

27 Pharmacy

The Alabama Medicaid Agency pays for certain legend and non-legend drugs that meet both of the following criteria:

- Prescribed by medical doctors and other practitioners including, but not limited to, nurse practitioners, dentists, and optometrists who are legally authorized to prescribe these drugs and who are enrolled in the Alabama Medicaid program as a Medicaid provider or as an Ordering, Referring, or Prescribing Only provider (new PT 97)
- Dispensed and/or administered by a licensed pharmacist or licensed authorized physician in accordance with state and federal laws

The policy provisions for Pharmacy providers can be found in the *Alabama Medicaid Agency Administrative Code*, Chapter 16.

27.1 Enrollment

Gainwell enrolls Pharmacy providers and issues provider contracts to applicants who meet the licensure and/or certification requirements of the state of Alabama, the Code of Federal Regulations, the *Alabama Medicaid Agency Administrative Code*, and the *Alabama Medicaid Provider Manual*.

Federal requirements mandate providers re-validate periodically with the Alabama Medicaid program. Providers will be notified when they are scheduled to re-validate. Failure to re-validate and provide appropriate documentation to complete enrollment will result in an end-date being placed on the provider file. Once a provider file has been closed for failure to timely re-validate, providers will have to submit a new application for enrollment.

Refer to Chapter 2, Becoming a Medicaid Provider, for general enrollment instructions and information. Failure to provide accurate and truthful information or intentional misrepresentation might result in action ranging from denial of application to permanent exclusion.

National Provider Identifier, Type, and Specialty

A provider who contracts with Alabama Medicaid as a pharmacy provider is added to the Medicaid system with the National Provider Identifiers provided at the time application is made. Appropriate provider specialty codes are assigned to enable the provider to submit requests and receive reimbursements for pharmacy related claims.

NOTE:

The 10-digit NPI is required when filing a claim.

Pharmacy providers are assigned a provider type of 24 (Pharmacy). Valid specialties for Pharmacy providers include the following:

- Government Pharmacy 241
- Institutional Pharmacy 242
- Retail Pharmacy 240

Enrollment Policy for Pharmacy Providers

To participate in the Alabama Medicaid Program, Pharmacy providers must meet the following requirements:

- Operate under a permit or license to dispense drugs as issued by the Alabama State Board of Pharmacy or appropriate authority in the State where the service is rendered. Enrolled locations must follow Federal and State rules for dispensing drugs off site.
- Agree to abide by the rules and regulations of third party billing procedures. Refer to Section 3.3.6, Third Party Liability, for more information.

Maintain records, including prescriptions, to fully disclose the extent of services rendered. Pharmacies should maintain records, such as purchase invoices and recipient signature logs, within the state of Alabama. At a minimum, prescription files, recipient signature logs, and invoices must be available for examination.

- Agree that Medicaid or its designated representative may conduct audits of required records as necessary. Invoice records must be maintained and readily available for inspection.

Out-of-State Pharmacies

Under State and Federal regulations, a pharmacy must sign an agreement with Alabama Medicaid Agency. However, when a recipient is in another state and requires service, the following procedure has been adopted.

Pharmacies Bordering Alabama

- Pharmacies bordering Alabama may participate in the Alabama Medicaid Program by completing an application for out-of-state pharmacies, and upon certification of the State Board of Pharmacy in that state that the pharmacy is registered and has been issued a permit.
- The pharmacy must then sign a Pharmacy Vendor Agreement with Alabama Medicaid Agency and agree to abide by the State pharmacy provider tax law.
- Pharmacies bordering Alabama are defined as those pharmacies located not more than 30 miles from the border of Alabama.

Pharmacies Not Bordering Alabama

- Drugs dispensed must be in concurrence with the limitations in place for in-state providers.
- Reimbursement will be made only for hemophilia factor products and specialty drugs which are not readily available in-state, and drugs dispensed to Medicaid recipients who may be traveling outside the state of Alabama.
- Providers of specialty drugs shall list the names of the drugs for which they intend to request reimbursement as well as the GCN or NDC numbers for each drug in the letter requesting enrollment with the Alabama Medicaid Agency.
- Pharmacies not bordering Alabama will be enrolled by the Medicaid fiscal agent on a temporary basis.
- Pharmacies not bordering Alabama are defined as those pharmacies located more than 30 miles from the border of Alabama.

Change of Ownership (CHOW) and Closures

Medicaid will mirror Medicare's Change of Ownership (CHOW) policy. Refer to Chapter 19, Hospital for additional information on Change of Ownership.

Part B Claims and DME Through a Pharmacy

Medicare covers certain prescription drugs under Part B with J codes (HCPC Codes) instead of NDC codes. Medicaid will allow these claims to be billed secondary to Medicare effective January 1, 2006. Examples of these drugs include hemophilia clotting factors, some immunosuppressive drugs for transplant patients (if the transplant was paid for by Medicare), some oral cancer drugs, erythropoietin analogs if the patient has End Stage Renal Disease, some injectable osteoporosis drugs, and some antigens if they are administered under doctor supervision. For more information on this issue, please visit the CMS website. A pharmacy must enroll as a DME provider to bill these services.

If the Alabama Medicaid pharmacy provider does not already have a provider number (ie enrolled as a DME provider) for filing Part B crossover claims, then the pharmacy provider will need to complete a separate provider enrollment application under a DME NPI in order to be allowed to bill for these services secondary to Medicare. Medicaid allows payment up to our allowed amount. Providers will be issued an additional pharmacy provider number, which will be used for filing secondary claims only. Once a provider number is received, Part B claims should crossover automatically to Medicaid from Medicare. However, if the Part B crossover claim did not crossover automatically, then the Part B crossover claim should be filed on a Medicaid/Medicare related claim form, or electronically through Provider Electronic Solutions software. Claim forms and software can be ordered by calling Provider Assistance at 1-800-688-7989.

In addition, a pharmacy may bill DME items (such as diabetic supplies, infusion supplies, etc.) through a 'medical' claim using HCPC Codes instead of NDC codes. A pharmacy must enroll as a DME provider to bill these services. Please see Chapter 14 of this manual for more

information on DME enrollment. The Enrollment application can be found on the Medicaid website.

27.2 Benefits and Limitations

This section describes program-specific benefits and limitations. Refer to Chapter 3, Verifying Recipient Eligibility, for general benefit information and limitations. Refer to Chapter 7, Understanding Your Rights and Responsibilities as a Provider for general criteria on Medical Necessity/ Medically Necessary Care.

Medicaid pays for approved drug items when they are properly prescribed for eligible Medicaid recipients and dispensed in accordance with the *Alabama Medicaid Agency Administrative Code*, Chapter 16.

The number of outpatient pharmacy prescriptions for all recipients except as specified below is limited to four brand name drugs/ five total drugs per month per recipient. In no case can total prescriptions exceed ten per month per recipient. Prescriptions for Medicaid eligible recipients under age 21 in the Child Health Services/Early and Periodic Screening, Diagnosis and Treatment (EPSDT) Program and prescriptions for Medicaid eligible nursing facility residents are excluded from these limitations.

Anti-psychotic, anti-retroviral and anti-epileptic agents may be paid up to ten prescriptions per month but in no case can total prescriptions exceed ten per month per recipient.

Coverage of up to ten brand name prescriptions per month may be allowed through overrides for drugs classified by American Hospital Formulary Services (AHFS) or First Data Bank (FDB) Therapeutic Class as Antineoplastic Agents, Antiarrhythmic Agents, Cardiotonic Agents, Miscellaneous Vasodilating Agents, Miscellaneous Cardiac Agents, Nitrates and Nitrites, Alpha Adrenergic Blocking Agents, -Beta Adrenergic Blocking Agents, Dihydropyridines, Miscellaneous Calcium Channel Blocking Agents, Diuretics, Angiotensin-Converting Enzyme Inhibitors, Angiotensin II Receptor Antagonists, Mineralocorticoid (Aldosterone) Receptor Antagonists, Central Alpha Agonists, Direct Vasodilators, Peripheral Adrenergic Inhibitors, Miscellaneous Hypotensive Agents, Hemostatics, Calcium Replacements, Electrolyte Depleters, Immunosuppressives, Alpha Glucosidase Inhibitors, Amylinomimetics, Biguanides, Dipeptidyl Peptidase-4 Inhibitors, Incretin Mimetics, Insulins, Meglitinides, Sulfonylureas, Thiazolidinediones and Miscellaneous Diabetic Agents. Overrides will be granted only in cases in which the prescribing physician documents medical necessity for the recipient to be switched from a product in one of the above named classes to a brand name product within the same therapeutic class in the same calendar month. The first product must have been covered by Medicaid.

Medicaid will not compensate pharmacy providers for:

- DESI and IRS drugs which may be restricted in accordance with Section 1927(d)(2) of the Social Security Act
- Agents when used for anorexia, weight loss, or weight gain except for those specified by the Alabama Medicaid Agency

- Agents when used to promote fertility except for those specified by the Alabama Medicaid Agency
- Agents when used for cosmetic purposes or hair growth except for those specified by the Alabama Medicaid Agency
- Agents when used for the symptomatic relief of cough and cold except for those specified by the Alabama Medicaid Agency
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations and others as specified by the Alabama Medicaid Agency
- Nonprescription drugs except for those specified by the Alabama Medicaid Agency
- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee
- Agents when used for the treatment of sexual or erectile dysfunction unless prior approved through medical necessity.

Refer to the *Alabama Medicaid Agency Administrative Code*, Chapter 16 for drugs not covered by Alabama Medicaid.

Unit Dosing in Nursing Facilities

Covered drug items may be dispensed to recipients, using an approved unit dose system for solid oral forms of the prescribed drug. Only one claim per drug per recipient may be submitted each month by any pharmacy using an approved unit dose system. Only the amount of the prescribed drug actually consumed by the patient may be billed.

Each dose of a drug dispensed using an approved unit dose system must be individually packaged in a sealed, tamper proof container and carry full disclosure labeling, including, but not limited to, product name and strength, manufacturer's or distributor's name, lot number and expiration date.

Prescriptions for controlled drugs must be filled or dispensed from a signed original or direct copy of the physician's prescription order.

27.2.1 Prescription Requirements

Medicaid reimburses for prescriptions documented and dated appropriately for legend and over-the-counter drugs covered by Medicaid.

Schedule II drug prescriptions require the manual signature of the prescribing physician before dispensing. Stamped or typewritten signatures are not acceptable. In accordance with the Code of Federal Regulations, § 1306.05, all prescriptions for schedule II substances shall be dated and signed by the prescribing physician the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name and address and registration number of the practitioner.

Prescriptions dispensed by telephone for drugs other than Schedule II drugs are acceptable without subsequent signature of the practitioner.

Pharmacy providers should document any changes to the original prescription, such as physician approved changes in dosage, on the original prescription.

The pharmacy may refuse to accept Medicaid reimbursement for a Medicaid-covered item and bill the recipient as a regular paying patron if the provider informs the recipient prior to dispensing the prescription. The recipient has the right to have the prescription filled by any other authorized Medicaid pharmacy.

Effective April 1, 2008, all prescriptions for outpatient drugs for Medicaid recipients which are executed in written (and non-electronic) form must be executed on tamper-resistant prescription pads. The term "written prescription" does not include e-prescriptions transmitted to the pharmacy, prescriptions faxed to the pharmacy, or prescriptions communicated to the pharmacy by telephone by a prescriber. This requirement does not apply to refills of written prescriptions which were executed before April 1, 2008. It also does not apply to drugs provided in nursing facilities, intermediate care facilities for the mentally retarded, and other institutional and clinical settings to the extent the drugs are reimbursed as part of a per diem amount or where the order for a drug is written into the medical record and the order is given directly to the pharmacy by the facility medical staff.

- If a written prescription is received which is not on a tamper-resistant prescription blank, the pharmacy must contact the prescribing provider and either have the prescription re-submitted in compliant written form or convert the prescription, where otherwise allowable, into verbal, faxed or electronic form.
- In an emergency situation where the pharmacy is unable to contact the prescribing provider, the pharmacy may choose to fill the prescription from the non-compliant form and subsequently obtain a prescription in compliant form. If a compliant prescription cannot be obtained within 72 hours, the pharmacy must withdraw the claim.
- To be considered tamper-resistant on or after April 1, 2008, a prescription pad must contain at least one of the following three characteristics:
 1. one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form; or
 2. one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; or
 3. one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.
- To be considered tamper-resistant on or after October 1, 2008, a prescription pad must contain all of the foregoing three characteristics.

Effective May 1, 2008, an override will be required for a brand name drug with an exact generic equivalent submitted with a Dispense as Written code of 1. In this case, the provider must provide documentation of the medical necessity for the brand name, rather than the available generic equivalent and receive an override. This override applies to those instances where the prescriber has written a prescription for a brand name drug when a pharmaceutically and therapeutically equivalent drug product is available generically. Exclusions to this process include carbamazepine, levothyroxine, phenytoin, and warfarin. Overrides may be completed and faxed or mailed to the Pharmacy Administrative Services contractor, currently Keystone Peer Review Organization, Inc. (Kepro).

In accordance with Section 5042 of the SUPPORT Act, effective October 1, 2021, prescribers of Medicaid eligible recipients are required to check the Alabama PDMP (Prescription Drug Monitoring Program) prior to prescribing a Schedule II controlled substance. If the prescriber does not check the PDMP, the prescriber is required to document the reason in the medical record. Exclusions to this requirement include prescriptions written for hospice patients, patients with an active cancer diagnosis, residents of a long-term care nursing facility, and children under the age of 18 (Schedule II prescriptions for ADHD only).

27.2.2 Appropriate Utilization of Dispense As Written (DAW) Codes

Dispense As Written (DAW) product selection codes are an integral part of accurate billing to the Alabama Medicaid Agency and provide the agency with the reason why a specific brand or generic is dispensed based on the prescriber's instructions. Failure to accurately use DAW codes results in misinformation to the Pharmacy program and its decision making process. Misinformation on claims may also result in retrospective pharmacy review and/or recoupment. Inaccurate usage of DAW codes is among one of the discrepancies found during an audit and is one of the Primary Pharmacy Audit Components listed in the Provider Billing Manual Section 27.2.5. The following codes are the various DAW codes available to the Alabama Medicaid Pharmacy program with explanations that have been taken from the National Council on Prescription Drug Programs (NCPDP) version 5.1 data dictionary for field 408-D8 Product Selection Codes. Providers should utilize the correct codes based upon the information submitted on the prescription and the prescriber's signature:

- **0=No Product Selection Indicated**-This is the field default value that is appropriately used for prescriptions where product selection is not an issue. Examples include prescriptions written for single source brand products and prescriptions written using the generic name and a generic product is dispensed.
- **1=Substitution Not Allowed by Prescriber**-This value is used when the prescriber indicates, in a manner specified by prevailing law, that the product is to be Dispensed As Written.

- **2=Substitution Allowed-Patient Requested Product Dispensed**-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the patient requests the brand product. This situation can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources. *(Not permitted by Alabama Medicaid)*
- **3=Substitution Allowed-Pharmacist Selected Product Dispensed**-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the pharmacist determines that the brand product should be dispensed. This can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources.
- **4=Substitution Allowed-Generic Drug Not in Stock**-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the brand product is dispensed since a currently marketed generic is not stocked in the pharmacy. This situation exists due to the buying habits of the pharmacist, not because of the unavailability of the generic product in the marketplace.
- **5=Substitution Allowed-Brand Drug Dispensed as a Generic**- This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the pharmacist is utilizing the brand product as the generic entity.
- **6=Override** *(Not permitted by Alabama Medicaid)*
- **7=Substitution Not Allowed-Brand Drug Mandated by Law**- This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted but prevailing law or regulation prohibits the substitution of a brand product even though generic versions of the product may be available in the marketplace.
- **8=Substitution Allowed-Generic Drug Not Available in Marketplace**-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the brand product is dispensed since the generic is not currently manufactured, distributed, or is temporarily unavailable. *(In the event of an audit, provider shall make available documentation to validate product unavailability).*
- **9=Substitution Allowed- Plan Requests Brand Dispensed –** This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted,

but the plan's formulary requests the brand product to be dispensed.

To indicate instructions to the dispensing pharmacy, a physician simply signs the prescription in a manner specified by prevailing law to indicate to a providing pharmacy whether or not generic substitution is allowed. Effective May 1, 2008 an override form and Medwatch 3500 form is required in order to medically justify a provider's reason for requesting a branded product when an exact generic equivalent is available. DAW overrides and the Medwatch 3500 form should be submitted to the Pharmacy Prior Authorization contractor.

27.2.3 Quantity Limitations

Claims must be submitted in the units specified on the prescription by the prescribing physician up to a 34 day supply. Medications supplied in a dosage form that would prevent the dispensing of an exact 30-34 day supply for chronic medications, such as insulin, may require quantities that exceed the 34 day maximum and would not be subject to recoupment as long as the pharmacist can provide appropriate documentation.

Pharmacies may not split a prescription into small units and submit them as separate claims in order to obtain additional dispensing fees.

A pharmacist should not change quantities (units) of drugs prescribed by a physician except by authorization of the physician. The pharmacist must contact the prescribing physician for authorization to reduce the quantity of any Medicaid prescription and note physician authorization on the prescription form.

If the prescription to be paid by Medicaid exceeds the drug's maximum unit limit allowed per month, the prescriber or pharmacist must request an override for the prescribed quantity. If the override is denied, then the excess quantity above the maximum unit limit is non-covered and the recipient can be charged as a cash recipient for that amount in excess of the maximum unit limit. In other words, for a prescription to be "split billed" (the maximum unit allowed paid by Medicaid and the remainder paid by the patient), a maximum unit override must be requested by the provider and denied. A prescriber should not write separate prescriptions, one to be paid by Medicaid and one to be paid as cash, to circumvent the override process.

NOTE:

A provider's failure or unwillingness to go through the process of obtaining an override does not constitute a non-covered service.

If the full quantity prescribed is not available at the time of dispensing, the pharmacist may dispense the quantity available. In this case the pharmacist must note on the prescription the number of units dispensed and retain the claim until the balance of medication is dispensed. Only one claim with one dispensing fee may be billed.

Long Term Maintenance Supply

Effective October 1, 2013, the Alabama Medicaid Agency reimburses for a three month supply of Agency designated maintenance medications

dispensed to recipients. A maintenance medication is an ordered/prescribed medication generally used to treat chronic conditions or illnesses and taken regularly and continuously. The following criteria apply to the three month supply:

- The medications will be designated by the Agency
- The three month supply medications listing(s) will be available to the public on the State's website: www.medicaid.alabama.gov
- The recipient must demonstrate 60 consecutive days of stable therapy (same strength and dose) within a 90 day timeframe, according to Medicaid claims data, prior to the State reimbursing the provider for dispensing a three month supply. This means the patient must have shown to be compliant/stable on the medication according to Medicaid claims data.
- An opt out program for recipients who may not be candidates for maintenance supplies will be available. The recipient's prescribing physician will need to provide documentation regarding the opt out reasons for each applicable recipient.
- Effective May 1, 2014, drugs on Medicaid's three month maintenance medication list will be excluded from the monthly five prescription limit of adults. This exclusion is regardless of whether the claim is for a three month supply or one month supply (during the first 60 days to establish stable therapy).
- The three month supply medications require that 90% of the medication be exhausted before they can be refilled.

NOTE:

If the drug to be dispensed is included in the Agency's three month supply program, a pharmacist may shift a patient to a three month supply of prescribed drug using the existing prescription, pending enough units are remaining on the prescription authorized by the physician. Pharmacists may not add total units to a prescription unless authorized by the prescriber and documented in the patient file.

Short Acting Opioid Naïve Limits

Effective November 1, 2018, the Alabama Medicaid Agency began implementing limits on short-acting opiates for opioid naïve recipients. The Agency defines "opioid naïve" as a recipient with no opioid claim in the past 180 days.

Edit Details:

- A 7-day supply limit for adults age 19 and older
- A 5-day supply limit for children age 18 and younger
- A maximum of 50 morphine milligram equivalents (MME) per day allowed on a claim for an opioid naïve recipient
- Any claim for a short acting opioid for an opioid naïve recipient exceeding the maximum days' supply limit or MME limit will be denied.

- Claims prescribed by oncologists will bypass the edit.
- Long term care and hospice recipients are excluded.
- Refills of remaining quantities and/or new prescriptions filled within 180 days of the initial opioid naive claim **will require an override.**
- Refills of remaining quantities of prescriptions that are partially-filled will be allowed per State and federal law* but will require an override through Medicaid. See below for more details from the State Board of Pharmacy.
- For adults, the refill of the quantity remaining on the partial fill **will not count** towards the prescription limit if filled within 30 days of the original prescription. Monthly maximum unit quantities still apply.
- Overrides for quantities exceeding the maximum days' supply limit or MME limit may be submitted to Keystone Peer Review Organization, Inc. (Kepro). Please see the Pharmacy Override External Criteria Booklet for information about override requirements. Please refer to the following link for more information regarding overrides for opioid naïve patients: http://medicaid.alabama.gov/alert_detail.aspx?ID=12978
- A Recipient Information Sheet for prescribers and pharmacists to provide to recipients can be found at http://www.medicaid.alabama.gov/content/4.0_Programs/4.3_Pharmacy-DME.aspx

NOTE:

A recipient may not pay cash for the remaining amount over 7 days for the same prescription of a Medicaid-paid opioid claim (ie a single fill/dispense/claim may not be 'split billed' to both Medicaid and cash). If the prescription to be paid by Medicaid exceeds the drug's limit allowed, an override may be requested. Only if the override is denied, then the excess quantity above the maximum unit limit is deemed a non-covered service, and the recipient can be charged as a cash recipient for that amount *in excess* of the limit. A prescriber must not write separate prescriptions, one to be paid by Medicaid and one to be paid as cash, to circumvent the override process. FAILURE TO ABIDE BY MEDICAID POLICY MAY RESULT IN RECOUPMENTS AND/OR ADMINISTRATIVE SANCTIONS.

27.2.4 Prescription Refill

Prescriptions cannot exceed eleven refills for non-controlled prescriptions and five refills for Control III-V prescriptions. Medicaid will deny claims for prescription refills exceeding eleven for non-controlled prescriptions and five for Control III-V prescriptions. Prescriptions may be refilled only with the prescribing provider's authorization. Failure of the prescribing provider to designate refills on a prescription will be interpreted as no refills authorized. If a prescription is refilled, the date the prescription is refilled must appear on the prescription.

Pharmacy providers should refill all prescriptions only in quantities corresponding to dosage schedule and refill instructions.

The use of automatic refills by pharmacies is not allowed by the Medicaid Agency. Prescriptions that have been filled but not picked up by the patient or patient's authorized representative should be credited back to pharmacy stock and Medicaid through claims reversal within sixty days.

Violations of these policies may result in unauthorized charges. The pharmacy may be held liable or Medicaid may cancel the pharmacy vendor agreement.

Early/Timely Refills

Medicaid allows timely refills, defined as utilization of 85% of opioid agonist and opioid partial agonist claims, 90% of drugs on the 3-month maintenance list, and 75% of all other medications. Timely refills are based on the days' supply on a pharmacy claim; day's supply is an integral part of a valid claim, and should represent the actual days' supply of a claim based on the prescriber's instructions and quantity of drug dispensed. Claims processed prior to the timely refill allowance will require an override.

Medicaid utilizes an accumulation edit to limit dispensing of early refills to no more than seven extra days' worth of medication per 120 rolling days. Claims that exceed or result in the accumulation of more than seven extra days' worth of medication in a 120 - day time period will deny.

NOTE:

Medicaid may recoup payments for early refills.

Keystone Peer Review Organization, Inc. (Kepro) is contracted with the Alabama Medicaid Agency to assist pharmacists receiving hard denials, such as early refills, therapeutic duplication and excessive quantity. Pharmacies must receive an override from Kepro before payment will be made. **Contact Kepro at 1 (800) 748-0130.** Only Kepro can issue the necessary override.

NOTE:

HOLDING OF MEDICATIONS FOR LTC RESIDENTS

When a resident leaves a LTF facility and is expected to return, the facility shall hold all medications until the return of the resident. All continued or re-ordered medications will be placed in active medication cycles upon the return of the resident. If the resident does not return to the facility within 30 days, any medications held by the facility shall be placed with other medications for destruction or distribution as permitted by the State Board of Pharmacy regulations. If at the time of discharge it is known that the patient will not return, medications may be destroyed or donated as allowed by State law.

If the medications are not held in accordance with this policy, the facility will be responsible for all costs associated with replacement of the medication.

27.2.5 Reimbursement for Covered Drugs and Services

This section describes reimbursement for multiple source drugs, over-the-counter medications and other drugs, dispensing fees, vaccine administration and pricing.

Medicaid pays for certain legend and non-legend drugs prescribed by practitioners legally licensed by the state of Alabama to prescribe the drugs authorized under the program and dispensed and/or administered by a licensed pharmacist or licensed authorized physician in accordance with state and federal laws as stated in Administrative Code Rule 560-X-16-.01.

A. Notwithstanding specific reimbursement described in this section, payment for covered outpatient drugs (both brand and generic) dispensed by a:

1. Retail community pharmacy
2. Specialty pharmacy
3. Long-term care or institutional pharmacy (when not included as an inpatient stay)
4. 340B eligible entities (including 340B contract pharmacies) not listed on the U.S. Department of Health and Human Services Health Resources & Service Administration (HRSA) 340B Drug Pricing Program Database
5. Indian Health Service, Tribal and Urban Indian pharmacy

Shall not exceed the lowest of:

- a. Effective January 1, 2021, The Alabama Average Acquisition Cost (AAC) of the drug; when no AAC is available, the Wholesale Acquisition Cost (WAC)-4% for brand drugs and WAC + 0% for generic drugs, plus a professional dispensing fee of \$10.64,
 - b. The Federal Upper Limit (FUL), plus a professional dispensing fee of \$10.64, or
 - c. The provider's Usual and Customary (U&C) charge to the general public regardless of program fees.
- B. Payment for blood clotting factor products will be the Average Sales Price (ASP) + 6% plus a professional dispensing fee of \$10.64.
- C. For eligible 340B entities listed on the U.S. Department of Health and Human Services Health Resources & Service Administration (HRSA) 340B Drug Pricing Program Database, payment shall not exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with the Veterans Health Care Act of 1992, plus a professional dispensing fee of \$10.64.
- D. For facilities purchasing drugs through the Federal Supply Schedule (FSS), payment shall not exceed the entity's actual acquisition cost for the drug, plus a professional dispensing fee of \$10.64.
- E. For facilities purchasing drugs at Nominal Price, payment shall not exceed the entity's actual acquisition cost for the drug, plus a professional dispensing fee of \$10.64.
- F. Physician Administered Drugs (PADs) are reimbursed at a rate of ASP+ 6%. For PADs that do not have a published ASP, the reimbursement is

calculated based on published compendia pricing such as Wholesale Acquisition Cost (WAC). For PADs administered by 340 entities, payment shall not exceed the entity's actual acquisition cost for the drug.

G. Investigational drugs not approved by the FDA are not covered.

Prescription Compounding

Alabama Medicaid pays for prescription drugs through the billing of NDCs. Pharmacists may dispense compounded medications when prescribed and must bill for each ingredient with a valid NDC on a single claim. Bulk products (i.e. powders) used for compounded medications are non-covered for adults (aged 21 and older). Some exclusions may apply. Bulk products must be submitted as a compound claim. Bulk products submitted on a pharmacy claim will deny.

The finished compound must not be available as a legend or over-the-counter product in an equivalent dosage form/route of administration. Compound products are subject to review, must meet medical criteria and may require peer-reviewed medical literature before being covered.

The maximum payable amount for a compounding product is \$200 per claim. Requests for overrides for compounded products that exceed \$200 should be referred to Kepro at 1 (800) 748-0130.

Other Drugs

Reimbursement for covered drugs other than multiple source drugs will not exceed the lower of the Alabama Estimated Acquisition Cost (AEAC) for the drug plus a reasonable dispensing fee, OR the provider's Usual and Customary Charge to the general public for the drug. For blood clotting factor products, Medicare Part B Drug pricing plus a reasonable dispensing fee is utilized.

Dispensing Fees

A reasonable dispensing fee is set by the Agency. The fee is reviewed periodically for reasonableness and, when deemed appropriate by Medicaid, may be adjusted. The dispensing fee paid by the agency effective September 22, 2010 is \$10.64.

Only one dispensing fee is allowed for a 34 day supply of the same drug per month unless the recipient qualifies for an "early refill". To qualify for an "early refill", the recipient must have used 75% of the original supply or there is a documented consultation with the prescribing physician authorizing the refill.

Over-the-Counter Medications (OTCs)

Medicaid pays for certain OTCs through the Medicaid pharmacy program. OTCs dispensed to an eligible Medicaid recipient may be submitted for payment by utilizing the appropriate NDC number.

Over-the-counter medications require a prescription from a physician or other practitioner legally licensed by the State of Alabama to prescribe the drugs authorized under the program. Telephone prescriptions are acceptable for OTCs.

Long term care facilities may bill OTC insulins covered by the Medicaid pharmacy program by submitting for payment the NDC number utilized. All other OTCs should be billed by the nursing facility using the facility cost report.

Do not dispense more medication than indicated on the prescription unless authorized by the prescribing physician to do so.

Medicaid will reimburse for covered OTCs as stated under Multiple Source Drugs.

Non-Drug Items

Alabama Medicaid Agency reimburses for certain non-drug items, including but not limited to spacers, syringes, and tablet splitters, through the pharmacy program with a valid prescription and NDC number. Other supplies such as blood glucose testing strips and lancets may be billed through Durable Medical Equipment. Please refer to chapter 14.2 for complete information.

Vaccine Administration

Alabama Medicaid will reimburse Medicaid-enrolled pharmacy providers for the administration of all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) for ages 19 and older. A list of ACIP recommended vaccines can be located on the CDC website under the vaccine page.

Claims for a vaccine and the administration of the vaccine will be submitted on the same claim. Pharmacy providers should submit a claim for the vaccine (i.e. ingredient) with the appropriate NDC along with the administration fee in the Incentive Amount Submitted field (NCPDP Field 438-E3) on the same claim as the vaccine being administered.

A maximum reimbursement of \$5 is allowed for each vaccine administration (current exception of \$40 administration for COVID vaccine). Only one dispensing fee (for the ingredient) and copay (if applicable) will be applied to the claim. There is a maximum quantity for each vaccine administered of 1 injection per recipient within a timeframe in accordance with the CDC dosing regimen.

A prescription or standing order is required for each vaccine administered and should be retained on file for documentation purposes.

To facilitate coordination of care, Pharmacy providers are required to inform (via phone, fax, email, or mail) each recipient's PMP upon administration of any vaccines for which an administration claim is submitted. Documentation must be kept on file at the pharmacy of the notification to the PMP. If the PMP is unknown, the pharmacy may call the Alabama Medicaid Automated Voice Response System (AVRS) at 1-800-727-7848 to obtain the PMP information. Pharmacy providers may also notify the recipient's local Alabama Coordinated Health Network (ACHN) region to assist with finding a PMP; ACHN contact information can be located on the Agency website under Contacts/ACHN Contacts. A suggested Immunization Provider Notification Letter, which can be used to notify the PMP, can be found on the Agency website under Pharmacy/Vaccines.

Alabama State Board of Pharmacy law and regulations should be followed regarding dispensing and administration of legend drugs/vaccines.

Total Parenteral Nutrition

Alabama Medicaid Agency may reimburse for total parenteral nutrition (TPN) through the pharmacy program if the order/prescription and recipient meets certain requirements. TPN solutions include those used for hyperalimentation, intradialytic parenteral nutrition (IDPN) and intraperitoneal nutrition (IPN). Please refer to chapters 35.2 and 28.2 for complete information.

TPN prescriptions/orders are written to provide a sufficient amount of medication necessary for the duration of the illness or an amount sufficient to cover the interval between physician's visits. TPN prescriptions/orders should be billed using a compound pharmacy claim based on a month's supply. It is Medicaid's policy that a prescription shall not be split into small units and submitted as separate claims in order to obtain additional dispensing fees.

340 B Pricing

The Veterans Health Care Act of 1992 enacted section 340 B of the Public Health Services Act, "Limitation on Prices of Drugs Purchased by Covered Entities". This Section provides that a manufacturer who sells covered outpatient drugs to eligible 340B entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge to Medicaid a price for covered outpatient drugs that will not exceed the average manufacturer price decreased by a rebate percentage.

Eligible entities are defined in 42 U.S.C. § 256b(a)(4).

When an eligible 340B entity other than a disproportionate share hospital, a children's hospital excluded from the Medicare prospective payment system, a free-standing cancer hospital exempt from the Medicare prospective payment system, sole community hospital, rural referral center, or critical access hospital submits a bill to the Medicaid Agency for a drug purchased by or on behalf of a Medicaid recipient, the amount billed shall not exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with the Veterans Health Care Act of 1992, plus the dispensing fee established by the Medicaid Agency.

A disproportionate share hospital, children's hospital excluded from the Medicare prospective payment system, free-standing cancer hospital exempt from the Medicare prospective payment system, sole community hospital, rural referral center, or critical access hospital may bill Medicaid the total charges for the drug. As manufacturer price changes occur, the entities must ensure that their billings are updated accordingly.

Eligible 340B entities are identified on the Department of Health and Human Service's website. These entities shall notify Medicaid of their designation as a 340B provider.

Audits of the eligible entities' (claims submissions and invoices) will be conducted by the Medicaid Agency. Eligible 340B entities, other than the providers listed above, must be able to verify acquisition costs through review of actual invoices for the time frame specified. Charges to Medicaid in excess of the actual invoice costs will be subject to recoupment by the Medicaid Agency in accordance with Chapter 33 of the Administrative Code.

27.2.6 Primary Pharmacy Audit Components

The following information serves as a general guide to the components of a Medicaid Pharmacy Audit. Although the list provided may not be all-inclusive, it covers most of the discrepancies found through on-site and desk review audits. Non-compliant prescriptions may result in recoupments. Questions regarding this information may be directed to Medicaid at (334) 353-4584.

- **Rx Hardcopy Requirements**
 - **Tamper Resistant Prescriptions** – Prescriptions for outpatient drugs for Medicaid recipients which are executed in written (and non-electronic) form must be executed on tamper-resistant prescription pads.
 - **Controlled Substance Prescriptions** – Medicaid follows all DEA and Alabama State Board of Pharmacy rules and regulations regarding controlled substance prescriptions. The prescribing physician must authorize all changes from the original prescription before dispensing, and any change must be documented on the prescription. Written controlled substance prescriptions require a manual signature by the practitioner.

- **Total Parenteral Nutrition (TPN) - TPN** prescriptions/orders include those used for hyperalimentation intradialytic parenteral nutrition (IDPN), and intraperitoneal nutrition (IPN). A certification statement of medical necessity must be written or stamped on the prescription/order, or accompany all TPN prescriptions/orders.

- **Claims Submission**
 - **Dispense As Written (DAW) Codes** - Use of DAW codes will be audited on a regular basis to ensure correct billing. For a detailed explanation of each DAW code, see Section 27.2.2 of the Provider Billing Manual.
 - **Emergency Prior Authorization (PA)** - The use of the emergency PA code is to be used only in cases of emergency. This code will be monitored, and recoupments will be initiated if the code is found to have been used inappropriately.

- **Other Coverage Code (OCC)** - Pharmacy providers should file a patient's primary insurance prior to filing Medicaid. Once the primary payer has responded, the patient's claim can be submitted to Medicaid. The use of OCC's will be monitored regularly. For detailed information on OCC's, see Section 27.5.6 of the Provider Billing manual.
 - **Timely Prescription Reversal** - If a patient or a patient's authorized representative has not picked up his/her prescription within sixty (60) days, the pharmacy is required to reverse the claim and credit Medicaid the amount originally billed.
 - **High Cost Claims** - High cost prescription claims will be reviewed on a regular basis. The NDC number of the product actually dispensed should be billed, and the days supply should be clinically appropriate according to prescription instructions. All aspects of the claims will be reviewed for accuracy.
 - **Inaccurate Billing** - Certain drug products are at increased risk for billing errors. Claims for these prescriptions will be reviewed on a regular basis. The NDC number of the product actually dispensed should be billed, and the days supply should be clinically appropriate according to prescription instructions. All aspects of the claim will be reviewed for accuracy.
 - **Usual & Customary (U&C)** - For specified products, submitted charge will be compared to cash price to general public. Adjustments may be initiated.
 - **Out of State Providers** - Claims submitted by out of state providers will be reviewed regularly to ensure the medication dispensed is in accordance with the provider's enrollment guidelines.
 - **Compound Prescriptions** - Claims for compounded prescriptions will be audited to ensure they follow all guidelines set forth in Chapter 27.2.4 in the Provider Billing Manual.
-
- **Multiple Dispensing Fees** - Providers must have documentation to include call-in and hard copy prescriptions to support the multiple dispensing of the same product to the same patient within an appropriate period of time.
 - **Recipient Signatures** - Recipient signatures are required for all pharmacy claims to validate the service was rendered to the recipient and to ensure the recipient was offered appropriate counseling. For pharmacy items that have been delivered, the signature of the recipient or his/her designee is required. Pharmacies should maintain recipient signature logs for examination.

Continued violations of Medicaid claims processing policies may result in recoupment and referral to the Alabama Attorney General's Office for investigation of fraud. Please visit CMS' Medicaid Program Integrity (MPIE) website at www.cms.gov. The site provides educational resources

for providers, beneficiaries, managed care plans (MCPs) and other stakeholders and promotes best practices and awareness of Medicaid fraud, waste and abuse.

27.2.7 Drug Utilization Review (DUR)

The objective of DUR is to improve the quality of pharmaceutical care by ensuring that prescriptions are appropriate, medically necessary, and unlikely to result in adverse medical outcomes.

This section contains information about the components of the DUR Program:

- General Information
- Prospective Drug Utilization Review (Pro DUR)
- Online Drug Utilization Review (Online DUR)
- National Council for Prescription Drug Programs (NCPDP) Standards
- Retrospective Drug Utilization Review (Retro DUR)

General Information

The DUR Program uses educational tools directed to physicians and pharmacists in order to reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care by addressing:

- Potential and actual drug reactions
- Therapeutic appropriateness
- Over-utilization
- Under-utilization
- Appropriate use of generic products
- Therapeutic duplication
- Drug/disease contraindications
- Drug interactions
- Incorrect drug dosage or duration
- Drug allergy interactions
- Clinical abuse/misuse

The DUR Program reviews, analyzes and interprets patterns of drug usage against standards consistent with the American Medical Association Drug Evaluations, United States Pharmacopoeia Drug Index, American Hospital Formulary Service Drug Index, and peer reviewed medical literature.

DUR will be conducted for drugs dispensed to residents of nursing facilities.

NOTE:

Pharmacists should refer cases of possible fraud or abuse to the Medicaid Program Integrity Division. Information may be provided through the Medicaid Agency's Fraud hotline by calling 1(866) 452-4930. Calls may be made anonymously.

Prospective DUR

Prospective DUR (Pro-DUR) is required at the point of sale or distribution before each prescription is filled or delivered to a Medicaid recipient. It must include screening, patient counseling, and use of patient profiles.

Pro-DUR screening is the responsibility of each Medicaid participating pharmacy and is a requirement for participation in the program.

Online DUR

Medicaid provides an online system to assist the dispensing pharmacist. Incoming drug claims are compared to the patient's medical and pharmacy claims history files to detect potential therapeutic problems. DUR alert messages are returned to the pharmacist for significant problems discovered by this review.

Potential problems identified include:

- Therapeutic duplication – Examples of therapeutic duplication, involving overlapping periods of time where such therapy is not medically indicated, include:
 - Two or more doses of the same drug
 - At least two drugs from the same therapeutic class
 - At least two drugs from different therapeutic classes with similar pharmacological effects being used for the same indication
- Drug/Disease contraindications
- Drug interactions
- Incorrect dosage or duration of drug treatment
- Drug allergy interactions
- Clinical abuse or misuse
- Preferred drug status

Medicaid distributes criteria and standards to providers in Medicaid Provider Notices and Bulletins.

Pharmacists must respond to prospective DUR alerts to continue claims processing through Gainwell.

Pharmacies without computers must screen based on guidelines provided by the Alabama State Board of Pharmacy Practice Act and criteria and standards endorsed by Medicaid's DUR Board.

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 the system generates a DUR alert. Displaying these fields to the pharmacist facilitates communication when health care providers discuss the potential therapeutic problems discovered by online prospective DUR.

This section explains DUR fields and information, lists standard response fields and codes, shows example DUR alert messages, and lists DUR alerts in order of priority.

Field Name	Information Displayed in the Field
Conflict Code	Alerts the pharmacist that the incoming drug claim conflicts with information in the patient's history file or with predetermined screening criteria ER = Early Refill TD = Therapeutic duplication DD = Drug Interaction EQ = Excessive Quantity
Clinical Significance/Severity Index Code	Indicates database-assigned significance of the conflict. 0 = Not applicable 1 = Major 2 = Moderate 3 = Minor
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
Previous Date of Fill	The last recorded date of the active medication in the patient's history file with which the incoming drug claim conflicts.
Quantity of Previous Fill	Quantity of previously filled prescription with which the incoming drug claim conflicts
Database Indicator	Identifies source of DUR conflict information 0 = Not applicable 1 = First DataBank. 4 = Processor Developed
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
Free Text Message	30-character field that transmits decoded information regarding the DUR conflict.

To respond to an alert, the pharmacist must enter the corresponding codes to describe the action taken on the alert in the response fields. For a claim that generates multiple alerts, the pharmacist's response indicates that each alert has been considered and the response should be applied to all alerts generated by this claim.

The pharmacist should respond to alerts with the appropriate conflict code. For example, enter TD for Therapeutic Duplicate in response to a therapeutic duplication alert.

Do not change any claim information such as the NDC code or Quantity unless you are indicating your change with the appropriate Outcome Codes listed in the table below. Changing claim information could cause your claim to deny online.

Response fields and codes are listed in the following table:

Response Field	Response Codes
Conflict Codes	HD – High Dose ER – Early Refill LR – Late Refill DD – Drug-Drug Interaction TD – Therapeutic Duplication PS – Product Selection
Intervention Codes	M0 – Prescriber consulted P0 – Patient consulted R0 – Pharmacist consulted other source
Outcome Codes	1A - Filled As Is, False Positive 1B - Filled Prescription As Is 1C - Filled, with Different Dose 1D - Filled, with Different Directions 1E - Filled, with Different Dose 1F - Filled, with Different Quantity 2A - Prescription Not Filled 2B - Not Filled, Directions Clarified

NOTE:

Intervention codes contain the number zero, not the letter O. Using the letter O will cause your claim to deny online.

Proprietary pharmacy software for prescription processing systems may display DUR alerts in different formats. Examples of standard content of DUR messages are presented below. These may differ from the message actually displayed on the pharmacist's computer screen.

Example DUR Alert Messages
<p>On April 2, 1998, the pharmacist attempts to dispense an aspirin-containing product to a patient currently receiving welfare in prescribed by the same physician and filled at another pharmacy:</p> <p>CONFLICT CODE: DD - DRUG INTERACTION SEVERITY: 1 = Major OTHER PHARMACY INDICATOR: 3 = Other Pharmacy PREVIOUS FILL DATE: 19980315 (March 15, 1998) QUANTITY OF PREVIOUS FILL: 30 DATABASE INDICATOR: 1 = First DataBank OTHER PRESCRIBER INDICATOR: 1 = Same Prescriber MESSAGE: Coumadin</p>
<p>On April 19, the pharmacist attempts to dispense a refill for which the previous prescription has greater than 25 percent of days supply remaining:</p> <p>CONFLICT CODE: ER - OVERUTILIZATON OTHER PHARMACY INDICATOR: 1 = Same Pharmacy PREVIOUS FILL DATE: 19980301 (March 1, 1998) QUANTITY OF PREVIOUS FILL: 90 OTHER PRESCRIBER INDICATOR: 1 = Same Prescriber</p>
<p>The pharmacist attempts to dispense a refill of levothyroxine on May 15, a date equal to greater than 125 percent of previous prescription's days supply:</p> <p>CONFLICT CODE: LR - UNDERUTILIZATION OTHER PHARMACY INDICATOR: 1 = Same Pharmacy PREVIOUS FILL DATE: 19980401 (April 1, 1998) QUANTITY OF PREVIOUS FILL: 30 OTHER PRESCRIBER INDICATOR: 1 = Same Prescriber</p>

Example DUR Alert Messages	
On May 12, the pharmacist attempts to dispense flurazepam to a patient with an active prescription for triazolam:	
CONFLICT CODE:	TD - THER. DUPLICATION
OTHER PHARMACY INDICATOR:	3 = Other Pharmacy
PREVIOUS FILL DATE:	19980501 (May 1, 1998)
QUANTITY OF PREVIOUS FILL:	30
DATABASE INDICATOR:	1 = First DataBank
OTHER PRESCRIBER INDICATOR:	2 = Other Prescriber
MESSAGE:	Triazolam
The pharmacist attempts to dispense acetaminophen w/codeine, three tablets every 4 hours (dose exceeds usual adult daily maximum):	
CONFLICT CODE:	HD - HIGH DOSE
DATABASE INDICATOR:	1 = First DataBank
The pharmacist attempts to dispense an NDC that is not a preferred drug.	
CONFLICT CODE:	PS - PRODUCT SELECT OPPORTUNITY
DATABASE INDICATOR:	4 = Processor Developed

The system displays up to three DUR alerts for a prescription. To access additional alerts pertaining to the prescription, the pharmacist may call the Gainwell Help Desk at 1(800) 456-1242.

Multiple alerts on a prescription are prioritized according to the following hierarchy:

1. Drug-drug interactions
2. Therapeutic duplication
3. Overutilization (early refill)
4. Incorrect dose (high dose)
5. Underutilization (late refill)
6. Preferred drug

Retrospective DUR

The retrospective DUR Program reviews, analyzes and interprets patterns of recipient drug usage through periodic examination of claims data to identify patterns of fraud and abuse, gross overuse, and inappropriate or medically unnecessary care.

27.3 Prior Authorization and Referral Requirements

Pharmacy providers must contact Keystone Peer Review Organization, Inc. (Kepro) at 1(800) 748-0130 for overrides and prior authorization of drugs requiring prior approval. Only Kepro can issue prior authorizations and overrides.

Kepro should respond within 24 hours of receipt of requests for prior authorization and overrides. In cases of emergency, Kepro will make provisions for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug.

Federal Law also makes a provision for a 72-hour supply by using the following authorization number: 0000999527. This number is to be used only in cases of emergency. Utilization of this code will be strictly monitored and recoupments will be initiated when the code is found to have been used inappropriately.

27.3.1 Hemophilia Management Standards of Care

In order to be paid for providing blood clotting factor to Alabama Medicaid recipients, the provider must agree to provide, at the minimum, the following clinically appropriate items and services to their patients with hemophilia and blood clotting factor-related diseases:

- (1) Home or office delivery of blood clotting factor and supplies. All shipments/delivery of clotting factor, including overnight deliveries, must use appropriate cold chain management and packaging practices to ensure proper temperature, drug stability, integrity, and efficacy are maintained during shipment.
- (2) Educational materials and programs.
 - (a) The provider shall develop a training library at each enrolled provider location with materials for patient use, to include but not limited to, audio, video, electronic, and written materials.
 - (b) The provider shall offer educational materials to patient or family/caregiver at minimum at initiation of participation with the provider, yearly during the in-home assessment, and upon the request of Medicaid, the prescribing physician, or patient or family/caregiver. Topics of education shall include, but not be limited to, specific patient and family/caregiver education aimed at preventing injury that would result in a bleed, self-administration and reconstitution of blood clotting products.
- (3) Medically necessary ancillary supplies required to perform the actual IV administration of clotting factor. Supplies may be billed to Medicaid through the Durable Medical Equipment (DME) program. In addition, sharps containers and any other necessary biohazardous waste containers shall be provided, as well as pickup and disposal of waste containers according to national, state and local biohazardous waste ordinances.
- (4) Emergency telephone support 24 hours a day, 7 days a week to ensure patients are directed appropriately for care in emergent situations.
- (5) For the purposes of this Rule and the Alabama Medicaid Agency hemophilia management standards of care, “clinical staff trained in hemophilia and related blood clotting factor related diseases” is defined as follows:
 - (a) Pharmacists are required to obtain a minimum of 2 Continuing Education (CE) credit hours per year that are specific to hemophilia or related blood clotting factor-related diseases.
 - (b) Nurses and social workers are required to obtain a minimum of 4 Continuing Education (CEU) hours per year that are specific to hemophilia or related blood clotting factor-related diseases.

Continuing education must be specific to hemophilia or related blood clotting factor-related diseases and recognized by a state or national hemophilia or bleeding disorder education/support group (for example: Hemophilia Federation of America or the National Hemophilia Association).

(6) Emergency delivery of blood clotting factor within 24 (with a target of less than 12) hours of the receipt of a prescription for a covered person's emergent situation, or notification of the patient with an existing valid prescription. Emphasis should be placed during patient education of the importance of keeping an adequate supply on hand and self-administration for emergent situations.

(7) A pharmacist, nurse, and/or a case representative assigned to each patient. A case representative shall maintain, at a minimum, monthly telephone contact with the patient or family/caregiver to include, but not limited to:

- Inquiry regarding patient's current state of well-being
- Assessment of patient/family compliance/adherence, and persistence with the medical treatment plan
- Incidence of adverse events
- Incidences of supply or equipment malfunctions
- Home inventory check of factor and supplies
- Confirmation of next delivery date

Case representatives may include administrative support staff but must coordinate with clinical staff (as described in (5) above) in the event a clinical issue should arise.

(8) Compliance programs.

(a) The provider must assess patient adherence on monthly telephone contact (see (7) above) and on all in-home visits by a pharmacist, nurse, or case manager.

(b) The provider must verify the amount of clotting factor the patient has on hand prior to each dispense. Blood clotting factor and related products are not to be sent to the patient on an auto-ship basis. The provider shall discourage "stockpiling" of product.

(c) The number of bleeds and infusions from the prior shipment shall be tracked to validate the need for additional product or non-compliance with the medical treatment plan.

(9) Notification of product recalls or withdrawals.

(a) Any stock of recalled medications/equipment/supplies shall be removed from stock and quarantined immediately.

(b) Any recalled items dispensed to patients shall be retrieved and quarantined; notification to patients must occur within 24 hours of the recall receipt.

(c) The prescribing physician shall be notified of a medication recall. A prescription for an alternative product shall be obtained, if necessary.

(10) Visiting clinical services.

(a) At minimum, an initial and subsequent yearly in-home assessment of the patient, family/caregiver, and environment shall be conducted by a nurse or pharmacist trained in blood clotting factor related diseases.

(b) Additional in-home assessments of the patient, family/caregiver, and environment deemed necessary by the physician or patient situation shall be conducted.

(c) Visits may be provided directly by the provider or by arrangement with a qualified local home health care agency. All hemophilia-related clinical staff must be trained in hemophilia and bleeding disorder related diseases.

(11) A registered pharmacist trained in blood clotting factor related diseases to perform assay to prescription management. Variance in assay to prescription/target dose should not exceed +/- 10%. Providers shall strive to dispense as close to the prescribed target dose within the assay variance as possible without breaking a new vial (i.e. do not dispense 'extra' vials, even if the 'extra' vials fall within the +/-10% variance). Extra vials dispensed within the +/-10% assay variance may be subject to recoupment. Pharmacists/pharmacy staff shall not change a Medicaid recipient's therapy based on the cost of the medication without prior written approval from the prescriber and noted in the patient chart.

(12) Adverse drug reaction and drug interaction monitoring and reporting.

(a) Pharmacists shall counsel the patient or family/caregiver in accordance with the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) to encourage appropriate medication use, promote realistic therapy expectations, help recipients manage or minimize expected adverse effects and encourage compliance.

(b) Pharmacists shall report any issues or concerns related to the patient's medications to the physician. For significant events, utilization of the FDA 3500 MedWatch voluntary reporting form is encouraged.

(13) Continuation of Care. The provider shall not present any bill to or collect any monies from a covered Medicaid recipient with whom the provider has agreed to the provision of services and supplies for the home treatment of bleeding episodes associated with hemophilia, except as follows:

(a) to collect the copayments/coinsurance amounts the covered person is required to pay under the terms defined by Medicaid, or

(b) if the service/product has been deemed "non-covered" and the recipient has been notified in advance as outlined in the Alabama Medicaid Agency Administrative Code and Provider Billing Manual.

Upon discontinuation of services by the provider, the provider shall, at a minimum, coordinate for another designated health care provider to provide services to covered persons, prior to withdrawal of any hemophilia-related services from the home of any covered person. The provider shall continue to provide services and supplies to a covered individual until the individual obtains an alternate source of services and supplies. Every effort shall be made by the provider (including notification to the Medicaid Director of Pharmacy) to find an alternative provider to

ensure that the coordination of care/transition follows the minimum standards of care as set forth in this document.

(14) The Alabama Medicaid Agency (or its designated representative), to ensure clinically appropriate services are being given to hemophilia patients, shall monitor providers of blood clotting factor by prospective and retrospective audits, as well as administer a patient/family/caregiver satisfaction survey to include, but not limited to, measurement of:

- (a) staff availability
- (b) staff knowledge
- (c) timeliness of deliveries
- (d) accuracy of supplies and equipment
- (e) overall satisfaction

If a provider does not meet one or more of the standards for care, as outlined in this Rule, the Alabama Medicaid Agency shall provide a written notice of that determination, with an explanation therefore, to the provider. The provider will not be reimbursed for blood clotting factor or hemophilia related services until the provider meets the standards as approved by the Agency.

27.4 Cost Sharing (Copayment)

Copayment amounts vary and are described in this section. **Copayments do not apply to services provided for pregnant women, long term care (nursing home) residents, emergencies, recipients under 18 years of age, or family planning.**

Copayments do not apply to Native American Indians that present an “active user letter” issued by Indian Health Services (IHS). The provider must enter a value of ‘4’ in the prior authorization type code field indicating co-pay exemption for a Native American Indian with an active user letter.

A provider may not deny services to any eligible Medicaid recipient because of the recipient’s inability to pay the cost sharing (copayment) amount imposed.

- If the physician has indicated on the prescription that the recipient is pregnant, enter “P” in the copay block.

NOTE:

Do not enter a dollar amount in the copay block.

The copayment schedule is based on the total charge amount (ingredient cost plus dispensing fee):

<i>Pharmacy Charge</i>	<i>Copay Amount</i>
\$10.00 or less	\$0.65
\$10.01 to \$25.00	\$1.30
\$25.01 to \$50.00	\$2.60
\$50.01 or more	\$3.90

NOTE:

Copayment amount should be collected on the original prescription as well as any refills.

Providers may use various resources to verify recipient eligibility:

- Provider Electronic Solutions software
- Software developed by the provider's billing service, using specifications provided by Gainwell
- Automated Voice Response System (AVRS) at 1(800) 727-7848
- Contacting the Gainwell Provider Assistance Center at 1(800) 688-7989

Appendix B, Electronic Media Claims Guidelines, provides an overview of the Gainwell Provider Electronic Solutions software, which providers may use to verify recipient eligibility and submit claims. Instructions for requesting the software are also included in this appendix.

Providers who use a billing service may be able to verify eligibility through the billing service's software, providing the service obtained a copy of the vendor specification. Please refer to Appendix B for contact information.

Appendix L, AVRS Quick Reference Guide, provides instructions for using AVRS to verify recipient eligibility. Providers can obtain a faxed response verifying eligibility by following the instructions provided.

27.5 Completing the Claim Form

To enhance the effectiveness and efficiency of Medicaid processing, provider should bill Medicaid claims electronically.

Pharmacy providers who bill Medicaid claims electronically receive the following benefits:

- Faster claim processing turnaround
- Immediate claim correction
- Enhanced online adjustment functions
- Improved access to eligibility information

Refer to Appendix B, Electronic Media Claims Guidelines, for more information about electronic filing.

Most pharmacy claims are submitted electronically for online adjudication. Claims filed electronically use Provider Electronic Solutions software from Gainwell or Point of Sale proprietary pharmacy software.

NOTE:

When filing a claim on paper, an XIX-DC-10-093 pharmacy claim form is required.

Paper claims may also be filed. The pharmacist must initiate a two-part Medicaid Pharmacy Claim. The pharmacy must retain the original claim for State and audit purposes and submit a duplicate claim to Gainwell for payment. Gainwell will furnish pharmacy claim forms upon request.

Pharmacy claim forms can be purchased from Gainwell for \$35.44 per 1,000 forms. Claim forms will be mailed after receipt of payment.

This section describes program-specific claims information. Refer to Chapter 5, Filing Claims, for general claims filing information and instructions.

27.5.1 Time Limit for Filing Claims

Medicaid requires all claims for Pharmacy providers to be filed within one year of the date of service. Refer to Section 5.1.4, Filing Limits, for more information regarding timely filing limits and exceptions.

27.5.2 Diagnosis Codes

Diagnosis Codes do not apply when filing the pharmacy claim form.

27.5.3 Procedure Codes and Modifiers

Procedure Codes and Modifiers do not apply to Pharmacy billing.

27.5.4 Place of Service Codes

Formerly named Patient Location Code, new code values have been assigned. A value of either 31, 32, or 54 in 307-C7 will indicate the patient is in a Long Term Care (LTC) facility and the claim will be processed accordingly.

27.5.5 Required Attachments

Attachments are not required for pharmacy claims.

27.5.6 Third Party Liability (TPL) Payments

As a general rule, pharmacy providers are required to file a patient's primary insurance prior to filing Medicaid. Once the primary payer has responded, the patient's claim can be submitted to Medicaid. Medicaid will pay the Medicaid rate less any payment and applicable contractual adjustment. Medicaid should not pay more than the sum of the health plan's patient co-pay, coinsurance and/or deductible.

The following NCPDP codes should be used when billing Medicaid as the secondary payer:

- Other coverage code "02" (NCPDP field 308-C8) will require a TPL amount (431-DV) greater than zero.
- Other coverage codes "02" and "04" (NCPDP field 308-C8) will require a patient responsibility amount (352-NQ) greater than zero.
- Other coverage code "03 - Other coverage exists- claim not covered" (NCPDP field 308-C8) will not require either TPL amount or patient responsibility amount to be greater than zero.

An exception to the rule is when the patient has a point of sale (POS) drug plan, which requires the cost of the prescription to be paid up front by the patient. Then a claim can be submitted to the insurance plan for reimbursement directly to the patient. These POS drug plans require special handling when the patient is also a Medicaid recipient.

Click the following link for special instructions for pharmacies when the recipient has both Medicaid and a point-of-sale drug plan: https://medicaid.alabama.gov/content/7.0_Providers/7.1_Third_Party/7.1.6_Coord_Benefits.aspx

27.5.7 Prescription Origin Code

The code indicating the means used to deliver a prescription to a pharmacy – this is a required field. Valid values are:

- 0 = Not Known
- 1 = Written
- 2 = Telephone
- 3 = Electronic
- 4 = Facsimile
- 5 = Pharmacy

27.6 For More Information

This section contains a cross-reference to other relevant sections in the manual.

Resource	Where to Find It
XIX-DC-10-093 Claim Filing Instructions	Chapter 5
Medical Necessity/Medically Necessary Care	Chapter 7
Electronic Media Claims (EMC) Submission Guidelines	Appendix B
AVRS Quick Reference Guide	Appendix L
Alabama Medicaid Contact Information	Appendix N

27.7 Alabama Medicaid Pharmacy Questions and Answers (Q&A)

The Medicaid Pharmacy Q&A has been developed to provide guidance and clarification on pharmacy issues. Questions may be submitted to:

Medicaid Program Management, Fax (334) 353-7014

Responses will be published in the quarterly Medicaid Pharmacy Newsletter.

Are original prescriptions and signatures required for all drugs?

Medicaid requires original, signed prescriptions for Schedule II drugs. Schedule III, IV, and V drugs may be called in, as allowed by state pharmacy regulations.

Can I make a therapeutic or strength substitution without calling the prescribing physician?

No. Alabama State law requires the pharmacist to have the approval of the prescribing physician before dispensing anything other than what has been indicated on the prescription. If the physician has indicated product selection is allowed, the pharmacist may dispense generic substitution without subsequent contact with the physician.

What is the appropriate action when a physician writes a prescription that exceeds the Medicaid monthly dosing units?

When a prescription is denied for excessive quantity or monthly limit exceeded, claims will deny. In order to receive an override, providers (either the pharmacy or physician) should contact the HID help desk at 1(800) 748-0130 for consideration of an override.

Can I “split bill” a prescription if the prescribed quantity exceeds the maximum units allowed?

If a prescription to be paid by Medicaid exceeds the drug’s maximum unit limit allowed per month, the prescriber or pharmacist must request an override for the prescribed quantity. If the override is denied, then the excess quantity above the maximum unit limit is non-covered and the recipient can be charged as a cash recipient for that amount in excess of the maximum unit limit. In other words, for a prescription to be “split billed” (the maximum unit allowed paid by Medicaid and the remainder paid by the patient), a maximum unit override must be requested by the provider and denied. Note: A provider’s failure or unwillingness to go through the process of obtaining an override does not constitute a non-covered service.

How long is a prescription valid?

In accordance with state law, controlled substance prescriptions, for schedule III-V, may be refilled up to five times within six months from the original issue date. Non-controlled prescriptions are reimbursable by Medicaid for up to 12 months from the date of the original dispensing date.

Can I receive authorization for additional refills from the prescribing physician after the 12 months have expired?

No. A new prescription should be obtained after 12 months from the date of the original dispensing date. Medicaid will make payment for up to 5 refills on an original prescription for Control III-V prescriptions and 11 refills on non-controlled prescriptions.

Why is it important that I bill the exact NDC number dispensed if the product is a generic?

According to the State Board of Pharmacy, pharmacies dispensing controlled substances and submitting claims with different NDC numbers would have problems with the Drug Enforcement Agency (DEA). Additionally, Medicaid provider contracts require that claims be submitted accurately. Under federal law, manufacturers rebate Medicaid for use of their drugs. When an NDC is submitted on a claim that is not the actual NDC dispensed, Medicaid may incorrectly invoice the manufacturer for the rebate. Rebate dollars provide a significant source of money to offset pharmacy benefit costs. Therefore, NDC numbers reported on pharmacy claims should be the exact NDC number dispensed to the patient.

Can referrals be made to the Medicaid Agency when a provider believes a recipient is defrauding the program?

Yes. Any information regarding inappropriate and/or illegal drug-related activity by Medicaid recipients can be referred to the **Medicaid Fraud Hotline at 1(866) 452-4930**. All complaints are researched. If evidence is

found to support recipient abuse or fraud, recipients can be locked in to one physician and one pharmacy or removed from the Medicaid program.

Does Medicaid make payment for benefits when a patient is in a state or county correctional facility?

Medicaid benefits are not available for individuals who are inmates of public institutions as defined by CFR 435.1009. It is the responsibility of the correction facility to provide medical care. Incarcerated recipients still receiving Medicaid benefits may be referred to the **Medicaid Fraud Hotline at 1(866) 452-4930**.

If a provider receives multiple dispensing fees for the same patient, same drug and strength within the same month, will the additional dispensing fees be recouped?

Medicaid auditors look specifically for providers who split 30-day prescriptions into shorter time periods and amounts. Intentionally splitting prescriptions to receive multiple dispensing fees is fraud and monies paid will be recouped. Multiple dispensing fees within the same month for the same patient and same drug are acceptable if the provider has documentation supporting the need for multiple dispensings. Example: A child needs a 10 mg tablet for school and a 20 mg tablet for home to take at night; the provider should have in his documentation prescriptions for both.

If a provider is audited and cannot produce documentation while Medicaid auditors are in the store, is there a period of time allowed to provide the documentation before recoupments are initiated?

If an auditor requests documentation that is not present in the provider's facility, the provider should indicate to the auditor where the documentation is and when it can be provided for review. If additional information is needed by the state as a result of discrepancies identified in an audit, the provider should submit the requested information within 30 days of the request. Failure to submit documentation within 30 days may result in recoupment.

Is it important to bill the correct days supply?

Yes, days supply is an instrumental portion of a legitimate claim. Retroactive audits may consider the day supply billed, along with quantity of medication billed, in regards to the original prescription. Day supply billed should be clinically appropriate according to the physician's instructions on the prescription.

Can a pharmacy provider advertise waived copays for their Medicaid patients?

No. Advertising the waiver of or routinely waiving Medicaid copayments is a prohibited remuneration under Section 22-1-11, Code of Alabama and 1128B of the Social Security Act (SSA). Please refer to the Provider Manual, Chapter 7 "Understanding your rights and responsibilities as a provider", Section 7.1.8 "Provider Certification" for more information on offering incentives and advertising discounts.

Can a pharmacy enroll in Alabama Medicaid and dispense drugs off site?

No*. Per the Alabama Medicaid Agency provider enrollment agreement: *“1.3.3: All claims or encounters submitted by Provider must be for services actually rendered by Provider.”* This means that the dispensing of drugs to an Alabama Medicaid Agency recipient must occur by the rendering provider, who is enrolled and billing per the pharmacy NPI.

In addition, per Alabama Medicaid Administrative Code: Rule No. 560-X-16-.02 Requirements for Participation *(1) A pharmacy must be operating under a permit or license to dispense drugs as issued by the Alabama State Board of Pharmacy or appropriate authority in the State where the service is rendered. (2) A pharmacy applicant must submit and have approved a pharmacy agreement signed by owner, authorized representative, pharmacist, or dispensing physician. (3) Pharmacies and dispensing physicians must agree to abide by the rules and regulations of the program; must agree that payment for covered services will be accepted as payment in full.* Therefore, unless approved by the Alabama Board of Pharmacy, the permitted pharmacy is permitted by the Alabama Board of Pharmacy for that particular location, and the dispensing from that permitted location must match the billing/service location of the enrolled pharmacy's NPI.

*The only exception allowed by Alabama Board of Pharmacy is: Section 34-23-70 of the Alabama Practice of Pharmacy Act 205: Management; display of permit and license; poisons; prescription requirements; violations: *(e) No pharmacy shall authorize any person, firm, or business establishment to serve as a pick-up station or intermediary for the purpose of having prescriptions filled or delivered, whether for profit or gratuitously. Except with respect to controlled substances, any facility recognized as a federally qualified health center, as defined in 42 U.S.C. §1396d(l)(2)(B), operating health care practices and providing pharmacy services in the state is expressly exempt from this subsection. Each eligible federally qualified health center is authorized to fill certain prescriptions at one location and deliver medications to clinics for patient pick-up subject to the review of the board.*

Sources: <https://www.albop.com/StatutesAndRules.aspx> ; https://medicaid.alabama.gov/documents/9.0_Resources/9.2_Administrative_Code/9.2_Adm_Code_Chap_16_Pharmaceutical_Services_12-14-20.pdf

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