EXHIBIT J

DEPARTMENT OF HEALTH

SUBJECT: Rules for the State Kidney Disease Program, 20 CAR pt. 260

DESCRIPTION: The proposed amendments to the Rules for the State Kidney Disease Program are to enact changes from Acts 2025, No. 852, which for the purpose of efficiency converts the State Kidney Disease Commission into the State Kidney Disease Advisory Council.

PUBLIC COMMENT: No public hearing was held on this rule. The public comment period expired on August 6, 2026. The agency indicated that it received no comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The agency indicated that this rule has no financial impact.

LEGAL AUTHORIZATION: This rule implements Act 852 of 2025. The Act, sponsored by Representative Ryan Rose, amended the State Kidney Disease Commission to be an advisory council to the Department of Health. The Act gave the Department of Health the authority, in consultation with the State Kidney Disease Advisory Council, to make rules for eligibility for financial assistance under the state kidney disease treatment assistance program. Ark. Code Ann. § 20-15-306, *as amended by* Act 852.

QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT Arkansas Department of Health
BOARD/COMMISSION Division for Health Protection, Personal Care Services Branch
BOARD/COMMISSION DIRECTOR Dr. Charles Bedell, Branch Chief
CONTACT PERSON S. Craig Smith, Attorney
ADDRESS 4815 West Markham Street, Slot 31, Little Rock, AR 72205
PHONE NO. (501) 534-6293 **EMAIL** Stephan.Smith@arkansas.gov
NAME OF PRESENTER(S) AT SUBCOMMITTEE MEETING
S. Craig Smith; Dr. Charles Bedell
PRESENTER EMAIL(S) Stephan.Smith@arkansas.gov; charles.bedell@arkansas.gov

INSTRUCTIONS

In order to file a proposed rule for legislative review and approval, please submit this Legislative Questionnaire and Financial Impact Statement, and attach (1) a summary of the rule, describing what the rule does, the rule changes being proposed, and the reason for those changes; (2) both a markup and clean copy of the rule; and (3) all documents required by the Questionnaire.

If the rule is being filed for permanent promulgation, please email these items to the attention of Rebecca Miller-Rice, miller-ricer@blr.arkansas.gov, for submission to the Administrative Rules Subcommittee.

If the rule is being filed for emergency promulgation, please email these items to the attention of Director Marty Garrity, garritym@blr.arkansas.gov, for submission to the Executive Subcommittee.

Please answer each question completely using layman terms.

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1. What is the official title of this rule?
Rules for the Arkansas Kidney Disease Program

2. What is the subject of the proposed rule? The program administers the State Kidney Disease Program that pr

3. Is this rule being filed under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☑

If yes, please attach the statement required by Ark. Code Ann. § 25-15-204(c)(1).

If yes, will this emergency rule be promulgated under the permanent provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☐

4. Is this rule being filed for permanent promulgation? Yes ☑ No ☐

If yes, was this rule previously reviewed and approved under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☑

If yes, what was the effective date of the emergency rule? _____

On what date does the emergency rule expire?_____

5. Is this rule required to comply with a *federal* statute, rule, or regulation? Yes ☐ No ☑

If yes, please provide the federal statute, rule, and/or regulation citation.

6. Is this rule required to comply with a *state* statute or rule? Yes ☑ No ☐

If yes, please provide the state statute and/or rule citation.

Ark. Code Ann. § 20-15-601, et seq.

7. Are two (2) rules being repealed in accord with Executive Order 23-02? Yes ☐ No ☑

If yes, please list the rules being repealed.
If no, please explain.

The proposed amendments to the Rules for the Arkansas Kidney Disease Program to enact changes from Acts 2025, No. 852 which for the purpose of efficiency converts the State Kidney Disease Commission into the State Kidney Disease Advisory Council.

8. Is this a new rule? Yes ☐ No ☑

Does this repeal an existing rule? Yes ☐ No ☑
If yes, the proposed repeal should be designated by strikethrough. If it is being replaced with a new rule, please attach both the proposed rule to be repealed and the replacement rule.

Is this an amendment to an existing rule? Yes ☑ No ☐
If yes, all changes should be indicated by strikethrough and underline. In addition, please be sure to label the markup copy clearly as the markup.

9. What is the state law that grants the agency its rulemaking authority for the proposed rule, outside of the Arkansas Administrative Procedure Act? Please provide the specific Arkansas Code citation(s), including subsection(s).

Ark. Code § 20-15-603

10. Is the proposed rule the result of any recent legislation by the Arkansas General Assembly?
Yes ☑ No ☐

If yes, please provide the year of the act(s) and act number(s).

Acts 2025, No. 852

11. What is the reason for this proposed rule? Why is it necessary?

The proposed amendments to the Rules for the Arkansas Kidney Disease Program to enact changes from Acts 2025, No. 852 which for the purpose of efficiency converts the State Kidney Disease Commission into the State Kidney Disease Advisory Council.

12. Please provide the web address by which the proposed rule can be accessed by the public as provided in Ark. Code Ann. § 25-19-108(b)(1).

https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules

13. Will a public hearing be held on this proposed rule? Yes ☐ No ☑

If yes, please complete the following:

Date: _____

Time: _____

Place: _____

Please be sure to advise Bureau Staff if this information changes for any reason.

14. On what date does the public comment period expire for the permanent promulgation of the rule? Please provide the specific date. 08/06/2026

15. What is the proposed effective date for this rule? 10/01/2026

16. Please attach (1) a copy of the notice required under Ark. Code Ann. § 25-15-204(a)(1) and (2) proof of the publication of that notice.

17. Please attach proof of filing the rule with the Secretary of State, as required by Ark. Code Ann. § 25-15-204(e)(1)(A).

18. Please give the names of persons, groups, or organizations that you anticipate will comment on these rules. Please also provide their position (for or against), if known.

None known at this time.

19. Is the rule expected to be controversial? Yes ☐ No ☑

If yes, please explain.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEPARTMENT Arkansas Department of Health
BOARD/COMMISSION Division for Health Protection, Personal Care Services Branch
PERSON COMPLETING THIS STATEMENT S. Craig Smith, Attorney
TELEPHONE NO. (501) 534-6293 **EMAIL** Stephan.Smith@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the Financial Impact Statement and email it with the questionnaire, summary, markup and clean copy of the rule, and other documents. Please attach additional pages, if necessary.

TITLE OF THIS RULE Rules for the Arkansas Kidney Disease Program

1. Does this proposed, amended, or repealed rule have a financial impact?
   Yes ☐ No ☑

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?
   Yes ☑ No ☐

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☑ No ☐

   If no, please explain:

   (a) how the additional benefits of the more costly rule justify its additional cost;

   (b) the reason for adoption of the more costly rule;

   (c) whether the reason for adoption of the more costly rule is based on the interests of public health, safety, or welfare, and if so, how; and

   (d) whether the reason for adoption of the more costly rule is within the scope of the agency's statutory authority, and if so, how.

4. If the purpose of this rule is to implement a *federal* rule or regulation, please state the following:

   (a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$0.00	Total	$0.00

(b) What is the additional cost of the state rule?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$0.00	Total	$0.00

5. What is the total estimated cost by fiscal year to any private individual, private entity, or private business subject to the proposed, amended, or repealed rule? Please identify those subject to the rule, and explain how they are affected.

Current Fiscal Year	**Next Fiscal Year**
$ 0.00	$ 0.00

6. What is the total estimated cost by fiscal year to a state, county, or municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year	**Next Fiscal Year**
$ 0.00	$ 0.00

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes ☐ No ☑

If yes, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

(1) a statement of the rule's basis and purpose;

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

(3) a description of the factual evidence that:
(a) justifies the agency's need for the proposed rule; and
(b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

(4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
(a) the rule is achieving the statutory objectives;
(b) the benefits of the rule continue to justify its costs; and
(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

Summary of Proposed Changes
Rules for Arkansas Kidney Disease Program

I. Summary of Key Changes in Act 852 (**HB 1456) of 2025.**	1. The State Kidney Disease Commission transitioned to the State Kidney Disease **Advisory Council**. (a) The terms of the members of the State Kidney Disease Commission shall expire on the effective date of Act 852. (b) The State Board of Health shall appoint new members to the State Kidney Disease Advisory Council on and after the effective date of Act 852. (c) Members of the erstwhile commission may apply to the State Board of Health for appointments to the nascent advisory council.
II. Section revisions based on key changes	**Supporting information**
Powers, Duties, Structure, & Membership	**20 CAR § 260-102**
(a) Powers & Duties	Verbiage revisions- stricken language, & Model language added for clarification.
(b) Subcommittees & Ad hoc committees	Verbiage revisions- stricken language, & Model language added for clarification.
(c) KD Ad. Council Structure and Membership	KD Commission transition to KD Advisory Council. Model language created by ADH to meet requirements of Act 852 of 2025.
	Membership reduction from 9 to 7.
	Membership appointment authority is State BOH.
	Members representing hospital administration reduced from 2 to 1.
	Members appointed from the public at large reduced from 2 to 1.
	Frequency of meetings reduced from at least one time each **calendar quarter** to at least one time each **calendar year**.
	The number of members requesting a meeting is reduced from 4 to 3.
	Secretary of the ADH is no longer required to be a member, nor serve as secretary and disbursement officer on the Advisory council.
Chain of Life Award	**20 CAR § 260-103**
	Verbiage revisions- stricken language, & Model language added for clarification of Award types and eligible nominees.
	Revised as "Recognition and Awards." Language moved and revised for better flow of Rules. Model language added for clarification of Award types and eligible nominees.
Program Eligibility Criteria	**20 CAR § 260-104**
	Verbiage revisions- stricken language, & Model verbiage added for clarification and better flow of Rules.
• Certificate of Eligibility/Ineligibility:	(a) Proof of diagnosis language edited to replace "Physician Certification Requirement" with "Medical certification as Proof of Diagnosis." (b) "Physician assistant" added as certifier of proof of diagnosis. ESRD replaced with "acute or chronic kidney disease."
• Application:	Model language added as revision of the initial referral process from paper-based to online referral.
• Effective Date of Service:	Deleted.
• Effective Date of Eligibility:	Model language added for clarification, and better flow of Rules. Replaces "effective date of service."
• Other Resources/Similar Benefits:	Deleted. Redundant.
• Termination of Service:	Deleted.
• Termination of Eligibility:	Model language added for clarification, and better flow of Rules. Replaces "termination of service."
• Annual Review:	Revised. Model language added for clarity and better flow of Rules.
Effective Date of Eligibility	**20 CAR § 260-105**
	Verbiage revisions- stricken language, & Model verbiage added for clarification and better flow of Rules.
Assistance	**20 CAR § 260-106**
	Verbiage revisions- stricken language; verbiage moved for better flow of Rules & Model verbiage added for clarification.
• Covered Services	Revised. Model language added for clarity and better flow of Rules.
• Referral Services	Deleted. Not supported by Act 852 of 2025.
• Payment for Covered Services to Vendors	Revised. Model language added for clarity and better flow of Rules.
Confidentiality, Use, & Release of Client Records & Information	**20 CAR § 260-107**
	Verbiage revisions- stricken language, & Model verbiage added for clarification and better flow of Rules.

NOTICE OF PUBLIC COMMENT PERIOD

The Arkansas Department of Health (ADH) is accepting public comments on the Rules Governing the Kidney Disease Program in Arkansas promulgated under the Authority of Act 852 (HB 1456) of 2025, from Monday, July 6, 2026, to Thursday, August 6, 2026. The proposed changes transition the Arkansas Kidney Disease Commission to the Arkansas Kidney Disease Advisory Council and other programmatic changes. The proposed rule revision with a summary of changes can be viewed online at https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules or you may request a copy from our office at 501-661-2433 or 501-686-2807.

Comments on the proposed changes can be mailed to:

Arkansas Department of Health
4815 West Markham, Slot 35
Little Rock Arkansas, 72205,

or emailed to: adh.akdc@arkansas.gov.

Proposed Rulemaking

~~Title~~Rules for the State Kidney Disease Program

Promulgated by:
~~State Kidney Disease Commission~~Department of Health

Title 20. Public Health and Welfare

Chapter IV. State Kidney Disease ~~Commission~~Program, Department of Health

Subchapter A. Generally

Part 260. Rules for the State Kidney Disease ~~Commission~~ Program ~~Rules~~

Subpart 1. Generally

20 CAR § 260-101. Legislative findings and purpose.

(a) Legislative findings declared and found that one (1) 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.

(b) 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.

(c) 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.

(d) 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.

20 CAR § 260-102. ~~State Kidney Disease Commission~~Department of Health - Kidney Disease Advisory Council.

(a) **Powers and duties of the ~~commission~~Department.** The ~~State Kidney Disease Commission~~Department of Health, in consultation with the Kidney Disease Advisory Council shall ~~have the following functions, powers, and duties~~:

(1)(A) ~~To establish~~ Administer a program to assist persons suffering from acute or chronic renal failure in obtaining care and treatment requiring dialysis.

(B) 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~~Department of Health, 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;

(2) ~~To develop standards~~Develop rules for determining eligibility for assistance in defraying the cost of care and treatment of renal disease under this program, to be recommended for adoption by the State Board of Health;

(3) ~~To cooperate~~ Cooperate with hospitals, private groups, 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;

(4) ~~To cooperate~~ 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;

(5) ~~To establish criteria and standards~~Establish rules 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~~ rules for eligibility for financial assistance in defraying the cost of the care and treatment from funds appropriated to the ~~commission~~ advisory council for renal disease treatment purposes;

(6) ~~To accept~~ 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 part 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; and

(7) ~~To accept~~ 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.

(b) **~~Commission~~ Advisory Council subcommittees and ad hoc committees.**

(1) The ~~commission~~ Advisory Council may establish subcommittees or ad hoc committees from time to time.

(2) The ad hoc committees shall review issues and make recommendation to the full ~~commission~~advisory council.

(c) Kidney Disease Advisory Council

(1) The Advisory Council shall consist of seven (7) members who shall be appointed by the State Board of Health, as follows:

(A) Three (3) members who:

(i) are knowledgeable in renal medicine and the treatment of end-stage renal disease;

(ii) are physicians licensed to practice in Arkansas; and

(iii) are actively engaged in the private practice of medicine in this state;

(B) One (1) member who:

(i) is knowledgeable in renal medicine and the treatment of end-stage renal disease;

(ii) is a physician licensed to practice in Arkansas; and

(iii) is primarily engaged in the institutional practice of medicine;

(C) One (1) member who is engaged in hospital administrative activities;

(D) One (1) member from the public at large, who:

(i) has demonstrated interest in the treatment and cure of renal diseases; and

(ii) may be a representative from an Arkansas-based nonprofit organization dedicated to the treatment and cure of renal diseases;

(E) One (1) member representing the elderly, who:

(i) is sixty (60) years of age or older;

(ii) appointed from the state at-large;

(ii) is not actively engaged in or retired from any profession, occupation, or industry which is regulated pursuant to Arkansas Code §20-15-601, et seq.

(2) The Department shall establish procedures for interested persons to apply to the Department and for submission of qualified candidates to the State Board of Health for appointment to the Kidney Disease Advisory Council.

(3) Members of the Kidney Disease Advisory Council shall be appointed for terms of four (4) years to expire on January 14 of the member's fourth year of the appointed term.

(4) The advisory council shall annually elect one of its members as chair and one of its members as vice chair, and other such officers as the advisory council deems necessary.

(5) The advisory council shall meet at least once annually, as called by the chair, or upon written request of any three (3) members.

(6) A quorum shall consist of a simple majority of the current appointed members of the advisory council.

(7) Members shall qualify by taking the oath of office as prescribed by law.

(8) If a vacancy occurs on the advisory council due to death, resignation, or other cause, the vacancy shall be filled by appointment of the State Board of Health of

a person eligible for the initial appointment for the remainder of the unexpired portion of the term of the member.

20 CAR § 260-103. Chain of Life award.

(a) The ~~State~~ Kidney Disease ~~Commission's~~ Advisory Council ~~Chain of Life award~~ may recognize~~s~~ individuals who have:

(1) made a living kidney donation to a current resident of Arkansas who is in need of kidney transplantation with the Chain of Life Award; or~~.~~

(2) made substantial contributions to the kidney disease patient community in the state of Arkansas, and whose specific, cumulative contributions demonstrably benefitted the kidney disease patient community in the state, with the Bob Abbott Award.

(b) Nominations for the award are received by the ~~commission~~Department of Health ~~-~~ and presented to the ~~Board of the State Kidney Disease Commission~~Kidney Disease Advisory Council for approval.

(c) The ~~commission~~ Department 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.

20 CAR § 260-104. Eligibility for assistance.

(a)(1) Persons suffering from chronic renal failure may be referred to the ~~State Kidney Disease Commission~~Department of Health.

(2) Referrals ~~shall~~ may come from:

(A) Clients themselves;

(B) Physicians;

(C) Social workers;

(D) Hospital or kidney dialysis center personnel;

(E) Pharmacists;

(F) Rehabilitation counselors; and

(G) Others, including individuals and agencies familiar with the person's kidney disease.

(b) **Eligibility requirements.**

(1) Eligibility requirements shall be applied without regard to:

(A) Sex;

(B) Race;

(C) Creed;

(D) Color; or

(E) National origin.

(2) With respect to age, no upper or lower limit shall be set as a guide to turn away a referral.

(c) **Residency ~~requirement~~.**

(1) Clients must be a resident of Arkansas.

(2) 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.

(d) **~~Physician~~ Medical certification ~~requirement~~as proof of diagnosis.** Certification by a nephrologist (or other physician), physician assistant, or advanced practice registered nurse is required ~~confirming~~ to confirm the applicant has a diagnosis of ~~ESRD~~ acute or chronic kidney disease with an indication that the individual is in need of regular renal dialysis treatments or has been the recipient of a kidney transplant.

(e) **Financial eligibility.**

(1) A client's annual income may not exceed two hundred fifty percent (250%) of the federal poverty level percentage for the year in which they are applying for assistance.

(2)(A) The ~~commission~~ Department shall consider the available financial resources of the total household.

(B) Income sources to be considered include:

(i) Wages;

(ii) Business income;

(iii) Social Security, Social Security Disability Insurance, and Supplemental Security Income benefits;

(iv) Retirement income;

(v) Veteran's benefits;

(vi) Income from stocks, bonds, or other investments; and

(vii) Other identifiable liquid assets.

(C)(i) If the applicant is a dependent, the resources of the parent or parents shall be determined.

(ii) The exception is if the applicant is a dependent and is receiving Supplemental Security Income benefits, he or she may be considered a family of one (1).

(f) **Insurance eligibility.**

(1) Clients with insurance must provide proof of insurance coverage.

(2) Individuals with or without insurance are not prohibited from receiving ~~services~~ assistance on the basis of their insurance status.

(3) However, the ~~commission~~ Department shall be payor of last resort.

(g) **Application ~~for services~~.**

(1) Individuals applying for or being referred to the Department for ~~services~~ assistance available through the program shall complete the ~~commission's~~ Department's Initial Referral Application through the Department's online application portal.

(2) The Initial Referral Application includes the ~~required nephrologist or other health professional~~medical certification indicating the applicant has acute or chronic kidney disease ~~ESRD~~ or has been the recipient of a kidney transplant.

(3) Documentation of eligibility shall be submitted with the application packet, including but not limited to:

(A) Proof of residency;

(B) Proof of income;

(C) Proof of insurance;

(D) Signed statement of medical certification; and

(E) Additional documentation as requested by the Department.

(4) The Department may also request documentation evidencing the individual applied for and was either accepted or denied for all applicable assistance programs available to the individual. The Department shall only supplement these benefits.

~~(h) **Certificate of eligibility/ineligibility.**~~

~~(1) 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.~~

~~(2) The State Kidney Disease Commission Program Manager shall:~~

~~(A) 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; and~~

~~(B) Sign the Certificate of Eligibility/Ineligibility for each applicant, indicating the applicant's eligibility or ineligibility.~~

~~(i) **Other resources/similar benefit.**~~

~~(1) Applicants shall be required to apply and provide evidence of acceptance/denial from all applicable pharmaceutical company patient assistance programs.~~

~~(2) Any services that the applicant may receive or be eligible to receive from other sources shall be used first.~~

~~(3) The commission may only supplement these benefits.~~

~~(j) **Copayment.**~~

~~(1) The commission shall establish a copayment for services paid by a client of the program at the point of sale.~~

~~(2) The copayment amount is two dollars ($2.00) for each medication each month.~~

20 CAR § 260-105. Effective date of ~~service~~eligibility.

~~(a)(1) The effective date a client shall be eligible to receive paid for services provided by the State Kidney Disease Commission shall be established by the program.~~

~~(2) An applicant must be determined eligible prior to funds being authorized.~~

~~(3) The commission shall not authorize payment for any services provided prior to the effective date of service.~~

(a) Applicants shall receive notification of eligibility prior receiving assistance for covered services.

(1) The effective date of eligibility to receive covered services shall be determined by the Department of Health after eligibility is determined.

(2) No payment for services may be issued for any services provided prior to the effective date of eligibility.

(3) The Department may establish a co-payment for services paid by a client of the program at the point of sale.

(A) The co-payment amount shall be two dollars ($2.00) for each medication each month.

(b) **Financial cap.**

(1)(A) The ~~commission~~ Department, after consultation with the Kidney Disease Advisory Council, 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 the prior year.

(B) This annual cap is subject to change based on increases or decreases in the number of patients in the programs and or changes in program funding.

(2) Exceptions may be made on a case-by-case basis ~~as determined by the commission~~.

(3) During the course of a fiscal year, should expenditures for a client exceed the limit allowed, the case will be referred to the ~~commission~~ Department for review to determine a course of action.

(c) **Termination of ~~services~~eligibility.**

(1) The ~~commission~~ Department will pay for services and medication prescribed up to the client's date of death.

(2) Eligibility for ~~covered services~~assistance ~~will also be ended~~shall end 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.

(d) **Annual ~~review~~renewal.**

(1) Individuals determined eligible to receive ~~commission services~~ assistance under the Kidney Disease Program shall submit an eligibility renewal application annually to determine continued program eligibility.

~~(2) The review process will consist of a determination as to whether the individual continues to meet program medical, residential, and financial need eligibility criteria.~~

(~~3~~2)(A) Clients who meet eligibility requirements will ~~continue to~~ receive ~~commission services~~notification of continued eligibility.

(B) Any client who no longer meets program eligibility requirements shall be issued a ~~letter~~ notification of termination of services effective thirty (30) days after the date of ~~review~~termination.

(4) The ~~commission~~ Department shall not pay for services for patients who fail to renew within one (1) ~~and one-half (1 1/2)~~ year~~s~~ of their last date of eligibility ~~(year of eligibility, plus six-month grace period)~~.

~~(5) Medications prescribed within a client's annual eligibility period (plus six-month grace period) shall be covered, even if the claim is received by the commission after the patient's eligibility has lapsed.~~

20 CAR § 260-106. ~~Services~~Assistance.

(a)(1) The ~~services~~ financial assistance provided by the ~~State Kidney Disease Commission~~Department shall be dependent on the availability of funds.

~~(2) The commission may determine specific services to be funded by the program prior to the beginning of each new state fiscal year.~~

~~(3) Covered services may include:~~

~~(A) Outpatient pharmaceutical drugs and nutritional supplements;~~

~~(B) Pretransplant dental services;~~

~~(C) Transportation;~~

~~(D) Patient education; and~~

~~(E) Referral.~~

(42) Specific ~~services~~ assistance to the ~~commission's clients~~program's recipients, including those in need of continuing services, shall be provided based upon the availability of funds.

(53)(A) During the course of a fiscal year should it be determined that available funding is insufficient to fund services ~~provided~~ covered by the program at existing levels ~~for the remaining portion of the fiscal year~~, the ~~commission~~ Department shall establish the manner in which assistance for services will be curtailed or, if required, terminated for the remainder of that fiscal year.

~~(B) Should the curtailing of services result, preference will be given to those in need of continuing services, as determined by the commission.~~

(b) ~~Financial assistance from the commission~~Assistance for covered services may include:

(1)(A) Outpatient prescriptions.

(B) The ~~commission~~ Department may provide financial assistance for no more than three (3) outpatient prescriptions per month.

(C) Amount payable to pharmacy is the allowable amount in the formulary fee schedule, after insurance payment and less client copayment;

(2)(A) Immunosuppressant drugs.

(B) The ~~commission~~ Department may provide financial assistance for ~~immuno~~immune-suppressant drugs.

(C) A client copay for allowable drugs is required.

(D) The ~~commission~~ Department shall only participate in the purchase of ~~immuno~~immune-suppressant medications as a copayer.

(E) Program copayment for ~~immuno~~immune-suppressant drugs shall not exceed twenty percent (20%) of the Medicare allowable rate;

(3)(A) Nutritional supplements.

(B) The ~~commission~~ Department may provide for nutritional supplements if ordered by physician.

(C) Amount payable to pharmacy is the allowable amount in the formulary fee schedule, after insurance and less client copayment;

(4)(A) Transportation.

(B) The ~~commission~~ Department may provide for dialysis appointment transportation mileage reimbursement, at the state employee mileage reimbursement rate for the applicable year.

(C) Clients who prove they must take a taxi, ride share, or other paid transportation service are eligible for transportation mileage reimbursement.

(D) Patients must first attempt to use personal or Medicaid transportation, if available, prior to engaging a taxi, ride share, or other paid transportation.

(E) Evidence of efforts to use Medicaid transportation must be provided.

(F) Taxi or paid transportation receipt is required prior to mileage reimbursement; and

(5)(A) Dental.

(B) The ~~commission~~ Department may ~~provide for~~cover 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.

(C) Payment for services rendered will be prior approved and consistent with the ~~established~~ current Delta Dental~~dental~~ fee schedule ~~herein attached as Appendix A~~.

(c) **Patient education.** The ~~commission~~ Department 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.

~~(d) **Referral services.** The commission may assist clients diagnosed with ESRD with referral to other programs, including vocational rehabilitation.~~

(e) **Formulary.**

(1) The ~~commission~~ Department, in consultation with the Kidney Disease Advisory Council, shall establish a formulary.

(2) The formulary will include nutritional supplements designed for kidney dialysis patients.

(3) The formulary and fee schedule may be updated periodically and is attached as Appendix A.

(f) **Payment for services to vendors.**

(1) The ~~commission~~ Department shall process payment for covered services to program clients when in receipt of a signed vendor statement or ~~letter~~ claim that includes:

(A) The client's name and other necessary identifiable information;

(B) A description of services provided;

(C) Date or dates of service provision; and

(D) Cost.

(2) ~~Claims~~ Pharmacy claims: ~~made for payment of prescription drugs or transportation reimbursement are to be submitted on the appropriate commission claim form or applicable online form if available.~~

(A) Participating pharmacies must utilize the Department's online portal for submission of claims.

(B) Pharmacists are encouraged to submit claims within a reasonable amount of time, preferably within 60 days of dispensing of prescriptions.

(C) Medications prescribed within a client's annual eligibility period shall be covered, even if the claim is received by the Department after the patient's eligibility is terminated.

(3) The ~~commission~~ Department shall not prepay for a service~~, only providing payment after the service has been rendered~~. Payment shall only be provided after the service has been rendered.

(4) Requests for payment for services rendered must be received by the program within one (1) calendar year of the date of service.

(5) The ~~commission~~ Department ~~will~~ shall not provide remittance for those requests for payment that exceed the one-year from date of service limit.

20 CAR § 260-107. Confidentiality, use, and release of client records and information.

(a)(1) The ~~State Kidney Disease Commission~~Department of Health shall maintain a case record for applicants and individuals determined eligible to receive ~~services~~ assistance available through the program.

(2) Client information developed or received by the ~~commission~~ Department is the property of the program.

(3) Information contained in the case record shall only be used for:

(A) Determining eligibility/ineligibility for the ~~commission's~~ Department's services;

(B) Providing payment for services rendered; or

(C) Other program operations.

(4) The ~~commission~~ Department shall maintain personal information contained in the case record in a secure manner and treat such information with the highest degree of confidentiality.

(b)(1) The ~~commission Program Manager~~Department is designated as the custodian of applicant and client case records.

(2) The ~~Program Manager~~Department has the responsibility of ensuring such information is maintained in a safe and secure manner consistent with state and federal law, rule, or regulation.

~~(3) The Program Manager shall provide training to the commission staff regarding how applicant and client information will be developed, maintained, and shared with affected parties.~~

~~(4) The Program Manager is responsible for the destruction of all closed case files.~~

(c)(1) When requested in writing, the ~~commission~~ Department shall make available to the applicant or client or, if appropriate, the individual's representative, information contained in that person's case record.

(2) Should the applicant or client or, if appropriate, that individual's representative believe information contained in the case record to be inaccurate or misleading, a written request can be made to the ~~program~~ Department to amend such information.

(3) In the event another agency or organization requests personal information contained in the case record of a ~~commission~~ department applicant or client, the program shall only release such information with written consent of the applicant or client or, if appropriate, that individual's representative.

(4) It is the responsibility of the ~~commission~~ Department and parties involved to respect the confidential nature of personal information and limit information exchanged to that minimally necessary.

(5) The ~~commission~~ Department shall release personal information contained in the case record in response to investigations in connection with law enforcement, fraud, and abuse, unless:

(A) Expressly prohibited by state and federal laws and~~,~~ rules~~, and regulations~~; and

(B) In response to an order issued by a judge, magistrate, or other authorized judicial official.