310-V - PRESCRIPTION MEDICATIONS/PHARMACY SERVICES

EFFECTIVE DATES: 10/01/94, 01/01/18, 10/01/18, xx/xx/xx[1]

~~REVISION~~ APPROVAL DATES: 10/01/96, 10/01/97, 10/01/01, 06/01/05, 01/01/06, 04/01/06, 10/01/09, 10/01/10, 08/01/11, 04/01/12, 10/01/12, 01/01/13, 03/01/14, 08/01/14, 02/01/15, 01/01/16, 07/01/16, 04/01/17, 11/16/17, 05/17/18, 03/21/19[2]

I. PURPOSE

This Policy applies to AHCCCS Complete Care (ACC), ALTCS ~~/~~E/PD, DCS/CMDP (CMDP), DES/DDD (DDD), RBHA Contractors; and Fee-For-Service (FFS) Programs ~~delineated within this Policy~~[3] including: Tribal ALTCS, TRBHAs, and the American Indian Health Program (AIHP), and all FFS ~~populations~~providers[4], excluding Federal Emergency Services (FES). (For FES, see AMPM Chapter 1100). The purpose of this Policy is to outline medication/pharmacy coverage requirements and limitations of the AHCCCS pharmacy benefit.

II. DEFINITIONS

340B CEILING PRICE	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 minus the Federal Unit Rebate Amount.
340B CONTRACTED PHARMACIES	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.
340B COVERED ENTITY	An organization as defined by 42 United States Code section 256b that participates in the 340B drug pricing program.
340B DRUG PRICING PROGRAM	The discount drug purchasing program described in section 256b of 42 United States Code.
ACTUAL ACQUISITION COST	The purchase price of a drug paid by a pharmacy net of all discounts, rebates, chargebacks and other adjustments to the

[1] Date Policy is Effective
[2] Date Policy presented at APC
[3] Removed; formatting
[4] Revised to FFS providers; formatting standard

price of the drug, not including professional fees.

ADVERSE DRUG EVENT (ADE)

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.

~~**AHCCCS BEHAVIORAL HEALTH DRUG LIST**~~[5]

~~A list of preferred behavioral health medications that are to be used by AHCCCS FFS and all Contractors responsible for the administration of behavioral health pharmacy benefits, including but not limited to Long Term Care, Children's Rehabilitative Services, and RBHAs. This drug list is limited to federally and state reimbursable behavioral health medications that are supported by current evidence-based medicine. The AHCCCS Behavioral Health Drug List was developed to encourage the use of safe, effective, clinically appropriate, and the most cost-effective behavioral health medications.~~

AHCCCS DRUG LIST

A list of federally and state reimbursable behavioral health and physical health care ~~preferred drugs~~ medications [6] that is~~are~~ to be used by AHCCCS FFS Programs and all Contractors responsible for the administration of acute and long-term care pharmacy benefits. This drug list identifies specific federally and state reimbursable medications and related products, which are supported by current evidence-based medicine. 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.

AVERAGE MANUFACTURER PRICE (AMP)[7]

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

~~**AHCCCS DRUG LISTS**~~

~~Refers to both the AHCCCS Drug List and the AHCCCS Behavioral Health Drug List~~[8]

BIOSIMILAR

A biological drug approved by the 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

[5] Removed we now have the AHCCCS Drug List which combines both BH and Physical Health Care Drugs.
[6] Adding clarity to the definition.
[7] Definition added because AMP is used later in the policy
[8] Removed; Drug Lists to be combined

	from the reference product.
CMS	Refers to the Centers for Medicare and Medicaid Services and is 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.[9]
FEDERAL SUPPLY SCHEDULE (FSS)[10]	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. FSS prices for the pharmaceutical schedule are negotiated by the VA and are based on the prices that manufacturers charge their "most-favored" non-Federal customers under comparable terms and conditions.[11]
GENERIC DRUG	A drug that contains the same active ingredient(s) 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.
HEALTH CARE DECISION MAKER	An individual who is authorized to make health care treatment decisions for the patient. As applicable to the particular situation, this may include a parent of an unemancipated minor or a person lawfully authorized to make health care treatment decisions pursuant to A.R.S. title 14, chapter 5, article 2 or 3; or A.R.S. §§ 8-514.05, 36-3221, 36-3231 or 36-3281.
MEDICATION ERROR	The inappropriate use of a drug that may or may not result in harm; such errors may occur during prescribing, transcribing, dispensing, administering, adherence, or monitoring of a drug.
NOMINAL PRICE	A drug that is purchased for a price that is less than 10% of the Average Manufacturer Price in the same quarter for which the AMP is computed. [12]
NON-PREFERRED DRUG	A medication that is not listed on the AHCCCS Drug List or the AHCCCS Behavioral Health Drug List. Non-preferred drugs require prior authorization.

[9] Defining the acronym for CMS which will be used further down in the policy
[10] Adding the acronym since it is used in the definition.
[11] Definition needed because the terminology is used later in the policy.
[12] Added this definition because it is used later in the policy

PALLIATIVE CARE[13]	Medical care for members with a chronic or terminal illness. It focuses on providing members with relief from symptoms and the stress of illness. The goal is to improve the quality of life for both the member and his or her families. It is appropriate at any age and any stage in the illness and can be provided in conjunction with curative treatment outside the context of hospice care.
PHARMACY AND THERAPEUTICS (P&T) COMMITTEE	The advisory committee to ~~the~~ AHCCCS ~~Administration~~[14], which is responsible for developing, managing, updating, and administering the AHCCCS Drug List~~, and AHCCCS Behavioral Health Drug List~~[15]. The P&T Committee is primarily comprised of physicians, pharmacists, nurses, other health care professionals and community members.
PREFERRED DRUG	A medication that has been clinically reviewed and approved by the AHCCCS P&T Committee for inclusion on the AHCCCS Drug List and/or the AHCCCS Behavioral Health Drug List as a preferred drug due to its proven clinical efficacy and cost effectiveness.
PRIMARY CARE PROVIDER (PCP)[16]	"Primary care provider" or "PCP" means an individual who meets the requirements of A.R.S. § 36-2901 (14), and who is responsible for the management of a member's health care.
PROFESSIONAL FEE	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.
SERIOUS MENTAL ILLNESS (SMI)	A diagnosis of~~,~~ a condition defined in A.R.S. §36-550 ~~and diagnosed~~[17] in a person 18 years of age or older.
STANDING ORDER	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.[18]

[13] This definition is in this Policybecause of the opioid 5-day limitation and its exception
[14] Re-naming 'AHCCCS Administration' to 'AHCCCS' throughout Policy
[15] Removing behavioral health drug list- there is only one list.
[16] Added acronym
[17] Simplifying the language.
[18] Definition needed to address Naloxone in the policy. Some of the language is fom the Center for Substance Abuse Research
University of Maryland.

STEP THERAPY 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.

USUAL & CUSTOMARY PRICE (U&C) The dollar amount of a pharmacy's charge for a prescription to the general public–, a special population, or an inclusive category of customers[19] that reflects all advertised savings, discounts, special promotions, or other programs including membership based discounts.[20]

III. POLICY

AHCCCS and its Contractors shall cover m~~M~~edically necessary, cost-effective and federally and state reimbursable medications for members as prescribed and/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 ~~are covered for members consistent with~~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 who have a diagnosis of SMI, pursuant to A.R.S. §36-550.

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. Refer to AMPM Policy 320-T for additional requirements.[21]

~~THE AHCCCS DRUG LIST AND THE AHCCCS BEHAVIORAL HEALTH DRUG LIST ALSO TO BE REFERRED TO AS THE AHCCCS DRUG LISTS~~

A. THE AHCCCS DRUG LIST

The AHCCCS ~~Pharmacy and Therapeutics (~~P&T~~)~~ Committee is responsible for developing, managing, and updating the AHCCCS Drug List ~~and the AHCCCS Behavioral Health Drug List~~[22] to assist providers in selecting clinically appropriate and cost-effective drugs for AHCCCS members. The AHCCCS P&T Operational Policy can be located at:
https://www.azahcccs.gov/PlansProviders/Downloads/PharmacyUpdates/PTCOperationalPolicy.pdf

[19] Simplifying the language; inclusive category of customers is any group the pharmacy may market to solicit participation in a pharmacy discount program; or when pharmacy has a free program but requires registration paperwork.
[20] Adding a definition for U & C to reflect our practices & U&C will be used later in the policy
[21] Listed applicable grants
[22] The AHCCCS Drug List and Behavioral Health Drugs List have been combined into the AHCCCS Drug List

Each Contractor is required to maintain its own drug list to meet the unique needs of the members they serve. At a minimum, the Contractor's drug list ~~must~~shall[23] include all of the drugs listed on the AHCCCS Drug List~~s~~ as further detailed below.

The AHCCCS Drug List~~s~~ is~~are~~ not an all-inclusive list~~s~~ of medications for AHCCCS members. Contractors are required to cover *all* medically necessary, clinically appropriate, and cost-effective medications that are federally and state reimbursable regardless of whether or not these medications are included on this ~~ese~~ list~~s~~.

1. Preferred Drugs

   The AHCCCS Drug List~~s~~ designates medications that are P~~p~~referred D~~d~~rugs for specific therapeutic classes. Contractors are required to maintain P~~p~~referred D~~d~~rug lists that include each and every drug exactly as listed on the AHCCCS Drug List~~s~~~~, as applicable~~[24]. When the AHCCCS Drug List~~s~~ specifies~~y~~ a P~~p~~referred D~~d~~rug(s) in a particular therapeutic class, Contractors are not permitted to add other P~~p~~referred D~~d~~rugs to their P~~p~~referred D~~d~~rug lists in those therapeutic classes.

   Contractors shall inform their Pharmacy Benefit Managers (PBM) of the P~~p~~referred D~~d~~rugs and shall require the PBM to institute point-of-sale edits that communicate back to the pharmacy the **P~~p~~referred D~~d~~rug(s) of a therapeutic class whenever a claim is submitted for a N~~n~~on-P~~p~~referred** D~~d~~rug. Preferred D~~d~~rugs recommended by the AHCCCS P&T Committee and approved by AHCCCS are effective on the first day of the first month of the quarter following the P&T Meeting unless otherwise communicated by AHCCCS.

   Contractors shall approve the P~~p~~referred D~~d~~rugs listed for the therapeutic classes contained on the AHCCCS Drug List~~s~~, as appropriate, before approving a N~~n~~on-P~~p~~referred D~~d~~rug unless:
   a. The member has previously completed S~~s~~tep T~~t~~herapy using the P~~p~~referred D~~d~~rug(s), or
   b. The member's prescribing clinician supports the medical necessity of the N~~n~~on-P~~p~~referred D~~d~~rug over the P~~p~~referred D~~d~~rug for the particular member.

   Contractors are not required to provide a Notice of Adverse Benefit Determination (NOA) when the prescribing clinician is in agreement with the change to the P~~p~~referred D~~d~~rug. A Prior Authorization (PA) request may be submitted for the N~~n~~on-P~~p~~referred D~~d~~rug when the prescribing clinician is not in agreement with transition to the P~~p~~referred D~~d~~rug. Contractors shall issue a NOA in accordance with ACOM Policy 414 for Service Authorizations when a PA request is denied or a previously approved authorization is terminated, suspended, or reduced.

[23] Replaced 'must' with 'shall' throughout policy
[24] Removing "as applicable" because we have just one drug list.

2. Grandfathering of Non-Ppreferred Drugs

Grandfathering of Nnon-Ppreferred Ddrugs refers to the continued authorization of Nnon-Ppreferred Ddrugs for members who are currently utilizing Nnon-Ppreferred Ddrugs without having completed Sstep Ttherapy of the Ppreferred Ddrug(s) on the AHCCCS Drug Lists, as appropriate.

The AHCCCS P&T Committee shall make recommendations to AHCCCS on the grandfathering status of each Nnon-Ppreferred Ddrug for each therapeutic class reviewed by the committee. AHCCCS shall communicate to Contractors the Nnon-Ppreferred Ddrugs that have been approved for grandfathering. Contractors are required to grandfather members on these medications.

3. Prior Authorization

The AHCCCS Drug Lists specifiesy which medications require PA prior to dispensing the medication.

Contractors may establish PA criteria based on clinical appropriateness, scientific evidence, and standards of practice that include, but are not limited, to all of the following:

a. Food and Drug Administration (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, and
k. Other drug reference resources

All federally and state reimbursable drugs that are not listed on the AHCCCS Drug Lists or the Contractors' drug lists mustshall be available through the PA process.

A federally and state reimbursable medication shall not be denied solely due to the lack of a FDA indication. Off-Label prescribing may be clinically appropriate as outlined and evidenced by a. through k. above.

Contractors are prohibited from adding PA and/or Sstep Ttherapy requirements to medications listed on the AHCCCS Drug Lists when the List does not specify these requirements.

In addition, Contractors are prohibited 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 insuror's grievance and appeals process has been completed. Contractors must evaluate the medical necessity of the submitted prior authorization for all federally and state reimbursable medications including those listed ands those not listed on the –AHCCCS Drug List.[25]

In addition, for medications that are Nn~~n~~on-Pp~~p~~referred Dd~~d~~rugs and not listed on the AHCCCS Drug List~~s~~, Contractors shall evaluate the submitted PA request on an individual basis.

~~The RBHA Contractors and the AHCCCS Administration shall cover medically necessary federally and state reimbursable behavioral health medications for persons who are Title XIX, Title XXI, and for persons who are SMI, regardless of whether or not they are eligible for Title XIX or Title XXI. It is not a basis to deny coverage of a medically necessary medication when the member's insurer, other than Medicare Part D, refuses to approve the request or appeal for a medication listed on the AHCCCS Behavioral Drug List.~~[26]

4. Requests for Changes to the AHCCCS Drug List

   Requests for medication additions, deletions or other changes to the AHCCCS Drug List~~s~~ shall be reviewed by the AHCCCS P&T Committee. Requests ~~must~~shall be submitted no later than 60 days prior to the AHCCCS P&T Meeting to the AHCCCS Pharmacy Department email at:
   AHCCCSPharmacyDept@azahcccs.gov

   The request ~~must~~shall include all of the following information:
   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~~s~~,
   f. ~~Adverse Drug Events~~ADE[27] 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.

5. Quantity Limits / Step Therapy

[25] ~~Added vergiage to address eligible drugs not listed on the AHCCCS Drug List.~~
[26] Language removed; last sentence retained and moved under PA section
[27] Replaced with acronym as abbreviated in Definitions

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.

For all Ppreferred Ddrugs specified on the AHCCCS Drug Lists, Contractors ~~must~~shall adopt the quantity limits and Sstep Ttherapy requirements exactly as they are presented on the AHCCCS Drug Lists. For therapeutic classes where there are no Ppreferred Ddrugs identified on the AHCCCS Drug Lists, Contractors may develop Sstep Ttherapy requirements.

Contractors are not required to provide a NOA when the prescribing clinician is in agreement with the change to the first-line drug. A PA may be submitted for the second-line drug when the prescribing clinician is not in agreement with the transition request to the first-line drug. Contractors shall issue a NOA in accordance with ACOM Policy 414 for Service Authorizations when a PA request is denied, or a previously approved authorization is terminated, suspended, or reduced.

B. GENERIC AND BIOSIMILAR DRUG SUBSTITUTIONS

1. Contractors ~~must~~shall utilize a mandatory Ggeneric Ddrug substitution policy that requires the use of a generic equivalent drug whenever one is available. The exceptions to this requirement are:
   a. A brand name drug may be covered when a generic equivalent is available when the Contractor's negotiated rate for the brand name drug is equal to or less than the cost of the Ggeneric Ddrug, and
   b. AHCCCS may require Contractors to provide coverage of a brand name drug when the cost of the Ggeneric Ddrug 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. Prescribing clinicians ~~must~~shall clinically justify the use of a brand-name drug over the use of its generic equivalent through the PA process.

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

4. AHCCCS Contractors shall not transition to a Bbiosimilar drug until AHCCCS has determined that the Bbiosimilar drug is overall more cost-effective to the state than the continued use of the brand name drug.

C. ADDITIONAL INFORMATION FOR ~~BEHAVIORAL HEALTH~~ MEDICATION COVERAGE

1. Members transitioning to a different health plan or FFS are covered for medications as follows: ~~Behavioral Health Medication Coverage for FFS and ACC members transitioning to a TRBHA or a RBHA:~~

~~The AHCCCS Administration and its Contractors shall provide coverage for medically necessary, cost-effective, and federally and state reimbursable behavioral health medications until such time that the member transitions to a TRBHA or a RBHA Contract~~[28]

a. The transferring Contractor or AHCCCS shall 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~~.~~

b. All Contractors, FFS Program providers[29], and TRBHAs are responsible for coordinating care when transferring a member to a new health plan or FFS Program to ensure that the member's ~~behavioral health~~ medications are continued during the~~is~~ transition.

~~Behavioral Health Medications Prescribed by the PCP for the Treatment of Anxiety, Depression, and Attention Deficit Hyperactivity Disorder (ADHD), and/or Opioid Use Disorder (OUD).~~[30]

2. Contractors and FFS Programs[31] shall provide coverage for medically necessary, cost- effective, and federally and state reimbursable behavioral health medications provided by a PCP within their scope of practice. For the antipsychotic class of medications, prior authorization may be required. This includes the monitoring and adjustments of behavioral health medications. For additional information refer to the AMPM Policy 510.

~~The AHCCCS Administration and its Contractors shall provide coverage for medically necessary, cost-effective, and federally and state reimbursable behavioral health medications prescribed by a PCP when used to treat anxiety, depression (including postpartum depression), ADHD, and/or OUD. This includes the monitoring and adjustments of behavioral health medications.~~

3. Behavioral Health Medication Coverage for AHCCCS members transitioning between a Behavioral Health Medical Professional (BHMP) and a PCP.

For members transitioning from a BHMP to a PCP or from a PCP to a BHMP:
PCPs and BHMPs shall coordinate the care and ensure that the member has a sufficient supply of medication(s) to last through the date of the member's first appointment with the PCP or BHMP.

4. Behavioral Health Medication Coverage for members who are not enrolled in an integrated plan ~~single entity~~ to obtain ~~for~~ both Physical and Behavioral Health services.

[28] Removed due to redundency
[29] Adding for clarity – FFS providers are also responsible for care coordination
[30] Revised to within PCP scope of practice
[31] Revised to Contractors and FFS Programs shall…

For Contractor requirements regarding payment responsibility for physical and behavioral health services refer to ACOM Policy 432.~~.~~

For FFS program requirements regarding payment responsibility for physical and behavioral health services refer to FFS Billing Manual.[32]

5. Crisis Drug List

The RBHAs shall coordinate and develop a single Crisis Drug List of medications. ~~that are federally and state reimbursable.~~ The RBHAs shall provide coverage of these medications that are prescribed for Non-Title XIX/XX1 – Non-SMI individuals that receive crisis services.

Federal and state reimbursable behavioral health medications including those on the AHCCCS ~~Behavioral Health~~ Drug List shall be available when prescribing behavioral health medications for Title XIX/XXI and SMI members requesting crisis services.

The initial prescription shall be written for up to a 7-day supply with one refill if applicable.

The Crisis Drug List shall be submitted annually to the AHCCCS Pharmacy Department for review and approval or when a change is requested.

The RBHAs shall post the Crisis Drug List on their respective websites.

6. ~~Courtesy~~ Guest[33] Dosing of Methadone or Bupenorphine

An~~ person~~ individual receiving M~~m~~ethadone or Bupenorphine administration services who is not a recipient of take home medication may receive ~~up to two courtesy doses~~guest dosing of M~~m~~ethadone or Bupenorphine from the area Contractor when the ~~person~~ individual is traveling ~~outside of their home RBHA area~~outside of home OTP center. Refer to AMPM Policy 660[34]. ~~All incidents of the provision of courtesy dosing must be reported to the person's home RBHA. The Contractor home RBHA must reimburse the other RBHA providing the courtesy doses, upon receipt of properly submitted bills or encounters.~~ [35]

D. OVER-THE-COUNTER MEDICATION

AHCCCS and its Contractors may cover an over-the-counter medication under the pharmacy benefit when it is prescribed in place of a covered prescription medication that

[32] Added language for FFS programs to refer to FFS Billing Manual
[33] POST APC CHANGE: updated to Guest to align with federal guidelines
[34] AMPM 660 is under revision to include additional details.
[35] Cleaning up the language since all Contractors provide methadone treatment programs.

is clinically appropriate, equally safe and effective, and more cost effective than the covered prescription medication.

E. PRESCRIPTION DRUG COVERAGE, BILLING LIMITATIONS AND PRESCRIPTION DELIVERY[36]

1. A new prescription or refill prescription in excess of a 30-day supply ~~or a 100-unit dose~~ is not covered unless:
   a. The medication is prescribed for chronic illness and the prescription is limited to no more than a ~~100~~90-day supply ~~or 100-unit dose, whichever is greater~~,
   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 ~~100~~ 90 days ~~or 100-unit dose, whichever is greater~~, or
   c. The medication is prescribed for contraception and the prescription is limited to no more than a ~~100~~90[37]-day supply.

2. Prescription drugs for covered transplant services will be provided in accordance with AMPM Policy 310-DD.

3. AHCCCS covers the following for persons diagnosed with SMI and AHCCCS members who are eligible to receive Medicare:
   a. Over-the-counter 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, and
   b. A drug that is excluded from coverage under Medicare Part D by CMS and the drug is medically necessary and federally reimbursable.[38]

4. Pharmacies shall not 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.[39]

5. Pharmacies shall not split bill the cost of a prescription claim to AHCCCS or it Contractors' PBMs for an AHCCCS member. Contractors' PBMs Pharmacies shall not 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.[40]

[36]
[37] Changed to conform to AAC R9-22-209.
[38] Just moved the language up from below- no changes.
[39] Added to disallow members paying cash for prescriptions
[40] Added to address drug diversion,

6. Pharmacies are prohibited from auto-filling prescription medications[41].

7. Pharmacies shall[42] not submit prescriptions claims for reimbursement in excess of the U&C[43] charged to the general public.
   a. The sum of charges for both the product cost and dispensing fee may not exceed a pharmacy's U&C Price for the same prescription, and
   b. The U&C submitted ingredient cost shall be 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.

8. Pharmacies that purchase drugs at a Nominal Price outside of 340B or the FSS[44] shall bill their Actual Acquisition Cost of the drug.

9. Pharmacies, at their discretion, may deliver or mail prescription medications to an AHCCCS member or to an AHCCCS registered provider's office for a specific AHCCCS member.

~~3.1.AHCCCS covers the following for persons diagnosed with SMI and AHCCCS members who are eligible to receive Medicare:~~

~~a. Over-the-counter medications that are not covered as part of the Medicare Part D prescription drug program and which meet the requirements in section D of this policy, and~~

~~b.a. A drug that is excluded from coverage under Medicare Part D by CMS and the drug is medically necessary and federally reimbursable.~~

F. PRIOR AUTHORIZATION REQUIREMENTS FOR LONG-ACTING OPIOID MEDICATIONS

1. PA is required for all long-acting opioid prescription medications unless the member's diagnosis is one the following:

   1. Active oncology diagnosis with neoplasm related pain.

   2. Hospice care, or

   3. End of life care (other than hospice).

The prescriber shall obtain approval or an exception for all long-acting opioid prescription medications from the Contractor, Contractor's Pharmacy Benefit Management (PBM) or ~~the~~ AHCCCS ~~Administration~~ ~~'s~~ PBM, as applicable.

[41] Moved from section I- no changes to the language
[42] Change may to shall
[43] Replaced with acronym as abbreviated in Definitions
[44] Replaced with acronym as abbreviated in Definitions

G. 5-DAY SUPPLY LIMIT OF PRESCRIPTION SHORT ACTING[45] OPIOID MEDICATIONS- ~~CONTRACTOR[46] REQUIREMENTS~~

1. Members under 18 years of age
   a. Except as otherwise specified in Section G(1)(b), *Conditions and Care Exclusion from the 5-day Supply Limitation*, a prescriber shall 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,
   An **initial** prescription for a short-acting opioid medication is one in 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,
   b. Conditions and Care Exclusion from the 5-day Supply Limitation:
      i. 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:
         1) Active oncology diagnosis,
         2) Hospice care,
         3) End-of-life care (other than hospice),
         4) Palliative C~~c~~are,
         5) Children on opioid wean at time of hospital discharge,
         6) Skilled nursing facility care,
         7) Traumatic injury, excluding post-surgical procedures, and
         8) Chronic conditions for which the provider has received PA approval through the Contractor.
      ii. 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 post-surgical 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.

      For additional information on the exclusions, refer to Attachment B.

      For additional information on the traumatic injury ICD-10 codes, refer to Attachment C.

2. Members 18 years of age and older
   a. Except as otherwise specified in Section G(2)(b), *Conditions and Care Exclusion from the 5-day Supply Limitation*, a prescriber shall 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,

[45] Adding clarifying language for short acting
[46] Removing since this will also apply to IHS/638 facilities as of 4/1/19. Implementation date is 6/1/2019.

An **initial** prescription for a short-acting opioid medication is one in 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,

b. Conditions and Care Exclusion from the 5-day Initial Supply Limitation. 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 Ceare,
   iv. Skilled nursing facility care,
   v. Traumatic injury, excluding post-surgical procedures, and
   vi. Post-surgical procedures.

   Initial prescriptions for short-acting opioid medications for post-surgical procedures are limited to a supply of no more than 14 days.

   For additional information on the exclusions, refer to Attachment B.

   For additional information on the traumatic injury ICD-10 codes, refer to Attachment C.

H. ADDITIONAL FEDERAL OPIOID LEGISLATION (SUPPORT ACT P.L. 115-271) MONITORING REQUIREMENTS[47]

AHCCCS and its Contractors shall implement automated processes to monitor the following:

1. Opioid safety edits at the Point-of-Sale.[48]

2. Member utilization when the cumulative current utilization of opioid(s) is a Morphine Daily Equivalent Dose of greater than 90.

3. Members with concurrent use of an opiod(s) in conjunction with benzodiazepine(s) and antipsychotic(s).

4. Antipsychotic prescribing for children.

5. Fraud, Waste and Abuse by enrolled members, pharmacies and prescribing clinicians.

I. NALOXONE[49]

[47] Added to address CMS requirements for the Support Act
[48] All bullet points are requirements of the opioid legislation.
[49] Naloxone section added to because it is part of our opioid initiatives. We thought it should be included in the policy because there is a standing order at the pharmacy and we are trying to increase awareness.

Naloxone is a prescription medication that reverses the effects of an opioid overdose. AHCCCS and its Contractors cover and consider Naloxone an essential prescription medication to reduce the risk and prevent an opioid overdose death. AHCCCS requires a prescription, ordered by an AHCCCS registered provider, be on file at the pharmacy when Naloxone is dispensed to or for a specific AHCCCS member.

1. A Standing Order written by the Director of the Arizona Department of Health Services is on file at all Arizona pharmacies.

2. Eligible candidates that may obtain Naloxone include but are not limited to:
   a. Members:
      i. Using illicit or non-prescription opioids with a history of such use,~~;~~
      ii. With a history of opioid misuse, intoxication, and/or a recipient of emergency medical care for acute opioid poisoning,
      iii. Prescribed high dose opioid prescriptions of 90 MEDD or less if there are other risk factors,
      iv. Prescribed an opioid with a known or suspected concurrent alcohol use,
      v. From opioid detoxification and mandatory abstinence programs,
      vi. Treated with methadone for addiction or pain,
      vii. With an opioid addiction and smoking/COPD or other respiratory illness or obstruction,
      viii. Prescribed opioids who also have renal, hepatic, cardiac or HIV/AIDs disease,
      ix. Who may have difficulty accessing emergency services~~;~~, and/or
      x. Assigned to a pharmacy and or prescribing clinician,~~;~~
   b. Persons who voluntarily request Naloxone and are the family member or friend of a member at risk of experiencing an opioid related overdose,~~;~~ and
   c. Persons who voluntarily request Naloxone and are in the position to assist a member at risk of experiencing an opioid related overdose.

3. AHCCCS and its Contractors cover the following:
   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.

4. Every recipient[50] shall be educated on the use of Naloxone by the pharmacist dispensing the medication in accordance with Arizona State Board of Pharmacy Regulations.

5. Naloxone is contraindicated for members with a known history of hypersensitivity to Naloxone or any of its ingredients.

~~I.~~J. AHCCCS PHARMACY BENEFIT EXCLUSIONS

[50] POST APC Change

The following are excluded and are not covered:~~from the pharmacy benefit:~~

1. Medications prescribed for the treatment of a sexual or erectile dysfunction, unless:
   a. The medication is prescribed to treat a condition other than a sexual or erectile dysfunction, and
   b. The FDA has approved the medication for the specific condition.

2. 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.

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

4. Outpatient medications for members under the Federal Emergency Services Program, except for dialysis related medications for Extended Services individuals.

5. Medical Marijuana (refer to AMPM Policy 320-M).

6. Drugs eligible for coverage under Medicare Part D for AHCCCS members eligible for Medicare whether or not the member obtains Medicare Part D coverage.

~~7.~~1.~~Pharmacies are prohibited from auto-filling prescription medications.~~

7. Experimental medications ~~are excluded from coverage~~.

8. ~~-~~Medications furnished solely for cosmetic purposes.

~~J.~~K. RETURN OF AND CREDIT FOR UNUSED MEDICATIONS

AHCCCS and its Contractors shall 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. A payment/credit reversal shall be issued for unused prescription medications by the outpatient pharmacy to ~~the~~ AHCCCS ~~Administration~~ or the appropriate AHCCCS Contractor. The pharmacy may charge a reasonable restocking fee as agreed upon with ~~the~~ AHCCCS ~~Administration~~ and its Contractors. The return of unused prescription medication shall be in accordance with Federal and State laws. A.A.C. R4-23-409 allows for this type of return and the redistribution of medications under certain circumstances. Documentation ~~must~~shall be maintained and ~~must~~shall include the quantity of medication dispensed and utilized by the member. A credit ~~must~~shall be issued to ~~the~~ AHCCCS ~~Administration~~, if the member is enrolled in the AIHP, TRBHA, or FFS Program, or to the member's Contractor for members who are not FFS when the unused medication is returned to the pharmacy for redistribution.

~~K.~~L. DISCARDED PHYSICIAN-ADMINISTERED MEDICATIONS

Discarded federally and state reimbursable physician-administered medications shall not be billed to AHCCCS or its Contractors. A.A.C. R9-22-209(C) provides that pharmaceutical services are covered only if they are prescribed. The unused portion of a physician administered drug is not covered because it is not medically necessary or prescribed.

A.R.S. §36-2918(A)(1) prohibits a person from making a claim for an item or service that the person knows or has reason to know was not provided as claimed.

A.R.S. §36-2918(A)(3)(b) prohibits a person from submitting a claim for items and services that substantially exceed the needs of the patient.

~~L.~~M. PRIOR AUTHORIZATION CRITERIA FOR SMOKING CESSATION AIDS

AHCCCS has established prior authorization criteria for smoking cessation aids (refer to AMPM ~~Policy 320-K, Exhibit 320-K-1~~Exhibit 300-1[51]).

~~M.~~N. PA CRITERIA FOR DIRECT ACTING ANTIVIRAL TREATMENT FOR HEPATITIS C

AHCCCS has established PA criteria for the use of medications for the treatment of Hepatitis C (refer to AMPM Policy 320-N).

~~N.~~O. VACCINES AND EMERGENCY MEDICATIONS ADMINISTERED BY PHARMACISTS TO PERSONS AGE 19 YEARS AND OLDER

AHCCCS covers 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 state law A.R.S. §32-1974.

1. For purposes of this section, "Emergency Medication" means emergency epinephrine and diphenhydramine. "Vaccines" are limited to AHCCCS covered vaccines as noted in the AMPM Policy 310-M.

2. The pharmacy providing the vaccine ~~must~~shall be an AHCCCS registered provider (see note below regarding Indian Health Services (IHS)/638 outpatient facilities).

3. Contractors retain the discretion to determine the coverage of vaccine administration by pharmacists and coverage is limited to the Contractor's network pharmacies.

4. IHS and 638 facilities may bill the outpatient all-inclusive rate for pharmacist vaccine administration of adult vaccines as noted above.

[51] Replaced with AMPM Exhibit 300-1; AMPM 320-K is reserved

~~O.~~P. 340B COVERED ENTITIES AND CLAIM SUBMISSION

A.R.S. §36-2930.03. requires:

1. 340B covered entities to submit AHCCCS Member point-of-sale prescription and physician-administered drug claims, that are identified on the 340B pricing file, whether or not the drugs are purchased under the 340B Ddrug Ppricing Pprogram at the lesser of:
   a. The Aactual Aacquisition Ccost, or
   b. The 340B Cceiling Pprice.

2. Drugs dispensed to AHCCCS members by a 340B Ccovered Eentity pharmacy shall be reimbursed a Pprofessional Ffee.

3. Drugs administered to AHCCCS members by a 340B Ccovered Eentity provider shall not be reimbursed a Pprofessional Ffee.

4. The administration and its contractors shall not reimburse 340B Contracted Pharmacies for drugs that are purchased, dispensed, or administered as part of or subject to the 340B Ddrug Ppricing Pprogram.

Licensed hospitals and outpatient facilities that are owned or operated by a licensed hospital are excluded from this statute.

For additional details on claim submission and reimbursement refer to A.R.S. §36-2930.03

A.A.C. R-9-22-710(C) describes the reimbursement methodology to be used by AHCCCS and its Contractors for Federally Qualified Health Center (FQHC) and FQHC Look-Alike Pharmacies for 340B drugs as well as reimbursement for Contract Pharmacies that have entered into a 340B drug purchasing arrangement with any 340B entity. The Rule also specifies reimbursement for FQHC and FQHC Look-Alike Pharmacies for drugs, which are not part of the 340B Drug Pricing Pprogram. The rule is located on the A.A.C. R9-22-709.

~~P.~~Q. PHARMACEUTICAL REBATES

The Contractor, including the Contractor's PBM, is prohibited from negotiating any rebates with drug manufacturers for preferred or other pharmaceutical products when AHCCCS has a supplemental rebate contract for the product(s). A listing of products covered under supplemental rebate agreements will be available on the AHCCCS website under the Pharmacy Information section. If the Contractor or its PBM has an existing rebate agreement with a manufacturer, all outpatient drug claims, including provider-administered drugs for which AHCCCS is obtaining supplemental rebates, ~~must~~shall be exempt from such rebate agreements.

~~Q.~~R. INFORMED CONSENT

Informed consent ~~must~~shall be obtained from the member, or as applicable, the member's Health Care Decsion Maker~~/guardian/designated representative~~ for each psychotropic medication prescribed. The comprehensive clinical record ~~must~~shall include documentation of the essential elements for obtaining informed consent. Essential elements for obtaining informed consent for medication are contained within Attachment A. The use of Attachment A is recommended as a tool to document informed consent for psychotropic medications. Additional information is contained in AMPM Policy 320-Q.

~~R.~~S. YOUTH ASSENT

Youth and Psychotropic Medications

Youth under the age of 18 are to be educated on options, allowed to provide input, and encouraged to assent to medication(s) being prescribed. Information is discussed with the youth in a clear and age-appropriate manner consistent with the developmental needs of the youth.

The information to be shared with a minor patient shall be consistent with the information shared in obtaining informed consent from adults. Informed consent for a minor shall be obtained through the minor's authorized Health Care Decision Maker unless the minor is emancipated.

Discussion of the youth's ability to give consent for medications at the age of 18 years old is begun no later than age 17½ years old, especially for youth who are not in the custody of their parents.

Special attention shall be given to 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.

Evidence of the youth's consent to continue medications after his/her 18th birthday may be documented through use of Attachment A.

~~S.~~T. COMPLEMENTARY AND ALTERNATIVE MEDICINE

Complementary and Alternative Medicine is not AHCCCS reimbursable.