

ARKANSAS REGISTER

Transmittal Sheet

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**For Office
Use Only:**

Effective Date _____ Code Number _____

Name of Agency Arkansas Department of Health

Department Center for Health Protection

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Statutory Authority for Promulgating Rules § 20-27-2501 et seq.

Rule Title: Rules Pertaining to Arkansas Kidney Disease Commission

Intended Effective Date
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Emergency (ACA 25-15-204)

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Other _____
(Must be more than 10 days after filing date.)

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Reviewed by Legislative Council

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Date

01/31/2022

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Electronic Copy of Rule e-mailed from: (Required under ACA 25-15-218)

Laura Shue
Contact Person

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7/11/2022
Date

CERTIFICATION OF AUTHORIZED OFFICER

I Hereby Certify That The Attached Rules Were Adopted
In Compliance with the Arkansas Administrative Act. (ACA 25-15-201 et. seq.)

Signature

501-661-2297

Phone Number

Laura.Shue@arkansas.gov

E-mail Address

General Counsel

Title

07/11/2022

Date

ARKANSAS KIDNEY DISEASE COMMISSION

RULES



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Effective Date: July 21, 2022

INTRODUCTION

Pursuant to A.C.A. § 20-15-603 these Rules delineates operation and standards for the program administered by the Arkansas Kidney Disease Commission. Changes, additions, and deletions shall be made from time to time in order to insure the best possible services for clients with permanent kidney failure who are residents of the State of Arkansas. Rule changes shall only be considered during Commission meetings when a quorum is declared. A majority vote is required for any change. Promulgation of a rule revision is required for any Commission decision which affects patient qualification or services. No Rule, Rule amendment or Rule revision shall be effective until promulgation under the Arkansas Administrative Procedure Act at § 25-15-201 et seq.

Arkansas Kidney Disease Commission

RULES

AUTHORITY

The Arkansas Kidney Disease Commission (AKDC) was established by the General Assembly of the State of Arkansas through Act 450 of 1971 to establish a program for the care and treatment of persons suffering from chronic renal disease. The legislation charged the AKDC to “provide financial assistance for persons suffering from chronic renal disease who require life-saving care and treatment to the extent as determined by the Commission.”

Act 910 of 2019 authorizes the Secretary of the Arkansas Department of Health as the disbursing officer of funds appropriated by the Arkansas General Assembly and any other funds made available to the Commission for such purposes.

Legislative Findings and Purpose

Legislative findings declared and found that one of the major problems facing medicine and the public health and welfare is the lack of an adequate program to assist in the treatment and cure of persons suffering from chronic kidney disease. It is estimated that a number of citizens of this State annually are confronted with chronic kidney disease, requiring complicated and expensive treatment, which is often beyond the financial resources of such individuals. There is a critical shortage of adequate facilities within the State for the discovery, evaluation, diagnosis, treatment, and cure of individuals suffering from chronic kidney disease. In order to provide for the care and treatment of persons suffering from acute or chronic kidney disease, and in order to encourage and assist in the development of adequate treatment facilities for persons suffering from acute or chronic kidney disease, it is essential that the State develop a program of financial assistance to aid in defraying a portion of the cost for the care and treatment of chronic renal disease to the extent that the individual suffering from such disease is unable to pay for such services on a continuing basis.

COMMISSION

Powers and Duties of the Commission

The Commission shall have the following functions, powers and duties:

- To establish a program to assist persons suffering from acute or chronic renal failure in obtaining care and treatment requiring dialysis. The program shall provide financial assistance for persons suffering from chronic renal diseases who require life-saving care and treatment for the renal disease to the extent, as determined by the Commission, that a person is unable to pay for such services on a continuing basis without causing unjust and unusual hardship to himself or herself and his or her immediate family, including without limitation a drastic lowering of the standard of living.

- To develop standards for determining eligibility for assistance in defraying the cost of care and treatment of renal disease under this program.
- To cooperate with hospitals, private groups, and organizations, and public agencies in the development of positive programs to bring about financial assistance and support of evaluation and treatment of patients suffering from chronic kidney disease.
- To cooperate with the national and state kidney foundations and with medical programs of the state and federal government for the purpose of obtaining the maximum amount of federal and private assistance possible in support of a kidney disease treatment program.
- To establish criteria and standards for evaluating the financial ability of persons suffering from chronic renal disease to pay for their own care, including the availability of third party insurance coverage, for the purpose of establishing standards for eligibility for financial assistance in defraying the cost of the care and treatment from funds appropriated to the commission for renal disease treatment purposes.
- To accept gifts, grants, and donations from private sources, and the federal government and support from municipal and county governments to be used for the purposes of this Act in defraying costs incurred by persons suffering from acute or chronic renal disease who are unable to meet the total cost of life-saving care and treatment for renal disease.
- To accept gifts, grants, and donations from private sources and the federal government and support from municipal and county governments to be used to honor persons who have provided living kidney donations to Arkansans in need of kidney transplantation.

Commission Committees: The Commission may establish ad hoc committees from time to time. The ad hoc committees shall review issues and make recommendation to the full Commission.

CHAIN OF LIFE AWARD

The AKDC Chain of Life award recognizes individuals who have made a living kidney donation to a current resident of Arkansas who is in need of kidney transplantation. Nominations for the award are received by the AKDC and presented to the Commission Board for approval. The AKDC shall not use state funds appropriated for program services but may accept gifts, grants, and donations from private sources and the federal government and support from municipal and county governments to maintain the award.

ELIGIBILITY

Persons suffering from chronic renal failure may be referred to the Arkansas Kidney Disease Commission. Referrals shall come from clients themselves, physicians, social workers, hospital or kidney dialysis center personnel, pharmacists, rehabilitation counselors, and others including individuals and agencies familiar with the person's kidney disease.

Eligibility Requirements

Eligibility requirements shall be applied without regard to sex, race, creed, color, or national origin. With respect to age, no upper or lower limit shall be set as a guide to turn away a referral.

Residency Requirement

Clients must be a resident of Arkansas. To be eligible, an applicant must provide a copy of his or her driver's license or identification card issued by the State of Arkansas.

Physician Certification requirement

Certification by a Nephrologist (or other physician) or Advance Practice Registered Nurse is required confirming the applicant has a diagnosis of ESRD with an indication that the individual is in need of regular renal dialysis treatments or has been the recipient of a kidney transplant.

Financial Eligibility

A client's annual income may not exceed 250% of the Federal Poverty Level (FPL) percentage for the year in which they are applying for assistance. The AKDC shall consider the available financial resources of the total household. Income sources to be considered include wages; business income; social security, SSDI, and SSI benefits; retirement income; veteran's benefits; income from stocks, bonds, or other investments; and other identifiable liquid assets.

If the applicant is a dependent, the resources of the parent(s) shall be determined. The exception is if the applicant is a dependent and is receiving SSI benefits, he/she may be considered a family of one.

Insurance Eligibility

Clients with insurance must provide proof of insurance coverage. Individuals with or without insurance are not prohibited from receiving services on the basis of their insurance status. However, AKDC shall be payor of last resort.

Application for Services

Individuals applying for services available through the program shall complete the AKDC Initial Referral Application. The Initial Referral Application includes the required Nephrologist or other health professional certification indicating the applicant has ESRD or has been the recipient of a kidney transplant.

Certificate of Eligibility/Ineligibility

A certificate of eligibility-ineligibility (AKDC-10) shall be completed prior to the provision of services, or the refusal of services, as the case may be. The AKDC Program Manager shall review the Initial Referral Application, applying the established financial needs and residential criteria and ensuring the applicant's physician has certified that the applicant meets the medical criteria. AKDC Program Manager sign the Certificate of Eligibility/Ineligibility for each applicant,—indicating the applicant's eligibility or ineligibility

Other Resources/ Similar Benefit

Applicants shall be required to apply and provide evidence of acceptance/denial from all applicable pharmaceutical company patient assistance programs. Any services that the applicant may receive, or be eligible to receive from other sources shall be used first. The AKDC may only supplement these benefits.

Co-Payment

The Commission shall establish a co-payment for services paid by a client of the program at the point of sale. The copayment amount is \$2.00 for each medication each month.

EFFECTIVE DATE OF SERVICE

The effective date a client shall be eligible to receive paid for services provided by the AKDC shall be established by the program. An applicant must be determined eligible prior to funds being authorized. The AKDC shall not authorize payment for any services provided prior to the effective date of service.

Financial Cap

The Commission may establish an annual limit on per-client expenditures prior to the beginning of the new state fiscal year, based on funds available and number of clients participating in the program in prior year. This annual cap is subject to change based on increase or decreases in the number of patients in the programs and or changes in program funding. Exceptions may be made on a case by case basis as determined by the Commission. During the course of a fiscal year, should expenditures for a client exceed the limit allowed, the case will be referred to the Commission for review to determine a course of action.

Termination of Services

AKDC will pay for services and medication prescribed up to the client's date of death. Eligibility for covered services will also be ended the day a client moves out of state or the last day of the month a client's course of dialysis is terminated unless the individual has received a kidney transplant.

Annual Review

Individuals determined eligible to receive AKDC services shall submit an eligibility renewal application annually to determine continued program eligibility. The review process will consist of a determination as to whether the individual continues to meet program medical, residential and financial need eligibility criteria. Clients who meet eligibility requirements will continue to receive AKDC services. Any client who no longer meets program eligibility requirements shall be issued a letter of termination of services effective thirty (30) days after the date of review. AKDC shall not pay for services for patients who fail to renew within one and a half years of their last date of eligibility (year of eligibility, plus six-month grace period). Medications prescribed within a client's annual eligibility period (plus six-month grace period) shall be covered, even if the claim is received by AKDC after the patient's eligibility has lapsed.

SERVICES

The services provided by the AKDC shall be dependent on the availability of funds. The Commission may determine specific services to be funded by the program prior to the

beginning of each new state fiscal year. Covered services may include outpatient pharmaceutical drugs and nutritional supplements; pre-transplant dental services; transportation, patient education and referral. Specific services to AKDC clients, including those in need of continuing services, shall be provided based upon the availability of funds. During the course of a fiscal year should it be determined that available funding is insufficient to fund services provided by the program at existing levels for the remaining portion of the fiscal year, the Commission shall establish the manner in which services will be curtailed, or if required, terminated for the remainder of that fiscal year. Should the curtailing of services result, preference will be given to those in need of continuing services, as determined by the Commission.

Financial assistance from the AKDC may include:

- Outpatient prescriptions: AKDC may provide financial assistance for no more than 3 outpatient prescriptions per month. Amount payable to pharmacy is the allowable amount in the formulary fee schedule, after insurance payment and less client co-payment.
- Immunosuppressant drugs: AKDC may provide financial assistance for immunosuppressant drugs. A client co-pay for allowable drugs is required. The AKDC shall only participate in the purchase of immuno-suppressant medications as a co-payer. Program co-payment for immuno-suppressant drugs shall not exceed twenty percent of the Medicare allowable rate.
- Nutritional supplements: AKDC may provide for nutritional supplement if ordered by physician. Amount Payable to pharmacy is the allowable amount in the formulary fee schedule, after insurance and less client co-payment.
- Transportation: AKDC may provide for dialysis appointment transportation mileage reimbursement, at the state employee mileage reimbursement rate for the applicable year. Clients who prove they must take a taxi or other paid transportation service are eligible for transportation mileage reimbursement. Patients must first attempt to use personal or Medicaid transportation if available, prior to engaging a taxi or other paid transportation. Evidence of efforts to use Medicaid transportation must be provided. Taxi or paid transportation receipt is required prior to mileage reimbursement.
- Dental: AKDC may provide for dental care when a dental problem jeopardizes the health and treatment program outlined by the renal specialist and may be covered only for the purpose of kidney transplantation. Payment for services rendered will be prior approved and consistent with the established dental fee schedule herein attached as Appendix A.

Patient Education

The AKDC may partner with local, state, regional, and national agencies and organizations to educate its clients and the public at large regarding the importance of prevention and/or treatment of kidney disease.

Referral Services

The AKDC may assist clients diagnosed with ESRD with referral to other programs including vocational rehabilitation.

Formulary

AKDC shall establish a formulary. The formulary will include nutritional supplements designed for kidney dialysis patients. The formulary and fee schedule may be updated periodically and is attached as Appendix A.

Payment for Services to Vendors

The AKDC shall process payment for covered services to program clients when in receipt of a signed vendor statement or letter that includes the client's name and other necessary identifiable information, a description of services provided, date(s) of service provision, and cost. Claims made for payment of prescription drugs or transportation reimbursement are to be submitted on the appropriate AKDC claim form or applicable online form if available. The AKDC shall not pre-pay for a service, only providing payment after the service has been rendered. Requests for payment for services rendered must be received by the program within one calendar year of the date of service. The AKDC will not provide remittance for those requests for payment that exceed the one-year from date of service limit.

Confidentiality, Use, and Release of Client Records and Information

The AKDC shall maintain a case record for applicants and individuals determined eligible to receive services available through the program. Client information developed or received by the AKDC is the property of the program. Information contained in the case record ~~may~~ shall only be used for determining eligibility/ineligibility for AKDC services, providing payment for services rendered, or other program operations. The AKDC shall maintain personal information contained in the case record in a secure manner and treat such information with the highest degree of confidentiality.

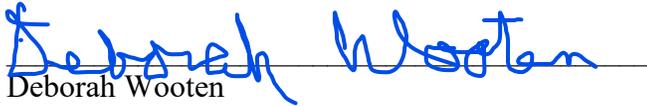
The AKDC Program Administrator is designated as the custodian of applicant and client case records. The Program Manager has the responsibility of ensuring such information is maintained in a safe and secure manner consistent with State and Federal law, rule or regulation. The Program Manager shall provide training to AKDC staff regarding how applicant and client information will be developed, maintained, and shared with affected parties. The Program Manager is responsible for the destruction of all closed case files.

When requested in writing, the AKDC shall make available to the applicant or client, or if appropriate the individual's representative, information contained in that person's case record. Should the applicant or client or, if appropriate, that individual's representative believes information contained in the case record to be inaccurate or misleading, a written request can be made to the program to amend such information.

In the event another agency or organization requests personal information contained in the case record of an AKDC applicant or client, the program ~~will~~ shall only release such information with written consent of the applicant or client or, if appropriate, that individual's representative. It is the responsibility of the AKDC and parties involved to respect the confidential nature of personal information and limit information exchanged to that minimally necessary. The AKDC shall release personal information contained in the case record in response to investigations in connection with law enforcement, fraud, and abuse unless expressly prohibited by State and Federal laws and regulations and in response to an order issued by a judge, magistrate, or other authorized judicial official.

CERTIFICATION

This will certify that the Arkansas Kidney Disease Commission Rules were adopted by the Arkansas Kidney Disease Commission at a regular session of said Commission held in Little Rock, Arkansas on the 17th day of March 2021.

A handwritten signature in blue ink that reads "Deborah Wooten". The signature is written in a cursive style and is positioned above a horizontal line.

Deborah Wooten

Chairman

Arkansas Kidney Disease Commission

Arkansas Kidney Disease Commission

Formulary

COMMON NAME OF DRUG	BRAND NAME
CALCIUM ACETATE	667 mg tablets/capsules not to exceed 360 tablets/capsules each month.
SEVELAMER	800 mg tablets or 0.8 gram packets not to exceed 360 tablets or packets each month.

THE FOLLOWING PHOSPHATE BINDING AGENTS ARE COVERED WITH PRIOR APPROVAL ONLY

FOSRENOL	LANTHANUM- Generic 1000 mg tablets or 1000 mg packets not to exceed 360 tablets or packets each month.
VELPHORO	SUCROFERRIC OXYHYDROXIDE 500 mg tablets not to exceed 360 tablets each month.
AURYXIA	FERRIC CITRATE 210 mg tablets not to exceed 360 tablets each month

For initiation of therapy with phosphate binders, patients shall be prescribed calcium acetate or sevelamer prior to initiation of therapy with other listed phosphate binder medications. Medications other than calcium acetate and sevelamer can be requested only:

- After the patient fails to achieve targeted phosphate levels, based on clinical guidelines, on at least 3 dosage formulations (capsules, tablets, etc.) of calcium acetate or sevelamer with each meal along with dietary restrictions, or
- If patient has adverse side effects to sevelamer or calcium acetate, or
- If patient is unable to swallow calcium acetate or sevelamer or
- If calcium acetate or sevelamer is not available due to shortage, recall or discontinuation.

ADDITIONAL MEDICATIONS COVERED WITH PRIOR APPROVAL ONLY

AKDC payment for the following medications cannot exceed the [National Average Drug Acquisition Cost](#) (NADAC), plus a dispensing fee for each prescription that matches the dispensing fee paid by the Arkansas Medicaid program. AKDC will revise coverage restrictions annually, using the most up-to-date NADAC costs prior to the start of the new state fiscal year. If no NADAC is listed for a particular drug, AKDC will pay the insurance allowable cost of the drug, less the client co-pay and insurance payment.

SENSIPAR NULOJIX VELTASSA LOKELMA	CINACALCET- Generic
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IMMUNOSUPPRESSANT DRUGS**COMMON NAME OF DRUG** **BRAND NAME**

AKDC payment for the following medications cannot exceed the [National Average Drug Acquisition Cost \(NADAC\)](#), plus a dispensing fee for each prescription that matches the dispensing fee paid by the Arkansas Medicaid program. AKDC will revise coverage restrictions annually, using the most up-to-date NADAC costs prior to the start of the new state fiscal year. If no NADAC is listed for a particular drug, AKDC will pay the insurance allowable cost of the drug, less the client co-pay and insurance payment.

AZATHIOPRINE	IMURAN
CYCLOSPORINE	NEORAL, GENGRAF
EVEROLIMUS	ZORTRESS
MYCOPHENOLATE MOFETIL	CELLCEPT
MYFORTIC	MYCOPHENOLIC ACID
PREDNISONE	
SIROLIMUS	RAPAMUNE
TACROLIMUS	PROGRAF

OTC DRUGS**COMMON NAME OF DRUG** **BRAND NAME**

FAMOTIDINE	PEPCID
LORATADINE	CLARITIN
OMEPRAZOLE	PRILOSEC
RANITIDINE	ZANTAC

COMMON NAME OF DRUG **DISPENSED FORM** **BRAND NAME****A**

ACYCLOVIR		ZOVIRAX
AMLODIPINE BESYLATE		NORVASC
AMOXICILLIN	CAPS, SUSP	AMOXIL
AMOXICILLIN W/CLAVULANIC ACID	TABS, SUSP	AUGMENTIN, CLAVULIN
AMPICILLIN	CAPS, SUSP	
ATENOLOL		TENORMIN
AZITHROMYCIN		ZITHROMAX, Z PACK

B

BACITRACIN W/POLYMYXIN B AND NEOMYCIN	OINT	NEOSPORIN
BECLOMETHASONE DIPROPIONATE	CR, OINT, GEL	PROPADERM, Q-VAR
BENZAEPRILOL		LOTENSIN
BUMETANIDE		BUMEX

C

CALCITRIOL		ROCALTROL
CALCIUM ACETATE		PHOSLO
CAPTOPRIL		CAPOTEN
CARVEDILOL		COREG
CEFACLOR		CECLOR
CEPHALEXIN MONOHYDRATE		KEFLEX
CHLORPROMAZINE		THORAZINE
CIPROFLOXACIN	IR TAB	CIPRO
CLONIDINE		CATAPRES
CLOPIDOGREL BISULFATE		PLAVIX
CYCLOPHOSPHAMIDE		CYTOXAN

D

DIAZEPAM		VALIUM
DILTIAZEM	TABS, XR	CARDIZEM, TIAZAC
DIPHENOXYLATE/ATROP		LOMOTIL
DIPYRIDAMOLE		PERSANTINE
DISOPYRAMIDE PHOSPHATE		RYTHMODAN
DOXAZOSIN MESYLATE		CARDURA
DOXYCYCLINE HYCLATE		VIBRAMYCIN

E

ENALAPRIL MALEATE		VASOTEC
ENALAPRIL MALEATE HCTZ		VASERETIC
ESTRADIOL		ESTRACE
ESTROPIPATE		OGEN

F

FLUOXETINE		PROZAC
FUROSEMIDE		LASIX

G

GABAPENTIN		NEURONTIN
GEMFIBROZIL		LOPID
GLUCOSE TEST STRIPS		
GLYBURIDE		DIABETA, MICRONASE
GUANFACINE HCL		TENEX
GLIPIZIDE		GLUCOTROL
GLIMEPIRIDE		AMARYL

NYSTATIN	CREAM, OINT, TABS	
NYSTATIN W/TRIAMCINOLONE ACETONIDE		CREAM, OINT
NOVOLOG	INSULIN	FLEXPEN

O

OLMESARTAN		BENICAR
ONDANSETRON	TABS, ODT	ZOFRAN
OXYCODONE HCL	IR TABS	
OXYCODONE / APAP		

P

PAROXETINE		PAXIL
PENICILLIN W/ POTASSIUM		
PENTOXIFYLLINE		TRENTAL
PIOGLITAZONE		ACTOS
PRAVASTATIN SODIUM		PRAVACHOL
PROCHLORPERAZINE		COMPAZINE
PROPAFENONE HYDROCHLORIDE		RYTHMOL
PROPRANOLOL		INDERAL
PRORANOLOL AND HYDROCHLOROTHIAZIDE		INDERIDE

Q

QUINAPRIL HYDROCHLORIDE		ACCUPRIL
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R

RENAL VITAMINS	VITAMIN	RENAVITE, DIALYVITE, NEPROVITE
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S

SIMVASTATIN		ZOCOR
SODIUM POLYSTYRENE SULFONATE (SPS)		KAYEXALATE
SUCRALFATE	TABS	CARAFATE

T

TEMAZEPAM		RESTORIL
TERAZOSIN HYDROCHLORIDE		HYTRIN
THEOPHYLLINE	TABS	
TRIMETHOPRIM/SULFAMETHOXAZOLE - SS, DS		BACTRIM, SEPTRA

V

VELPHORO		SUCROFERRIC OXYHYDROXIDE
VANCOMYCIN		

VERAPAMIL HYDROCHLORIDE
VANGANCICLOVIR

COVERA HS, CALAN, VERELAN, ISOPTIN
VALCYTE-3-13-2017

W

WARFARIN SODIUM

COUMADIN

Z

ZOLPIDEM

AMBIEN

- Generic medications shall be utilized unless prescribed medication does not have a generic equivalent, is required per patient's treating physician, or is unavailable due to shortage/recall.

NUTRIONAL SUPPLIMENTS

NEPRO NUTRITION SHAKE (*)

(*) Nutritional supplements listed on formulary may be provided, pending funding availability, to patients enrolled in Arkansas Kidney Disease Program.