~~**310-V PRESCRIPTION MEDICATION/PHARMACY SERVICES**~~

~~REVISION DATE: MM/DD/YYYY, 9/30/2020, 7/3/2015, 9/15/2014~~
~~EFFECTIVE DATE: June 30, 1994~~

~~The Division's pharmaceutical medication and pharmacy services is delegated to Administrative Subcontractor Services (AdSS) health plans. Please see AdSS Policy 310-V (Prescription Medication/Pharmacy Services) for details of those policy requirements.~~

~~The Division's Fee-For-Service pharmaceutical medication and pharmacy services provided to the American Indian/Alaskan Native population is delegated to Administrative Subcontractor Services (AdSS) Pharmacy Benefit Management company. Please see AdSS Policy 310-V (Prescription Medication/Pharmacy Services) for details of those policy requirements.~~

310-V PRESCRIPTION MEDICATION/PHARMACY SERVICES

REVISION DATE: MM/DD/YYYY, 9/30/2020, 7/3/2015, 9/15/2014
EFFECTIVE DATE: June 30, 1994
REFERENCES: **42 CFR 431.52, 42 CFR 438.3(s), A.R.S. § 32-1974, A.R.S. § 36-550, A.R.S. §36-551, A.R.S. § 36-2918(A)(1), A.R.S. §36-2918(A)(3)(b), A.R.S. § 36-2930.03, A.A.C. R4-23-409, R9-22-201 et seq, A.A.C. R9-22-209(C), A.A.C. R9-22-702, A.A.C. R9-22-709, A.A.C. R9-22-710(C), A.A.C. R9-22-711, A.A.C. R9-28-201 et seq, A.A.C. R9-31-201 through R9-31-216, AMPM 310-M, AMPM 320-N, AMPM 320 T-1, AMPM 320 T-2, AMPM 660, AMPM Attachment 310-V (A), AMPM Attachment 310-V (B), AMPM Exhibit 300-1, AHCCCS Fee For Service Billing Manual Chapter 12, AHCCCS IHS/Tribal Provider Billing Manual Chapter 10, ACOM 111, ACOM 201, ACOM Policy 414, ACOM 432, Division Medical 310-DD, Division Medical 320-M, Division Medical 320-Q, Division Medical 510.**

PURPOSE

This policy specifies the requirements for the the Division of Developmental Disabilities (Division) oversight and monitoring of the medication, Device and pharmacy coverage requirements and limitations of the Arizona Health Care Cost Containment System (AHCCCS) pharmacy benefit administered by the Administrative Services Subcontractors (AdSS) for Division Members enrolled in health plans managed by the AdSS and Members enrolled in the Tribal Health Program (THP) pharmacy benefits administered by AHCCCS Division of Fee-For-Service Management (DFSM) and it's contracted Pharmacy Benefits Manager (PBM).

DEFINITIONS

1. "340B Ceiling Price" means the maximum price that drug manufacturers may charge covered entities participating in the 340B Drug Pricing Program as reported by the drug manufacturer to the United States Department of Health and Human Services. The 340B Ceiling Price per unit is defined as

the Average Manufacturer Price (AMP) minus the Federal Unit Rebate Amount.

2. "340B Contracted Pharmacies" means a separate pharmacy that a 340B Covered Entity contracts with to provide and dispense prescription and physician-administered drugs using medications that are subject to 340B Drug Pricing Program.

3. "340B Covered Entity" means an organization as defined by 42 United States Code Section 256b that participates in the 340B Drug Pricing Program.

4. "340B Drug Pricing Program" means the discount drug purchasing program described in Section 256b of 42 United States Code.

5. "Abuse" means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Division program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care, including beneficiary practices that result in unnecessary cost to the

Division Program.

6. "Actual Acquisition Cost" or "AAC" means the purchase price of a drug paid by a pharmacy net of all discounts, rebates, chargebacks, and other adjustments to the price of the drug, not including Professional Fees.

7. "Adverse Drug Event" or "ADE" means an injury resulting from medical intervention related to a drug including harms that occur during medical care that are directly caused by the drug including but not limited to Medication Errors, adverse drug reactions, allergic reactions, and overdose.

8. "AHCCCS/Division of Fee-For-Service Management" or "DFSM" means the division responsible for the clinical, administrative and claims functions of the Fee-For-Service (FFS) members.

9. "AHCCCS Drug List" means a list of Preferred Drugs in specific therapeutic categories that are Federally and State reimbursable behavioral health and physical health care medications and Medical Devices that the Division utilizes for the administration

of acute and long-term care pharmacy benefits. The AHCCCS Drug List includes Preferred Drugs and was developed to encourage the use of safe, effective, clinically appropriate, and the most cost-effective medications and is supported by current evidence-based medicine.

10. "AHCCCS Fee For Service (FFS) PA criteria effective 10/1/22" means criteria which is based on clinical appropriateness, scientific evidence, and any of the following standards of practice:

a. FDA approved indications and limits;

b. Published practice guidelines and treatment protocols;

c. Comparative data evaluating the efficacy, type and frequency of side effects and potential drug interactions among alternative products as well as the risks, benefits, and potential Member outcomes;

d. Drug Facts and Comparisons;

e. American Hospital Formulary Service Drug Information;

f. United States Pharmacopeia – Drug Information;

g. DRUGDEX Information System;

h. UpToDate;

i. MicroMedex;

j. Peer-reviewed medical literature, including randomized clinical trials, outcomes, research data and pharmacoeconomic studies; or

k. Other drug reference resources.

11. "AHCCCS Pharmacy and Therapeutics Committee" or "AHCCCS P&T Committee" means the advisory committee to AHCCCS, which is responsible for developing, managing, updating, and administering the AHCCCS Drug List. The AHCCCS Pharmacy and Therapeutics Committee (AHCCCS P&T Committee) is primarily composed of physicians, pharmacists, nurses, other health care professionals and community members.

12. "Average Manufacturer Price" or "AMP" means the average price

paid by wholesalers for drugs distributed to the retail class of trade, net of customary prompt pay discounts.

13. "Biosimilar" means a biological drug approved by the Food and Drug Administration (FDA) based on a showing that it is highly similar to an FDA-Approved biological drug, known as the reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product.

14. "Centers For Medicare and Medicaid Services" or CMS" means the Federal agency within the United States Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with State governments to administer Medicaid.

15. "Chronic Intractable Pain" means as specified in A.R.S. § 32-3248.01, meets both of the following:

a. The pain is excruciating, constant, incurable and of such severity that it dominates virtually every conscious moment; and

b. The pain produces mental and physical debilitation.

16. "Dual Eligible Member" means a Member who is eligible for both Medicare and Medicaid. There are two types of Dual Eligible Members:
    a. A Qualified Medicare Beneficiary (QMB) Dual Eligible Member (a QMB Plus or a QMB Only); or
    b. A Non-QMB Dual Eligible Member (a Special Low-Income Beneficiary [SLMB] Plus or an Other Full Benefit Dual Eligible).
17. "Emergency Medication" means for the purposes of this policy, emergency epinephrine and diphenhydramine.
18. "Federal Supply Schedule" or "FSS" means the collection of multiple award contracts used by Federal agencies, U.S. territories, Indian tribes, and other specified entities to purchase supplies and services from outside vendors. Federal Supply Schedule (FSS) prices for the pharmaceutical schedule are negotiated by the Veterans Affairs and are based on the prices that manufacturers charge their "most-favored" non-Federal customers under comparable terms and conditions.

19. "Federal Unit Rebate Amount" means a calculation using the drug manufacturer's pricing. The specific methodology used is determined by statute, and depends upon whether a drug is classified as:

a. Single source ("S" drug category) or Innovator multiple source ("I" drug category);

b. "S" or "I" Line Extension Drug;

c. Non-innovator multiple source ("N" drug category);

d. Clotting Factor drug (CF); or

e. Exclusively Pediatric drug (EP).

20. "First Line Drug" a generic drug or lower-cost drug.

21. "Fraud" means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person, including any act that constitutes Fraud under applicable State or Federal law.

22. "Generic Drug" means a drug that contains the same active

ingredients as a brand name drug and the FDA has approved it to be manufactured and marketed after the brand name drugs patent expires. Generic Drug substitution shall be completed in accordance with Arizona State Board of Pharmacy rules and regulations.

23. "Grandfathering of Non-Preferred Drugs" means the continued authorization of Non-Preferred Drugs for Members who are currently utilizing Non-Preferred Drugs without having completed Step Therapy of the Preferred Drugs on the AHCCCS Drug List, as appropriate.

24. "Guest Dosing" means A mechanism for Members who are not eligible for take-home medication to travel from their home clinic for business, pleasure, or family emergencies and which also provides an option for Members who need to travel for a period of time that exceeds the amount of eligible take-home doses.

25. "Initial Prescriptions for Short Acting Opioid Medication" means a short-acting opioid medication for which the Member has not previously filled any prescription for a short-acting opioid

medication within 60 days of the date of the pharmacy filling the current prescription as evidenced by the Member's PBM prescription profile.

26. "JW Modifier" means a Healthcare Common Procedure Coding System (HCPCS) Level II modifier required to be reported on a claim to report the amount of drug that is discarded and eligible for payment under the discarded drug policy.

27. "Medical Device" means per Section 201(h) of the Food, Drug, and Cosmetic Act, a Device is: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article, including a component part, or accessory which is:

a. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them;

b. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals;

c. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals; and

d. Which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "Device" does not include software functions excluded pursuant to Section 520(o) of the Federal Food, Drug and Cosmetic Act.

28. "Member" means the same as "Client" as defined in A.R.S. § 36-551.

29. "Naloxone" means a prescription medication that reverses the effects of an opioid overdose.

30. "Nominal Price" means a drug that is purchased for a price that is less than 10% of the AMP in the same quarter for which the

AMP is computed.

31. "Non-Preferred Drug" means a medication that is not listed on the AHCCCS Drug List. Non-Preferred Drugs require Prior Authorization (PA).

32. "Non-Title XIX/XXI Member" means a Member who needs or may be at risk of needing covered health-related services but does not meet Federal and State requirements for Title XIX or Title XXI eligibility.

33. "Preferred Drug" means a medication that has been clinically reviewed and approved by the AHCCCS P&T Committee for inclusion on the AHCCCS Drug List as a Preferred Drug due to its proven clinical efficacy and cost effectiveness.

34. "Professional Fee" means the amount paid for the professional services provided by the pharmacist for dispensing a prescription. The Professional Fee does not include any payment for the drug being dispensed.

35. "Repack" or "Repackage" means the act of taking a finished drug

product or unfinished drug from the container in which it was placed in commercial distribution and placing it into a different container without manipulating, changing, or affecting the composition or formulation of the drug.

36. "Responsible Person" means the parent or guardian of a minor with a developmental disability, the guardian of an adult with a developmental disability or an adult with a developmental disability who is a client or an applicant for whom no guardian has been appointed A.R.S. §36-551.

37. "Standing Order" means an AHCCCS registered prescriber's order that can be exercised by other health care workers for a Member that meets the designated criteria by the prescribing provider.

38. "Step Therapy" means the practice of initiating drug therapy for a medical condition with the most cost-effective and safe drug and stepping up through a sequence of alternative drug therapies if the preceding treatment option fails.

39. "Usual and Customary Price" or "U&C Price" means the dollar amount of a pharmacy's charge for a prescription to the general public, a special population, or an inclusive category of customers that reflects all advertised savings, discounts, special promotions, or other programs including membership-based discounts.

~~1.~~40. "Waste" means over-utilization or inappropriate utilization of services, misuse of resources, or practices that result in unnecessary costs to the Medicaid Program.

POLICY

A. THE AHCCCS DRUG LIST

1. The Division shall require the AdSS to maintain its own drug list to meet the unique needs of the Members they serve. The Division shall ensure the AdSS drug list includes all the drugs listed on the AHCCCS Drug List.

2. The Division shall require the AdSS to cover all medically necessary, clinically appropriate, and cost-effective medications

that are Federally and State reimbursable regardless of whether these medications are included on the AHCCCS Drug List.

3. The Division shall require the AdSS to maintain Preferred Drug lists that include every drug exactly as listed on the AHCCCS Drug List.

4. The Division shall not permit the AdSS to add other Preferred Drugs to their Preferred Drug lists in those therapeutic classes when the AHCCCS Drug List specifies a Preferred Drug in a particular therapeutic class.

5. The Division shall require the AdSS to inform their Pharmacy Benefit Managers (PBM) of the Preferred Drugs and shall require the AdSS' PBM to institute Point-of-Sale (POS) edits that communicate back to the pharmacy the Preferred Drugs of a therapeutic class whenever a claim is submitted for a Non-Preferred Drug.

6. The Division shall require the AdSS to cover the Preferred Drugs recommended by the AHCCCS P&T Committee and approved by

AHCCCS, with an effective date by the first day of the first month of the quarter following the AHCCCS P&T Committee meeting, unless otherwise communicated by AHCCCS.

7. The Division shall require AdSS to approve the Preferred Drugs listed for the therapeutic classes contained on the AHCCCS Drug List, as appropriate, before approving a Non-Preferred Drug unless:

   a. The Member has previously completed Step Therapy using the Preferred Drugs; or

   b. The Member's prescribing clinician provides documentation supporting the medical necessity of the Non-Preferred Drug over the Preferred Drug for the Member.

8. The Division shall require that the AdSS does not disadvantage one Preferred Drug over another Preferred Drug when AHCCCS has approved Preferred Drugs or supplemental rebates for a therapeutic class.

9. The Division shall not permit ~~that (Prior Authorization) PA criteria is not required by the~~ the AdSS to require a trial and failure of

one preferred agent when there are others that are also preferred and have the same indication as part of their Prior Authorization(PA) criteria.

10. The Division shall require the AdSS to require PA for the Non-Preferred Drug when the prescribing clinician is not in agreement with transition to the Preferred Drug.

11. The Division shall not require the AdSS to provide a Notice of Adverse Benefit Determination when the prescribing clinician agrees with the change to the First Line or Preferred Drug.

12. The Division shall require the AdSS to issue a Notice of Adverse Benefit Determination for service authorizations when a PA request for a Preferred Drug is denied or a previously approved authorization is terminated, suspended, or reduced.

13. The Division shall require the AdSS to Grandfather Members on medications that AHCCCS has communicated to the Division and AdSS as approved for Grandfathering.

14. The Division shall ensure all Federally and State reimbursable

drugs that are not listed on the AHCCCS Drug List or the AdSS drug lists are available through the PA process.

15. The Division shall require the AdSS to not deny a Federally and State reimbursable medication solely due to the lack of an FDA indication. Off-Label prescribing may be clinically appropriate when evidenced by subsections (a) through (k) above.

16. The Division shall prohibit the AdSS from adding PA or Step Therapy requirements to medications listed on the AHCCCS Drug List when the List does not specify these requirements.

17. The Division shall prohibit the AdSS from denying coverage of a medically necessary medication when the Member's primary insurer, other than Medicare Part D, refuses to approve the request and the primary insurer's grievance and appeals process has been completed.

18. The Division shall require the AdSS to evaluate the medical necessity of the submitted PA for all Federally and State reimbursable medications, including those listed and those not

listed on the AHCCCS Drug List.

19. The Division shall require the AdSS to evaluate the submitted PA request on an individual basis for medications that are Non-Preferred Drugs and not listed on the AHCCCS Drug List.

20. The Division shall require the AdSS to submit requests for medication additions, deletions, or other changes to the AHCCCS Drug List to the AHCCCS P&T Committee for review no later than 60 days prior to the AHCCCS P&T Committee meeting to the AHCCCS Pharmacy Department email at: AHCCCSPharmacyDept@azahcccs.gov.

21. The Division shall require the AdSS to provide the following information with the request for medication additions, deletions, or other changes to the AHCCCS Drug List:

a. Name of medication requested (brand name and generic name);

b. Dosage forms, strengths, and corresponding costs of the medication requested;

c. Average daily dosage;

d. FDA indication and accepted off-label use;

e. Advantages or disadvantages of the medication over currently available products on the AHCCCS Drug List;

f. Adverse Drug Event (ADE) reported with the medication;

g. Specific monitoring requirements and costs associated with these requirements; and

h. A clinical summary for the addition, deletion, or change request.

22. The Division shall require the AdSS to adopt the quantity limits and Step Therapy requirements exactly as they are presented on the AHCCCS Drug List for all Preferred Drugs specified on the AHCCCS Drug List.

23. The Division shall require the AdSS to develop Step Therapy requirements for therapeutic classes when there are no Preferred Drugs identified on the AHCCCS Drug List.

24. The Division shall require the AdSS to obtain PA for the second-line drug when the prescribing clinician is not in agreement with

the transition request to the first-line drug.

25. The Division shall require the AdSS to issue a Notice of Adverse Benefit Determination for service authorizations when a PA request for quantity limits or Step Therapy is denied, or a previously approved authorization is terminated, suspended, or reduced.

B. GENERIC AND BIOSIMILAR DRUG SUBSTITUTIONS

1. The Division shall require the AdSS to utilize a mandatory Generic Drug substitution policy that requires the use of a generic equivalent drug whenever one is available, except for the following:

a. A brand name drug shall be covered when a generic equivalent is available and the AHCCCS negotiated rate for the brand name drug is equal to or less than the cost of the Generic Drug; or

b. When the cost of the Generic Drug has an overall negative financial impact to the State. The overall financial impact to the State includes consideration of the Federal and

supplemental rebates.

~~b.~~ The Division shall ensure the AdSS provides coverage of a brand name drug when the cost of the Generic Drug has an overall negative financial impact to the State. The overall financial impact to the State includes consideration of the Federal and supplemental rebates.

2. The Division shall require the AdSS to require prescribing clinicians to clinically justify the use of a brand-name drug over the use of its generic equivalent through the PA process.

3. The Division shall not permit the AdSS to transition to a Biosimilar drug until AHCCCS has determined that the Biosimilar drug is overall more cost-effective to the State than the continued use of the brand name drug.

4. The Division shall require the AdSS to provide the Generic Drug substitution policy during the Operational Review.

5. The Division shall review the Generic Drug substitution policy provided by the AdSS during the Operational Review.

C. ADDITIONAL INFORMATION FOR MEDICATION COVERAGE

1. The Division shall require the AdSS to cover medications for Members transitioning to a different health plan or FFS as follows:

   a. The transferring AdSS or AHCCCS DFSM provide coverage for medically necessary, cost-effective, and Federally and State reimbursable medications until such time that the Member transitions to their new health plan or FFS Program; and

   a. The AdSS, providers, and Tribal Regional Behavioral Health Authorities (TRBHAs) are responsible for coordinating care when transferring a Member to a new health plan or FFS Program to ensure that the Member's medications are continued during the transition.

2. The Division shall require the AdSS to provide coverage for medically necessary, cost-effective, and Federally and State reimbursable behavioral health medications provided by a

Primary Care Physician (PCP) within their scope of practice which includes the monitoring and adjustments of behavioral health medications.

3. The Division shall require the AdSS to obtain PA for antipsychotic medication class based on age limits depending on the form of the medication.

4. The Division shall require the AdSS to ensure PCPs and BHMPs coordinate the Member's care and that the Member has a sufficient supply of medications to last through the date of the Member's first appointment with the PCP or BHMP when a Member is transitioning from a BHMP to a PCP or from a PCP to a BHMP.

5. The Division shall require the AdSS to allow an individual receiving Methadone or Buprenorphine administration services who is not a recipient of take-home medication to receive Guest Dosing of Methadone or Bupenorphine from the area contractor when the individual is traveling outside of home Opioid Treatment Program (OTP) center.

6. The Division shall require the AdSS to allow a Member to be administered sufficient daily dosing from an OTP center other than their home OTP center when:
   a. A Member is unable to travel to the home OTP center, or
   b. When traveling outside of the home OTP center's area.

7. The Division shall require the AdSS to allow a Member to receive Guest Dosing from another OTP center (guest OTP center) within their Geographic Service Areas (GSA), or outside their GSA.

8. The Division shall require the AdSS to approve Guest Dosing outside the State of Arizona when the prescribing physician determines the Member's health would be endangered if travel were required back to the state of residence.

9. The Division shall require the AdSS to permit a Member to qualify for Guest Dosing when:
   a. The Member is receiving administration of Medications for Opioid Use Disorder (MOUD) services from a SAMHSA-Certified OTP (Substance Abuse and Mental Health Services Administration);

b. The Member needs to travel outside their home OTP center area,

c. The Member is not eligible for take home medication, and

d. The home OTP center (sending OTP center) and guest OTP center have agreed to transition the Member to the guest OTP center for a scheduled period of time.

10. The Division shall require the AdSS does not charge Title XIX/XXI Members for Guest Dosing except as permitted by A.A.C. R9-22-702 and A.A.C. R9-22-711.

11. The Division shall require the AdSS does not charge Non-Title XIX/XXI eligible Members copayments for Guest Dosing.

D. OVER THE COUNTER MEDICATION

The Division shall require the AdSS to cover an over-the-counter (OTC) medication under the pharmacy benefit when it is prescribed in place of a covered prescription medication when it is clinically appropriate, equally safe, effective, and more cost effective than the

covered prescription medication.

E. PRESCRIPTION DRUG COVERAGE, BILLING LIMITATIONS, AND PRESCRIPTION DELIVERY

1. The Division shall require the AdSS to not cover a new prescription or refill prescription in excess of a 30-day supply unless:
   a. The medication is prescribed for chronic illness and the prescription is limited to no more than a 90-day supply;
   b. The Member will be out of the provider's service area for an extended period of time and the prescription is limited to the extended time period, not to exceed 90 days; or
   c. The medication is prescribed for contraception and the prescription is limited to no more than a 90-day supply.
2. The Division shall require the AdSS to provide prescription drugs for covered transplant services in accordance with AdSS Medical Policy Manual Policy 310-DD.
3. The Division shall require the AdSS to cover the following for

Members who are eligible to receive Medicare:

a. OTC medications that are not covered as part of the Medicare Part D prescription drug program and the drug meets the requirements in Section (D) of this policy;

b. A drug that is excluded from coverage under Medicare Part D by the Centers For Medicare and Medicaid Services (CMS) and the drug is medically necessary and Federally reimbursable; and

c. Cost sharing for medications to treat behavioral health conditions for individuals with an SMI designation.

4. The Division shall not permit the AdSS to allow pharmacies to charge a Member the cash price for a prescription, other than an applicable copayment, when the medication is Federally and State reimbursable and the prescription is ordered by an AHCCCS registered prescribing clinician.

5. The Division shall not permit the AdSS to allow pharmacies to split-bill the cost of a prescription claim to the AdSS PBMs for

Members.

6. The Division shall not permit the AdSS PBMs pharmacies to allow a Member to pay cash for a partial prescription quantity for a Federally and State reimbursable medication when the ordered drug is written by an AHCCCS registered prescribing clinician.

7. The Division shall require the AdSS to communicate to the pharmacies that they are prohibited from auto-filling prescription medications.

8. The Division shall not permit the AdSS to allow pharmacies to submit prescription claims for reimbursement in excess of the Usual and Customary Price (U&C Price) charged to the general public.

9. The Division shall require the AdSS to ensure that the sum of charges for both the product cost and dispensing fee does not exceed a pharmacy's U&C Price for the same prescription.

10. The Division shall require the AdSS to ensure that the U&C Price submitted ingredient cost is the lowest amount accepted from

any Member of the general public who participates in the pharmacy provider's savings or discount programs including programs that require the Member to enroll or pay a fee to join the program.

11. The Division shall require the AdSS to ensure pharmacies that purchase drugs at a Nominal Price outside of 340B or the FSS bill their Actual Acquisition Cost (AAC) of the drug.

F. PA REQUIREMENTS FOR LONG-ACTING OPIOID MEDICATIONS

1. The Division shall require the AdSS, AdSS' PBM or AHCCCS' PBM, as applicable, to require the prescriber to obtain PA for all long-acting opioid prescription medications unless the Member's diagnosis is one the following:
   a. Active oncology diagnosis with neoplasm related pain;
   b. Hospice care; or
   c. End of life care (other than hospice).

2. The Division shall require the AdSS, AdSS' PBM or AHCCCS' PBM as applicable, to require the prescriber to obtain their approval

or an exception for all long-acting opioid prescription medications.

G. 5-DAY SUPPLY LIMIT OF PRESCRIPTION SHORT-ACTING OPIOID MEDICATIONS FOR MEMBERS UNDER 18 YEARS OF AGE

1. The Division shall require the AdSS to require a prescriber to limit the initial and refill prescriptions for any short-acting opioid medication for a Member under 18 years of age to no more than a 5-day supply, except as otherwise specified in Section (G) (2) below, "Conditions and Care Exclusion from the 5-day Supply Limitation".

2. The Division shall require the AdSS abide by the following Conditions and Care Exclusions from the 5-day Supply Limitation:

   a. The initial and refill prescription 5-day supply limitation for short- acting opioid medications does not apply to prescriptions for the following conditions and care instances:

i. Active oncology diagnosis;

ii. Hospice care;

iii. End-of-life care (other than hospice);

iv. Palliative Care;

v. Children on an opioid wean at the time of hospital discharge;

vi. Skilled nursing facility care;

vii. Traumatic injury, excluding post-surgical procedures;

viii. Chronic conditions for which the provider has received PA approval through the AdSS;

b. The initial prescription 5-day supply limitation for short-acting opioid medications does not apply to prescriptions for post-surgical procedures. However, Initial Prescriptions for Short-Acting Opioid Medications for postsurgical procedures are limited to a supply of no more than 14 days. Refill prescriptions for short-acting opioid medications for post-surgical procedures are limited to no more than a 5-day supply.

H. 5-DAY SUPPLY LIMIT OF PRESCRIPTION SHORT-ACTING OPIOID MEDICATIONS FOR MEMBERS 18 YEARS OF AGE AND OLDER

1. The Division shall require the AdSS to require a prescriber to limit the initial prescription for any short-acting opioid medication for a Member 18 years of age and older to no more than a 5-day supply, except as otherwise specified in Section (H) (2) below, "Conditions and Care Exclusion from the 5-day Supply Limitation".

2. The Division shall require the AdSS to abide by the following Conditions and Care Exclusions from the 5-day Initial Supply Limitation:

a. The initial prescription 5-day supply limitation for short-acting opioid medications does not apply to prescriptions for the following conditions and care instances:

i. Active oncology diagnosis;

ii. Hospice care;

iii. Palliative Care;

iv. Skilled nursing facility care;

v. Traumatic injury, excluding post-surgical procedures;

vi. Post-surgical procedures; and

vii. The medication is for SUD treatment.

b. Initial Prescriptions for Short-Acting Opioid Medications for post-surgical procedures are limited to a supply of no more than 14 days.

I. ADDITIONAL FEDERAL OPIOID LEGISLATION (42 USC 1396A(OO)) MONITORING REQUIREMENTS

1. The Division shall require the AdSS to implement automated processes to monitor the following opioid safety edits at the POS:

a. A 5 days supply limit for opioid naïve members;

b. Quantity limits;

c. Therapeutic duplication limitations;

d. Early fill limitations;

e. Opioid naïve Members prescribed an opioid, and the Morphine Equivalent Daily Dose (MEDD) is 50 or greater;

f. Member utilization when the cumulative current utilization of opioids is a MEDD of greater than 90 and the Member

is not opioid naive;

g. Members with concurrent use of an opioid in conjunction with a benzodiazepine or an antipsychotic;

h. Members are prescribed an opioid after being prescribed drugs used for MOUD for an Opioid Use Disorder (OUD);

i. OUD diagnosis;

j. Antipsychotic prescribing for children;

k. Fraud, Waste, and Abuse by enrolled Members, pharmacies, and prescribing clinicians; and

l. Prospective and retrospective opioid reviews.

2. The Division shall require the AdSS to report Drug Utilization Review management activities annually to the Division.

3. The Division shall require the AdSS to allow a health care professional to write for a prescription that is more than 90 Morphine Milligram Equivalents (MME) per day if the prescription is:

a. A continuation of a prior prescription order issued within the previous 60 days;

b. An opioid with a maximum approved total daily dose in the labeling as approved by the U.S. Food and Drug Administration (FDA);

c. For a Member who has an active oncology diagnosis or a traumatic injury;

d. Receiving opioid treatment for perioperative surgical pain;

e. For a Member who is hospitalized;

f. For a Member who is receiving hospice care, end-of-life care, palliative care, skilled nursing facility care or treatment for burns;

g. For a Member who is receiving MAT for a substance use disorder; or

h. For chronic intractable pain.

J. NALOXONE

1. The Division shall require the AdSS to cover and consider Naloxone as an essential prescription medication to reduce the risk and prevent an opioid overdose death.

2. The Division shall require the AdSS to require a prescription, ordered by an AHCCCS registered provider, be on file at the pharmacy when Naloxone is dispensed to or for a specific Member.

3. The Division shall require the AdSS to adhere to the following process:

a. Have a Standing Order written by the Director of the Arizona Department of Health Services on file at all Arizona pharmacies;

b. Identify the following eligible candidates that may obtain Naloxone:

i. Members who use illicit or non-prescription opioids with a history of such use;

ii. Who have a history of opioid misuse, intoxication, or a recipient of emergency medical care for acute opioid poisoning;

iii. Members who have been prescribed high dose opioid prescriptions of 90 MEDD or less if there are other risk factors;

iv. Members who have been prescribed an opioid with a known or suspected concurrent alcohol use;

v. Members who are from opioid detoxification and mandatory abstinence programs;

vi. Members who have been treated with methadone for addiction or pain;

vii. Members who have an opioid addiction and smoking or Chronic Obstructive Pulmonary Disease (COPD) or other respiratory illness or obstruction;

viii. Members who have been prescribed opioids who also have renal, hepatic, cardiac, or HIV/AIDs (Human

Immunodeficiency Virus/Acquired Immunodeficiency Syndrome) disease;

ix. Members who have difficulty accessing emergency services;

x. Members who have been assigned to a pharmacy or prescribing clinician;

xi. Members who voluntarily request Naloxone and are the family member or friend of a Member at risk of experiencing an opioid related overdose; and

xii. Members who voluntarily request Naloxone and are in the position to assist a Member at risk of experiencing an opioid related overdose.

4. The Division shall require the AdSS to cover:

a. Naloxone Solution plus syringes,

b. Naloxone Nasal Spray known as Narcan Nasal Spray, and

c. Refills of the above Naloxone products on an as needed basis.

5. The Division shall require the AdSS to require the pharmacy to educate every Member on the use of Naloxone by the pharmacist dispensing the medication in accordance with Arizona State Board of Pharmacy Regulations.

K. PHARMACY BENEFIT EXCLUSIONS

1. The Division shall require the AdSS to treat the following pharmacy benefits as excluded and shall not be covered:
   a. Medications prescribed for the treatment of a sexual or erectile dysfunction, unless:
      i. The medication is prescribed to treat a condition other than a sexual or erectile dysfunction, and
      ii. The FDA has approved the medication for the specific condition.
   b. Medications that are personally dispensed by a physician, dentist, or other provider except in geographically remote areas where there is no participating pharmacy or when

accessible pharmacies are closed;

c. Drugs classified as Drug Efficacy Study Implementation (DESI) drugs by the FDA;

d. Outpatient medications for Members under the Federal Emergency Services Program, except for dialysis related medications for extended services individuals;

e. Medical Marijuana;

f. Drugs eligible for coverage under Medicare Part D for Members eligible for Medicare whether or not the Member obtains Medicare Part D coverage except for Dual Eligible Members that have creditable coverage or individuals with an SMI designation;

g. Experimental medications as specified in A.A.C. § 9-22-203;

h. Medications furnished solely for cosmetic purposes;

i. Medications used for weight loss treatment; or

j. Complementary and Alternative Medicines.

L. RETURN OF AND CREDIT FOR UNUSED MEDICATIONS

1. The Division shall require the AdSS to require the return of unused medications to the outpatient pharmacy from Nursing Facilities (NFs) upon the discontinuance of prescriptions due to the transfer, discharge, or death of a Member.

2. The Division shall require the AdSS to have the outpatient pharmacy issue a payment or credit reversal to the AdSS or the AdSS PBM for unused prescription medications. The pharmacy may charge a restocking fee when agreed upon with AHCCCS and the Division or AdSS.

3. The Division shall require the AdSS to require the return of unused prescription medication in accordance with Federal and State laws.

4. The Division shall require the AdSS to maintain documentation and include the quantity of medication dispensed and utilized by the Member.

5. The Division shall require the AdSS to issue a credit to AHCCCS if the Member is enrolled in the THP, TRBHA, or FFS Program, to the Member's AdSS for Members who are not FFS when the unused medication is returned to the pharmacy for redistribution.

M. DISCARDED PHYSICIAN-ADMINISTERED MEDICATIONS

1. The Division shall allow any discarded portion of Federally and State reimbursable, physician-administered drugs that are unit-dose or unit-of-use designated products in MediSpan or First DataBank to be billed to the AdSS.

2. The Division shall require AdSS to ensure prescribers use the most cost-effective product(s) for the required dose to be administered.

3. The Division shall require the AdSS to not allow billing from the prescriber or reimburse the prescriber for any use or discarded portion of a unit-of-use or unit dose Repackaged drugs.

4. The Division shall require the AdSS to ensure, for multidose products, prescribers only bill for the actual amount of drug that was used and the AdSS only reimburse the actual amount of used drug.

N. PRIOR AUTHORIZATION CRITERIA FOR SMOKING CESSATION AIDS

The Division shall require the AdSS to follow the AHCCCS established PA criteria for tobacco cessation aids.

O. VACCINES AND EMERGENCY MEDICATIONS ADMINISTERED BY PHARMACISTS TO INDIVIDUALS THREE YEARS OF AGE AND OLDER

1. The Division shall require the AdSS to cover vaccines and Emergency Medication without a prescription order when administered by a pharmacist who is currently licensed and certified by the Arizona State Board of Pharmacy consistent with the limitations of this Policy and A.R.S. § 32-1974.

2. The Division shall require the AdSS to ensure pharmacists, pharmacy technicians, and pharmacy interns under the supervision of a pharmacist, within their scope of practice, only

administer influenza and COVID immunizations to Members who are at least three years of age through 18 years of age.

3. The Division shall require the AdSS to ensure pharmacists, pharmacy technicians, and pharmacy interns under the supervision of a pharmacist, within their scope of practice, administer AHCCCS covered immunizations to adults at least 18 years and older as specified in A.R.S. § 32-1974.

4. The Division shall require the AdSS to ensure the pharmacies providing the vaccine are an AHCCCS registered provider.

5. The Division shall require the AdSS to retain the discretion to determine the coverage of vaccine administration by pharmacists, pharmacy interns and technicians under the supervision of a pharmacist and that coverage is limited to the AdSS network pharmacies unless otherwise directed by AHCCCS.

P. 340B COVERED ENTITIES AND CLAIM SUBMISSION

1. The Division shall require the AdSS to ensure that 340B covered

entities submit the AAC of the drug for Member's POS prescription and physician-administered drug claims that are identified on the 340B pricing file, whether or not the drugs are purchased under the 340B Drug Pricing Program.

2. The Division shall require the AdSS to reimburse POS claims at the lesser of:

a. The AAC, or

b. The 340B Ceiling Price, and

c. A Professional Fee (dispensing fee).

3. The Division shall require the AdSS to ensure physician administered drugs are reimbursed at the lesser of the AAC or the 340B ceiling price, and the Professional (dispensing) Fee is not reimbursed and is not permitted when a physician administered drug is administered by the prescribing clinician.

4. The Division shall require the AdSS to not reimburse 340B Contracted Pharmacies for drugs that are purchased, dispensed, or administered as part of or subject to the 340B Drug Pricing Program.

5. The Division shall require the AdSS to comply with any changes to reimbursement methodology for 340B entities.

Q. PHARMACEUTICAL REBATES

1. The Division shall require the AdSS, including the THP PBM and AdSS' PBM, to be prohibited from negotiating any rebates with drug manufacturers for preferred or other pharmaceutical products when AHCCCS has a supplemental rebate contract for the product.

2. The Division shall require the AdSS or its PBM's consider outpatient drug claims, including provider-administered drugs for which AHCCCS is obtaining supplemental rebates, to be exempt from such rebate agreements if they have an existing rebate agreement with a manufacturer.

R. INFORMED CONSENT

1. The Division shall require the AdSS to ensure the prescriber

obtains informed consent from the Responsible Person for each psychotropic medication prescribed.

2. The Division shall require the AdSS to ensure that prescribers are documenting the essential elements for obtaining informed consent in the comprehensive clinical record, utilizing AMPM Attachment 310-V (A).

S. YOUTH ASSENT

1. The Division shall require the AdSS to ensure prescribers educate youth under the age of 18 on options, are allowed to provide input, and are encouraged to assent to medications being prescribed.

2. The Division shall require the AdSS to ensure prescribers discuss this information with the youth in a clear and age-appropriate manner consistent with the developmental needs of the youth.

3. The Division shall require the AdSS to ensure prescribers share information with Members who are under the age of 18 that is

consistent with the information shared in obtaining informed consent from adults.

4. The Division shall require the AdSS to ensure the prescribers obtain informed consent for a minor through the minor's authorized Responsible Person unless the minor is emancipated.

5. The Division shall require the AdSS to ensure prescribers discuss the youth can give consent for medications when they turn 18.

6. The Division shall require the AdSS to begin the discussion about consent for medication no later than age 17½ years old, especially for youth who are not in the custody of their parents.

7. The Division shall require the AdSS to ensure prescribers address the effect of medications on the reproductive status and pregnancy, as well as long term effects on weight, abnormal involuntary movements, and other health parameters.

8. The Division shall require the AdSS to ensure the prescribers document evidence of the youth's consent to continue medications after their 18th birthday through use of AMPM

Attachment 310-V (A).

T. PRESCRIPTION DRUG COUNSELING

The Division shall require the AdSS to communicate to the pharmacy network that pharmacists, and graduate and non-graduate pharmacy interns, under the supervision of a pharmacist are to provide counseling on prescription drugs, prescribed and dispensed to AHCCCS members, in accordance with the Arizona State Board of Pharmacy A.A.C. 4-23-402.

~~R.~~**U.** DIVISION OVERSIGHT AND MONITORING

1. The Division shall oversee the AdSS utilizing the following methods to ensure compliance with policy:
   a. Annual Operational Review of each AdSS,
   b. Review and analyze deliverable reports submitted by the AdSS, and
   c. Conduct oversight meetings with the AdSS for the purpose of:

i. Reviewing compliance,

ii. Addressing concerns with access to care or other quality of care concerns,

iii. Discussing systemic issues, and

iv. Providing direction or support to the AdSS as ~~1.~~ necessary.

SUPPLEMENTAL INFORMATION

1. A controlled substance is defined in A.R.S. § 32-3248.01. For opioid prescribing guidelines refer to the Arizona Opioid Epidemic Act.

2. The Division shall require the AdSS to cover medically necessary, cost-effective and federally and State reimbursable medications and devices for Members as prescribed or administered by a physician, physician's assistant, nurse practitioner, dentist, or other AHCCCS registered practitioner with prescriptive authority in the State of Arizona and dispensed by an AHCCCS registered licensed pharmacy pursuant to 9 A.A.C. 22 Article 2, 9 A.A.C. 28

Article 2, and 9 A.A.C. 31 Article 2, and for persons with a SMI designation, pursuant to A.R.S. § 36-550.

3. Generic and Biosimilar substitutions shall adhere to Arizona State Board of Pharmacy rules and regulations.

4. Arizona 340B entity hospitals, and outpatient facilities owned and operated by a 340B entity hospital, are not exempt from the reimbursement methodology listed in Section (P) (2).

5. Effective with a future date to be determined, 340B hospitals and outpatient facilities, owned and operated by a 340B hospital, shall be required to submit claims at the entity's AAC.

6. The provider shall use the most cost-effective product(s) for the required dose to be administered. For example, if the dose to be administered is 12mg and the product is available in a 10mg and 50mg vial, the provider shall use two - 10mg vials to obtain the 12mg dose. The 12mg dose shall be billed as the administered dose and 8mg shall be billed as discarded waste using the JW modifier.

7. Effective 01/01/22, repackaged medications are not Federally and State reimbursable.

8. Mental Health Block Grant (MHBG) provisions shall apply to Children with Serious Emotional Disturbance (SED), Individuals in First Episode Psychosis (FEP), and Adults with SMI designation. For individuals with a Substance Use Disorder (SUD), Substance Abuse Block Grant (SABG) provisions shall apply.

9. The AHCCCS Pharmacy and Therapeutics (P&T) Committee is responsible for developing, managing, and updating the AHCCCS Drug List to assist providers in selecting clinically appropriate and cost-effective drugs or devices for Members.

10. The AHCCCS Drug List is not an all-inclusive list of medications for Members.

11. The AHCCCS P&T Committee shall make recommendations to the AdSS on the Grandfathering status of each Non-Preferred Drug for each therapeutic class reviewed by the committee.

12. The AHCCCS Drug List specifies which medications require PA prior to dispensing the medication.

13. Step Therapy programs apply coverage rules at the point of service when a claim is adjudicated that typically require the use of a more cost effective drug that is safe and effective to be used prior to approval of a more costly medication.

14. Guest Dosing is consistent with Substance Abuse and Mental Health Services Administration's (SAMHSA's) guidance regarding medication safety and recovery support.

15. Pharmacies, at their discretion, shall deliver or mail prescription medications to a Member or to an AdSS registered provider's office for a specific Member.

The Sending OTP Center

1. The Sending OTP Center shall forward information to the Receiving OTP Center prior to the Member's arrival, information shall include:

a. A valid release of information signed by the Member;

b. Current medications;

c. Date and amount of last dose administered or dispensed;

d. Physician order for Guest Dosing, including first and last dates of Guest Dosing;

e. Description of clinical stability including recent alcohol or illicit drug Abuse; and

f. Any other pertinent information.

2. The Sending OTP Center shall provide a copy of the information to the Member in a sealed, signed envelope for the Member to present to the Receiving OTP Center.

3. The Sending OTP Center shall submit notification to the AdSS of enrollment of the Guest Dosing arrangement.

4. The Sending OTP Center shall accept the Member upon return from the Receiving OTP Center unless other arrangements have been made.

The Guest OTP Center

1. The Guest OTP Center shall:

a. Respond to the Sending OTP Center in a timely fashion, verifying receipt of information and acceptance of the Member for guest medication as quickly as possible;

b. Provide the same dosage that the Member is receiving at the Member's Sending OTP Center, and change only after consultation with Sending OTP Center;

c. Bill the Member's Contractor of enrollment for reimbursement utilizing the appropriate coding and modifier;

d. Provide address of Guest OTP Center and dispensing hours;

e. Determine appropriateness for dosing prior to administering a dose to the Member. The Guest OTP Center has the right to deny medication to a Member if they present inebriated or under the influence, acting in a bizarre manner, threatening violence, loitering, or inappropriately interacting with other Members;

f. Communicate any concerns about a guest-dosing the

Member to the Sending OTP Center including termination of guest-dosing if indicated; and

g. Communicate the last dose date and amount back to the Sending OTP Center.

Signature of Chief Medical Officer: