Certification Page
Regular and Emergency Rules

Revised September 2016

☐ Emergency Rules *(After completing all of Sections 1 through 3, proceed to Section 5 below)* ■ Regular Rules

1. General Information

a. Agency/Board Name Wyoming Department of Health		
b. Agency/Board Address 6101 Yellowstone Road, Suite 210	c. City Cheyenne	d. Zip Code 82002
e. Name of Agency Liaison Cori Cooper	f. Agency Liaison Telephone Number (307) 777-6016	
g. Agency Liaison Email Address cori.cooper@wyo.gov	h. Adoption Date January 9, 2019	
i. Program Medicaid		

2. Legislative Enactment

For purposes of this Section 2, "new" only applies to regular rules promulgated in response to a Wyoming legislative enactment not previously addressed in whole or in part by prior rulemaking and does not include rules adopted in response to a federal mandate.

a. Are these rules new as per the above description and the definition of "new" in Chapter 1 of the Rules on Rules?

■ No. ☐ Yes. Please provide the Enrolled Act Numbers and Years Enacted:

3. Rule Type and Information

a. Provide the Chapter Number, Title, and Proposed Action for Each Chapter.

(Please use the Additional Rule Information form for more than 10 chapters and attach it to this certification)

Chapter Number:	Chapter Name:	
10	Pharmaceutical Services	☐ New ■ Amended ☐ Repealed
		☐ New ☐ Amended ☐ Repealed
		☐ New ☐ Amended ☐ Repealed
		☐ New ☐ Amended ☐ Repealed
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		☐ New ☐ Amended ☐ Repealed
		☐ New ☐ Amended ☐ Repealed

3. State Government Notice of Intended Rulemaking

a. Date on which the Proposed Rule Packet (consisting of the Notice of Intent as per W.S. 16-3-103(a), Statement of Principal Reasons, strike and underscore format and a clean copy of each chapter of rules were: November 15, 2018

- approved as to form by the **Registrar of Rules**; and
- provided to the **Legislative Service Office** and **Attorney General:**

4. Public Notice of Intended Rulemaking

a. Notice was mailed 45 days in advance to all persons who made a timely request for advance notice. ☐ No. ■ Yes. ☐ N/A

b. A public hearing was held on the proposed rules. ■ No. ☐ Yes. **Please complete the boxes below.**

Date:	Time:	City:	Location:

c. If applicable, describe the emergency which requires promulgation of these rules without providing notice or an opportunity for a public hearing:

5. Final Filing of Rules

a. Date on which the Certification Page with original signatures and final rules were sent to the **Attorney General's Office for the Governor's signature:** January 11, 2019

b. Date on which final rules were approved as to form by the **Secretary of State** and sent to the Legislative Service Office: January 11, 2019

c. ■ The Statement of Reasons is attached to this certification.

6. Agency/Board Certification

The undersigned certifies that the foregoing information is correct.

Signature of Authorized Individual	Thomas O Forslund
Printed Name of Signatory	Thomas O. Forslund
Signatory Title	Director
Date of Signature	1/9/19

7. Governor's Certification

I have reviewed these rules and determined that they:

1. Are within the scope of the statutory authority delegated to the adopting agency;
2. Appear to be within the scope of the legislative purpose of the statutory authority; and, if emergency rules,
3. Are necessary and that I concur in the finding that they are an emergency.

Therefore, I approve the same.

Governor's Signature	
Date of Signature	

WYOMING MEDICAID RULES

AMENDMENT OF CHAPTER 10

PHARMACEUTICAL SERVICES

SUMMARY OF COMMENTS

The Wyoming Department of Health did not receive any public comments.

Chapter 10

Pharmaceutical Services

Wyoming Medicaid Rules

Intent to Amend Rules

Statement of Reasons

The Wyoming Department of Health proposes to amend Chapter 10 of the Department's Medicaid Rules pursuant to its statutory authority in the Wyoming Medical Assistance and Services Act at Wyoming Statutes §§ 42-4-101 through -121. Chapter 10 governs Pharmacy providers, defines covered pharmaceutical services, and establishes the process for reimbursement calculations for Pharmacy providers.

The Chapter 10 Amended Rule updates the State's reimbursement methodology for pharmacy providers and client copay responsibilities to align with the approved State Plan Amendment. Additionally, this amendment specifies the composition and duties of the Pharmacy and Therapeutics Committee.

The amendment also updates the rule's formatting and standard provisions in order to comply with current requirements.

As required by Wyoming Statute § 16-3-103(a)(i)(G), this proposed change meets minimum substantive state statutory requirements.

CHAPTER 10

PHARMACEUTICAL SERVICES

Section 1. Authority.

This Chapter is promulgated by the Department of Health pursuant to the Wyoming Medical Assistance and Services Act at Wyoming Statutes §§ 42-4-101 through -121.

Section 2. Purpose and Applicability.

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

(b) The Department may issue manuals and bulletins to interpret the provisions of this Chapter. Such manuals and bulletins shall be consistent with and reflect the policies contained in this Chapter. The provisions contained in manuals or bulletins shall be subordinate to the provisions of this Chapter.

Section 3. Definitions. Except as otherwise specified in Chapter 1 of the Wyoming Medicaid Rules or as defined in this section, the terminology used in this chapter is the standard terminology and has the standard meaning used in healthcare, Medicaid, and Medicare.

(a) "AB Rated." An "AB rated" generic drug product is one that the FDA has determined to be bioequivalent to a branded drug. A generic drug is considered bioequivalent to a branded drug if it contains the same active pharmaceutical ingredient as the branded drug and there is no significant difference in the formulation, quality, and effectiveness of the two (2) drugs.

(b) "Average wholesale price (AWP)." A national average of list prices charged by wholesalers to pharmacies.

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

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

(e) "Compound Drug." A drug prepared by a pharmacist who mixes or adjusts drug ingredients to customize a medication to meet a patient's individual needs.

(f) "Device." Any article or healthcare product intended for use in the diagnosis of disease or other condition or for use in the care, treatment, or prevention of disease that does not achieve any of its primary intended purposes by chemical action or by being metabolized.

(g) "Drug Efficacy Study Implementation (DESI) drugs." Drugs determined by the United States Food and Drug Administration (FDA) to be less than effective. This definition applies to all drugs that are similar, related, or identical to these drugs pursuant to FDA designation.

Compound formulations which contain a DESI drug are considered to be DESI compounds/DESI drugs.

(h) "Drug Utilization Review (DUR) requirements." The Drug Utilization Review Requirements as set forth in Chapter 9 of the Board of Pharmacy Rules and 42 C.F.R. Part 456. A DUR program shall include prospective drug review, retrospective drug use review, and an educational program.

(i) "Federal Upper Limit (FUL)." The maximum amount the federal government (Centers for Medicare and Medicaid Services) will pay for multiple source drugs.

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

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

(l) "Gross Amount Due (GAD)." The sum of the submitted product component cost and the dispensing fee submitted by the pharmacy on a prescription claim.

(m) "Ingredient Cost Submitted." The product cost submitted by the pharmacy on a prescription claim.

(n) "Maintenance drug." A covered prescription drug prescribed for a chronic condition (i.e., diabetes, arthritis, high blood pressure, or heart conditions).

(o) "Multiple source drug." A drug marketed or sold by two (2) or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two (2) or more different proprietary names.

(p) "National Average Drug Acquisition Cost (NADAC)." A drug price point that is calculated based on average pharmacy acquisition cost of a particular drug.

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

(r) "One month supply." The quantity of drugs sufficient to last up to thirty-four (34) days.

(s) "Pharmaceutical service." Drugs, devices or medical supplies that are covered services, as defined in this Chapter.

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

(u) “Pharmacy Therapeutics (P&T) Committee.” An advisory committee that shall review evidence based research and provide recommendations to the Department as to the clinical effectiveness of a service or medication within a therapeutic drug class.

(v) “Preferred Drug List (PDL).” A list of preferred pharmaceutical substances for selected pharmacologic or therapeutic classes that is maintained by the Department, is designed to maximize clinical and economic outcomes, and is incorporated herein by reference.

(w) “Prescription drug.” A drug 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.

(x) “Wholesale Acquisition Cost (WAC).” The list price paid by a wholesaler, distributor and other direct accounts for drugs purchased from the wholesaler's supplier not including discounts or rebates.

(y) “Wholesaler.” An individual or entity that furnishes drugs, medical supplies, or both, to pharmacies or pharmacists.

Section 4. Provider Participation.

(a) Compliance with Chapter 3. An individual or entity that wishes to receive Medicaid funds for pharmaceutical services furnished to a client shall meet the requirements of Chapter 3 of the Wyoming Medicaid Rules.

(b) Eligible pharmaceutical services providers include non-excluded

(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 and are enrolled as a Medicaid pharmacy services provider. Except as otherwise specified in this Chapter, such a physician shall meet the standards and follow the procedures established for a pharmacist provider.

Section 5. Provider Records.

(a) Compliance with Chapter 3. A provider of pharmaceutical services shall comply with the record-keeping requirements of Chapter 3 of the Wyoming Medicaid Rules.

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

(i) Invoices for drugs;

(A) Pharmacies shall 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 a format generated and sent by wholesaler.

(ii) Prescriptions;

(A) All prescriptions shall be reduced to writing. Prescriptions for brand name drugs with multi-source generics that are not considered preferred brand name drugs by the Department shall contain the certification "medically necessary," shall be received and on file within thirty days after the oral prescription, and shall meet the requirements of Section 9 of this Chapter;

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

(iv) Client account records; and

(v) Copies of claim forms.

Section 6. Verification of Client Data. A provider of pharmaceutical services shall comply with the verification of client data requirements of Chapter 3 of the Wyoming Medicaid Rules.

Section 7. DUR Requirements. A provider of pharmaceutical services shall comply with the Drug Utilization Review (DUR) requirements of 42 C.F.R. Part 456 and Chapter 9 of the Board of Pharmacy Rules.

Section 8. Covered Services.

(a) Prescription drugs. Prescription drugs are covered in the quantity prescribed by a practitioner, subject to the dispensing limitations of Section 9 and the exclusions of Section 11.

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

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

(ii) Conform to State and Federal laws governing prescription refills; and

(iii) Be within one (1) year of the date of the original prescription.

(c) Brand name drugs. Non-preferred brand name drugs with multi-source generics shall be certified in writing by the prescribing practitioner as medically necessary.

(d) Compound drugs. Compound drugs shall be paid per line item if each ingredient is a prescription or Over-the-Counter (OTC) drug covered pursuant to subsections (a) and (e) and is not classified by the FDA as a Drug Efficacy Study Implementation (DESI) drug. One (1) dispensing fee is paid per compound prescription.

(e) OTC drugs and medical supplies. Select OTC drugs and medical supplies are covered pharmacy services if they:

(i) Are dispensed to a client who is not a resident of a nursing facility, not admitted as an inpatient or outpatient in a hospital, and not occupying a swing bed;

(ii) Are prescribed by a practitioner;

(iii) Are rebatable OTC drugs;

(iv) Have been assigned a National Drug Code (NDC) number; and

(v) Are medically necessary.

(A) The Department shall, from time to time, designate OTC drugs and medical supplies as covered services based on their therapeutic value, clinical consultation with practitioners, and applicable Centers for Medicare and Medicaid Services (CMS) guidelines. The Department shall disseminate current lists of covered OTC drugs and medical supplies to providers through manuals, bulletins, facsimiles, designated websites, or other appropriate means.

Section 9. Dispensing Limitations.

(a) Generic drugs. Practitioners shall prescribe generic drugs except in the following circumstances:

(i) When a brand name drug is medically necessary and the appropriate prior authorization criteria has been met,

(ii) When there is not an AB rated generic available, or

(iii) When the brand name drug is listed on the Department's preferred drug list as preferred instead of the generic.

(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 (1) 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 (1) month supply of a maintenance drug may be dispensed to allow a client 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 ninety (90) day supply.

(iii) All other drugs. The maximum quantity dispensed for all other conditions shall be a one (1) month supply unless the Department has designated a minimum days supply for a specific drug that exceeds 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 directions as prescribed, or

(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.

(d) Tamper resistant prescription pads. Prescriptions written for Medicaid clients shall be written on tamper resistant prescription pads per Section 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007. The law requires that all written, non-electronic prescriptions for Medicaid outpatient drugs shall be executed on tamper resistant pads in order for them to be reimbursable by the federal government. In addition to all current Wyoming Board of Pharmacy requirements for tamper resistant prescription forms, all prescriptions paid for by Wyoming Medicaid shall meet the following requirements to help ensure against tampering:

(i) Written or computer printed prescriptions shall contain all of the following characteristics:

(A) One (1) or more industry recognized features designed to prevent unauthorized copying of a completed or blank prescription or prescription form. In order to meet this requirement, all written or computer printed prescriptions shall contain some type of "void" or "illegal" pantograph that appears if the prescription is copied.

(B) One (1) or more industry recognized features designed to prevent the erasure or modifications of information written on the prescription by the prescriber. This requirement applies only to prescriptions written for controlled substances. In order to meet this requirement, all written or computer printed prescriptions shall contain:

(I) Quantity check-off boxes plus numeric form of quantity values or alpha and numeric forms of quantity values, and

(II) Refill indicator (circle or check number of refills or "NR") plus numeric form of refill values or alpha and numeric forms of refill values.

(C) One (1) or more industry recognized features designed to prevent the use of counterfeit prescription forms. In order to meet this requirement, all written or computer

printed prescriptions shall contain security features and descriptions listed on the front and back of the prescription blank.

(ii) In addition to the guidance outlined above, the tamper resistant requirement does not apply when a prescription is communicated by the prescriber to the pharmacy electronically, verbally, or by fax; when a managed care entity pays for the prescription; or, in most situations, when drugs are provided in designated institutional and clinical settings. The guidance also allows emergency fills with a non-compliant written prescription as long as the prescriber provides a verbal, faxed, electronic, or compliant written prescription within seventy-two (72) hours.

(iii) Audits of pharmacies may be performed by the Department to ensure that the above requirements are being followed.

Section 10. Relationship to Other Programs.

(a) This Chapter does not limit the services available to clients under age twenty-one (21) pursuant to Chapter 6 of the Wyoming Medicaid Rules.

(b) This Chapter does not affect services available pursuant to Chapter 29 of the Wyoming Medicaid Rules.

Section 11. Excluded Services. The following prescription drugs are excluded:

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

(b) Fertility drugs;

(c) Hair growth products;

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

(e) Cosmetic agents such as Retin-A, provided to clients age twenty-one (21) years or over;

(f) OTC drugs and medical supplies, except as designated in Section 8(e) of this Chapter;

(g) DESI drugs;

(h) Drugs supplied by a manufacturer that has not entered into and does not have in effect a rebate agreement which meets the requirements of 42 U.S.C. § 1396r-8, including any amendments or updates, except as otherwise specified by that Section; and

(i) 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 swing bed.

(j) Any drug, supply or service not designated as a covered service under this Chapter.

Section 12. Pharmacy and Therapeutics (P&T) Committee.

(a) Pharmacy Services shall have a P&T Committee to meet the DUR requirements designated in Section 7 of this Chapter. The P&T Committee shall be made up as follows:

(i) At least one third (1/3), but not more than fifty-one percent (51%) physicians;

(ii) At least one third (1/3), but not more than fifty-one (51%) pharmacists; and

(iii) At least one physician's assistant or nurse practitioner.

(b) The responsibilities of the P&T Committee include:

(i) Prospective Drug Utilization Review, including determination of prior authorization criteria in accordance with Section 13 of this Chapter;

(ii) Retrospective Drug Utilization Review including periodic review of client profiles and claims data in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, or clients, or associated with specific drugs or groups of drugs;

(iii) Provider education programs to include written or live dissemination of information in group or individual settings;

(iv) Review of literature and providing recommendations to Medicaid Pharmacy Services for the purpose of creating the Preferred Drug List in accordance with Section 15 of this chapter;

(v) Providing recommendations and feedback to Medicaid Pharmacy Services regarding pharmacy policy in general; and

(vi) Other duties as requested by the Department.

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 manuals or bulletins.

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

(A) Are covered services;

(B) Are consistent with the client'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 client.

(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 client may request reconsideration of the denial of prior authorization pursuant to Chapter 4 of the Wyoming Medicaid Rules. If a timely request for reconsideration is made, the services shall be furnished for up to sixty (60) 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 subsection (B).

(iii) Failure to timely request prior authorization. The failure to obtain prior authorization before providing services requiring 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 client'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. Notice of services requiring prior authorization can be found in manuals, bulletins, faxes, and designated websites published by the Department.

(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 P&T Committee, a provider, a client, an organization of providers or clients, 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 P&T Committee. Any request for designation received by or made by the Department shall be referred to the P&T Committee.

(C) Review by P&T Committee. The P&T Committee may review a referral received from the Department to designate a service as requiring prior authorization. In reviewing any such referral, the P&T Committee may consider the:

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

(1.) peer-reviewed clinical literature;

(2.) nationally recognized practice standards; and

(3.) the consensus of the members of the P&T Committee;

(II) Cost effectiveness of the service;

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

(IV) The availability of lower cost alternatives; and

(V) Comments received from interested parties for services which are under consideration for designation as requiring prior authorization.

(D) Recommendation to the Department. The P&T Committee 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 services.

(E) Consideration of recommendation. The Department may consider the recommendation of the P&T Committee 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 P&T Committee, but the Department shall not designate a service as requiring prior authorization until it has received the P&T Committee'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 manuals, bulletins, facsimiles, designated websites, or other appropriate means.

(B) If additional services are designated pursuant to this section, the Department shall disseminate notice of the additional services which require prior authorization to providers through manuals, bulletins, facsimiles, designated websites, or other appropriate means.

Section 14. Copayment.

(a) Clients shall pay a three dollar and sixty-five cent ($3.65) per prescription copayment for Brand Name drugs, or a sixty-five cent ($0.65) per prescription copayment for multiple source drugs, except as specified in subsection (b).

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

(i) Residents of a nursing facility or swing beds;

(ii) Family planning products;

(iii) Pregnant clients;

(iv) Clients under age twenty-one (21) years;

(v) American Indians and Alaska Natives;

(vi) Emergency Services;

(vii) Hospice Services; and

(viii) Vaccine products administered in the pharmacy.

(c) Notification of copayment amount. The Department shall notify providers of the copayment amount by means including, but not limited to, manuals, bulletins, facsimiles, or designated websites. The Department shall notify clients by bulletin or other means of communication designated by the Department.

(d) 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 collected.

(e) Denial of services. A provider may not deny pharmaceutical services to a client because of the client's inability to make the copayment, except when a client regularly refuses to make copayments.

(i) For purposes of this Section, a client who refuses to make a copayment two (2) or more times has "regularly refused" to make copayments.

Section 15. Preferred Drug List.

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

(i) Is a covered service;

(ii) Is cost-effective; and

(iii) Has been reviewed by the P&T Committee.

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

(i) Review by the Pharmacy and Therapeutics (P&T) Committee. The P&T Committee shall review services of the same therapeutic class in order to determine if one (1) 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 P&T Committee shall consider the clinical efficacy of the services as determined by consensus of the P&T Committee utilizing:

(A) Evidence-based research reports;

(B) Peer-reviewed clinical literature; and

(C) Nationally recognized practice standards.

(ii) In order to solicit comments, the P&T Committee may provide notice to interested parties of services which are under consideration for designation on the Preferred Drug List and the criteria applied to such services.

(iii) Recommendation to the Department. The P&T Committee shall make a recommendation to the Department about whether one (1) or more services are more clinically safe or effective than others in the same therapeutic class.

(iv) Consideration of recommendation. The Department may consider the recommendation of the P&T Committee 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 P&T Committee, but the Department shall not assign services to the Preferred Drug List until it has received and considered the P&T Committee'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 P&T Committee 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 Department may change or update prior authorization criteria to include the new services until the P&T Committee can make recommendations to the Department in regard to the services.

(ii) In the event the Department changes the preferred service for a therapeutic class, the Department may ask the P&T Committee 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 P&T Committee or changes in pricing.

(e) Notice of services on the Preferred Drug List. 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 bulletins, manuals, 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 specified in subsection (b) of this section, the Medicaid allowable payment for pharmaceutical services shall be of the calculation below with the lowest reimbursement:

(i) The National Average Drug Acquisition Cost (NADAC) of the ingredient(s) plus the dispensing fee specified in subsection (d);

(ii) When no NADAC is available, Medicaid shall substitute Wholesale Acquisition Cost (WAC) + 0% plus the dispensing fee specified in subsection (d);

(iii) When neither NADAC nor WAC are available, Medicaid shall substitute Average Wholesale Price (AWP) – 11% plus the dispensing fee specified in subsection (d);

(iv) The Federal Upper Limit (FUL) plus the dispensing fee specified in subsection (d);

(v) The Department set maximum allowable cost for specified drugs or drug categories plus the dispensing fee specified in subsection (d);

(vi) The ingredient cost submitted by the pharmacy on the claim plus the dispensing fee specified in subsection (d);

(vii) The gross amount due; or

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

(b) Covered entities purchasing drugs under Section 340B of the Public Health Service Act. Entities that purchase products under Section 340B of the Public Health Service Act shall request, in writing to use these drugs for Wyoming Medicaid clients. 340B entities who are granted such an arrangement shall bill Medicaid no more than their actual acquisition cost (AAC) for the drug and shall be reimbursed no more than the AAC plus the dispensing fee specified in subsection

(d). 340B entities that fill Wyoming Medicaid client prescriptions with drugs not purchased under Section 340B of the Public Health Service Act will be reimbursed in accordance with subsection (a).

(c) Pharmacies which are operating as contract pharmacies in the 340B program shall not utilize drugs purchased under Section 340B of the Public Health Service Act for Wyoming Medicaid clients.

(d) 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 specified in (i) or (ii) below. The dispensing fee shall be adjusted as specified in subsection (f).

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

(ii) Pharmacies. The dispensing fee for pharmacies shall be ten dollars and sixty-five cents ($10.65) per prescription or compound.

(e) 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 clients 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.

(f) 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 subsection (i), the Department may 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 manuals, bulletins, facsimiles, designated websites, or other appropriate means.

(g) 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.

(h) Proof of delivery.

(i) A Provider shall keep a dated log that maintains a record of when a client or client's representative picks up, or takes delivery of, every prescription paid for by the Department. All signatures shall be original at the time each prescription is dispensed; electronic or other methods of reproducing past signatures are not acceptable. The signature log can be either manual or electronic and should comply with all Health Insurance Portability and Accountability Act (HIPAA), State, and Federal regulations.

(ii) Prescriptions that are mailed to clients shall be recorded in a dated log that shall contain the prescription number, date of fill, client's name and address that the prescription is mailed to as well as the name of the person mailing or delivering the mail to the mail carrier. If a single prescription to be mailed has a dollar amount paid by the Department exceeding five hundred dollars ($500.00), a receipt that indicates that the prescription was mailed shall be obtained and attached to the log.

(iii) The above requirements also apply to clients living in nursing or institutional facilities.

Section 17. Submission and Payment of Claims. Except as otherwise specified in this Chapter, submission and payment of claims shall be pursuant to the provisions of Chapter 3 of the Wyoming Medicaid Rules.

Section 18. Recovery of Overpayments. The Department may recover overpayments pursuant to Chapter 16 of the Wyoming Medicaid Rules.

Section 19. Audits. Audits are subject to the provisions of Chapter 16 of the Wyoming Medicaid Rules.

Section 20. Reconsideration. A provider may request reconsideration of the decision to recover overpayments pursuant to Chapter 16 of the Wyoming Medicaid Rules.

Section 21. Disposition of recovered funds. The Department shall dispose of recovered funds pursuant to the provisions of Chapter 16 of the Wyoming Medicaid Rules.

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 manuals and bulletins, which are inconsistent with this Chapter.

Section 24. Severability. If any portion of these rules is found invalid or unenforceable, the remainder shall continue in full force and effect.

Section 25. Incorporation by Reference.

(a) For any code, standard, rule, or regulation incorporated by reference in these rules:

(i) The Department has determined that incorporation of the full text in these rules would be cumbersome or inefficient given the length or nature of the rules;

(ii) The incorporation by reference does not include any later amendments or editions of the incorporated matter beyond the applicable date identified in subsection (b) of this section; and

(iii) The incorporated code, standard, rule, or regulation is maintained at the Department and is available for public inspection and copying at cost at the same location.

(b) Each rule or regulation incorporated by reference in these rules is further identified as follows:

(i) Referenced in Sections 3 and 7 of this Chapter is Chapter 9 of the Board of Pharmacy Rules, incorporated as of the effective date of this Chapter and can be found at https://rules.wyo.gov/.

(ii) Referenced in Sections 3 and 7 of this Chapter is 42 C.F.R. Part 456, incorporated as of the effective date of this Chapter and can be found at https://ecfr.gov.

(iii) Referenced in Sections 3, 9, 12, and 15 of this Chapter is the Preferred Drug List, incorporated as of the effective date of this Chapter and can be found at www.wymedicaid.org.

(iv) Referenced in Section 9 of this Chapter is Section 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007, incorporated as of the effective date of this Chapter and can be found at https://www.congress.gov.

(v) Referenced in Section 11 of this Chapter is 42 U.S.C. § 1396r-8, incorporated as of the effective date of this Chapter and can be found at https://www.gpo.gov.

(vi) Referenced in Section 16 of this Chapter is Section 340B of the Public Health Service Act, incorporated as of the effective date of this chapter and can be found at https://www.federalregister.gov.

~~**WYOMING MEDICAID RULES**~~

CHAPTER 10

PHARMACEUTICAL SERVICES

Section 1. Authority.

This Chapter is promulgated by the Department of Health pursuant to the Wyoming Medical Assistance and Services Act at ~~W.S.~~ Wyoming Statutes §§ 42-4-101 ~~et seq.~~ through -121. ~~and the Wyoming Administrative Procedures Act at W.S. 16-3-101.~~

Section 2. Purpose and Applicability.

(a) This Chapter has been adopted to establish~~es~~ the standards and procedures for the provision of and payment for pharmaceutical services under Medicaid. It shall apply to all pharmaceutical services provided on or after the effective date of this rule.

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

Section 3. ~~General Provisions.~~ **Definitions.** Except as otherwise specified in Chapter 1 of the Wyoming Medicaid Rules or as defined in this section, the terminology used in this chapter is the standard terminology and has the standard meaning used in healthcare, Medicaid, and Medicare.

~~(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 that 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." An "AB rated" generic ~~D~~drug product~~s~~ is one that the FDA has determined to be bioequivalent to a branded drug. A generic drug is considered bioequivalent to a branded drug if it contains the same active pharmaceutical ingredient as the branded drug and there is no significant difference in the formulation, quality, and effectiveness of the two (2) drugs. ~~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~~b) "Average wholesale price~~" or "~~(AWP)." A national average of list prices charged by wholesalers to pharmacies.~~The average wholesale price as computed intermittently by First Data Bank, its agent, designee, or successor.~~

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

(e) "Compound Drug." A drug prepared by a pharmacist who mixes or adjusts drug ingredients to customize a medication to meet a patient's individual needs.

~~(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~~f) "Device." Any article or healthcare product intended for use in the diagnosis of disease or other condition or for use in the care, treatment, or prevention of disease that does not achieve any of its primary intended purposes by chemical action or by being metabolized.~~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~~g) "Drug Efficacy Study Implementation (DESI) drugs." Drugs determined by the United States Food and Drug Administration (FDA)~~,~~ to be less than effective. This definition applies to all drugs ~~which~~that are similar, related, or identical to ~~DESI~~these drugs pursuant to FDA designation. Compound formulations which contain a DESI drug are considered to be DESI compounds/DESI drugs.

(h) "Drug Utilization Review (DUR) requirements." The Drug Utilization Review Requirements as set forth in Chapter 9 of the Board of Pharmacy Rules and 42 C.F.R Part 456. A DUR program shall include prospective drug review, retrospective drug use review, and an educational program.

~~(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~~i) "Federal Upper Limit~~" or "~~(FUL)." The maximum amount the federal government (Centers for Medicare and Medicaid Services) will pay for multiple source drugs.~~The CMS established upper limit for multiple source drugs.~~

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

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

(l) "Gross Amount Due (GAD)." The sum of the submitted product component cost and the dispensing fee submitted by the pharmacy on a prescription claim.

(m) "Ingredient Cost Submitted." The product cost submitted by the pharmacy on a prescription claim.

(~~nn~~n) "Maintenance drug." A covered prescription drug prescribed for a chronic condition (i.e., diabetes, arthritis, high blood pressure, or heart conditions).~~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~~o) "Multiple source drug." A drug marketed or sold by two (2) or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two (2) or more different proprietary names.

(p) "National Average Drug Acquisition Cost (NADAC)." A drug price point that is calculated based on average pharmacy acquisition cost of a particular drug.

(~~xx~~q) "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~~r) "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~~s) "Pharmaceutical service." Drugs, devices or medical supplies that are covered services, as defined in this Chapter.

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

(u) "Pharmacy and Therapeutics (P&T) Committee." An advisory committee that shall review evidence based research and provide recommendations to the Department as to the clinical effectiveness of a service or medication within a therapeutic drug class.

~~(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 or 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~~v) "Preferred Drug List (PDL)." A list of preferred pharmaceutical substances for selected pharmacologic or therapeutic classes that is maintained by the Department, is designed to maximize clinical and economic outcomes, and is incorporated herein by reference.~~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~~w) "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.

(x) "Wholesale Acquisition Cost (WAC)." The list price paid by a wholesaler, distributor and other direct accounts for drugs purchased from the wholesaler's supplier not including discounts or rebates.

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

Section ~~5~~4. Provider ~~p~~Participation.

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

(b) Eligible pharmaceutical services providers include non-excluded~~.~~

(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~~and are enrolled as a Medicaid pharmacy services provider. Except as otherwise specified in this Chapter, such ~~as~~ a physician ~~must~~shall meet the standards and follow the procedures established for a pharmacist provider.

Section ~~6~~5. Provider ~~r~~Records.

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

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

(i) Invoices for drugs~~.~~;

(A) Pharmacies ~~must~~shall 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 a format generated and sent by wholesaler.

(ii) Prescriptions~~.~~;

(A) All prescriptions ~~must~~shall be reduced to writing. Prescriptions for brand name drugs with multi-source generics that are not considered preferred brand name drugs by the Department ~~must~~shall contain the certification "medically necessary," ~~in the prescribing practitioner's hand-writing,~~ ~~must~~shall be received and on file within thirty days after the oral prescription, and ~~must~~shall meet the requirements ~~as defined in~~of Section ~~10~~9 of this Chapter;

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

(iv) ~~Recipient~~Client account records; and

(v) Copies of claim forms.

Section ~~7~~6. Verification of ~~recipient~~Client ~~d~~Data. A provider of pharmaceutical services ~~must~~shall comply with the verification of ~~recipient~~client data requirements of Chapter 3 of the Wyoming Medicaid Rules~~, which are incorporated by this reference~~.

Section ~~8~~7. DUR ~~r~~Requirements. A provider of pharmaceutical services ~~must~~shall comply with the Drug Utilization Review (DUR) requirements of 42 C.F.R. Part 456 and Chapter 9 of the Board of Pharmacy Rules.

Section ~~9~~8. Covered ~~s~~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~~9 and the exclusions of Section 1~~2~~1.

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

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

(ii) ~~Such authorization must c~~Conform to State and Federal laws governing prescription refills~~.~~; and

(iii) Be within one (1) year of the date of the original prescription.

(c) Brand name drugs. Non-preferred ~~B~~brand name drugs with multi-source generics shall be certified in writing by the prescribing practitioner as medically necessary~~ by the prescribing practitioner~~.

(d) Compound drugs. Compound drugs ~~are~~shall be paid per line item if each ingredient is a prescription or Over-the-Counter (OTC) drug covered pursuant to subsections (a) and (e)~~,~~ and is not classified by the FDA as a Drug Efficacy Study Implementation (DESI) drug. One (1) dispensing fee is paid per compound prescription.

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

(i) Are ~~Furnished~~dispensed to a ~~recipient~~client who is not a resident of a nursing facility, not admitted as an inpatient or outpatient in a hospital, and not occupying a swing bed;

(ii) Are ~~P~~prescribed by a practitioner;

(iii) Are rebatable OTC drugs;

(~~ii~~iv) ~~The drug has~~Have been assigned a~~n~~ National Drug Code (NDC) number; and

(~~i~~v) Are medically necessary.

~~(f)~~ ~~(A) Covered OTC drugs and products. OTC drugs or products as designated by the Department.~~ The Department shall, from time to time, designate OTC drugs and medical supplies as covered services based on their therapeutic value, clinical consultation with practitioners, and applicable Centers for Medicare and Medicaid Services (CMS) guidelines. The Department shall disseminate ~~a~~ current lists of covered OTC drugs and medical supplies ~~which are covered services~~ to providers through ~~Provider M~~manuals, ~~Provider B~~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~~9. Dispensing ~~l~~Limitations.

(a) Generic drugs. Practitioners ~~must~~shall prescribe generic drugs except in the following circumstances:

(i) ~~w~~When a ~~name~~ brand name drug~~s~~ ~~are~~is medically necessary and the appropriate prior authorization criteria has been met,

(ii) When~~or~~ there is not an AB rated generic available, or

(iii) When the brand name drug is listed on the Department's preferred drug list as preferred instead of the generic.

(b) Quantities dispensed.

(i) Maintenance drugs.

(A) Minimum quantities. Except as provided in subparagraph (~~c~~C), maintenance drugs shall be dispensed in a quantity sufficient for at least a one (1) 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 (1) month supply of a maintenance drug may be dispensed to allow a ~~recipient~~client 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~~ninety (90) day supply.

(iii) All other drugs. The maximum quantity dispensed for all other conditions shall be a one (1) ~~-~~month supply unless the Department has designated a minimum days supply for a specific drug that exceeds 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 directions as prescribed~~.~~, or

(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.

(d) Tamper resistant prescription pads. Prescriptions written for Medicaid clients shall be written on tamper resistant prescription pads per Section 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007. The law requires that all written, non-electronic prescriptions for Medicaid outpatient drugs shall be executed on tamper resistant pads in order for them to be reimbursable by the federal government. In addition to all current Wyoming Board of Pharmacy requirements for tamper resistant prescription forms, all prescriptions paid for by Wyoming Medicaid shall meet the following requirements to help ensure against tampering:

(i) Written or computer printed prescriptions shall contain all of the following characteristics:

(A) One (1) or more industry recognized features designed to prevent unauthorized copying of a completed or blank prescription or prescription form. In order to meet this requirement, all written or computer printed prescriptions shall contain some type of "void" or "illegal" pantograph that appears if the prescription is copied.

(B) One (1) or more industry recognized features designed to prevent the erasure or modifications of information written on the prescription by the prescriber. This requirement

applies only to prescriptions written for controlled substances. In order to meet this requirement, all written or computer printed prescriptions shall contain:

(I) Quantity check-off boxes plus numeric form of quantity values or alpha and numeric forms of quantity values, and

(II) Refill indicator (circle or check number of refills or "NR") plus numeric form of refill values or alpha and numeric forms of refill values.

(C) One (1) or more industry recognized features designed to prevent the use of counterfeit prescription forms. In order to meet this requirement, all written or computer printed prescriptions shall contain security features and descriptions listed on the front and back of the prescription blank.

(ii) In addition to the guidance outlined above, the tamper resistant requirement does not apply when a prescription is communicated by the prescriber to the pharmacy electronically, verbally, or by fax; when a managed care entity pays for the prescription; or, in most situations, when drugs are provided in designated institutional and clinical settings. The guidance also allows emergency fills with a non-compliant written prescription as long as the prescriber provides a verbal, faxed, electronic, or compliant written prescription within seventy-two (72) hours.

(iii) Audits of pharmacies may be performed by the Department to ensure that the above requirements are being followed.

Section ~~11~~(10). Relationship to ~~o~~Other ~~p~~Programs.

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

(~~b~~a) This Chapter does not limit the services available to ~~recipients~~clients under age twenty-one (21) pursuant to Chapter 6 of the Wyoming Medicaid Rules.

(~~c~~b) This Chapter does not affect services available pursuant to Chapter 29 of the Wyoming Medicaid Rules.

Section ~~12~~11. Excluded ~~s~~Services.

~~(a)~~ The following prescription drugs are excluded:

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

(~~ii~~b) Fertility drugs;

(~~iii~~c) Hair growth products;

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

~~(v~~e) ~~Cosmetic~~ agents such as Retin-A, provided to ~~recipients~~clients age twenty-one (21) years or over;

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

(~~b~~f) OTC drugs and medical supplies, except as designated in Section ~~9~~8(e) of this Chapter;~~.~~

(~~c~~g) DESI drugs;~~.~~

(~~d~~h) 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)~~42 U.S.C. § 1396r-8, 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.~~; and

(~~e~~i) 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 swing bed~~, are not separately reimbursable pursuant to this Chapter.~~

(j) Any drug, supply or service not designated as a covered service under this Chapter.

Section 12. Pharmacy and Therapeutics (P&T) Committee.

(a) Pharmacy Services shall have a P&T Committee to meet the DUR requirements designated in Section 7 of this Chapter. The P&T Committee shall be made up as follows:

(i) At least one third (1/3), but not more than fifty-one percent (51%) physicians;

(ii) At least one third (1/3), but not more than fifty-one (51%) pharmacists; and

(iii) At least one physician's assistant or nurse practitioner.

(b) The responsibilities of the P&T Committee include:

(i) Prospective Drug Utilization Review, including determination of prior authorization criteria in accordance with Section 13 of this Chapter;

(ii) Retrospective Drug Utilization Review including periodic review of client profiles and claims data in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, or clients, or associated with specific drugs or groups of drugs;

(iii) Provider education programs to include written or live dissemination of information in group or individual settings;

(iv) Review of literature and providing recommendations to Medicaid Pharmacy Services for the purpose of creating the Preferred Drug List in accordance with Section 15 of this chapter;

(v) Providing recommendations and feedback to Medicaid Pharmacy Services regarding pharmacy policy in general; and

(vi) Other duties as requested by the Department.

Section 13. Prior ~~a~~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 M~~manuals or ~~Provider B~~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~~client'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~~client.

(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~~client may request reconsideration of the denial of prior authorization pursuant to Chapter ~~3~~4 of the Wyoming Medicaid Rules. If a timely request for reconsideration is made, the services shall be furnished for up to sixty (60) 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 subsection (B).

(iii) Failure to timely request prior authorization. The failure to obtain prior authorization before providing services ~~which~~ requiring~~e~~ ~~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~~client'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. Notice of services requiring prior authorization can be found in manuals, bulletins, faxes, and designated websites published by the Department.

(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~~ P&T Committee, a provider, a ~~recipient~~client, an organization of providers or ~~recipient~~clients, 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~~ P&T Committee. Any request for designation received by or made by the Department shall be referred to the ~~DUR Board~~ P&T Committee.

(C) Review by ~~DUR Board~~ P&T Committee. The ~~DUR Board~~ P&T Committee ~~shall~~ may review a referral received from the Department to designate a service as requiring prior authorization. In reviewing any such referral, the ~~DUR Board~~ P&T Committee ~~shall~~ may 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~~ P&T Committee;

(II) Cost effectiveness of the service;

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

(IV) The availability of lower cost alternatives~~.~~; and

(V) Comments received from ~~The DUR Board may provide notice to~~ interested parties ~~of~~ for 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~~ P&T Committee 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~~ may consider the recommendation of the ~~DUR Board~~ P&T Committee 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~~ P&T Committee, but the Department shall not designate a service as requiring prior authorization until it has received the ~~DUR Board's~~ P&T Committee'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 M~~manuals, ~~Provider B~~bulletins, facsimil~~led~~s, 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 M~~manuals, ~~Provider B~~bulletins, facsimil~~led~~s, designated websites, or other appropriate means.

Section 14. Copayment.

(a) ~~Recipient~~Clients ~~must~~shall pay a three dollar and sixty-five cent ($3.~~00~~65) per prescription copayment for ~~non-preferred~~ Brand Name drugs, ~~or a two dollar $2.00 per prescription copayment for preferred Brand Name drugs~~, or a sixty-five cent ($~~1.00~~0.65) 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~~b) Exemptions. The following ~~recipients~~clients and pharmaceutical services are exempt from the copayment requirement:

(i) Residents of a nursing facility or ~~in~~ swing bed~~s~~;

(ii) Family planning products;

(iii) ~~Pharmaceutical services provided to a p~~Pregnant ~~recipient~~clients; ~~and;~~

(iv) ~~Pharmaceutical services provided to a recipient~~Clients under age twenty-one (21) years;

(v) American Indians and Alaska Natives;

(vi) Emergency Services;

(vii) Hospice Services; and

(viii) Vaccine products administered in the pharmacy.

(~~d~~c) Notification of copayment amount. The Department shall notify providers of the copayment amount by means including, but not limited to, ~~Provider M~~manuals, ~~Provider B~~bulletins, facsimil~~les~~, or designated websites. The Department shall notify ~~recipients~~clients by bulletin or other means of communication designated by the Department.

(~~e~~d) 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~~collected.

(~~f~~e) ~~Prohibition or d~~Denial of services. A provider may not deny pharmaceutical services to a ~~recipient~~client because of the ~~recipient's~~client's inability to make the copayment, except when a client regularly refuses to make copayments.~~:~~

(i) ~~A recipient regularly refuses to make copayments.~~For purposes of this Section, a client who refuses to make a copayment two (2) or more times has "regularly refused" 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; and

(iii) ~~Evidence-based research is available and h~~Has been reviewed by the ~~PDLAC~~P&T Committee.

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

(i) Review by the ~~Preferred Drug List Advisory~~ Pharmacy and Therapeutics (P&T) Committee ~~PDLAC~~. The ~~PDLAC~~P&T Committee shall review services of the same therapeutic class in order to determine if one (1) 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~~P&T Committee shall consider the clinical efficacy of the services as determined by consensus of the ~~PDLAC~~P&T Committee utilizing:

(A) ~~e~~Evidence-based research reports;

(B) ~~p~~Peer-reviewed clinical literature; and~~/or~~

(C) ~~n~~Nationally recognized practice standards.

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

(iii) Recommendation to the Department. The ~~PDLAC~~P&T Committee shall make a recommendation to the Department about whether one (1) or more services are more clinically safe or effective than others in the same therapeutic class.

(iv) Consideration of recommendation. The Department ~~shall~~ may consider the recommendation of the ~~PDLAC~~P&T Committee 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~~P&T Committee, but the Department shall not assign services to the Preferred Drug List until it has received and considered the ~~PDLAC~~P&T Committee'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 ~~DURBoard~~P&T Committee 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~~Department may change or update prior authorization criteria to include the new service~~(s)~~ until the ~~PDLAC~~P&T Committee 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~~P&T Committee 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~~P&T Committee 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 B~~bulletins, ~~or Provider M~~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 ~~p~~Payment.

(a) Reimbursement Limits. Except as ~~otherwise~~ specified in subsection (b) of this section, the Medicaid allowable payment for pharmaceutical services shall be ~~the lower~~ of the calculation below with the lowest reimbursement:

(i) The National Average Drug Acquisition Cost (NADAC) ~~estimated acquisition cost~~ of the ingredient(s) plus the dispensing fee specified in subsection (d); ~~or~~

(ii) When no NADAC is available, Medicaid shall substitute Wholesale Acquisition Cost (WAC) + 0% plus the dispensing fee specified in subsection (d);

(iii) When neither NADAC nor WAC are available, Medicaid shall substitute Average Wholesale Price (AWP) – 11% plus the dispensing fee specified in subsection (d);

(iv) The Federal Upper Limit (FUL) plus the dispensing fee specified in subsection (d);

(v) The Department set maximum allowable cost for specified drugs or drug categories plus the dispensing fee specified in subsection (d);

(vi) The ingredient cost submitted by the pharmacy on the claim plus the dispensing fee specified in subsection (d);

(vii) The gross amount due; or

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

(b) Covered entities purchasing drugs under Section 340B of the Public Health Service Act. Entities that purchase products under Section 340B of the Public Health Service Act shall request, in writing to use these drugs for Wyoming Medicaid clients. 340B entities who are granted such an arrangement shall bill Medicaid no more than their actual acquisition cost (AAC) for the drug and shall be reimbursed no more than the AAC plus the dispensing fee specified in subsection (d). 340B entities that fill Wyoming Medicaid client prescriptions with drugs not purchased under Section 340B of the Public Health Service Act will be reimbursed in accordance with subsection (a).

(c) Pharmacies which are operating as contract pharmacies in the 340B program shall not utilize drugs purchased under Section 340B of the Public Health Service Act for Wyoming Medicaid clients.

~~(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, which regulations are hereby incorporated by reference, plus the dispensing fee specified in subsection (d);~~

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

(~~c~~d) 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 specified in (i) or (ii) below. The dispensing fee shall be adjusted as specified in subsection (~~d~~f).

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

(ii) Pharmacies. The dispensing fee for pharmacies shall be ten dollars and sixty-five cents ($10.65) per prescription or compound.

(~~d~~e) 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~~clients 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~~f) 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~~subsection (~~I~~i), the Department ~~shall~~may 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~~ Mmanuals, ~~Provider B~~bulletins, facsimiles, designated websites, or other appropriate means.

(~~f~~g) 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~~h) Proof of delivery.

(i) 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 ofthe 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.~~ shall keep a dated log that maintains a record of when a client or client's representative picks up, or takes delivery of, every prescription paid for by the Department. All signatures shall be original at the time each prescription is dispensed; electronic or other methods of reproducing past signatures are not acceptable. The signature log can be either manual or electronic and should comply with all Health Insurance Portability and Accountability Act (HIPAA), State, and Federal regulations.

(ii) Prescriptions that are mailed to clients shall be recorded in a dated log that shall contain the prescription number, date of fill, client's name and address that the prescription is mailed to as well as the name of the person mailing or delivering the mail to the mail carrier. If a single prescription to be mailed has a dollar amount paid by the Department exceeding five hundred dollars ($500.00), a receipt that indicates that the prescription was mailed must be obtained and attached to the log.

(iii) The above requirements also apply to clients living in nursing or institutional facilities.

Section 17. Submission and Payment of ~~c~~Claims.

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

Section 19. Audits. Audits are subject to the provisions of Chapter 16 of the Wyoming Medicaid Rules.

~~(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.~~ reconsideration of the decision to recover overpayments pursuant to Chapter 16 of the Wyoming Medicaid Rules.

Section 21. Disposition of recovered funds. The Department shall dispose of recovered funds pursuant to the provisions of Chapter 16 of the Wyoming Medicaid Rules.~~, 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 e<u>E</u>ffect. This Chapter supersedes all prior rules or policy statements issued by the Department, including ~~Provider M~~<u>m</u>anuals and ~~Provider B~~<u>b</u>ulletins, which are inconsistent with this Chapter.

Section 24. Severability. If any portion of ~~this~~ <u>these rules</u> ~~Chapter~~ is found ~~to be~~ invalid or unenforceable, the remainder shall continue in full force and effect.

<u>Section 25. Incorporation by Reference.</u>

<u>(a) For any code, standard, rule, or regulation incorporated by reference in these rules:</u>

<u>(i) The Department has determined that incorporation of the full text in these rules would be cumbersome or inefficient given the length or nature of the rules;</u>

<u>(ii) The incorporation by reference does not include any later amendments or editions of the incorporated matter beyond the applicable date identified in subsection (b) of this section; and</u>

<u>(iii) The incorporated code, standard, rule, or regulation is maintained at the Department and is available for public inspection and copying at cost at the same location.</u>

<u>(b) Each rule or regulation incorporated by reference in these rules is further identified as follows:</u>

<u>(i) Referenced in Sections 3 and 7 of this Chapter is Chapter 9 of the Board of Pharmacy Rules, incorporated as of the effective date of this Chapter and can be found at https://rules.wyo.gov/.</u>

<u>(ii) Referenced in Sections 3 and 7 of this Chapter is 42 C.F.R. Part 456, incorporated as of the effective date of this Chapter and can be found at https://ecfr.gov.</u>

<u>(iii) Referenced in Sections 3, 9, 12, and 15 of this Chapter is the Preferred Drug List, incorporated as of the effective date of this Chapter and can be found at www.wymedicaid.org.</u>

<u>(iv) Referenced in Section 9 of this Chapter is Section 7002(b) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007, incorporated as of the effective date of this Chapter and can be found at https://www.congress.gov.</u>

<u>(v) Referenced in Section 11 of this Chapter is 42 U.S.C. § 1396r-8, incorporated as of the effective date of this Chapter and can be found at https://www.gpo.gov.</u>

<u>(vi) Referenced in Section 16 of this Chapter is Section 340B of the Public Health Service Act, incorporated as of the effective date of this chapter and can be found at https://www.federalregister.gov.</u>