To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

Table of Contents

Related Clinical Coverage Policies
Refer to https://medicaid.ncdhhs.gov/for the related coverage policies listed below:
9A, Over the Counter Products
9B, Hemophilia Specialty Pharmacy Program

1.0   Description of the Procedure, Product, or Service

The following policy applies to NC Medicaid (Medicaid) and NC Health Choice (NCHC) covered legend drugs and covered over the counter (OTC) products dispensed by outpatient pharmacy providers.

1.1   Definitions

None Apply.

2.0   Eligibility Requirements

2.1   Provisions

2.1.1   General

(***The term "General" found throughout this policy applies to all Medicaid and NCHC policies***)

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
   2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise)* Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.
c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.
d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2   Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. **Medicaid**

   None Apply.

b. **NCHC**

   None Apply.

2.2   Special Provisions

2.2.1   EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. **42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure that is:

1. unsafe, ineffective, or experimental or investigational.
2. not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. **EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NC Tracks Provider Claims and Billing*

Assistance Guide, and on the EPSDT provider page. The Web addresses are specified below.

NC Tracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page: https://medicaid.ncdhhs.gov/

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;

b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and

c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

The Medicaid and NCHC Outpatient Pharmacy Programs shall cover prescribed drugs when they meet all the following guidelines and specific criteria listed in this policy:

a. The prescribed drug must have Federal Drug Administration (FDA) approved indications for which it is being prescribed;

b. The prescribed drug must bear the federal legend statement

c. A legend drug must be manufactured by a company that has signed a National Medicaid Drug Rebate Agreement with the Centers for Medicare and Medicaid Services (CMS);

Selected OTC products including insulin are covered when they meet the criteria listed in clinical coverage-policy 9A, *Over the Counter Products,* at https://medicaid.ncdhhs.gov/;

d. The prescription must be written for whom the claim is billed;

e. The vaccine is a covered service when the pharmacy is compliant with all North Carolina Medicaid Billing Procedures, Federal laws, and State laws with regard to vaccines;

f. Prenatal vitamins and fluoride; and

g. Legend Calcitriol (vitamin D) when used for predialysis beneficiaries, dialysis beneficiaries, and hypoparathyroidism beneficiaries.

Providers who determine that the indication or dosing for a particular drug is medically necessary for a beneficiary, but those parameters fall outside of the FDA approved guidelines and evidence-based standards for that drug, may submit medical record information and compendia/peer-reviewed medical literature supporting its use (as per 42U.S.C. 1396r 8(g)(1)(B)) to the DHB Director of Pharmacy and Ancillary Services for a case-by-case review. The address to send this information is:

Director of Pharmacy and Ancillary Services
Division of Health Benefits
2501 Mail Service Center
Raleigh, NC 27699-2501.

3.3   Coverage of Compounded Drugs

Medicaid and NCHC shall cover compounded products when:

a. a mixture of two or more ingredients is physically inseparable;

b. at least one of the components of the compounded drug is a legend drug;

c. it is expected that the quantity of legend drug is sufficient to have a therapeutic effect; and

d. the legend drug is manufactured by a company that has signed a national Medicaid Drug Rebate Agreement with Centers for Medicaid and Medicare Services (CMS).

A compounded prescription contains a quantity of a legend drug sufficient to have a therapeutic effect and cannot be two different drugs (capsules or tablets) separable but dispensed in the same bottle.

Refer to **Attachment A, Section J, Compounded Drugs,** for additional information on billing and reimbursement.

3.4   Medicaid and NCHC Drug Rebate Program

3.4.1   Federal Drug Medicaid Rebate Program

https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd091802.pdf
The Medicaid and NCHC Outpatient Pharmacy Programs shall cover drugs from manufacturers who have signed a national Medicaid Drug Rebate Agreement with CMS. Drug companies sign the agreement for specific drug manufacturer codes. Drug coverage is determined by the manufacturer code and not by the manufacturer name. The manufacturer code is indicated by the first five digits of the 11-digit National Drug Code (NDC) number.

Rebates are determined by North Carolina's Medicaid utilization data. Pharmacies are required to use the NDC number of the drug actually dispensed.

If accurate NDCs are not used, there is the potential for denial of claims, sanctions, and termination of provider agreements.

The Medicaid and NCHC programs shall supply pharmacy providers with a list of any additions or deletions to the list of covered Medicaid Rebate Manufacturers through newsletters posted on NC Medicaid's website at https://medicaid.ncdhhs.gov/.

3.4.2 N.C. Medicaid Supplemental Drug Rebate Program

The Medicaid Outpatient Pharmacy Program also participates in a supplemental drug rebate program for the Medicaid program. The State negotiates supplemental rebates in additional to federal rebates for both programs. Payment of supplemental rebates results in a drug being added to the preferred drug list. **Refer to Subsection 5.2, N.C. Medicaid and N.C. Health Choice Preferred Drug Lists.**

3.4.3 N.C. Health Choice Drug Rebate Program

The State negotiates separate rebates for the NCHC program.
Payment of rebates by drug manufacturers for the NCHC program is voluntary.

3.5 Medicaid Additional Criteria Covered

None Apply.

3.6 NCHC Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when the:

a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0;**

b. the beneficiary does not meet the criteria listed in **Section 3.0;**

c. the procedure, product, or service duplicates another provider's procedure, product, or service; or

d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

Medicaid and NCHC shall not cover the following:

a. OTC products. Refer to **Subsection 3.2.1(b)** Federal legend drugs or their generic equivalents that are on the Drug Efficacy Study Implementation (DESI) list established by the FDA;

b. Any drug manufactured by a company that has not signed a rebate agreement. Exception shall be made for CroFab, and selected vaccines and radiopharmaceuticals;

c. Fertility drugs;

d. Drugs used for cosmetic indications;

e. Medical supplies and devices. **Refer to Attachment A, Subsection C.6, Claims Processing for Selected Durable Medical Equipment (DME) Products;**

f. Diaphragms, which are a family planning service;

g. Intravenous (IV) fluids (Dextrose 500 ml or greater) and irrigation fluids; except for living arrangement codes 10 (Private Living Arrangement (not 1/3 reduction), 11 (Private Living Arrangement (with 1/3 reduction) (Medicaid Only), 13 (Living with Supplemental Security Income (SSI) Beneficiary), 52 (Domiciliary care, Six or More Beds (Special Assistance for the Aged (SAA), Special Assistance for the Disabled (SAD), 53 (Foster Care (Medicaid for Families (MAF), Medicaid for Infants and Children (MIC), State Foster Home Fund (HSF), Medicaid with IV-E Adoption Subsidy and Foster Care (IAS)) or 80 (Adoptive Home (MAF, MIC, MRF (Refugee Medical Assistance), HSF, IAS));

h. Erectile dysfunction drugs;

i. Weight loss and weight gain drugs;

j. Drug samples;

k. Drugs obtained from any patient assistance program;

l. Drugs used for the symptomatic relief of cough and colds that contain expectorants or cough suppressants;

m. Legend vitamins and mineral products. Refer to **Subsection 3.2.1(b);**

n. All DESI drugs and combinations equivalent to a DESI drug in compounded prescriptions. Drugs described by the FDA as DESI are products that the FDA has found to be less than effective or not proven to be as effective as indicated. Drug products that are identical, related or similar to DESI drugs are considered DESI. Updates and corrections are published in the Pharmacy Newsletters on Medicaid's website, https://medicaid.ncdhhs.gov/; or

o. A compounded prescription which is equivalent to an OTC product.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:

1. No services for long-term care.
2. No nonemergency medical transportation.
3. No EPSDT.
4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Authorization

Medicaid and NCHC shall require prior authorization for selected prescription drugs. Refer to http://nctracks.nc.gov/ for a list of prescription drugs that require prior authorization (PA). The website lists the medical necessity criteria for coverage for each medication that requires prior approval. Refer to **Attachment C** for instructions on requesting prior authorization.

72-Hour Emergency Supply

A 72-hour emergency supply may be provided if a beneficiary is waiting for acknowledgment of the prior authorization request. The pharmacy is reimbursed for the supply if the prescription is changed to an alternative medication. Refer to **Attachment C** for information on the processing of a 72-hour emergency supply.

5.1.1 Prior Authorization Process for Pharmacists Serving Long Term Care Facilities

Pharmacists serving nursing facilities, adult care homes, and Intermediate Care Facilities for Individuals with Intellectual Disabilities(ICF/IID) are allowed to request prior authorization.

5.2 N.C. Medicaid and N.C. Health Choice Preferred Drug List

The N.C. General Assembly [Session Law 2009-451, Sections 10.66(a)-(d)] authorized the establishment of the N.C. Medicaid Preferred Drug List (PDL), which allows the Division of Medical Assistance to obtain better prices for covered outpatient drugs through supplemental rebates. All therapeutic drug classes for which the drug manufacturer provides a supplemental rebate under the Medicaid program are considered for inclusion on the list.

The N.C. General Assembly [Session Law 2011-145, Section 10.31(d)(2)(r)(6)] authorized establishment of a Preferred Drug List for the N.C. Health Choice program. The State negotiates separate rebates for the NCHC program. Payment of rebates by drug manufacturers for the NCHC program is voluntary.

Refer to https://medicaid.ncdhhs.gov/ for more information about the NC Medicaid and NCHC PDL.

5.3 Management of Polypharmacy and Low Adherence

A beneficiary with low adherence to chronic medications and polypharmacy shall be referred to the Community Care of North Carolina Network for medication therapy management to ensure coordinated care.

5.4 Dispensing and Maximum Supply

The maximum supply for all drugs is a 34-day supply unless the medication meets the criteria described below:

5.4.1 Birth Control and Hormone ReplacementTherapies

Up to 12 months of oral birth control medications and up to three months of prepackaged hormone replacement therapies are allowed.

5.4.2 Non-Controlled Maintenance Medications

Medicaid and NCHC beneficiaries may obtain a 90-day supply of medications if the claim is for a non-controlled, maintenance medication.

This is at the sole discretion of the beneficiary's health care provider. Only one co-pay is collected and only one dispensing fee is paid for the 90-day supply.

5.4.3 Quantity and Episodic Drugs

Some drugs are meant to be used episodically and dispensed in quantities that support less than daily use. NC Medicaid may impose quantity limitations for episodic drugs based on advice from the North Carolina Physician Advisory Group (NCPAG), which considers FDA labeling, evidence-based guidelines, systematic reviews, and consultation with the DHHS designated contractor as to North Carolina community and best practice standards about precise duration of use.

The NCPAG may recommend for each drug that is designated as an episodic drug other restrictions or actions currently available under the Outpatient Pharmacy Program including:
a. Evaluating the applicability of quantity limitations of episodic drugs for a beneficiary who normally receives their legend medications packaged in a specialized distribution system;
b. Prior authorization criteria and requirements; and
c. Actions that minimize the number of dispensing fees for drugs that are prescribed in limited quantities.

For quantity limitations refer to the Preferred Drug List or the specific Prior Authorization policy found at http://www.nctracks.nc.gov/

NC Medicaid shall monitor utilization of designated episodic drugs on an annual basis or more frequently if necessary, in order to assess the need for changes in the limits. This data is shared with the NCPAG.

5.5 Co-payments

5.5.1 Medicaid Co-payment Requirements

An eligible Medicaid beneficiary, who receives prescribed drugs, is required to make a co-payment of $3.00 for each prescription received unless they are exempt for one of the reasons listed below in **Subsection 5.5.2**. A provider may not deny services to any Medicaid beneficiary because of the individual's inability to pay a deductible, coinsurance or co-payment amount. A provider may not willfully discount copays for a Medicaid beneficiary, and an individual's inability to pay does not eliminate his or her liability for the cost sharing charge. The provider shall open an account for the beneficiary, collect the amount owed at a later date, and document all attempts to collect the copay. If the account has not been paid, the pharmacy may in the course of normal accounting principles, write-off the charges and stop monitoring the claim.

5.5.2 Co-payment Exemptions for a Medicaid beneficiary

A Medicaid beneficiary is exempt from a co-payment for any one of the following:

a. The beneficiary is under 21 years of age;

b. The beneficiary resides in a nursing home facility, Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) or a mental health hospital;

c. Adult care home and hospice beneficiaries are responsible for co-payment.

d. The drug is classified as family planning (birth control medication). Exemption from the co-pay for family planning drugs is indicated on the drug file and does not require any additional indicators. Do not collect a co-pay for oral contraceptives;

e. The beneficiary is classified as a CAP beneficiary as indicated on the beneficiary's Medicaid Identification Card (MID card);

f. The beneficiary is pregnant. The co-payment exemption is made automatically by the claims processing system for an eligible beneficiary. In the event that the system does not override the copay, the pharmacy may use any of the ICD-10-CM codes listed in **Attachment J** to indicate pregnancy; or

g. A "4" in the Prior Authorization Type Code or a "2" in the pregnancy indicator field on a point-of-sale (POS) claim also indicates an exemption from the co-payment deduction for pregnancy.

h. The beneficiary is a member of a federally recognized tribe.

5.5.3 NCHC Co-payment Requirements

An eligible NCHC beneficiary who receives prescribed drugs is required to make a co-payment according to the income levels listed below:

Income Level	Co-payment
Class A Less than or equal to 150% of Family Poverty Level AND Native American OR Alaska Native	• No Co-payment
Class J Less than or equal to 150% of Family Poverty Level	• Generic $1.00 • Brand with no generic $1.00 • Brand with generic $3.00 • OTC medication $1.00
Class K 151% - 200% of Family Poverty Level	• Generic $1.00 • Brand with no generic $1.00 • Brand with generic $10.00 • OTC medication $1.00
Class S 151% - 200% of Family Poverty Level AND Native American OR Alaska Native	• No Co-payment
Class L (Optional Extended Coverage) 201% - 225% of Family Poverty Level	• Generic $1.00 • Brand with no generic $1.00 • Brand with generic $10.00 • OTC medication $1.00

5.5.4 Co-payment Exemptions for NCHC beneficiaries

NCHC beneficiaries are exempt from co-payments if they are eligibility type MIC-A or MIC-S. There are no other co-payment exemptions for NCHC beneficiaries.

5.6 Returned Medication

Pharmacists shall follow the N.C. Board of Pharmacy regulations for returned medications. **A credit must be issued** for all prescriptions that are allowed to be returned to stock under N.C. Board of Pharmacy regulations. Credits must be handled by completing a reversal of a Point-of-Sale (POS) claim.

Refer to **Attachment A, Section K, Point-of-Sale Reversals**; and **Section O, Resubmission of Rejected or Denied Claims,** for additional information.

5.7 Automatic Refills and Shipments

Automatic refills and automatic shipments are not allowed. Medicaid and NCHC shall not pay for any prescription (original or refill) based on a provider's auto refill policy. Medicaid and NCHC shall not pay for any prescription without an explicit request from a beneficiary or the beneficiary's responsible party, such as a caregiver, for each refilling event. The pharmacy provider shall not contact the beneficiary in an effort to initiate a refill unless it is part of a good faith clinical effort to assess the beneficiary's medication regimen. The possession, by a provider, of a prescription with remaining refills authorized does not in itself constitute a request to refill the prescription. A beneficiary or

provider shall not waive the explicit refill request and enroll in an electronic automatic refill program. Any prescriptions filled without a request from a beneficiary or their responsible party are subject to recovery. Any pharmacy provider with a policy that allows filling prescriptions on a regular date or any type of cyclical procedure is subject to audit, claim recovery or possible suspension or termination of their provider agreement. This does not prohibit a pharmacy from using refill reminders to encourage a beneficiary's adherence to their medication regimen, as long as the reminders are for medications the beneficiary is currently receiving.

5.8 Generic Substitution

Refer to **Subsection 5.11** for information on Narrow Therapeutic Index (NTI) drugs.

The General Assembly authorizes and mandates pharmacists participating in Medicaid to substitute generic drugs for brand or trade name drugs unless the prescriber specifically orders the brand name drug. A prescription for a drug designated by a brand or trade name for which one or more equivalent drugs are available is considered an order for the drug by its generic name, except when the prescriber personally indicates in his or her own handwriting on the prescription order "**medically necessary**." Current Session Law states:

"Dispensing of generic drugs. – Notwithstanding G.S. 90-85.27 through G.S. 90-85.31, or any other law to the contrary, under the Medical Assistance Program (Title XIX of the Social Security Act), and except as otherwise provided in this subsection for drugs listed in the narrow therapeutic index, a prescription order for a drug designated by a trade or brand name shall be considered to be an order for the drug by its established or generic name, except when the prescriber has determined, at the time the drug is prescribed, that the brand-name drug is medically necessary and has written on the prescription order the phrase "medically necessary."

An initial prescription order for a Medicaid or NCHC beneficiary that is for a drug listed in the narrow therapeutic drug index that does not contain the phrase "medically necessary" shall be considered an order for the drug by its established or generic name, except that a pharmacy shall not substitute a generic or established name prescription drug for subsequent brand or trade name prescription orders of the same prescription drug without explicit oral or written approval of the prescriber given at the time the order is filled. Generic drugs shall be dispensed at a lower cost to the Medical Assistance Program rather than trade or brand-name drugs.

Notwithstanding this subdivision to the contrary, the Secretary of Health and Human Services may prevent substitution of a generic equivalent drug, including a generic equivalent that is on the state maximum allowable cost list, when the net cost to the State of the brand-name drug, after consideration of all rebates, is less than the cost of the generic equivalent. As used in this subsection, "brand name" means the proprietary name the manufacturer places upon a drug product or on its container, label, or wrapping at the time of packaging; and "established name" has the same meaning as in section 502(e)(3) of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 352(e)(3).

The selection of a drug product must not be more expensive than the brand or trade name originally written by the prescriber. The pharmacist shall fill the prescription with the least expensive generic in the pharmacy, unless a specific brand or trade

name is specified by the prescriber in the required manner or the net cost to the State of the brand-name drug has been determined to be less than the cost of the generic equivalent. NC Medicaid may use a certification form and procedures for "medically necessary" brand-name drugs. For audit purposes, the brand name and manufacturer must be documented on the prescription.

5.8.1 Generic Substitution for Brand Medically Necessary Medications

A prescription for a drug written under its brand or trade name must be filled with a generic version of the drug when one is available unless the net cost to the State of the brand-name drug has been determined to be less than the cost of the generic equivalent OR the prescriber has indicated that the brand name drug is medically necessary for the beneficiary to receive. The prescriber shall indicate this by writing "medically necessary" on the prescription order for the drug. If the pharmacist receives a prescription for a drug written by its brand or trade name with the medical necessity documentation on the face of the prescription even though there is a generic version of the drug available, the pharmacist shall dispense the brand name drug. If the prescription is written by the brand or trade name of the drug but "medically necessary" is not written on the face of the prescription by the prescriber, the pharmacist shall dispense a generic version of the drug.

NC Medicaid may impose prior authorization requirements on brand-name drugs for which the phrase "medically necessary" is written on the prescription.

5.8.2 Generic Substitution for Narrow Therapeutic Index Drugs

A new prescription for a drug that is on the Narrow Therapeutic Index (NTI) list that is written under its brand or trade name must be filled with a generic version of the drug when one is available, unless the prescriber has indicated that the brand name drug is necessary by writing "medically necessary" on the prescription order for the drug. A prescription for a narrow therapeutic index drug must be refilled using only the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription, unless the prescriber is notified by the pharmacist prior to the dispensing of another manufacturer's product, and the prescriber and the beneficiary give documented consent to the dispensing of the other manufacturer's product. For purposes of this subsection, the term "refilled" means a new prescription written at the expiration of a prescription which continues the beneficiary's therapy on a narrow therapeutic index drug. When utilizing a brand NTI drug in accordance with the rules above, use Dispense as Written (DAW) 7 to indicate brand required and to override any NADAC generic rate or MAC.

5.9 Maximum Allowable Cost (MAC)

The Outpatient Pharmacy Program utilizes a state MAC list for generic and multi-source brand drug products that do not have a NADAC brand or generic price. The determination of which drug products are assigned a state MAC is the direct responsibility of NC Medicaid. The state MAC list contains mostly products with A-rated equivalents, and in the great majority of cases, products marketed by at least two labelers. The State's MAC reimbursement is based on the application of a percentage factor applied to the lowest priced generic. In cases where the calculated MAC rate, based on

the primary percentage factor, results in a price less than the cost of the second lowest generic product, at least an additional 10 percent margin is added to the cost of the second-lowest drug to establish the MAC price. The MAC pricing factor is set by NC Medicaid and may change as deemed appropriate.

The additional margin is variable due to the wide range of differences in cost from product to product.

For established generic drugs with only one supplier, the MAC price is established between the actual acquisition cost and average wholesale price of the generic drug. A minimum reimbursement of 20 percent above actual acquisition is guaranteed for these drugs. In most cases, MAC pricing is substantially higher than this 20 percent, which allows the State and pharmacies to share in the cost savings of using the generic product.

Drugs subjected to MAC pricing must be in adequate supply. Drug shortage information is verified through the national pharmacy websites as well as through information provided by national drug wholesalers.

The federal and state MAC lists work in conjunction with one another. The lowest price at any given time will be the current reimbursement for a drug claim.

5.9.1 NADAC generic rate and MAC Override

It is possible to override either the NADAC generic rate or the state MAC limitations if a prescriber certifies that a specific brand of drug, which has a NADAC generic rate or MAC limitation, is medically necessary for a particular beneficiary (refer to **Subsection 5.8, Generic Substitution**). This certification must fall under federal and state regulations, which specify that the certification "Medically Necessary" must be in the prescriber's own handwriting and signed by the prescriber. This can be written directly on the face of the prescription or on a separate document, which must be attached to the original prescription.

Dispense as Written (DAW) 1 on a POS claim is a NADAC generic rate and MAC override. NC Medicaid may impose prior authorization requirements on brand-name drugs for which the phrase "medically necessary" is written on the prescription.

Dispense as Written (DAW 7) on a POS claim is a NADAC generic rate and MAC override. This override shall apply when a prescription for a drug on the NTI list is written under its brand name and the prescriber has indicated the brand name drug is necessary by writing "medically necessary" on the prescription order. NC Medicaid may impose prior authorization requirements on brand-name drugs for which the phrase "medically necessary" is written on the prescription.

Dispense as Written (DAW 8) on a POS claim is a NADAC generic rate and MAC override. This override shall be used only when a multi-source Brand generic equivalent is not available in the marketplace. NC Medicaid may impose prior authorization requirements on brand-name drugs for which the phrase "medically necessary" is written on the prescription.

Dispense as Written (DAW 9) on a POS claim is a NADAC generic and MAC override. This override shall apply only to multi-source Brand drug products that are preferred on the NC Medicaid and NCHC PDL and have a nonpreferred generic equivalent. NC Medicaid may impose prior authorization requirements

on brand-name drugs for which the phrase "medically necessary" is written on the prescription.

5.9.2 Provider State MAC Inquiries

The North Carolina Medicaid Program contracts with a vendor in maintaining the State Maximum Allowable Cost (State MAC) program for generic drugs and hemophilia drugs.

Providers may contact the vendor regarding specific questions or concerns about the State MAC rate, rate calculation process, changes in the acquisition cost of a drug, changes in product availability, or to obtain a copy of the State MAC list. Contact information is posted on the NC Medicaid website.

Providers with questions about a State MAC rate will be asked to complete a "State MAC Pricing Inquiry Worksheet." This request should be completed by providing the information requested and submitting copies of drug purchase records which represent the current price paid for the particular drug(s) in question.

Based on the information obtained, the vendor may conduct additional inquiries with other pharmacies to obtain additional drug purchase records to determine if there has been a change in the market. The vendor may also contact drug manufacturer(s) to confirm any reports of market unavailability. After reviewing the data submitted by the pharmacy, and any additional information obtained, the vendor will prepare an analysis of the inquiry for review by NC Medicaid.

The results of NC Medicaid's review will be communicated to the pharmacy as soon as a final decision is made. If a rate adjustment is approved, a file will be prepared to update the State MAC rate and its effective date in the pharmacy claims processing/payment system.

5.9.3 Unacceptable Practices for Drugs with MAC Prices

a. The prescriber is not allowed to indicate "Medically Necessary" over the telephone or e-prescription for the pharmacist to document on the prescription if the drug is a MAC drug.

   Note: If the drug is not a MAC drug, the pharmacist may receive oral authorization not to substitute from the prescriber, write "Medically Necessary" on the prescription, and initial it. If a telephone prescription or e-prescription requiring brand only is accepted, the prescriber must send a new prescription within 72 hours with "Medically Necessary" written on the prescription in the prescriber's own handwriting.

b. A prescriber's signature over a printed statement indicating "Dispense as Written" or "Medically Necessary" with a check or X in a box on the prescription indicating "Dispense as Written" is unacceptable.

c. A handwritten statement transferred to a rubber stamp and then stamped on the prescription is unacceptable.

d. The abbreviation "DAW" on the prescription by the prescriber is unacceptable.

   If a physician has properly authorized for the dispensing of a brand name drug product when that drug product is a MAC drug, the pharmacist can bill for reimbursement based on the lower of the usual and customary charge or

the reimbursement rate of the brand name drug plus the dispensing fee. To indicate that the prescriber has documented "Medically Necessary" and bill for the brand, indicate DAW 1 on an online POS claim. Do not use DAW 1 for brand name, single source drugs. The MAC override must only be used to override a MAC price.

5.9.4 Prenatal Vitamins

Due to the many variations in the ingredients in prenatal vitamins and the corresponding variation in the ingredient cost, a single MAC rate for prenatal vitamins is established and maintained. Current marketplace acquisition cost, average wholesale price and wholesale acquisition cost are evaluated to determine the single MAC rate. Prenatal Vitamins pay at NADAC rates first, but when no NADAC is on file, the single MAC rate applies.
Refer to **Attachment H** for DAW codes.

5.10 Hemophilia Specialty Pharmacy Program

The General Assembly [Session Law 2012-142, Section 10.48(a2)] mandates that the N.C. Medicaid and N.C. Health Choice Pharmacy programs establish a specialty pharmacy program for hemophilia drugs. Refer to clinical coverage policy 9B, *Hemophilia Specialty Pharmacy Program,* at https://medicaid.ncdhhs.gov/.

5.11 Narrow Therapeutic Index Drugs

N.C. General Statute 90-85.27 defines Narrow Therapeutic Index (NTI) drugs to mean those pharmaceuticals having a narrowly defined range between risk and benefit. Such drugs have less than a twofold difference in the minimum toxic concentration and minimum effective concentration in the blood or are those drug product formulations that exhibit limited or erratic absorption, formulation-dependent bioavailability, and wide intrapatient pharmacokinetic variability that requires blood-level monitoring.

Drugs identified as having narrow therapeutic indices are designated as NTI drugs by the Secretary of the N.C. Department of Health and Human Services upon the advice of the State Health Director, the N.C. Board of Pharmacy, and the N.C. Medical Board, and are subject to the provisions of NCGS 90-85.28(b1).

The list of NTI drugs is reviewed on an annual basis and submitted to the Office of Administrative Hearings by the N.C. Board of Pharmacy for publication in the N.C. Register. Refer to **Attachment D, Narrow Therapeutic Index Drugs,** for the current list of drugs designated as NTI. Refer to G.S. 90-85.27 through G.S. 90-85.31 in **Subsection 5.8** for information regarding generic substitution, and **Subsection 5.9.1** for information regarding NADAC generic rate or MAC Overrides.

5.12 Billing for Partial Fills

Medicaid and NCHC shall not pay for medications that the beneficiary has not received. Pharmacists cannot issue an I owe you (IOU) to a beneficiary when the pharmacy is unable to dispense the full amount of a prescription and then bill Medicaid and NCHC for the total quantity of the prescription. If the remaining quantity is not dispensed and the pharmacist has received payment for the total quantity prescribed, it is considered fraudulent and appropriate action will be taken.

5.13   Incorrect Units for Unbreakable Packages

Billing inaccurate package sizes creates extra costs and delays for the Medicaid and NCHC programs when collecting drug rebates from manufacturers. Frequently, the quantity billed for drops does not match the package size, such as, 5 ml is billed for the 10 ml NDC. Bill the quantity that matches the package size for the NDC billed. If a different package size is used for the refill, the prescription must be updated to match the drug dispensed with the drug on the label, as is required by law.

The Outpatient Pharmacy Program accepts metric decimal quantities. The actual manufacturer package size (or multiples of the package size) must be indicated on the claim.

The table below shows some examples of NDCs and the correct corresponding package size that must be used when billing these products. For example, Lovenox must be billed in milliliters, so if 10 syringes are dispensed for the NDC indicated below, the metric decimal quantity would be 6 ml.

NDC	Drug	Metric Decimal Quantity
00075150616	Nasacort AQ Nasal Spray	16.5
00597001314	Combivent Inhaler	14.7
00186107008	Rhinocort AQUA Nasal Spray	8.6
00075062160	Lovenox 60mg prefilled syringe	0.60
00013830304	Xalatan 0.005% Eye Drops	2.5
00069313019	Zithromax 200mg/5ml Suspension	22.5
00065064835	Tobradex Eye Ointment	3.5
00054309036	Butorphanol 10mg/ml Spray	2.5
00085113201	Proventil HFA 90 mcg Inhaler	6.7
61570003775	Viroptic 1% Eye Drops	7.5

5.14   Beneficiary Management Lock-In Program

The North Carolina Administrative Code, 10A NCAC 22F .0704 and 10A NCAC 22F .0104, Session Law 2015-241, Section 12F.16.(l), along with 42 CFR 431.54 and the State Plan Amendment supports the State's development of procedures for the control of beneficiary overutilization of Medicaid benefits which includes implementing a Beneficiary Management Lock-In program. The Beneficiary Management Lock-In Program does not apply to the NCHC program. NC Medicaid has developed criteria for inclusion in the Beneficiary Management Lock-In Program.

A Medicaid beneficiary identified for the lock-in program is restricted to a single prescriber and pharmacy in order to obtain opioid analgesics, benzodiazepines and certain anxiolytics. The beneficiary shall obtain all prescriptions for these medications from their lock-in prescriber and lock-in pharmacy in order for the claim to pay. Claims submitted that are written by a prescriber or filled at a pharmacy other than those listed on the lock-in file are denied.

A beneficiary who qualifies for the program shall be notified and locked in for two years after which time they shall be removed from the program if they no longer meet the

criteria. A beneficiary who continues to meet the criteria is locked in for another two years. Once released from the lock-in program, prescription claims continue to be monitored. If a beneficiary meets the criteria again after being released from the program, they shall be re-identified for the lock-in program. The beneficiary cannot change their lock-in prescriber or pharmacy without authorization from NC Medicaid.

5.14.1 Inclusion in the Beneficiary Management Lock-In Program

A NC Medicaid beneficiary shall be locked-in to one prescriber and one pharmacy for controlled substances categorized as opiates or benzodiazepines and certain anxiolytics when one or more of the following criteria are met:

1. Beneficiary who has at least ONE of the following:
    a. Benzodiazepines and certain anxiolytics: six (6) or more claims in two (2) consecutive months.
    b. Opiates: six (6) or more claims in two (2) consecutive months.
2. Receiving prescriptions for opiates and/or benzodiazepines and certain anxiolytics from three (3) or more prescribers in two (2) consecutive months.

5.14.2 Exclusion from the Beneficiary Management Lock-In Program

Health Choice beneficiaries will not be part of the Lock-In Program

5.14.3 Emergency Supplies for the Beneficiary Management Lock-In Program

The N.C. Medicaid Program shall reimburse an enrolled Medicaid pharmacy for a four (4)-day supply of a prescription dispensed to a beneficiary locked into a different pharmacy and prescriber in response to an emergent situation. The provider shall be paid for the drug cost only and the beneficiary shall be responsible for the appropriate copayment. One emergency occurrence is reimbursed per beneficiary during each year of the two (2) year lock-in period. Paid quantities for more than a four (4)-day supply are subject to recoupment.

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid or NCHC qualifications for participation;

b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and

c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

In order to participate in the Medicaid and NCHC Outpatient Pharmacy Programs, pharmacists shall abide by the rules and regulations of the program, be in compliance with Title VI of the Civil Rights Act, agree that NC Medicaid or its DHHS designated contractors may conduct audits as necessary, and **accept payment for covered services as payment in full**. Pharmacies shall operate under permit or license to dispense drugs issued by the appropriate state or federal authority.

6.2 Filling Prescriptions

A provider of prescribed drugs shall file prescriptions numerically and in chronological order, either in normally occurring order with other prescriptions filled by the provider or in a separate file and each authorized refill must be recorded. Electronic versions of prescriptions are acceptable if they can be readily retrieved and the electronic images are retained according to the provider's NC Medicaid enrollment agreement. Refer to **Subsection 7.2, Record Retention.**

6.3 Changes in Pharmacy Status

Providers are responsible for notifying NC Medicaid within 30 calendar days when information related to their business or practice changes. Refer to the NC Tracks website at http://www.nctracks.nc.gov/provider/cis.html or Medicaid's website at https://medicaid.ncdhhs.gov/ for the Provider Change form or Provider Enrollment packet and additional information required for submission regarding the change if applicable.

NC Medicaid shall be notified of the following changes:
a. **Change of Ownership**

   The pharmacy shall apply for a new provider number and complete a new participation agreement and Electronic Commerce Services agreement if there is an ownership change of greater than 50 percent.
b. **Change of Pharmacy Name and Tax Name**
c. **Change of Billing Address**
d. **Change of Site (physical location) Address**
e. **Change of Billing Contact Information or Site Contact (physical location) Information such as** change of telephone number, fax number and e-mail address.
f. **Change to National Provider Identifier (NPI)**
g. **Change of Tax Number**
h. **Change in Pharmacy Permit**
i. **Closing a Pharmacy or Voluntary Participation Termination**

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:
a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

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7.2   Record Retention

Refer to the provider enrollment agreement for information on the record retention requirements for the Medicaid and NCHC programs.

Pharmacy providers utilizing automated data processing systems as record keeping systems shall be able to produce sight-readable documents of all original and refilled prescription information. The term sight-readable means that a representative of the State of North Carolina shall be able to examine the record and read the information from a CRT, microfiche, microfilm, or hard-copy printout.

Medicaid and NCHC records must be easily retrievable and kept on-site. Payments that cannot be audited because records are not easily retrievable and on-site are subject to recoupment.

7.3   Pharmacy Audits

Pharmacy records are audited periodically. The purpose of these audits is to ensure that the contractual agreement with NC Medicaid is being upheld. This contractual agreement between the pharmacy provider and NC Medicaid requires that the provider agrees to:

a. file prescriptions numerically and in chronological order on-site, either in normally occurring order with other prescriptions filled by the provider or in a separate file;

b. maintain as a permanent record on-site, an individual prescription for each drug submitted for reimbursement;

c. maintain as a permanent record on-site, purchase invoices representing the cost paid for all covered drugs and supplies reimbursed by NC Medicaid; and

d. follow rules published by the N.C. Board of Pharmacy for manual and computerized record-keeping related to drug ordering, dispensing, filling, and refilling.

7.4   Medicaid and NCHC Recoupments

The Program Integrity Section conducts regular post payment reviews in an ongoing attempt to ensure that Medicaid and NCHC payments are made only for the services that are covered under Medicaid and NCHC policy. When overpayments are identified, the provider is given written information about the errors and is required to refund the overpayment amount. It is vital that providers use these overpayment notices to educate billing staff concerning the importance of following policies. If additional billing guidance is needed, the provider may request a visit from NC Medicaid's fiscal agent's Provider Services unit.

Overpayments are addressed in the following ways:

a. NC Medicaid shall seek restitution of any and all improper payments made to providers by the Medicaid and NCHC programs. Recovery may be by lump sum payment, by a negotiated payment schedule not to exceed one (1) year or by withholding from the provider's pending claims the total or portion of the recoupment amount.

b. A provider may argue all or a part of a recoupment imposed by NC Medicaid by requesting a Reconsideration Review of the investigative findings and, thereafter, an Executive Decision.

In order to keep recoupment amounts to a minimum, NC Medicaid encourages providers to refer to the general bulletins and medical coverage policy information available on

Medicaid's website at https://medicaid.ncdhhs.gov/. Should you or your staff have questions about the policies or billings, it is vital to contact DHHS fiscal contractor's Provider Services unit at 800-688-6696.

Questions may be addressed to NC Medicaid's Chief Hearing Officer at 919-647-8200 or the NC Medicaid Program Integrity Pharmacy Review Section at 919-647-8000.

7.5 Emergency Preparedness Protocol

In the event of a state of emergency or disaster declared by the NC Governor, FEMA, or the US President, the following protocol must be enacted at the direction of the NC Secretary of Health and Human Services to prevent a significant disruption to the access of life saving prescriptions medications for NC Medicaid and NC Health Choice beneficiaries:

a. Waive utilization management requirements (that is PAs where applicable) and lift "refill -too -soon" edits.
b. Allow an affected enrollee to obtain the maximum extended day supply, if requested and available at the time of refill.

Once the Emergency Preparedness Protocol is enacted, NC Medicaid enrolled pharmacy providers shall submit these pharmacy claims with "09" (Emergency Preparedness) in the PA Type Code field and a valid value for an E.R override in the Reason for Service, Professional Service and Result of Service fields to override a denial for an early refill. Values cannot be placed in the Submission Clarification Code field. This early refill override for emergency preparedness is allowed for all medications. Co-pay requirements are also applicable to these pharmacy claims. The use of this override is allowed while the state of emergency order remains in place.

8.0   Policy Implementation/Revision Information

Original Effective Date: January 1, 1999

Revision Information:

Date	Section Revised	Change
09/01/2005	All sections and attachment(s)	Changes were made throughout the policy to correspond with approved amendments to the State Plan.
11/01/2005	Subsection 5.6.1 and Attachment G	Co-payment information was updated to reflect a change in the State Plan.
12/01/2005	Subsection 2.2	The Web address for DMA's EDPST policy instructions was added to this section.
02/01/2006	Attachment A	Billing information for drugs covered under hospice was added to the attachment as section I and the remainder of the attachment was renumbered accordingly.
05/01/2006	Subsection 4.1 and Attachment G	Erectile dysfunctions drugs and anorexia, weight loss and weight gain drugs were added to the list of non -covered services in compliance with mandated legislation.
05/01/2006	Subsection 5.2.3	Information regarding how to bill for drugs that are packaged in an unbreakable package was clarified.
05/01/2006	Subsection 5.2.4	Service requirements for Quantity and Episodic Drugs were added to the policy.
05/01/2006	Attachments A, Item G	Information regarding cost avoidance claims processing was clarified.
05/01/2006	Attachment P	The list of Episodic Drugs Quantity Dispensing Limits was added to the policy
06/01/2006	Subsection 5.1, 5.1.1, and 5.1.2	The established limit of six prescriptions per month was deleted. Policy requirements associated with the new prescription limit including the medication therapy management program requirements were added to the policy.
06/01/2006	Subsection 5.3	This section pertaining to the recipient opt-in program was deleted and replaced with section 5.1.3.
06/01/2006	Subsection 5.4	This section pertaining to the establishment of a pharmacy of record was deleted from the policy.
06/01/2006	Attachment A, Section E	Procedural information related to the six prescription payment for the pharmacy of record was deleted from the policy and the remaining sections were renumbered accordingly.
06/01/2006	Attachment A, Section Q.5	Information related to pharmacy of record adjustment requests was deleted from the policy.
06/01/2006	Attachment A, Section R	Procedural information related to exemptions from the prescription limitation was added to the policy.
06/01/2006	Attachment A, Section S	Information related to the recipient opt-in program was added to the policy.
06/01/2006	Attachment A, Section T	Information related to the Medication Management Fee was added to the policy.
06/01/2006	Attachment B	The Six-Prescription Limit Override form was deleted from the policy.

Date	Section Revised	Change
07/01/2006	Throughout	The term "dispensing fee" changed to "professional services fee."
07/01/2006	Subsection 5.1.1	The first sentence was revised to indicate that pharmacists may override the monthly prescription limit with three additional prescriptions per recipient per month for recipients aged 21 and older. The second sentence was revised to indicate that the decision to override the monthly prescription limit is at the discretion of the pharmacist and does not require consultation with the recipient's physician.
07/01/2006	Subsection 5.1.3	The sentence pertaining to the systematic removal of recipients from the Opt-in Program was rewritten to clarify the process.
07/01/2006	Subsection 7.1 and 7.2	Clarification was added to indicate that pharmacy records must be maintained on-site.
07/01/2006	Subsection 7.3	The phone number for the DMA Pharmacy Review Officer was corrected.
12/01/2006	Subsection 2.2	The special provision related to EPSDT was revised.
12/01/2006	Sections 3.0, 4.0, and 5.0	A note regarding EPSDT was added to these sections.
03/01/2007	Attachment A, Section H	A requirement for the ICD-9-CM code to appear at the bottom of the form was added.
03/01/2007	Subsection 5.8.1 and Attachment A, Section I	Removed references to **NCPDP** 1.1 batch billing
03/01/2007	Attachment A, Section I	Added a requirement to bill claims over $9,999.00 on paper
05/01/2007	Subsection 5.6	Information regarding prescription drugs requiring prior approval was clarified.
05/01/2007	Subsections 5.7 and 5.7.1	Clarified paragraphs regarding North Carolina law.
05/01/2007	Sections 2 through 5	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.
08/01/2007	Subsection 5.1, subsections 1 through 4; Attachment A	Changed references to Medication Therapy Management Program to Focused Risk Management (FORM) Program; updated requirements.
08/01/2007	Subsection 5.1.3	Clarified parameters for removal from the opt-in program.
08/01/2007	Subsection 5.1.5	Added new section on FORM process oversight.
08/01/2007	All sections and attachment(s)	Changed "professional services fee" to "dispensing fee."
08/01/2007	Attachment A, S.2	Updated contact information.
11/01/2007	Subsection 5.7	Added the information that DMA may use a certification form and procedures for medically necessary brand-name drugs.
11/01/2007	Attachments A and F	Added clarification for claims submitted by 340B providers.
11/01/2007	Attachment A, letter I	Added narcotic analgesics and narcotic analgesic combination drugs to the list of those that don't allow a hospice edit override.

Date	Section Revised	Change
11/01/2007	Attachment E, E.3	Changed last paragraph to read "… except in **three** areas:" and added the third item (letter c).
01/01/2008	Subsections 5.1.2, 5.1.3	Added the word "unduplicated" to references to 11 or 12 prescriptions.
07/01/2008	Subsection 2.2	Added legal citation for EPSDT information.
07/01/2008	Subsection 4.2	Added drug samples and drugs obtained from patient assistance programs to non-covered services.
10/10/2008	Subsection 5.9; Attachment A, subsections B.3, B.5, and G	Added instructions for the Enhanced Specialty Discount Drug List; renumbered old subsections 5.9 through 5.12 to 5.10 through 5.13.
02/01/2009 (eff. 04/01/2008)	Attachment N	Revised description of Prescription Advantage List.
05/01/2009	Attachment D	Added tacrolimus to the list of Narrow Therapeutic Index drugs.
06/01/2009 (eff. 05/22/2009)	Attachment H	Added DAW 8 to the list of codes for dispense as written.
06/01/2009	Attachment J	In the Note to Item 5, corrected "six-prescription limitation" to "eight-prescription limitation." This is a correction of an oversight, not a change in policy.
06/01/2009	Attachment O	Added Zolpidem and Zaleplon to their respective drug classes; deleted GCN14281 from the Halcion and Triazolam row. This is a correction of an oversight, not a change in policy.
08/01/2009	Attachment H	Added prescription origin codes.
08/01/2009	Attachment O	Added triptans to the episodic drug list.
10/05/2009	Subsection 5.8 and Attachment A, item B.4	The maximum allowable cost was change from 150% to 190% of the lowest priced generic.
10/05/2009	Attachment A, item B.3	Methodology for the cost of the drug was changed from the Average Wholesale Price - 10% to the WAC + 7 percent; the federal or state MAC price; the enhanced specialty discount, if applicable; or the usual and customary charge and to indicate that WACs are updated weekly via File Transfer Protocol (FTP) from First Data Bank.
10/05/2009	Attachment F, item h.	The calculated Medicaid price was changed from the MAC price or Average Wholesale Price - 10 % to the MAC price or the WAC + 7% + the dispensing fee.
12/01/2009	Subsection 4.2	Added o: Drugs used for the symptomatic relief of cough and colds that contain expectorants or cough suppressants
12/01/2009	Attachment F, k.	Added t: Drugs used for the symptomatic relief of cough and colds that contain expectorants or cough suppressants
07/01/2010	All sections and attachment(s)	Policy Conversion: Implementation of Session Law 2009-451, **Section 10.32 "NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY."**

Date	Section Revised	Change
08/15/2010	Attachment E	Revised following sections to limit use of 04 Lost Prescription override code to one occurrence on one date of service each 365-day time period: C.2., G.6.j., G.9., G.10. Overutilization (ER). Corrected the word "Point" in the title of section G.
08/26/2010	Subsection 5.14	Implementation of Recipient Management Lock-In Program. Added sections 5.14 - 5.14.3.
08/31/2010	Section 8.0	Implementation Table updates
09/14/2010	Header	Corrected revised date to August 26,2010
12/15/2010	Subsection 5.1.2	Eliminate Focused Risk Management (FORM) Program
12/15/2010	Subsection 5.1.3	Delete reference to FORM
12/15/2010	Subsection 5.1.5	Eliminate FORM Process oversight
12/15/2010	Attachment A (S.1)	Delete reference to FORM
12/15/2010	Attachment A (T.)	Delete Professional Services Fee for FORM program
12/15/2010	Subsection 5.2.4.c	Delete reference to Prescription Advantage List
12/15/2010	Subsection 5.6	Subsection 5.6 Prescription Drugs Requiring Prior Authorization moved to Subsection 5.1 Prior Approval
12/15/2010	Subsection 5.7	Updated section with new legislative language to allow substitution of a brand name drug when the net cost of the brand name drug is less than the generic version
12/15/2010	Subsection 5.7.1	Updated section with new legislative language to allow substitution of a brand name drug when the net cost of the brand name drug is less than the generic version
12/15/2010	Subsection 5.7.2	Removed atypical antipsychotics from this section
12/15/2010	Subsection 5.8.1	Added language to allow prior authorization on brand-name medically necessary drugs (DAW1)
12/15/2010	Subsection 5.13	Eliminate Prescription Advantage List
12/15/2010	Subsection 7.2	Removed reference to 5 year record retention requirement and inserted reference to Basic Medicaid Billing Guide for record retention policy
12/15/2010	Subsection 7.3	Removed reference to 5 year record retention requirement
12/15/2010	Attachment E, E.3 Patient Counseling - Impact on Pharmacies (d.)	Removed reference to 5 year record retention requirement
12/15/2010	Attachment N	Eliminate Prescription Advantage List
04/13/2011	Subsection 4.2	Added: All legend vitamins and mineral products, except prenatal vitamins and fluoride
04/13/2011	Attachment F	Added: All legend vitamins and mineral products, except prenatal vitamins and fluoride
01/01/2012	Subsection 5.7	Added: Automatic Refills
01/01/2012	Attachment A	Added: C8 Claims Processing for Selected DME Products
01/01/2012	Attachment A	Removed: K Billing for Allergy Vaccines
01/01/2012	Attachment E	Added: Only one 5-consecutive day occurrence each 365-day time period will be allowed for non-controlled medications TO C2, G6, G9 and G10.

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Date	Section Revised	Change
03/12/2012	All sections and attachment(s)	To be equivalent where applicable to NC DMA's Clinical Coverage Policy #1A-5 under Session Law 2011-145, Section 10.41(b).
05/01/2012	Subsection 5.9	Updated the State Maximum Allowable Cost (SMAC) language
05/01/2012	Subsection 5.9.3	Add Prenatal Vitamins to the SMAC section
05/01/2012	Attachment A, B.4	Updated the State Maximum Allowable Cost (SMAC) language
05/01/2012	Attachment B	Updated attachment to reflect NCPDP D.0
05/01/2012	Attachment H	Updated attachment to reflect NCPDP D.0
08/16/2012	Attachment A	Removed specific rates on dispensing fees, effective 2/1/2012. Added link to State Plan, (http://www.ncdhhs.gov/dma/plan/) Attachment 4.19-B, Section 12, Page 1a for dispensing fees.
08/16/2012	Attachment A	Added link to NCEAC website, State Plan, (http://www.ncdhhs.gov/dma/plan/) Attachment 4.19-B, Section 12, Page 1a
08/16/2012	Attachment F	Removed WAC +7%, effective 2/1/2012. Added NCEAC.
01/31/2013	All sections and attachment(s)	Changed recipient to beneficiary
01/31/2013	All sections and attachment(s)	Changed DUR alert titles to new ones under NCPDP D.0
01/31/2013	Subsection 5.1	Removed reference to terminated Clinical Coverage Policy No. 9B, *Prior Authorization for Outpatient Pharmacy Point of Sale Medications*.
01/31/2013	Subsection 5.11	Added new section 5.11 Hemophilia Specialty Pharmacy Program
01/31/2013	Attachment A, B.3	Added references to new Hemophilia Specialty Pharmacy program
01/31/2013	Attachment A, B.6	Added new section B.6 Hemophilia Specialty Pharmacy Program
01/31/2013	Attachment F, g.	Added reference to new Hemophilia Specialty Pharmacy Program
02/07/2013	Subsection 5.3	Removed Subsection 5.3 Prescription Limitations
02/07/2013	Subsection 5.3 (New)	Added new Subsection 5.3 for CCNC medication therapy management for polypharmacy and low adherence
02/07/2013	Attachment A, C.2.b	Removed reference to prescription limitations
02/07/2013	Attachment A, H.	Removed reference to prescription limitations
02/07/2013	Attachment A, I.	Removed reference to prescription limitations
02/07/2013	Attachment A, Q	Removed indicating exemption from the prescription limitations
02/07/2013	Attachment A, R.1 – R.3	Removed Recipient Opt-In program sections
02/07/2013	Attachment B	Removed references to prescription limitations
02/07/2013	Attachment H	Removed references to prescription limitations
02/07/2013	Attachment J	Removed references to prescription limitations
02/07/2013	Attachment K	Removed references to prescription limitations

Date	Section Revised	Change
07/01/2013	All sections and attachment(s)	Removed references to paper billing, manual claims, and Pharmacy Adjustment Claim Forms
07/01/2013	All sections and attachment(s)	Removed references to Hewlett Packard, (HP) or ACS/Xerox and replaced them with Computer Science Corp., (CSC)
07/01/2013	Attachment A, C.1	Removed Requesting Online Point-of-Sale for Pharmacy Claims
07/01/2013	Attachment A, C.2	Amended Online Point of Sale Processing Hours to Online Point of Sale Down Time
07/01/2013	Attachment A, C.3	Amended Placeholder for Compound Prescriptions Claims on Point-of-Sale to Compound Prescription Claims on Point-of-Sale
07/01/2013	Attachment A, C.4	Amended Point-of –Sale Claims over $9,999
07/01/2013	Attachment I	Removed entire attachment: Pharmacy Online Request for Medicaid and NCHC Claims
07/01/2013	Attachments J, J-1, J-2	Removed entire attachments: Instructions for Completing the manual Pharmacy Claim Form, Example of Manual Claims Form, and Example of Manual Claim Form for Compound Drug
07/01/2013	Attachment K	Removed entire attachment: Completing the Pharmacy Adjustment Request Form
07/01/2013	Attachment L	Renumbered to now become Attachment I with the deletions to Attachments I, J, K. Updated references throughout the policy to reflect this change.
07/01/2013	Attachment I	Amended Pharmacy Remittance Advice (RA)
07/01/2013	Attachment H	Added Origin Code: 5 - Pharmacy
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
10/01/2016	All Sections and attachments	Updated pricing guidelines around National Average Drug Acquisition Cost (NADAC) pricing
10/01/2016	Section 3.4	Changed NDC to be require on claims
10/01/2016	Section 4.2.1	Added Vitamin-D and vaccines as covered items
10/01/2016	Section 5.2	Clarified PDL webpage information
10/01/2016	Section 5.4.1	Removed 90 days supply requirement for Depo-Provera
10/01/2016	Section 5.5.1	Clarified Medicaid Co-Payment Requirements
10/01/2016	Section 5.5.2	Corrected Co-payment Exemptions for Medicaid Beneficiaries
10/01/2016	Section 5.8.2	Clarified Generic Substitution for Narrow Therapeutic Index Drugs
10/01/2016	Section 5.10	Eliminated Enhanced Specialty Discount on Single Source Specialty Drugs
10/01/2016	Section 5.15	Section changed to 5.14 and Updated Beneficiary Management Lock-In Program
10/01/2016	Section 5.15.3	Eliminated Beneficiary Management Lock-In Oversight
10/01/2016	Section 7.4	Updated Medicaid and NCHC Recoupments

Date	Section Revised	Change
10/01/2016	Attachment A	Removed Section B.5 Enhanced Specialty Discount Drug List; Defined Section E.1 Full Dual Eligible Beneficiaries; Added Section E.2 QMB Beneficiaries; Updated Section F. Billing Remainder of a Third-Party Prescription to Medicaid; Updated Section I. Billing for Drugs Covered under Hospice; Added Vaccine billing procedures
05/01/2017	Attachment E	Added language regarding change in early refill alert for benzodiazepines and opioid analgesics
05/01/2017	Section 5.7	Added reminder that pharmacies may use refill reminders to encourage a beneficiary's adherence to their medication regimen for medications the beneficiary is currently taking
06/01/2017	All Sections and Attachments	Policy posted 06/01/2017 with an Amended Date of 05/01/2017
11/01/2018	Section 4.2.1(b)	Added language to reference exception to Rebate agreement requirement for CroFab
11/01/2018	Section 4.2.1 (g)	Added description for the living arrangement codes
11/01/2018	Section 5.9	Added Provider State MAC Inquiries as 5.9.2 under section 5.9 Maximum Allowable Cost (MAC)
11/01/2018	Section 5.9.2 (a)	Added e-prescribing to language; Section 5.9.2 amended to 5.9.3
11/01/2018	Section 5.9.3	Amended to 5.9.4
11/01/2018	Section 7.5	Added new Subsection "Emergency Preparedness Protocol"
11/01/2018	Section 4.2.1(a) and (m)	Change to Refer to Subsection 3.2.1(b)
11/01/2018	Section 4.2.1(m)	Removed the word "and" in last sentence
11/01/2018	Section 5.4	Remove words Days and days'
11/01/2018	Section 5.4.3 second paragraph	Removed "but not limited to"
11/01/2018	Section 5.5.2 first sentence	Removed the word "any"
11/01/2018	All sections and attachments	Replaced "recipient" with "beneficiary"
11/01/2018	All sections and attachments	Replace "patient(s)" with "beneficiary"
11/01/2018	All sections and attachments	Replaced "DMA" with "NC Medicaid"
11/01/2018	Attachment E F.1	Changed days' to day
11/01/2018	Section 3.2.1	Removed word of
11/01/2018	Section 6.2	Replaced as long as with if
11/01/2018	Section 5.1	Added sentence Medicaid and NCHC shall require prior authorization for selected prescription drugs.
11/15/2018	All sections and attachments	Policy posted on this date, with an Amended Date of November 1, 2018
7/22/2019	Subsection 3.2.1	Add clarification related FDA indication of drugs,
7/22/2019	Subsection 5.5.2	Add copay exemption for federally recognized tribal members

Date	Section Revised	Change
7/22/2019	Subsection 7.3	Remove "on-site" related to audits and add requirement for maintaining invoices as a permanent record.
7/22/2019	Subsection 5.9.1	NADAC generic rate and MAC override - Added DAW 7, DAW 8, DAW 9
7/22/2019	Subsection 6.2	Filling Prescriptions- Replaced record retention policy with provider's enrollment agreement
7/22/2019	Subsection 7.2	Record Retention - Removed "refer to NCTracks Claims and Billing Guide" and corresponding link and "current information; replace with provider enrollment agreement
7/22/2019	Attachment A B4	Revised "340B Provision as It Pertains to the Cost for the Drug" to remove all "plus the dispensing fee" and reference to Medicaid website for state upper limits for 340B purchased hemophilia drugs
7/22/2019	Attachment A C1	Revised A.1 Obtaining Point-of-Sale Software from a Vendor to add "Override MAC prices with DAW 9" (insert as d; previous d became e.)
7/22/2019	Attachment F (g)	Revised 340B Provisions to remove all "plus the dispensing fee" and reference to Medicaid website for state upper limits for 340B purchased hemophilia drugs
7/22/2019	Attachment F (h)	Created 1-4 format for when NADAC generic rate and MAC overrides are allowed to include DAW 7 DAW 8 and DAW9
7/22/2019	Attachment H (3)	Added to "Dispense as written codes currently" DAW codes 2, 3, 4, 6, 9 with descriptions
7/22/2019	Footer and Attachment A	Remove Public Comment from footer in page 41 through 71; and remove underline in attachment A
01/13/2020	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP."
01/13/2020	Attachment A	Added, "Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines".
05/07/2021	Section 5.1, Section 5.4.3 and Attachment K	List of Pharmacy Prior Approval Drugs and Criteria added in Attachment K; links updated to NC Medicaid Website throughout policy from NC Tracks. No change made to Amended Date
07/1/2021	Sections 5.4, 5.41, 5.42 and Attachment F	Allowing coverage of claims for up to 12 months supply of oral birth control products and for claims for up to a 90 day supply of maintenance medications.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. General Information

Each time Medicaid and NCHC services are rendered, the provider must verify the beneficiary's eligibility on the date of service through a point-of-sale E1 transaction or through the Eligibility Verification System for proof of eligibility. The prescription must be verified for coverage. All claim fields must be completed. The pharmacist shall retain a copy of the claim on file.

Refer to **Attachment F** for a summary of the billing requirements.

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. Directions for Drug Reimbursement

Reimbursement is determined using the cost per unit times the quantity dispensed plus the dispensing fee. Reimbursement is limited to the applicable price in effect on the date of service, not on the date of payment. Refer to **Section B.4, Cost of the Drug**.

B.1 Vaccines

Vaccines must be billed using a professional claim with the appropriate CPT codes. Pharmacies shall use their NPI and proper taxonomy to bill vaccines.

B.2 Dispensing Fee

The dispensing fee for generic drugs or brand name drugs is added to the cost of the drug to equal the maximum allowed "Billed Amount" for each claim. The dispensing fee for generic drugs is based on a pharmacy's quarterly generic dispensing rate. Applicable dispensing fees are available in the State Plan, Attachment 4.19-B, Section 12, Page 1a, on NC Medicaid's website at https://medicaid.ncdhhs.gov/

Changes in the dispensing fee amount are reported in the NC Medicaid Pharmacy Newsletters or on Remittance Advice (RA) banner messages. The dispensing fee is automatically deducted from each repeated drug within the same calendar month.

B.3 Definition of Repeat or Refill Drugs in the Same Month of Service

The pharmacy program mandates that a dispensing fee, or professional fee, cannot **be paid for repeats or refills** of the same drug twice within the same calendar month (an exception is made for clotting factors for which professional dispensing fee is paid per unit); nor shall two prescriptions for the same drug be billed on the same day.

The following defines what constitutes the same or different drug in the same month of service:

a. A drug in which the active portion is different and is not generically equivalent to any other drug dispensed to the same beneficiary in the same calendar month shall be considered a different drug.

Such as: Tetracycline, pilocarpine, and meprobamate are three different drugs.

b. A different dosage form (liquid, tablet, suppository, injection, etc.) of the same drug constitutes a different drug.

Such as: Phenergan tablets and suppositories are two different drugs.

c. A different strength of the same drug constitutes a different drug.

Such as: Mellaril 10 mg and 50 mg are two different drugs.

d. A different chemical form of the same basic drug does not constitute a different drug if the dosage form and strength is the same.

Such as: Tetracycline hydrochloride and tetracycline metaphosphate buffered are the same drug.

e. A generic equivalent by different trade name does not constitute a different drug.

Such as: Tetracycline by Geneva, tetracycline by Rugby, and Achromycin are all the same drug.

B.4 Cost of the Drug

Cost data is currently being obtained from First Data Bank. The cost of the drug is calculated from the North Carolina Average Acquisition Cost (AAC); North Carolina shall base brand and generic drug ingredient pricing on an average acquisition cost (AAC). The AAC is defined as the price paid by pharmacies based on an average of actual acquisition costs determined by a survey of retail pharmacy providers. The National Average Drug Acquisition Cost (NADAC) pricing must be used for AAC when available and the lessor of NADAC or Usual and Customary & Reasonable Charges (UCR) determines the cost of the drug.

If NADAC is unavailable, then the AAC is defined as Wholesale Acquisition Cost (WAC). If WAC is used then the lessor of WAC; the state MAC price; the hemophilia enhanced specialty discount, if applicable; or the UCR determines the cost of the drug. WACs are updated weekly via File Transfer Protocol (FTP) from First Data Bank. State MACs are updated monthly.

The state MAC lists and the hemophilia enhanced specialty discount list are published on Medicaid's website at https://medicaid.ncdhhs.gov/. The AAC is available in the State Plan, Attachment 4.19-B, Section 12, Page 1a, on NC Medicaid's website at https://medicaid.ncdhhs.gov/.

340B Provision as It Pertains to the Cost for the Drug

340B providers must be listed on the HRSA website (http://www.hrsa.gov/opa/). 340B providers must submit the actual purchased drug price in the usual and customary charge field. Providers who maintain two separate inventories—one for the 340B beneficiaries and a purchased inventory for non-340B beneficiaries—may not dispense a 340B-purchased drug and bill Medicaid or NCHC the calculated Medicaid price for non-340B beneficiaries. For hemophilia drugs, 340B providers may submit the state upper limit established for a 340B purchased hemophilia drug.

B.5 State Maximum Allowable Cost (SMAC) List

The state MAC list contains products with A-rated equivalents, and, in the great majority of cases, products marketed by at least two labelers. The State's MAC reimbursement is based on the application of a percentage factor applied to the lowest priced generic. In cases where the calculated MAC rate, based on the primary percentage factor, results in a price less than the cost of the second lowest generic product, at least an additional 10 percent margin is added to the cost of the second-lowest drug to establish the MAC price. The MAC pricing factor is set by NC Medicaid and may change as deemed appropriate.

The additional margin is variable due to the wide range of differences in cost from product to product. The SMAC list is posted on the NC Medicaid website, https://medicaid.ncdhhs.gov/.

For established generic drugs with only one supplier, the MAC price is established between the actual acquisition cost and average wholesale price of the generic drug. A minimum reimbursement of 20 percent above actual acquisition is guaranteed for these drugs. In most cases, MAC pricing is substantially higher than this 20 percent, which allows the state and pharmacies to share in the cost savings of using the generic product.

Drugs subjected to MAC pricing must be in adequate supply. Drug shortage information is verified through national pharmacy websites as well as through information provided by national drug wholesalers.

Due to the many variations in the ingredients in prenatal vitamins and the corresponding variation in the ingredient cost, a single MAC rate for prenatal vitamins is established and maintained. Current marketplace acquisition cost, average wholesale price and wholesale acquisition cost are evaluated to determine the single MAC rate.

B.6 Hemophilia Specialty Pharmacy Program

The General Assembly [Session Law 2012-142, Section 10.48(a2)] mandates that the N.C. Medicaid and N.C. Health Choice Pharmacy programs establish a specialty pharmacy program for hemophilia drugs. Refer to Clinical Coverage Policy No: 9B, *Hemophilia Specialty Pharmacy Program,* on NC Medicaid's website at https://medicaid.ncdhhs.gov/.

B.7 National Drug Code (NDC)

The NDC is an arrangement of eleven (11) digits used to identify a drug product and package size manufactured or distributed by a specific manufacturer. It is comprised of three "fields" of data as follows:

Drug Code Structure	AAAAA	BBBB	CC
Number of digits in each field	5	4	2
The Manufacturer	AAAAA		
The Drug Product		BBBB	
The Package Size			CC

Leading zeros must be used for proper placement of numbers or letters in the NDC number field of the pharmacy claim form or pharmacy software for electronic billing. Failure to record all 11 digits in the proper position will result in a claim denial.

Such as: Inderal 20 mg Tablet 0046 422 81 must be spaced:

0 0 0 4 6 0 4 2 2 8 1

B.8 Defining the Drug Units

All quantities must be submitted in metric units. If the quantity is a decimal, then it must be billed as such. Refer to **Attachment G** for the instructions and examples that apply to drug units.

C. Billing Pharmacy Claims through Online, Real-Time Point of Sale

NC Medicaid mandates that all providers use the online, real-time POS system to process pharmacy claims. Each pharmacy needs to work with their software vendor regarding online capabilities. Claims are submitted through the "switching" companies.

The online POS system automatically performs eligibility verification, drug validation, pricing, and edits and audits followed by Prospective Drug Utilization Review (Pro-DUR) before the pharmacy dispenses a prescription. Immediate assurance of the amount to be paid for the prescription reimbursement submitted through online claims is sent on the next check write. POS reduces follow-up accounting for claims by allowing for the correction of any errors before the beneficiary gets the prescription. Pharmacists receive all of the reject codes immediately when a claim is submitted through POS; other submission methods are limited to returning the first reject encountered.

The same policies for MAC overrides, co-pay exemption, and prescription limit overrides are in effect for POS as for other claims processing media.

Refer to **Attachment H** for a summary of POS codes and other information for current claim format.

C.1 Obtaining Point-of-Sale Software from a Vendor

Most software vendors are certified as capable of meeting the requirements to bill Medicaid and NCHC online. The billing pharmacy provider shall ensure that the software is capable of performing the following functions:

a. Override rejects for DUR conflicts, when needed, by resubmitting the rejected claim with DUR reason for service, professional service, and result of service codes.
b. Submit payments from other insurance plans for claims in an "Other Payer" field.
c. Override MAC prices with DAW 1 when proper documentation is provided by the prescriber.
d. Override MAC prices with DAW 9 when NC Medicaid or NCHC preferred Brand was dispensed when generic equivalent is nonpreferred.
e. Send the NPI number as the prescriber identifier.

C.2 Online Point-of-Sale Processing Downtime

Monday   12:01a.m. – 4:00 a.m.

DHHS designated contractor's Provider Services unit is available from 8:00 a.m. through 5:00 p.m. weekdays to answer general pharmacy questions at 1-800-688-6696.

All communication/technical POS problems must be directed to your "switch vendor" especially **National Council for Prescription Drug Programs (NCPDP)** reject codes 99 for Host Processing Error.

C.3 Compound Prescription Claims on Point-of-Sale

All compound claims must be submitted at Point-of Sale. Compounds claims at point of sale are limited to 25 ingredients.

C.4 Point-of-Sale Claims over $9,999

Claims over $9,999 require manual review for validity. POS claims are captured, but the response is that there is no judgment on beneficiary eligibility or payment until the claim is manually reviewed assurance that the claim has been accepted and reviewed. Please check your RA or log into NC Tracks at www.nctracks.nc.gov to check the claim for payment.

C.5 Time Limit for Point-of-Sale Claims

POS claims must be billed within one year of the dispensing date.

C.6 Claims Processing for Selected DME Products

Claims for diabetic test strips, control solutions, lancets, lancing devices, and syringes submitted at point-of-sale must be billed using the NDC. Test strips must be billed in multiples of 50 or 51 and syringes and lancets must be billed in multiples of 100. For Medicaid and NCHC billing, 1 lancing device equals 1 unit. Rates apply to these diabetic supplies; therefore, no copayments and no dispensing fees apply. Diabetic supply limits are the same as under the DME Program. Prior authorization requests for additional quantities or for non-preferred diabetic supplies must go through the DME Program.

D. Provider Retroactive Pharmacy Claims Billing

When a provider accepts a private patient, bills the private patient personally for services covered under Medicaid or NCHC, and the patient is later found to be retroactively eligible for Medicaid or NCHC, the provider may file for reimbursement with Medicaid or NCHC. Upon receipt of Medicaid or NCHC reimbursement, the provider shall refund to the beneficiary all money paid by the beneficiary for services covered by Medicaid or NCHC, with the exception of any third-party payments or cost-sharing amounts.

E. Billing Medicare before Medicaid

E.1 Full Dual Eligible Beneficiaries

When a Medicaid beneficiary has both Medicare and Medicaid coverage, pharmacy providers are required to bill Medicare first for the limited number of pharmaceutical products covered by that program. If the Medicare reimbursement does not equal 100 percent of the Medicare allowable rate and not more than the Medicaid allowable rate, the pharmacy provider may then bill Medicaid for the outstanding balance (coinsurance/deductible).

Due to restrictions imposed by Medicare on some drugs, such as restrictions to certain diagnoses, an override is available whereby Medicaid can be billed for these drugs when not covered by Medicare. For example, Imuran and methotrexate are only covered for the diagnosis of cancer, so Medicaid would need to be billed for any other diagnosis. To override the edit using POS, place a "1" (numeric) in the PA field.

A co-pay shall not be collected on any of the claims billed to Medicare. Once Medicare has paid, bill Medicaid for the remaining amount. The system cannot deduct a co-pay for these crossover claims.

The NC Medicaid Outpatient Pharmacy Program denies specific drugs that must be billed to Medicare first for an identified beneficiary who is eligible for drug coverage under Medicare Part B.

Medicaid may be billed for the unpaid portion of a claim paid by Medicare by entering the following information in the appropriate fields:

a.   the amount paid by Medicare in the Other Coverage Field;

b.   the Medicaid reimbursement rate in the Amount Billed Field (dollars/cents).

Medicaid pays an amount equal to the Medicare allowable rate less the amount paid by Medicare.

E.2   Qualified Medicare Beneficiaries (QMB)

QMB Medicaid beneficiaries have both Medicare and Medicaid coverage and pharmacy providers are required to bill Medicare first for the limited number of pharmaceutical products covered by that program. Medicaid pays the cost share on these medications.

For QMB claims, the pharmacy shall submit values in any of these three fields (353-NR, 351-NP, and 352-NQ) when applicable for the claim. These fields are used to identify the beneficiary's Medicare Coinsurance, Medicare Deductible, and Medicare Copayment amounts.

F. Billing Remainder of a Third-Party Prescription to Medicaid

Medicaid is always the payor of last resort when a beneficiary has other insurance that covers prescription drugs. If a beneficiary has **other insurance,** such as **Medicare**, which pays for prescriptions, that insurance plan must be billed first. Medicaid may be billed for the unpaid portion of a claim paid by another insurance company by entering the following information in the appropriate fields on the claim:

a.   The amount paid by the other insurance in Other Coverage Field

b.   The Medicaid reimbursement rate in the Amount Billed field (dollars/cents)

c.   Medicaid pays an amount equal to the Medicaid reimbursement rate less the co-payment, where applicable, less the amount paid by the other insurance.

Medicaid reimbursement rate
- Amount paid by other insurance
- Medicaid co-payment according to Medicaid Drug and Eligibility files

Medicaid payment
The POS checks for current third-party coverage on the eligibility file. A message is sent back by the POS system telling the provider that the beneficiary has third-party coverage for that date of service. The other third party must be billed as the primary payor, and then Medicaid can be billed as the second payor. In the event that the beneficiary cannot produce another insurance or the beneficiary states they do not have other insurance, the pharmacy shall use a 01 – No Other Coverage Identified in the Other Coverage Code, claim segment 308-C8 for NCPDP D.0 transactions. NC Medicaid pays the pharmacy and chases the third party for payment. The pharmacy cannot be held liable for any payments made in these cases.

d.   When a claim is denied for other coverage, the POS system will deny the claim and will be indicated to submit to another payer.

- *Override Codes for Cost Avoidance Process - Claim Segment defined as 308-C8 (Other Coverage Code)*

- Required/Optional/Not Used: Optional
- Field Type: N
- Max length: 2
- North Carolina Medicaid Specifications (override codes)

01= No Other Coverage Identified

02 = Other Coverage Exists - Payment Collected (The member has other coverage and the payor has returned a payment amount. The payment amount is submitted in field 431-DV to the secondary payor (e.g.: Medicaid).

03 = Other Coverage Exists - This Claim Not Covered (Claim not covered under primary Third-Party Plan. If primary denied the claim as Refill Too Soon, the claim would be submitted to the secondary payor with the Other Coverage Code 3. In this situation, claim would more than likely be too early for Medicaid as well)

04 = Other Coverage Exists - Payment Not Collected (Used when the member has other coverage and that payor has accepted the claim but did not return any payment. This would be an example in which the member had a deductible amount to meet under the primary payor. The member is responsible for 100% of the payment, and the payor returns 100% of the payment, and the payor returns $0.)

The override codes listed above will be reported back to Medicaid on a monthly basis.

Example: After third-party insurer has paid, the claim can be billed to Medicaid with the other coverage amount indicated. For example, if a $100.00 claim is billed to PCS and they pay $65.00 (the beneficiary has a $20.00 co-pay), the claim is then submitted to Medicaid with $100.00 billed amount and $65.00 in the other coverage field (431-DV).

The system will calculate the Medicaid allowable and then subtract $65.00 from that amount. There should not be a reference to the $20.00 co-pay.

G. NCHC Secondary Insurance

Pursuant to N.C. General Statute §108A – 70.18(8): Health Choice *does* not allow *secondary insurance*. It is the beneficiary's duty to notify the local Department of Social Services (DSS) prior to approval, or within 10 calendar days of receipt of the other health insurance. The DSS, upon receipt of notice, shall disenroll the child from the Program.

"Uninsured" means the applicant for Program benefits is not covered under any private or employer – sponsored comprehensive health insurance plan on the date enrollment.

H. Billing for Nursing Home Prescriptions and IV Therapy

Due to special packaging or storage requirements for nursing home prescriptions and the stability problems associated with IV therapy, a single prescription may have to be dispensed several times during the month in small quantities. Because of the special circumstances involved in their dispensing, **prescriptions for nursing home beneficiaries and prescriptions for IV therapy may be billed once per month**. The monthly billed amount should reflect a total of all dispensing for that one prescription for the month less any credit that might have occurred during the monthly period.

I. Billing for Drugs Covered under Hospice

A beneficiary who is enrolled in the hospice program is covered under a per diem rate, which covers all services related to the beneficiary's terminal illness. The pharmacist is notified via the POS system if a beneficiary is enrolled in hospice. All drug claims are denied with the message "beneficiary claim covered by hospice."

If the drug is to be used for an indication not directly related to the beneficiary's terminal illness, an override is available. A "1" entered in the PA field and the ICD-10-CM code for the beneficiary's terminal illness entered in the diagnosis field will override the hospice edit. Pharmacists shall not use the ICD-10-CM code for the indication of the drug.

There are some drug classes where overrides are not allowed. For these drug classes, the claim denies with Explanation of Benefits (EOB), "Recipient claim covered under Hospice". These drug classes include narcotic analgesics and narcotic analgesic combinations, hematinics, antiemetics, most chemotherapeutics and antineoplastic aromatase inhibitors.

Questions concerning drug coverage for a hospice beneficiary are directed to the beneficiary's hospice agency.

Pharmacists shall contact NC Medicaid (919-855-4300) with questions regarding Medicaid or NCHC coverage of pharmacy claims in the drug classes for which overrides are not allowed. If it is determined that Medicaid or NCHC coverage is appropriate, the provider is informed of billing instructions at the time of the call.

J. Compounded Drugs

J.1 Billing for Compounded Drugs

If the compound prescription contains all legend products, then the claim for the compound can be submitted by using POS (**NCPDP D.0**).

NCPDP D.0 (POS) Instructions

If the compound is billed using **NCPDP D.0** (POS), the total ingredients billed must match the compound ingredient component count. If they do not match, the claim denies. The cost for each ingredient must be indicated and the dispensing fee should be included in the total billed amount listed on the header. If NDCs are included in the compound that are not covered by Medicaid or NCHC, the claim continues to process with the payable ingredients only. The POS system assumes "8" in the submission clarification field, which means "PROCESS COMPOUND FOR APPROVED INGREDIENTS."

J.2 Reimbursement for Compound Drugs

Medicaid and NCHC shall reimburse only for federal legend drugs contained in the compound that are manufactured by companies who have signed a national Medicaid Drug Rebate Agreement with CMS. If one prescription drug in the compound is not covered under the rebate agreement, reimbursement is withheld for that drug only. The remainder of the compound is paid if applicable. OTC products are also only reimbursed if the manufacturer has signed a national Medicaid Drug Rebate Agreement with CMS and when contained in a compound with at least one covered legend drug.

J.3 Summary of Compound Drug Reimbursement

Reimbursable compounds:

a. Mixture of two or more physically inseparable ingredients, with at least one legend ingredient.

b. Only legend drugs from manufacturers who signed the Drug Rebate Agreement will be reimbursed.

Non-reimbursable compounds:

EOB	Requirement not met
905	A compound without a legend-covered drug
905	A compound with only non-rebate drugs
038	OTC and DESI drugs as only ingredients
009	A compound equivalent to an OTC drug
009	OTC ingredients only
009	Two physically separable drugs (tablets and capsules) in the same bottle

K. Point-of-Sale Reversals

Claims submitted using POS may be credited with a POS reversal for up to **12 consecutive months** after the dispense date. It is recommended that pharmacies submit reversals weekly or, at a minimum, monthly. Pharmacies may obtain information on submitting a reversal, if needed, from their pharmacy software vendor. DHHS fiscal contractor can reverse claims submitted using POS if required.

POS reversals may be completed for claims submitted with incorrect quantities or NDCs. POS reversals also allow the pharmacist to help beneficiaries who need additional medication when they have already received the maximum number of prescriptions by permitting the reversal of a less expensive prescription in order to allow billing of a more expensive prescription.

L. High Dosage Edit

The system checks for high dosage by comparing the units that are billed for the days supply limit indicated with what has been approved by the FDA. If the units billed on the claim exceed this limit, an edit notifies the provider that the units and days supply need to be verified for accuracy. To override the edit and indicate that the units and days supply have been verified and are correct, enter a "2" in the prior authorization field or in the submission clarification field.

M. Time Limit Overrides

NC Medicaid frequently receives requests to waive the federally prescribed 12-consecutive month claims filing time limit. NC Medicaid has extremely limited authority to override the time limit when eligibility was not approved within the year or for court decisions or hearings, which authorize eligibility retroactively. Failure of the provider to file and follow up timely is not a basis for override and results in denial of claims.

Medicaid and NCHC claims, other than crossover and third party, must be received by DHHS fiscal contractor within 365 calendar days from the date of service. Hospital inpatient, long-term care, and home health claims must be received within 365 calendar days from the last date of service on the

claim. Medicare and Medicaid crossover and other third-party claims must be received within 180 calendar days from the date of payment or denial from the third-party payor or 365 calendar days from the date of service, whichever is later. Proof that the claim was submitted timely includes:

a.   correspondence about the claim received from NC Medicaid or DHHS fiscal contractor;

b.   an explanation of Medicare or third-party benefits dated 180 calendar days from the date of payment or denial;

c.   a copy of the remittance and status report (RA) showing the claim pending or denied.

It is the provider's responsibility to file claims in a timely manner and to follow up within the time limit for claims not reported back on the RA. When claims are initially filed, providers should allow approximately 30 calendar days for the transactions to appear on the RA. If there is no indication on the RA that the claim was received, providers may use NC Tracks or the Automated Voice Response System to determine the status of the claim. If the claim has not been received by the DHHS fiscal contractor, providers should resubmit immediately to prevent denial for timely filing.

N. Pharmacy Remittance Advice

The Remittance Advice (RA) is a computer-generated document showing the status of all claims submitted to CSC along with a detailed breakdown of payment. The RA is produced at the same time that checks are issued.

Refer to **Attachment I** for instructions for using the RA.

O. Resubmission of Rejected or Denied Claims

O.1 Explanation of Benefit Codes

Rejected or denied claims are identified on the pharmacist's RA with an explanation of benefit (EOB) code, which explains why the claim was rejected or denied. The EOB assists the pharmacist in correcting and resubmitting a rejected or denied claim.

O.2 Resubmitting a Claim

All claims must be submitted to CSC within 365 calendar days of the date of service. If a claim is paid incorrectly or a claim is rejected or denied, providers have 18 consecutive months from the date of the RA denial to resubmit a claim for processing.

Claims that are denied with no payment can be resubmitted as new claims. Claims that are denied with no payment include:

a.   invalid date of service;

b.   missing or invalid information such as quantity or billed amount;

c.   NDC not on file.

   Note: Claims that deny with this EOB message must be verified to ensure that the correct NDC was listed on the original claim form.

Do not submit a new claim if a partial payment was received. If partial payment is received on a claim, providers shall edit the claim and resubmit.

O.3 Name and Number Mismatch

To avoid a name and number mismatch, do not use the beneficiary's middle initial on the claim form. The beneficiary's first and last name are sufficient. Enter the beneficiary's MID number and name as shown on the MID card or, if the beneficiary's name has changed, according to the eligibility file.

O.4 Eligibility Follow-Up

Because a beneficiary's eligibility status may change from one (1) month to the next if the financial and/or household circumstances change, providers shall verify the beneficiary's eligibility through a point-of-sale E1 transaction or through the Eligibility Verification System for proof of eligibility each time a service is rendered. The most common EOBs received for eligibility denials are these:

EOB Code	Message
011	Recipient not eligible on service date.
120	Recipient MID number missing
143	Recipient MID number not on State eligibility file
191	Recipient MID number does not match patient name

Refer to the following instructions to resolve a claim denied for eligibility.

Check for Errors on the Claim. Compare the beneficiary's MID card to the information entered via NCPDP. If the beneficiary's name or MID number were not entered correctly on the claim, complete corrections and resubmit. If they are correct, call the DHHS fiscal contractor to verify eligibility.

Attachment B: Table of Exemptions to Co-payment and Specific Edit Override Information

Condition	Exemption			NCPDP		
	Co-pay			Beneficiary Residence	PA Code	Submission Clarification Field
Co-pay Exemption						
Family Planning	Y				Drug File	
Intermediate Care Facility/Mental Retardation	Y			9		
Skilled Nursing Facility	Y			2		
Nursing Facility	Y			3		
Pregnancy	Y				4 or Eligibility File	
Exempt from co-pay only	Y				4	
Health Check < 21 years old	Y				Eligibility File	
CAP	Y				Eligibility File	
Locations with No Automatic Exemptions						
Hospice	N			11		
Rest Home	N			5		
Specific Edit Overrides						
Edit 907 (Dosage over FDA guidelines)	N					2
Edit 946 (Medicare Edit)	N				1	
Early Refill Override – Vacation (in addition to DUR override)	N					3
Early Refill Override – Lost prescription (in addition to DUR override)	N					4
Early Refill Override – Change in Therapy (in addition to DUR override)	N					5
PDL Overrides – If "Meets PA Criteria" is documented	N				1	2

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Attachment C: Requesting Prior Authorization for Prescription Drugs

The process to request authorization for the prescription drugs indicated in **Subsections 5.1 and 5.2** is as follows:

a. The prescriber contacts the CSC clinical call center online at www.nctracks.nc.gov, by telephone, or by fax. The prior authorization process is substantially quicker if done through the web portal NCTracks and could be auto approved.

b. Hours of operation are Monday through Friday, 7:00 a.m. to 11:00 p.m. and Saturday through Sunday, 7:00 a.m. to 6:00 p.m.

    Phone: 1-866-246-8505

    Fax: 1-866-246-8507

    The prescriber offers information as specified on the prior authorization form for the drug being requested. Copies of the forms are available online at http://nctracks.nc.gov. All requests will be answered within 24 hours of receipt.

c. If the request for prior authorization is approved, CSC updates the system. The POS claims processing system manages the PA information.

d. The billing pharmacy submits the claim for reimbursement. If the prescriber has not obtained prior authorization, the POS will return a message of either PA REQ. PRESCRIBER CALL CSC or CLAIM DENIED. PA LIMITS EXCEEDED. If the billing pharmacy receives one of these messages, they may utilize the NCTracks web portal or CSC may be contacted at 1-866-246-8505 to verify the status of the prior authorization request. Please notify the prescriber to call CSC if a prior authorization has not been completed.

e. 72-Hour Emergency Supply

    If the prior authorization request is approved, the emergency supply should be billed through POS as part of the original fill.

    If the prior authorization request is not approved, the system will bypass the prior authorization requirement if an emergency supply is indicated. A "3" in the Level of Service field (418-DI) should be used to indicate that the transaction is an emergency fill. The claims will only allow a 72-hour supply. Co-payments will apply and only the drug cost will be reimbursed. Edit 383 has also been developed which will prevent the days supply edit 907 from being overridden for prior authorization emergency fills. The new edit 383 indicates the following message to the provider: "CANT USE OVERRIDE WITH A PA EMER FILL".

f. Retroactive Prior Authorization

    A prescriber or long term care pharmacist may request retroactive prior authorization (PA) for medications in the pharmacy PA program for dates of service up to one year after dispensing. **(Note**: Long term care pharmacists may not request prior authorization for Brand Name Schedule II narcotics or sedative hypnotics.) Retroactive requests may be made by contacting the CSC clinical call center and will be considered on a case-by-case basis. If no other PA exists and the beneficiary meets criteria for full approval, a retroactive PA may be entered to include backdates and forward for full approval period.

    Additional information regarding the prior authorization process can be found at www.nctracks.nc.gov

Attachment D: Narrow Therapeutic Index Drugs

(As published in the N.C. Register, Volume 23, Issue 17, March 2, 2009)

The following list of NTI drugs is reviewed on an annual basis and submitted to the Office of Administrative Hearings by the N.C. Board of Pharmacy for publication in the N.C. Register.

- Carbamazepine: all oral dosage forms
- Cyclosporine: all oral dosage forms
- Digoxin: all oral dosage forms
- Ethosuximide
- Levothyroxine sodium tablets
- Lithium (including all salts): all oral dosage forms
- Phenytoin (including all salts): all oral dosage forms
- Procainamide
- Tacrolimus: all oral dosage forms
- Theophylline (including all salts): all oral dosage forms
- Warfarin sodium tablets

Attachment E: Drug Use Review Program

Overview of the Drug Use Review Program

In accordance with the Social Security Act of 1927 and the Omnibus Budget Reconciliation Act (OBRA) of 1990, North Carolina established a Drug Use Review (DUR) program for outpatient drugs to assure that the prescriptions dispensed to beneficiaries are:

a. Appropriate.
b. Medically necessary.
c. Not likely to result in adverse medical results.

The program enhances the quality and appropriateness of beneficiary care by educating physicians and pharmacists on common drug therapy problems to improve prescribing and dispensing practices. The DUR program consists of the following components.

A. NC Medicaid

NC Medicaid will establish the Drug Use Review Board (DUR). The DUR Board will not have rule making authority. NC Medicaid can reject the recommendations of the DUR Board by notifying the Board in writing to allow the Board an opportunity to reconsider its decision. The criteria and standards for the drug therapy review adopted by NC Medicaid upon recommendation by the DUR Board shall be available to pharmacists, prescribers, and the general public.

B. DUR Board

The Board is composed of the NC Medicaid Use Review Coordinator, five licensed, actively practicing physicians, five licensed, actively practicing pharmacists and at least two additional individuals who have expertise in the clinically appropriate prescribing, dispensing, and monitoring of covered outpatient drugs, drug use review, evaluation, and intervention or medical quality assurance. One pharmacist and one physician shall act as co-chair on the Board. Co-chairs are elected for a one year term by their peers and are eligible for a co-chair position after one year on the Board. The term of membership shall be 12 months, with the option to renew for two additional 1-year periods.

The North Carolina Association of Pharmacists, the North Carolina Medical Society and the Old North State Medical Society shall be asked to make nominations for some positions on the Board. The Director will have the right to reject or accept nominations. The activities of the DUR Board include establishing standards, retrospective DUR, and ongoing educational interventions. At least quarterly, the drug claims, in conjunction with other medical claims as needed for clinical purposes, shall be screened against the standards established by the DUR Board. The State assures it will prepare an annual report to the Secretary, which incorporates a report from the State DUR Board, and that the State will adhere to the plans, steps, and procedures as described in OBRA 90.

C. Prospective DUR

C.1 Purpose

The purpose of **Prospective Drug Utilization Review (Pro-DUR)** is to improve the quality of care and promote cost savings by preventing adverse drug events before a prescription is dispensed or used. Pro-DUR is an additional source of information for the pharmacist to use in making decisions affecting pharmaceutical care.

A prospective review of drug therapy is conducted at the time a new prescription is filled. This review involves comprehensive screening of the prescription. Potential drug therapy problems based upon predetermined standards include, but are not limited to:

1. Therapeutic duplication.
2. Drug–disease contraindications.
3. Drug–drug interactions.
4. Drug interactions with nonprescription or over-the-counter drugs.
5. Drug–disease interactions.
6. Incorrect drug dosage or duration of therapy.
7. Drug allergy interactions.
8. Clinical abuse/misuse.

Pharmacies participating in Medicaid and NCHC must conduct the Pro-DUR screening. To comply with these standards, pharmacies must use either a prospective DUR software database or written standards consistent with the DUR Board policy. Additional Pro-DUR screening is provided for claims submitted using POS.

The National Council of Prescription Drug Programs (**NCPDP**) Pro-DUR alerts the dispensing pharmacist of potential conflicts. This requires a professional service or result of service coding before payment is made for the prescription. If the pharmacist determines that the prescription should be dispensed, the pharmacist must document his/her professional judgment by responding to the DUR alert. If more than one DUR alert is received, it is only necessary for the pharmacist to respond to the first alert. All of the criteria required to respond to the DUR alert is included in the DUR information sent with the alert. A DUR conflict must be documented with **NCPDP** DUR result of service and professional service codes in order to receive payment for a resubmitted prescription.

C.2 Procedure for Responding to DUR Alerts

1. The pharmacist receives a DUR alert message(s) on the computer screen; claim is rejected for DUR.
2. The pharmacist reviews and resolves identified DUR conflict(s) by contacting the prescriber, talking with the beneficiary, and/or using other resources or professional judgment.
3. If the pharmacist decides not to dispense the prescription, the pharmacist accepts the reject.
4. The pharmacist does not resubmit the claim and does not receive payment.
5. If the pharmacist decides to resolve and dispense the prescription, the pharmacist resubmits the correct claim with a DUR reason for service code, DUR professional service code, and DUR result of service code.
6. If the alert is for an early refill, the pharmacist must include one of the approved reason codes in the prescription clarification field:

03	Vacation Supply	To be used if the beneficiary is going out of town and needs medication refilled early. **Note:** This will not allow more than 34 days to be indicated in the days supply field. Only one 5-consecutive day occurrence each 365-day time period will be allowed for non-controlled medications.

04   **Lost Prescription**   To be used if the beneficiary has lost their medication. Only one occurrence on one date of service each 365-day time period will be allowed for non-controlled medications

05   **Therapy Change**   To be used if the dosage is changed on a current medication.

Note: Vacation supply and lost prescriptions are not allowed for controlled substances.

7. The pharmacist receives a paid response if DUR documentation was used and the prescription was filled.

Up to three DUR alerts can be returned for a prescription in the **NCPDP** standard. If there are more than three DUR alerts, a DUR overflow message will be returned. If the pharmacist wants to dispense a prescription that creates more than three alerts and wants to know the overflow alerts, he/she may call NC Medicaid's fiscal agent's Provider Services unit at 919-851-8888 or 1-800-688-6696.

DUR alert messages contain standard codes and language, but may be displayed in various ways, depending on the pharmacy software in use.

If an override is not requested for a prescription that is rejected with a DUR reason for service code, it will be assumed that the prescription was not filled. Return of a Not Filled result of service code is not required.

Medicaid and NCHC Pro-DUR is based on a beneficiary's prescriptions from all prescribers and all pharmacies utilizing criteria established by the State and by a controllable database updated by First DataBank.

Submitting an accurate days supply is very important. The day's supply divided by the quantity is used to calculate the daily dose for Pro-DUR. Excessively high or low daily doses result in rejects for High and Low Dose DUR alerts. In addition to high and low daily dose edits, there are also edits for an early fill before 75 percent of the prescription is used and 85 percent for narcotic analgesics and benzodiazepine prescriptions and for a 34-day maximum (or 90 days if applicable). The maximum days supply cannot be overridden.

C.3 Counseling

Pharmacists **must** offer to discuss those matters with each Medicaid and NCHC beneficiary presenting a prescription, which they, in their professional judgment, deem to be significant. This **counseling** may include but is not limited to the following:

1. Name and description of the medication.
2. Dosage form, dosage, route of administration, and duration of therapy.
3. Special directions, precautions for preparation, administration, and use by the beneficiary.
4. Common severe side effects, adverse effects or interactions, drug allergies, and therapeutic contraindications.
5. Techniques for self-monitoring.
6. Proper storage.
7. Refill information.
8. Actions in case of a missed dose.

Although the beneficiary may refuse counseling, the offer must be made.

C.4 Information on Medicaid and NCHC Beneficiaries

The pharmacies are required to make a reasonable effort to obtain, record, and maintain **information on Medicaid and NCHC beneficiaries** receiving prescriptions to include at least the following information:

1. beneficiary's name, age, gender, address, and phone number
2. Individual beneficiary history including a list of medications and devices
3. Pharmacist's comments

The Division of Medical Assistance will monitor compliance with the requirements for prospective DUR screening, counseling, and maintenance of beneficiary information as required by federal law and regulations.

D. Retrospective DUR

D.1 Overview

OBRA 90 requires that NC Medicaid use Medicaid paid claims data to identify patterns of behavior involving physicians, pharmacists, and individual beneficiaries or patterns associated with specific drugs or groups of drugs and patterns of fraud and abuse. These analyses are based on explicit predetermined standards including the screens as described in the prospective review process. Pharmacists and prescribers' response to the interventions undertaken shall be tracked. The DUR Board may establish selection criteria for intensified review and monitoring of individual pharmacists and prescribers.

OBRA 90 also requires that the DUR program introduce remedial strategies, when necessary, to improve the quality of care for beneficiaries and to conserve program funds. These strategies include educational intervention, general or specific information dissemination, written, oral or electronic reminders, face-to-face discussion or intensified review or monitoring of practitioners. The DUR Board determines the interventions that will be used and, after the appropriate amount of time, evaluates the results to determine the effectiveness on improved drug therapy. The DUR Board may also establish referral processes to the Board of Pharmacy, the Board of Medical Examiners, the Board of Dental Examiners, other health care licensing agencies, or NC Medicaid Program Integrity Section for pharmacists or prescribers. This can occur if pharmacists or prescribers continue to demonstrate patterns of prescribing or dispensing which put the beneficiary at risk from drug therapy problems even after repeated warnings through Drug Use Review interventions.

Retrospective DUR (Retro-DUR) is well-suited for identifying aggregate provider-centered prescribing problems. The integration of prospective DUR online and retrospective DUR has the potential to promote improved prescribing practices and beneficiary outcomes. Retro-DUR can detect new relationships and problems among medications and diseases and can be used ongoing to update the Pro-DUR systems.

Retro-DUR is theoretically designed to accomplish the following:
1. Detect the full range of prescribing problems.
2. Recommend corrective actions for controlling costs and improving beneficiary outcomes.
3. Improve rational prescribing.
4. Identify preventable drug therapy problems.
5. Remind physicians of basic principles and provide up-to-date information needed for optimal prescribing.
6. Promote proactive pharmacy intervention processes.

7. Evaluate the effectiveness of interfacing programs.

DUR is education of prescribers and pharmacists to improve the quality of care for beneficiaries while reducing expenditures. Primary tangible cost reductions will be affected by:

8. Prescribing and dispensing of equally effective, less expensive drugs such as generic drugs.
9. Decreasing the incidences of unnecessary therapeutic duplications.
10. Averting prescribing problems that may precipitate unnecessary physician visits, ER visits, and hospitalizations.

D.2 Profiling Systems Used by the Retrospective Drug Use Review Program

The DUR Program uses two retrospective profiling methods to characterize drug use patterns and to help providers assure the quality of care in prescribing medications. These methods are Provider Profiling and Beneficiary Profiling.

Provider Profiling

The Provider Profiling System uses the Drug Enforcement Agency (DEA) number to identify prescribing practices that deviate from accepted norms. These norms are taken from the published literature or developed by the DUR Board. provider numbers are used to identify similar dispensing practices.

The Provider Profiling System accommodates criteria within the following major multi-factor problem types:

1. Overtreatment.
2. Undertreatment.
3. Treatment failure.
4. Drug-to-diagnosis interactions.
5. Drug-to-drug interactions.
6. Iatrogenic effects.
7. Adverse effects.
8. Therapeutic duplication.
9. Drug use without diagnosis.
10. Drug use without laboratory/diagnostic procedures.
11. Empiric prescribing.
12. Specialty-prescriber use issues.

Providers who are accepted in the Provider Profiling System receive an educational letter and a profile showing every drug claim paid using the prescriber's DEA or State-approved provider identifier for each beneficiary who received the specific drug therapy. The packet also includes prescribing information related to the specific drug therapy and response sheets for providers to indicate the appropriateness and usefulness of the intervention to the individual's practice.

Beneficiary Profiling

Beneficiary Profiling is designed to use specific criteria to characterize drug utilization patterns among beneficiaries. The criteria can identify the following multi-factor problem types:

1. Overutilization.
2. Underutilization.
3. Treatment failure.
4. Drug-to-diagnosis interactions.
5. Drug-to-drug interactions.
6. Iatrogenic effects.
7. Adverse reactions.

Profiles, which show the entire medical and drug claims paid for a particular beneficiary, are produced. DUR staff and the DUR review committee review these profiles and decide if the providers involved in the beneficiary's care should receive educational letters explaining the concern for the appropriateness and necessity for the drug therapy and the possibility of said therapy resulting in clinically significant adverse effects. The packets sent to prescribers and pharmacists include the educational letter, beneficiary profile, pertinent information relating to the drug therapy issue, and response sheets indicating the usefulness of this intervention to the individual's practice.

E. Statutory DUR Requirements and Impact on Pharmacies

OBRA required that the drug use review (DUR) program be implemented by January 1, 1993. The following guidelines are provided to assist retail pharmacies in complying with the DUR program.

E.1 Beneficiary Profiles

Statutory Requirement

Section 1927 of the Act requires **the pharmacist** to make a **reasonable effort** to obtain, record, and maintain for beneficiaries the following information:

a. Name, address, telephone number, age (or birth date), and gender.
b. Individual history where significant, including disease state(s), known allergies, drug reactions, a comprehensive list of medications, and relevant devices.
c. Pharmacist comments relevant to the beneficiary's drug therapy.

Impact on Pharmacies

a. **The pharmacist,** as defined in State Pharmacy Practice Acts, **is responsible** for collecting, recording, and maintaining beneficiary profile information.
b. **The pharmacist** may rely upon **ancillary personnel** to collect, record, and obtain beneficiary profile information, but **the pharmacist must review and interpret** beneficiary profile information and clarify confusing or conflicting information.
c. Once beneficiary information is obtained, **this information shall be reviewed and updated by the pharmacist** or registrant **before each prescription is filled or delivered,** typically at the point-of-sale or point-of-distribution to screen for potential drug therapy problems listed under the "screening" section below.
d. A **"reasonable effort"** to obtain profile information will be a good faith effort to obtain from the beneficiary or representative the foregoing beneficiary's information.

e. It is expected that **the pharmacist** will be guided by **professional judgment** as to whether and when individual history information should be sought from the physician or other health care providers.

E.2 Screening

Statutory Requirement

a. Section 1927 (g)(2)(A) of the Social Security Act (the Act) **requires Pro-DUR** at the point-of-sale or distribution **before each prescription is filled or delivered** to beneficiaries. This review shall include screening for potential drug therapy problems due to any of the following:

- Therapeutic duplication.
- Drug–disease contraindications.
- Drug interactions.
- Incorrect dosage or duration of drug treatment.
- Drug allergy interactions.
- Clinical abuse/misuse.

b. Prospective DUR screening **must use predetermined standards that are based upon** the following compendia:

- American Hospital Formulary Service Drug Information.
- United States Pharmacopoeia Drug Information.
- American Medical Association Drug Evaluations.
- Peer reviewed medical literature which has been critically reviewed by unbiased independent experts.

Impact on Pharmacies

a. **Prospective DUR screening is the responsibility of each participating pharmacy.**

b. Medicaid and NCHC shall supplement DUR on POS claims with alerts for

- Therapeutic duplication
- Drug–disease contraindications
- Drug interactions
- Incorrect dosage

c. Pharmacies may use commercially available DUR database packages to assist with prospective DUR. Pharmacies are not required to have their databases/software certified by the State DUR Board.

d. Such data base packages must be able to screen for the therapeutic problems specified in the statute using explicit standards.

e. It is not expected that these databases will contain **beneficiary-specific diagnosis or allergy information.** When, in the **pharmacist's professional judgment,** obtaining such information is essential to the health and well-being of the beneficiary, the pharmacist should consult the beneficiary or the beneficiary's health care provider.

f. **Pharmacies without computers,** or those who choose not to use prospective DUR database packages, **must undertake prospective DUR screening manually. To perform prospective DUR screening manually, the pharmacist** must screen using **predetermined standards,** which are **based upon** the listed compendia.

E.3 Beneficiary Counseling

Statutory Requirement

Section 1927 (g)(2)(A)(ii)(I) of the Act requires that **pharmacists offer** to discuss with **each Medicaid beneficiary** or a caregiver, **in person** whenever practicable, or by toll free telephone for long distance calls, matters which in his/her **professional judgment** the pharmacist deems significant. Such counseling is subject to standards for counseling under the State Pharmacy Practice Act. Such counseling **is to be provided unless refused** by the beneficiary or caregiver.

The statute lists the following subjects for inclusion in counseling:

a. The name and description of the medication
b. The route of administration, dosage form, dosage, and duration of drug therapy
c. Special directions and precautions for preparation, administration, and use by the beneficiary
d. Common severe side or adverse effects of interactions and therapeutic contraindications that may be encountered, including how they may be avoided and the actions required if they occur
e. Techniques for self-monitoring drug therapy
f. Proper storage
g. Prescription refill information
h. Action to be taken in the event of a missed dose

Impact on Pharmacies

a. **The pharmacist,** as defined in State Pharmacy Practice Acts, **is responsible** for the **offer to counsel** and for **conducting of counseling** when it occurs.
b. The **pharmacist** may have **ancillary personnel** make the offer of counseling, but **the pharmacist must personally conduct counseling if the offer is accepted.**
c. Pharmacies whose primary beneficiary population are accessible through local measured or toll free exchange are not required to offer toll free service.
d. **Pharmacists shall be required** to, at least, **document refusal** to accept an offer of counseling. States may impose additional documentation requirements with regard to counseling. **Records** resulting from compliance with the DUR requirements shall be maintained for **six years**.
e. States may choose to apply counseling requirements to all beneficiaries of prescriptions, not just Medicaid beneficiaries.
f. Counseling requirements apply to both **new and refill prescriptions.** However, **professional judgment** shall be exercised in determining whether or not to **offer counseling for prescription refills.**
g. Alternative forms of beneficiary information (such as written material) may be used to supplement beneficiary counseling, but **cannot be used as a substitute for counseling.**
h. The content of counseling is governed solely by the **professional judgment of the pharmacist.**

The DUR requirements have been incorporated into the State of North Carolina Pharmacy Practice Act and are therefore consistent with the requirements of the Board of Pharmacy except in three areas:

a. The requirements address **manual prospective DUR screening** in the absence of a computer DUR database/software package.

b. A recoupment of the total claim may be imposed on the pharmacy provider for non-adherence to this statutory requirement.

F. Requirement for Accurate Data on Pharmacy Claims

The DUR program depends on the submission of accurate data on pharmacy claims to minimize false positives and unnecessary referrals to pharmacies.

The following fields on the pharmacy claims are **very important.**

F.1 Day Supply

The DUR Program uses this information to compute the dose per day, which is often an indication of the therapeutic use. For example, a once daily dosing of cimetidine 400 mg would indicate that the medication is maintenance therapy as opposed to acute therapy. The information provided in this field is also used as an indicator for determining if the beneficiary overutilizes or underutilizes medications, as well as identifying potentially inadequate dosing and excessive dosing.

F.2 Prescriber Identification Number

The correct prescriber identification number is critical in identifying the prescribers and pharmacists involved in the beneficiary's drug therapy. A beneficiary with multiple prescribers often risks medication complications of a different magnitude as opposed to a beneficiary using one primary provider. One of the functions of DUR is to determine if the beneficiary's use of multiple prescribers results in overutilization of services. NC Medicaid currently uses the NPI to identify the prescribers on the pharmacy claim. It is imperative that the NPI be entered accurately on the claim.

F.3 Quantity Dispensed

The accuracy of the data entered in this field is critical to the DUR Program and the Drug Rebate Program. The quantity and days' supply are used to calculate the dose per day.

G. Point-of-Sale/Online Prospective Drug Use Review

G.1 Introduction

According to the Omnibus Budget Reconciliation Act of 1990 (OBRA), pharmacists must maintain beneficiary medication records; must screen prescriptions for potential therapeutic problems before medications are delivered to beneficiaries; and must counsel beneficiaries on all new or changed prescriptions and on refills when the pharmacist deems it warranted or the beneficiary requests it.

G.2 OBRA '90 and Outpatient Drug Use Review

OBRA mandates that each state Medicaid agency establish a comprehensive DUR program. The law also requires that states establish a DUR Board to assist in reviewing criteria, establishing standards and assessing their effect upon the quality of care delivered to beneficiaries. The objective of DUR is to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical events.

DUR is an administrative process of utilization review and quality assessment. It includes predetermined criteria to describe appropriate medical care and standards to define the allowable deviation from the criteria.

The predetermined criteria used in the DUR program must meet the following requirements:
a. Source materials must be consistent with the peer-reviewed medical literature, American Hospital Formulary Service Drug Information, United States Pharmacopoeia Drug Information, and American Medical Association Drug Evaluations.
b. Differences among source materials are resolved by a consensus of physicians and pharmacists.
c. Criteria are non-proprietary and readily available to providers of services.
d. Criteria are clinically based and scientifically valid.
e. Criteria are tested against claims data prior to adoption.
f. Predetermined standards for prospective and retrospective DUR are compatible.
g. Criteria are subject to ongoing evaluation and modification either as a result of actions by their developer or by the DUR Board.

G.3 Objectives

The objective of online prospective DUR is to assist pharmacists in screening select drugs for potential drug therapy problems before the prescription is delivered to the beneficiary.

G.4 Point-of-Sale System Operations

Prior to DUR processing, pharmacy claims are processed by the online adjudication system to verify beneficiary eligibility, ensure validity (valid dates, NDC numbers, pharmacy and prescriber provider numbers), determine appropriate payment, and comparison with previously paid claims to enforce program service limitations and nonpayment for duplicate claims.

G.5 Prospective Drug Use Review System

DUR processing begins after the claim is certified payable. Incoming drug claims are compared to the beneficiary's pharmacy claims history files to detect potential therapeutic problems. DUR alert messages are returned to the pharmacist for all problems discovered by this review.

Online prospective DUR provides for review of drug therapy before each prescription is filled or delivered to the beneficiary and includes screening for potential drug therapy problems due to any of the following:
a. Drug–drug interactions.
b. Therapeutic duplication.
c. Incorrect drug dosage (low dose or high dose).
d. Overutilization (clinical abuse or misuse).
e. Underutilization (clinical abuse or misuse).

Pro-DUR screens the beneficiary's profile across multiple pharmacies and prescribers to improve the quality of care and reduce costs by supplying pharmacists with information regarding potential adverse drug incidents and overutilization. Medicaid and NCHC Pro-DUR documents pharmaceutical care with National Council for Prescription Drug Programs (**NCPDP**) DUR professional service and result of service codes required to override DUR alerts. Accurate days' supply is essential for Pro-DUR minimum and maximum dosages.

Prospective DUR applies to systemic drug dosage forms as well as non-systemic forms. Systemic routes of administration include parenteral, buccal, inhalation, translingual, sublingual, transdermal, oral, rectal, vaginal, mucous membrane and nasal dosage forms. Non-systemic refers to dental, irrigation, urethral, ophthalmic, otic and topical dosage forms.

G.6 National Council for Prescription Drug Programs (NCPDP) Standards

Pharmacy claim telecommunication standards dictate the order and content of the fields relayed to the pharmacist when a DUR alert is generated. A description of these fields follows.

a. Reason for Service Code

Alerts the pharmacist that the incoming drug claim conflicts with information in the beneficiary's history file or with predetermined screening criteria.

b. Clinical Significance/Severity Index Code

Indicates database-assigned significance of the conflict.

0 = Not applicable, 1 = Major, 2 = Moderate, 3 = Minor

c. Other Pharmacy Indicator

Informs the pharmacist of the originating location of the claim with which the incoming drug claim conflicts.

0 = Not applicable, 1 = Your Pharmacy, 3 = Other Pharmacy

d. Previous Date of Fill

The last recorded date of the active medication in the beneficiary's history file with which the incoming drug claim conflicts.

e. Quantity of Previous Fill

Quantity of previously filled prescription with which the incoming drug claim conflicts.

f. Database Indicator

Identifies source of DUR conflict information.

0 = Not applicable, 1 = First DataBank.

g. Other Prescriber Indicator

Identifies the prescriber of the previously filled prescription with which the incoming drug claim conflicts.

0 = Not applicable, 1 = Same Prescriber, 2 = Other Prescriber

h. Free Text Message

30-character field that transmits decoded information regarding the DUR conflict.

Medicaid and NCHC will use this for the Drug Name and Strength of the conflicting drug, the health condition contraindicated in drug–disease conflicts, or the minimum and maximum dose for utilization conflicts.

i. **NCPDP DUR Codes**

Reason for Service Codes	Additional Message Text
DD - Drug–Drug Interaction	"Drug Name with Strength" of interacting drug
TD - Therapeutic Duplication	"Drug Name with Strength duplicates this Rx"
ER - Overuse Precaution	"Refill is _____ days early"
LR - Underuse Precaution	"Refill is ____ days late"
DC - Drug–Disease Precaution	"Condition contraindicates use of prescribed drug"
LD - Low Dose Alert	"Minimum dose, Maximum dose, dose unit"
HD - High Dose Alert	"Minimum dose, Maximum dose, dose unit"

NCPDP Codes, continued

Professional Service Codes
M0 - Prescriber Consulted
P0 - Patient Consulted
R0 - Pharmacist Consulted Other Source
00 - No Intervention
Blank Not Specified

Result of Service Codes
1A – Filled, False Positive
1B - Filled Prescription as is
1C - Filled with different dose
1D - Filled with different directions
1E - Filled with different drug
1F - Filled with different quantity
1G - Filled with prescriber approval
2A - Prescription not filled
2B - Prescription not filled – directions clarified

j. **Approved Prescription Clarification Codes for Early Refill**

03   Vacation Supply   To be used if the beneficiary is going out of town and needs medication refilled early. Only one 5-consecutive day occurrence each 365-day time period will be allowed for non-controlled medications.

04   Lost Prescription   To be used if the beneficiary has lost their medication. Only one occurrence on one date of service each 365-day time period will be allowed for non-controlled medications.

05   Therapy Change   To be used if the dosage is changed on a current medication.

Note: Vacation supply and lost prescription codes are not allowed on controlled substances.

G.7 DUR Alert Message Examples

Proprietary pharmacy software for prescription processing systems may display DUR alerts in different formats. The following examples are provided to acquaint the reader with the standard content of DUR messages. These may differ from the message actually displayed on the pharmacist's computer screen.

a. On July 6, 1996, the pharmacist attempts to dispense an aspirin-containing product to a beneficiary currently receiving warfarin prescribed by the same physician and filled at another pharmacy. The messages related to the alert are:

Reason for Service Code:	DD - DRUG INTERACTION
SEVERITY:	1 = Major
OTHER PHARMACY INDICATOR:	3 = Other Pharmacy
PREVIOUS FILL DATE:	19960630 (June 30, 1996)
QUANTITY OF PREVIOUS FILL:	30
DATABASE INDICATOR:	1 = First DataBank
OTHER PRESCRIBER INDICATOR:	1 = Same Prescriber
MESSAGE:	Coumadin

b. On July 19, the pharmacist attempts to dispense a refill for which the previous prescription has greater than 25 percent of days supply remaining:

Reason for Service Code:	ER - OVERUTILIZATON
OTHER PHARMACY INDICATOR:	1 = Same Pharmacy
PREVIOUS FILL DATE:	19960628 (June 28, 1996)
QUANTITY OF PREVIOUS FILL:	90
OTHER PRESCRIBER INDICATOR:	1 = Same Prescriber

c. The pharmacist attempts to dispense a refill of levothyroxine on June 15, a date equal to greater than 125 percent of previous prescription's days supply:

Reason for Service Code:	LR - UNDERUTILIZATION
OTHER PHARMACY INDICATOR:	1 = Same Pharmacy
PREVIOUS FILL DATE:	19960501 (May 1, 1996)
QUANTITY OF PREVIOUS FILL:	30
OTHER PRESCRIBER INDICATOR:	1 = Same Prescriber

d. The pharmacist attempts to dispense acetaminophen w/codeine, three tablets every 4 hours (dose exceeds usual adult daily maximum):

Reason for Service Code:	HD - HIGH DOSE
DATABASE INDICATOR:	1 = First DataBank

e. The pharmacist attempts to dispense propranolol 20mg, 1 daily (dose is less than usual adult daily minimum):

Reason for Service Code:	LD - LOW DOSE
DATABASE INDICATOR:	1 = First DataBank

G.8 DUR Alert Priority

All DUR alerts for a prescription will be relayed to the pharmacist on line. However, only 3 DUR override codes can be entered. If there are more than 3 alerts, override the first 3 DURs listed.

Multiple alerts on a prescription are prioritized according to the following hierarchy (**subject to DUR Board approval**):

a. Overutilization.
b. Drug–Drug Interactions.
c. Therapeutic Duplication.
d. Incorrect Dose.
e. Drug–Disease Contraindications.
f. Underutilization.

G.9 DUR Alert Definitions

Overutilization

Overutilization is use of a drug in quantities or for durations which put the beneficiary at risk of an undesirable effect due to a course of drug therapy. The Overutilization screening system warns pharmacists when beneficiaries attempt to obtain early refills. The pharmacist must indicate one of the approved reason codes in order for this alert to be overridden. The approved codes are as follows:

03 – Vacation supply (Only one 5-consecutive day occurrence each 365-day time period will be allowed for non-controlled medications.

04 – Lost prescription (Only one occurrence on one date of service each 365-day time period will be allowed for non-controlled medications.)

05 – Therapy dosage change

Drug–Drug Interactions

Drug–drug interactions create the potential for an adverse medical event when beneficiaries receive simultaneous prescriptions with conflicting pharmacology. The Drug–Drug Interaction screening system warns pharmacists when a beneficiary receives drugs, which result in a different pharmacologic response from that which is expected when the drugs are given separately. This screen accounts for serum half-life when editing for active medications in the beneficiary's medication history. The pharmacist is notified when severity level 1 interactions occur, i.e., those that are the most significant, usually requiring action to reduce risk of serious injury.

Therapeutic Duplication

Therapeutic duplication is the prescribing of two or more drugs from the same therapeutic class such that the combined daily dose increases the risk of toxicity or incurs additional program costs without additional therapeutic benefit. The Therapeutic Duplication screening system warns pharmacists when a claim is submitted for a systemically absorbed drug that shares the same therapeutic class or a non-systemic drug with identical route of administration and same therapeutic class as another drug currently in the beneficiary's active medication history.

Incorrect Dosage

An incorrect dosage is one which lies outside the adult daily dosage range necessary to achieve therapeutic benefit. The Incorrect Dosage screening system alerts pharmacists when doses fall outside the normal adult range for common indications for the drug. Beneficiary-specific information is not required since dose ranges are predicated on a 70 kg adult male with normal hepatic and renal function. Geriatric doses are not included in the incorrect dosage alert.

Drug–Disease Contraindication

Drug–disease contraindications create the potential for an adverse medical event when beneficiaries receive prescriptions, which are contraindicated in the beneficiary's disease state. A drug–disease contraindication occurs when certain drugs are prescribed for beneficiaries with specific medical conditions that may be aggravated by the new drug prescribed. Diseases are inferred from the indication of drugs on the beneficiary's profile.

Underutilization

Underutilization is use of a drug in insufficient quantity to achieve a desired therapeutic effect. The Underutilization screening system warns pharmacists when subtherapeutic patterns of prescription use are detected by a beneficiary's failure to renew prescriptions for maintenance drugs on a timely basis. This alert is for informational purposes only.

G.10 Online DUR Criteria

Drug–Drug Interactions (DD)

Processing: The drug interaction edit screens each new claim against all active medications in the beneficiary's pharmacy claims history file. To account for residual drug in the body, a factor of 15 percent is added to each active claims' days supply. Severity level 1, major significance, interaction alerts are sent to the pharmacist.

Alert: DD - Drug–Drug Interaction

Message: (Label name)

Manual DUR Protocol: Pharmacists using explicit written criteria (manual DUR) shall maintain ingredient-specific beneficiary profiles. Prior to dispensing any medication, the prescription must be checked against the existing medication profile to identify interacting drugs.

Therapeutic Duplication (TD)

Processing: The Therapeutic Duplication edit screens incoming prescriptions against all active drugs in a beneficiary's claims history. Duplication exists when a beneficiary receives two systemically absorbed drugs or two non-systemic drugs by the same route of administration that share the same therapeutic class.

Alert: TD - Therapeutic Duplication

Message: (Label name)

Manual DUR Protocol: Pharmacists using explicit written criteria (manual DUR) shall maintain ingredient-specific beneficiary profiles. Prior to dispensing any medication, the prescription must be checked against the existing drug profile to identify products in the same therapeutic categories.

Incorrect Dosage (LD/HD)

Processing: The Incorrect Drug Dosage screen creates warnings when the prescribed dose is outside the usual adult range for common indications for that drug. Pediatric doses are checked using ten levels of age/weight minimum and maximum doses for beneficiaries less than 18 years old.

    Alerts: HD - High Dose

    LD - Low Dose

Manual DUR Protocol: Pharmacists using explicit written criteria (manual DUR) shall screen prescriptions against the usual adult daily dose for a 70 kg adult male with normal hepatic and renal function.

Drug–Disease Contraindication (DC)

Processing: The Drug–Disease Contraindication edit screens each new claim against all medications in the beneficiary's pharmacy claims history file. A Drug–Disease Contraindication occurs when certain drugs are prescribed for beneficiaries with specific medical conditions that may be aggravated by the new drug prescribed. Diseases are inferred from the indication of drugs on the beneficiary's profile.

Alert: DC - Drug–Disease Contraindication

Manual DUR Protocol: Pharmacists using explicit written criteria (manual DUR) shall maintain ingredient-specific beneficiary profiles. Prior to dispensing any medication, the prescription must be checked against the existing medication profile to identify any drug–disease contraindications.

Overutilization (ER)

Processing: The Overutilization screen warns the pharmacist of early fills and/or potential abuse situations. This screen identifies prescriptions submitted for another supply of the same drug when the beneficiary's medication history shows greater than 25 percent of the previously dispensed days supply remains or 9 days early if the previous claims days supply is greater than 34 days. For benzodiazepines and opioid analgesics, the system will alert when the beneficiary's medication history indicates greater than 15 percent of the previously dispensed days supply remains. The process to override an early fill alert is to respond to the DUR alert and to indicate one of the approved reason codes in the Rx Clarification Field (also referred to as the Submission Clarification Code). The approved codes are as follows:

03 – Vacation supply (Only one 5-consecutive day occurrence each 365-day time period will be allowed for non-controlled medications.

04 – Lost prescription (Only one occurrence on one date of service each 365-day time period will be allowed for non-controlled medications.)

05 – Therapy dosage change

Alert: ER - Overuse Precaution

Manual DUR Protocol: Pharmacists using explicit written criteria (manual DUR) must maintain accurate prescription dates of service. Prior to dispensing any medication, prescriptions must be checked against the existing drug profile to identify products with identical route of administration and active ingredient(s). If previous prescriptions for identical products have at least 25 percent of the days supply remaining (15 percent for

benzodiazepines and opioid analgesics) or 9 days early if the previous claims days supply is greater than 34 days, early refill is present.

Underutilization (LR)

Processing: The Underutilization screen creates warnings when subtherapeutic patterns of prescription use are detected. Alerts are generated when beneficiaries fail to renew prescriptions for maintenance drugs on a timely basis. Pharmacists are notified when the renewal request interval is greater than 125 percent of the previous days supply. This alert is sent for informational purposes only. No override is needed to fill the prescription.

> Alert: LR - Underuse Precaution

Manual DUR Protocol: Pharmacists using explicit written criteria (manual DUR) must maintain accurate prescription dates of service. Prior to dispensing any medication, prescriptions must be checked against the existing drug profile to identify products with identical route of administration and active ingredient(s). If previous prescriptions for identical products exceed 125 percent of the days supply, late refill is present.

G.11 Procedure for Responding to DUR Alerts

a. Pharmacist receives DUR alert message(s) on computer screen; claim is rejected for DUR

b. Pharmacist reviews and resolves identified DUR conflict(s) by contacting the prescriber, talking with the beneficiary, and/or using other resources or professional judgment

c. If the pharmacist decides not to dispense the prescription, the pharmacist accepts the reject. Pharmacist does not resubmit claim and does not receive payment.

d. If the pharmacist decides to resolve and dispense the prescription, the pharmacist resubmits the correct claim with a DUR reason for service code, DUR professional service code, and DUR result of service code. (See additional information needed to override an early fill alert).

e. Pharmacist receives a paid response if the prescription was filled with DUR documentation.

DUR alert messages contain standardized codes and language, but may be displayed in various ways, depending on the pharmacy software in use. The **content of the DUR Alert message** includes:

a. **Reason for Service Code**

This two-character alphabetic code identifies the conflict between the submitted drug claim and information in the beneficiary's history file or predetermined screening criteria.

b. **Clinical Significance/Severity Index Code**

This numeric value indicates the database-assigned significance of the conflict.

0 = Not applicable, 1 = Major, 2 = Moderate, 3 = Minor

c. **Other Pharmacy Indicator**

This numeric value identifies the originating location of the history claim with which the submitted drug claim conflicts.

0 = Not applicable, 1 = Your Pharmacy, 3 = Other Pharmacy

d. **Previous Date of Fill**

This value identifies the last recorded date of service for the active medication in the beneficiary's history file with which the submitted drug claim conflicts.

e. **Quantity of Previous Fill**

This value identifies the quantity of the prescription in the beneficiary's history file with which the submitted drug claim conflicts.

f. Database Indicator

This value identifies the source of DUR screening criteria.

0 = Not applicable, 1 = First DataBank, 2 = Medi-Span, 3 = Red Book,
4 = Processor Developed, 5 = Other

g. Other Prescriber Indicator

This numeric value identifies the prescriber of the history claim with which the submitted drug claim conflicts.

0 = Not applicable, 1 = Same Prescriber, 2 = Other Prescriber

h. Free Text Message

This 30-character field provides additional information regarding the DUR conflict. Medicaid and NCHC will use the Drug Name and Strength of the conflicting drug, the health condition contraindicated in drug–disease conflicts, or the minimum and maximum dose for utilization conflicts.

H. Point-of-Sale/Pro-DUR Transaction Flows

Flow 1	POS No Pro-DUR Screening
Flow 2	POS No Pro-DUR Alerts
Flow 3	POS/Pro-DUR Alerts Found - Provider Overrides
Flow 4	POS/Pro-DUR Alerts Found - Provider Cancels
Flow 5	POS/Pro-DUR Alerts Found - Provider Cancels and Resubmits
Flow 5a	POS/Pro-DUR Alerts Found - Provider Changes Rx and Resubmits
Flow 6	POS/Pro-DUR Alerts Found - No Provider Response
Flow 7	POS Provider Sends Reason for Service/Professional Service/Result of Service Codes on a New Claim; DUR Reason for Service Codes DD, TD, ER
Flow 7a	POS Provider Sends Reason for Service/Professional Service/Result of Service Codes on a New Claim; DUR Reason for Service Codes HD, LD, LR
Flow 8	POS Reversal Transaction - Transaction is Accepted
Flow 9	POS Reversal Transaction - Edit Errors are Found
Flow 10	POS Reversal Transaction - Original Claim Not Found on File

1 POS/Pro-DUR Transaction Flow
No Pro-DUR Screening

1. **Pharmacist** submits a claim.
2. **Processor** POS receives claim and finds edit errors. Pro-DUR screening is bypassed.
3. **Processor** sends "rejected" response (response status = "R").
4. **Pharmacist** receives reject response; there will be no Medical Assistance reimbursement for providing service.

2 POS/Pro-DUR Transaction Flow
No Pro-DUR Alerts

1. **Pharmacist** submits a claim.
2. **Processor** POS receives claim and finds no edit errors. Pro-DUR screening is performed. No Pro-DUR screens fail.
3. **Processor** sends "payable" response (response status = "P").
4. **Pharmacist** receives "payable" response.

3 POS/Pro-DUR Transaction Flow
Pro-DUR Alerts Found—Provider Overrides

1. **Pharmacist** submits a claim.
2. **Processor** POS receives claim and finds no edit errors. Pro-DUR screening is performed. One or more Pro-DUR screens fail. POS suspends claim. Provider must respond to override the alert or cancel the claim.
3. **Processor** sends "rejected" response with reason for service code (s) (response status = "R").
4. **Pharmacist** receives "rejected" response. Resolves DUR conflict(s); selects **one** reason for service code; resubmits claim with 6-character reason for service/professional service/result of service code indicating override.
5. **Processor** POS receives claim with reason for service/professional service/result of service code; POS matches claim to suspended claim; Pro-DUR screens overridden.
6. **Processor** sends "payable" response (response status = "P").
7. **Pharmacist** receives "payable" response.

4 POS/Pro-DUR Transaction Flow
Pro-DUR Alerts Found—Provider Cancels

1. **Pharmacist** submits a claim.
2. **Processor** POS receives claim and finds no edit errors. Pro-DUR screening is performed. One or more Pro-DUR screens fail. POS suspends claim. Provider must respond to override the alert or cancel the claim.
3. **Processor** sends "rejected" response with reason for service code (s) (response status = "R").
4. **Pharmacist** receives "rejected" response. Realizes there will be no Medical Assistance reimbursement for providing service. Selects **one** reason for service code. Sends informational transaction with 6-character reason for service/professional service/result of service code indicating cancellation.
5. **Processor** POS receives transaction with reason for service/professional service/result of service code; POS matches claim to suspended claim.
6. **Processor** sends acknowledgment of cancellation (response status = "P"; payable amount = $0).
7. **Pharmacist** receives acknowledgment.

5 POS/Pro-DUR Transaction Flow
Pro-DUR Alerts Found— Provider Cancels & Resubmits

1. **Pharmacist** submits a claim.
2. **Processor** POS receives claim and finds no edit errors. Pro-DUR screening is performed. One or more Pro-DUR screens fail. POS suspends claim. Provider must respond to override the alert or cancel the claim.
3. **Processor** sends "rejected" response with reason for service code (s) (response status = "R").
4. **Pharmacist** receives "rejected" response. Changes claim's drug, quantity, and/or days supply. Cancels original claim. Sends informational transaction with 6-character reason for service/professional service/result of service code indicating cancel.
5. **Processor** POS receives claim with reason for service/professional service/result of service code; POS matches claim to suspended claim.
6. **Processor** sends acknowledgment of cancellation (response status = "P"; payable amount = $0).
7. **Pharmacist** receives acknowledgment.
8. **Pharmacist** submits new claim with changed drug, quantity, and/or days supply.

5a   POS/Pro-DUR Transaction Flow
Pro-DUR Alerts Found—
Provider Changes Rx & Resubmits

1. **Pharmacist** submits a claim.
2. **Processor** POS receives claim and finds no edit errors. Pro-DUR screening is performed. One or more Pro-DUR screens fail. POS suspends claim. Provider must respond to override the alert or cancel the claim.
3. **Processor** sends "rejected" response with reason for service code (s) (response status = "R").
4. **Pharmacist** receives "rejected" response. Changes claim's drug, quantity, and/or days supply. Resubmits with 6-character reason for service/professional service/result of service code indicating override.
5. **Processor** POS receives claim with reason for service/professional service/result of service code; POS matches claim to suspended claim. Pro-DUR screening is performed. One or more Pro-DUR screens fail. POS suspends claim. Provider must respond to override the alert or cancel the claim.
6. **Processor** sends "rejected" response with reason for service code (s) (response status = "R").
7. **Pharmacist** receives "rejected" response. Resolves DUR conflict(s). Selects one reason for service code. Resubmits claim with 6-character reason for service/professional service/result of service code indicating override.
8. **Processor** POS receives and matches claim to suspended claim. Pro-DUR screens overridden.
9. **Processor** sends "payable" response (response status = "P").
10. **Pharmacist** receives "payable" response.

OR

7. **Pharmacist** receives "rejected" response. Sends informational transaction with 6-character reason for service/professional service/result of service code indicating cancel.
8. **Processor** POS receives and matches to suspended claim.
9. **Processor** sends acknowledgment of cancellation (response status = "P"; payable amount = $0).
10. **Pharmacist** receives acknowledgment.

6   POS/Pro-DUR Transaction Flow
Pro-DUR Alerts Found—No Provider Response

1. **Pharmacist** submits a claim.
2. **Processor** POS receives claim and finds no edit errors. Pro-DUR screening is performed. One or more Pro-DUR screens fail. POS suspends claim. Provider must respond to override the alert or cancel the claim.
3. **Processor** sends "rejected" response with reason for service code (s) (response status = "R").
4. **Pharmacist** receives "rejected" response but supplies no return response.
5. **Processor** Claim remains suspended and is subsequently cancelled by the system.

7   POS/Pro-DUR Transaction Flow
Provider Sends C/I/O Codes on a New Claim
DUR Reason for Service Codes DD, TD, ER

1. **Pharmacist** submits a claim with reason for service/professional service/result of service codes for DUR reason for service codes DD, TD, ER.
2. **Processor** POS receives claim with reason for service/professional service/result of service codes. POS does not find a suspended claim that matches the new claim. The reason for service/professional service/result of service codes are ignored and Pro-DUR screening is performed. Claim is treated as a first-time submission (any of the other flows may occur).

7a   POS/Pro-DUR Transaction Flow
Provider Sends C/I/O Codes on a New Claim
DUR Reason for Service Codes HD, LD, LR

1. **Pharmacist** submits a claim with reason for service/professional service/result of service codes for DUR reason for service codes HD, LD, LR.
2. **Processor** POS receives claim with reason for service/professional service/result of service codes. POS does not find a suspended claim that matches the new claim. The reason for service/professional service/result of service codes are recorded and Pro-DUR screening is performed. One or more Pro-DUR screens fail. POS suspends the claim. The provider must respond to override the alert or cancel the claim.
3. **Processor** sends "rejected" response with reason for service code (s) **except** those on original claim (response status = "R").

4. **Pharmacist** receives "rejected" response. Resolves DUR conflict(s); selects one reason for service code; resubmits claim with 6-character reason for service/professional service/result of service code indicating override.
5. **Processor** POS receives claim with reason for service/professional service/result of service code; matches claim to suspended claim; Pro-DUR screens overridden.

OR

4. **Pharmacist** receives "rejected" response. Sends informational transaction with 6-character reason for service/professional service/result of service code indicating cancel.
5. **Processor** POS receives and matches claim to suspended claim; sends acknowledgment of cancellation (response status = "P"; payable amount =$0).
6. **Pharmacist** receives acknowledgment.

8 POS/Pro-DUR Transaction Flow
Accepted Reversal Transaction

1. **Pharmacist** submits a reversal.
2. **Processor** POS receives reversal; finds no edit errors; finds original claim in "paid" status; reverses claim; sends acknowledgment of reversal (response status = "A").
3. **Pharmacist** receives acknowledgment.

9 POS/Pro-DUR Transaction Flow
Rejected Reversal Transaction

1. **Pharmacist** submits a reversal.
2. **Processor** POS receives reversal; finds edit errors; sends "rejected" response (response status = "R").
3. **Pharmacist** receives "rejected" response.

10 POS/Pro-DUR Transaction Flow
Reversal Transaction—Original Claim Not on File

1. **Pharmacist** submits a reversal.
2. **Processor** POS receives reversal; finds no edit errors; does not find original claim; sends "rejected" response (response status = "R").
3. **Pharmacist** receives "rejected" response.

I. Drug–Drug Interaction Example

Amiodarone and Warfarin interact with a Severity Level of 1. The beneficiary's claim history shows that 30 days supply of Amiodarone 200 mg was filled on August 1, 2004. The incoming claim, on date of service September 3, 2004, is for 5 mg of Warfarin.

Processing
Evaluate Beneficiary History
Each of the beneficiary's history claims is evaluated to determine the date on which the drug is no longer active in the beneficiary's system. The formula to determine the active end date is as follows:

1. Multiply the Days Supply by the Days Supply Percentage for Drug–Drug (usually 115%)
2. Add the number of days to the Date of Service

Using this formula, Drug 1 is active until 09/05/2004 (30 x 1.15 = 35 Days; 08/01/2004 plus 35 days = 09/05/2004). The drug is considered active if the calculated end date is greater than the incoming drug's date of service.

Determine Drug–Drug Interaction
The Drug–Drug precautions are searched using the active history drug as Drug 1 and the incoming claim drug as Drug 2. If a match is found, an alert is issued.

Results
This drug combination will cause a severity level 1 Drug–Drug alert (DD) to be returned.

J. Over Utilization/Early Refill Example

The beneficiary's claim history shows that 30 days supply of Propranolol 40 mg tablet was filled on August 1, 2004. Incoming claim information is for Propranolol 40 mg tablet on August 22, 2004.

Processing
Evaluate Beneficiary History
The beneficiary's history is searched for a drug matching the incoming claim. If a match is found, the following formula is applied to the history claim to determine if the refill is too soon:

1. Multiply the Days Supply by the Days Supply Percentage for Over Utilization (usually 75% and 85 % for benzodiazepine and opioid analgesic prescriptions)
2. Add the number of days to the Date of Service

For this example, the calculated date is 08/24/2004. (30 x 0.75 = 23; 08/01/2004 plus 23 days = 08/24/2004). The refill is considered early if the calculated date is greater than the incoming claim's date of service.

Results
An Over Utilization alert (ER) will be returned since the calculated date, 08/24/2004, is greater than the date of service, 08/22/2004.

K. Under Utilization/Late Refill Example

Theophylline 300 mg tablet is prescribed as a maintenance drug. The beneficiary's claim history shows 30 days supply filled on July 1, 2004. Incoming claim information is for date of service August 15, 2004.

Processing

Note: Processing for this screening is for maintenance drugs only.

Evaluate Beneficiary History

The beneficiary's history is searched for a drug matching the incoming claim. If a match is found, the following formula is applied to the history claim to determine if the refill is late:

1. Multiply the Days Supply by the Days Supply Percentage for Under Utilization (usually 125%)

2. Add the number of days to the Date of Service

For this example, the calculated date is 08/08/2004 (30 x 1.25 = 38 Days; 07/01/2004 plus 38 days = 08/08/2004). The refill is considered late if calculated date is less than the incoming claim's date of service.

Results

An Under Utilization alert (LR) will be returned, since the calculated date, 08/08/2004, is less than the date of service, 08/15/2004.

L. Low Dose/High Dose Example

Low Dose/High Dose Precautions		
Drug	**Minimum Dose**	**Maximum Dose**
Cimetidine 400 mg tablet	1 tablet	6 tablets
Captopril 50 mg tablet	1 tablet	9 tablets

Incoming Claim Information		
Drug	**Quantity**	**Days Supply**
1. Cimetidine 400 mg tablet	30 tablets	60
2. Captopril 50 mg tablet	360 tablets	30

Processing

The Dose is calculated by dividing the Quantity by Days Supply. The Dose is then compared to the Low Dose/High Dose criteria.

A low dose alert will be returned if the calculated dose is less than the minimum dose for the drug.

A high dose alert will be returned if the calculated dose is greater than the maximum dose for the drug.

For claim 1, the dose is 0.5 tablet per day (30 divided by 60).

For claim 2, the dose is 12 tablets per day (360 divided by 30).

Results

Claim 1 will return a low dose alert (LD) since 0.5 is less than the minimum dose of 1 tablet per day.

Claim 2 will return a high dose alert (HD) since 12 is greater than the maximum dose of 9 tablets per day.

M. Therapeutic Duplication Example

Drug	Name	Therapeutic Class
1	Diazepam 10 mg oral tablet	H2F
2	Triazolam 0.125 mg oral tablet	H2F
3	Triamcinolone topical cream	P5C
4	Flunisolide topical ointment	P5C

Beneficiary Claim History		
Drug	Date of Service	Days Supply
Drug 1: Diazepam 10 mg tablet	08/01/2004	30
Drug 3: Triamcinolone topical cream	08/15/2004	5

Incoming Claim Information	
Drug	Date of Service
Drug 2: Triazolam 0.125 mg tablet	08/15/2004
Drug 4: Flunisolide topical ointment	08/18/2004

Processing

Evaluate Beneficiary History

The beneficiary's history is searched for a drug in the same therapeutic class. If a match is found, the following formula is applied to determine if the prescription is still active:

1. Calculate end Rx date by adding Days Supply to Date of Service.

For this example, the calculated end Rx date for Drug 1 is 08/31/2004 (08/01/2004 + 30 days = 08/31/2004). The calculated date for Drug 3 is 08/20/2004 (08/15/2004 + 5 days = 08/20/2004).
If incoming claim's date of service is less than end Rx date, an alert is returned.

Determine Therapeutic Duplication

Two drugs are considered therapeutic duplicates under the following conditions:

1. The drugs belong to the same Therapeutic Class AND both drugs are systemic.
2. The drugs belong to the same Therapeutic Class, the incoming drug is not systemic, AND both drugs have the same route of administration.

Results

For Drugs 1 and 2, the history drug and the incoming claim drug belong to the same Therapeutic Class, both drugs are systemic and the incoming claim's date of service is less than the calculated end Rx date; therefore, a Therapeutic Duplication alert (TD) is returned.

For Drugs 3 and 4, the history drug and the incoming claim drug belong to the same Therapeutic Class, the incoming claim drug is NOT systemic but matches route of administration, and the incoming claim's date of service is less than the calculated end Rx date; therefore, a Therapeutic Duplication alert (TD) is returned.

Attachment F: Summary of Billing Requirements

a. The subscriber ID is the beneficiary's MID number consisting of nine (9) digits plus one (1) alpha character in the tenth position.

b. The prescriber's NPI number is the number used to identify the prescriber of the prescription.

c. The maximum days supply for all drugs, except birth control medications, prepackaged hormone replacement therapies, and maintenance medications is a 34-day supply unless the medication meets the criteria described in **Subsection 5.4, Dispensing and Maximum Days Supply.**

d. The dispensing fee is deducted for additional prescriptions dispensed within the same month (except for clotting factors).

e. Compounds – Refer to **Attachment A, Section J**, **Compounded Drugs**.

f. Nursing Home providers may combine all of the prescriptions dispensed during a month as one prescription and submit it at the end of month.

g. The Amount Billed should be the lower of usual and customary charge or the calculated Medicaid price. The calculated Medicaid price is the **MAC price or NCAAC+ the dispensing fee**. Federal or State MAC prices or NADAC generic prices are used unless they are overridden with auditable required documentation.

340B Provision

340B providers must be listed on the HRSA website (http://www.hrsa.gov/opa/). 340B providers must submit the actual purchased drug price in the usual and customary charge field. Providers who maintain two separate inventories—one for the 340B beneficiaries and a purchased inventory for non-340B beneficiaries—may not dispense a 340B-purchased drug and bill Medicaid or NCHC the calculated Medicaid price for non-340B beneficiaries. For hemophilia drugs, 340B providers may submit the state upper limit established for a 340B purchased hemophilia drug 340B providers must submit POS claims with an '8' in the basis of cost determination field (NCPDP D.0 field 423-DN) and a '20' in the submission clarification code field (NCPDP D.0 field 420-DK) to indicate they are dispensing a 340B product. This will eliminate duplicate discounts as the claims will be pulled from rebate collections.

h. NADAC generic rate and MAC overrides are allowed:

1. if the prescriber hand writes brand "Medically Necessary" on the face of the prescription. NADAC generic rate and MAC overrides are billed with DAW 1.
2. if the prescriber has indicated the brand drug is necessary by writing "medically necessary" on the prescription order for a brand NTI drug. NADAC generic rate and MAC overrides are billed with DAW 7
3. when a multi-source Brand generic equivalent is not available in the market place. NADAC generic rate and MAC overrides are billed with DAW 8.
4. When the NC Medicaid and NCHC preferred Brand was dispensed when the generic equivalent was non-preferred. NADAC generic rate and MAC overrides are billed with DAW 9.

i. Other Payor amounts must be included when applicable for Medicaid and NCHC, as the payor of last resort, to pay the calculated Medicaid price minus the co-pay and the Other Payor Amount field.

j. Exclusions from payment:

1. OTCs (except insulin and selected OTC products per Clinical Coverage Policy 9A, Over-The-Counter Products at https://medicaid.ncdhhs.gov/)
2. devices
3. diaphragms

4. DESI drugs

5. compounds equivalent to DESI drugs

6. fertility medications

7. medications for cosmetic purposes

8. medications for non-FDA approved uses

9. drugs from manufacturers who have not signed Drug Rebate agreements

10. inpatient hospital prescriptions

11. drugs administered in the prescriber's offices, which should be submitted by the prescriber using J codes

12. routine immunizations

13. durable medical equipment

14. prescriptions dispensed by providers who are not enrolled with Medicaid or NCHC

15. IV fluids (Dextrose 500 ml or greater) and irrigation fluids used by Medicaid or NCHC beneficiaries in an inpatient facility are not billed through the Medicaid and NCHC Outpatient Pharmacy Program; they are billed by the facility as ancillary services.

16. Erectile dysfunction drugs

17. Weight loss and weight gain drugs

18. Drug samples

19. Drugs obtained from any patient assistance program

20. Drugs used for the symptomatic relief of cough and colds that contain expectorants or cough suppressants

21. Legend vitamins and mineral products (except prenatal vitamins, fluoride, and calcitriol (vitamin-D) when the calcitriol is being used for predialysis beneficiaries, dialysis beneficiaries, and hypoparathyroidism beneficiaries.

Attachment G: Defining the Drug Unit

1. **Tablets, capsules, and suppositories:** The unit is "one" or "each." For example, if 10 tablets are dispensed, the quantity is 10.

2. **Ointments, creams, balms, and bulk powders:** The unit is "gram." For example, if a 15 gram tube of ointment is dispensed, the quantity is 15.

3. **Liquids, suspensions, solutions, large volume IV solutions, and irrigations:** The unit is "ml." For example, if a 4 ounce bottle of liquid is dispensed, the quantity is 120.

4. Injectable items:

    a. If the product is **in solution**, the unit is "ml" and the quantity is the volume size. For example, if a 100 ml bag of Sodium Chloride is dispensed, the quantity is 100.

    b. If the product is a **partial-fill**, the unit is "ml" and the quantity is the amount of fill volume containing the actual drug. For example, if Dextrose 5% 250 ml in a 500 ml bottle is dispensed, the quantity is 250.

    c. If the product is a **powder filled vial for reconstitution before injection**, the unit is "one" or "each." For example, if a vial of injectable Ampicillin has to be reconstituted into solution by the pharmacist, the quantity is 1. Note that when a product comes with a separate vial or ampule or diluent it is still treated as a powder for reconstitution under this policy.

5. **Packets:** The unit is "one" or "each" regardless of whether the packet is labeled with the weight or not. For example, if 10 packets of Questran are dispensed, the quantity is 10.

6. **Disposable enemas:** If the individual enema is labeled by volume, the unit is "ml" and the quantity dispensed is the number of milliliters in the enema container. If the individual enema is not labeled by volume, the unit is "one" or "each" and the quantity is 1 for each enema.

7. **Aerosols, jellies, and gels**: If the product is labeled in weight, the unit is "gram." For example, if an aerosol is dispensed as 16.8 grams, the quantity is 16.8. Similarly, if the product is labeled in volume, the unit is "ml." If the product is not labeled by weight or volume, the unit is "one" or "each".

8. **Reconstituted non-injectable liquid dosage forms:** For antibiotic oral suspensions, eye drops, and other non-injectable forms that require reconstitution prior to dispensing and that are labeled by volume, the unit is "ml." For example, if a 150 ml Amoxicillin Oral Suspension is dispensed, the quantity is 150.

9. **Granulex Spray:** The unit is "ml." For example, if a 4 ounce can is dispensed, the quantity is 120.

10. **Combination packages:** For drug products that contain more than one drug in separate dosage forms and that are packaged and dispensed in an "unbreakable" container, the unit is "one" or "each."

11. **Metric package sizes:** The quantity or total number of units is always the actual metric package size as supplied by the manufacturer/distributor. If the actual metric package is unavailable, the following conversions are used:

    1 fluid ounce = 30 ml
    1 pint = 480 ml
    1 ounce = 30 gm
    1 pound = 454 gm

Attachment H: Summary of Point-of-Sale Codes and Other Information for Current Claim Format

1. Use of PA Code field (**NCPDP D.0**):

    "1" -PA Code   USED TO OVERRIDE THE MEDICARE EDIT*

    "4" -PA Code   CO-PAY-EXEMPT

    "2" -Submission Clarification Code   SUPPLY-OVERRIDE

2. Use **NCPDP D.0** Beneficiary Residence location values instead of unique NC values:

Type of Facility	NCPDP Location
Not Specified	0
Home	1
Skilled Nursing Facility	2
Nursing Facility	3
Assisted Living Facility	4
Custodial Care Facility	5
Group Home	6
ICF/Mental Retardation	9
Hospice	11
Correctional Institution	15
Adult Care Home	

3. Dispense as Written Codes Currently Available

    The following DAW codes are currently accepted on Medicaid and NCHC claims:

DAW 0	No product selection indicated
DAW 1	Substitution not allowed by Prescriber. Prescriber indicated brand is "Medically Necessary"
DAW 2	Substitution allowed. Patient requested product dispensed.
DAW 3	Substitution allowed. Pharmacist selected product dispensed.
DAW 4	Substitution allowed. Generic drug not in stock.
DAW 5	Substitution allowed. Brand drug dispensed as a generic.
DAW 6	Override.
DAW 7	Substitution not allowed. Brand drug mandated by law (can be used for NTI drugs)
DAW 8	Substitution allowed. Generic drug not available in Marketplace
DAW 9	Substitution allowed by prescriber but Plan requests brand- Patient's Plan requested brand product to be dispensed.

4. Use of Prescription Origin Code in **NCPDP** field 419-DJ:

1	Written
2	Telephone
3	Electronic
4	Facsimile
5	Pharmacy

    Note: Zero and null values are not accepted.

5. Valid Values for Other Coverage Code

00=Not Specified

01=No Other Coverage Identified

02=Other Coverage Exists-Payment Collected

03=Other Coverage Exists-This Claim Not Covered

04=Other Coverage Exists-Payment Not Collected

6. Valid Values for Submission Clarification Code

02=Other Override (Supply Override) and PA/Non-Preferred Drug Override

03=Vacation Supply

04=Lost Prescription

05=Therapy Change

Submit Usual and Customary in addition to Gross Amount

Attachment I: Pharmacy Remittance Advice (RA)

1. Retain all RAs to assist in keeping claims and payment records current.
2. The last RA the provider receives each year serves as the annual 1099 form.
3. Refer to the RA first if questions arise about a particular claim.
4. If the RA cannot resolve questions on claims payment, please correspond with CSC using the following procedures:
   a. Call CSC at 1-800-686-6696
5. The RA is also a status report. It gives the current status of active claims. If a submitted claim does not appear by the third RA, please inquire about it using the following procedure:
   a. Go to the NCTracks portal at www.nctracks.nc.gov to view the claim
   b. Call the AVR system.
   c. Call CSC at 1-800-686-6696

Attachment J: ICD-10-CM Codes to Indicate Pregnancy

ICD-10-CM					
O09.00	O09.293	O09.521	O09.72	O09.90	Z34.02
O09.01	O09.299	O09.522	O09.73	O09.91	Z34.03
O09.02	O09.30	O09.523	O09.811	O09.92	Z34.80
O09.03	O09.31	O09.529	O09.812	O09.93	Z34.81
O09.10	O09.32	O09.611	O09.813	O36.80x0	Z34.82
O09.11	O09.33	O09.612	O09.819	O36.80x1	Z34.83
O09.12	O09.40	O09.613	O09.821	O36.80x2	Z34.90
O09.13	O09.41	O09.619	O09.822	O36.80x3	Z34.91
O09.211	O09.42	O09.621	O09.823	O36.80x4	Z34.92
O09.212	O09.43	O09.622	O09.829	O36.80x5	Z34.93
O09.213	O09.511	O09.623	O09.891	O36.80x9	
O09.219	O09.512	O09.629	O09.892	Z33.1	
O09.291	O09.513	O09.70	O09.893	Z34.00	
O09.292	O09.519	O09.71	O09.899	Z34.01	

Attachment K: Pharmacy Prior Approval Criteria

Below is a list of prescription drugs that require prior authorization (PA).
Refer to https://medicaid.ncdhhs.gov/ for the medical necessity criteria for coverage for each medication that requires prior approval.

Pharmacy Prior Approval Drugs and Criteria
- Agents for Duchenne Muscular Dystrophy
- Antifungal Agents - Vusion
- Antinarcolepsy/Antihyperkinesis Agents
- Cialis
- Crinone
- Cystic Fibrosis
- Emend
- Emflaza
- Entresto
- Epidiolex Initial PA Criteria
- Epinephrine Auto-Injections
- Evrysdi
- Gattex
- Gocovri and Osmolex ER
- Growth Hormones
- Hematinics (Procrit, Epogen, Aranesp, Mircera, Retacrit)
- Hepatitis C medications
- Hetlioz
- Immunomodulators
- Juxtapid
- Lupus Medications
- Migraine Therapy - Calcitonin Gene-Related Inhibitors
- Monoclonal Antibodies
- Movement Disorders
- Neuromuscular Blocking Agents (Botox, Myobloc, Dysport, Xeomin)
- Opioid Analgesics
- Opioid Dependence Therapy Agents
- PCSK9 Inhibitors
- Mu-Opioid Receptor Antagonists, Peripherally-Acting (Relistor)
- Sedative Hypnotics
- Synagis
- Therapeutic Continuous Glucose Monitoring Systems (CGM) and Related Supplies
- Topical Antihistamines
- Topical Anti-Inflammatories
- Topical Local Anesthetics
- Triptans
- Zolgensma
- Behavioral Health Clinical Edits Criteria - Pediatric
- Behavioral Health Clinical Edits Criteria - Adult