Health, Department of

Medicaid

Chapter 10: Pharmaceutical Services

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WYOMING MEDICAID RULES

CHAPTER 10

PHARMACEUTICAL SERVICES

Section 1. Authority.

This Chapter is promulgated by the Department of Health pursuant to the Medical Assistance and Services Act at W.S. 42-4-101 et seq. and the Wyoming Administrative Procedures Act at W.S. 16-3-101 et seq.

Section 2. Purpose and Applicability.

(a) This Chapter establishes the standards and procedures for the provision of and payment for pharmaceutical services under Medicaid. It shall apply to all pharmaceutical services provided on the effective date of this rule.

(b) The Department shall issue Provider Manuals, Provider Bulletins, or both, to interpret the provisions of this Chapter. Such Provider Manuals and Provider Bulletins shall be consistent with and reflect the policies contained in this Chapter. The provisions contained in Provider Manuals or Provider bulletins shall be subordinate to the provisions of this Chapter.

Section 3. General Provisions.

(a) Terminology. Except as otherwise specified, the terminology used in this Chapter is the standard terminology and has the standard meaning used in health care, Medicaid, and Medicare.

(b) The incorporation by reference of any external standard is intended to be the incorporation of that standard as it is in effect on the effective date of this Chapter.

Section 4. Definitions. The following definitions shall apply in the interpretation and enforcement of these rules. Where the context in which words are used in these rules indicates that such is the intent, words in the singular number shall include the plural and vice versa. Throughout these rules gender pronouns are used interchangeably except where the context dictates otherwise. The drafters have attempted to utilize each gender pronoun in equal numbers in random distribution. Words in each gender shall include individuals of the other gender.

(a) "AB Rated." Drug products made by different distributors and/or repackagers that are considered therapeutically equivalent based on demonstrated bioequivalence.

(b) "Abuse." "Abuse" as defined in Chapter 16, which definition is incorporated by this reference.

(c) "Average wholesale price" or "AWP." The average wholesale price as computed intermittently by First Data Bank, its agent, designee, or successor.

(d) "Board of Pharmacy." The Wyoming State Board of Pharmacy, its agent, designee or successor.

(e) "Board of Pharmacy Chapter 9." Chapter 9, Patient Counseling and Drug Use Review Regulations, of the Wyoming State Board of Pharmacy Rules.

(f) "Brand name." The proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label or wrapping at the time of packaging.

(g) "CMS." The Centers for Medicare and Medicaid Services, its agent, designee, or successor.

(h) "Chapter 1." Chapter 1, Rules for Medicaid Administrative Hearings, of the Wyoming Medicaid Rules.

(i) "Chapter 3." Chapter 3, Provider Participation, of the Wyoming Medicaid Rules.

(j) "Chapter 4." Chapter 4, Third Party Liability, of the Wyoming Medicaid Rules.

(k) "Chapter 6." Chapter 6, Health Check (formerly EPSDT), of the Wyoming Medicaid Rules.

(l) "Chapter 7." Chapter 7, Wyoming Nursing Home Reimbursement System, of the Wyoming Medicaid Rules.

(m) "Chapter 9." Chapter 9, Hospital Services, of the Wyoming Medicaid Rules.

(n) "Chapter 16." Chapter 16, Medicaid Program Integrity, of the Wyoming Medicaid Rules.

(o) "Chapter 26." Chapter 26, Covered Services, of the Wyoming Medicaid Rules.

(p) "Chapter 29." Chapter 29, Medicaid Case Management, of the Wyoming Medicaid Rules.

(q) "Chapter 39." Chapter 39, Recovery of Excess Payments, of the Wyoming Medicaid

Rules.

(r) "Claim." A request by a provider for Medicaid payment for services provided to a recipient.

(s) "Compound drug." A mixture of two or more ingredients to form a drug.

(t) "Copayment." The charge to a recipient seeking pharmaceutical services.

(u) "Covered services." Services which are Medicaid reimbursable pursuant to the rules of the Department.

(v) "Department." The Wyoming Department of Health, its agent, designee or successor.

(w) "Device." Equipment or apparatus used to remedy or compensate for a physical deficiency, e.g., a prosthetic device.

(x) "Dispensing fee." The amount of Medicaid reimbursement allowed by the Department as payment for the service of dispensing any prescribed drug as determined pursuant to Section 16. Until redetermined pursuant to that Section, the dispensing fee is $5.00.

(y) "DUR board." The Wyoming Drug Utilization Review Board, established pursuant to 42 C.F.R. § 456.716, which is incorporated by this reference.

(z) "DUR requirements." The Drug Use and Review Requirements as set forth in Board of Pharmacy Chapter 9 and 42 C.F.R. Part 456, which requirements are incorporated by this reference.

(aa) "Drug."

(i) Substances recognized as drugs in official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them, all of which are incorporated by this reference;

(ii) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in a person;

(iii) Substances (other than food) intended to affect the structure or any function of a person's body; or

(iv) Substances intended for use as a component of any article specified in (I) through

(iii).

(v) “Drug” includes over-the-counter (OTC) drugs.

(bb) "Drug Efficacy Study Implementation (DESI) drugs." Drugs determined by the United States Food and Drug Administration, to be less than effective. This definition applies to all drugs which are similar, related, or identical to DESI drugs pursuant to FDA designation. Compound formulations which contain a DESI drug are considered to be DESI drugs.

(cc) "Elderly and physically disabled waiver services." Services provided to elderly and/or physically disabled persons pursuant to section 1915 (c) of the Social Security Act (codified at 42 U.S.C. 1396n).

(dd) “Emergency." The sudden onset of a medical condition, including labor and delivery, manifesting itself by acute symptoms of sufficient severity (including severe pain) that the absence of immediate medical attention could reasonably be expected to result in:

(i) Placing the patient's health in serious jeopardy;

(ii) Serious impairment of bodily functions; or

(iii) Serious dysfunction of any bodily organ or part.

(ee) "Estimated acquisition cost" or "EAC." The cost of drugs for which no Federal Upper Limit price has been determined. The EAC is the department's best estimate of the price generally and currently paid by providers in the state for a drug marketed or sold by a particular manufacturer or laborer in the package size of drug most frequently purchased by providers. The EAC for a drug is:

(i) AWP minus eleven percent (11%); or

(ii) the Department may set an allowable acquisition cost for specified drugs or drug categories when the department determines that acquisition cost is lower than (i) based on data provided by the drug pricing file contractor.

(ff) “Excess payment." "Excess payment" as defined in Chapter 39, which definition is incorporated by this reference.

(gg) "FDA." The Food and Drug Administration of the United States of America, its agent, designee, or successor.

(hh) "Federal Upper Limit" or "FUL." The CMS established upper limit for multiple source

drugs.

(ii) "Formulary." A compilation, by the Department, of therapeutically effective drugs and medical supplies deemed appropriate by the Department for inclusion in the formulary. The formulary may be changed from time to time.

(i) New or different legend drugs will automatically be added to the formulary if:

(A) There is a rebate agreement in effect which meets the requirements of Pub. L. No. 101-508, Section 4401(a) including any amendments or updates; and

(B) The drug is not within a class of drugs which is not a covered service.

(ii) OTC drugs may be added to the formulary if they become covered services pursuant to subsection 9(f);

(iii) Medical supplies may be added to the formulary if they become covered services pursuant to subsection 9(h).

(iv) The Department shall distribute to providers a list of drugs and medical supplies which are excluded services. That list shall be distributed through Provider Manuals, Provider Bulletins, facsimiles, designated websites, or other appropriate means and shall be updated as necessary. Drugs which are not designated as excluded services shall be covered services. Medical supplies which are not designated as covered services shall be excluded services.

(jj) "Fraud." "Fraud" as defined in Chapter 16, which definition is incorporated by this reference.

(kk) "Hospital." "Hospital" as defined by Chapter 9, which definition is incorporated by this reference.

(ll) "Legend drug." A drug that is required by Federal law to be dispensed pursuant to a prescription.

(mm) "Local trade area." The geographic area surrounding the recipient's residence, including portions of states other than Wyoming, commonly used by other persons in the same area to obtain pharmaceutical services.

(nn) "Maintenance drug." Drugs furnished to an individual with a chronic illness or condition. The Department shall, from time to time, designate drugs as maintenance drugs based on therapeutic value, clinical consultation with practitioners, and applicable CMS guidelines. The Department shall disseminate

a current list of maintenance drugs which are covered services to providers through Provider Manuals, Provider Bulletins, facsimiles, designated websites, or other appropriate means.

(oo) "Medicaid." Medical assistance and services provided pursuant to Title XIX of the Social Security Act and/or the Wyoming Medical Assistance and Services Act. "Medicaid" includes any successor or replacement program enacted by Congress or the Wyoming Legislature.

(pp) "Medicaid allowable payment." The maximum Medicaid reimbursement for covered services as specified by this Chapter.

(qq) "Medicaid Fraud Control Unit (MFCU)." The Medicaid Fraud Control Unit of the Wyoming Attorney General's Office, its agent, designee, or successor.

(rr) "Medically necessary." A pharmaceutical service that is:

(i) Consistent with the recipient's diagnosis or condition;

(ii) Recognized as the prevailing standard or current practice among the provider's peer group; and

(iii) Rendered in response to a life-threatening condition or pain; to treat an injury, illness or infection; to treat a condition that could result in physical or mental disability; to care for a mother and child through the maternity period; or to achieve a level of physical or mental function which is consistent with prevailing community standards; or is a preventive pharmaceutical service.

(ss) "Medical supplies." Disposable, semi-disposable or expendable medical supplies. "Medical supplies" does not include durable medical equipment, oxygen or oxygen supplies.

(tt) "Medicare." The health insurance program for the aged and disabled under Title XVIII of the Social Security Act.

(uu) "Medicare cross-over claim." A claim seeking reimbursement for a pharmaceutical service provided to a person who is eligible for Medicaid and Medicare.

(vv) "PDAP rule." Chapter 1, Prescription Drug Assistance Program, of the Department's rules.

(ww) "Multiple source drug." A drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names .

(xx) "National drug code" or "NDC." The code number determined for and assigned to a drug by the FDA.

(yy) "Nursing facility." "Nursing facility" as defined in Chapter 7, which definition is incorporated by this reference.

(zz) "Nursing facility services." "Nursing facility services" as defined in Chapter 7, which definition is incorporated by this reference.

(aaa) "One month supply." The quantity of drugs sufficient to last up to thirty-four

(34) days.

(bbb) "Overpayments." "Overpayments" as defined in Chapter 39, which definition is incorporated by this reference.

(ccc) "Over-the counter (OTC) drugs." Drugs which are legally available without a prescription.

(ddd) "Pharmaceutical service." Drugs, devices or medical supplies that are covered services.

(eee) "Pharmacist." A person licensed to practice pharmacy by the Wyoming State Board of Pharmacy or a similar board or agency in another state.

(fff) "Pharmacy." An entity licensed to operate a pharmacy by the Wyoming State Board of Pharmacy or a similar board or agency in another state.

(ggg) "Physician." A person licensed to practice medicine or osteopathy by the Wyoming State Board of Medical Examiners or a similar board or agency in another state.

(hhh) "Practitioner." A physician or other licensed practitioner of the healing arts authorized to prescribe drugs and practicing within the scope of professional practice as defined under Wyoming Statutes or the laws of another state.

(iii) "Preferred Drug List." A listing of services for selected therapeutic classes that the Department in consultation with the Preferred Drug List Advisory Committee has determined to represent clinical effectiveness and is available at a better price compared with other services in a particular class.

(jjj) "Preferred Drug List Advisory Committee (PDLAC)." An advisory committee.

(i) Composition. The PDLAC shall consist of ten members: four physicians, three

pharmacists, two representatives of health insurance companies, and one consumer. The PDLAC shall also have two ex-officio members: a physician affiliated with the Department and DUR Coordinator, provided he or she is an R.Ph.

(ii) Appointment and terms of service. The members of the PDLAC shall be appointed by and serve at the pleasure of the Director of the Department, or the Director's designee. Each member shall serve until a replacement is named, the member resigns, or the member is removed by the Director. Members shall not receive compensation for their service, but shall be reimbursed for their reasonable travel expenses, and may receive an honorarium as established by the Director.

(iii) Responsibilities. The PDLAC shall meet no more than four times per year, unless otherwise determined by the Director, and shall review evidence-based research and provide recommendations to the Department as to the clinical effectiveness

of a service within a therapeutic drug class.

(kkk) "Prescription." A written, faxed, or oral order, as required by the Board of Pharmacy, from a practitioner that a certain drug, medical supply, device or service is medically necessary.

(lll) "Prescription drug." A drug, including a legend drug, or medical supply that is:

(i) Prescribed by a practitioner acting within the scope of his practice; and

(ii) Dispensed by a provider pursuant to a written prescription that is recorded and maintained in the provider's records.

(mmm) "Prior authorized." Approved prior to distribution or sale pursuant to Section 13.

(nnn) "Provider." A pharmacy, pharmacist or physician that is:

(i) Located in the State of Wyoming and has signed a provider agreement; or

(ii) Located outside the State of Wyoming, and

(A) Within the local trade area and has signed a provider agreement;

(B) Provides pharmaceutical services to a recipient:

(I) As the result of an emergency which occurs while the recipient is outside the State of Wyoming; or

(II) Who is less than 19 years of age;

and:

(1) Is a foster child not covered by Title IV-E of the Social Security Act and resides with a foster family outside the State of Wyoming; or

(2) Has been placed in an out-of-state institution.

(ooo) "Provider Agreement." A provider agreement as defined by Chapter 3, which definition is incorporated by this reference.

(ppp) "Recipient." A person who has been determined eligible for Medicaid.

(qqq) "Recipient age twenty-one or over." A recipient after the month in which he or she turns twenty-one years of age.

(rrr) "Recipient under age twenty-one." A recipient before or during the month in which he or she turns twenty-one years of age.

(sss) "Residence." The place a recipient uses as his or her primary dwelling place, and intends to continue to use indefinitely for that purpose.

(ttt) "Service limitations." "Service limitations" as defined by the PDAP rule, which definition is incorporated by this reference.

(uuu) "Services." Drugs, medical supplies and devices that are reimbursable pursuant to this Chapter.

(vvv) "Services and supplies included in the per diem rate." "Services and supplies included in the per diem rate" as defined in Chapter 7, which definition is incorporated by this reference.

(www) "Swingbed." A bed in a hospital which is certified for either inpatient hospital services or nursing facility services.

(xxx) "TPL waiver." A waiver granted by CMS of the third party liability requirements of Chapter 4.

(yyy) "Usual and customary." The provider's charge to the general public for the same or similar services.

(zzz) "Wholesaler." An individual or entity that furnishes drugs, medical supplies, or both, to pharmacies or pharmacists.

Section 5. Provider participation.

(a) Compliance with Chapter 3. An individual or entity that wishes to receive Medicaid funds for pharmaceutical services furnished to a recipient must meet the requirements of Chapter 3, which requirements are incorporated by this reference.

(b) Eligible pharmaceutical services providers.

(i) Pharmacies;

(ii) Pharmacists; and

(iii) Physicians who practice in a local trade area where pharmacy services are not available from a pharmacy or pharmacist may enroll as a Medicaid pharmacy services provider. Except as otherwise specified in this Chapter, such as a

physician must meet the standards and follow the procedures established for a pharmacist provider.

Section 6. Provider records.

(a) Compliance with Chapter 3. A provider of pharmaceutical services must comply with the record-keeping requirements of Chapter 3, which are incorporated by this reference.

(b) Additional requirements. In addition to the requirements of Chapter 3, providers of pharmaceutical services must retain records that include:

(i) Invoices for drugs. Pharmacies must be able to supply all drug invoices in the format requested by the Department. This format may include but is not limited to: paper, electronic, or generated and sent by wholesaler.

(ii) Prescriptions. All prescriptions must be reduced to writing. Prescriptions for brand name drugs must contain the certification "medically necessary," in the prescribing practitioner's hand-writing, must be received and on file within thirty days after the oral prescription, and must meet the requirements as defined in Section 10;

(iii) A signature log in the form specified by the Department;

(iv) Recipient account records; and

(v) Copies of claim forms.

Section 7. Verification of recipient data. A provider of pharmaceutical services must comply with the verification of recipient data requirements of Chapter 3, which are incorporated by this reference.

Section 8. DUR requirements. A provider of pharmaceutical services must comply with the DUR requirements.

Section 9. Covered services.

(a) Prescription drugs. Prescription drugs included in the formulary are covered in the quantity prescribed by a practitioner, subject to the dispensing limitations of Section 10 and the exclusions of Section 12.

(b) Refill of prescription. In addition to the criteria specified in subsection (a), a refill of a prescription must:

(i) Be authorized by the practitioner who originally prescribed the drug; and

(ii) Such authorization must conform to State and Federal laws governing prescription refills.

(c) Brand name drugs certified in writing as medically necessary by the prescribing practitioner.

(d) Compound drugs are paid per line item if each ingredient is a prescription or OTC drug covered pursuant to subsections (a) and (e), and is not classified by the FDA as a DESI drug. One dispensing fee is paid per compound prescription.

(e) OTC drugs and medical supplies. The OTC drugs specified in subsection (f) and (g) and the medical supplies specified in subsection (h) are covered services if:

(i) Furnished to a recipient who is not a resident of a nursing facility, not admitted as an inpatient or outpatient in a hospital, and not occupying a swingbed;

(ii) Prescribed by a practitioner;

(iii) The drug has been assigned an NDC number; and

(iv) Are medically necessary.

(f) Covered OTC drugs and products . OTC drugs or products as designated by the Department. The Department shall, from time to time, designate OTC drugs as covered services based on their therapeutic value, clinical consultation with practitioners and applicable CMS guidelines. The Department shall disseminate a current list of OTC drugs which are covered services to providers through Provider Manuals, Provider Bulletins, facsimiles, designated websites, or other appropriate means.

(g) Procedure for requesting coverage of OTC drugs not covered pursuant to subsection (f). A practitioner, or a pharmacist on behalf of a practitioner, may request that an OTC drug not covered pursuant to subsection (f) be considered for coverage. Such request shall be directed to the Department and shall be in the form and contain the information specified by the Department. The Department may limit coverage to specified recipients for a specified period of time, or the Department may add the OTC drug to the formulary.

(h) Medical supplies which have been:

(i) Assigned an NDC;

(ii) Prescribed by a practitioner; and

(iii) Designated as covered medical supplies by the Department.

(A) The Department shall, from time to time, designate medical supplies as covered services based on their therapeutic value, clinical consultation with

practitioners and applicable CMS guidelines.

(B) The Department shall disseminate a current list of medical supplies which are covered services to providers through Provider Manuals, Provider Bulletins, facsimiles, designated websites, or other appropriate means.

Section 10. Dispensing limitations.

(a) Generic drugs. Practitioners must prescribe generic drugs except when name brand drugs are medically necessary and the appropriate prior authorization criteria has been met or there is not an AB rated generic available.

(b) Quantities dispensed.

(i) Maintenance drugs.

(A) Minimum quantities. Except as provided in subparagraph (c) maintenance drugs shall be dispensed in a quantity sufficient for at least a one month supply.

(B) Maximum quantities. Maintenance drugs shall not be dispensed in an amount which exceeds a ninety (90) day supply.

(C) Less than a one month supply of a maintenance drug may be dispensed to allow a recipient to be stabilized on a new or adjusted maintenance drug.

(ii) Oral contraceptives. The maximum quantity of oral contraceptive which may be dispensed is a three month supply.

(iii) All other drugs. The maximum quantity dispensed for all other conditions shall be a one-month supply.

(c) Days supply. A prescription's day supply must equal the quantity of drug dispensed divided by the daily dose prescribed. A prescription claim will be subject to subsequent recovery if:

(i) The days supply submitted is not supported by the dosing direction as prescribed.

(ii) The dosing directions are given as take as directed and the pharmacist has not taken appropriate action to obtain and document on the prescription the actual dosing directions given by the practitioner.

(iii) Extra Doses. The Department does not pre-emptively pay for extra doses in the anticipation of lost or wasted medication.

Section 11. Relationship to other programs.

(a) This Chapter does not affect the service limitations or copay requirement of the PDAP rule.

(b) This Chapter does not limit the services available to recipients under age twenty-one pursuant to Chapter 6.

(c) This Chapter does not affect services available pursuant to Chapter 29.

Section 12. Excluded services.

(a) The following prescription drugs are excluded:

(i) Anorexiants, except Amphetamines and derivatives which are prescribed for narcolepsy and hyperkinetic conditions;

(ii) Fertility drugs;

(iii) Hair growth products;

(iv) Weight gain agents, including androgenic or anabolic steroid agents when used for weight gain;

(v) Cosmetic agents such as Retin-A, provided to recipients age twenty-one or over; and

(vi) Products containing nicotine and used for smoking cessation.

(b) OTC drugs and medical supplies except as designated in Section 9(e).

(c) DESI drugs.

(d) Drugs supplied by a manufacturer that has not entered into and does not have in effect a rebate agreement which meets the requirements of Pub. L. No. 101-508, Section 4401(a), including any amendments or updates, except as otherwise specified by that Section. Pub. L. No. 101-508, Section 4401(a) is hereby incorporated by this reference.

(e) Any services and supplies included in the per diem which are furnished to a resident of a nursing home, an individual admitted as an inpatient or an outpatient in a hospital, or an individual in a swingbed, are not separately reimbursable pursuant to this Chapter

Section 13. Prior authorization.

(a) Procedures. A provider seeking reimbursement for services which require prior authorization shall request prior authorization pursuant to the procedures and in the format specified by the Department and disseminated to providers through Provider Manuals or Provider Bulletins.

(i) Criteria for review. Prior authorization shall be granted if the proposed services:

(A) Are covered services;

(B) Are consistent with the recipient's diagnosis;

(C) Are medically necessary;

(D) Are cost-effective;

(E) Meet the criteria established by the rules of the Department; and

(F) Are not reimbursable by any third party payer.

(ii) Denial of prior authorization. The Department shall provide written notice of the denial of prior authorization to the provider and the recipient.

(A) If a request for prior authorization is denied, the provider may submit a revised request for prior authorization or additional documentation as necessary for the Department to reconsider the matter; or

(B) The provider or recipient may request reconsideration of the denial of prior authorization pursuant to Chapter 3. If a timely request for reconsideration is made, the services shall be furnished for up to sixty days while the Department reconsiders the denial. The Department shall provide a written notice of its decision on reconsideration.

(C) The denial of prior authorization precludes Medicaid reimbursement for the services in question, except to the extent services are furnished pending reconsideration pursuant to (B).

(iii) Failure to timely request prior authorization. The failure to obtain prior authorization before providing services which require prior authorization precludes Medicaid reimbursement for such services.

(iv) Effect of prior authorization. Granting prior authorization shall constitute approval for the provider to receive Medicaid reimbursement for the approved services to be furnished, subject to the other requirements of this and the other Medicaid rules of the Department and post payment review. Prior authorization is not a guarantee of the recipient's eligibility or a guarantee of Medicaid payment.

(b) Services that require prior authorization.

(i) This and other rules of the Department specify services that require prior authorization.

(ii) Designation of additional services. The Department may designate additional services that require prior authorization pursuant to this paragraph.

(A) Request for designation. The Department, the DUR Board, a provider, a recipient, an organization of providers or recipients, or any other person, may request that the Department consider designating a service as requiring prior authorization. Except when requested by the Department, such a request shall be delivered to the Department, in the form and manner specified by the Department.

(B) Referral to the DUR Board. Any request for designation received by or made by the Department shall be referred to the DUR Board.

(C) Review by DUR Board. The DUR Board shall review a referral received

from the Department to designate a service as requiring prior authorization. In reviewing any such referral, the DUR Board shall consider the:

(I) Clinical efficacy of the service as demonstrated by:

(1) peer-reviewed clinical literature;

(2) nationally recognized practice standards: and/or

(3) the consensus of the members of the DUR Board;

(II) Cost effectiveness of the service;

(III) Potential for over-utilization of the services; and

(IV) The availability of lower cost alternatives.

(V) The DUR Board may provide notice to interested parties of services which are under consideration for designation as requiring prior authorization, the criteria to be applied to such services, and solicit comments from such parties.

(D) Recommendation to the Department. The DUR Board shall make a recommendation to the Department about whether it should designate a service as requiring prior authorization. Such recommendation shall include the criteria to be used in determining whether to prescribe such service(s).

(E) Consideration of recommendation. The Department shall

consider the recommendation of the DUR Board in determining whether to designate services as requiring prior authorization. The Department may also consider information from CMS, and other sources of clinical information, which it deems relevant to the determination. The Department shall not be bound by the recommendation of the DUR Board, but the Department shall not designate a service as requiring prior authorization until it has received the DUR Board's recommendation.

(iii) Notice of services which require prior authorization.

(A) The Department shall, from time to time, disseminate a current list of services which require prior authorization to providers through Provider Manuals, Provider Bulletins, facsimilles, designated websites., or other appropriate means.

(B) If additional services are designated pursuant to this section, the Department shall disseminate notice of the additional service(s) which require prior authorization to

providers through Provider Manuals, Provider Bulletins, facsimilled, designated websites, or other appropriate means.

Section 14. Copayment.

(a) Recipients must pay a $3.00 per prescription copayment for non-preferred Brand Name drugs, or a $2.00 per prescription copayment for preferred Brand Name drugs, or a $1.00 per prescription copayment for multiple source drugs, except as specified in subsection (b).

(b) This does not affect the copayment requirements of the PDAP rule.

(c) Exemptions. The following recipients and pharmaceutical services are exempt from the copayment requirement:

(i) Residents of a nursing facility or in swingbeds;

(ii) Family planning products;

(iii) Pharmaceutical services provided to a pregnant recipient; and;

(iv) Pharmaceutical services provided to a recipient under age twenty-one;

(d) Notification of copayment amount. The Department shall notify providers of the copayment amount by means including but not limited to Provider Manuals, Provider Bulletins, facsimilles or designated websites. The Department shall notify recipients by bulletin.

(e) Collection of copayment. Providers are responsible for collecting the copayment. The amount of the copayment shall be automatically deducted by the

Department from the Medicaid allowable payment, regardless of whether the copayment is actually paid.

(f) Prohibition or denial of services. A provider may not deny pharmaceutical services to a recipient because of the recipient's inability to make the copayment, except when:

(i) A recipient regularly refuses to make copayments.

(ii) A recipient who refuses to make a copayment two or more times has "regularly refused" to make copayments for purposes of this Section.

Section 15. Preferred Drug List.

(a) Procedures. A service may be placed on the Preferred Drug List if the service:

(i) Is a covered service

(ii) Is cost-effective

(iii) Evidence-based research is available and has been reviewed by the PDLAC.

(b) Services that require listing on the Preferred Drug List.

(i) Review by the Preferred Drug List Advisory Committee. The PDLAC shall review services of the same therapeutic class in order to determine if one or more services are more clinically effective than others in the same class, or if all services in the class are determined to be clinically equivalent. In reviewing therapeutic classes, the PDLAC shall consider the clinical efficacy of the services as determined by consensus of the PDLAC utilizing:

(A) evidence-based research reports;

(B) peer-reviewed clinical literature; and/or

(C) nationally recognized practice standards.

(ii) The PDLAC may provide notice to interested parties of services which are under consideration for designation on the Preferred Drug List, the criteria applied to such services, and solicit comments from such parties.

(iii) Recommendation to the Department. The PDLAC shall make a recommendation to the Department about whether one or more services are more clinically safe or effective than others in the same therapeutic class.

(iv) Consideration of recommendation. The Department shall consider the recommendation of the PDLAC in determining whether to assign services to the Preferred Drug List. The Department may also consider information from CMS, and other sources of clinical information, which it deems relevant to the determination. The Department shall not be bound by the recommendations of the PDLAC, but the Department shall not assign services to the Preferred Drug List until it has received and considered the PDLAC's recommendation.

(c) Once the Department has chosen services for the Preferred Drug List for a therapeutic class, the Department will refer all non-preferred services to the DUR Board for recommendations on prior authorization, and the criteria to be used for those services.

(i) As new drugs in a therapeutic class are introduced, the DUR Board may change or update prior authorization criteria to include the new service(s) until the PDLAC can make recommendations to the Department in regard to the service(s).

(ii) In the event the Department changes the preferred service for a therapeutic class, the Department may ask the DUR Board to review and update the prior authorization criteria based upon changes to the non-preferred services.

(d) The Department may make changes to the Preferred Drug List for a therapeutic class based upon recommendations from the PDLAC or changes in pricing.

(e) Notice of services on the Preferred Drug List

(i) If additional services are designated pursuant to this section, the Department shall disseminate notice of the additional services on the Preferred Drug List to providers through Provider Bulletins or Provider Manuals, and/or a designated website.

(f) Procedure for requesting other service coverage. A provider seeking reimbursement for services not listed as the Preferred Drug in its therapeutic class may request prior authorization pursuant to the procedures as defined in Section 13.

Section 16. Medicaid Allowable payment.

(a) Reimbursement Limits. Except as otherwise specified in this section, the Medicaid allowable payment for pharmaceutical services shall be the lower of:

(i) The estimated acquisition cost of the ingredient(s) plus the dispensing fee specified in subsection (d); or

(ii) The provider's usual and customary charge.

(b) Multiple source drugs. The Medicaid allowable payment for multiple source drugs shall be the lower of:

(i) The cost of the drug as determined pursuant to 42 C.F.R. 447.331-332, which regulations are hereby incorporated by reference, plus the dispensing fee specified in subsection (d); or

(ii) The provider's usual and customary charge.

(c) Dispensing fee. Except as specified below, the dispensing fee shall be the lower of the provider's usual and customary dispensing fee or the dispensing fee. The dispensing fee shall be adjusted as specified in subsection (e).

(i) Physicians. The dispensing fee for physicians who dispense pharmacy services shall be $2.00 per prescription.

(d) Adjustment of dispensing fee. The dispensing fee shall be adjusted pursuant to subsection (f) when necessary to:

(i) Enlist enough providers so that pharmaceutical services are available to recipients to the extent that those services are available to the general population; and

(ii) Ensure that payments are consistent with efficiency, economy and quality of care.

(e) Method of adjusting dispensing fee. The dispensing fee shall be adjusted as follows:

(i) The Department shall conduct a usual and customary survey which may include a review of other insurance payers in-state, and Medicaid pharmacy programs in surrounding areas.

(ii) Using the data collected pursuant to paragraph (I), the Department shall redetermine the fee.

(iii) The Department may use an appropriate indicator of pharmacy costs to adjust the dispensing fee.

(iv) The Department shall notify providers of any adjustment in the dispensing fee through a Provider Manual, Provider Bulletin, facsimiles, designated websites, or other appropriate means.

(f) Prescription splitting. If a provider does not have sufficient supplies of a drug to fill a prescription completely, the provider may fill the prescription to the extent possible and claim a dispensing fee. When the balance of the prescription is dispensed, the provider may not seek an additional dispensing fee.

(g) Proof of delivery. A Provider must maintain a signature log, in the form specified by the Department, to act as proof of delivery of prescription drugs. Each recipient, or an individual acting on behalf of the recipient, must sign the log each time a prescription drug is delivered. For prescription drugs delivered to a nursing facility, the individual charged with ensuring the security of pharmaceutical supplies may sign the log after verifying delivery of all prescription drugs.

Section 17. Submission and Payment of claims.

(a) Except as otherwise specified in this Chapter, submission and payment of claims shall be pursuant to the provisions of Chapter 3, which are incorporated by this reference.

(b) Medicaid is the payer of last resort unless otherwise specified in a CMS TPL waiver for pharmaceutical services.

Section 18. Recovery of excess payments or overpayments.

(a) The Department may recover excess payments pursuant to Chapter 39, which is incorporated by this reference.

(b) The Department may recover overpayments pursuant to Chapter 16, which is incorporated by this reference.

Section 19. Audits.

(a) The Department or CMS may audit a provider at any time to determine whether the provider has received excess payments or overpayments.

(b) The Department or CMS may perform audits through employees, agents, or through a third party. Audits shall be performed in accordance with generally accepted auditing standards.

(c) Disallowances. The Department shall recover excess payments or overpayments pursuant to Chapter 39.

(d) Reporting audit results. If at anytime during a financial audit or a medical audit, the Department discovers evidence suggesting fraud or abuse by a provider, that evidence, in addition to the Department's final audit report regarding that provider, shall be referred to the MFCU.

Section 20. Reconsideration. A provider may request that the Department reconsider a decision to recover excess payments or overpayments. The request for reconsideration, the reconsideration, and any administrative hearing shall be pursuant to the reconsideration provisions of Chapter 3, which are incorporated by this reference.

Section 21. Disposition of recovered funds. The Department shall dispose of recovered funds pursuant to the provisions of Chapter 16, which provisions are incorporated by this reference.

Section 22. Interpretation of Chapter.

(a) The order in which the provisions of this Chapter appear is not to be construed to mean that any one provision is more or less important than any other provision.

(b) The text of this Chapter shall control the titles of its various provisions.

Section 23. Superseding effect. This Chapter supersedes all prior rules or policy statements issued by the Department, including Provider Manuals and Provider Bulletins, which are inconsistent with this Chapter.

Section 24. Severability. If any portion of this Chapter is found to be invalid or unenforceable, the remainder shall continue in full force and effect.