INDIANA HEALTH COVERAGE PROGRAMS

PROVIDER REFERENCE MODULE

Pharmacy Services

Note:	*This module is intended as a policy and procedure reference for the Indiana Health Coverage Programs (IHCP) **fee-for-service** (FFS) pharmacy benefit only. For information pertaining to **managed care** pharmacy benefits – including those covered under the Healthy Indiana Plan (HIP), Hoosier Care Connect or Hoosier Healthwise programs – see the links for the IHCP-contracted managed care entities (MCEs), available on the Pharmacy Services page at in.gov/medicaid/providers.* *For updates to information in this module, see IHCP Banner Pages and IHCP Bulletins at in.gov/medicaid/providers.*

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Revision History

Version	Date	Reason for Revisions	Completed By
1.0	Policies and procedures as of Oct. 1, 2015 Published: Feb. 25, 2016	New document	FSSA, OptumRx, and HPE
1.1	Policies and procedures as of April 1, 2016 Published: June 23, 2016	Scheduled update	FSSA, OptumRx, and HPE
1.2	Policies and procedures as of April 1, 2016 (*Core*MMIS updates as of Feb. 13, 2017) Published: Feb. 13, 2017	*Core*MMIS update	FSSA, OptumRx, and HPE
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7.0	Policies and procedures as of Jan. 1, 2023 Published: March 31, 2023	Scheduled update: • Revised "OptumRx" to "Optum Rx" • Updated the *Fee-for-Service Pharmacy Benefit Manager* section and *Table 2 – Websites for IHCP Pharmacy Providers* to include references to Contraception Formulary, Preferred Diabetes Supply List, and COVID-19 OTC Test Kits and Vaccination Information • Updated the introduction to *Section 2: Pharmacy Coverage and Reimbursement* • Updated the *Vaccination Administration Fee* section to reflect that pharmacies may now participate in the VFC program	FSSA, Optum Rx and Gainwell

Version	Date	Reason for Revisions	Completed By
		• Updated the *OTC Drug Formulary, Pharmacy Supplements Formulary and Contraception Formulary* section to add references to the Contraception Formulary • Updated the *Preferred Diabetes Supply List Products* section, including adding information about CGM items and replacing the PDSL table with a reference to the version online • Added the *Compound Prescription Claims – Billing and Reimbursement* section • Added PROS agents to *Table 5 – Exclusions to $5,000 Limit* • Added codes to *Table 8 – Valid Patient Gender Code Values (Field 305-C5)* • Added *Prescription Origin Codes* section • Added reference to Medicare Part C in the *Claim Processing for Dually Eligible (Medicare and Medicaid) Members* section • Added where to find additional information for DUR requirements to the introductory text of *Section 6: Drug Utilization Review Processes* • Updated the *On-Site Audits* section to add a reference to consultation documentation • Updated the *Proof of Delivery* section	

Table of Contents

Section 1: Introduction

The Indiana Health Coverage Programs (IHCP) is administered by the Indiana Family and Social Services Administration (FSSA), with policy and operational oversight provided through the FSSA Office of Medicaid Policy and Planning (OMPP). This document provides relevant information about the IHCP pharmacy benefit.

Updates to this document are issued periodically. In the interim, providers should read and retain the bulletins and banner pages published by the IHCP. Current and archived copies of these publications are accessible from the *Bulletins, Banner Pages and Reference Modules* page at in.gov/medicaid/providers. These publications advise providers of program changes that occur between published updates to this document.

The IHCP pharmacy benefit is a dynamic program and, as such, this document does not contain all applicable information. A significant amount of program information is available and maintained in an up-to-date format at the websites listed on the *Pharmacy Services* page at in.gov/medicaid/providers.

All payments made to providers are subject to audit and recoupment based on requirements listed in this module.

Pharmacy Benefit Managers

The FSSA contracts with other entities to serve as pharmacy benefit managers (PBMs) for IHCP members:

- PBMs contracted with each of the five managed care entities (MCEs) serving Healthy Indiana Plan (HIP), Hoosier Care Connect and Hoosier Healthwise members manage pharmacy benefits and process pharmacy claims for IHCP managed care programs.
- Optum Rx serves as the PBM and pharmacy claim processor for IHCP fee-for-service (FFS) programs.

Pharmacy providers can verify whether a member's coverage is FFS or managed care and obtain MCE assignment information through the Eligibility Verification System (EVS) options:

- IHCP Provider Healthcare Portal, accessible from the home page at in.gov/medicaid/providers
- Interactive Voice Response (IVR) system at 800-457-4584
- 270/271 electronic transactions

The PBM information may also be listed on the member's ID card. For more information on IHCP programs, see the *Member Eligibility and Benefit Coverage* module.

Managed Care Pharmacy Benefit Managers

Pharmacy providers can contact the IHCP member's MCE (or its associated PBM) for questions about pharmacy services covered under the managed care pharmacy benefit. See the *IHCP Quick Reference Guide* at in.gov/medicaid/providers for contact information. Links to the PBMs for managed care programs can be found on the *Pharmacy Services* page at in.gov/medicaid/providers.

Fee-for-Service Pharmacy Benefit Manager

As PBM for the fee-for-service pharmacy benefit, Optum Rx has the following responsibilities:

- Prior authorization (PA) and related clinical call center operations
- Preferred Drug List (PDL) development and maintenance
- Over-the-Counter (OTC) Drug Formulary, Pharmacy Supplements Formulary and Contraception Formulary maintenance
- Preferred Diabetes Supply List (PDSL) maintenance
- COVID-19 OTC Test Kits and Vaccination Information
- Drug Utilization Review (DUR) Board and Therapeutics Committee and Mental Health Quality Advisory Committee (MHQAC) support functions
- Federal and state supplemental drug rebate program administration (see the *Federal Rebate Program* section)
- Required federal and state reporting
- Stakeholder communications
- Retrospective Drug Utilization Review (retro-DUR)
- Adjudication of and payment for pharmacy claims
- Pharmacy benefit systems support
- Pharmacy-related provider and member assistance functions
- Administration and maintenance of the Indiana Medicaid Maximum Allowable Cost (state MAC) program, including development of state MAC rates (see the *State Maximum Allowable Cost Program* section)
- Development and maintenance of state MAC rates for OTC Drug Formulary, Pharmacy Supplements Formulary and Contraception Formulary
- Audits, including real-time audits, self-audits, desk audits, invoice audits and on-site audits

See Table 1 for FFS pharmacy-related contact information. Optum Rx hosts technical and clinical help desks via a call center (referred to as the Optum Rx Clinical and Technical Help Desk). The Optum Rx Clinical and Technical Help Desk is open 24 hours a day, seven days a week and can be contacted toll-free at 855-577-6317. All pharmacy and member calls directly related to FFS pharmacy claim processing or pharmacy-related inquiries, including clinical inquiries or requests for FFS pharmacy prior authorization, should be directed to Optum Rx. Calls related to provider enrollment, physician-administered drugs, the IHCP Provider Healthcare Portal (IHCP Portal) and all other nonpharmacy calls are handled by Gainwell Technologies, which can be contacted toll-free at 800-457-4584.

Table 1 – Fee-for-Service Pharmacy Benefit Contact Information

Contact Information	Reason for Contact
Optum Rx Clinical and Technical Help Desk: Telephone: 855-577-6317 Fax: 855-678-6976 PA Fax: 855-577-6384	All pharmacy and member calls directly related to FFS pharmacy prior authorization or claim processing, including clinical inquiries and requests for pharmacy PA
State of Indiana Optum Rx Pharmacy Audit Department 150 W. Market Street, Suite 300 Indianapolis, IN 46204 Fax: 866-926-0168 Email: Rxaudit.INM@Optum.com	Pharmacy audit documentation and questions regarding the pharmacy audit process, including documentation requirements
MS07 Pharmacy Benefit Contract Manager Indiana Family and Social Services Administration Office of Medicaid Policy and Planning, Pharmacy Unit 402 W. Washington St., Room W374 Indianapolis, IN 46204	Appeals of pharmacy audit
Optum Rx – PA P.O. Box 44085 Indianapolis, IN 46244-0085	Administrative review requests related to pharmacy prior authorization determinations
Optum Rx – Manual Claim Processing P.O. Box 29044 Hot Springs, AR 71903	Paper claims (including paper replacement claims)
Optum Rx electronic funds transfer (EFT) Fax: 866-244-8543	For submitting the completed *Electronic Funds Transfer (EFT) Request Form*
Provider Refund Lock Boxes: First Class Mail: Optum Rx Claims 26594 Network Place Chicago, IL 60673-1265 Courier Mail: Optum Rx Claims LBX 26594 JP Morgan Chase 131 South Dearborn – 6th floor Chicago, IL 60603	The following should be sent to either of the Provider Refund lock boxes: • Refunds • Payments • Overpayments
Optum Rx – MAC Rate Review Requests P.O. Box 44085 Indianapolis, IN 46244-0085 Optum Rx MAC Provider Relations: Telephone: 800-880-1188 Fax: 866-285-8652 Email: MAC@Optum.com	All state MAC documentation and inquiries, including state MAC rate review requests
Optum Rx Indiana Drug Rebate Operations 5775 Peachtree-Dunwoody Rd., Suite C-600 Atlanta, GA 30342 Email**:** indiana.rebates@Optum.com	Questions and correspondence related to the Indiana Drug Rebate Program

Additional Pharmacy-Related Services and Contact Information

The following sections discuss IHCP pharmacy-related functions that are not handled by the PBM.

IHCP General Provider Services

Pharmacy providers can call Gainwell Technologies at **800-457-4584** for assistance related to the following areas of responsibility:

- Member eligibility data source
- Primary third-party liability (TPL) data source
- Provider enrollment functions
- Provider communications

Drugs and Drug-Related Medical Supplies Billed on a Professional Claim

To request prior authorization for drugs and drug-related medical supplies billed as FFS on a professional claim (*CMS-1500* claim form or electronic equivalent), call the FFS medical PA contractor, Gainwell, at **800-457-4584, option 7** or send fax to **800-689-2759**. For mailing addresses and additional contact information, see the *IHCP Quick Reference Guide* at in.gov/medicaid/providers.

Right Choices Program

For information regarding the Right Choices Program (RCP) Administrator for FFS programs, contact Gainwell at **800-784-3981**. See the *Right Choices Program* module for more information about the RCP.

Websites

Table 2 provides a list of websites that IHCP pharmacy providers may find useful.

Table 2 – Websites for IHCP Pharmacy Providers

Name	Description	Address
Optum Rx Indiana Medicaid	The official website for IHCP pharmacy providers that includes fee-for-service pharmacy forms; publications; PDL; PDSL; OTC Drug Formulary; Pharmacy Supplements Formulary; Contraception Formulary; COVID-19 vaccine and OTC test coverage; PA request forms; pharmacy frequently asked questions (FAQs) for providers and members; and DUR Board, Therapeutics Committee, and MHQAC meeting agendas and minutes Includes the Indiana state MAC lists and drug rebate labelers	inm-providerportal.optum.com (accessible from the *Pharmacy Services* page at in.gov/medicaid/providers)
Indiana Administrative Code (IAC)	Regulations pertaining to the Indiana Medicaid benefit	in.gov/legislative/iac See Title 405, Office of the Secretary, FSSA

Name	Description	Address
National Plan and Provider Enumeration System (NPPES) National Provider Identifier (NPI) Lookup Tool	Provides access to provider NPIs at no charge	npiregistry.cms.hhs.gov
NPI Number Lookup Tool	Provides access to provider NPIs at no charge	npinumberlookup.org
Centers for Medicare & Medicaid Services (CMS)	The official website for CMS	cms.gov
Medicaid	The official U.S. government website for people with Medicaid	medicaid.gov
Medicare	The official U.S. government website for people with Medicare	medicare.gov

Section 2: Pharmacy Coverage and Reimbursement

The Indiana Health Coverage Programs (IHCP) fee-for-service (FFS) pharmacy benefit program operates under the following basic parameters. Providers must be aware of and abide by these provisions:

- The scope of coverage and reimbursement methodologies is as set out in the IHCP rule at *Indiana Administrative Code 405 IAC 5-24*.
- All covered drugs require a prescriber's order or prescription, as defined in Indiana Board of Pharmacy law.
- The program is a payer of medically necessary covered services provided in accordance with applicable law. The program is jointly funded by federal and state monies and, as such, is subject to federal and state requirements.
- Although the program strives to have system edits in place whenever feasible and possible to enforce program policy and parameters, **it is not systematically possible to have edits for each and every dispensing situation. Therefore, the pharmacy provider must ensure that services rendered are covered by the program, rendered in accordance with pharmacy practice law and all other applicable laws, and do not exceed any established program limits.** Payments that may result from a pharmacy provider's failure to exercise due diligence in this regard are subject to recoupment.
- Providers are required to accept IHCP reimbursement for covered services as payment in full.
- IHCP members are not required to use their Medicaid benefits.
- IHCP members are not prohibited from using an alternative payment methodology (for example, cash, discount cards, and so on) for services that are not covered by Medicaid.
  - The member must understand, before receiving the service, that the service is not covered under the IHCP and that the member is responsible for the service charges.
  - The provider must maintain documentation in the member's file that clearly demonstrates that the member voluntarily chose to receive the service, knowing it was not covered by the IHCP.
- Providers are encouraged to report issues of suspected Medicaid member fraud, such as cash payments for services covered by Medicaid that would exceed predetermined standards as outlined in *Code of Federal Regulations 42 CFR 456.709(b).* See the *Medicaid/Public Assistance Fraud* page at in.gov/fssa.

Legend Drug Coverage

The IHCP FFS pharmacy benefit program covers legend (prescription) drugs in accordance with the IHCP rule *405 IAC 5-24-3 Coverage of legend drugs*, which, at the time of publication of this document, is as follows:

***405 IAC 5-24-3* Coverage of legend drugs**

Authority: *IC 12-15-1-10; IC 12-15-21-2*
Affected: *IC 12-13-7-3; IC 12-15*

Sec. 3. (a) A legend drug is covered by Indiana Medicaid if the drug is:

(1) approved by the United States Food and Drug Administration;

(2) not designated by the Centers for Medicare and Medicaid Services (CMS) as less than effective, or identical, related, or similar to a less than effective drug;

(3) subject to the terms of a rebate agreement between the drug's manufacturer and the CMS; and

(4) not specifically excluded from coverage by Medicaid.

(b) The following are not covered by Medicaid:

(1) Anorectics or any agent used to promote weight loss.

(2) Topical minoxidil preparations.

(3) Fertility enhancement drugs.

(4) Drugs when prescribed solely or primarily for cosmetic purposes.

Medically Accepted Indication

Based on federal law *United States Code 42 USC 1396r-8*, a state may exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication.

The term "medically accepted indication" means any approved use for a covered outpatient drug under the *Federal Food, Drug, and Cosmetic Act*, or a use that is supported by one or more citations included (or approved for inclusion) in any of the following compendia:

- American Hospital Formulary Service Drug Information
- United Status Pharmacopeia-Drug Information (or its successor publications)
- DRUGDEX Information System

For an indication that is not approved by the U.S. Food and Drug Administration (FDA) (including appropriate duration for a medically accepted indication), pharmacy providers must document approved compendia supporting the indication and make the documentation available for audit review upon request. Claims that do not have a medically accepted indication documented are subject to audit and recovery.

Federal Rebate Program

Federal law requires that, for a legend or nonlegend drug to be covered by state Medicaid programs, the manufacturer must have a drug rebate agreement in effect with the Centers for Medicare & Medicaid Services (CMS).

The drug rebate program was created by the federal *Omnibus Budget Reconciliation Act of 1990* (OBRA-90) and applies to *covered outpatient drugs.* In accordance with that law, a manufacturer that holds legal title to the National Drug Code (NDC) for a prescription drug, nonprescription drug, or biological product, must have a rebate agreement with the federal government in effect to ensure coverage of its products by state Medicaid agencies. By signing the rebate agreement, a manufacturer agrees to pay each state, in the form of a rebate, a portion of the expenditure the state paid to providers for that manufacturer's covered outpatient drugs. Each calendar quarter, an invoice is produced by the state and sent to each rebating manufacturer, detailing the utilization for each NDC and the amount due the state in the form of a rebate. A complete list of manufacturers by labeler code (the first five digits of the NDC) that have entered into a rebate agreement with the federal government is available by selecting **Manufacturer Information > Drug Rebate Labelers** on the Optum Rx Indiana Medicaid website, accessible from the *Pharmacy Services* page at in.gov/medicaid/providers.

It is essential that pharmacies check this list for the status of a drug manufacturer before dispensing and submit the exact 11-digit NDC (which includes the last two digits [package size]) from the package from which the product was dispensed. Claims submitted with incorrect NDCs are subject to recoupment. If the labeler code of the manufacturer of any given drug does not appear in the list, the drug is not covered by the IHCP, and providers are not entitled to reimbursement for such products. See the *National Drug Codes – Configuration* section for more information.

Federal Drug Efficacy Study and Implementation Program

The *Federal Food, Drug, and Cosmetics Act of 1938* established the requirement that a manufacturer prove the safety of a drug before the drug could be marketed in the United States. In 1962, this act was amended to require that drugs sold in the United States be regulated more closely. All new drugs must demonstrate, via adequate studies, safety and efficacy before introduction into the market. The Drug Efficacy Study and Implementation (DESI) Program was established to ensure that drugs that did not have proven efficacy were ultimately removed from the market and not reimbursed by state Medicaid programs in the interim.

Federal law prohibits state Medicaid agencies from reimbursing for so-called less-than-effective (LTE) drugs, commonly called DESI drugs, or any drug that the federal government has determined to be identical, related or similar (IRS) to such a drug. These drugs are not covered by the IHCP, and providers are not entitled to reimbursement for them. If providers have a question about a specific drug's DESI status, they can contact Optum Rx toll-free at 855-577-6317.

Mandatory Generic Substitution and Brand Medically Necessary

Generic substitution under the IHCP FFS pharmacy benefit program is mandatory, as set out by statute at *Indiana Code IC 16-42-22-10 Substitution Prohibited.* For exceptions, the FFS Preferred Drug List quick link can be accessed from the Optum Rx Indiana Medicaid website. Pharmacy providers must be aware of the mandatory substitution law and dispense wholly in accordance with that law. Failure by the provider to do so can result in Medicaid payment that is out of accord with program policy, with the risk of recoupment. In particular, pharmacy providers must be fully aware of and dispense in accordance with the *brand medically necessary* provisions of Medicaid rule *405 IAC 5-24-8 Prior Authorization; Brand Name Drugs* and state statute *IC 16-42-22 Drugs: Generic Drugs*.

Dispense-as-Written Codes

For purposes of the IHCP FFS pharmacy benefit, only dispense-as-written (DAW) codes 0, 1, 5, 8 and 9 should be submitted by providers. Incorrect use of these codes may result in full or partial recoupment. Table 3 shows general information about these codes:

Table 3 – DAW Codes

DAW Code	Code Description
0	No product selection indicated
1	Substitution not allowed by prescriber
5	Substitution allowed-brand drug dispensed as a generic
8	Substitution allowed-generic drug not available in marketplace
9	Substitution allowed by prescriber but plan requests brand – Patient's plan requested brand product to be dispensed

*Note: Phoned-in prescriptions indicating DAW **1** must be followed up with a written or electronic request from the physician stating, "brand medically necessary" (IC 16-42-22-10(b) Substitution Prohibited). The phoned-in prescription alone, without the subsequent written or electronic prescription order indicating the brand medically necessary request, is not sufficient and the corresponding claims are subject to audit and recovery.*

Brand Medically Necessary

A prescriber's specification of *brand medically necessary (BMN), DAW code=1,* requires prior authorization (PA). The following medications do not require PA for BMN but are subject to all other BMN requirements as specified in *405 IAC 5-24-8*:

- Dilantin
- Coumadin
- Lanoxin
- Premarin
- Tegretol
- Provera
- Synthroid

Tamper-Resistant Prescriptions

All handwritten or computer-generated prescriptions processed by the IHCP pharmacy benefit must be fully compliant with CMS and state guidance for prescription tamper resistance. These prescriptions must contain *at least one* industry recognized feature *from each of the three* categories of tamper resistance:

- One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form
- One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber
- One or more industry-recognized features designed to prevent the use of counterfeit prescription forms

The Family and Social Services Administration (FSSA) suggests that prescribers consider using Indiana Board of Pharmacy security prescriptions to facilitate compliance with this mandate. The printing vendor must be registered with the state Board of Pharmacy. A listing of approved security-feature-prescription-pad vendors may be accessed from the *Pharmacy Resources* page of the Professional Licensing Agency website at in.gov/pla.

Computer-generated prescriptions *may be printed on plain paper* and be fully compliant with all three categories of tamper resistance – provided they contain at least one feature from each of the three categories. See Table 4 for the three categories and their descriptions.

Table 4 – Three Categories of Tamper Resistance

Category	Feature	Description
1. Copy Resistance	A) Void/Illegal/Copy Pantograph with or without Reverse Rx	The word "Void," "Illegal," or "Copy" appears when the prescription is photocopied.
	B) Microprint signature line for prescriptions generated by an electronic medical record (EMR) if they cannot produce Void/Illegal/Copy Pantograph with or without Reverse Rx	Very small font, which is legible (readable) when viewed at 5x magnification or greater, and illegible when copied
2. Erasure or Modification Resistance	A) Uniform nonwhite background color (for written prescriptions)	Background that consists of a solid color or consistent pattern that has been printed onto the paper. This will inhibit a forger from physically erasing written or printed information on a prescription form. If someone tries to erase or copy, the consistent background color will look altered and show the color of the underlying paper.
	B) Quantity check-off boxes, refill indicator (circle number of refills or "NR"), or border characteristics (dispense and refill # bordered by asterisks and optionally spelled out) for prescriptions generated by an EMR	In addition to the written quantity on the prescription, quantities are indicated in ranges. Quantities and refill # are surrounded by special characters, such as asterisks, to prevent modification. For example: QTY **50**
3. Counterfeit Resistance	A) Security features and descriptions listed on the prescription	A complete list of the security features on the prescription paper aids pharmacists in identification of features and determines compliance.
	B) Encoding Techniques	Bar codes on prescription. Serial number or batch number is encoded in a bar code.

In an emergency situation, a prescription written on a non-tamper-resistant pad is permitted as long as the prescriber provides a verbal, faxed, electronic or compliant written prescription within 72 hours after the date on which the prescription was filled.

Prescriptions that are telephoned, faxed or electronically prescribed (e-prescribed) are exempt from tamper-resistant prescription requirements.

For more information regarding security features, see the NCPDP letter to Medicaid directors.
For questions about tamper-resistant prescriptions, contact Optum Rx toll-free at 855-577-6317.

Legend and Nonlegend Product Reimbursement

For FFS claims, covered legend and nonlegend products (including compounds containing legend and nonlegend ingredients) are reimbursed at the lowest of the following:

- The National Average Drug Acquisition Cost (NADAC) as published by the CMS pursuant to *42 USC 1396r-8(f)*, as of the date of dispensing, plus any applicable professional dispensing fee.
- The state Maximum Allowable Cost (state MAC) as determined by the state as of the date of dispensing, plus any applicable professional dispensing fee.
- The provider's submitted charge, representing the provider's usual and customary charge for the service, as of the date of dispensing.
- The federal upper limit (FUL) as determined by the CMS pursuant to *42 CFR 447.514*, as of the date of dispensing, plus any applicable professional dispensing fee.
- The wholesale acquisition cost (WAC) according to the state's drug database file contracted from a nationally recognized source such as Medi-Span or First Databank, minus a percentage as determined by the state through analysis of the dispensing cost survey or other methodology approved by the CMS, as of the date of dispensing, plus any applicable professional dispensing fee. *(Note: The purpose of the percentage is to ensure that the applicable WAC rate sufficiently reflects the actual acquisition cost of the provider. The WAC will only be considered if there is no applicable NADAC, FUL or state MAC rate.)*

State Maximum Allowable Cost Program

State MAC rates are used for many drugs reimbursed under the IHCP fee-for-service delivery system. Optum Rx is responsible for the development and ongoing maintenance of all such rates, as well as for the day-to-day administration of the state MAC program. State MAC rates are calculated for drug groups using acquisition cost data, with a multiplier applied to ensure that the applicable state MAC rate is sufficient to allow reasonable access by providers to the drug at or below the established state MAC rate. As a condition of participation in the IHCP, pharmacies are required to provide acquisition cost data, if requested by the FSSA or its contractor. Acquisition cost data is obtained from a small group of pharmacies on a monthly basis. Only pharmacy acquisition cost observations that are within 90 days of the current month are used in the state MAC rate-setting process. On a semiannual basis, a sample of at least 150 pharmacy providers is surveyed for acquisition cost data. This sample has chain/independent and urban/rural characteristics reflective of the overall Medicaid provider population, but it excludes the providers that submit data on a monthly basis.

Optum Rx manages all aspects of the administration of the state MAC program for federal legend drugs and blood factors and establishes OTC Drug Formulary and Pharmacy Supplements Formulary MAC rates. Optum Rx is responsible for the development and ongoing maintenance of all state MAC rates, as well as for the day-to-day administration of the state MAC program. All inquiries related to the state MAC program should be directed to Optum Rx MAC Provider Relations at the telephone number or email address provided in Table 1. State MAC correspondence, including rate review requests, should be sent to the corresponding mailing address in Table 1.

Optum Rx maintains the state MAC rates. Providers may access the Indiana FFS SMAC quick link from the Optum Rx Indiana Medicaid website.

Usual and Customary Charge

Providers must bill the program for covered services with only the provider's usual and customary charge to the general public, including any special pricing (for example, $4 generic programs), for the covered service. The provider's usual and customary charge includes any dispensing fee that the provider may charge to the general public. Usual and customary charges are subject to verification by Optum Rx audits.

Professional Dispensing Fee

At the time of publication of this module, the IHCP selected a single professional dispensing fee of $10.48, which is the weighted mean cost of dispensing prescriptions to IHCP members, inclusive of both specialty and nonspecialty pharmacies. The professional dispensing fee reimbursed to pharmacy providers is determined based on a *Cost of Dispensing* survey, which is performed every two years. The survey identifies costs associated with the dispensing function of prescription services, regardless of product or setting. A provider is entitled to dispensing fees in accordance with the IHCP rule at *405 IAC 5-24-6 Dispensing Fee.* A maximum of one professional dispensing fee per month is allowable per member per drug order for legend products provided to Medicaid recipients residing in Medicaid certified long-term care facilities. Providers are not entitled to any professional dispensing fee reimbursement that is not in accordance with this requirement of law.

The practice of split-billing, defined as the dispensing of less than the prescribed amount solely for the purpose of collecting more dispensing fees than would otherwise be allowed, is prohibited. In cases in which the pharmacist's professional judgment dictates that a quantity less than the amount prescribed be dispensed, the pharmacist should contact the prescribing practitioner for authorization to dispense a lesser quantity. The pharmacist should also inform members of any additional copayments they may incur. The pharmacist must document the result of the contact and the pharmacist's rationale for dispensing less than the amount prescribed on the prescription or in the pharmacist's records. This documentation must be made available for review upon audit request.

Vaccination Administration Fee

The IHCP reimburses IHCP-enrolled pharmacy providers for covered vaccines and their administration when a pharmacist (or pharmacist's designee, if applicable) employed by the pharmacy provider administers the vaccine to eligible IHCP members 19 years of age and older. Additionally, effective March 10, 2022, the IHCP reimburses IHCP-enrolled pharmacies for the administration of covered vaccines in the Vaccines for Children (VFC) program if the pharmacy is enrolled with the Indiana Department of Health (IDOH) as a participating VFC provider. The VFC program is a federal program that provides vaccines at no cost for children under 19 years of age who are enrolled in Medicaid.

Pharmacy claims for this service must be submitted through the standard point-of-sale (POS) system or via paper pharmacy claims. Vaccinations for IHCP members who are dually eligible for Medicaid and Medicare must be billed to Medicare. The maximum allowable reimbursement for the administration component of the service is consistent with reimbursement for vaccines administered by medical providers. For vaccine administration reimbursement information, see the current Outpatient Fee Schedule and Professional Fee Schedule, accessible from the *IHCP Fee Schedules* page at in.gov/medicaid/provider.

For reimbursement consideration, the IHCP requires that prescriptions, drug orders, or protocols for vaccines administered by a pharmacist be written by an IHCP-enrolled provider that meets the requirements of *IC 25-26-13-31.2* for the following vaccines only:

- Coronavirus disease 2019 (COVID-19)
- Haemophilus influenza type B (Hib)
- Hepatitis A
- Hepatitis B
- Human papilloma virus (HPV) infection
- Influenza
- Measles, mumps and rubella
- Meningitis
- Pneumonia
- Shingles (herpes zoster)
- Tetanus, diphtheria, and acellular pertussis (whooping cough)
- Varicella

Blood Factor Reimbursement

The IHCP pharmacy program reimburses FFS claims submitted via point-of-sale for blood factor products dispensed in an outpatient pharmacy setting at the lowest of the following:

- The NADAC as published by the CMS pursuant to *42 USC 1396r-8(f)*, as of the date of dispensing, plus any applicable professional dispensing fee.
- The blood factor state MAC as determined by the state as of the date of dispensing, plus any applicable professional dispensing fee.
- The provider's submitted charge, representing the provider's usual and customary charge for the service, as of the date of dispensing.
- The FUL as determined by the CMS pursuant to *42 CFR 447.514*, as of the date of dispensing, plus any applicable professional dispensing fee.
- The WAC according to the state's drug database file contracted from a nationally recognized source such as Medi-Span or First Databank, minus a percentage as determined by the state through analysis of the dispensing cost survey or other methodology approved by the CMS, as of the date of dispensing, plus any applicable professional dispensing fee. The purpose of the percentage is to ensure that the applicable WAC rate sufficiently reflects the actual acquisition cost of the provider. The WAC will only be considered if there is no applicable NADAC, FUL or state MAC rate.

Questions regarding product availability, rates, or other related matters should be directed to the Optum Rx Clinical and Technical Help Desk: call toll-free at 855-577-6317 or fax toll-free at 855-678-6976.

The blood factor state MAC rate can be accessed from the Indiana FFS SMAC quick link on the Optum Rx Indiana Medicaid website.

Drugs Carved Out of Managed Care

The IHCP designates certain drugs as "carved-out" of the managed care delivery system. These drugs are reimbursed as FFS for all IHCP members, including those enrolled in Healthy Indiana Plan (HIP), Hoosier Care Connect and Hoosier Healthwise:

- For a list of drugs that are carved out of managed care under the **pharmacy benefit**, see *Drug Therapies Carved-Out of the Managed Care Pharmacy Benefit*, accessible from the Carved-out Drug Benefits quick link on the Optum Rx Indiana Medicaid website. All pharmacy claims and PA requests (if applicable) for these agents must be submitted to the FFS pharmacy benefit manager, Optum Rx. The FFS Preferred Drug List (PDL), prior authorization requirements, and billing guidelines apply. Questions regarding the FFS PDL, PA criteria, billing procedures, or other related matters for these drugs should be directed to the Optum Rx Clinical and Technical Help Desk; call toll-free at 855-577-6317 or fax toll-free at 855-678-6976. The FFS PDL and PA criteria can also be accessed from the Optum Rx Indiana Medicaid website.
- For a list of physician-administered drugs that are carved out of managed care under the **medical benefit**, see *Physician-Administered Drugs Carved Out of Managed Care and Reimbursable Outside the Inpatient Diagnosis-Related Group*, accessible from the *Code Sets* page at in.gov/medicaid/providers. These physician-administered drugs must be billed to Gainwell using the professional claim for all members. If applicable, PA requests must be submitted to the IHCP FFS medical PA contractor. For additional information about physician-administered drugs, see the *Injections, Vaccines and Other Physician-Administered Drug* module.

For drugs that have been designated as carved out of managed care, PA requests or claims submitted to a member's managed care entity (MCE) will be denied.

Storage and Handling Requirements

Pharmacy providers must follow all specified storage and handling requirements mandated by the U.S. FDA. Certain products must be kept in their original packaging to protect from product breakdown, loss of potency or contamination. This requirement is typically indicated on the packaging itself as well as in the manufacturer's package insert and the patient medication guide.

It is always best practice to carefully read all drug labels and medication inserts before dispensing. Claims for products not being dispensed in accordance with the FDA requirements are subject to audit and recovery.

It is critical that the "days supply" does not exceed the product's shelf life. Providers are strongly encouraged to communicate this information to the patient during counseling, with instructions to discard any product remaining after the indicated shelf life. Additionally, a days supply that exceeds the product's shelf life may cause an inappropriate "refill too soon" rejection for a refill request, leading to the member having restricted access to the medication.

OTC Drug Formulary, Pharmacy Supplements Formulary and Contraception Formulary

The Over-the-Counter (OTC) Drug Formulary, the Pharmacy Supplements Formulary and the Contraception Formulary can all be accessed from the Optum Rx Indiana Medicaid website.

The OTC Drug Formulary, the Pharmacy Supplements Formulary and the Contraception Formulary were developed and recommended to the IHCP by the Indiana Drug Utilization Review (DUR) Board. The DUR Board reviews the OTC Drug Formulary, Pharmacy Supplements Formulary and Contraception Formulary on a periodic basis to ensure that products listed on the formularies are reasonable, appropriate and medically necessary, as well as to ensure that sufficient products are included on the formularies. Providers with suggestions for inclusion of OTC drug products, pharmacy supplements or contraception products on the OTC Drug Formulary, Pharmacy Supplements Formulary or Contraception Formulary should forward the suggestions to PDL.FSSA@fssa.in.gov.

> *Note: Only **drugs** are eligible for inclusion on the OTC Drug Formulary. Nondrug items cannot be considered for inclusion. Only those drugs that are listed on the OTC Drug Formulary and are from rebating manufacturers are reimbursable by the program. The formulary is specific to drug, strength and dosage form to the extent noted on the formulary. For example, if a drug is listed on the formulary only as a 10 milligram (mg) tablet, and other strengths exist, only the 10 mg tablet is reimbursable. All drugs included on the OTC Drug Formulary have applicable MAC rates.*

Active Pharmaceutical Ingredients

According to the CMS, an active pharmaceutical ingredient (API) is a bulk drug substance. Bulk drug substance is defined by the FDA as any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in production of a drug, becomes an active ingredient in the drug product. APIs may be included in extemporaneously compounded prescriptions and may serve as the active drug component in a compounded formulation. APIs are not considered to be covered outpatient drugs and thus are not subject to the provisions of the federal rebate program. Therefore, APIs do not have to be from rebating manufacturers to be covered by the IHCP.

Covered APIs are reimbursable only when included in a compounded prescription. APIs may be billed on the *IHCP Compounded Prescription Claim Form*, a National Council for Prescription Drug Programs (NCPDP) transaction or as a professional claim (*CMS-1500* claim form, IHCP Portal professional claim or 837P electronic transaction). APIs must be billed with their corresponding NDCs.

Medical Supplies and Equipment

The IHCP has established FFS pharmacy claim and PA submission processes for Preferred Diabetes Supply List (PDSL) products, diabetes supplies and holding chambers for inhaled medications.

Durable medical equipment (DME) providers should follow the billing and PA processes outlined in the *Durable and Home Medical Equipment and Supplies* module, including for PDSL products.

Preferred Diabetes Supply List Products

The current PDSL and related information can be found on the Optum Rx Indiana Medicaid website, by selecting Preferred Diabetes Supplies List (PDSL) from the Preferred Products menu.

IHCP pharmacy providers must submit FFS claims for items on the PDSL as point-of-sale (POS) pharmacy claims to Optum Rx, using the same ID, bank identification number (BIN) and process control number (PCN) as are used for all FFS drug claims. Optum Rx will respond as follows, depending on the type of item being billed:

- For PDSL blood glucose monitors – Using POS messaging, Optum Rx will provide pharmacies with the ID, BIN, PCN and RX Group information required to *resubmit* claims for PDSL blood glucose monitors to the appropriate PDSL vendor.
- For PDSL test strips – Optum Rx will directly process claims for PDSL test strips.
- For PDSL continuous glucose monitoring (CGM) receivers, sensors and transmitters – Optum Rx will directly process pharmacy claims for CGM products.

Other Diabetes Supplies and Holding Chambers for Inhaled Medication

IHCP pharmacy providers may submit claims for the following supplies for FFS members as POS pharmacy claims to Optum Rx:

- Alcohol swabs
- Disposable insulin delivery devices
- Glucose calibration liquid
- Glucose urine testing strips
- Holding chambers for inhaled medications
- Lancets
- Lancing devices
- Needles
- Pen needles
- Sharps containers
- Syringes

Pharmacy providers should use the same ID, BIN and PCN (no RX Group code) for these supplies as are used for all FFS drug claims. The reimbursement for these supplies will be calculated at the lesser of the submitted charge or the state MAC. No professional dispensing fee will be applied.

Pharmacy Copayment

The IHCP pharmacy copayment is set out in Indiana Medicaid rule at *405 IAC 5-24-7 Copayment for legend and nonlegend drug*, which, at the time of publication of this document, is as follows:

***405 IAC 5-24-7* Copayment for legend and nonlegend drugs**

Authority: *IC 12-15-1-10; IC 12-15-21-2*
Affected: *IC 12-13-7-3; IC 12-15-6*

Sec. 7. (a) Under *IC 12-15-6*, a copayment is required for legend and nonlegend drugs in accordance with the following:

(1) The copayment shall be paid by the member and collected by the provider at the time the service is rendered. Medicaid reimbursement to the provider shall be adjusted to reflect the copayment amount for which the member is liable.

(2) In accordance with *42 CFR 447.15*, the provider may not deny services to any eligible individual on account of the individual's inability to pay the copayment amount. Under *42 CFR 447.15*, this service guarantee does not apply to an individual who is able to pay, nor does an individual's inability to pay eliminate his or her liability for the copayment.

(3) The amount of the copayment will be three dollars ($3) for each covered drug dispensed.*

The pharmacy provider shall collect a copayment for each drug dispensed by the provider and covered by Medicaid.

(b) The following pharmacy services are exempt from the copayment requirement:

(1) Emergency services provided in a hospital, clinic, office, or other facility equipped to furnish emergency care.

(2) Services furnished to individuals less than eighteen (18) years of age.**

(3) Services furnished to pregnant women if such services are related to the pregnancy or any other medical condition that may complicate the pregnancy.

(4) Services furnished to individuals who are inpatients in hospitals, nursing facilities, intermediate care facilities for individuals with intellectual disabilities, or other medical institutions.

(5) Family planning services and supplies furnished to individuals of child bearing age.

* *The copayment amount in 405 IAC 5-24-7(a)(3) is applicable to nonexempt members in all FFS programs except the following:*

- *Presumptive Eligibility–Adult (PE Adult), which has a $4 copayment for each preferred-drug prescription and an $8 copayment for each covered nonpreferred-drug prescription*
- *Package C – Children's Health Insurance Program (SCHIP) which (even when delivered as fee-for-service) has a $3 copayment for each covered generic drug dispensed and a $10 copayment for each covered name-brand drug dispensed.*

** *The exemption in 405 IAC 5-24-7(b)(2) is not applicable to Package C.*

> *Note: 42 CFR 447.15 mandates that a provider may not refuse to provide services to a member who cannot afford the copayment. IHCP policy is that the member remains liable to the provider for the copayment, and the provider may take action to collect it. The provider may bill the member for that amount and take action to collect the delinquent amount in the same manner that the provider collects delinquent amounts from private pay customers. Providers may set office policies for delinquent payment of incurred expenses including copayments. The policy must apply to private pay patients as well as IHCP members. The policy should reflect that the provider will not continue serving a member who has not made a payment on past due bills for "X" months, has unpaid bills exceeding "Y" dollars, and has refused to arrange for, or not complied with, a plan to reimburse the expenses. Notification of the policy must be made in the same manner that notification is made to private pay customers.*

Proof of copayment collection must be maintained and provided upon audit request. Documentation for claims dispensed where members are unable to pay the copayment must also be maintained and submitted upon audit request.

See the *Member Eligibility and Benefit Coverage* module for more information about copayments.

Emergency Services Only: Package E

Prescription coverage for Package E members is limited to prescriptions written during the course of a covered emergency medical service. Coverage is limited to a maximum of a four-day supply of the prescribed drug. Prospective drug utilization evaluation will be performed for the drug listed on the claim form.

For Package E pharmacy billing instructions, see the *Billing Procedures for Emergency Services Only: Package E* section.

For general information about Package E, see the *Member Eligibility and Benefit Coverage* module.

> *Note: Emergency Services Only (Package E) should not be confused with "emergency supply."*

Family Planning Eligibility Program

Prescription coverage for Family Planning Eligibility Program members is limited to supplies related to covered family planning services, including contraceptive drugs and drugs prescribed for the initial treatment of sexually transmitted diseases and infections (STDs/STIs).

See the *Family Planning Eligibility Program* module for more information.

Pharmacy Services Provided Prior to Indiana Medicaid Eligibility Determination

PA requests for pharmacy services provided prior to member eligibility determination will be considered on a case-by-case basis and only if the request form is completed and submitted by the prescribing provider within 12 months of issuance of the member's Medicaid acceptance. The request form can be accessed from the Optum Rx Indiana Medicaid website by selecting PA Criteria and Administrative Forms. If it is determined that PA criteria is applicable on the date of service, the pharmacy provider may submit a claim for service. See *IAC 405 5-3-5*, *IAC 405 5-3-9* and *IAC 405 5-3-10*.

Coverage of Drug Products for Treating Tobacco Dependence

The IHCP reimburses pharmacy providers for tobacco dependence drug products, including over-the-counter products, only when a licensed practitioner prescribes them for a member within the scope of the practitioner's license under Indiana law.

> *Note: Only patients who agree to participate in tobacco dependence counseling may receive prescriptions for tobacco dependence drug products. The prescribing practitioner may want to have the patient sign a commitment to establish a "quit date" and to participate in counseling as the first step in tobacco dependence treatment. A prescription for such products serves as documentation that the prescribing practitioner has obtained assurance from the patient that counseling will occur concurrently with the receipt of tobacco dependence drug products. See the Behavioral Health Services module for information about tobacco dependence counseling, including reimbursement.*

The list of tobacco dependence drug products covered by the IHCP includes, but is not limited to, the following:

- Sustained-release bupropion products
- Varenicline tablets
- Nicotine replacement drug products, such as a patch or gum

The IHCP enhanced its coverage of tobacco dependence drug treatment to allow preferred agents, including Chantix, to be used as first-line therapy and to allow the use of Chantix concurrently with other nicotine replacement therapy. Additionally, the IHCP removed the requirement to obtain prior authorization for the use of tobacco dependence drug products exceeding 180 days.

Pharmacy Reimbursement of Methadone

IC 12-15-35.5-7.5 allows Medicaid reimbursement for methadone on a pharmacy claim if the drug is prescribed for the treatment of pain or pain management. Accordingly, the IHCP reimburses pharmacy claims for methadone only under the following conditions:

- The drug must be prescribed for the treatment of pain or pain management.
- The daily dosage cannot exceed 60 milligrams without PA.
- A daily dosage greater than 60 milligrams requires PA based on proof of medical necessity.

Compound Prescription Claims – Billing and Reimbursement

The IHCP requires pharmacies to enter the Compound Ingredient Drug Cost (449-EE) field of the *NCPDP Version D.0 Transaction Payer Sheet* for compound ingredients. The Compound Ingredient Drug Cost value should be present for each ingredient submitted in the compound claim, in addition to the gross amount due for the entire product.

Compound submissions with unidentifiable ingredients ("dummy NDCs") will be rejected with code 771 – *Compound contains unidentifiable ingredient(s); submission clarification code override not allowed.* Reject code 771 notifies the pharmacy that the claim-processing vendor, Optum Rx, does not recognize one or more ingredients submitted on the compound claim. The pharmacy cannot resubmit the claim with a

submission clarification code of 08 to override this edit for unidentifiable ingredients. The 08 submission clarification code may still be used to override compound items with valid, but nonreimbursable NDCs. Reimbursement will only be provided for valid and reimbursable NDCs. If a reject code 771 value is received, the pharmacy must obtain and use a product with a recognizable NDC for reimbursement, except for water and flavoring agents. For compounds containing water and flavoring agents, the claim submission should exclude these products. The complete list of ingredients, including water and flavoring agents, should still be included on the pharmacy's compound worksheet.

FFS pharmacy claims for compounds containing legend and nonlegend drugs are reimbursed according to the methodology described in the *Legend and Nonlegend Product Reimbursement* section.

Compounded Prescription Claims Equal to or Greater Than $500

All compounded prescription claims with submitted charges equal to or greater than $500 require PA. The purpose of the PA requirement is to confirm the accuracy of the claim and determine the medical necessity of the prescribed compound.

Compounded prescription claims with charges equal to or greater than $500 that are submitted via point of sale (POS) without PA will be rejected with a message stating, "Compounded claims >/= $500 require prior authorization."

These guidelines should be followed:

- If the submitted charge and quantity dispensed on the claim are not correct, the pharmacy provider can correct the information and resubmit the claim.
- If the submitted charge and quantity dispensed on the claim are correct, the prescriber must contact Optum Rx for PA by calling toll-free at 855-577-6317.

Prescribers requesting PA should complete a *Compound Claim Prior Authorization Form* and fax it to the Optum Rx Clinical and Technical Help Desk at 855-577-6384. An Optum Rx clinical pharmacist will review the request and approve or deny it within 24 hours.

Pharmacy PA criteria and PA forms are available under the Optum Rx Indiana Medicaid website.

Pharmacy Claims Equal to or Greater Than $5,000

Pharmacy claims with submitted charges equal to or greater than $5,000 are denied (excluding the drug classes listed in Table 5). If the submitted charge and quantity dispensed on the claim are not correct, the pharmacy provider can correct the information and resubmit the claim. If the submitted charge and quantity dispensed on the claim are correct, the prescriber must contact Optum Rx for medical necessity PA by calling toll-free at 855-577-6317.

Table 5 – Exclusions to $5,000 Limit

Drug Class Description	Full Exclusion/ Partial Exclusion from Limit	Notes
Adrenocorticotrophic hormones	Full	
Agents to treat multiple sclerosis	Full	
Alkylating agents	Full	
Alpha-1-proteinase inhibitors	Full	
Anticonvulsants	Partial	

Drug Class Description	Full Exclusion/ Partial Exclusion from Limit	Notes
Antihemophilic factors	Full	
Antiinfectives, erythromycin	Partial	
Anti-inflammatory tumor necrosis factor inhibitor	Full	
Antileprotics	Partial	Thalomid requires PA
Antimalarials	Partial	
Antineoplastic – mTOR kinase inhibitors	Full	
Antineoplastic immunomodulator agents	Full	
Antineoplastic systemic enzyme inhibitors	Full	
Antineoplastic, histone deacetylase inhibitors, HDIS	Full	
Antineoplastics antibody/antibody-drug complexes	Full	
Antipsychotics	Partial	
Antisera	Full	
Antiviral monoclonal antibodies	Full	
Antivirals, HIV-specific, fusion inhibitors	Full	
CXCR4 chemokine receptor antagonist	Full	
Cystic fibrosis agents	Partial	
Drugs to treat hereditary tyrosinemia	Full	
Gastric enzymes	Partial	Sucraid requires PA
Growth hormones	Full	
Hematinics, other	Full	
Heparin and related preparations	Full	
Hepatitis C Treatment Agents	Full	
Immunomodulators	Full	
Leukocyte (WBC) stimulants	Full	
LHRH (GNRH) agonist analog pituitary suppressants	Full	
Metabolic DX enzyme replace, mucopolysaccharidosis	Full	
Metabolic modifiers	Partial	
Metallic poison, agents to treat	Full	
Monoclonal Antibodies to IG	Full	
Movement disorders (drug therapy)	Full	
Opioids, sublingual fentanyl	Partial	
PIK3CA-related overgrowth spectrum (PROS) agents	Full	
PKU Tx Agent	Full	
Pulmonary anti-HTN, endothelin receptor antagonist	Full	
Pulmonary anti-HTN, sel. C-GMP phosphodiesterase T5 inhibitor	Full	
Pulmonary antihypertensives, prostacyclin-type	Full	
Sickle cell agents	Partial	
Systemic enzyme inhibitors	Full	
Thrombopoetin receptor agonists	Partial	

Pharmacy Claims Equal to or Greater Than $10,000

Pharmacy claims with submitted charges equal to or greater than $10,000 are denied for the drug classes listed in Table 6. If the submitted charge and quantity dispensed on the claim are not correct, the pharmacy provider can correct the information and resubmit the claim. If the submitted charge and quantity dispensed on the claim are correct, the prescriber must contact Optum Rx for PA by calling toll-free at 855-577-6317.

Table 6 – Drug Classes with $10,000 Limit

Drug Class Description	Full Inclusion/Partial Inclusion in the Limit
Aminoglycosides	TOBI inhalation solution only
Anticonvulsants	Sabril packets and tablets only
Antimetabolites	Xeloda only
ARTV CMB Nucleoside	Atripla only
Drugs to Tx Chronic Inflammation Disease of Colon	Cimzia only
Hepatitis C Treatment Agents	Full
Monoclonal Antibodies to IG	Full
Skeletal Muscle Relaxants	Lioresal IT only

Section 3: Pharmacy Billing Policy and Procedures

This section outlines Indiana Health Coverage Programs (IHCP) pharmacy billing policy and procedures.

Methods of Submitting IHCP Drug Claims

Pharmacy providers can submit IHCP drug claims by the following methods:

- Point-of-sale (POS) transaction
- Paper pharmacy claim forms
- Professional billing (*CMS-1500* claim form or electronic equivalent)

POS Transaction

In a POS transaction, the pharmacy enters the Member ID (also known as RID) and the prescription information into the pharmacy computer and transmits the claim using the approved telecommunication or switching vendor and any National Council for Prescription Drug Programs (NCPDP) version D.0. From that information, online, real-time claim editing, including the posting of Prospective Drug Utilization Review (pro-DUR) alerts, occurs within seconds. Responses to the provider are based on the submitted information and historical paid claim information. For claim-formatting information, providers should review the *IHCP Companion Guide: NCPDP Version D.0 Transaction Payer Sheet* (FFS NCPDP D.0 payer sheet) available from the Optum Rx Indiana Medicaid website, accessible through the Optum Rx link on the *Pharmacy Services* page at in.gov/medicaid/providers.

> *Note: Pharmacy claims for Package E members cannot be submitted via POS transaction. Package E pharmacy claims must be submitted using the appropriate paper claim form (IHCP Drug Claim Form or the IHCP Compounded Prescription Claim Form). See the Billing Procedures for Emergency Services Only: Package E section for complete billing instructions.*

Paper Pharmacy Claim Forms

Paper pharmacy claim forms, as well as detailed billing instructions, are available on the Optum Rx Indiana Medicaid website. Providers must submit all paper pharmacy claims to Optum Rx at the following address:

Optum Rx – Manual Claim Processing
P.O. Box 29044
Hot Springs, AR 71903

Because of the mandatory use of the National Provider Identifier (NPI) for IHCP claims, the *IHCP Compounded Prescription Claim Form* and the *IHCP Drug Claim Form* must be submitted to the IHCP with NPI information in the billing provider and prescriber fields. If these forms are not submitted with the prescriber's NPI, the IHCP returns the unprocessed claim form to the provider.

Professional Billing – Paper and Electronic Claims

For detailed instructions on billing professional claims using the *CMS-1500* claim form, 837P electronic transaction or IHCP Provider Healthcare Portal (IHCP Portal) professional claim, see the *Claim Submission and Processing* module.

> *Note: Providers must submit the product National Drug Code (NDC), the NDC unit of measure (UOM) and NDC quantity of units, along with the procedure code, when submitting claims to the IHCP for all procedure-coded drugs. For more information, see the Injections, Vaccines and Other Physician-Administered Drugs module.*

Timely Filing Limit for Claim Submissions

The timely filing limit on claims for services rendered through the fee-for-service (FFS) delivery system is **180 calendar days from the date of service**.

See the *Claim Submission and Processing* module for more information about the timely filing limit, including exceptions and extensions.

Claim Reimbursement Adjustments

Adjustments may be initiated only when an incorrect payment has been made on a claim, including a claim that incorrectly paid zero dollars. The following rules also apply to filing limitations related to claim adjustments:

- When a payment is made by Medicare, a crossover claim is not subject to the filing limit. (Medicare-denied services are not considered crossover claims and are not exempt from the filing limit.)
- Overpayment adjustment requests are not subject to the timely filing limit. Any overpayment identified by a provider must be returned to the IHCP regardless of the filing limit.

Claims are submitted for adjustment following NCPDP standards.

Mandatory Reversal of Paid Claims for Unclaimed "Return-to-Stock" Prescriptions

If prescriptions are unclaimed (filled but not delivered to or obtained by the member or the member's representative) and the claims for those prescriptions have been submitted to and reimbursed by the program, the claims must be reversed within 15 calendar days from the claim's date of fill. Claims for prescriptions that are unclaimed but not reversed within 15 calendar days are subject to audit and recovery.

General Billing Information

The following sections provide some general information about billing IHCP pharmacy claims.

Pharmacy Drug File – Medi-Span

The IHCP uses Medi-Span for pharmacy product data to process drug claims. Medi-Span provides Optum Rx with daily updates of the Master Drug file, which is the most comprehensive database of drug product. In addition, the Medi-Span drug file provides Prospective Drug Utilization Review (pro-DUR) criteria.

Place of Service Code Required for Pharmacy Claims

The IHCP requires the place of service code (NCPDP field 307-C7) on all FFS pharmacy claims. Place of service codes specify the setting in which the member received pharmacy services. FFS claims submitted by providers with a nonvalid or null (missing) place of service code will be rejected with the message "*missing or invalid (M/I) place of service code*." For a list of place of service codes, see the *IHCP Companion Guide: NCPDP Version D.0 Transaction Payer Sheet* (FFS NCPDP D.0 payer sheet) available from the Optum Rx Indiana Medicaid website.

Billing Units

Billing units for some drug products, such as tablets or capsules, are easy to determine; they are billed as *each*. Correct billing units for injectable products and other products are not as easy to determine. The claim-processing system is designed to identify potentially misbilled units. Even with these edits, some products result in a large number of manufacturer rebate disputes, due to provider misunderstanding of correct billing units.

The IHCP accepts only the following three billing units:

- Each (ea) – Billing unit for capsules, tablets, kits, and vials for reconstitution
- Milliliters (ml) – Billing unit for liquid dosage form having a uniform concentration
- Grams (gm) – Billing unit for products packaged by weight, such as ointments, creams and powders that are reconstituted for injection

Common Billing Errors

Analysis consistently reveals the following factors as the most common causes for rebate disputes:

- Incorrect billing unit, such as billing for the number of milliliters in a vial instead of billing *each* to specify the entire contents of the vial
- Provider data entry errors, including those involving decimal or fractional quantities
- Units billed exceeding what would be expected as being within the normal range for the product
  - For example, the billed units appear inconsistent with a normally dispensed quantity.
- Submitted charge on the claim suggesting a generic might have been dispensed when a brand name NDC was submitted on the claim
- Products that the manufacturer distributes in a box or package, but the units are individually labeled with the drug name, expiration date, lot number and NDC
  - These products should be dispensed as individual units to dispense the proper quantity prescribed and for the days supply billed.
- Quantities submitted for topical products that suggest a partial amount of the package was dispensed or multiple package sizes were used to dispense a certain quantity
- Days supply for insulin products not calculated based on units used per day
  - "Sliding scale" or "as directed" without a daily maximum is not sufficient.
- Drugs administered for a single dose, but dose covers a greater days supply than "1"
  - These drugs should be billed with the days supply of total coverage. For example, Medroxyprogesterone Injection for contraception is administered once every 90 days; correct days supply is 90, not 1.

National Drug Codes − Configuration

Each medication is assigned a unique three-segment number. This number is known as the NDC, and it identifies the labeler or vendor, product, and package size.

The NDC of a dispensed drug must be used on the claim submitted to Optum Rx for the drug and **must match** the code on the package or container from which it was dispensed. NDCs must be configured as follows, to match to the Medi-Span drug file:

- Labeler code (assigned by the Food and Drug Administration [FDA]) – First five digits
- Product code (drug name, strength, dosage form) – Next four digits
- Package code (size of package) – Last two digits

NDCs submitted to the IHCP must be exactly 11 digits in length and must follow this 5-4-2 configuration. If the product label displays the code using fewer than 11 digits, a zero must be added at the beginning of the appropriate segment to achieve the 5-4-2 format. Hyphens and spaces are omitted when submitting the NDC number on a claim. For example, if a package displays an NDC as 12345-1234-1, a zero must be added to the beginning of the third segment to create an 11-digit NDC as follows: **12345123401**. If a package displays an NDC as 12345-123-01, a zero must be added to the beginning of the second segment to create an 11-digit NDC as follows: **12345012301**

An improperly configured NDC that does not match the corresponding code listed on the drug pricing file results in denial of the billed service because the improperly configured code is not recognizable to the claim-processing system. NDCs submitted that do not exactly match the NDC dispensed are subject to audit and full recovery. Providers with questions about the correct configuration of codes they are attempting to bill should contact Optum Rx toll-free at 855-577-6317.

Patient Residence Code

It is the responsibility of the pharmacist or pharmacy dispensing the prescription to ensure that the Patient Residence (NCPDP field 384-4X) is populated correctly. See Table 7 for the list of valid values for the Patient Residence field.

Table 7 – Patient Residence Codes

Code	Description
1	Home
2	Skilled nursing facility
3	Nursing facility
4	Assisted living facility
5	Custodial care facility
6	Group home
7	Inpatient psychiatric facility
9	Intermediate care facility for individuals with intellectual disability
11	Hospice
12	Psychiatric residential treatment facility
13	Comprehensive inpatient rehabilitation facility

Pharmacies use the Patient Residence field to communicate to the IHCP whether a member is a resident of a long-term care (LTC) facility. Patient residence values drive the following:

- Number of allowable dispensing fees when a member is in an LTC facility
- Elimination of copays when a member is in an LTC facility
- Adjudication of claims for services that are reimbursed *per diem* in an LTC facility and not separately billable to the IHCP
- Appropriate retro-Drug Utilization Review (DUR) screening

The use of this field in claim adjudication is subject to pharmacy audit. Providers should direct questions about the patient residence code to the Optum Rx Clinical and Technical Help Desk by calling toll-free 855-577-6317.

Patient Gender Code and Pregnancy Indicator

The IHCP requires inclusion of a Patient Gender Code (NCPDP field 305-C5) on all FFS pharmacy claims. See Table 8 for a list of valid Patient Gender Code values.

Table 8 – Valid Patient Gender Code Values (Field 305-C5)

Code	Description
0	Not specified/Unknown
1	Male
2	Female
3	Non-binary
4	Unidentified

The IHCP will reimburse FFS pharmacy claims submitted with a Pregnancy Indicator (NCPDP field 335-2C) of "2 – Pregnant*"* only if the Patient Gender Code is "2 – Female.*"* All claims submitted with a Patient Gender Code other than "2 – Female" combined with a *Pregnancy Indicator* of "2 – Pregnant*"* will be rejected. The Pregnancy Indicator is used to notify the payer that the member is pregnant and, therefore, excluded from the copayment requirement. See Table 9 for a list of valid Pregnancy Indicator values.

Table 9 – Valid Pregnancy Indicator Values (NCPDP Field 335-2C)

Code	Description
Blank	Not specified/Unknown
1	Not Pregnant
2	Pregnant

The pharmacy provider is responsible for ensuring that the Patient Gender Code and Pregnancy Indicator fields are populated correctly. The use of these fields in claim adjudication is subject to pharmacy audit.

National Provider Identifier

The National Provider Identifier (NPI) is a *Health Insurance Portability and Accountability Act* (HIPAA) Administrative Simplification Standard. The NPI is a unique identification number for covered health care providers. Covered healthcare providers and all health plans and healthcare clearinghouses must use the NPIs in the administrative and financial transactions adopted under HIPAA.

The Family and Social Services Administration (FSSA) and its contractors monitor providers' compliance to NPI requirements via postpayment review and, if necessary, refer noncompliant providers to the Indiana Medicaid Fraud Control Unit (IMFCU).

Pharmacy Provider Identifier

Identification of the pharmacy provider is necessary for the IHCP to maintain compliance with federal requirements. All pharmacy claims require the pharmacy provider's 10-digit NPI in the **Service Provider ID** field.

Prescribing Provider Identifier

Identifying the prescriber is necessary for the state to maintain compliance with federal requirements for a Drug Utilization Review (DUR) program. Without this information, the effectiveness of DUR is significantly compromised. Pharmacy claims require the 10-digit NPI in the **Prescriber ID** field on all pharmacy claims. If the dispensing pharmacy does not know the NPI for the prescribing practitioner, the pharmacy can contact the prescriber directly to attain the NPI. Also, see the *National Provider Identifier* page at in.gov/medicaid/providers, *NPPES NPI Registry* at cms.hhs.gov and *NPI Number Lookup* at npinumberlookup.org for more assistance.

Key claim-processing points include the following:

- Except in the case of an emergency supply, the prescribing provider must be enrolled in the IHCP:
  - Use the Ordering, Prescribing or Referring (OPR) Provider Search tool, accessible from in.gov/medicaid/providers, to determine if the prescribing provider is enrolled in the IHCP.
  - If the prescriber is not enrolled, a pharmacist may dispense and be reimbursed for up to a 72-hour supply of a covered outpatient drug as an "emergency supply."
  - In all other cases where the prescribing provider is not enrolled in the IHCP, claims deny with the NCPDP reject 71 – *Prescriber is not covered,* followed by a custom message: *Prescriber not enrolled in IHCP.*

> *Note: Providers that do not bill the IHCP for services rendered but wish to enroll for the sole purpose of ordering, prescribing, or referring services and supplies for IHCP members, may enroll as provider type 50 – Ordering, Prescribing or Referring Provider. See the Provider Enrollment module and the Ordering, Prescribing or Referring Providers page at in.gov/medicaid/providers for more information.*

- Reporting the prescribing provider's NPI applies to third-party liability (TPL) as well as Medicaid-primary claims.
- For prescriptions written by a prescriber within an IHCP-enrolled hospital or a federally qualified health center (FQHC), the pharmacy provider may use the NPI of the hospital or FQHC in the prescriber field.
- Using inaccurate NPIs, such as using one prescriber's NPI on a claim for a prescription from a different prescriber, is strictly forbidden and subjects the pharmacy provider to recoupment of IHCP payment and possible sanction. This rule applies to midlevel prescribers as well; submitting the supervising prescriber's NPI is not permitted. The Family and Social Services Administration (FSSA) and its contractors monitor providers' compliance via post-payment review, and if necessary, refer noncompliant providers to the Indiana Medicaid Fraud Control Unit (IMFCU).

Prescription Origin Codes

Pharmacy providers are required to accurately submit the prescription origin code (POC) to reflect how the prescription was originally presented to the pharmacy. Any claim submitted with an incorrect POC is subject to audit and recovery. See Table 10 for a list of valid POCs.

Table 10 – Valid Prescription Origin Codes (NCPDP Field 419-DJ)

Prescription Origin Code	Description
0	Unknown
1	Written
2	Telephone
3	Electronic
4	Facsimile (fax)
5	Pharmacy

Note: A POC of 0 should be used only when the origin code is truly unknown.

Third-Party Liability, Coordination of Benefits and Cost Avoidance

By law, the Medicaid program is the payer of last resort. If another insurer or program has the responsibility to pay for medical costs incurred by a Medicaid-eligible individual, that entity is generally required to pay all or part of the cost of the claim prior to Medicaid making any payment. This requirement is known as "third-party liability" or TPL. Third parties that may be liable to pay for services include private health insurance, Medicare, employer-sponsored health insurance, settlements from a liability insurer, workers' compensation, long-term care insurance and other state and federal programs (unless specifically excluded by federal statute). Third-party payers are not responsible for reimbursing Medicaid for any services that are not covered under the Medicaid State Plan.

In general, if the state of Indiana has determined that a potentially liable third party exists, it must attempt to ensure that the provider bills the third party first before sending the claim to Medicaid. This process is known as "cost avoidance." See the *Third-Party Liability* module for more information.

If a provider submits electronic claims for members who have pharmacy TPL coverage on file and who have no evidence of TPL for collection on the claim, the claim is denied with an NCPDP reject code of 41 − *Submit Bill to Other Processor*. Members who state that they do not have primary pharmacy insurance must contact the TPL Unit to have the coverage removed. Members can contact the TPL Unit by mail, telephone or fax using the following contact information:

IHCP Third-Party Liability (TPL)
P.O. Box 7262
Indianapolis, IN 46207-7262

Toll-Free Telephone: 800-457-4584
Toll-Free Fax: 866-667-6579

The program recognizes there are times when, despite the provider's efforts, a TPL payment is not collected. To accommodate these situations, override codes are available. The TPL-related codes are shown in Table 11.

Table 11 – Other Coverage Codes (NCPDP Field 308-C8)

Code	Description	Additional Explanation
1	No other coverage	Code used in coordination of benefits transactions to convey that no other coverage is available
2	Other coverage exists – Payment collected	Code used in coordination of benefits transactions to convey that other coverage is available, the payer has been billed, and payment received
3	Other coverage billed – Claim not covered	Code used in coordination of benefits transactions to convey that other coverage is available, the payer has been billed, and payment denied because the service is not covered
4	Other coverage exists – Payment not collected	Code used in coordination of benefits transactions to convey that other coverage is available, the payer has been billed, and payment has not been received

Submitting a value greater than 1 for the Other Coverage Code (field 308-C8) indicates that another payer (the primary payer) has already adjudicated the claim, and the Coordination of Benefits (COB)/Other Payments segment is required to be included in this claim submission. Table 12 shows the list of fields to be included in the COB/Other Payments segment.

Table 12 – Coordination of Benefits/Other Payments Segment Fields

Field #	NCPDP Field Name	Valid Values	Additional Information
337-4C	COORDINATION OF BENEFITS/ OTHER PAYMENTS COUNT	Count of other payment occurrences. Maximum count of 9	
338-5C	OTHER PAYER COVERAGE TYPE	Blank = Not Specified Ø1 = Primary – First Ø2 = Secondary – Second Ø3 = Tertiary – Third Ø4 = Quaternary – Fourth Ø5 = Quinary – Fifth Ø6 = Senary – Sixth Ø7 = Septenary – Seventh Ø8 = Octonary – Eighth Ø9 = Nonary – Ninth	
443-E8	OTHER PAYER DATE	Payment or denial date of the claim submitted to the other payer. Used for coordination of benefits.	Required if identification of the Other Payer Date is necessary for claim/encounter adjudication.
341-HB	OTHER PAYER AMOUNT PAID COUNT	Count of the payer amount paid occurrences.	Required if Other Payer Amount Paid Qualifier (342-HC) is used.

Field #	NCPDP Field Name	Valid Values	Additional Information
342-HC	OTHER PAYER AMOUNT PAID QUALIFIER	Ø1 = Delivery Ø2 = Shipping Ø3 = Postage Ø4 = Administrative Ø5 = Incentive Ø6 = Cognitive Service Ø7 = Drug Benefit Ø9 = Compound Preparation Cost 1Ø = Sales Tax	Required if Other Payer Amount Paid (431-DV) is used.
431-DV	OTHER PAYER AMOUNT PAID	Amount of any payment known by the pharmacy from other sources.	Required if other payer has approved payment for some/all of the billing. Not used for patient financial responsibility only billing. Required if Total Amount Paid (5Ø9-F9) from Other Payer is greater than zero (Ø).
471-5E	OTHER PAYER REJECT COUNT	Maximum count of 5	Required if Other Payer Reject Code (472-6E) is used.
472-6E	OTHER PAYER REJECT CODE	The error encountered by the previous Other Payer in Reject Code (511-FB). 3-character alphanumeric	Required when the other payer has denied the payment for the billing, designated with Other Coverage Code (3Ø8-C8) = 3 (Other Coverage Billed – claim not covered).
353-NR	OTHER PAYER-PATIENT RESPONSIBILITY AMOUNT COUNT	Maximum count of 9 (Maximum count of 1 per Other Payer)	Required if Other Payer-Patient Responsibility Amount Qualifier (351-NP) is used.
351-NP	OTHER PAYER-PATIENT RESPONSIBILITY AMOUNT QUALIFIER	Ø6 = Patient Pay Amount (5Ø5- F5) as reported by previous payer. Used to indicate the provider is submitting the amount reported by a prior payer as the patient's responsibility.	Required if Other Payer-Patient Responsibility Amount (352-NQ) is used. Required if Patient Pay Amount (5Ø5-F5) from Other Payer is greater than zero (Ø).
352-NQ	OTHER PAYER-PATIENT RESPONSIBILITY AMOUNT	The patient's cost share from a previous payer as found in Patient Pay Amount (5Ø5-F5)	Required if necessary for patient financial responsibility only billing. Required if necessary for state/federal/regulatory agency programs. Required if Patient Pay Amount (5Ø5-F5) from Other Payer is greater than zero (Ø).

Providers are required to maintain documentation that substantiates the circumstances under which any given TPL codes were used. For example, if the provider uses code 3 − *Other coverage billed − Claim not covered*, the provider must maintain documentation from the insurance carrier that the code billed is a noncovered service. Appropriate use of override codes is closely monitored via postpayment audits. Instances of inappropriate use may result in payment recoupment and possible imposition of sanctions against the provider.

Billing Procedures for Specific Services and Programs

The following sections provide billing information and guidelines for pharmacy providers to use for specific services and programs.

Billing Procedures for Compounds and Drug Products Requiring Reconstitution

For the process for billing compounds or multiple NDCs for drug products requiring reconstitution, see the *NCPDP D.0 Payer Sheet,* which is located on the Optum Rx Indiana Medicaid website. Compounds containing a Medicare Part D-covered drug product will not be covered for IHCP members who are also eligible for Medicare Part D coverage.

Billing Procedures for Enteral Nutrition Therapy

For billing procedures for enteral nutrition therapy, see the *Durable and Home Medical Equipment and Supplies* module and the *Home Health Services* module.

IHCP Policy and Billing Requirements for the 340B Program

Section 340B of the *Public Health Service Act* limits the cost of covered outpatient drugs to entities such as certain federal grantees, FQHCs, FQHC look-alikes and qualified disproportionate share hospitals, enabling these entities to purchase drugs at discounted rates and stretch scarce federal resources. IHCP policy regarding the 340B program follows:

- Federal law allows eligible entities to decide if they do or do not want to serve Medicaid members using 340B stock. This decision is wholly at the discretion of the entity. However, when an eligible entity decides to serve or not serve Medicaid members with 340B stock, the entity is "locked into" that decision and not permitted to dispense a mix of 340B and non-340B drugs to Medicaid members.
- If the entity wishes to serve Medicaid members using 340B stock, it must only dispense 340B stock drugs and bill the program accordingly at its actual acquisition cost for the drug, plus the Medicaid dispensing fee. The IHCP requires that any entities enrolled in the 340B program (that intend to use 340B stock to Medicaid members) be listed in the *Medicaid Exclusion File*, accessible from the Health Resources and Services Administration (HRSA) 340B Office of Pharmacy Affairs Information System (OPAIS) website at 340bopais.hrsa/gov.
- If the entity wishes to serve Medicaid members using a separate, non-340B stock, it may not use 340B stock at any time. The entity is to bill the program at its usual and customary (U&C) charge.
- Drugs acquired through the 340B drug pricing program and dispensed by 340B contract pharmacies are not covered under the fee-for-service pharmacy benefit. Contract pharmacies may not dispense 340B stock to fee-for-service Medicaid members.
- Upon an audit request, the provider must submit all documentation requested for ***both*** inventories.
- When billing for 340B drugs on professional claims (*CMS-1500* claim form, IHCP Portal professional claim or 837P electronic transaction) or institutional claims (*UB-04* claim form, IHCP Portal institutional claim or 837I electronic transaction), see instructions in the *Injections, Vaccines and Other Physician-Administered Drugs* module.

Billing Procedures for Emergency Services Only: Package E

For a description of Emergency Services Only (Package E) benefits, see the *Member Eligibility and Benefit Coverage* module. Prescription coverage for Package E members is limited to prescriptions written during the course of a covered emergency medical service. Coverage is limited to a maximum of a four-day supply of the prescribed drug.

Pharmacy claims for members with Package E cannot be submitted electronically and must be submitted using the *IHCP Drug Claim Form* or the *IHCP Compounded Prescription Claim Form*, as appropriate. These forms are available from the PA Criteria and Administrative Forms quick link on the Optum Rx Indiana Medicaid website. Claim forms for Package E must be completed as directed in Table 13.

Table 13 – Pharmacy Claim Form Instructions for Package E: Emergency Services Only Members

Claim Form	Location
IHCP Drug Claim Form	**Field Number 03:** EMERGENCY – Enter **YES** for emergency services. **Field Number 11:** DAYS SUPPLY – Days supply must be less than or equal to four days for emergency services.
IHCP Compounded Prescription Claim Form	**Field Number 04:** EMERGENCY – Enter **YES** for emergency services. **Field Number 13:** DAYS SUPPLY – Days supply must be less than or equal to four days for emergency services.

Electronic Funds Transfer Payments

The FFS pharmacy benefit offers electronic funds transfer (EFT) for pharmacy payments.

To enroll for this service, providers must complete the *Electronic Funds Transfer (EFT) Request Form*, available from the PA Criteria and Administrative Forms quick link on the Optum Rx Indiana Medicaid website. The completed form must be faxed to Optum Rx at 866-244-8543. Providers must include a copy of a voided check or a letter from their financial institution with all the requested information.

Optum Rx processes the form and transitions the provider's payments to EFT status within approximately 10 days from receipt of a completed form. Questions regarding EFT enrollment should be directed to the Optum Rx Provider Relations Department via email at provider.relations@Optum.com.

Additionally, paper Remittance Advices (RAs) are not generated with EFT payments. Instead, electronic forms (835 transactions) with remittance information are provided for each payment cycle.

Providers must register with Optum Rx to receive the 835 transaction. Providers must complete the *835 Payment Advice Request Form*, also available from the PA Criteria and Administrative Forms quick link on the Optum Rx Indiana Medicaid website, and fax it to Optum Rx at 866-244-8543. Upon registration, providers receive an email indicating that a file is available to download along with login information. Questions regarding 835 registration should be directed to Optum Rx via email at pharmacy.operations@Optum.com.

Section 4: Medicare Prescription Drug Coverage

The Indiana Health Coverage Programs (IHCP) does not reimburse for Medicare-covered prescription drugs for members who are enrolled in both Medicaid and Medicare (dual eligibility). The IHCP reimburses only for drugs excluded from the Medicare program, and then only to the extent the drugs are covered under the IHCP pharmacy benefit. Members entitled to receive traditional Medicare and who receive full IHCP benefits are eligible for Medicare Part D. Medicare pays for the majority of prescription drugs for these members. Medicare Part D is a pharmacy benefit administered by the Centers for Medicare & Medicaid Services (CMS). For current Medicare Part D program information or for answers to questions pertaining to the benefit, providers should contact the CMS at 800-MEDICARE (800-633-4227) or see medicare.gov for additional information.

IHCP Drug Coverage for Dually Eligible (Medicare and Medicaid) Members

For dually eligible members, Medicaid may provide coverage for Medicare Part D excluded drugs that are covered by the IHCP benefit. This benefit includes over-the-counter (OTC) drugs and pharmacy supplements that are on the *State of Indiana Over-the-Counter Drug Formulary and Pharmacy Supplements Formulary*. Medicare prescription drug plans (PDPs) may choose to cover Medicare Part D excluded drugs; therefore, pharmacy providers must attempt to bill Medicare before submitting claims to the IHCP. See the *Indiana Medicaid Pharmacy Benefit Coverage for Medicare Part D Excluded Products* document for a comprehensive list of drugs covered by the IHCP for dually eligible members. This list is available from the Medicare Prescription Drug Coverage quick link on the Optum Rx Indiana Medicaid website, accessible from the *Pharmacy Services* page at in.gov/medicaid/providers. Covered agents are still subject to PA criteria and preference status on the Preferred Drug List.

Pharmacies and prescribing practitioners should contact Optum Rx with any questions related to the Preferred Drug List (PDL) by calling toll-free 855-577-6317.

The IHCP does not pay for emergency supplies of a Medicare Part D covered drug for members who decline Medicare prescription drug coverage. Per *United States Code 42 USC 1396r-8(d)(5)*, emergency supply provisions apply only to Medicare Part D covered drugs. Members who receive Medicare benefits and also receive full IHCP benefits and who decline or disenroll from Medicare prescription drug coverage do not have prescription drug coverage through the IHCP.

Claim Processing for Dually Eligible (Medicare and Medicaid) Members

Pharmacy claims for dually eligible members are adjudicated based on covered benefits determined by the IHCP. Covered benefits represent drugs that are excluded by Medicare but are covered by the IHCP. Claims for members with Medicare Part D are subject to edits as described in this section. PDPs have a formulary of all Medicare-covered drugs. The IHCP does not track specific PDP formularies. The IHCP does not reimburse for a drug solely because it is excluded from a PDP formulary; it must be *excluded by Medicare Part D*. The claim-processing system maintains and edits against the primary Medicare Part D excluded and the IHCP covered services.

IHCP pharmacy claims process according to the member's IHCP benefits. Important claim-processing information follows:

- Pharmacy claims for Medicare Part D covered drugs for dually eligible members are cost avoided for Medicare coverage. The pharmacy must bill Medicare before billing the IHCP.
- Pharmacy claims for Medicare Part D do not cross over. Copayments for drugs covered by Medicare Part D are not billable to the IHCP.
- Crossover may apply for a member's coinsurance or copayment for Medicare Part B pharmacy-covered services. For members with Qualified Medicare Beneficiary (QMB)-Also, QMB-Only and Specified Low-Income Medicare Beneficiary (SLMB)-Also coverage, including those with Medicare Part C (Medicare Advantage Plan) coverage, the coinsurance portion of a claim for Medicare Part B pharmacy-covered services is submitted as a crossover claim via the *IHCP Drug Claim Form*.
- Pharmacy claims for members who receive Medicare Part D benefits and who also receive full Medicaid benefits are subject to Part D editing, as follows:
  - National Council on Prescription Drug Programs (NCPDP) reject 70 − with a custom message stating *Member eligible for Medicare B/D*
    - This message explains that the claim was denied because the drug is not a Medicare D excluded drug. Therefore, the drug could be covered by Medicare Part D and, as such, is not reimbursed by the IHCP.

Section 5: Medicaid-Certified Long-Term Care Facilities

This section contains information that applies only to services rendered to members who reside within a Medicaid-certified long-term care (LTC) facility.

Medical and Nonmedical Supplies and Equipment

Medical and nonmedical supplies and equipment are subject to the provisions of Indiana Medicaid rule *Indiana Administrative Code 405 IAC 5-24-10*, which, at the time of publication of this document, are as follows:

***405 IAC 5-24-10* Medical and nonmedical supply items for long term care facility residents**

Authority: *IC 12-15-1-10; IC 12-15-21-2*
Affected: *IC 12-13-7-3; IC 12-15*

Sec. 10. The cost of both medical and nonmedical supply items is included in the per diem rate for long term care facilities. Under no circumstances shall medical or nonmedical supplies and equipment be billed through a pharmacy or other provider.

For more information, see the *Long-Term Care* module. For durable medical equipment (DME) and supply billing codes, see the *Durable and Home Medical Equipment and Supply Codes* on the *Code Sets* page at in.gov/medicaid/providers.

See *405 IAC 5-19 Medical Supplies and Equipment* for additional information about Medicaid coverage and reimbursement for medical supplies and equipment.

> *Note: Pharmacy providers are not entitled to separate reimbursement for any Indiana Health Coverage Programs (IHCP)-covered service that is reimbursed solely on a per diem basis.*

Unit Dose Packaging

The program reimburses for covered, manufacturer-packaged, unit-dose medication. Such items are reimbursable only when provided to residents of Medicaid-certified LTC facilities.

It is not the intent or the policy of the IHCP to reimburse a pharmacy for costs associated with a pharmacy's packaging of its own unit-dose medications. See *405 IAC 5-24-1(b) Reimbursement Policy*.

Returned Medications

The following state laws allow for the return of medications from LTC facilities to the pharmacy that dispensed the medications, under certain circumstances:

- *Indiana Code IC 25-26-13-25(k) – Prescriptions: numbering, filing, and inspection: refills; duration of validity; demise of practitioner or patient; resale or distribution of returned medication*
- *IAC 1-21-1 – Resale of returned substances under certain circumstances*

> *Note: Medications returned to the dispensing pharmacy that are placed back in stock for redispensing **must** be credited to the program within 30 days of being returned to the pharmacy.*

To credit the program, providers submit a credit request for the amount of the returned medication, less any applicable dispensing fee. This amount is applied against future payments. The credited amount is posted to the provider Remittance Advice, and totals on the *Provider 1099 Summary Report* are adjusted.

The IHCP requires that the LTC pharmacy and the LTC facility to which it is providing services must document the medications being returned and credited to the program. Both providers are required to document any medications being destroyed. Providers must have documentation that clearly shows the following:

- Prescription number
- Name of medication
- Date the medication was returned and credited or destroyed
- Quantity returned and credited, or quantity destroyed
- To whom it was returned for destruction if the medication was destroyed
- Documentation of patients discharged from a facility, then readmitted and requiring an override of an "early refill" denial, including detailed records of any returned or destroyed medications

Optum Rx verifies compliance with these requirements. LTC pharmacies and LTC facilities found to be noncompliant are referred, as deemed appropriate, to the Indiana Medicaid Fraud Control Unit (IMFCU).

Section 6: Drug Utilization Review Processes

The *Omnibus Budget Reconciliation Act of 1990* (OBRA-90) specifies Drug Utilization Review (DUR) requirements for the Indiana Health Coverage Programs (IHCP). Federal rules require that each Medicaid program include comprehensive DUR. These guidelines provide maximum flexibility, but the state must ensure that drugs are dispensed appropriately, and that drug use is retrospectively reviewed.

DUR is an administrative process of utilization review and quality assessment. The process includes criteria to describe appropriate drug use standards and to describe the allowable deviation from the criteria. The Indiana Medicaid DUR Board reviews and approves the criteria. More information about the Indiana Medicaid DUR Board, its members and duties is available from the Boards and Committees tab on the Optum Rx Indiana Medicaid website, accessible from the *Pharmacy Services* page at in.gov/medicaid/providers).

For additional information about DUR requirements, go to the Optum Rx Indiana Medicaid website and select **Boards and Committees**, then **Drug Utilization Review Board (DUR)**.

Prospective Drug Utilization Review

The purpose of the Prospective Drug Utilization Review (pro-DUR) is to improve the quality and cost-effectiveness of drug use by ensuring that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical reactions. This systematic review of selected claims, before adjudication, provides pharmacists with valuable information that can affect decisions about dispensing medications and alerts the pharmacist to potential drug therapy problems before medication is dispensed to the member. The pro-DUR edits are not intended to meet all the OBRA-90 responsibilities of the dispensing pharmacist. The pharmacist should contact the prescriber for any drug-related concerns, regardless of whether a pro-DUR alert is posted. All contact with the prescriber regarding any DUR intervention must be documented on the prescription drug order. Only those claims submitted via POS are subjected to pro-DUR. Per the OBRA-90, pharmacy providers are responsible for performing many of the required activities, as follows:

- Patient counseling
- Proper patient record maintenance
- Pro-DUR therapeutic screening

OBRA-90 requires pharmacists to review the member's entire drug profile before filling prescriptions, including checking for the following:

- Therapeutic duplication
- Drug-disease contraindications
- Drug-drug interactions, including serious interactions with nonprescription or over-the-counter drugs
- Incorrect drug dosage or duration of drug treatment
- Drug-allergy interactions
- Evidence of clinical abuse or misuse

Pro-DUR criteria and standards were adopted from the following sources:

- American Hospital Formulary Service Drug Information
- United States Pharmacopeia Dispensing Information
- American Medical Association (AMA) Drug Evaluations
- Other peer-reviewed medical literature

Patient Counseling Standards

OBRA-90 also requires states to establish standards governing patient counseling. In particular, dispensing pharmacists must offer to discuss the unique drug therapy regimen of each IHCP member when filling prescriptions.

Such discussions must involve matters that are significant, in the professional judgment of the pharmacist, and include, but are not limited to, the following information:

- Name and description of the medication
- Route of administration
- Dose
- Dosage form
- Duration of drug therapy

OBRA-90 also mandates that pharmacists discuss special directions and precautions for preparation of drugs and include the following details:

- Administration and use by the patient
- Common severe side effects that may be encountered, including avoidance, and the action required should they occur
- Techniques for self-monitoring drug therapy
- Proper storage
- Refill information
- Action taken in case of a missed dose

Patient Record Maintenance

Under OBRA-90, IHCP pharmacy providers must also make reasonable efforts to obtain, record and maintain at least the following IHCP patient information:

- Name
- Address
- Telephone number
- Age
- Gender
- Individual history, where significant, including disease state or states, known allergies and drug reactions
- Comprehensive list of medications and relevant devices
- Pharmacist comments about the individual's drug therapy

Pro-DUR Therapeutic Screening

Dispensing pharmacists are responsible for conducting therapeutic screenings before filling prescriptions. Pharmacists can use their own explicit criteria, or the information returned from the claim-processing

system, to conduct pro-DUR screening. Indiana's therapeutic screening detection system alerts pharmacists to the following potential conflicts:

- Drug-drug interaction
- Drug age precaution
- Drug disease alerts
- Drug pregnancy alert
- High- and low-dose alerts
- Over- and under-use precaution
- Therapeutic duplication

Alert Process

Claims that fail a pro-DUR alert post a claim rejected response that includes the pro-DUR alert information, as follows:

- Drug conflict code
- Clinical significance code or severity
- Other pharmacy indicator
- Previous date of fill
- Quantity of previous fill
- Database indicator
- Other prescriber indicator
- Free text

In the case of drug-drug interaction alerts, therapeutic duplication alerts and early refill alerts, the free-text area contains the name of the drug in history and the dispense dates of the drugs causing the alert.

Response Process

Rejected claims requiring a DUR response will not process with a paid status until the provider submits an updated claim that includes:

- Corresponding reason-for-service code
- Professional service code
- Result-of-service code

The reason for service code on the updated claim must match at least one of the alert codes on the rejected claim. Updated claims received with a reason for service code that does not match the alert code on the rejected claim or an invalid reason for or result of service code are rejected with an appropriate explanation of benefits (EOB). When submitting a response for a rejected claim that triggers more than one DUR alert, the pharmacist must choose the reason for service code to send with each claim. Because the National Council on Prescription Drug Programs (NCPDP) standard format allows for only one reason for service code to be returned with a response, the pharmacist should choose the reason for service code that best reflects the actual situation. Occasionally, a pharmacy may receive a false positive early refill rejection due to varying factors. In this instance, the pharmacy should contact Optum Rx toll-free at 855-577-6317 for a prior authorization.

Early Refill Policy and Criteria

Policy requires at least 85% of a prescription claim's days supply to elapse to allow subsequent prescription claims to pay or PA requests to be approved. An early refill for a change in dose will be approved after confirmation from the pharmacy that 85% of the prescription claim's days supply has elapsed with the dose change (for example, a dose change from 1 tablet to ½ tablet daily or twice daily would not constitute an early refill approval if 85% had not yet elapsed). Claims that bypass early-refill edits due to incorrect submission of days supply are subject to audit and recovery. Use of the emergency supply override to bypass refill-too-soon rejections is strictly prohibited. Violations will be subject to financial recoupment and/or referral to Family and Social Services Administration (FSSA) Program Integrity.

The following tables illustrate early refill scenarios for retail pharmacies and, separately, for long-term care (LTC) pharmacies.

Table 14 – Early Refill Scenarios for Retail Pharmacies

Retail Pharmacy Scenario	**Authorized Provider**	**Additional Information** ***Note: Approvals are for one date of service only.***
Pharmacy has entered wrong days supply	Pharmacy	Approved only after call center agent has verified claim in claims history and pharmacy was unable to resubmit claim with correct days supply
Controlled substance medication has been lost, spilled or damaged	Prescriber	Approved only after prescriber has confirmed medication has been lost, spilled or damaged
Noncontrolled substance medication has been lost, spilled or damaged	Pharmacy	Approved only after pharmacy has confirmed medication has been lost, spilled or damaged
Controlled substance medication has been stolen	Prescriber	Approved only after law enforcement and/or insurance documentation has been received by call center
Noncontrolled substance medication has been stolen	Pharmacy	Approved only after law enforcement and/or insurance documentation has been received by call center
Controlled substance medication has been destroyed by fire	Prescriber	Approved only after law enforcement and/or insurance documentation has been received by call center
Noncontrolled substance medication has been destroyed by fire	Pharmacy	Approved only after law enforcement and/or insurance documentation has been received by call center
Controlled substance medication has been destroyed by a natural disaster (for example, tornado, flooding and so forth)	Prescriber	Approved only after confirmation from prescriber
Noncontrolled substance medication has been destroyed by a natural disaster (for example, tornado, flooding and so forth)	Pharmacy	Approved only after confirmation from pharmacy
Vacation/absence from Indiana place of residence to place outside Indiana	Pharmacy	Approved only after confirmation from pharmacy; only one request per medication per member per 365 rolling calendar days is allowed
Change in dosage	Pharmacy	Approved only after confirmation from pharmacy
School or work supply for nontransportable items	Pharmacy	Approved only after confirmation from pharmacy

Retail Pharmacy Scenario	Authorized Provider	Additional Information *Note: Approvals are for one date of service only.*
Released from hospital, LTC facility or group home	Pharmacy	Approved only after confirmation from pharmacy

Table 15 – Early Refill Scenarios for Long-Term Care Pharmacies

LTC Pharmacy Scenario	Authorized Provider	Additional Information *Note: Approvals are for one date of service only.*
Pharmacy has entered wrong days supply	Pharmacy	Approved only after call center agent has verified claim in claims history and pharmacy was unable to resubmit claim with correct days supply
Change in dosage	Pharmacy	Approved only after confirmation from pharmacy
LTC facility has lost, spilled or damaged medication or medications have been stolen	NA	Denied
Pharmacy is taking on new LTC facility and wants to do a one-time rollover for all patients	NA	Denied
New admit or re-admit	Pharmacy	Approved only after confirmation from pharmacy
Patient is going on leave of absence	Pharmacy	Approved only after confirmation from pharmacy
LTC facility returned medication by mistake	NA	Denied
Patient has a *pro re nata* (PRN) order and a routine order with different prescription numbers	Pharmacy	Approved only after confirmation from pharmacy

Retrospective Drug Utilization Review

Retrospective Drug Utilization Review (retro-DUR) is a function of the DUR Board and involves the retrospective review and analysis of paid pharmacy claims data to identify patterns of fraud, abuse, gross overuse or inappropriate or medically unnecessary care associated with specific drugs or groups of drugs. Retro-DUR *interventions* are a component of the DUR Board's outreach programs, are educational and not punitive in nature, and are conducted primarily by means of faxed letters to selected prescribing practitioners. The intent of retro-DUR interventions is to call practitioners' attention to patient-specific information, based on paid pharmacy claims, which may assist the practitioners in better managing the care of their patients. Retro-DUR activities are administered by the IHCP fee-for-service pharmacy benefit manager (PBM), Optum Rx.

Audits of pharmacy providers are necessary for the Indiana Health Coverage Programs (IHCP) to meet federal requirements regarding protections against fraud, waste and abuse. Audits also serve as a means to assist providers in correcting billing practices that may not be in compliance with program requirements. Violations by pharmacy providers of applicable law (as enforced by the Indiana Board of Pharmacy or other entities) that are detected by auditors will be remanded to the appropriate oversight agency. Paid claims that are attributable to prescriptions that do not fully meet all applicable requirements of law or Medicaid policies and procedures are subject to recoupment.

Types of Pharmacy Audits

The state's fee-for-service pharmacy benefit manager (PBM), Optum Rx, provides the IHCP with pharmacy audit services. In general, there are five distinct types of pharmacy audits, as briefly described in the following sections.

Real-Time/Telephone Audits

Real-time/telephone audits are conducted via telephone. The goals of real-time/telephone audits are to:

- Reduce the burden on pharmacy providers as related to documentation requests.
- Reduce the number of claims subject to the appeals process.
- Minimize recurring incorrect billing practices.
- Correct the claim before it is dispensed.

All provider claims are subjected to real-time/telephone audits. If a claim is found to be aberrant, the provider is so notified by telephone call or secure email from Optum Rx. The provider has the opportunity to correct and resubmit the claim. If the claim is not corrected and resubmitted, it will be included in a subsequent desk audit and may be referred to FSSA Program Integrity.

Self-Audits

Self-audits are audits that contain a list of claims that are emailed or faxed to the provider with a request to review the claims for accuracy. The provider may be requested to furnish the prescription label directions and is asked to indicate whether or not corrections were made.

Desk Audits

Desk audits are audits that are performed internally by Optum Rx and do not require on-site audit activities. These audits are performed on a routine basis and involve the application of sophisticated algorithms to provider claims data. Desk audits are designed to ensure correct claim submissions by providers and to recover overpayments that are caused by billing errors made by providers. The desk audit program uses letters, faxes and email to request information from providers. If a claim is selected for review during a desk audit, the dispensing provider receives a letter requesting documentation related to the claim associated with the prescription. Any applicable documentation may be requested to confirm the accuracy and appropriateness of the claims at issue, including the following:

- Copies of prescriptions
- Patient labels including directions for use
- Proof of copayment collection

- Signature or delivery logs
- Compound worksheets
- Any other applicable documentation (such as prescriber clarifications/verifications and supporting compendia documentation)

Invoice Reconciliation Audits

Invoice reconciliation audits are audits that Optum Rx sends to providers, by email or fax, to request the following:

- A comprehensive drug utilization report that includes all payers for National Drug Codes (NDCs) requested (protected health information [PHI] redacted)
- Summary statements of purchases, by NDC, from the pharmacy provider's distributors

Distributors are required to submit responses directly to Optum Rx. Distributor information may include records from reverse distributors and purchases from other pharmacies. The drug utilization report and distributor summary statements must be submitted to Optum Rx in Microsoft Excel format. Upon request, copies of the following items must be provided:

- Drug pedigree documentation
- Front and back of cancelled checks to support purchases

Any denial to invoice reconciliation audit requests is a denial of access.

On-Site Audits

On-site audits, like desk audits, are performed on a routine basis. Focus areas of on-site audits may include, but are not limited to, reviews of signature logs and consultation documentation, purchasing records, on-hand inventory, usual and customary pricing, and pharmacy operating procedures. Providers are notified in advance of scheduled full-scope, on-site audits; however, all providers are subject to unannounced visits by auditors to assess compliance. At the conclusion of on-site audits, if deficiencies are noted, a *Notice of Corrective Action* may be issued. Providers will have 15 calendar days to correct deficiencies. Failure to correct deficiencies may result in a referral to the FSSA Program Integrity team and/or the Indiana Board of Pharmacy.

Process and Requirements for Appealing Pharmacy Audit Determinations

Pharmacy providers may submit an appeal if they do not agree with the final findings of a pharmacy audit. When appealing an audit determination, the provider must follow the established process and document requirements:

- The final audit findings are identified in the *Notice of Final Determination* that is sent to the provider. Appeal of the findings must be submitted in writing within 60 calendar days of receipt of the notice.
- The appeal must state facts demonstrating that the provider is the person or entity to whom the final determination is specifically directed, and that the provider is aggrieved or adversely affected or that the provider is entitled to a review under law.
- Documentation submitted with the appeal must include:
  - A Statement of Issues setting forth the reasons the provider believes the determination is in error and detailing the specific findings, actions or determinations that the provider is appealing
  - The *Notice of Final Determination*, marked to indicate which claims the provider is appealing

  - References to all statutes and rules supporting the provider's contentions of error
  - Prescription hardcopies or paper copies of other documentation relating to the claims
- The appeal documentation must be submitted to the following address:

  MS07
  Pharmacy Benefit Contract Manager
  Indiana Family and Social Services Administration
  Office of Medicaid Policy and Planning, Pharmacy Unit
  402 W. Washington St., Room W374
  Indianapolis, IN 46204

> *Note: Appeals sent to Optum Rx, the IHCP FFS Pharmacy Benefit Manager, will not be processed.*

Submitting an appeal does not discharge the provider's obligation to repay the identified overpayment amount. Repayment of the overpayment, along with interest already accrued, will keep additional interest from accruing while an appeal is pending. If the provider prevails on appeal, the repayment will be refunded with interest. The provider will receive an *Overpayment Option Form* with the *Notice of Final Determination*. The provider should complete and return the form following the instructions provided on the form itself, to specify the provider's repayment option of choice. Indiana law requires the amount of the final calculation be repaid within 300 calendar days of receipt of the *Notice of Final Determination*.

If an appeal is not filed within the 60-calendar-day time frame, the provider may forego the right to appeal. A *Demand Letter* will be issued explaining how the overpayment, including interest, will be recouped.

Providers can direct any audit questions to the Optum Rx Pharmacy Audit Department by email at RxAudit.INM@Optum.com.

Requirements for Prescriptions and Drug Orders

Prescriptions, including faxed prescriptions, and drug orders should comply with *Indiana Code IC 25-26-13* and *Indiana Administrative Code 856 IAC 1-31-2*. The following subsections also include IHCP requirements for prescriptions and drug orders.

Tamper-Resistant Prescription Pads (TRPPs)

For all information regarding tamper-resistant prescriptions, see the *Tamper-Resistant Prescriptions* section.

Required Pharmacy Documentation

Documentation retained by the provider must clearly demonstrate that all IHCP-reimbursed services rendered by the provider were provided in compliance with all applicable laws, policies and program rules.

Documentation required by Optum Rx specifically for desktop and on-site audits includes, but is not necessarily limited to, the following:

- For long-term care (LTC) pharmacies:
  - Prescriber's original written order or prescription
  - Telephoned prescription or drug order called in by the prescriber or the prescriber's representative
  - Faxed prescription or drug order
  - Discharge orders
  - Signed monthly physician's order summary dated within the previous 12 months of the fill date
  - Medication administration records

  - Faxed refill authorizations
  - Proof of delivery

- For retail pharmacies:
  - Original written prescription
  - Telephoned prescription
  - Computer or fax refill authorization containing all relevant information
  - Faxed prescription
  - E-prescription
  - Signed and dated signature log and/or proof of delivery

- For compound prescriptions:
  - Documentation described in the previous bullets
  - Compound worksheet including the following information:
    - All NDCs used
    - Lot numbers
    - Expiration dates
    - Quantities
    - Beyond use date
    - Date made
    - Individuals involved in preparation and verification and correlation to the claim being audited

> *Note: For reconsideration or appeal, Optum Rx cannot accept telephone orders. The provider must obtain a copy of the prescription from prescriber via fax, mail or electronic prescription.*

Questions regarding acceptable forms of documentation should be directed to the Optum Rx Pharmacy Audit Department by email at RxAudit.INM@Optum.com.

Proof of Delivery

Providers must maintain proof of service delivery and be able to provide this documentation upon request for audit.

Outpatient pharmacies must maintain signature logs and, upon request, provide these signature logs for audit. Each entry of the signature log must be dated with the dispense date and signed by the member or designee. Providers must not predate signature logs. Stickers that show the fill dates do not fully satisfy the requirements for proof of delivery.

For deliveries to LTC facilities, the billing provider must maintain signed records of delivery as proof of the pharmacy service being delivered. These records must include the prescription number, drug, quantity and date signed.

For mail delivery services, the delivery service's tracking number or other linking documentation that can be traced back to a specific claim is required. For deliveries where a signature is not provided, Optum Rx may request documentation that the patient authorized the prescription to be filled. For prescriptions filled by a pharmacy provider and delivered to another provider for dispensing or administration, the pharmacy provider must provide proof that the member received or was administered the drug.

> *Note: For dates of service from March 1, 2020, through July 31, 2021, the signature requirement for proof of delivery was suspended. Pharmacies were requested to complete the signature line with "COVID" in lieu of obtaining a signature. Signature requirements for proof of delivery resumed on Aug. 1, 2021.*

Corrected Claims

Auditing of pharmacy claims may identify instances in which a provider billed in a manner that resulted in payments to which the provider was not entitled. In some instances, these cases can be corrected by adjustment of the claim by Optum Rx. In other instances, Optum Rx cannot adjust the claim fields that would require modification to be correct. Optum Rx **cannot** adjust the following fields:

- Cardholder ID
- National Drug Code (NDC)
- Dispense-as-written (DAW) codes
- Override codes

If the claim is **180 days old or less**, it may be reversed, and the pharmacy must resubmit the replacement claim via POS to accurately reflect the dispensing situation at issue.

Claims with dates of service **more than 180 days old** require the use of a **paper** replacement claim, which must be submitted in accordance with the following:

1. Prepare the paper replacement claim for the service at issue with the correct billing information.
2. Complete the *Overpayment Option Form* and indicate acceptance of the recovery of the inappropriately billed claim.
3. Send the paper replacement claim and the *Overpayment Option Form* to Optum Rx as instructed in the audit letter.

Be sure to clearly indicate on all replacement claims the internal control number (ICN)/Claim ID of the audited claim that is being replaced.

Please note the following regarding paper replacement claims:

- The process as described in the preceding steps must be followed to prevent the paper replacement claims from being denied as a duplicate.
- Paper replacement claims are not to be submitted and will not be processed unless the provider has agreed to recovery of the overpayment.
- Providers must correct the error identified on the audited claim. Submitting the paper replacement claim exactly as it was originally billed results in the claim being re-audited.
- Optum Rx accepts paper replacement claims **only** when both of the following apply:
  - More than 180 days past the date of service
  - Subject to the audit and recovery process

Reporting of Suspected Fraud/Abuse

Providers are strongly encouraged to report any information related to potential fraud or abuse to the appropriate authorities:

Provider Concerns line: 800-457-4515

Program Integrity email: program.integrity@fssa.in.gov

Information regarding reporting of suspected Medicaid fraud or abuse is located in the *Provider and Member Utilization Review* module.

Section 8: Preferred Drug List and Prior Authorization Requirements

The Indiana Health Coverage Programs (IHCP) initiated the Indiana Rational Drug Program (IRDP), and the Preferred Drug List (PDL) evolved from that initiative. Prior authorization (PA), a key part of the PDL, is a utilization management tool that helps to ensure that only medically necessary services are authorized for payment. In this manner, the IHCP prescription benefit is based on both clinically appropriate and fiscally sound prescribing practices. See PA Criteria and Administrative Forms quick link on the Optum Rx Indiana Medicaid website, accessible from the *Pharmacy Services* page at in.gov/medicaid/providers).

Preferred Drug List

Not all drug classes covered by the IHCP pharmacy benefit are subject to the PDL. Drugs in classes that are subject to the PDL have a *preferred* or *nonpreferred* status. In general, *preferred* drugs do not require PA, whereas *nonpreferred* drugs do require PA. It is the prescriber who must initiate and submit a PA request for a nonpreferred drug.

The Therapeutics Committee, a subcommittee of the Drug Utilization Review (DUR) Board, evaluates therapeutic classes based upon clinical (first) and fiscal (second) considerations. The Therapeutics Committee makes recommendations to the DUR Board regarding the content of the PDL. The DUR Board performs a review of the PDL in its entirety annually. See the Optum Rx Indiana Medicaid website for information about the PDL, Therapeutics Committee, DUR Board and PDL Evaluation Report. Providers should direct all questions about the PDL to Optum Rx toll-free at 855-577-6317.

Prior Authorization Requirements

Pharmacy PA requests must be initiated, completed, and submitted by the prescriber. Policies are dynamic in nature; therefore, providers should always refer to the PDL and IHCP bulletins and banner pages for the most up-to-date program information. Pharmacy providers may intervene when receiving the "PA required" notifications shown in Table 16. These notifications are considered "false positives," not requiring PA, with nonclinical information provided by the pharmacist. See *Indiana Administrative Code 405 IAC 5-3-5, Sec. 10*.

Table 16 – Prior Authorization Criteria

Criteria Name	Criteria
Atypical antipsychotic 15-day limit	Pharmacy has claims in history prior to Medicaid eligibility or is able to confirm the use of drug samples
Early refill/duplicate fill	See the *Early Refill Prior Authorization for Legend Drugs* section of this document
Severity level 1 drug/drug interaction	Pharmacy has received direction to discontinue one of the drugs involved in the interaction
Edits based upon $ limits/parameters	Pharmacy to confirm the quantity and price of the claim only

For information on the criteria pertaining to or authorization requirements for these drugs, access the PA Criteria and Administrative Forms quick link on the Optum Rx Indiana Medicaid website or call Optum Rx toll-free at 855-577-6317.

Automated Pharmacy Prior Authorization ("SilentAuth")

Optum Rx executes real-time prior authorization decisions by using clinical PA edits supported by the member's medical and pharmacy claims data. This process results in quicker PA determinations for pharmacy claims processed by the fee-for-service (FFS) pharmacy benefit, with less intervention on the part of pharmacy and prescribing providers.

Automated prior authorization ensures that the prescribed therapy meets Indiana-specific evidence-based criteria for appropriate use. Based on recommendations from the Indiana Medicaid Drug Utilization Review Board, Therapeutics Committee and Mental Health Quality Advisory Committee (applicable only to mental health drugs), the Family and Social Services Administration (FSSA) reviews and approves the clinical edits and criteria used in processing claims. If applicable edit criteria are met, the claim continues through the pharmacy claim-processing system. If the criteria are not met, the claim is denied, and the provider receives notification to contact Optum Rx.

Clinical edits are added after the approval process noted previously. Providers are given advance notification of implementation of new edits, via provider bulletins or banner pages.

Access the Optum Rx Indiana Medicaid website for additional information regarding prior authorization edits.

Pro-DUR Edits Requiring Prior Authorization

The following Prospective Drug Utilization Review (pro-DUR) edits require prior authorization:

- Drug – Drug severity level 1 interactions
- Overutilization (early refill [ER]) – See the *Early Refill Prior Authorization for Legend Drugs* section
- >34-day supply for nonmaintenance medications and >100-day supply for maintenance medications (see the *Days Supply – Maintenance and Nonmaintenance Medications* section)

The *prescriber* must call Optum Rx toll-free at 855-577-6317 and provide medical necessity justification for consideration of an override of a drug-drug interaction in which both medications are being taken concurrently.

The *dispensing pharmacist* may call Optum Rx for the following:

- An override of a drug-drug interaction that involves a discontinued medication (for example, a "false positive")
- Overrides of overutilization (ER) edits

Early Refill Prior Authorization for Legend Drugs

The IHCP requires at least 85% of a prescription claim's days supply to elapse to allow subsequent prescription claims to pay or PA requests to be approved.

Early Refill Prior Authorization for Drugs on the OTC Drug Formulary Dependent on Allowed Amount

PA is not required for an early refill (ER) request for drugs included on the Over-the-Counter (OTC) Drug Formulary when the Medicaid-allowed amount for the claim is less than or equal to $20. The pharmacy receives a rejection message of "DUR Reject Error," which allows the pharmacist to override the rejection with the appropriate DUR response codes. For early refill rejections received on federal legend drugs and the OTC Drug Formulary medications with allowed amounts greater

than $20, the pharmacy receives rejections of "Pro-DUR Alert Requires PA." For overrides of overutilization (ER) edits, the pharmacist may call Optum Rx toll-free at 855-577-6317.

Emergency Supply

In instances in which PA cannot be immediately obtained, a pharmacist may dispense and be reimbursed for up to a 72-hour supply of a covered outpatient drug as an "emergency supply."

In addition, to allow for holidays, weekends and other times when prior authorization offices are closed, operational policy regarding "emergency supply" is that pharmacies can be paid for claims representing a maximum of a four-day supply of a covered outpatient drug, without prior authorization. For packaging that inherently cannot be broken down to a four-day or less supply (example: metered dose inhalers), the pharmacy should dispense the smallest quantity possible that is adequate for the "emergency supply." The provider should internally document that the quantity dispensed was, due to manufacturer packaging constraints, the least that could be dispensed while meeting the patient needs for the "emergency supply."

All "emergency supply" claims (both paper and electronic/POS [point of sale]) should be submitted with the Level of Service = 03 ("Emergency" Indicator) and the actual "days supply" being dispensed, up to but not exceeding "4."

Emergency Indicator = 03 Level of Service
Days Supply = Less than or equal to four days

If the prior authorization has not been approved after an initial emergency supply has been dispensed, the pharmacy provider should contact the Optum Rx call center to confirm whether a prior authorization request was submitted and determine whether the use of an additional emergency supply is appropriate.

Provision of emergency supplies must be documented on the hardcopy of the prescription. Pharmacy providers should also document the circumstances that support providing the emergency supply. Claims for emergency supplies are subject to postpayment review.

The purpose of the "emergency supply" policy is to comply with federal law pertaining to Medicaid prior authorization programs. **The IHCP does not reimburse for "emergency supply" claims for Medicare Part D covered drugs for dually eligible members.**

The IHCP does not intend for "emergency supply" provisions to allow pharmacy providers to circumvent otherwise applicable program parameters, such as PDL status, *brand medically necessary* requirements, PDL step-therapy edits or early refill edits.

For questions about "emergency supply" provisions, the pharmacist may call Optum Rx toll-free at 855-577-6317. Compliance with IHCP "emergency supply" provisions is monitored via provider audits. Applicable sanctions may be imposed for violations of policy.

> *Note: "Emergency supply" should not be confused with Emergency Services Only (Package E).*

Days Supply – Maintenance and Nonmaintenance Medications

Fee-for-service claims for maintenance medications are limited in quantity to no more than a 100-day supply per dispensation. A *maintenance medication* is a drug that is prescribed for chronic, long-term conditions and is taken on a regular, recurring basis.

Nonmaintenance medications are limited in quantity to no more than a 34-day supply per dispensation.

Mental Health Medications and Mental Health Quality Advisory Committee

State legislation *House Enrolled Act* (HEA) 1325 created the Mental Health Quality Advisory Committee (MHQAC) as an advisory body to the Office of Medicaid Policy and Planning (OMPP). Pursuant to statute (*Indiana Code IC 12-15-35-51*), the MHQAC members include:

- Director of Health Policy and Medicaid (who chairs the committee)
- Medical director of the Division of Mental Health and Addiction (DMHA)
- FSSA representative
- Statewide mental health advocacy organization representative
- Statewide mental health provider organization representative
- Representative from a managed care entity (MCE) that participates in the state's Medicaid program
- Member with expertise in psychiatric research representing an academic institution
- Pharmacist licensed under Indiana law
- Commissioner of the Department of Corrections or the Commissioner's designee

The purpose of the committee is to advise the OMPP and make recommendations concerning the clinical use of mental health and addition medications. All recommendations made by the MHQAC must be reviewed and approved by the Indiana Medicaid DUR Board prior to implementation in the IHCP pharmacy benefit.

Mental Health Drug Utilization Edits

Mental health drug utilization edits are defined as pharmacy claim-processing edits, some of which require a medical necessity review through the PA process, addressing prescribing situations that are inconsistent with established pharmacokinetic principles and clinical practice guidelines. Mental health drug utilization edits include, but are not limited to:

- Drug interactions
- Frequency of refills
- Dose optimization
- Age
- Days supply
- Compounded drug claims
- Quantities dispensed
- Quality (for example, therapeutic indication, therapeutic duplications and so on)

The intent of the mental health drug utilization edits is to promote patient adherence to medication regimens and ensure safe, appropriate use of medications in the IHCP population. Mental health drug utilization and medical necessity quality edits do not constitute formulary restrictions. Mental health drug utilization edits are reviewed quarterly by the MHQAC and DUR Board. The mental health drug utilization edits are consistent with the rules and regulations published in *IC 12-15-35.5-7 Drug Utilization Review*. Providers should refer to bulletins and banner pages for the most current information regarding utilization edits. For an up-to-date list of the mental health drug utilization edits, see the Mental Health Quality Advisory Committee selection in the Boards and Committees tab on the Optum Rx Indiana Medicaid website.

Administrative Review and Appeal Process for Prior Authorization Denial

A prescriber desiring a review of a modification or denial decision of a prior authorization request must submit a written request for administrative review within seven business days of the receipt of notification of the modification or denial. The request for administrative review should be sent to the address indicated in Table 1.

The following information must be included with the prescriber's written request for administrative review:

- Written *Medicaid Prior Review and Authorization Request* form (copy of original)
  -or-
  Summary letter with requested services described in detail; include the prior authorization number, member name and Medicaid number (IHCP Member ID)
- Documentation, including medical records, equipment, consultations, case histories and/or therapy evaluations; include any documentation supporting the provider/appellant case

Please note the following important information:

- Failure by a prescriber to request an administrative review in a timely fashion will result in the loss of the right to request an administrative hearing – *Indiana Administrative Code 405 IAC 1.1 General Provisions*.
- The review decision of the contractor will be rendered within seven business days of receipt of the request for administrative review.
- The review will assess medical information pertinent to the case in question.
- The Medicaid medical director, or that individual's designee, will perform the review.
- The requesting prescriber and the member will receive written notification of the decision containing:
  - The determination reached by the Medicaid contractor and the rationale for the decision
  - Prescriber/member appeal rights through the FSSA