TABLE OF CONTENTS

CHAPTER SIXTEEN

PHARMACEUTICAL SERVICES

Chapter 16 - Pharmaceutical Services

Rule No. 560-X-16-.01 Pharmacy Services - General

(1) The State Plan provides for the payment of certain legend and non-legend drugs prescribed by Doctors of Medicine, and other practitioners including, but not limited to nurse practitioners, dentists, and physician assistants who are legally authorized to prescribe these drugs and when dispensed and/or administered by a licensed pharmacist or licensed authorized physician in accordance with state and federal laws.

(2) In accordance with the Medicaid Drug Amendments contained in the Omnibus Budget Reconciliation Act of 1990, (Public Law 101-508), the following shall apply: with the exception of allowable published exclusions, only those drugs manufactured by companies having signed rebate agreements with the Secretary of Health and Human Services are compensable. The exclusions are:

(a) DESI and IRS drugs which may be restricted in accordance with Section 1927(d)(2) of the Social Security Act

(b) Agents when used for anorexia, weight loss, or weight gain except for those specified by the Alabama Medicaid Agency

(c) Agents when used to promote fertility except for those specified by the Alabama Medicaid Agency

(d) Agents when used for cosmetic purposes or hair growth except for those specified by the Alabama Medicaid Agency

(e) Agents when used for the symptomatic relief of cough and cold except for those specified by the Alabama Medicaid Agency

(f) Prescription vitamin and mineral products, except prenatal vitamins and fluoride preparations and others as specified by the Alabama Medicaid Agency

(g) Nonprescription drugs except for those specified by the Alabama Medicaid Agency

(h) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated test or monitoring services be purchased exclusively from the manufacturer or its designee

(i) Agents when used for the treatment of sexual or erectile dysfunction, unless authorized for medical necessity

(3) Medicaid will pay for approved drug items when they are properly prescribed for eligible Medicaid recipients.

(4) Telephone prescriptions are not allowed for Schedule II controlled substances. The pharmacist must obtain an original prescription and maintain that documentation on file. EXCEPTION: In accordance with Alabama pharmacy law, Controlled Substances Act, §20-2-58(c), a prescription written for Schedule II substances for a resident of a long-term care facility may be transmitted by the practitioner or the agent of the practitioner to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription.

(5) The pharmacist initiates a two part Medicaid Pharmacy Claim. The original part of the claim must be retained by the pharmacy for State and audit purposes, and the duplicate is submitted to the fiscal agent for payment. Claims for services may be filed electronically if the provider has signed an electronic claim agreement with the Alabama Medicaid Agency.

(6) Eligible recipients have freedom of choice in the selection of a pharmacy that has a current Pharmacy Vendor Agreement, and must be accorded the same courtesies and services rendered to all other patrons of the pharmacy.

(7) Title XIX (Medicaid) prescriptions should be written and dated for either legend or over-the-counter drugs. Signatures by the prescribing physician are required on all prescriptions for Schedule II drugs. Stamped or typewritten signatures are not acceptable. Schedule II drugs may not be dispensed to Medicaid recipients without an original prescription. Therefore, call-in prescriptions are not acceptable for Schedule II drugs. Telephone prescriptions for non-controlled drugs and drugs other than Schedule II drugs are acceptable without subsequent signature of the practitioner. EXCEPTION: In accordance with Alabama pharmacy law, Controlled Substances Act, §20-2-58(c), a prescription written for Schedule II substances for a resident of a long-term care facility may be transmitted by the practitioner or the agent of the practitioner to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription.

(a) 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.

1. 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.

2. 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.

3. To be considered tamper-resistant on or after April 1, 2008, a prescription pad must contain at least one of the following three characteristics:

(i) one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form; or

(ii) one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber; or

(iii) one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

4. To be considered tamper-resistant on or after October 1, 2008, a prescription pad must contain all of the foregoing three characteristics.

(8) Pharmacies shall use the correct physician license number when submitting a pharmacy claim to Medicaid.

(9) Pharmacies should not dispense refill medication to recipients until such time that the designated amount of the original prescription has been utilized. For quantities up to a 34 day supply, the designated amount is 75% of the original days' supply. For quantities greater than a 34 day supply, the designated amount is 90% of the original days' supply. Pharmacists must have documentation on the original prescription that the prescribing physician was consulted and the physician approved. Payments for early refills may be recouped by the Medicaid Agency.

(10) Pharmacies receiving hard denials such as early refill, therapeutic duplication and excessive quantity must receive an override from Medicaid or its designated agent before payment will be made.

(11) Any changes to the original prescription, such as physician approved changes in dosage, should be documented on the original prescription.

(12) A provider agrees to accept as payment in full the amount paid by the State, plus any cost-sharing amount to be paid by the recipient, for covered items, and further agrees to make no additional charge or charges for covered item to the recipient, sponsor, or family of the recipient. However, a provider may bill the recipient for the appropriate allowable copayment amount.

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

Author: Tiffany D. Minnifield, Associate Director, Pharmacy Administrative Services.
Statutory Authority: State Plan Attachment 3.1-A and 4.18-B; Title XIX, Social Security Act; 42 CFR Section 447.15, 447.331 & Section 401, et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508), and Public Law 110-28 (SSA Sec. 1903(i)).
History: Rule effective October 1, 1982. Amended July 8, 1983; March 12, 1984; July 9, 1984; June 8, 1985; April 11, 1986; November 10, 1987; April 14, 1992; March 13, 1993; January 1, 1994; March 15, 1994; April 12, 1996; February 11, 1997; November 12, 1997; February 10, 1998; and June 10, 1999. **Amended:** Filed December 19, 2005;

effective March 17, 2006. **Amended:** Filed March 20, 2006; effective June 16, 2006. **Amended:** Emergency Rule filed and effective April 1, 2008. **Amended:** Filed April 21, 2008; effective July 16, 2008. **Amended:** Filed October 20, 2009; effective January 15, 2010. **Amended:** Emergency Rule filed and effective November 2, 2009. **Amended:** Filed November 18, 2009; effective February 15, 2010. **Amended:** Filed November 19, 2010; effective March 1, 2011. **Amended:** Filed December 11, 2012; effective January 15, 2013. **Amended:** Filed December 12, 2013; effective January 16, 2014.

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.

(4) Pharmacy providers must agree to abide by the rules and regulations of third party billing procedures (See Chapter 20 Third Party).

(5) Pharmacy providers must agree to keep records, including prescriptions, to fully disclose extent of services rendered. Records, including purchase invoices, recipient signature logs, etc., should be maintained within the State of Alabama. At a minimum the following records and/or documentation must be available for examination: (1) prescription files and (2) invoices.

(6) Pharmacy providers must agree that the Alabama Medicaid Agency or its representative may conduct audits of required records as necessary. Invoice records must be maintained and be readily available for inspection. If, due to the location of the provider's records, Medicaid personnel are required to go out of state for an audit, the organization being audited will bear all expenses and costs related to the audit, including, but not limited to, travel and reasonable living expenses.

(7) All Medicaid participating pharmacies must be in compliance with Title VI and VII of the Civil Rights Act of 1964 and with Section 504 of the Rehabilitation Act of 1973.

Authority: State Plan Attachment 3.1A and 4.18B; Title XIX, Social Security Act; 42 C.F.R. Section 447.331 & Section 401, Et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) Rule effective October 1, 1982. Amended October 7, 1983

and April 14, 1992. Amended March 15, 1994. Amended November 12, 1997. Effective date of this amendment is February 10, 1998.

Rule No. 560-X-16-.03 Drugs Dispensed by a Physician

(1) A physician may dispense drugs under the Alabama Medicaid Program if he has a current agreement to dispense drugs with the Alabama Medicaid Agency.

(2) Dispensing physicians are enrolled as drug providers in the Pharmacy Program only where adequate pharmacy services are not available.

(3) A dispensing physician may be enrolled as a drug provider in the Pharmacy Program only if his practice is located more than 50 miles or 50 minutes from the nearest Medicaid-enrolled pharmacy.

Author: Lynn Sharp, Associate Director, Policy Development Unit.
Statutory Authority: State Plan, Attachment 3.1-A and 4.19-B; Title XIX, Social Security Act; 42 CFR, Section 447.331 and Section 401; et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508).
History: Rule effective October 1, 1982. Amended April 14, 1992. Amended: Filed August 20, 1999; effective November 10, 1999.

Rule No. 560-X-16-.04 Pharmacy Services in Hospitals

(1) Hospitals. Payment for drugs for inpatient hospital care under the Title XIX Program is based on reasonable cost which allows payment (per diem) not to exceed Medicare levels.

Authority: State Plan Attachment 3.1A and 4.18B; Title XIX, Social Security Act; 42 C.F.R. Section 447.331 & Section 40l,Et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) Rule effective October 1, 1982. Rule amended April 14, 1992. Amended November 12, 1997. Effective date of this amendment is February 10, 1998.

Rule No. 560-X-16-.05 Long Term Care Facilities

(1) (a) The nursing facility must meet the State and Federal Standards and the Title XIX rules and regulations for pharmacy services.

(b) The payment limit for prescription drugs dispensed to patients confined in the Long Term Care facilities must not exceed the upper limits as contained in Rule 560-X-16-.06.

(2) Over-the-counter insulins, covered through the Medicaid pharmacy program may be submitted for payment by utilizing the NDC number. All other OTC

medications/products should be included in the facility cost report. See Rule No. 560-X-16-.12.

(3) Payment for drugs dispensed with a unit dose system will be limited to those pharmacies that make application and are approved by the Medicaid Pharmacy Program.

(4) As an attachment to or included with such application, the pharmacy must include a detailed explanation of the delivery system employed to provide drugs to the nursing facility.

(5) The furnishing of solid oral dosage form of a covered drug item by an approved unit dose system is an acceptable method for providing drugs under the program.

(6) The basis of payment for the unit dose drug distribution system cannot exceed the upper limits of payment as set forth by the regulations.

(7) The Alabama Medicaid Agency requires that all prescriptions for Medicaid nursing home patients who are on long-term therapy or maintenance drugs be written for a 30 up to a 34-day supply. A 90-day supply is permitted for certain maintenance therapies. Payment for units greater than 34 days, unless otherwise permitted, may be recouped by Medicaid unless the pharmacist can provide documentation to support the units dispensed. EXCEPTION: This requirement does not apply to those pharmacies that are utilizing a unit dose system approved by the Alabama Medicaid Agency.

(8) Each pharmacy using an approved unit dose system must submit only one claim per drug per recipient each month and only the amount of the prescribed drug actually consumed by the patient may be included.

(9) All medication orders are filled and/or dispensed from a signed original or direct copy of the physician's prescription order as authorization for approved unit dose pharmacies. Exception: Telephoned prescriptions for non-controlled drugs are acceptable without the subsequent signature of the practitioner.

(10) Each dose is individually packaged in a sealed, tamper proof container and carries full disclosure labeling, including, but not limited to, product name and strength, manufacturer's or distributor's name, lot number and expiration date.

(11) When a resident leaves the facility and is expected to return, a 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.

Author: Bakeba R. Thomas, Associate Director, Pharmacy Clinical Support.
Statutory Authority: State Plan, Attachment 3.1-A and 4.19-B; Title XIX, Social Security Act; 42 C.F.R. Section 447.331 & Section 401, et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508).
History: Rule effective October 1, 1982. Amended April 14, 1992; November 12, 1997; and February 10, 1998. **Amended:** Filed March 19, 1999; effective June 10, 1999. **Amended:** Filed June 20, 2003; effective September 15, 2003. **Amended:** Filed April 20, 2005; effective July 15, 2005. **Amended:** Filed November 19, 2010; effective March1, 2011.

Rule No. 560-X-16-.06 Reimbursement for Covered Drugs and Services

(1) 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 Rule 560-X-16-.01.

(2) Multiple Source Drugs. Reimbursement for covered multiple source drugs in the Medicaid Program shall not exceed the lowest of:

(a) The federally mandated upper limit (FUL) for certain multiple source drugs as established and published by CMS plus a reasonable dispensing fee as discussed in paragraph (6) below; or

(b) The Alabama Estimated Acquisition Cost (AEAC) for the drug plus a reasonable dispensing fee. AEAC is defined by Medicaid as the Average Acquisition Cost (AAC) of the drug or, in cases where no AAC is available, the Wholesale Acquisition Cost (WAC) + 0%; or

(c) The provider's Usual and Customary charge to the general public for the drug; or

(d) The Alabama State Maximum Allowable Cost (State MAC) plus a reasonable dispensing fee. The State MAC is defined as the AAC of a drug multiplied by at least 1.0 that will apply to all multiple source drugs within a particular grouping. The State MAC reimbursement will apply to certain multiple source drug products that meet therapeutic equivalency, market availability, and other criteria deemed appropriate by the Alabama Medicaid Agency. Reimbursement methodology for the State MAC shall be as follows:

- Drugs are subject to a State MAC if there is at least one non-innovator multiple source alternative product available.
- The Alabama Medicaid Agency or its designated representative will collect and review pharmacy invoices and other information deemed necessary by the Alabama Medicaid Agency in an effort to determine AAC in accordance with applicable State and Federal law.

- This information will be collected from Medicaid-participating pharmacies via surveys. The AAC is multiplied by at least 1.0 to derive the State MAC rate that will apply to all multiple source drugs within the particular grouping.
- The Alabama Medicaid Agency will periodically review the rates and adjust them as necessary to reflect the Alabama Medicaid Agency's understanding of prevailing market conditions.

EXCEPTION: The FUL and/or State MAC may be waived for a brand innovator multiple-source drug. For these cases the prescriber must provide documentation of the medical necessity for the brand name rather than the available generic equivalent and receive an override.

(3) Other Drugs. Reimbursement for covered drugs other than multiple source drugs shall not exceed the lower of:

(a) The Alabama Estimated Acquisition Cost (AEAC) for the drug plus a reasonable dispensing fee. AEAC is defined by Medicaid as the Average Acquisition Cost (AAC) of the drug or, in cases where no AAC is available, the Wholesale Acquisition Cost (WAC) + 0%; or

(b) The provider's Usual and Customary charge to the general public for the drug; or

(c) For blood clotting factor products, Medicare Part B Drug pricing plus a reasonable dispensing fee.

(d) For certain specialty drugs, Wholesale Acquisition Cost (WAC) less a specified percentage.

(4) Blood clotting factor products. In addition to providing blood clotting factor, providers of the Alabama Medicaid Agency are required to provide, at the minimum, clinically appropriate items and services to their hemophilia patients as outlined in Rule No. 560-X-16-.31.

(5) The pharmacist shall submit claims in the units specified on the prescription by the prescribing physician up to a 34-day supply. A three month supply is permitted for certain maintenance therapies. Payment for units greater than 34 days, unless otherwise permitted, may be recouped by Medicaid unless the pharmacist can provide documentation to support the units dispensed. Medications supplied in a dosage form that would prevent the dispensing of an exact 30 up to a 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.

(6) Dispensing Fees. A reasonable dispensing fee is set by the Agency. This fee is reviewed periodically for reasonableness and, when deemed appropriate by Medicaid, may be adjusted.

(7) Unless the designated amount of the original days' supply has been utilized or there is a documented consultation with the prescribing physician, only one dispensing fee is allowed for a 30 up to a 34-day supply of the same drug per month. For quantities up to a 34-day supply, the designated amount is 75% of the original days' supply. For quantities greater than a 34-day supply, the designated amount is 90% of the original days' supply.

(8) Medicaid may reimburse for professional services provided by licensed pharmacists. Professional services may include vaccine administration, medication maintenance therapy adherence and other clinical services as designated by the Agency.

Author: Kelli D. Littlejohn, R.Ph., Pharm. D., Director, Clinical Services and Support.
Statutory Authority: State Plan, Attachment 3.1-A and 4.19-B; Title XIX, Social Security Act; 42 CFR Section 447.205 & Section 447.331; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508); Veterans Health Care Act of 1992 (Public Law 102-585).
History: Rule effective October 1, 1982. **Amended:** October 29, 1987: December 10, 1987; April 14, 1992; November 12, 1993; April 12, 1996; November 12, 1997; and February 10, 1998. **Amended:** Filed March 19, 1999; Effective June 10, 1999. **Amended:** Filed March 20, 2002; effective June 14, 2002. **Amended:** Filed April 20, 2005; effective July 15, 2005. **Amended:** Filed July 20, 2007; effective December 14, 2007. **Amended:** Filed January 22, 2008; effective May 1, 2008. **Amended:** Emergency Rule filed and effective November 2, 2009. **Amended:** Filed November 18, 2009; effective February 15, 2010. **Amended:** Filed May 20, 2010; effective August 13, 2010. **Amended:** Filed November 19, 2010; effective March 1, 2011. **Emergency Rule:** Filed and Effective October 1, 2012. **Amended:** Filed December 11, 2012; effective January 15, 2013. **Amended:** Filed August 13, 2013; effective September 17, 2013.

Rule No. 560-X-16-.07 Out-of-State Pharmacies

(1) 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.

(2) Pharmacies Bordering Alabama

(a) 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.

(b) The pharmacy must then sign a Pharmacy Vendor Agreement with Alabama Medicaid Agency and agree to abide by the State pharmacy provider tax law.

(c) Pharmacies bordering Alabama are defined as those pharmacies located not more than 30 miles from the border of Alabama.

(3) Pharmacies Not Bordering Alabama

(a) Drugs dispensed must be in concurrence with the limitations in place

for in-state providers.

(b) Reimbursement will be made only for hemophilia 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.

(c) 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.

(d) Pharmacies not bordering Alabama will be enrolled by the Medicaid fiscal agent on a temporary basis.

(e) Pharmacies not bordering Alabama are defined as those pharmacies located more than 30 miles from the border of Alabama.

Author: Lynn Sharp, Associate Director, Policy Development Unit
Statutory Authority: State Plan, Attachment 3.1A and 4.19B; Title XIX, Social Security Act; 42 CFR, Section 447.331, Section 401, Et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508).
History: Rule effective October 1, 1982. Amended June 8, 1984; April 14, 1992; November 12, 1997; and February 10, 1998. Amended: Filed April 20, 1999; effective July 13, 1999. Amended: Emergency rule filed and effective July 13, 1999. Amended: Filed October 20, 1999; effective January 12, 2000. Amended: Filed December 18, 2000; effective March 12, 2001.

Rule No. 560-X-16-.08 Injections

(1) Injectable drugs administered by physicians and outpatient hospitals are allowable.

(2) Claims for injectable medication administered by the physician should be made on the Physician's Claim Form and submitted to the fiscal agent for payment.

(3) Claims for injectable medications administered in an outpatient hospital should be made on the UB-8 92 and submitted to the fiscal agent by the outpatient facility.

(4) For information concerning injectable medications administered in renal dialysis facilities, please refer to Rule No. 560-X-24-.05.

(5) The Medicaid Pharmacy Program will review and have final approval of injectable medications and the rate of reimbursement that is billed to the fiscal agent by the physician or outpatient hospital.

Authority: State Plan, Attachment 3.1A and 4.18B; Title XIX, Social Security Act; 42 C.F.R. Section 447.331 & Section 401, Et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) Rule effective October 1, 1982. Amended May 9, 1984, November 10, 1987. Rule amended April 14, 1992. Amended November 12, 1997. Effective date of this amendment is February 10, 1998.

560-X-16-.09 Reserved

Rule No. 560-X-16-.10 Cost-Sharing

(1) Medicaid recipients are required to pay the designated co-pay amount for each prescription filled and each refill.

(2) The cost-sharing fee does not apply to family planning drugs and supplies, or to drugs prescribed for recipients under 18 years of age, recipients who are in a nursing facility or services furnished to pregnant women.

(3) When a pharmacy fills a prescription for a Medicaid recipient under eighteen (18) years of age, the pharmacist must verify the age of the individual by checking the date of birth on the eligibility card. Co-payment on drug claims for family planning drugs and supplies will be determined by the national drug code numbers. No further indication is necessary on the claim form for a Medicaid recipient under eighteen (18) years of age or for claims submitted for family planning drugs and supplies.

(4) When a pharmacy fills a prescription for a Medicaid recipient residing in a nursing facility in Alabama the pharmacy provider must indicate a large "I" in the Co-pay block on the Medicaid Pharmacy Claim Form or appropriate space for other approved drug claim submission methods (i.e., continuous feed form, tape-to-tape, etc.).

(5) When a pharmacist dispenses a prescription for a Medicaid eligible woman on which the physician has written PREGNANT, the pharmacist shall place a "P" in the Co-pay block on the Medicaid Pharmacy Claim Form or appropriate space for other approved drug claim submission methods (i.e., continuous feed form, tape-to-tape, etc.).

(6) Copayment Collection: Copayment is based on drug ingredient cost of the dispensed prescription. The schedule is furnished by the Medicaid Agency Pharmacy Program.

(7) A provider may not deny services to any eligible individual on account of the individual's inability to pay the copayment amount.

Authority: State Plan, Attachment 3.1A and 4.18B; Title XIX, Social Security Act; 42 C.F.R. Section 447.15, Section 447.53, & Section 447.331; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508). Rule effective October 1, 1982. Amended September 8, 1983, December 6, 1984 and June 8, 1985; Rule amended April 14, 1992. Amended November 12, 1997. Effective date of this amendment is February 10, 1998.

Rule No. 560-X-16-.11 Pharmacist Consultant Services in Nursing Facilities

(1) Federal regulations require pharmacy consultant services in nursing facilities as a condition of participation. This requirement recognizes the professional status of the pharmacist and makes him an integral part of the health care team.

(2) The requirement that there be pharmacy consultant services is imposed on the facility as a condition of participation. Thus, compensation is appropriately an arrangement between the facility and the consultant.

Authority: State Plan, Attachment 3.1A and 4.18B; Title XIX, Social Security Act; 42 C.F.R. Section 447.331 and Section 401, Et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) Rule effective October 1, 1982; Rule Amended April 14, 1992.

Rule No. 560-X-16-.12 Over-the-Counter Medications

(1) Over-the-counter medications/products require a signed prescription from a physician or other practitioner legally licensed by the State of Alabama to prescribe the drugs authorized under the program.

(2) Over-the-counter medications/products must be dispensed by a licensed Medicaid pharmacist in accordance with state and federal laws as stated in Rule 560-X-16-.01.

(3) Over-the-counter medications/products will be reimbursed as stated in Rule No. 560-X-16-.06 Reimbursement for Covered Drugs.

(4) Over-the-counter medications/products will be covered in long term care facilities as stated in Rule No. 560-X-16-.05 Long Term Care Facilities.

Author: Stephanie Frawley, CPhT, Pharmacy Services.
Statutory Authority: State Plan, Attachment 3.1-A and 4.19-B; Title XIX, Social Security Act.
History: Rule effective February 11, 1997. **Amended:** Filed March 20, 2002; effective June 14, 2002. **Amended:** Filed April 20, 2005; effective July 15, 2005.

Rule No. 560-X-16-.13 Claim Form Acquisition

The Medicaid fiscal agent will furnish claim forms upon request.

Authority: The Alabama Medicaid Agency Contract with Fiscal Agent for payment of claims. Rule effective October 1, 1982.

Rule No. 560-X-16-.14 Reserved

Rule No. 560-X-16-.15 Claim Filing Limitations

For claim filing limitations, refer to Chapter 1, Rule 560-X-1-.17.

Authority: State Plan, Attachment 3.1A; Title XIX, Social Security Act; 42 C.F.R. Section 401, Et seq. Rule effective October 1, 1982. Effective date of this amendment November 11, 1985.

Rule No. 560-X-16-.16 Automated Billing System

Refer to Rules 560-X-1-.17 and 560-X-1-.18.

Authority: State Plan, Attachment 3.1A; Title XIX, Social Security Act; 42 C.F.R. Section 401, Et seq. Rule effective October 1, 1982. Effective date of this amendment March 12, 1988.

Rule No. 560-X-16-.17 Restriction of Recipients

The recipient may be placed on restriction who has abused and/or over utilized pharmacy and/or physician services. The procedure to place an individual on restriction and limit the individual to a pharmacy and a physician is stated in Chapter 4 on S/UR in this Code.

Authority: State Plan; Title XIX, Social Security Act; 42 C.F.R. Section 401, Et seq. Rule effective October 1, 1982.

Rule No. 560-X-16-.18 Pharmacy Peer Review Committees

Composition and selection is as stated in Chapter 2 of this Code.

Authority: State Plan, Attachment 3.1A; Title XIX, Social Security Act; 42 C.F.R. Section 401, Et seq. Rule effective October 1, 1982. Rule amended April 14, 1992.

Rule No. 560-X-16-.19 Pricing Information

The Medicaid Physicians Program shall approve the rate of reimbursement for injectable drugs (for physicians or outpatient hospitals). The actual research and price determination is made by the fiscal agent as set forth in the fiscal agent contract. The drug pricing file is furnished to the fiscal agent who shall update and utilize for pharmacy claims processing within twenty-four (24) hours of receipt for pharmacy claims.

Authority: State Plan Attachment 3.1A and 4.18B; Title XIX, Social Security Act; 42 C.F.R. Section 447.331 and Section 401, Et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) Rule effective October 1, 1982. Effective date of amendment May 9, 1984. Rule amended April 14, 1992. Amended November 12, 1997. Effective date of this amendment is February 10, 1998.

Rule No. 560-X-16-.20 Quantity Limitations

(1) Prescriptions should be 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. A prescription shall not be split into small units and submitted as separate claims in order to obtain additional dispensing fees.

(2) The quantity for which a prescription is written should not exceed a maximum of eleven refills for non-controlled prescriptions or five refills for Control III-V prescriptions. Claims for prescription refills beyond eleven refills for non-controlled prescriptions or five refills for Control III-V prescriptions shall be denied.

(3) Quantities (units) of drugs prescribed by a physician shall not be arbitrarily changed by a pharmacist except by authorization of the physician.

(a) The pharmacist must contact the prescribing physician for authorization to reduce the quantity of any Medicaid prescription.

(b) Authorization to reduce the units of a prescription must be noted on the prescription form by the pharmacist.

(4) 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 is required to note on the prescription the number of units dispensed and retain the claim until the balance of medication is dispensed. The claim is then submitted with one dispensing fee. If more than one dispensing fee is received, recoupments may be initiated if the dispensing pharmacy cannot provide documentation to support why multiple dispensing fees were received within the same month.

(5) Maintenance medications are those generally used to treat chronic conditions or illnesses and are ordered/prescribed and taken regularly and continuously. Medicaid recipients can obtain a three month supply of maintenance medications as designated by the Agency. The patient must first have demonstrated stability for at least 60 days (same strength and dose) on a given maintenance medication. Only one co-pay is collected and only one dispensing fee is paid for the three month supply. A list of maintenance medications is available on the Medicaid website.

(6) Effective October 1, 2013, the number of outpatient pharmacy prescriptions for all recipients except as specified below is limited to four brand name and 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.

(a) 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.

(b) Effective November 22, 2004, 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 DataBank (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, Immunosuppresives, 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.

Author: Bakeba R. Thomas, Associate Director, Pharmacy Clinical Support.
Statutory Authority: State Plan, Attachment 3.1-A; Title XIX, Social Security Act; 42 CFR Section 401, et seq.
History: Rule effective October 1, 1982: Amended December 6, 1984; November 10, 1987; April 14, 1992; November 12, 1997; and February 10, 1998. **Amended:** Filed March 22, 2004; effective June 18, 2004. **Amended:** Filed August 20, 2004; effective November 22, 2004. **Amended**: Filed August 22, 2005; effective November 16, 2005. **Amended:** Filed August 20, 2007; effective November 16, 2007. **Amended:** Filed November 19, 2010; effective March 1, 2011. **Amended**: Filed June 20, 2011; effective September 15, 2011. **Amended:** Filed August 13, 2013; effective September 17, 2013.

Rule No. 560-X-16-.21 Prescription Refill

(1) Prescriptions will have a maximum of no more than eleven (11) refills for non controlled prescriptions or five (5) refills for Control III-V prescriptions authorized.

(2) Physicians are urged to designate refills or indicate non-refills on all Title XIX (Medicaid) prescriptions. If the physician does not designate refills or indicates no refill on the prescription, then the non-refill status will apply. If the physician grants oral authorization to refill a previously undesignated or non-refillable prescription, the pharmacist must indicate each authorization on the prescription.

(3) If a prescription is refilled, the date upon which the prescription is refilled must appear on the prescription.

(4) All prescriptions should be refilled only in quantities commensurate with dosage schedule and refill instructions.

(5) Violations of these policies may result in unauthorized charges for which the pharmacy may be held liable and/or cancellation of the pharmacy vendor agreement.

Author: Kelli Littlejohn, RPh, Director, Pharmacy Services
Statutory Authority: State Plan; Title XIX, Social Security Act; 42 CFR Section 401, et seq.
History: Rule effective October 1, 1982. Amended April 11, 1986, November 10, 1987, and April 14, 1992**. Amended:** Filed August 22, 2005; effective November 16, 2005.

Rule No. 560-X-16-.22 Signature Requirement for Manual Pharmacy Claim Form

For recipient and provider signature requirements, please refer to Rule No. 560-X-1-.18.

Authority: State Plan, Attachment 3.1A and 4.18B; Title XIX, Social Security Act; 42 C.F.R. Section 447.331 and Section 401, Et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508) Rule effective October 1, 1982. Amended November 10, 1987. Rule change April 14, 1992.

Rule No. 560-X-16.-23 Drug Utilization Review (DUR) - General

In accordance with the Medicaid Drug Amendments contained in the Omnibus Budget Reconciliation Act of 1990, (Public Law 101-508), the following shall apply:

(1) The Medicaid Agency shall provide, by not later than January 1, 1993, for a Drug Utilization Review (DUR) Program for covered outpatient drugs in order to assure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical results.

(2) The DUR Program is made up of the following components: Prospective Drug Utilization Review, Retrospective Drug Utilization Review, and an educational program.

(3) The Alabama Medicaid Agency has established a DUR Board. Board membership shall be composed of four practicing physicians, four practicing pharmacists, two representatives from the state's pharmacy schools, two representatives from the state's medical schools, and two representatives from the Alabama Medicaid Agency with knowledge and experience in:

(a) Clinically appropriate prescribing and dispensing of covered outpatient drugs
(b) Monitoring of covered outpatient drugs
(c) Drug use review, evaluation and intervention

(d) Medical quality assurance

(4) Physician and pharmacist DUR Board members must be licensed in Alabama.

(5) The activities of the DUR Board include:

(a) Retrospective DUR

(b) Application of prescribing standards

(c) Ongoing interventions for physicians and pharmacists targeting therapy problems or individuals identified in the course of retrospective DUR. Interventions include inappropriate instances:

1. Information dissemination
2. Written, oral, and electronic reminder
3. Face to face discussions
4. Intensified monitoring/review of providers/dispensers

(6) The DUR Program shall be designed to educate physicians and pharmacists to reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and patients associated with specific drugs, as well as 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 and clinical abuse/misuse.

(7) The DUR Program will review, analyze and interpret patterns of drug usage against predetermined criteria and 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. The predetermined criteria and standards are available from the Alabama Medicaid Agency or its designated agent.

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

Authority: State Plan , Pages 74, 74a, 74b; Title XIX, Social Security Act; 42 CFR Section 440.120; Public Law 101-508. Emergency Rule effective July 1, 1993. Permanent rule effective October 28, 1993. Amended February 11, 1997. Amended November 12, 1997. Effective date of this amendment is February 10, 1998.

Rule No. 560-X-16-.24 Prospective DUR

(1) Prospective DUR (PRODUR) 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 patient profiles.

(2) Screening - The review must include screening for potential drug therapy problems as specified by the Alabama State Board of Pharmacy. This includes screens for:

(a) Therapeutic duplication means the prescribing and dispensing, where overlapping periods of drug administration are involved and where such prescribing or dispensing is not medically indicated of: (1) two or more doses of the same drug, (2) at least two drugs from the same therapeutic class, or (3) at least two drugs from different therapeutic classes with similar pharmacological effects being used for the same indication.

(b) Drug/Disease contraindications
(c) Drug interactions
(d) Incorrect dosage or duration of drug treatment
(e) Drug allergy interactions, and
(f) Clinical abuse/misuse

(3) PRODUR screening must use predetermined standards which are based upon the peer-reviewed medical literature and the three compendia referenced in Rule No. 560-X-16-.23(7). Criteria and standards developed by the DUR Board will be distributed to the providers by Medicaid in Medicaid Provider Notices and/or Bulletins.

(4) PRODUR screening is the sole responsibility of each Medicaid participating pharmacy and is a requirement for participation in the program.

(5) Prospective DUR screening will be conducted through the Medicaid electronic claims processing system. Pharmacists must respond to prospective DUR alerts to continue claims processing through the Medicaid fiscal agent.

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

(7) In the absence of patient-specific diagnosis or allergy information, the pharmacist should consult the patient or the patient's health care provider, if in the pharmacist's judgment, obtaining such information is essential.

(8) Patient counseling shall be offered to all Medicaid recipients receiving new prescriptions and, where appropriate, refill prescriptions and such counseling will be in conformance with guidelines as established by the Alabama State Board of Pharmacy. This regulation includes prescriptions dispensed by mail-order pharmacies. The act specifies that it is permissible for the offer to counsel to be made in a written communication, by telephone, or in a manner determined by the pharmacist to be appropriate.

(9) Patient profiles shall be maintained on all Medicaid recipients receiving medications. The pharmacist must make a reasonable effort to obtain, record, and

maintain information as outlined in the Alabama State Board of Pharmacy Practice Act. At a minimum, profiles should contain.

(a) Patient name, age, gender, address and phone number;

(b) Individual patient history, including a list of prescription medications and devices, where appropriate; and

(c) Pharmacist comments.

(10) Each pharmacy provider shall maintain a recipient log that indicates whether or not counseling was offered, and provided.

Authority: State Plan, Page 74a; Title XIX, Social Security Act; 42 CFR Section 440.120; Public Law 101-508. Emergency rule effective July 1, 1993. Permanent rule effective October 28, 1993. Effective date of this amendment is February 11, 1997.

Rule No. 560-X-16-.25 Retrospective DUR

(1) The retrospective DUR Program reviews, analyzes and interprets patterns of recipient drug usage by applying criteria and standards, developed by the DUR Board, against claims data through periodic examination to identify patterns of fraud and abuse, gross overuse, and inappropriate or medically unnecessary care. Cases of possible fraud and/or abuse shall be referred to the Medicaid Program Integrity Division.

Authority: State Plan, Page 74a; Title XIX, Social Security Act; 42 CFR Section 440.120; Public Law 101-508. Emergency rule effective July 1, 1993. Permanent rule effective October 28, 1993.

Rule No. 560-X-16-.26 Educational Program

(1) The purpose of this program is to educate practitioners on common drug therapy problems to improve prescribing and dispensing practices.

(2) Drug use criteria and standards, established by the DUR Board shall be applied to the drug database after the medication is dispensed. In instances where pharmaceutical use deviates from the criteria and standards, the profile shall undergo further review and possible intervention if appropriate.

(3) Educational program intervention include:

(a) Dissemination of information to physicians and pharmacists in the State concerning the duties and powers of the DUR Board and the basis for the standards used in assessing drug use.

(b) Written, oral, or electronic reminders containing patient-specific or drug-specific information (or both) and suggested changes in prescribing or dispensing practices.

(c) Face-to-face discussions, with follow up discussions when necessary, between health care professionals expert in appropriate drug therapy and selected

prescribers and pharmacists who have been targeted for educational intervention on optimal prescribing, dispensing, or pharmacy care practices.

(d) Intensified review or monitoring of selected prescribers or dispensers.

Authority: State Plan, Page 74b; Title XIX, Social Security Act; 42 CFR Section 440.120; Public Law 101-508. Emergency rule effective July 1, 1993. Permanent rule effective October 28, 1993.

Rule No. 560-X-16-.27 Preferred Drug List

(1) The Alabama Medicaid Agency will utilize a preferred drug list for determination of drugs available for reimbursement under the Medicaid Program. Prescriptions for drugs within the scope of the Medicaid preferred drug list that are not included on the preferred drug list require prior authorization before being reimbursed. Notwithstanding the preceding sentence, Medicaid may, to the extent permitted under 42 U.S.C. § 1396r-8(d), enter into an agreement with a manufacturer to designate a drug that is subject to prior authorization as a preferred drug. For reimbursement under the Medicaid Program, use of the Preferred Drug list is mandatory. Medicaid shall strive to ensure any restriction on pharmaceutical use does not increase overall health care costs to Medicaid.

(2) Over the counter drugs covered by Medicaid will be considered preferred drugs for purposes of this rule. Over the counter drugs will not appear on the preferred drug list.

(3) The Alabama Medicaid Agency will utilize the Pharmacy and Therapeutics Committee to review and recommend drugs for the Preferred Drug List. The Committee will consist of three clinical pharmacists licensed to practice in the state of Alabama including at least one independent pharmacist and one long term care pharmacist, and at least five physicians licensed to practice medicine in the state of Alabama. Physician members will be appointed by the Medicaid Commissioner from a list of at least two nominees for each position submitted by Medical Association of the State of Alabama. Clinical pharmacist members will be nominated by the Alabama Pharmacy Association and appointed by the Medicaid Commissioner; pursuant to state law governing professional services. Members will serve staggered two year terms and may be reappointed to the Pharmacy and Therapeutics Committee for additional terms.

(4) Drugs will be considered for the preferred drug list based on the following:
- (a) clinical efficacy
- (b) side effect profiles
- (c) appropriate usage
- (d) cost

(5) Meetings of the Pharmacy and Therapeutics Committee shall meet the requirements of the State open meetings law, and documents relating to a

recommendation by the Committee shall be available under the State's public records law.

(6) Pharmaceutical manufacturers may request a product review by the Medicaid Pharmacy and Therapeutics Committee of any new pharmaceutical product falling within the scope of the Medicaid preferred drug list. The request must be in writing and directed to the Pharmacy Program Director. Reviews will be placed on the agenda for review in the order in which they are received.

(7) Medicaid will maintain a database of industry representatives for correspondence and notice regarding the Preferred Drug Program. Manufacturers are responsible for providing accurate contact information to Medicaid. Medicaid will update the information bi-annually. If no contact information is provided, Medicaid will utilize contact information on file with the Medicaid Drug Rebate Program.

(8) Medicaid will send written notice not less than thirty (30) calendar days prior to a meeting of the Pharmacy and Therapeutics Committee to manufacturers whose brand name drug(s) will be considered for preferred status at the meeting.

(9) A product or a product with a new indication must have been on the market for a minimum of six (6) months before a review can be requested by a pharmaceutical manufacturer. Requests must be in writing and clearly labeled as a request for product review. Evidence supporting inclusion of the product may be submitted in writing and clearly labeled as part of the request for product review.

(10) Pharmaceutical manufacturers may submit evidence supportive of inclusion of a product on the Medicaid Preferred Drug List to be reviewed by the Pharmacy and Therapeutics Committee. Written comments must meet the following requirements:

(a) Must be received by Medicaid at least twenty-one (21) calendar days prior to the Pharmacy and Therapeutics Committee meeting. Deadlines falling on weekends or holidays must be received by noon CST of the next business day.

(b) Must be clinically based.

(c) Must not contain cost information. Submissions with cost information will be rejected in its entirety.

(d) Must be clearly labeled and indicate the class of products represented.

(e) Must provide to Medicaid twenty (20) copies by the deadline.

(11) Pharmaceutical manufacturers may make oral presentations to the Pharmacy and Therapeutics Committee on products being reviewed for preferred status. Oral presentations must meet the following requirements:

(a) Limited to five (5) minutes per drug class.

(b) Limited to one (1) representative and one (1) presentation per product.

(c) Limited to branded products within the class being considered.

(d) No cost information can be addressed. Inclusion of cost information will terminate the presentation.

(e) Must submit a one (1) page summary of the presentation twenty-one (21) calendar days prior to the meeting. See 10(a) above.

(f) Must provide twenty (20) copies if summary is to be distributed to Committee members at meeting. Copies must be submitted to Medicaid at sign-in.

(g) Presenters must sign-in at the registration table a minimum of ten (10) minutes prior to the scheduled start time of meeting. Failure to sign-in will result in elimination of the oral presentation.

(h) No visual aids other than designated handouts are allowed.

(12) Manufacturers may request a reconsideration of a clinical recommendation of the Pharmacy and Therapeutics Committee. Written requests should be submitted to the Medicaid Pharmacy Director and received no later than thirty (30) calendar days following the posting of the final Preferred Drug List to the Medicaid website. Requests must include clinical documentation including references to justify a reconsideration. Manufacturer contact information should be included with the submission. Medicaid will respond to requests for reconsideration within ninety (90) calendar days of receipt.

Author: Allison Scott, Preferred Drug List Administrator
Statutory Authority: State Plan Attachment 3.1-A and 4.18-B; Title XIX, Social Security Act; 42 CFR Section 447.331 & Section 401, et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508).
History: New Rule Filed June 21, 2004; Effective September 17, 2004. **Amended:** Filed September 11, 2015; effective October 16, 2015.

Rule No. 560-X-16-.28 Prior Authorization

(1) The use and payment of drug items may be restricted and require prior authorization. The Alabama Medicaid Agency will utilize the Pharmacy and Therapeutics Committee to review and recommend drugs for prior authorization.

(2) Drug class is defined as a therapeutic group of pharmaceutical agents approved by the FDA as defined by the American Hospital Formulary Service. Medicaid or the Pharmacy and Therapeutics Committee may recommend a review to determine if prior authorization is appropriate for a single drug or a drug class. The Pharmacy and Therapeutics Committee will conduct such reviews, submit clinical data to Medicaid and make a recommendation. The Medicaid Commissioner will make the determination for placement on prior authorization.

(3) The requirement for prior authorization of a drug will be based on a clinical review by the Pharmacy and Therapeutics Committee of all relevant clinical and medical considerations including, but not limited to, Medicaid Drug Utilization Review (DUR) data, Surveillance Utilization Review (SUR) data, potential abuse, misuse, or inappropriate prescribing and/or dispensing patterns by Alabama providers, inconsistency with FDA approved labeling, inconsistency with uses recognized in the American Hospital Formulary Service Drug Information, the authoritative source on sound clinical

evidence found in labeling, drug compendia, and peer reviewed clinical literature on use of the drug.

(4) Clinical bases for recommendations of the Pharmacy and Therapeutics Committee will be in writing and available upon written request. Recommendations contrary to prevailing clinical evidence will be justified in writing and available upon written request. Medicaid will prepare a synopsis of the clinical reasoning supporting recommendations which will be available upon written request.

(5) Medicaid may require prior authorization for generic drugs only in instances when the cost of the generic product is significantly greater than the net cost of the brand product in the same American Hospital Formulary Services (AHFS) therapeutic class or when there is a clinical concern regarding safety, overuse or abuse of the product. Medicaid must document the reason for prior authorization of any generic product to include the cost effectiveness of such action or clinical concern.

(6) Medicaid will develop a set of medical criteria specifying the requirements for coverage authorization. The criteria will be available to the public.

(7) Requests for prior authorization must be initiated by the practitioner when deemed medically necessary.

(8) Prior authorizations will be reviewed by Medicaid or its designated agent. When medical criteria as determined by Medicaid are met, the prior authorization will be granted. If denied, adequate medical justification may be submitted in writing by the prescribing physician for reconsideration.

(9) Responses to requests for prior authorization should be issued within eight (8) hours but in no case more than twenty-four (24) hours after receipt of the request. In cases of emergency, provisions are made for dispensing a seventy-two (72) hour supply of a covered outpatient prescription drug.

(10) Effective March 18, 2011, the Alabama Medicaid Agency will implement a Gold Standard Program, an incentive program for high PDL compliant prescribing providers that will reward a limited group of providers with prior authorization (PA) exemption of drugs when certain prescription-based criteria are met in a given timeframe on a regular basis. Certain exclusions will apply. Alabama Medicaid will determine which providers meet and maintain the Gold Standard program criteria on a regular basis.

Author: Tiffany Minnifield, Associate Director, Pharmacy Administrative Services.
Statutory Authority: State Plan Attachment 3.1-A and 4.19-B; Title XIX, Social Security Act; 42 CFR Section 447.331 & Section 401, et seq.; Omnibus Budget Reconciliation Act of 1990 (Public Law 101-508).

History: New Rule Filed June 21, 2004; Effective September 17, 2004. **Amended:** Filed April 20, 2005; effective July 15, 2005. **Amended:** Filed December 20, 2010; effective March 18, 2011.

Rule No. 560-X-16-.29 Annual Report

(1) The DUR Board must submit an annual report to the Medicaid Agency containing information specified by the state. The Agency must submit, annually, a report to the secretary of Health and Human Services through the HCFA Regional Office that incorporates the DUR Board Report. It must include:

(a) A description of the nature and scope of the prospective drug review program.

(b) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

(c) Detailed information on the specific criteria and standards in use.

(d) A description of the steps taken by the State to include in the prospective and retrospective DUR program drugs dispensed to residents of a nursing facility that is not in compliance with approved drug regimen review procedures.

(e) A description of the actions taken by the State Medicaid agency and the DUR Board to ensure compliance with he requirements for predetermined standards and with the access to the predetermined standards requirement.

(f) A description of the nature and scope of the retrospective DUR program.

(g) A summary of the educational interventions used and an assessment of the effective of these educational interventions on the quality of care.

(h) A description of the steps taken by the State Agency to monitor compliance by pharmacies with the prospective DUR counseling requirements contained in Federal and State laws and regulations.

(i) Clear statements of purpose that delineate the respective goals, objectives, and scopes of responsibility of the DUR and surveillance and utilization review (SUR) functions.

(j) An estimate of the cost savings generated as a result of the DUR program. This report must identify costs of DUR and savings to the Medicaid drug program attributable to prospective and retrospective DUR.

Authority: State Plan, Title XIX, Page 74b; Social Security Act; 42 CFR Section 440.120; Public Law 101-508. Emergency rule effective July 1, 1993. Permanent rule effective October 28, 1993. The effective date of this amendment is February 11, 1997.

Rule No. 560-X-16-.30 Hospice Services

(1) Reimbursement for disease specific drugs related to the recipient's terminal illness and drugs related to the terminal illness found on the Hospice Palliative Drug List (HPDL) are included in the per diem for hospice covered services and will not be reimbursed through the Medicaid Pharmacy Program. The HPDL is on the agency website at www.medicaid.alabama.gov.

Author: Kelli Littlejohn, RPh, Director, Pharmacy Services
Statutory Authority: Title XIX, Social Security; 42 CFR Section 418.302; State Medicaid Manual; and State Plan.
History: New Rule: Filed April, 20, 2007; effective August 1, 2007.

Rule No. 560-X-16-.31 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.

(c) 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, CME or CEU) 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 must be recognized by a state or national health care professional accrediting body.

(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 and document, 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 and document 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. Providers should attempt to achieve the lowest assay percentage in each case. Variance in assay to prescription/target dose should not exceed +/- 10%.

(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 and/or the Agency may seek recoupment. Providers are to attest each year of their understanding and willingness to follow the standards by signing a new Standard of Care agreement each year.

Author: Kelli D. Littlejohn, RPh, Pharm D, Director, Pharmacy Services
Statutory Authority: State Plan, Attachment 3.1-A and Attachment 4.19-B; Title XIX, Social Security Act; 42 CFR Section 430.0, et seq.
History: New Rule: Filed September 20, 2007; effective December 14, 2007. **Amended:** Filed March 14, 2014; effective April 18, 2014.