 of the Social Security Act)

iv. Related rules: Title 42 Chapter IV (specific to managed care: 42 CFR § 438; see also 431 and 435)

v. Children’s Health Insurance Program (CHIP): Title XXI of the Social Security Act, as amended; 42 U.S.C. 1397; Regulations promulgated thereunder: 42 CFR 457

vi. Patient Protection and Affordable Care Act of 2010

vii. Health Care and Education Reconciliation Act of 2010, amending the Patient Protection and Affordable Care Act

viii. American Recovery and Reinvestment Act

ix. 42 CFR 435; XX-YY, Chapter ZZ of New Hampshire Department of Health and Human Services’ (“DHHS”) Eligibility Manual, NH Laws (RSAs), Regulations, State Plan

C. Pharmacy shall meet Medicare certification and be in good standing. Pharmacy represents that it is not, and does not employ or contract, directly or indirectly, with:

i. Any individual or entity excluded from Medicaid or other federal health care program participation under Sections 1128 or 1128A of the SSA for the provision of health care, utilization review, medical social work, or administrative services or who could be excluded under Section 1128(b)(8) of the Social Security Act as being controlled by a sanctioned individual;

ii. Any entity for the provision of such services (direct or indirect) through an excluded individual or entity;

iii. Any individual or entity excluded from Medicaid or New Hampshire participation by DHHS;
iv. Any individual or entity discharged or suspended from doing business with the State of New Hampshire;

v. Any entity that has a contractual relationship (direct or indirect) with an individual convicted of certain crimes as described in Section 1128(b)(8) of the Social Security Act; or

vi. Any providers or subcontractors excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Social Security Act [42 CFR 438.214(d)].

D. Pharmacy shall comply with the Civil Rights Act of 1964 (42 U.S.C. § 2000d), Title IX of the Education Amendments of 1972 (regarding education programs and activities), the Age Discrimination Act of 1975, the Rehabilitation Act of 1973, the regulations (45 C.F.R. Parts 80 & 84) pursuant to that Act, and the provisions of Executive Order 11246, Equal Opportunity, dated September 24, 1965, and all rules and regulations issued thereunder, and any other laws, regulations, or orders which prohibit discrimination on grounds of age, race, ethnicity, mental or physical disability, sexual or affectional orientation or preference, marital status, genetic information, source of payment, sex, color, creed, religion, or national origin or ancestry.

E. Pharmacy shall comply with the requirements of the Americans with Disabilities Act (ADA). In providing Services, Pharmacy will not directly or indirectly, through contractual, licensing, or other arrangements, discriminate against Medicaid beneficiaries who are qualified disabled individuals covered by the provisions of the ADA. A "qualified individual with a disability" defined pursuant to 42 U.S.C. § 12131 is an individual with a disability who, with or without reasonable modifications to rules, policies, or practices, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by a public entity (42 U.S.C. § 12131).

F. In connection with ensuring non-discrimination in enrollment, Pharmacy agrees:

i. To not discriminate against eligible Medicaid recipients because of race, color, creed, religion, ancestry, marital status, sexual orientation, national origin, age, sex, physical or mental handicap in accordance with Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d, Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. § 794, the Americans with Disabilities Act of 1990 (ADA), 42 U.S.C. § 12131 and rules and regulations promulgated pursuant thereto, or as otherwise provided by law or regulation.

ii. To not discriminate against eligible persons or eligible Medicaid recipients on the basis of their health or mental health history, health or mental health status, their need for health care services, the insurance reimbursement amount based on the eligible person's actuarial class, or pre-existing medical/health conditions.

G. Pursuant to 42 CFR 438.100(c), Pharmacy agrees that each eligible Medicaid recipient is free to exercise his/her rights, and an eligible Medicaid recipient’s exercise of those rights shall not adversely affect the way Pharmacy treats the eligible Medicaid recipient.
H. Pursuant to 42 CFR 438.206(c)(1)(ii), Pharmacy agrees to offer to eligible Medicaid recipients hours of operation that are no less than the hours of operation offered to commercial and FFS patients.

I. Pursuant to 42 CFR 438.106(c), 42 CFR 438.6(1), 42 CFR 438.230 and 42 CFR 438.204(a) and Section 1932(b)(6) of the Social Security Act, Pharmacy agrees that it may not bill any eligible Medicaid recipient any amount greater than would be owed if Pharmacy provided the services directly to the eligible Medicaid recipient, and the eligible Medicaid recipient was without any Medicaid or insurance coverage.

J. Pharmacy shall comply with the terms of the Federal False Claims Act, as set forth at 31 U.S.C. §§ 3729 to 3733, and with the New Hampshire False Claims Act, as set forth at N.H. Rev. Stat. Ann §§ 167:61b to e (and as each may be amended from time to time), including the whistleblower protections afforded by such laws.

K. Pharmacy shall comply with the Health Insurance Portability & Accountability Act of 1996 (as governed by 45 C.F.R. Section 164.504(e)), which will be provided on request from Pharmacy.

III. Pharmacy’s Acceptance of – and Compliance with –Terms Required by DHHS Medicaid Contract. Pharmacy acknowledges that Boston Medical Center Health Plan, Inc. (“BMCHP” or “Client”), doing business as Well Sense Health Plan in New Hampshire, has entered into a government agency contract with DHHS to manage and arrange for the provision of covered services to New Hampshire Medicaid enrollees (“DHHS Medicaid Contract”); that the term “BMCHP Medicaid Care Management Program” shall mean the Medicaid managed care program offered by BMCHP to New Hampshire Medicaid enrollees pursuant to the DHHS Medicaid Contract; that the DHHS Medicaid Contract contains provisions applicable to participating providers, including Pharmacies; and that Pharmacy agrees to comply with the terms and conditions of the DHHS Medicaid Contract applicable to Pharmacies, including without limitation the requirements reflected in the following:

A. Pharmacy agrees to submit and transmit all Claims information to Network, as directed by Network, so as to satisfy the terms of the DHHS Medicaid Contract.

B. Subject to applicable rules regarding patient confidentiality, Pharmacy shall, within the time required by Network and/or BMCHP, provide Network and/or BMCHP with copies of specified Member’ Pharmacy and other relevant records to enable Network and/or BMCHP to meet legal or contractually-imposed requirements, including without limitation, for purposes of resolving Member appeals and grievances. Pharmacy acknowledges that, because of substantial fines and penalties imposed under applicable laws and contracts, timely provision of records under this section is a material obligation of Pharmacy.

C. Network, its designee, or DHHS may conduct an audit pursuant to the DHHS Medicaid Contract or as required by DHHS. Pharmacy shall cooperate with and extend all reasonable and necessary support to Network, its designee, and/or DHHS to facilitate any review or audit.

D. To enable Network and Client to create and update Client’s Provider Directory and post accurately all DHHS required information concerning Pharmacy Network providers on a website accessible to participants who are eligible and enrolled in the BMCHP Medicaid Care Management Program (“Member”), Pharmacy agrees to provide Network, in writing, with the following information within twenty four (24) hours of any change to said

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information: (a) Pharmacy name; (b) Pharmacy location; (c) Pharmacy telephone number(s); (d) Pharmacy office hours; (e) whether Pharmacy offers non-English languages, and if so, which languages are offered; (f) if Pharmacy is not accepting new patients; or (g) any change in restrictions to Member’ freedom of choice.

E. Pharmacy agrees to accept a Member’s Medicaid ID Card as proof of enrollment until Member receives a BMCHP’s Medicaid Care Management Program ID Card.

F. Pharmacy agrees that, in no event, including without limitation, nonpayment by Network or Network’s insolvency, shall Pharmacy bill, charge, collect a deposit from, seek payment from, maintain any action at law or in equity or have any other recourse against a Member for items provided pursuant to BMCHP Medicaid Care Management Program. This provision does not prohibit Pharmacy from collecting from Member (i) Copayments or Deductibles consistent with BMCHP Medicaid Care Management Program; or (ii) charges for items not covered under BMCHP Medicaid Care Management Program delivered on a fee-for-service basis to Member who are informed in advance of the cost and agree in writing to accept payment responsibility for such non-covered items.

G. Pharmacy agrees to submit to any periodic Credentialing recertification processes by which client and/or Network periodically review, approve and recertify the credentials of Pharmacy pursuant to NCQA requirements and any comparable requirements defined by DHHS.

H. Pharmacy shall be responsive to the linguistic, cultural and other unique needs of any minority, homeless person, disabled individuals or other special populations that comprise BMCHP’s Membership, including the capacity to communicate with Member in languages other than English, when necessary, as well as those who are deaf, hard-of-hearing or deaf blind.

I. Pharmacy agrees to participate in a pharmacy satisfaction survey, approved by DHHS and administered by a third party, should Pharmacy be identified as a participant for said survey.

J. Pharmacy agrees to cooperate fully with client’s Quality Assessment and Performance Improvement ("QAPI") Program, as developed and approved by DHHS.

K. Pharmacy agrees to indemnify and hold harmless Network and client should any damages or liquidated damages be paid by either entity as a result of Pharmacy’s non-compliance or failure to satisfy any applicable federal or state law.

L. Pharmacy will not release and make public statements or press releases concerning the BMCHP Medicaid Care Management Program without the prior consent of BMCHP and DHHS.

M. Pharmacy also agrees to respond to a BMCHP disability survey, should it be asked to do so, that is developed by the State of New Hampshire, the attestation of which shall be kept on file by BMCHP and shall be available for inspection by the DHHS.

N. Pharmacy agrees to abide by the BMCHP’s written Fraud and Abuse policies and initiatives made available to Pharmacy, and if found to be not compliant with policies and initiatives, shall implement corrective actions.
as agreed to between the parties. Pharmacy shall further cooperate fully with any federal or state agency conducting Fraud and Abuse investigations concerning Member. Full cooperation includes, but is not limited to, timely exchange of information and strategies for addressing Fraud and Abuse, as well as allowing prompt direct access to information, free copies of documents and other available information related to Fraud and Abuse or other violations of government-sponsored health care programs. Pharmacy shall maintain the confidentiality of any such investigation.

O. A State Fair Hearing through the New Hampshire DHHS is an independent review by the state of a Pharmacies request for coverage of denied or partially approved services through EnvisionRx. A Pharmacy may be eligible for a State Fair Hearing appeal only after they have exhausted the EnvisionRx internal appeal process and have received a denial or partial approval. If a pharmacy wishes to request a State Fair Hearing, they must do so within one-hundred and twenty (120) calendar days of the date of the EnvisionRx appeal denial or partial approval letter. The pharmacy can refer to the DHHS website for full administrative appeals rights https://www.dhhs.nh.gov/oos/au/index.htm. Pharmacies are notified of this in the Notice of Rights for A State Fair Hearing Appeal insert which will accompany action and appeal correspondence from EnvisionRx.

Pharmacies may file a request for a State Fair Hearing Appeal in writing to:
New Hampshire Administrative Appeals
Unit 105 Pleasant Street
Main Building
Concord, NH 03301-6521

NEW JERSEY - COMMERCIAL LINE OF BUSINESS
The following provisions shall govern the contractual relationship between EnvisionRx and Pharmacies in the State of New Jersey:

A. Non-Clinical Claims Determination. If a Pharmacy disagrees with EnvisionRx non-clinical Claim determination for a commercial Claim payable by a fully-insured entity, the Pharmacy may initiate an appeal by submitting to EnvisionRx the New Jersey Department of Banking and Insurance “Health Care Provider Application to Appeal a Claims Determination Form” within ninety (90) calendar days following receipt of notice of the applicable Claims determination.

EnvisionRx will review the filed appeal and notify the Pharmacy within thirty (30) calendar days of the result of the appeal. If the Pharmacy disagrees with the appeals determination made by EnvisionRx, the Pharmacy may be eligible to submit the dispute to the New Jersey Program for Independent Claims Payment Arbitration (Arbitration). Information regarding Arbitration, including criteria for dispute eligibility, is available online at: https://njpicpa.maximus.com/. Please note: in order to be eligible for arbitration, the Pharmacy must submit its dispute within ninety (90) calendar days of the appeal determination.

B. Recoupment of Overpayments. With the exception of Claims that were submitted fraudulently or submitted by a Pharmacy that has a pattern of inappropriate billing or Claims that were subject to coordination of benefits, EnvisionRx will not seek reimbursement for overpayment of a Claim previously paid later than eighteen (18) months after the date the first payment on the Claim was made. EnvisionRx will not seek recoupment of overpayments on or before the 45th calendar day following the submission of the request to
the Pharmacy for reimbursement on an overpaid Claim. In the event that a Pharmacy does not refund the overpayment, EnvisionRx may exercise its right to withhold the requested overpayment amount from the next payment due the Pharmacy.

C. Complaints Not Involving Claims Payment or Compensation. If a Pharmacy has a dispute or complaint that does not relate to compensation matters or Claim determination matters, the Pharmacy may contact the EnvisionRx Provider Relations Department. Provider Relations will address complaints within (thirty) 30 business days from receipt of the complaint. If the Pharmacy is dissatisfied with the resolution reached through the Provider Relations, the Pharmacy may submit a verbal or written request directly to the Department of Banking and Insurance via phone call, fax or online complaint form (www.state.nj.us/dobi/consumer.htm#insurance).

D. Termination of Participating Pharmacy. EnvisionRx may terminate its Agreement with a participating Pharmacy at any time by providing ninety (90) days prior written notice to the participating Pharmacy. The termination notice will set forth the Pharmacy’s right to obtain a reason for the termination and its right to request a hearing concerning the company’s decision to terminate the Pharmacy from the EnvisionRx Network. To obtain a hearing, the terminated Pharmacy must submit a written request for a hearing within ten (10) business days following the receipt of the termination notice. Please note that the foregoing right to a hearing does not apply if the termination occurs due to: (1) the non-renewal of the Participating Provider Agreement, (2) a determination of fraud, (3) breach of contract by the Pharmacy, or (4) a determination by the company that the Pharmacy poses an imminent danger to Member or to public health, safety and welfare. EnvisionRx will hold a hearing within thirty (30) days following receipt of a written request for a hearing by a terminated Pharmacy before a panel appointed by EnvisionRx. Such hearing will meet the requirements set forth in N.J.A.C. 11:24A-4.9.

NORTH CAROLINA – FULLY-INSURED COMMERCIAL AND HMO LINE OF BUSINESS
EnvisionRx may amend the PPA and this Pharmacy Manual by providing a copy of the amendment to the Pharmacy. The amendment will be dated, labeled “Amendment,” signed by EnvisionRx and include the effective date of the amendment. N.C. Gen. Stat. § 58-50-280(a).

The notice of the amendment shall be deemed received: (i) five (5) business days following the date the notice is placed, first-class postage prepaid, in the United States mail; (ii) on the day the notice is hand delivered; (iii) for certified or registered mail, the date on the return receipt; or (iv) for commercial courier service, the date of delivery. Nothing in this section prohibits the use of an electronic medium for a communication other than an amendment if agreed to by the insurer and the Pharmacy. N.C. Gen. Stat. § 58-50-275.

The Pharmacy shall have sixty (60) days from the date of receipt to object to the amendment. The amendment will become effective upon the Pharmacy’s failure to object in writing within sixty (60) days. N.C. Gen. Stat. § 58-50-280(b). If the Pharmacy objects to the amendment, then the amendment is not effective and EnvisionRx shall be entitled to terminate the PPA upon sixty (60) days written notice to the Pharmacy. N.C. Gen. Stat. § 58-50-280(c). Nothing in this section prohibits EnvisionRx and the Pharmacy from negotiating contract terms that provide for mutual consent to an amendment, a process for reaching mutual consent, or alternative notice contacts. N.C. Gen. Stat. § 58-50-280(d).
For the purposes of this section, a change required by federal or state law, rule, regulation, administrative hearing, or court order is not considered an amendment. N.C. Gen. Stat. § 58-50-270.

**TEXAS - NETWORK ADMINISTRATION TECHNOLOGY FEE (NATF)**
For all applicable lines of business, EnvisionRx will not bill a NATF in compliance with Texas state law.

**WISCONSIN - MEDICAID LINE OF BUSINESS**
To be reimbursed for services provided to Members enrolled in Wisconsin Medicaid, BadgerCare Plus, or SeniorCare, Pharmacy is required to be enrolled in Wisconsin Medicaid.

Pharmacy acknowledges that the following requirements have been satisfied:

1. Pharmacy is medical assistance (MA) certified in accordance with DHS 105.01(3)

2. Pharmacy meets the requirements for registration and practice under ch. 450, Stats., and chs. Phar 1 to 17
### ACRONYMS

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<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ANDA</td>
<td>Abbreviated New Drug Application</td>
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<td>AWP</td>
<td>Average Wholesale Price</td>
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<td>BLA</td>
<td>Biologics License Application</td>
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<td>CFR</td>
<td>Code of Federal Regulations</td>
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<td>CMS</td>
<td>The Center for Medicare and Medicaid Services</td>
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<td>COB</td>
<td>Coordination of Benefits</td>
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<td>Dispense as Written</td>
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<td>DDPS</td>
<td>Drug Data Processing System</td>
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<td>National Provider Identifier</td>
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<td>NDC Structured Product Labeling Data Element</td>
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<td>Office of Inspector General</td>
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<td>Other Payer Amount</td>
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