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Pharmacy Manual

Supplemental Policies, Procedures and Regulations

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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 Elixir 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 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

Elixir 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 Elixir.

Elixir credentials potential pharmacies prior to their acceptance in any Elixir Network. Elixir monitors the credentials of its Pharmacies in accordance with Elixir policies, acceptable industry standards and/or as mandated by law. Pharmacies must respond promptly to provide Elixir 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. Elixir 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).

Elixir 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, visit NCPDP's website at [online.ncdp.org](https://www.ncdp.org). It is the responsibility of the Pharmacy to provide timely updates to NCPDP to ensure that Elixir has the most accurate and updated data.

Elixir 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 Elixir 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 Elixir or as authorized in the PPA.

ADVERTISING REQUESTS

Pharmacies are expressly denied any rights to use the Elixir name, likeness, logo, service marks, or trademarks in any advertisement, promotion, or otherwise without prior, written consent from Elixir. Note Elixir 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 Elixir can better serve our Members, they can complete the [Pharmacy Satisfaction Survey](#).

Department	Inquiry Type	Contact Information
Accounts Payable	Payments, electronic funds transfer (EFT) and electronic remittance advice (ERA)	Email: pharmacyaccountingissues@elixirsolutions.com
Fraud, Waste, and Abuse Hotline	Report suspected fraud, waste and abuse and other compliance related issues	Phone: 1-866-417-3069 Online: elixirsolutions.ethicspoint.com
MAC	MAC drug pricing and appeals	Email: MAC@elixirsolutions.com
Pharmacy Audits and Fraud, Waste, and Abuse	Ongoing audits, audit appeal, suspensions	Email: pharmacyaudits@elixirsolutions.com Fax: 844-236-3021
Pharmacy Help Desk	Billing/payment, formulary, disputes and appeals, Member eligibility, plan benefits, Pharmacy Network issues, and prior authorizations, dispute resolution, coverage determinations	Phone: 800-361-4542 TTY: 711
Provider Relations – Credentialing	Pharmacy enrollment, credentialing, and change of ownership	Email: providerenrollment@elixirsolutions.com
Provider Relations – Contracting	Pharmacy contracting, contract status, AWP drug pricing questions	Email: pharmacycontracting@elixirsolutions.com

NETWORK ENROLLMENT FORM AND CREDENTIALING GUIDELINES

Elixir utilizes NCPDP Part I and II as the source for credentialing information and documents in addition to the Pharmacy Network Enrollment Request form. Pharmacies are required to maintain Part I and II of their NCPDP profile with current and accurate information. If there are any discrepancies discovered with the information provided on the Pharmacy Network Enrollment Request form or the Pharmacy's NCPDP profile that the Pharmacy and any other facilities under the same ownership, may be denied, terminated, or suspended from access to the Elixir Network and may be subject to an audit as outlined in 42 C.F.R. § 423.504.

APPLYING FOR PARTICIPATION

To apply to become a Pharmacy in our Network, please fill out the Pharmacy Network Enrollment Request form located on our website and ensure Part I and II of your pharmacy's NCPDP profile is complete and accurate. Once

the completed Pharmacy Network Enrollment Request form is received, Provider Relations will review in addition to Part I and II of your pharmacy's NCPDP profile.

CREDENTIALING AND RECREDENTIALING GUIDELINES

Elixir credentials and continually monitors the credentials of participating Pharmacies prior to and after inclusion into the Elixir Network. Pharmacies are required to meet conditions of participation set forth by Elixir and adhere to governmental regulations and standards. Elixir uses primary-source verification during its review of independent pharmacy licensure and requires that chain and PSAO corporate offices do the same for their affiliated pharmacies. Independent pharmacies are required to maintain NCPDP Part 1 and 2 with accurate and current information at all times as Elixir utilizes this information during its review. Chain and PSAOs are credentialed/recruited at the corporate level and are required to provide proof of network requirements in addition to signing an annual credentialing attestation. Chain and PSAO corporates are responsible for the credentialing of their affiliated pharmacies. In addition, Pharmacies located in a HEAT Zone and affiliated with a PSAO are required to undergo an additional review by Elixir to ensure conditions of participation are met (for more information, see the [Pharmacy Credentialing and Recredentialing FAQ](#)).

The minimum requirements for network pharmacies are:

- Current DEA
- Current Pharmacy License
- Current Pharmacist-In-Charge (PIC) License
- Current ASSMCA License for Puerto Rico pharmacies
- Current Professional Liability Insurance of \$1,000,000 per occurrence/\$3,000,000 aggregate or an equivalent umbrella policy
 - For US territories limits of \$1,000,000 per occurrence/\$2,000,000 aggregate or an
- 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 Elixir

ENHANCED CREDENTIALING

At Elixir's discretion, pharmacies may be subjected to the Enhanced Credentialing (includes recredentialing) process and be required to provide additional information for review. This may be required for certain CMS designated and surrounding areas. If pharmacy is selected for Enhanced Credentialing, successful completion of the process is necessary for pharmacy to qualify for network entry or to continue participation as a network pharmacy. Lack of cooperation with the process constitutes pharmacy acknowledgement that it is no longer pursuing entry into the Elixir network. If pharmacy is currently part of the network, pharmacy may be subject to suspension or termination. Enhanced Credentialing applies to independent as well as PSAO-contracted pharmacies.

The Enhanced Credentialing process may include, but is not limited to, a review of the following:

- Pictures of designated pharmacy areas
- Wholesaler, manufacturers and distributor invoices for outlined time frame
- Comprehensive drug utilization report for outlined time frame (regardless of claim submission to Elixir)
- Comprehensive staff listing, including names, license numbers, Social Security numbers and/or dates of birth
- Pharmacy policies and procedures
- Bill of sales

- Completion of onsite audit
- Other information as deemed necessary.

If Pharmacy is denied entry into the Network due to the Enhanced Credentialing process, Pharmacy agrees and understands that it may not reapply for reinstatement into the Network until two (2) years after the date of denial. Pharmacy also agrees and understands that entry into the Network is at Elixir's sole discretion.

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 a person with LEP. All Pharmacies in the Elixir 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 Elixir 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 Elixir. Pharmacies will be notified of any audit communications via fax unless the Pharmacy Audit and Fraud, Waste, and Abuse Department has been notified of email preference.

NON-PREFERRED VS. PREFERRED STATUS

Pharmacies that currently have "preferred or non-preferred" status in an Elixir Network may lose that status if they change their current contract status with Elixir (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 Elixir, 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.

If Elixir identifies a potential dispensing error or other quality-related issue as a result of a member, prescriber, or plan complaint or response, or an FWA audit, and confirms with Pharmacy that such error or issue occurred, then the Pharmacy will be responsible for: (i) reviewing the information with the member (ii) documenting the error based on Pharmacy's internal policies and procedures and (iii) reporting the error to any appropriate regulatory agency (e.g. Institute of Safe Medical Practices (ISMP)/FDA Medwatch). For paid Claims with a dispensing error or other quality-related issue, Elixir reserves the right to reverse the Claim. Serious and/or multiple errors may result in additional audits or requests for information, such as how the Pharmacy plans to prevent future errors.

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 Elixir 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 within ten (10) business days of any changes in documentation or other information provided to Elixir in connection with enrolling as a Pharmacy in the network. The Pharmacy must update NCPDP within ten (10) business days of a change of ownership and may be subject to credentialing.

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 Elixir 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 Elixir, your Pharmacy must be willing to offer written attestation to its compliance of this section.

SUSPENSIONS AND TERMINATIONS

Elixir has a zero tolerance policy regarding fraud, waste and abuse matters. Elixir 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, Elixir 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 Elixir 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 and requiring Members to reconstitute the individual ingredients into a compounded drug
- 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.)
- Manipulating drug pricing in order to obtain paid claims
- Omitting information or providing inaccurate data on the Pharmacy Network Enrollment Request form or in the Pharmacy's NCPDP profile
- 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

- Billing and reversing large number of claims with different drugs to obtain higher reimbursement (“fishing”)
- Billing for an over the counter (OTC) drug or product without a prescription or plan-sponsor recognized document
- Billing for a higher priced drug or product when a lower cost alternative drug or product was previously prescribed or dispensed
- Billing for prescriptions that are not dispensed in order to decrease deductibles for dispensed medication or bypass utilization management edits
- Overriding DUR rejects without properly documenting the resolution
- Submitting claims with NDC that differs from the dispensed product package NDC
- Billing for drugs from a wholesaler that cannot provide supporting drug pedigree documentation
- Not documenting weight dosing calculations for weight-based drugs
- Failing to implement process changes or documentation requirements communicated in a previous audit
- Not reporting to Elixir when pharmacy is being investigated by any federal or state governmental agency or regulatory body

If a Pharmacy is being investigated for any reason, Elixir reserves the right to suspend the Pharmacy, until the investigation is complete. At the end of the suspension period, 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.

Elixir may temporarily withhold payment or cancel checks, in whole or in part, and/or prevent claims adjudication during the suspension period.

Elixir’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 Elixir under the Agreement, or at law, or equity. If Pharmacy is terminated from the Network, Pharmacy agrees and understands that Pharmacy may not apply for reinstatement into the Network until five (5) years after the date of the termination. Pharmacy also agrees and understands that reinstatement into the Network is at Elixir’s sole discretion.

Pharmacy may submit an appeal of the suspension or termination to Elixir by writing to the address provided in the Agreement or notice within fifteen (15) 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.

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 Elixir, 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. Elixir 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 Elixir 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 Elixir or about Member’s Plan Sponsor.

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.

Elixir 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 Elixir 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.

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 Elixir's standard for updating the MAC price lists and an applicable state law or regulation, Elixir will follow the stricter provision. Elixir utilizes the following national drug source compendia or sources to obtain drug price data for drugs that are subject to MAC: AmerisourceBergen Corporation, ANDA Incorporated, Cardinal Health, and McKesson Corporation.

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 is needed, Elixir 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 Elixir's standards for addressing MAC appeals and an applicable state law or regulation, Elixir will follow the stricter provision.

VACCINES

The purpose of the Elixir Pharmacy Vaccine Program is to provide a range of vaccines that may be appropriately administered in the Pharmacy setting. The vaccine schedule is listed at the Generic Product Indicator (GPI) level, allowing Pharmacies the flexibility to purchase various NDCs within that GPI. Elixir 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

GPI	Name
INFLUENZA VACCINES	
1710002046E620	Fluad
1710002086E520	Flublok Quadrivalent Preservative Free
1710002082E620	Flucelvax Quadrivalent
17100020821800	Flucelvax Quadrivalent
17100020541800	FluMist Quadrivalent
1710002024E620	Fluzone HD Preservative Free 20-21
17100020251820	Fluzone Quadrivalent INJ 2018-2019
1710002025E620	Afluria, Flulaval, Fluzone, & Fluarix Quadrivalent Preservative Free
17100020251800	Flulaval Quadrivalent
1710002025E610	Afluria & Fluzone Quadrivalent
1710002047E420	Fluad Quadrivalent
ADDITIONAL VACCINES	
17200030102100	ActHIB
18990003221815	Adacel
1720004015E620	Bexsero
18990003221820	Boostrix
18990003201830	Daptacel
18990002101810	Diphtheria/Tetanus Toxoi
17100010201827	Engerix-B
17100010201830	Engerix-B
17100065501800	Gardasil 9
1710006550E600	Gardasil 9
17100008001830	Havrix
17100008001840	Havrix

GPI	Name
1710001030E520	Hepelisav-B
17200030102122	Hiberix
18990003201840	Infanrix
17100050002250	IPOL
18990004351820	Kinrix & Quadracel
17200040442200	Menactra
17200040482100	Menveo
17109903102100	M-M-R II
18990005501820	Pediarix
17200030101820	PedvaxHIB
18990005301920	Pentacel
17200065002205	Pneumovax 23
17200065301800	Prevnar 13
1720006540E620	Prevnar 20
17109904201910	Proquad
17100010201815	Recombivax HB
17100010201820	Recombivax HB
17100010201840	Recombivax HB
17100075001920	Rotarix
17100075102020	RotaTeq
17100095401920	Shingrix
18990002202210	Tenivac
18990002201805	Tetanus-Diphtheria Toxoids (Td)
1720004012E610	Trumenba
1710990205E620	Twinrix
17100087102210	Varivax
17100008001860	Vaqta
17100008001870	Vaqta
18990006551820	Vaxelis
1899000655E620	Vaxelis

PART B VACCINE PROGRAM LIST

GPI	Name
1710002025E620	Afluria, Flulaval, Fluzone, & Fluarix Quadrivalent Preservative Free
1710002046E620	Fluad
17100020852000	Flublok
1710002086E520	Flublok Quadrivalent Preservative Free

1710002082E620	Flucelvax Quadrivalent
17100020821800	Flucelvax Quadrivalent
17100020251800	Flulaval Quadrivalent
17100020541800	FluMist Quadrivalent
17100020401800	Fluvirin
1710002040E605	Fluvirin
17100020251820	Fluzone Quadrivalent INJ 2018-2019
1710002047E420	Fluad Quadrivalent
1710002025D310	Fluzone Quadrivalent Intradermal
1710002025E610	Afluria & Fluzone Quadrivalent
1710002024E620	Fluzone HD Preservative Free 20-21
17200065002205	Pneumovax 23
17200065301800	Pevnar 13
1720006540E620	Pevnar 20

COVID-19 VACCINES

Elixir will support the adjudication of the COVID-19 Vaccine for commercial and Medicaid clients (if applicable). For beneficiaries enrolled in Medicare Advantage plans during CY 2020 and 2021, payment for the COVID-19 Vaccine and its administration will be made through the original fee-for-service Medicare program. The reject messaging for Medicare Part D BIN/PCN (PDP or MAPD), will be A5 (Not Covered Under Part D Law) with additional messaging to bill Medicare Part B FFS.

Effective March 15, 2021, Elixir will reimburse pharmacies an administration fee of \$40 per each COVID vaccine dose when administered to members. Pharmacies will be reimbursed the vaccine administration fee in accordance with state requirements (where applicable).

- The correct administration fee must be entered in the “**Incentive Amount Submitted**” field which appears as **FIELD #438-E3** on the Payer Sheet.

Multi-dose vaccines must be submitted with the NCPDP identified Submission Clarification Codes to differentiate between doses. For the first dose, pharmacies must submit the Submission Clarification Code of 2 “Other Override”. For the second dose, pharmacies must submit the Submission Clarification Code of 6 “Starter Dose”. For the booster dose, pharmacies must submit the Submission Clarification Code of either 7 “Medically Necessary” or 10 “Meets Plan Limitations”.

- The correct Submission Clarification Code (SCC) must be entered in the “**Submission Clarification Code**” field which appears as **FIELD #420-DK** on the Payer Sheet.

As with all vaccine claim submissions, pharmacies must submit “**MA**” in the “**Professional Service Code**” field which appears as **FIELD #440-E5** on the Payer Sheet.

Members will NOT have any cost share amount and should not be charged anything out of pocket.

For additional guidance on accurate claims submission, please review the “NCPDP Emergency Preparedness Guidance – COVID-19 Vaccines” (<https://www.ncdp.org/NCPDP/media/pdf/NCPDP-Emergency-Preparedness-Guidance-COVID-19-Vaccines.pdf>).

COVID Vaccine GPIs Currently Approved for Claim Submission (will be updated as new GPIs are available and approved):

GPI	Vaccine Name
17100002401820	Pfizer-BioNTech COVID-19 Vacc Suspension 30 MCG/0.3ML Intramuscular
17100002401840	Moderna COVID-19 Vaccine Suspension 100 MCG/0.5ML Intramuscular
17100002101840	Janssen COVID-19 Vaccine Intramuscular Suspension 0.5 ML
17100002401826	Pfizer Vaccine Injection 5-11Y

If your pharmacy is not currently a Medicare provider and would like to know how to become a vaccinator for the COVID-19 Vaccine, please visit the CMS website with instructions on how to do so:

<https://www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccine-shots>

In accordance with the CDC COVID-19 Vaccination Program Provider Agreement, pharmacies are responsible for administering the COVID-19 Vaccine in accordance with ACIP recommendations, complying with requirements on vaccine management, reporting vaccine administration errors and providing a completed COVID-19 vaccination record card to every vaccine recipient, parent or legal representative. Furthermore, you are required to administer the COVID-19 Vaccine regardless of the vaccine recipient's ability to pay. Pharmacies are not permitted to sell or seek reimbursement for any COVID-19 Vaccine or any diluent, syringes, needles, or other constituent products and ancillary supplies provided by the federal government.

PROCESSING A CLAIM

BIN NUMBER AND PCN INFORMATION

Current BIN and PCN numbers are located on the Elixir website at: <https://www.elixirsolutions.com/home/providers>.

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 Elixir 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. Elixir shall not be liable for any transmission charges for Claims data.

The Pharmacy shall submit the Claim to Elixir 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;
- xi. 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.

Elixir 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.

Elixir 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 Elixir that are not picked up by the Member, Elixir requires Pharmacies to reverse the Claim via the System within fourteen (14) days from the date the prescription was filled. Elixir 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 subject 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 Elixir. 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 approving prescriber or agent of the prescriber. Missing or incomplete 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. Pharmacy should be able to link the tracking information to the prescription record through supporting documents if requested. Pharmacy must validate the Member's address prior to mailing the prescription.
 - 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. Pharmacy initiated confirmation is unnecessary when the beneficiary personally requests the refill or new prescription (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. Elixir 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 Elixir:

- 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.
- c. Compound Prescription Documentation Requirements:
 - 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. Pharmacy must document the weight of tablets and capsules on the compound log when preparing weight/weight compound products such as creams and ointments. The tablet and capsule total weights must be accounted for to ensure medication strength in accordance with variation acceptable by USP.
 - iv. 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.

- v. 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.
- vi. Elixir does not permit substitution for compounds without a new prescription or a properly documented verbal authorization from prescriber. Elixir does not consider compounded medication as a generic drug for the purposes of any applicable state generic substitution law or regulation.
- vii. If requested by Elixir, 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.
- viii. 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.
- ix. 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.

AUDIT GUIDELINES

INTRODUCTION

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

Audit results are regularly reviewed by the Elixir Pharmacy Audit and Fraud, Waste, and Abuse Department and the Network Compliance Committee. Evidence of discrepancies may result in payment chargebacks, referrals to state/federal investigative agencies and/or state professional boards, negative impact on Network participation, or other corrective actions. 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

Elixir may conduct a desk audit, on-site audit, or investigational audit of a Pharmacy. Nothing prohibits Elixir 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. Elixir 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. Deadlines are typically shorter compared to routine desk audits. The time frame for reviewing documentation may be extended depending on the nature of the investigation.

REQUESTED DOCUMENTATION AND RECORDS

The Pharmacy must provide Elixir, 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
7. Proof of copayment collection

TYPICAL AUDIT PROTOCOL AND APPEALS PROCESS

Elixir 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.

Pharmacies are required to provide documents by the dates outlined within the audit correspondence: audit request letter, initial findings letter. Appeal documents received after the outlined due dates will not be considered for review. Elixir 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 Elixir. 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)
 - f. Manufacturer, wholesaler or distribution invoices
- 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 and/or Pharmacy's NCPDP number with the audit reference number as indicated on audit correspondence if bar code is not present.
 - b. Submit requested documentation to the Pharmacy Audits and Fraud, Waste, and Abuse Department via fax or email
 - c. If you don't have secure e-mail, you can send a request to the Pharmacy Audits and Fraud, Waste, and Abuse Department 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 and/or Pharmacy's NCPDP number with the audit reference number as indicated on audit correspondence if bar code is not present.
- 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 Department of any change to the contact information on file.
- 7. How do I appeal audit findings?**
- a. Each discrepancy (findings) 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. Elixir expects Pharmacies to respond to audit requests within the allotted time frame as indicated on the audit request and discrepancy letters. Audit extensions are considered on a case by case basis. All requests for audit extensions are handled in writing only via email or fax. Extension requests received less than three (3) days prior to the due date for an audit response will not be considered. Extension requests may be approved or denied at Elixir's discretion.
- 9. Can I still appeal if the initial audit response was not submitted?**
- a. Yes, gather requested documentation and submit your appeal by the deadline indicated on the discrepancy letter

- b. Pharmacies that did not respond to the audit request are voiding their right to appeal findings encountered upon record review
- c. Use the discrepancy letter with the QR code (two-dimensional bar code) as your cover page and/or Pharmacy's NCPDP number with the audit reference number as indicated on audit correspondence if bar code is not present

10. Can my Pharmacy obtain a list with the prescriptions that will be reviewed during the onsite audit?

- a. No, Elixir 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 the 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:*

CODE	Description	Explanation	Required Documents for Appeals
CFX	Cut Fax Header	Fax header removed from Rx document that would authenticate the origin submitted on claim as "Fax".	Prescriber statement*
CIN	Clinically Inappropriate	Billed claim goes against current accepted medical literature; without documentation of prescriber interaction and authorization.	Pharmacy and/or prescriber must provide current clinical literature validating the use of this drug and/or dose as prescribed.
COM	Missing or Incomplete Compound Log	Compound log not submitted or missing required elements.	Date and time stamped compound log with all required elements according to USP 795.
CPD	Compound Incorrectly billed	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.	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.
DAW	Incorrect DAW Code	DAW billed must be documented on the prescription hard copy.	Date and time stamped note in patient profile that documents patient's preference (electronically captured documentation) or medical record that supports prescriber's preference.
DEA	DEA Number Not Documented on Prescription	The hard copy prescription does not contain a DEA number (CII-CV drugs only).	No post audit documentation accepted. Federal regulations require the prescriber's DEA number as part of the prescription hard copy PRIOR to dispensing.
DPU	Delayed Pick-up from billed Date of Service	Prescriptions billed and not picked up or delivered within 14 days from date of service should be reversed. No post audit documentation accepted.	No post audit documentation accepted.
EXC	Excessive Quantity Billed/Overfilled	The quantity billed exceeds amount authorized by the prescriber or the quantity billed would last greater than the days' supply limit of the plan.	Prescriber statement* acceptable in cases of quantity billed that exceeds amount authorized by prescriber.
EXP	Expired Prescription	Prescription is filled greater than timeframe allowed by state and/or federal regulation.	Copy of the state or federal regulation defining the valid length of time the prescription can be filled.

CODE	Description	Explanation	Required Documents for Appeals
IDS	Incorrect Days' Supply	The days' supply billed is not consistent with the quantity and directions described by prescriber.	No post audit documentation accepted.
INV	Invalid Prescription	Prescription does not conform to all applicable regulatory requirements.	Prescriber statement*. No post audit documentation accepted for CII-CV.
IOC	Incorrect Origin Code	Origin code submitted differs from the hard copy prescription.	No post audit documentation accepted; informational citation.
IPO	Invalid Physician's Order	Physician's order is not valid for the billed date of service.	Copy of physician's order or interim order that authorized the date of service billed.
ISH	Drug Invoice Shortage	Pharmacy billed for a higher quantity of drugs compared to amount purchased.	Invoice data submitted by the wholesaler(s) reported on the signed 'Pharmacy Attestation of Wholesalers'.
ITX	Incomplete Transfer Information	Prescription does not have complete transfer information.	Prescriber statement*. No post audit documentation accepted for CII-CV.
LAB	Missing or Incomplete Rx label	Rx label not received or does not conform to regulatory requirements.	A computer generated label or sticker with all defined Rx elements for requested date of service.
MDP	Member Denies Prescription	Member denied receiving the prescription or knowing the pharmacy.	Member statement** and member's explanation to justify initial claim(s) denied.
MDR	Member Denies Ordering/Requesting Prescription Received	Member denied ordering or requesting prescription billed to member's benefit.	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.
MLL	Mis-labeled	Label discrepancy in which Rx directions are not accurately described on Rx label provided to patient.	If therapeutic impact, include incident report that documented the error in a timely manner and proof that the prescriber and patient were notified.
MSL	Missing Signature Log or Delivery Manifest	Signature log or proof of receipt by member not received.	Member statement** or facility statement*** confirming medication was received, OR signature captured electronically.
MSP	Missing Prescription	Copy of prescription cannot be found in documentation submitted.	Prescriber statement* or original prescription hard copy (front and back). Telephoned or called in prescription hard copies are not accepted during the appeal phase.
N	No Standing Discrepancy	No discrepancies encountered.	Not applicable
NPD	Not Part D	Claim not covered under Medicare Part D.	Will be specified depending on error.
NRS	No Response to Audit Request	Pharmacy failed to respond to audit request.	Original prescription hard copy (front and back) or prescriber statement*, Rx label, signature log and compound log (if applicable).
OTH	Other	Will be described depending on the error.	Will be specified depending on the error.
OTH2	Other	Will be described depending on the error.	Will be specified depending on the error.
PDP	Prescriber Denies Prescription	Prescriber denied authorizing prescriptions billed under his/her name.	Prescriber statement* with explanation to justify initial prescription denial and medical record to support prescriber statement.
RMA	Risk Management Authorization	No risk management authorization number recorded on prescription to authorize dispensing.	Original documentation or an archived profile note in the pharmacy system with time and date stamp that documents the date and RMA number.
RTS	Refill Too Soon	Refill too soon based on submission of correct days' supply.	No post audit documentation accepted.
SPL	Split quantity	Quantity billed is less than prescribed, resulting in frequent fills and dispensing fees and/or circumventing plan limitations.	No post audit documentation accepted.
SUP	Supervising MD Missing	Supervising MD name not on prescription hard copy written by mid-level practitioner.	Prescriber statement* from supervising MD. No post audit documentation accepted for CII-CV.
UAD	"Use As directed"/ No Directions Documented	Prescription hard copy missing specific, calculable directions.	Prescriber statement* containing one of the following specified directions 1.) Surface area <u>and</u> frequency or 2.) Maximum daily dose.

CODE	Description	Explanation	Required Documents for Appeals
URF	Unauthorized Refills Billed	Refills for adjudicated claim are not specified on the prescription hard copy.	Prescriber statement* that indicates refill was authorized PRIOR to dispensing date.
WDD	Wrong Drug Dispensed or Billed	Pharmacy billed a different medication than the one ordered by the prescriber, with no documentation on prescription hard copy or member profile.	Prescriber statement* to verify authorized change. Appeal documentation accepted for substitution due to therapeutic exchange only.
WMB	Wrong Member Billed	The member identified on the prescription hard copy is not the member identified on the paid claim.	No post audit documentation accepted.
WPS	Wrong Prescriber Submitted	Incorrect prescriber submitted for claim adjudication or inappropriate use of prescriber ID.	If the correct prescriber has been sanctioned or otherwise excluded by payor, claim will be reversed. No post audit documentation accepted.
WSL	Wrong Signature Log	Signature log copy submitted is for a different date of service or different medication.	Signature log/Electronically captured signature for requested Date of Service, Member statement** or facility statement*** confirming medication was received.
XDEA	XDEA Number Missing	No XDEA number on Suboxone or Subutex prescription hard copy that is required for opioid dependence treatment.	No post audit documentation accepted.

*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.

Refills are subject to recovery based upon the discrepancy encountered.

See below guidance table regarding recovery amounts and refill eligibility for each discrepancy code.

CODE	Recovery amount	Refills subject to recovery	CODE	Recovery amount	Refills subject to recovery
CFX	Full recovery	Yes	MSL	Full recovery	No
CIN	Partial or Full recovery depending on thenature of discrepancy	Yes	MSP	Full recovery	Yes
CPD	Partial to Full recovery	Yes	NCC	Full recovery	Yes
COM	Full Recovery	No	NPD	Full recovery	Yes
DAW	Partial or Full Recovery if used to bypass Prior Authorization requirement	Yes	NRS	Full recovery	Yes
DEA	Full recovery	Yes	OTH, OTH2	Partial or Full recovery depending on nature of discrepancy	OTH - No OTH2 - Yes
DPU	Full recovery	No	PDP	Full recovery	Yes
EXC	Partial recovery	Yes	RMA	Full recovery	No
IDS	Informational citation	Yes	RTS	Full recovery	Yes
INV	Full recovery	Yes	SPL	Full recovery	Yes
IOC	Informational citation	Yes	SUP	Full recovery if applicable per state regulations	Yes
IPO	Full recovery	No	UAD	Partial charge back depending on submitted days supply	Yes
ISH	Partial or Full recovery	Yes	URF	Full recovery	Yes
ITX	Full recovery	Yes	WDD	Full recovery	Yes
LAB	Full recovery	No	WMB	Full recovery	Yes
MDP	Full recovery	Yes	WPS	Informational citation or Full recovery if correct prescriber is a sanctioned prescriber	Yes

MDR	Full recovery	Yes	WSL	Full recovery	No
MLL	Full recovery if error causes Therapeutic Impact or Informational citation if error does not have therapeutic Impact	No	XDEA	Full recovery	Yes

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.

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.
2. Reason for Service Code NCPDP field = 439-E4.

3. Result of Service Code NCPDP field = 441-E6.

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

DUR Conflict Code	Description	Prof Service Code	Reason for Service Code	Result of Service Code
TD	Therapeutic Duplication	MR	TD	1B
DD	Drug-Drug Interaction	MR	DD	1B
ID	Ingredient Duplication	MR	ID	1B
PA	Drug Age Precaution	MR	PA	1B
HD	High Dose	MR	HD	1B

Drug-Drug Interaction: Reject 88:

- Use DD, MO/MR, 1B/1G. For >1 alert use 0000000003

Dose Check-High Dose Interaction: Reject 88:

- Use HD, DE/MO/MR, 1B/1G. For >1 alert use 0000000003

Drug-Age Interaction: Reject 88:

- Use PA, MO/MR, 1B/1G. For >1 alert use 0000000003

Drug-Sex Interaction: Reject 88:

- Use SX, MO/MR, 1B/1G. For >1 alert use 0000000003

Duplicate Drug: Reject 88:

- Use ID, MO/MR, 1B/1G. For >1 alert use 0000000003

Duplicate Therapy: Reject 88:

- Use TD, MO/MR, 1B/1G. For >1 alert use 0000000003

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 Elixir. 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 Elixir encourages Pharmacies to verify coordination of care when more than one prescriber is involved. Elixir 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.

Reject Code	925
Reject Message	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)
Resolution	Decrease prescription quantity and day supply to seven days or less and resubmit the claim

Resolution Alternatives	Service codes may only be used when the following apply: <ul style="list-style-type: none"> • 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	MØ: 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.

Reject Code	88
Reject Message	200 milligram Morphine equivalent limit: PA required
Resolution	Member or Member's representative must submit a coverage determination request to Elixir for review.

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

Reject Code	88
Reject Message	90 mg Morphine equivalence limit: consult prescriber and enter DUR codes if appropriate or PA required
Resolution	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.
Resolution Alternatives	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 Elixir for review.
Reason for Service Code	DR: Dose range conflict
Professional Service Code	MØ: Prescriber consulted
Result of Service Code	1G: Filled with prescriber approval; 4C: Dispensed, hospice; 4D: Dispensed, cancer treatment

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.

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

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.

Reject Code	88
Reject Message	Additive toxicity alert: review history of benzodiazepine use; enter DUR codes is safe and appropriate
Reject Message	Additive toxicity alert: review history of opioid use; enter DUR codes is safe and appropriate

Resolution	Service codes may be entered only after verifying that it is safe and appropriate for the Member to use opioid analgesics along with benzodiazepines.
Reason for Service Code	AT: Additive toxicity
Professional Service Code	MØ: Prescriber consulted; MR: Medication review
Result of Service Code	1B: Filled prescription as-is; 1G: Filled with prescriber approval; 4C: Dispensed, hospice; 4D: Dispensed, cancer treatment

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.

Reject Code	88
Reject Message	Opioid dependence treatment alert: enter DUR codes if appropriate to use opioids with Buprenorphine
Resolution	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.
Reason for Service Code	DC: Drug-disease (inferred)
Professional Service Code	MØ: Prescriber consulted; MR: Medication review
Result of Service Code	1B: Filled prescription as-is; 1G: Filled with prescriber approval; 4C: Dispensed, hospice; 4D: Dispensed, cancer treatment

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)

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 website. 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 Elixir of Pharmacy closures, acquisitions and mergers. Once Elixir 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, Elixir 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, Elixir 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. Elixir 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

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

¹ **Resources/Further Information:** FDA NDC Directory <http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm>

FDA NDC Directory FAQs <http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm>

FDA Orange Book <http://www.fda.gov/cder/ob/default.htm>

FDA Orange Book FAQs <http://www.accessdata.fda.gov/scripts/cder/ob/faqlink.cfm>

Medicare Prescription Drug Benefit Manual, Chapter 6 - Part D Drugs and Formulary Requirements

<http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Chapter6.pdf>

CMS Memo - Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance <http://www.fdaawblog.net/files/link-12.pdf>

² **Resources/Further Information:** Further CMS Guidance and Information regarding unique BIN requirements can be found at the following locations: CMS Memo- Clarification of Unique BIN (or BIN/PCN) Requirements as of January 1, 2012

http://www.cms.gov/PrescriptionDrugCovContra/Downloads/HPMSClarificationofUniqueBINRequirements_110810.pdf and

CMS 2102 Combined Call letter- <http://www.cms.gov/PrescriptionDrugCovContra/Downloads/Announcement2012final2.pdf>

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 and 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 Elixir 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 Elixir 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, Elixir 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 Elixir 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.

In the LTC setting, after the ninety (90) day transition period has expired, Elixir 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

³ **Resources/Further Information:** http://www.cms.gov/PrescriptionDrugCovContra/Downloads/MemoTransitionReminder_082710.pdf
Reminder of the Part D Transition Policy
http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoTransitionReminder_082710.pdf

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 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.⁴

Elixir 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, Elixir 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

⁴ **Resources/Additional Information:** NCPDP website <http://www.NCPDP.org/>

Medicare Prescription Drug Coverage and Your Rights

CMS Memorandum on Revised Guidance for Distribution of Standardized Pharmacy Notice (CMS-10147) to Medicare Advantage Organizations and Medicare Prescription Drug Plan Sponsors dated December 27, 2012, available at elixirsolutions.com

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 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

Elixir 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, Elixir will notify all Pharmacies with prior Claims for the Member to request the Claims be reversed and billed to the hospice provider. Elixir will send the hospice provider contact information to the Pharmacy if available.⁶

⁵ Resources/Additional Information:

Medicare Prescription Drug Coverage and Your Rights <http://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/downloads/yourrightsfactsheet.pdf>

⁶ CMS 2014 for Medicare Advantage Call Letter for 2014 Hospice Drug Policy - <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Advance2014.pdf>

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. Elixir will only accept Claims for a valid Type I Prescriber NPI.

Elixir 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.

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> or <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.

FIELD NAME	DEFINITION / VALUES
Pharmacy Service Type	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
Patient Residence	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
Submission Clarification Code	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
34 – LTC dispensing, 14 day supply
35 – LTC dispensing, 8-14 day dispensing not listed above
36 – LTC dispensing, outside short cycle, determined to be Medicare Part D after originally submitted to another payer

REQUIREMENTS 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.

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

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.

Valid Pharmacy Service Codes
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

**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.⁷

MEDICARE PART D AUTO REFILL

Effective January 1, 2020, CMS allows Plan Sponsors to opt-in to a voluntary auto-ship program. These Members can now fulfill auto-refills without an affirmative response with each refill. If a plan opts in, the following requirements need to be met:

- Consent needs to be received after an initial fill of a new drug
- Opt-in is on a drug-by-drug basis
- Allow opt-out at any time
- Minimum of two shipping reminders
- Full refund policy for any refills that an enrollee reports as unneeded or unwanted. The claim should be reversed and cost-sharing returned.

If you have any questions regarding a Member's eligibility for the Medicare auto-ship program, please contact the Pharmacy Help Desk.

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

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 elixirsolutions.com

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.

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).

9. **Low Income Subsidy (LIS) Level 3 Long Term Care (LTC) Claims:** For claims processed that are for a LIS Level 3 LTC member, the pharmacy should not collect the member copayment or reprocess the claim. Elixir will reverse and reprocess qualifying claims and if applicable, reimburse the pharmacy for any additional payment that is owed. The pharmacy is required to reimburse the member if a copayment was collected.

STATE SPECIFIC PROVISIONS

CALIFORNIA – MANAGED HEALTH CARE

Pharmacists may have the right to submit complaints under Cal. Health & Safety Code § 1371.39 and pharmacists may have rights as a provider under Cal. Health & Safety Code § 1375.7. The Pharmacy can visit <https://www.dmhc.ca.gov/AbouttheDMHC/ContactUs.aspx> for more information.

MICHIGAN MEDICAID HEALTH PLAN DISPENSING FEE

As a requirement for Michigan Medicaid Health Plans, Elixir pays qualifying pharmacies in compliance with Michigan Medicaid Health Plan dispensing fee requirements.

NEW JERSEY - COMMERCIAL LINE OF BUSINESS

The following provisions shall govern the contractual relationship between Elixir and Pharmacies in the State of New Jersey:

- A. **Non-Clinical Claims Determination.** If a Pharmacy disagrees with Elixir non-clinical Claim determination for a commercial Claim payable by a fully-insured entity, the Pharmacy may initiate an appeal by submitting to Elixir 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.

Elixir 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 Elixir, 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, Elixir 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. Elixir 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, Elixir 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 Elixir 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.** Elixir 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 Elixir 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. Elixir 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 Elixir. 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

Elixir 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 Elixir 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 Elixir 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 Elixir 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, Elixir 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

ANDA	Abbreviated New Drug Application
AWP	Average Wholesale Price
BLA	Biologics License Application
CFR	Code of Federal Regulations
CMS	The Center for Medicare and Medicaid Services
COB	Coordination of Benefits
DAW	Dispense as Written
DDPS	Drug Data Processing System
DEA	Drug Enforcement Administration
DUR	Drug Utilization Review
FDA	Food and Drug Administration
FWA	Fraud, Waste and Abuse
HHS	Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
IC	Ingredient Cost
LEP	Limited English Proficiency
LTC	Long Term Care
MAC	Maximum Allowable Cost
NCPDP	National Council for Prescription Drug Programs
NDA	New Drug Application
NDC	National Drug Code
NPI	National Provider Identifier
NSDE	NDC Structured Product Labeling Data Element
OIG	Office of Inspector General
OPA	Other Payer Amount
OPPRA	Other Payer-Patient Responsibility Amount
OTC	Over-the-Counter
PBM	Pharmacy Benefit Manager
PDEs	Prescription Drug Events
POS	Point Of Sale
PPA	Participating Provider Agreement
PRA	Patient Responsibility Amount
PSAO	Pharmacy Services Administration Organization
TrOOP	True Out Of Pocket
U&C	Usual and Customary
USPS	United States Postal Services