

**Department of State Health Services
Council Agenda Memo for State Health Services Council
June 25, 2009**

Agenda Item Title: Repeal of rules and new rules concerning Kidney Health Care (KHC)

Agenda Number: 4c

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background: The KHC program is located within the Family and Community Health Services Division, Specialized Health Services Section, Purchased Health Services Unit. The program serves Texas residents with end-stage renal disease (ESRD) diagnosis, who are not Medicaid eligible and who have a gross income less than \$60,000 annually.

ESRD is a permanent and irreversible disease state that requires the use of renal replacement therapy (renal dialysis or transplantation) to maintain life. The program provides Medicare Part D premium, deductible and coinsurance benefits; limited drug benefits; travel reimbursement for ESRD-related travel up to 13 round trips monthly; and allowable benefits for dialysis and access surgery (necessary to perform dialysis) to 18,091 clients of all ages. The program contracts with 815 providers to deliver covered services.

The KHC annual program budget is \$11,232,029 and is supported by Legislative appropriations from general revenue.

Summary: The purpose of the repeals and new rules is to strengthen eligibility requirements for benefits; reorganize and update information; delete and revise language; and correct grammar for clarity and ease of use. The rules affect KHC applicants, clients, and providers, and information was added to enhance understanding of their rights and responsibilities, including the right to an appeal.

The proposed repeals and new rules comply with the mandatory four-year review of agency rules required by Government Code, Section 2001.039.

The expected outcomes of the proposed rules are to: (1) enhance the understanding of KHC applicants, clients, and providers regarding program policy; (2) increase readability; and (3) accurately reflect program information.

The program expects to receive feedback from clients, providers and other interested parties. This input, where applicable, will be incorporated in training plans, newsletters and program policy updates.

Summary of Input from Stakeholder Groups:

Stakeholder input was solicited via email and regular mail on February 5, 2009, to 1,005 administrative and social work staff of all KHC contracted providers, and the following 13 advocacy groups:

American Association of Kidney Patients; American Diabetes Association; End-Stage Renal Disease Network of Texas #14; Juvenile Diabetes Research Foundation; National Association of Social Workers Texas Chapter; National Kidney Foundation of South and Central Texas; Texas Diabetes Council; National Kidney Foundation of North Texas, Inc.; National Kidney Foundation of Southeast Texas, Inc.; National Kidney Foundation of Southwest Texas, Inc.; National Kidney Foundation of West Texas, Inc.; Texas Renal Coalition; and Coastal Bend Kidney Foundation.

Stakeholder suggestions were received from 13 individuals. Stakeholders made recommendations that include:

- an increase to the travel reimbursement rate, extension of travel benefits, and addition of reimbursement rate in rules;
- an extension of benefits to allow physician care services in the three months prior to Medicare coverage;
- an increase in the number of drugs on the formulary and provide coverage for additional drugs per month;
- an increase to access surgery benefit rates and allow additional procedures;
- a determination of client eligibility from the date of the first dialysis treatment, instead of the date a complete application is received, and reimbursement of facilities retroactively;
- less stringent financial documentation and requirements for an applicant; and
- a requirement in the rules that training of hemodialysis and transplant clinic social workers and contracted pharmacists is a responsibility of the program.

The first five recommendations were not incorporated into the proposed rule text due to budgetary restrictions. It is the responsibility of KHC to accurately determine the eligibility of clients and utilize budget funds appropriately, so KHC does not agree that less stringent restrictions and financial documentation requirements would be fiscally responsible for the program. KHC policy covers the training of providers and a provider manual is under development, therefore, the program does not feel it is necessary to put the requirement for training in the rules.

Proposed Motion: Motion to recommend HHSC approval for publication of rules contained in agenda item #4c

Approved by Assistant Commissioner/Director: Evelyn Delgado	Date: 5/8/09	
Presenter: Jann Melton-Kissel	Program: Specialized Health Services Section	Phone No.: 458-7111, ext. 2002
Approved by CPCPI: Carolyn Bivens	Date: 5/08/2009	

Title 25. HEALTH SERVICES
Part 1. DEPARTMENT OF STATE HEALTH SERVICES
Chapter 61. Chronic Diseases
Subchapter A. Kidney Health Care
New §§61.1-61.11
Repeal §§61.1 - 61.4, 61.6 - 61.9, 61.13, 61.14

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes the repeal of §§61.1 - 61.4, 61.6 - 61.9, 61.13, 61.14, and new §§61.1 - 61.11 concerning Kidney Health Care (KHC).

BACKGROUND AND PURPOSE

The program for KHC serves Texas residents with end-stage renal disease (ERSD) diagnosis, who are not Medicaid eligible. The program contracts with providers to deliver covered services, including Medicare Part D premiums, deductibles, and co-insurance, travel reimbursement for ESRD related services, and allowable dialysis and access surgery benefits.

The proposed repeal and new rules strengthen eligibility requirements for benefits, reorganize and update information, delete and revise language, and make grammatical corrections to improve flow, accuracy, and clarity.

Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 61.1 - 61.4, 61.6 - 61.9, 61.13, and 61.14 have been reviewed, and the department has determined that reasons for adopting the sections continue to exist because rules on this subject are needed.

SECTION-BY-SECTION SUMMARY

New §61.1 groups the terms “purpose,” “confidentiality of information,” and “forms” together.

New §61.2 includes new definitions for terms used in this subchapter which include administrative review; client; date of service; denial; effective date; filing deadline; KHC formulary; low income subsidy; medical benefit; Medicare advantage plan; Medicare Part A; Medicare Part B; Medicare Part D; Medicare Prescription Drug Plan; Medigap plan; modification; program; qualified individual and Medicare beneficiary; reimbursement; specified low income Medicare beneficiary, and termination.

New §61.3 clarifies client eligibility requirements, financial criteria, and residency requirements.

New §61.4 clarifies the client application process and eligibility dates requirements.

New §61.5 clarifies existing language, includes new language regarding access to benefits by

Veterans Administration clients, and sets out conditions for KHC benefits and limitations.

New §61.6 clarifies provider enrollment criteria and effective dates.

New §61.7 includes language regarding claims submission and payment rates.

New §61.8 includes language regarding claims filing deadlines.

New §61.9 includes language regarding rights and responsibilities for applicants, clients, and providers.

New §61.10 includes language regarding modifications, suspensions, denials, and terminations for applicants, clients, and providers.

New §61.11 restores language regarding the appeal process and describes the process for administrative reviews and fair hearing requests.

FISCAL NOTE

Jann Melton-Kissel, RN, MBA, Director, Specialized Health Services Section, has determined that for each year of the first five-year period that the sections will be in effect, there will be no fiscal impact to state or local governments as a result of enforcing and administering the sections as proposed. The repeals and new sections are intended to clarify, update, and strengthen the subchapter, and are not anticipated to be controversial or have significant fiscal impact to the department or local government.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS FOR SMALL AND MICRO-BUSINESSES

Ms. Melton-Kissel has also determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed, because neither small businesses nor micro-businesses that are providers of the KHC program will be required to alter their business practices in order to comply with the sections, and an economic impact statement and regulatory flexibility analysis are not required.

ECONOMIC COST TO PERSONS AND IMPACT ON LOCAL EMPLOYMENT

There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

Ms. Melton-Kissel has determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is improved accuracy and consistency in the rules, and more accurate interpretation of their intent. In addition, the new rules will allow the

program to function more efficiently and effectively.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted by mail to Kathleen Ford, Purchased Health Services Unit, MC 1938, Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347; by telephone at (512) 458-7111, extension 6836; or by email to kathleen.ford@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Lisa Hernandez, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed repeal and new rules are authorized by Health and Safety Code, §42.003(c), which authorizes the Executive Commissioner of the Health and Human Services Commission to adopt rules necessary to carry out Chapter 42 and to provide adequate kidney care and treatment for the citizens of this state; and Government Code, §531.0055(e), and the Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001. Review of the sections implements Government Code, §2001.039.

The proposed repeal and new rules affect Government Code, Chapter 531; and Health and Safety Code, Chapters 42 and 1001.

Sections for repeal.

- §61.1. General.
- §61.2. Recipient Requirements.
- §61.3. Residency and Residency Documentation Requirements.
- §61.4. Applications.
- §61.6. Limitations and Benefits Provided.
- §61.7. Claims Submission and Payments Rates.
- §61.8. Claim Filing Deadlines.
- §61.9. Participating Providers.
- §61.13. Forms.
- §61.14. Confidentiality of Information.

Legend: (Proposed New Rule)
Regular Print = Proposed new language

§61.1. General.

(a) Purpose. The purpose of this subchapter is to establish rules for the Kidney Health Care (KHC) program. The authority for these rules is granted in the Texas Health and Safety Code, Chapter 42.

(b) Confidentiality of Information.

(1) All information submitted, as required by this subchapter, may be verified at the discretion of the Department of State Health Services (department) with or without notice to applicants, clients, or providers of KHC benefits or services. This information is confidential to the extent authorized by law.

(2) Information may be disclosed in summary, statistical, or other forms that do not identify particular individuals.

(c) Forms. The program provides approved forms to applicants, clients, and providers.

§61.2. Definitions.

Definitions. The following words and terms when used in this subchapter shall have the following meanings, unless the context clearly indicates otherwise.

(1) Access surgery--The surgical procedure which creates or maintains the access site necessary to perform dialysis.

(2) Action--A suspension, modification, denial, or termination of KHC eligibility, benefits, or participation.

(3) Administrative review--A process that allows applicants, clients, or providers the opportunity to request an informal review of any intended program action that would suspend, modify, deny, or terminate their eligibility, benefits or participation in the program.

(4) Allowable amount--The maximum amount that the program will pay or reimburse for a covered benefit or service.

(5) Applicant--An individual who has submitted an application for KHC benefits and has not received a final determination of eligibility.

(6) Claim--A request for payment or reimbursement of services.

- (7) Client--A person who has applied for program services and who meets all KHC eligibility requirements and is determined to be eligible for program services.
- (8) CMS--The Centers for Medicare and Medicaid Services.
- (9) Co-insurance--A cost-sharing arrangement in which a covered person is responsible for paying a specified percentage of the charge for a covered service or product.
- (10) Commissioner--The commissioner of the Department of State Health Services.
- (11) Co-pay/Co-payment--A cost-sharing arrangement in which a covered person is responsible for paying a specified or fixed charge for a covered service or product.
- (12) CRNA--Certified registered nurse anesthetist.
- (13) Date of service (DOS)--The date a service is rendered.
- (14) Denial--An action by the program that disallows program eligibility, benefits, or administrative review requests.
- (15) Department--The Department of State Health Services.
- (16) Effective date--The initial date of eligibility for a KHC client or provider.
- (17) End-Stage Renal Disease (ESRD)--The final stage of renal impairment that requires dialysis and/or kidney transplant to reduce uremic symptoms and/or prevent the death of the patient.
- (18) EOB--A form, in paper or electronic format, which provides an explanation of benefits. It is used to explain a payment or denial of a claim.
- (19) Fair hearing--The informal hearing process the department follows under §§1.51 - 1.55 of this title (relating to Fair Hearing Procedures).
- (20) Filing deadline--The last date that a claim may be received by the program and still be considered eligible for benefit.
- (21) Final decision--A decision that is made by a decision maker after conducting a fair hearing under §§1.51 - 1.55 of this title.
- (22) Interim approval--The status given by the program to an outpatient dialysis facility, free-standing or hospital-based, which has applied for participation as a KHC provider but has not executed an agreement with the program.
- (23) KHC--Kidney Health Care.

- (24) KHC formulary--A list of general therapeutic categories of drugs, over-the-counter products, and limited diabetic supplies that are covered for reimbursement by the program.
- (25) Low Income Subsidy (LIS)--The subsidy provided under the Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003 for Medicare Part D plan premiums and related costs, at varying levels, for some low-income Medicare beneficiaries.
- (26) Medical benefit--Any medical treatment or procedure approved by the program as a covered service.
- (27) Medicare Advantage Plan--A Medicare health plan that is similar to a health maintenance organization, participating provider organization, or other Medicare health plan, and includes medical, drug coverage and other benefits.
- (28) Medicare Part A--Hospital insurance for people age 65 or older, or under age 65 with certain disabilities, that helps cover inpatient hospital stays, care in a skilled nursing facility, hospice care, and some home health care.
- (29) Medicare Part B--Health insurance for people age 65 or older, or under age 65 with certain disabilities, and any age with ESRD, that helps cover medically necessary services, such as doctors' services and outpatient care, and some preventive services.
- (30) Medicare Part D--Established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), it provides members with prescription drug coverage, expanded health plan options, improved health care access for rural Americans, and preventive care services.
- (31) Medicare Part D out-of-pocket expenses--Include premiums, deductibles, and co-insurance amounts.
- (32) Medicare Part D Premium--The amount paid monthly under a Medicare Part D contract to insure coverage.
- (33) Medicare Prescription Drug Plan (PDP)--A stand-alone drug plan offered by insurers and other private companies to individuals eligible for Medicare Part D.
- (34) Medigap plan--A Medicare supplement insurance policy sold by private insurance companies to fill "gaps" in Medicare coverage.
- (35) Modification--A change made to a client's record that affects a program benefit or eligibility status.
- (36) Program--Kidney Health Care Program.

(37) Provider--Any individual or entity approved by the program to furnish covered services to KHC clients including:

- (A) outpatient dialysis facilities;
- (B) out-of-state outpatient dialysis facilities;
- (C) hospitals and ambulatory surgical centers (ASCs) located in Texas and operating in compliance with applicable law;
- (D) out-of-state hospitals and ASCs;
- (E) military or Veterans Administration hospitals located in Texas which have a renal unit approved by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association;
- (F) pharmacies approved as Texas Medicaid providers and licensed to operate within the United States and its territories, including mail order pharmacies;
- (G) physicians and certified registered nurse anesthetists (CRNAs) licensed in Texas;
- (H) out-of-state physicians and CRNAs; and
- (I) Medicare Prescription Drug Plan (PDP) and Medicare Advantage Plan (MA-PD) providers.

(38) Qualified Individual (QI)--A Medicaid program for beneficiaries who need help in paying for Medicare Part B premiums. The beneficiary must have Medicare Part A and limited income and resources and not be otherwise eligible for Medicaid. For those who qualify, the Medicaid program pays full Medicare Part B premiums only.

(39) Qualified Medicare Beneficiary (QMB)--A Medicaid program for beneficiaries who need help in paying for Medicare services. The beneficiary must have Medicare Part A and limited income and resources. For those who qualify, the Medicaid program pays Medicare Part A premiums, Part B premiums, and Medicare deductibles and coinsurance amounts for Medicare services.

(40) Reimbursement--Payment of a claim for allowable services or transportation.

(41) Reimbursement rate--The KHC payment rate for allowable products, services, and transportation determined annually for the following fiscal year.

(42) Specified Low Income Medicare Beneficiary (SLMB)--A Medicaid program that pays for Medicare Part B premiums for individuals who have Medicare Part A, a low monthly income, and limited resources.

(43) Suspension--Eligibility for benefits which is held without final action pending satisfaction of a program request or requirement.

(44) Termination--A final action by the program, which ends client or provider participation in the KHC program.

§61.3. Client Eligibility Requirements.

(a) A person shall meet all of the following requirements to be eligible for KHC benefits:

(1) have a diagnosis of ESRD, and

(A) require a regular course of chronic renal dialysis treatments; or

(B) have received a kidney transplant;

(2) satisfy the Texas residency criteria as specified in subsection (b) of this section and not be:

(A) in the custody of or incarcerated by a city, county, state, or federal entity; or

(B) a ward of the state;

(3) not be eligible for drug, transportation, and medical benefits under the Texas Medicaid Program;

(4) submit a complete application for benefits; and

(5) satisfy the financial criteria as specified in subsection (c) of this section.

(b) Residency Requirements.

(1) The following conditions must be met by an applicant and maintained by a client to satisfy the residency requirements in this section:

(A) physically reside within the state; and

(B) maintain a home or dwelling within the state.

(2) If the applicant is residing with a person establishing residency on behalf of the applicant (such as a parent, legal guardian, managing conservator, sibling, adult child, or spouse), then that person must meet all of the requirements of paragraph (1) of this subsection.

(3) All documents acceptable to meet residency requirements, as specified by the program, must be in the applicant's name, or in the name of the person establishing residency for the applicant, provide some verification of a Texas address or domicile, and be in English or be accompanied by an accurate English translation.

(c) Financial Criteria. The applicant or the person(s) who has a legal obligation, as defined by state law, to support the applicant must have an annual gross income of less than \$60,000. Income reported as "joint income" is considered as one income.

(d) Maintenance of Benefits Eligibility.

(1) A client must meet the following requirements within the first 3 months of KHC eligibility:

(A) apply for medical, drug, and transportation benefits and Medicare Savings Plans (QMB, SLMB and QI) under Title XIX, Social Security Act (Medicaid);

(B) apply for Medicare hospital and medical benefits under Title XVIII, Social Security Act (Medicare);

(C) enroll in Medicare Part D benefits and apply for Low Income Subsidy under the Medicare Prescription Drug Improvement and Modernization Act of 2003, if Medicare eligible;

(D) provide authorization for Medicare premium payments by the program as specified in §61.5 of this title (relating to Benefits and Limitations), if obligated to pay the Part A premium.

(2) A client must meet the following requirements to continue benefit eligibility:

(A) continue premium payments on health insurance plans under Medicare, individual or group health insurance plans, and prepaid medical plans, where enrollment was effective prior to KHC eligibility;

(B) reapply for LIS annually;

(C) reapply for Medicaid annually;

(D) reapply for Medicare hospital and medical benefits as requested by the program if there are changes in the client's status that would make the client potentially eligible for Medicare benefits; and

(E) notify the program within 30 days of changes in the following:

(i) permanent home address;

- (ii) treatment status;
- (iii) insurance coverage; and
- (iv) location of treatment.

§61.4. Applications. Persons meeting the eligibility requirements set forth in §61.3(a) - (c) of this title (relating to Client Eligibility Requirements) must make a complete application for benefits.

(1) A complete application must include all of the following:

(A) a complete and notarized Application for Benefits, with the applicant's, or the applicant's representative's, original signature or "mark";

(B) a copy of the completed, signed and dated Centers for Medicare and Medicaid Services (CMS) End-Stage Renal Disease Medical Evidence Report;

(C) documentation of Texas residency as required by §61.3 of this title ;

(D) a copy of the applicant's social security card issued by the Social Security Administration (SSA), or an allowable substitute, as follows:

(i) a copy of a SSA document which verifies the social security number; or

(ii) a copy of a valid Medicare card, if the Medicare account is established in the applicant's own social security number and the social security number is printed on the Medicare card.

(E) applicant's financial data. The applicant or the person(s) legally obligated to support the applicant must verify income by providing one of the following:

(i) a copy of the first page of the federal individual income tax return for the most recent tax year; or

(ii) a statement of estimated or declared income for the current tax year, and supporting documentation, if requested.

(2) Incomplete application. An application which does not meet all of the requirements of paragraph (1) of this section is incomplete. Incomplete applications may be returned to the submitting person or entity for correction or completion.

(3) Eligibility date for KHC benefits. The KHC eligibility date is the date the program receives a complete application.

(4) If KHC benefits are terminated, the eligibility date for any subsequent benefit period is the date the program receives a subsequent complete application for KHC benefits.

(5) An applicant whose eligibility for benefits is denied may appeal under §61.11 of this title (relating to Rights of Appeal).

§61.5. Benefits and Limitations.

(a) Benefits.

(1) Outpatient drugs and drug products listed on the current KHC formulary.

(2) Transportation reimbursement for ESRD-related medical services.

(3) Medical benefits, including:

(A) access surgery-related services; and

(B) chronic maintenance dialysis.

(4) Medicare Part A and B premium payment. To qualify for this benefit, clients must:

(A) be 65 years of age or older;

(B) be accepted for Medicare hospital and medical insurance;

(C) be obligated to pay the Part A premium;

(D) not be eligible for the following types of Medicare savings programs:

(i) QMB;

(ii) SLMB; or

(iii) QI; and

(E) promptly submit all Medicare premium due notice statements to the program for payment.

(5) Medicare Part B immunosuppressive drug co-insurance amounts. To qualify for this benefit, clients must:

(A) be eligible for KHC drug benefits;

- (B) be accepted for Medicare hospital and medical insurance;
- (C) enroll in a Texas Medicare Part D Stand-Alone Plan;
- (D) not be enrolled in a Medigap plan;
- (E) not be enrolled in a Medicare Advantage Plan with drug coverage;
- (F) not be eligible for the following types of Medicare Savings

and

Programs:

- (i) QMB;
- (ii) SLMB; or
- (iii) QI.

(6) Limited Medicare Part D out-of-pocket expenses. To qualify for this benefit, clients must:

- (A) be eligible for KHC drug benefits;
- (B) be accepted for Medicare Part D benefits;
- (C) enroll in a Texas Medicare Part D stand-alone plan;
- (D) not be eligible for LIS from Medicare that covers full premium and deductible amounts; and
- (E) not be enrolled in a Medicare Advantage Plan with drug coverage.

(7) Benefits are payable beyond the qualifying period for eligible clients who have applied for and have been denied Medicare coverage based on ESRD. Clients must submit a copy of the official Social Security Administration Medicare denial notification (based on chronic renal disease) to the department.

(b) Limitations.

(1) Only out-of-state providers approved by the program may provide covered services and KHC allowable drugs.

(2) Covered services are limited to a maximum allowable amount per client based upon:

- (A) available funds;

- (B) established limits for covered services by type or category;
 - (C) an agreement between the department and the client's provider;
 - (D) the reimbursement rates established by the department;
 - (E) any co-payment or co-insurance applied to client service benefits;
- and
- (F) any third-party liability.

(3) Clients eligible for drug coverage under an individual or group health insurance plan are not eligible to receive KHC drug benefits. A client that has exhausted drug coverage under an individual or group health insurance plan may be eligible to receive drug benefits from the program.

(4) Access surgery benefits are payable only if the services are performed on or after the date Texas residency is established and not more than 180 days prior to the client's KHC eligibility effective date.

(5) KHC medical benefits are payable during the Medicare three-month qualifying period. Benefits are payable for services received on or after the client's KHC eligibility effective date. The three-month qualifying period is calculated from the first day of the month the client begins chronic maintenance dialysis. When a client becomes eligible for Medicare during the three-month period, KHC medical benefits are not payable from the date of Medicare eligibility.

(6) Transportation reimbursement is available from the first day of the month following the KHC eligibility effective date for in-center dialysis clients or from the KHC effective date for transplant and home peritoneal dialysis clients.

(7) Clients eligible for hospital and medical benefits from Medicare, or other government programs which cover the treatment of ESRD are not eligible to receive KHC medical benefits.

(8) Clients receiving services, including access surgery, dialysis, or drug benefits through the Veterans Administration (VA) or the military may not be eligible to receive these services through the program, depending on the client's access to VA or military services.

(9) Clients eligible for hospital and medical benefits from private/group health insurance which covers the treatment of ESRD are not eligible for KHC medical benefits.

(10) The program is the payor of last resort. All third parties must be billed prior to the program. The Commissioner may waive this requirement in individually considered

cases where its enforcement will deny services to a class of ESRD patients because of conflicting state or federal laws or regulations, under the Texas Health and Safety Code, §42.009.

(11) If budgetary limitations exist, the department may:

(A) restrict or categorize covered services. Categories will be prioritized based upon medical necessity, other third party eligibility and projected third party payments for the different treatment modalities, caseloads, and demands for services. Caseloads and demands for services may be based on current and/or projected data. In the event covered services must be reduced, they will be reduced in a manner that takes into consideration medical necessity and other third party coverage. The department may change covered services by adding or deleting specific services, entire categories or by making changes proportionally across a category or categories, or by a combination of these methods; or

(B) establish a waiting list of eligible applicants. Information will be collected from each applicant who is placed on a waiting list to facilitate contacting the applicant when benefits become available and to allow efficient enrollment of the applicant for benefits.

§61.6. Provider Requirements and Effective Dates.

(a) Requirements.

(1) Outpatient dialysis facilities must:

- (A) execute an agreement with the program;
- (B) have Medicare certification and a Medicare ESRD provider number;
- (C) be a current Texas Medicaid provider;
- (D) be licensed by the department as an ESRD facility;
- (E) reimburse the program for any overpayments upon request; and
- (F) not be on suspension as a KHC provider, as a Texas Medicaid provider, as a Medicare certified ESRD facility, or as a licensed Texas ESRD facility.

(2) An out-of-state outpatient dialysis facility must:

- (A) meet all the requirements in paragraph (1)(A) - (C) and (E) of this subsection;
- (B) be licensed by its state, if applicable;
- (C) be a Medicaid provider in its state; and

(D) not be on suspension as a KHC provider, as a Texas Medicaid provider, as a Medicaid provider in its state, as a Medicare-certified ESRD facility, or by the ESRD licensing authority of its state.

(3) Any outpatient dialysis facility may be given interim approval according to the following:

(A) client applications for KHC benefits may be submitted by the facility during the period of interim approval.

(B) interim approval extends no longer than six months from the date the program mails the agreement to the facility.

(C) if interim approval lapses, the unexecuted agreement is nullified and a new agreement with term dates and the period of interim approval may be initiated by the program.

(D) claims for outpatient dialysis services shall not be considered for payment by the program until the program has a fully executed agreement with the facility.

(E) claim filing deadlines apply, as contained in §61.8 of this title (relating to Claim Filing Deadlines).

(4) A pharmacy, including a mail order pharmacy, must execute an agreement as a KHC provider through the Health and Human Services Commission Pharmacy Contracts and Rebates unit or designated contractor.

(5) A physician or CRNA must:

(A) execute an agreement with the program;

(B) be licensed to practice medicine in the State of Texas, if a physician;

(C) be certified to practice within the scope of his or her certification in the State of Texas, if a CRNA;

(D) be a Texas Medicaid provider;

(E) not be on suspension as a KHC provider, as a physician licensed to practice medicine in the State of Texas, as a CRNA certified to practice within the scope of the certification in the State of Texas, or as a Texas Medicaid provider; and

(F) reimburse the program for any overpayments upon request.

(6) An out-of-state physician and a CRNA must:

(A) meet all the requirements in paragraph (5)(A), (D) and (F) of this subsection;

(B) be licensed to practice medicine in the state in which services are provided, if a physician; or

(C) be certified to practice within the scope of his or her certification in the state in which services are provided, if a CRNA; and

(D) not be on suspension as a KHC provider, as a Texas Medicaid provider, as a physician licensed to practice medicine in the state in which services are provided, as a CRNA certified to practice within the scope of the certification in the state in which services are provided.

(7) A hospital or ambulatory surgical center (ASC) must:

(A) execute an agreement with the program;

(B) be in compliance with all applicable laws to provide hospital or ASC services in the State of Texas;

(C) be a current Texas Medicaid provider;

(D) have Medicare certification;

(E) not be on suspension as a KHC provider, as a hospital authorized under applicable law to provide hospital services in the State of Texas, as an ASC licensed to provide ASC services in the State of Texas, as a Texas Medicaid provider, or as a Medicare certified hospital or ASC; and

(F) reimburse the program for any overpayments upon request.

(8) An out-of-state hospital or ASC must:

(A) meet all the requirements in paragraph (7)(A), (C), (D) and (F) of this subsection;

(B) be licensed to provide hospital or ASC services in the state in which services are provided;

(C) not be on suspension as a KHC provider, as a Texas Medicaid provider, as a Medicaid provider in its state, as a hospital licensed to provide hospital services in the state in which services are provided, as an ASC licensed to provide ASC services in the state in which services are to be provided, or as a Medicare certified hospital or ASC;

- (9) A Medicare Prescription Drug Plan (PDP) must:
- (A) execute an agreement with the program;
 - (B) be Medicare approved as a PDP and maintain approval;
 - (C) share and exchange data in an acceptable format with the program for the coordination of drug benefits under the Medicare PDP (Part D);
 - (D) accept a program payment for premiums; and
 - (E) reimburse the program for any overpayments upon request.

(b) Effective dates.

(1) The effective date of all outpatient dialysis facility agreements shall be on or after the Medicare ESRD certification date.

(2) The effective date of all pharmacy agreements shall be determined by the Health and Human Services Commission Pharmacy Contracts and Rebates unit or its designated contractor.

(3) The effective date of all other provider agreements, listed in subsection (a)(5) - (9) of this section, shall be the first day of the sixth month prior to the program's receipt of the completed and signed provider agreement.

§61.7. Claims Submission and Payment Rates.

(a) Drug benefit claims must be submitted electronically by the pharmacy to the designated claims processor for the program, except when paper submissions are allowed or required.

(b) Medical benefit claims must be submitted to the program by the provider who rendered the service(s) to the KHC client.

(c) Transportation benefit claims must be submitted to the program by the client or the provider performing outpatient dialysis services. Claims must be submitted electronically through the Automated System for Kidney Information Tracking (ASKIT), or any other designated claims payment system, except when the program allows or requires paper submissions.

(d) Payments are made using the rates in effect on the date the service is rendered, and not prospectively.

(e) Incomplete or incorrect claims will not be considered for payment. Claims which are not received by the program within the deadlines established in §61.8 of this title (relating to Claim Filing Deadlines) will be denied payment.

§61.8. Claim Filing Deadlines.

(a) The program must receive all claims for transportation reimbursement, hospital, out-patient dialysis, and access surgery services, within the claim filing deadlines established in this section.

(1) Claims must be received no later than 95 days from the last day of the month in which services were provided.

(2) Claims must be received no later than 60 days from the date on the program's notice of eligibility for newly approved clients.

(b) In addition to the requirements in subsection (a) of this section, the program must receive claims for out-patient dialysis and access surgery services within 60 days from the date on the agreement approval letter for newly approved providers, but no later than 180 days from the date of service.

(c) The program must receive all billing statements for Medicare Part D premium benefits from eligible PDPs within 95 days from the last day of each month for which the premium coverage applies.

(d) The program must receive resubmitted claims within the deadlines established under subsections (a) - (c) of this section, or within 30 days from the date of the program's return letter or the program's EOB, whichever is later. Resubmitted claims must:

(1) be resubmitted with a copy of the program's return letter or the program's EOB, if applicable;

(2) be resubmitted on the original claim form, if applicable; and

(3) contain no new or additional charges for service.

(e) Pharmacies must submit claims for drug charges to the designated claims processor for the program in accordance with claim filing deadlines contained in 1 Texas Administrative Code, §354.1901, (relating to Pharmacy Claims).

§61.9. Rights and Responsibilities.

(a) The applicant and client shall have the right to:

(1) apply for eligibility determination;

- (2) choose providers subject to KHC limitations;
- (3) be notified of the program's decisions relating to modifications, suspensions, denials, or terminations;
- (4) appeal the program's decisions and receive a response within the deadline as described in §61.11 of this title (relating to Rights of Appeal); and
- (5) assurance that all information concerning his or her status as an applicant or client shall be confidential in the manner and to the extent authorized by law.

(b) Providers shall have the right to:

- (1) be notified of the program's decision relating to modifications, suspensions, denials, or terminations; and
- (2) assurance that all information concerning the provider's program status shall be confidential in the manner and to the extent authorized by law.

(c) The applicant and client shall have the responsibility to:

- (1) provide accurate medical information to providers and notify providers of KHC eligibility prior to delivery of services;
- (2) abide by KHC rules and policies; and
- (3) notify the program of any lawsuit(s) contemplated or filed concerning the cause of the medical condition for which the program has made payment.

(d) The provider shall have the responsibility to:

- (1) enroll as a KHC provider and submit a completed application to the program, including all documents requested;
 - (2) abide by the program rules and policies;
 - (3) not discriminate against applicants or clients based on source of payment;
- and
- (4) notify the program of any lawsuit(s) contemplated or filed concerning the cause of the medical condition for which the program has made payment.

§61.10. Modifications, Suspensions, Denials, and Terminations.

(a) An applicant's or client's eligibility for benefits may be modified, suspended, or denied for failing to comply with the applicant and client responsibilities listed in §61.3 of this

title (relating to Client Eligibility Requirements) and §61.9(c) of this title (relating to Rights and Responsibilities).

(b) A provider's participation may be modified, suspended or denied for failing to comply with the provider responsibilities listed in §61.6(a) of this title (relating to Provider Requirements and Effective Dates) and §61.9(d) of this title.

(c) A client's eligibility may be terminated for any of the following reasons:

(1) failing to maintain Texas residency or to furnish evidence upon demand of residency using the criteria in §61.3 of this title;

(2) failing to continue to meet the income requirements for eligibility or to provide income data as requested by the department to determine continued KHC eligibility;

(3) failing to reimburse the department as requested for overpayments made to the client;

(4) failing to apply for medical, drug, and transportation benefits under Title XIX, Social Security Act (Medicaid);

(5) becoming eligible for drug, transportation, and medical benefits under the Medicaid Program;

(6) regaining native kidney function;

(7) voluntarily discontinuing treatment for ESRD;

(8) becoming incarcerated by or in the custody of a city, county, state, or federal entity;

(9) becoming a ward of the state;

(10) determination by the program that the client made a material misstatement or misrepresentation on their application or any document required to support their application;

(11) determination by the program that the client submitted false claim(s); or

(12) lack of a claim for benefits paid by the program on behalf of the client for a minimum period of 12 consecutive months.

(d) Any action taken under subsections (a) or (c) of this section does not relieve the client, or the person(s) with legal obligation to support the client, of any financial obligation owed to the program.

(e) An applicant must reapply for KHC benefits when eligibility for KHC benefits is terminated.

(f) A client who loses eligibility will not be reinstated until all outstanding debts owed to the program by the client are paid or arrangements acceptable to the program are made for payment.

(g) A client whose benefits are modified or suspended, or whose eligibility is terminated, may appeal the program's decision under §61.11 of this title (relating to Rights of Appeal).

(h) A provider's participation may be terminated or suspended for any of the following reasons:

- (1) loss of approval or exclusion from participation in the Medicare program;
- (2) exclusion from participation in the Medicaid program;
- (3) providing false or misleading information regarding any participation criteria;
- (4) material breach of any contract or agreement with the program;
- (5) filing false or fraudulent information or claims for KHC benefits;
- (6) failure to submit a payable claim to the program during a minimum period of 12 consecutive months; or
- (7) failure to maintain the participation criteria contained in §61.6(a) of this title.

(i) Providers may appeal a termination or suspension under §61.11 of this title.

§61.11. Rights of Appeal.

(a) Administrative Review.

(1) When the program modifies, suspends, denies, or terminates eligibility or benefits, the program shall give written notice of and the reason for the action. Applicants, clients, and providers have the right to request an administrative review of the action within 30 days of the notice date.

(2) If the program does not receive a written request for administrative review within 30 days of the notice date, applicants, clients, and providers waive the right to the administrative review process.

(3) If a written request for administrative review is received within 30 days of the notice date, the program conducts an administrative review of the circumstances surrounding the action. The program must give written notice of the decision including the supporting reasons, within 30 days of receiving all information required to make a determination regarding the request for an administrative review.

(4) The department establishes the KHC reimbursement rates. Clients and providers may not request an administrative review of reimbursement amounts for claims that are paid in accordance with the reimbursement rates as described in §61.5 of this title (relating to Benefits and Limitations).

(b) Fair Hearing.

(1) Applicants, clients, and providers who disagree with a program administrative review decision may request a fair hearing in writing addressed to Kidney Health Care, Purchased Health Services Unit, MC 1938, Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347, within 20 calendar days following the date of receipt of the administrative review decision notice.

(2) If the fair hearing request is not received within 20 calendar days following the date of the receipt of the administrative review decision notice, the program will presume the fair hearing process has been waived, and the program may take final action.

(3) A fair hearing shall be conducted in accordance with §§1.51 - 1.55 of this title (relating to Fair Hearing Procedures).

(4) The program may not terminate KHC participation until a final decision is rendered under the department's fair hearings process.

(5) The program may withhold claims payment pending final decision under the department's fair hearings process.

(6) The program must release any withheld payments and reinstate participation if the final determination is in favor of the provider.

(7) The program shall not enter into, extend, or renew an agreement with a provider until a final decision is rendered under the department's fair hearings process.

~~§61.1. General.~~

~~———— (a) Purpose. The purpose of this Chapter is to establish rules for Kidney Health Care (KHC). The authority for these rules is granted in the Texas Health and Safety Code, Chapter 42.~~

~~———— (b) Definitions. The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise.~~

~~———— (1) Access surgery—The surgical procedure which creates or maintains the access site necessary to perform dialysis.~~

~~———— (2) Action—A denial, termination, suspension or reduction of KHC covered services or eligibility.~~

~~———— (3) Allowable amount—The maximum amount that KHC will pay or reimburse for a covered benefit or service.~~

~~———— (4) Applicant—An individual who has submitted an application for KHC benefits through a participating outpatient dialysis facility or hospital and has not received a final determination of eligibility.~~

~~———— (5) Claim—A request for payment or reimbursement of services.~~

~~———— (6) CMS—The Centers for Medicare and Medicaid Services, formerly known as the Health Care Financing Administration.~~

~~———— (7) Co insurance—A cost sharing arrangement in which a covered person is responsible for paying a specified percentage of the charge for a covered service or product.~~

~~———— (8) Commissioner—The commissioner of the Department of State Health Services.~~

~~———— (9) Co pay/Co payment—A cost sharing arrangement in which a covered person is responsible for paying a specified or fixed charge for a covered service or product.~~

~~———— (10) CRNA—Certified Registered Nurse Anesthetist.~~

~~———— (11) Department—The Department of State Health Services.~~

~~———— (12) End Stage Renal Disease (ESRD)—The final stage of renal impairment which is usually irreversible and permanent and requires dialysis and/or kidney transplant to reduce uremic symptoms and/or prevent the death of the patient.~~

~~———— (13) EOB—A form, in paper or electronic format, which provides an explanation of benefits. It is used to explain a payment or denial of a claim.~~

~~_____ (14) Fair hearing—The informal hearing process the department follows under §§1.51–1.55 of this title (relating to Fair Hearing Procedures).~~

~~_____ (15) Final decision—A decision that is made by a decision maker after conducting a fair hearing under §§1.51–1.55 of this title (relating to Fair Hearing Procedures).~~

~~_____ (16) Interim approval—The status given by KHC to an outpatient dialysis facility, free standing or hospital based, which has applied for participation as a KHC provider but has not executed an agreement with KHC.~~

~~_____ (17) KHC—The Kidney Health Care program.~~

~~_____ (18) Participating provider—Any individual or entity with KHC approval to furnish covered services to KHC recipients including:~~

~~_____ (A) outpatient dialysis facilities;~~

~~_____ (B) out of state outpatient dialysis facilities;~~

~~_____ (C) hospitals and ambulatory surgical centers (ASCs) located in Texas and operating in compliance with applicable law;~~

~~_____ (D) out of state hospitals and ASCs;~~

~~_____ (E) military or Veterans Administration hospitals located in Texas which have a renal unit approved by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA);~~

~~_____ (F) pharmacies approved as Texas Medicaid providers and licensed to operate within the United States and its territories, including mail order pharmacies;~~

~~_____ (G) physicians and Certified Registered Nurse Anesthetists (CRNAs);~~

~~_____ (H) out of state physicians and CRNAs; or~~

~~_____ (I) Medicare Prescription Drug Plan (PDP) and Medicare Advantage Plan (MA PD) providers.~~

~~_____ (19) Recipient—An individual who is eligible to receive KHC benefits.~~

~~_____ (20) Suspended benefits—Eligibility for benefits or claims which are denied and/or held pending satisfaction of a KHC request or requirement.~~

~~§61.2. Recipient Requirements.~~

~~_____ (a) A person shall meet all of the following requirements to be eligible for Kidney Health Care (KHC) benefits:~~

~~_____ (1) have a diagnosis of end-stage renal disease (ESRD) certified by a licensed physician who is board eligible or board certified in internal medicine, nephrology, or pediatric nephrology;~~

~~_____ (2) meet the Medicare criteria for ESRD;~~

~~_____ (3) be receiving a regular course of chronic renal dialysis treatments or have received a kidney transplant;~~

~~_____ (4) be a resident of Texas as determined in §61.3 of this title (relating to Residency and Residency Documentation Requirements); and not be:~~

~~_____ (A) incarcerated in a city, county, state, or federal jail, or prison;~~

~~_____ (B) a ward of the state; or~~

~~_____ (C) eligible for drug, transportation, and medical benefits under the Medicaid Program;~~

~~_____ (5) submit an application for benefits through a participating outpatient dialysis facility or hospital; and~~

~~_____ (6) have, or the person(s) who has a legal obligation to support the applicant have, a gross income of less than \$60,000. Income reported as "joint income" is considered as one income. The person or persons who have a legal obligation to support the recipient will be determined by the applicable state law.~~

~~_____ (b) A recipient's eligibility for KHC benefits may be terminated for any of the following reasons:~~

~~_____ (1) failure to maintain Texas residency or, upon demand, furnish evidence of such using the criteria in §61.3 of this title (relating to Residency and Residency Documentation Requirements);~~

~~_____ (2) failure to continue to meet the income requirements for eligibility or to provide income data as requested by the department to determine continued KHC eligibility;~~

~~_____ (3) failure to reimburse the department as requested for overpayments made to the recipient;~~

~~_____ (4) failure to apply for medical, drug, and transportation benefits under Title XIX, Social Security Act (Medicaid), if the applicant meets income and other eligibility requirements for Medicaid;~~

- ~~_____ (5) recipient is incarcerated in a city, county, state, or federal jail, or prison;~~
- ~~_____ (6) recipient regains kidney function;~~
- ~~_____ (7) recipient voluntarily stops treatment for ESRD;~~
- ~~_____ (8) recipient becomes a ward of the state;~~
- ~~_____ (9) recipient becomes eligible for drug, transportation, and medical benefits under the Medicaid Program;~~
- ~~_____ (10) KHC determines that the recipient has made a material misstatement or misrepresentation on their application or any document required to support their application;~~
- ~~_____ (11) KHC determines that the recipient has submitted false claim(s); or~~
- ~~_____ (12) KHC has not paid a claim for benefits on behalf of the recipient for a minimum period of 12 consecutive months.~~

~~_____ (c) A KHC recipient's benefits may be modified or suspended for any of the following reasons:~~

- ~~_____ (1) failure to apply for Medicare hospitalization and medical benefits under Title XVIII, Social Security Act (Medicare);~~
- ~~_____ (2) failure to reapply for Medicare hospitalization and medical benefits as requested by KHC if there are changes in the recipient's status that would make the recipient potentially eligible for Medicare benefits;~~
- ~~_____ (3) failure to continue premium payments on health insurance plans under Medicare, individual or group health insurance plans and prepaid medical plans, where eligibility was effective prior to KHC eligibility;~~
- ~~_____ (4) failure to provide authorization for Medicare premium payments by KHC as specified in §61.6 of this title (relating to Limitations and Benefits Provided), if not eligible for Medicare premium free hospitalization;~~
- ~~_____ (5) failure to enroll in Medicare Part D benefits and apply for Low Income Subsidy under the Medicare Prescription Drug Improvement and Modernization Act of 2003, if the recipient is potentially eligible for these benefits; or~~
- ~~_____ (6) failure to notify/verify KHC of changes in the following:~~
 - ~~_____ (A) permanent home address;~~
 - ~~_____ (B) treatment status;~~

~~_____ (C) insurance coverage; or~~

~~_____ (D) location of treatment.~~

~~_____ (d) Any action taken under subsection (b) or (c) of this section does not release the recipient, or the person(s) with legal obligation to support the recipient, of any financial obligation owed to KHC.~~

~~_____ (e) In order to requalify for KHC, an applicant shall reapply for KHC benefits when eligibility for KHC benefits is terminated.~~

~~_____ (f) A recipient who loses eligibility will not be reinstated until all outstanding debts owed to KHC by the recipient are paid or arrangements acceptable to KHC are made for payment.~~

~~_____ (g) A recipient whose benefits are modified or suspended, or whose eligibility is terminated, may appeal KHC's decision under the procedure contained in §§1.51—1.55 of this title (relating to Fair Hearing Procedures).~~

~~_____ (1) KHC may not terminate KHC participation until a final decision is rendered under the department's fair hearings process, if a hearing is requested by the recipient.~~

~~_____ (2) KHC may withhold payments on claims pending final decision under the department's fair hearings process.~~

~~_____ (3) KHC shall release withheld payments and reinstate participation in KHC if the final determination is in the recipient's favor.~~

~~§61.3. Residency and Residency Documentation Requirements.~~

~~_____ (a) The following conditions shall be met by an applicant and maintained by a recipient to satisfy the residency requirements in this section:~~

~~_____ (1) physically reside within the State; and~~

~~_____ (2) maintain a home or dwelling within the State.~~

~~_____ (b) If the applicant is a minor child; a legal dependent of, and residing with, a resident (such as an adult child or spouse); or a person under a legal guardianship, then the parent or parent(s), resident providing support, or legal guardian of the applicant shall meet all of the requirements of subsection (a) of this section.~~

~~_____ (c) If the applicant is a parent residing with their adult child who is a resident of Texas, residency may be determined through the adult child. If the applicant is a parent being supported by their adult child, whether or not the child is a resident of Texas, the residency may be determined by the adult child providing the required documents supporting the Texas residency of the parent. These provisions apply even if no legal guardianship has been established.~~

~~_____ (d) An applicant, or person establishing residency for the applicant under subsections (b) and (c) of this section, may submit a copy of any one of the following documents as evidence of residency. All documents shall be in the applicant's name, or in the name of the person establishing residency for the applicant, provide some verification of a Texas address or domicile, and be in English or, if required by KHC, accompanied by an accurate English translation.~~

~~_____ (1) a valid Texas driver's license, or an identification card issued by the Texas Department of Public Safety;~~

~~_____ (2) a valid Texas voter's registration card, or a copy of a validated (at the county clerk's office) application for a voter's registration card;~~

~~_____ (3) a current Texas motor vehicle registration or automobile license plate registration renewal form;~~

~~_____ (4) a mortgage payment receipt from any of the three months immediately preceding the date of the application;~~

~~_____ (5) a rent payment receipt from any of the three months immediately preceding the date of the application;~~

~~_____ (6) a written statement reflecting that the applicant is currently receiving rent free housing. The statement must be from any of the three months immediately preceding the date of the application, must be signed by the individual providing the rent free housing and must include the address and phone number of the individual providing the rent free housing;~~

~~_____ (7) a utility bill or payment receipt from any of the three months immediately preceding the date of the application;~~

~~_____ (8) a Texas property tax receipt for the most recently completed tax year;~~

~~_____ (9) a payroll or retirement check dated within the three months immediately preceding the date of the application;~~

~~_____ (10) employment/unemployment records prepared within the three months immediately preceding the date of the application;~~

~~_____ (11) a statement from a financial institution issued within the three months immediately preceding the date of the application; or~~

~~_____ (12) social security supplemental income or disability income records or social security retirement benefit records issued within the three months immediately preceding the date of application.~~

~~_____ (e) Applications submitted under subsections (b) and (c) of this section shall also include evidence of the legal relationship between the applicant and the resident, such as:~~

~~_____ (1) a marriage license or declaration of non-ceremonial marriage to document the marriage of the applicant and spouse;~~

~~_____ (2) a birth certificate establishing the parent/child relationship between the applicant and the resident;~~

~~_____ (3) a final order showing the appointment of the resident as guardian for the minor or adult ward;~~

~~_____ (4) a final order naming the applicant's managing conservator; or~~

~~_____ (5) an income tax return showing name and relationship of the applicant to the resident.~~

~~_____ (f) Any difference between the name of the applicant and the name on any document must be explained by additional documentation (Example: marriage license, divorce decree, or adoption decree).~~

~~§61.4. Applications. Persons meeting the eligibility requirements set forth in §61.2(a)(1), (2), (3), (4), and (6) of this title (relating to Recipient Requirements) must make an application for benefits through a Kidney Health Care (KHC) participating outpatient dialysis facility or hospital.~~

~~_____ (1) Complete application. A complete application is required before any eligibility determination will be made. A complete application shall consist of all of the following:~~

~~_____ (A) a complete and notarized Application for Benefits, with the applicant's, or the applicant's representative's, original signature or "mark";~~

~~_____ (B) a copy of the completed, signed and dated (MM/DD/YY) Health Care Financing Administration (HCFA) End Stage Renal Disease Medical Evidence Report;~~

~~_____ (C) documentation of Texas residency as required by §61.3 of this title (relating to Residency and Residency Documentation Requirements);~~

~~_____ (D) a copy (front and back) of the applicant's social security card issued by the Social Security Administration, or an allowable substitute, as follows:~~

~~_____ (i) a copy of a Social Security Administration document which verifies the social security number; or~~

~~_____ (ii) a copy of a valid Medicare card, if the Medicare account was established in the applicant's own social security number and the social security number is printed on the Medicare card.~~

~~_____ (E) applicant financial data. Acceptable data to establish the applicant's financial qualifications shall be submitted with the application. The applicant or the person(s) legally obligated to support the applicant may verify income by providing either of the following:~~

~~_____ (i) a copy of the first page of the federal individual income tax return for the most recent tax year; or~~

~~_____ (ii) a statement of estimated or declared income for the current tax year.~~

~~_____ (2) Incomplete application. Any application which does not meet all of the requirements of paragraph (1) of this subsection is incomplete. Incomplete applications may be returned to the submitting person or entity for correction or completion.~~

~~_____ (3) Eligibility date for KHC benefits. The KHC eligibility date will be the date KHC receives a complete application. If KHC benefits are terminated, the eligibility date for any subsequent benefit period will be the date on which KHC receives a subsequent completed application for KHC benefits.~~

~~_____ (4) An applicant whose eligibility for benefits is denied may appeal KHC's decision under the procedure contained in §§1.51—1.55 of this title (relating to Fair Hearing Procedures).~~

~~§61.6. Limitations and Benefits Provided.~~

~~_____ (a) Benefits payable by KHC are as follows:~~

~~_____ (1) KHC allowable outpatient drugs and drug products included on the Texas Drug Code Index (TDCI) (a list of KHC allowable drugs is available upon request from KHC, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756);~~

~~_____ (2) covered transportation based on the recipients treatment modality, as follows:~~

~~_____ (A) from the first day of the month following the KHC eligibility effective date for in-center dialysis recipients; or~~

~~_____ (B) from the KHC effective date for transplant and home peritoneal dialysis recipients;~~

~~_____ (3) access surgery (hospital charges, ambulatory surgical center charges, surgeon's fees, assistant surgeon's fees, anesthesiologist's fees, Certified Registered Nurse Anesthetist's fees);~~

~~_____ (4) outpatient chronic maintenance dialysis treatments;~~

~~_____ (5) inpatient chronic maintenance dialysis treatments (excluding treatment for emergency/acute dialysis);~~

~~_____ (6) Medicare Part A and B premiums. To qualify for this benefit, recipients:~~

~~_____ (A) cannot be eligible for:~~

~~_____ (i) "premium free" Part A coverage; or~~

~~_____ (ii) Medicaid to pay their Medicare premiums;~~

~~_____ (B) shall apply and be accepted for Medicare hospital and medical insurance; and~~

~~_____ (C) shall promptly submit all Medicare premium due notice statements to KHC for payment.~~

~~_____ (7) Medicare Part B immunosuppressive drug co-insurance amounts. To qualify for this benefit, recipients:~~

~~_____ (A) cannot be eligible for Medicaid to pay for their Medicare co-insurance amounts;~~

~~_____ (B) shall be eligible for KHC drug benefits; and~~

~~_____ (C) shall apply and be accepted for Medicare hospital and medical insurance.~~

~~_____ (8) Limited Medicare Part D out-of-pocket expenses, which include premiums, deductibles, and co-insurance amounts. To qualify for this benefit, recipients:~~

~~_____ (A) cannot be eligible for Low Income Subsidy from Medicare that covers full premium and deductible amounts;~~

~~_____ (B) shall be eligible for KHC drug benefits; and~~

~~_____ (C) shall apply and be accepted for Medicare Part D benefits.~~

~~_____ (b) All KHC benefits are limited to services received in Texas except for:~~

~~_____ (1) covered services received from an out-of-state participating provider; and~~

~~_____ (2) KHC allowable drugs submitted by any participating out-of-state pharmacy.~~

~~_____ (c) Depending on the recipient's eligibility status, KHC will pay for covered services up~~

to a maximum allowable amount per recipient based upon:

- ~~_____ (1) available funds;~~
- ~~_____ (2) established limits for covered services by type or category;~~
- ~~_____ (3) an agreement between the department and the recipient's participating provider;~~
- ~~_____ (4) the reimbursement rates established by the department;~~
- ~~_____ (5) any co-pay KHC may apply to client service benefits; and~~
- ~~_____ (6) any third-party liability.~~

~~_____ (d) Recipients eligible for drug coverage under a private/group health insurance plan are not eligible to receive KHC drug benefits. A recipient that has exhausted drug coverage under a private/group health insurance plan may be eligible to receive drug benefits from KHC.~~

~~_____ (e) Access surgery benefits are payable only if the services were performed on or after the date Texas residency was established and not more than 180 days prior to the recipient's KHC eligibility effective date.~~

~~_____ (f) KHC medical benefits are payable during the Medicare three-month qualifying period to recipients who do not have Medicare coverage. Benefits are payable for services received on or after the KHC eligibility effective date. The three-month qualifying period shall be calculated from the first day of the month the recipient begins chronic maintenance dialysis. If a recipient becomes eligible for Medicare during the three-month period, KHC medical benefits shall not be payable from the date of Medicare eligibility.~~

~~_____ (g) Limited medical benefits are available beyond the qualifying period for eligible recipients who have applied for and have been denied Medicare coverage based on end-stage renal disease (ESRD). Recipients shall submit a copy of an official Social Security Administration Medicare denial notification (based on chronic renal disease) to the department. Transplant patients who have been successfully transplanted for three years or more are not eligible for limited medical benefits.~~

~~_____ (h) Recipients eligible for hospital and medical benefits from Medicare, the Veterans Administration, the military, or other government programs which cover the treatment of ESRD are not eligible to receive KHC medical benefits.~~

~~_____ (i) Recipients eligible for hospital and medical benefits from private/group health insurance which covers the treatment of ESRD are not eligible for KHC medical benefits.~~

~~_____ (j) KHC is the payor of last resort. All third parties must be billed prior to KHC. The Commissioner may waive this requirement in individually considered cases where its~~

~~enforcement will deny services to a class of ESRD patients because of conflicting state or federal laws or regulations, under the Texas Health and Safety Code, §42.009.~~

~~————(k) If budgetary limitations exist, the department may:~~

~~—————(1) restrict or categorize covered services. Categories will be prioritized based upon medical necessity, other third party eligibility and projected third party payments for the different treatment modalities, caseloads, and demands for services. Caseloads and demands for services may be based on current and/or projected data. In the event covered services must be reduced, they will be reduced in a manner that takes into consideration medical necessity and other third party coverage. The department may change covered services by adding or deleting specific services, entire categories or by making changes proportionally across a category or categories, or by a combination of these methods; and/or~~

~~—————(2) establish a waiting list of eligible applicants. Appropriate information will be collected from each applicant who is placed on a waiting list. The information will be used to facilitate contacting the applicant when benefits become available and to allow efficient enrollment of the applicant for benefits.~~

~~§61.7. Claims Submission and Payment Rates.~~

~~————(a) Drug claims shall be submitted electronically to the designated claims processor for Kidney Health Care (KHC) by the participating pharmacy, except when paper submissions are allowed or required.~~

~~————(b) Claims for medical benefits shall be submitted to KHC by the participating provider who rendered the service(s) to the KHC recipient.~~

~~————(c) Claims for transportation benefits shall be submitted to KHC by the recipient or the participating provider performing outpatient dialysis services. Claims shall be submitted electronically through the KHC Automated System for Kidney Information Tracking (ASKIT), or any other designated claims payment system, except when KHC allows or requires paper submissions.~~

~~————(d) Payments will be made using rates in effect on the date services were rendered, and not prospectively.~~

~~§61.8. Claim Filing Deadlines.~~

~~————(a) Claims shall be received by Kidney Health Care (KHC) within the claim filing deadlines established in this section. Claims which are incomplete or incorrect will not be considered for payment until they are completed or corrected. Claims which are not received by KHC within the deadlines established in this section will be denied payment.~~

~~————(b) Claims for in-patient hospital services, other than access surgery, shall be received by KHC the later of:~~

~~_____ (1) 95 days from the last day of the month in which services were provided;~~

~~_____ (2) 60 days from the date on the third party explanation of benefits (EOB), but not later than 180 days from the date of discharge; or~~

~~_____ (3) 60 days from the date on the KHC notice of eligibility for newly approved recipients.~~

~~_____ (c) Claims for out-patient dialysis services from participating providers shall be received by KHC the later of:~~

~~_____ (1) 95 days from the last day of the month in which services were provided;~~

~~_____ (2) 60 days from the date on the third party EOB, but not later than 180 days from the date of service;~~

~~_____ (3) 60 days from the date on the KHC notice of eligibility for newly approved recipients; or~~

~~_____ (4) 60 days from the date on the agreement approval letter for newly approved participating providers, but not later than 180 days from the date of service.~~

~~_____ (d) Claims for access surgery charges shall be received by KHC the later of:~~

~~_____ (1) 95 days from the last day of the month in which services were provided;~~

~~_____ (2) 60 days from the date on the third party EOB, but not later than 180 days from the date of service; or~~

~~_____ (3) 60 days from the date on the KHC notice of eligibility for newly approved recipients.~~

~~_____ (e) Claims for travel reimbursement shall be received by KHC the later of:~~

~~_____ (1) 95 days from the last day of the month in which services were provided; or~~

~~_____ (2) 60 days from the date on the KHC notice of eligibility for newly approved recipients.~~

~~_____ (f) Claims for drug charges shall be submitted to the designated claims processor for KHC in accordance with claim filing deadlines contained in 1 Texas Administrative Code, §354.1901, (relating to Pharmacy Claims).~~

~~_____ (g) Resubmitted claims, other than drug claims, shall be received by KHC within the deadlines established under subsections (b), (c), (d), and (e) of this section, or within 30 days~~

from the date of the KHC return letter or KHC EOB, whichever is later. Resubmitted claims shall:

~~_____ (1) be resubmitted with a copy of the KHC return letter or KHC EOB, if applicable;~~

~~_____ (2) be resubmitted on the original claim form, if applicable; and~~

~~_____ (3) contain no new or additional charges for service.~~

~~§61.9. Participating Providers.~~

~~_____ (a) The following criteria must be met for a facility, pharmacy, or other provider to qualify for participation in KHC.~~

~~_____ (1) Outpatient dialysis facilities shall execute an agreement with KHC, and shall meet the following criteria:~~

~~_____ (A) have Medicare certification and a Medicare end-stage renal disease (ESRD) provider number;~~

~~_____ (B) be a current Texas Medicaid provider;~~

~~_____ (C) be licensed by the department as an ESRD facility;~~

~~_____ (D) reimburse KHC for any overpayments made to the facility by KHC upon request. KHC may withhold payment on claims submitted by the facility to recoup any overpayments; and~~

~~_____ (E) not currently be on suspension as a KHC participating provider, as a Texas Medicaid provider, as a Medicare certified ESRD facility, or as a licensed Texas ESRD facility.~~

~~_____ (2) KHC may enter into an agreement with an outpatient dialysis facility located in another state if the out of state facility meets all the requirements of paragraph (1)(A), (B), and (D) of this subsection, and is licensed by their respective state, if applicable. Outpatient dialysis facilities located in another state may not currently be on suspension as a KHC participating facility, as a Medicaid provider in Texas or their respective state, as a Medicare certified ESRD facility, or by the ESRD licensing authority of their applicable state.~~

~~_____ (3) Outpatient dialysis facilities requesting enrollment as participating providers may be given interim approval by KHC. Recipient applications for KHC benefits may be submitted by the facility during the period of interim approval. Interim approval will last no longer than six months from the date KHC mails the agreement to the facility. If interim approval lapses, the unexecuted agreement will be nullified and a new agreement with new term dates and period of interim approval may be initiated by KHC. Claims for outpatient dialysis~~

services will not be considered for payment by KHC until KHC has a fully executed agreement with the facility. Claim filing deadlines will apply, as contained in §61.8 of this title (relating to Claim Filing Deadlines).

~~_____ (4) Pharmacies, including mail order pharmacies, shall enter into an agreement to participate in KHC through the Health and Human Services Commission Pharmacy Contracts and Rebates unit or designated contractor.~~

~~_____ (5) Physicians and Certified Registered Nurse Anesthetists (CRNAs) providing allowable KHC services in the State of Texas shall meet the following criteria to participate in, or enter into an agreement to participate in, KHC:~~

~~_____ (A) if a physician, be licensed to practice medicine in the State of Texas, or if a CRNA, be certified to practice within the scope of their certification in the State of Texas;~~

~~_____ (B) be a current Texas Medicaid provider;~~

~~_____ (C) not currently be on suspension as a KHC participating provider, as a physician licensed to practice medicine in the State of Texas, as a CRNA certified to practice within the scope of their certification in the State of Texas, or as a Texas Medicaid provider; and~~

~~_____ (D) reimburse KHC for any overpayments made to the physician or CRNA by KHC upon request, and allow KHC to apply payment on claims submitted by the physician or CRNA to recoup any overpayments.~~

~~_____ (6) Physicians and CRNAs providing allowable KHC services outside the State of Texas shall meet the following criteria to participate in, or enter into an agreement to participate in, KHC:~~

~~_____ (A) if a physician, be licensed to practice medicine in the state in which services are provided, or if a CRNA, be certified to practice within the scope of their certification in the state in which services are provided;~~

~~_____ (B) be a current Texas Medicaid provider;~~

~~_____ (C) not currently be on suspension as a KHC participating provider, as a physician licensed to practice medicine in the state in which services are to be provided, as a CRNA certified to practice within the scope of their certification in the state in which services are provided, or as a Medicaid provider in Texas or their respective state; and~~

~~_____ (D) reimburse KHC for any overpayments made to the physician or CRNA by KHC upon request, and allow KHC to apply payment on claims submitted by the physician or CRNA to recoup any overpayments.~~

~~_____ (7) Hospitals and ambulatory surgical centers (ASCs) shall meet the following criteria to participate in, or enter into an agreement to participate in, KHC:~~

~~_____ (A) be in compliance with all applicable laws to provide hospital or ASC services in the State of Texas;~~

~~_____ (B) be a current Texas Medicaid provider;~~

~~_____ (C) have Medicare approval;~~

~~_____ (D) not currently be on suspension as a KHC participating provider, as a hospital authorized under applicable law to provide hospital services in the State of Texas, as an ASC licensed to provide ASC services in the State of Texas, as a Texas Medicaid provider, or as a Medicare certified hospital or ASC; and~~

~~_____ (E) reimburse KHC for any overpayments made to the hospital or ASC by KHC upon request, and allow KHC to apply payment on claims submitted by the hospital or ASC to recoup any overpayments.~~

~~_____ (8) Out of state hospitals and out of state ASCs shall meet the following criteria to participate in, or enter into an agreement to participate in, KHC:~~

~~_____ (A) be licensed to provide hospital or ASC services in the state in which services are to be provided;~~

~~_____ (B) be a current Texas Medicaid provider;~~

~~_____ (C) have Medicare certification;~~

~~_____ (D) not currently be on suspension as a KHC participating provider, as a hospital licensed to provide hospital services in the state in which services are provided, as an ASC licensed to provide ASC services in the state in which services are to be provided, as a Medicaid provider in Texas or their respective state, or as a Medicare certified hospital or ASC; and~~

~~_____ (E) reimburse KHC for any overpayments made to the hospital or ASC by KHC upon request, and allow KHC to apply payment on claims submitted by the hospital or ASC to recoup any overpayments.~~

~~_____ (9) Medicare Prescription Drug Plan (PDP) and Medicare Advantage Plan (MA-PD) providers may be KHC participating providers and must meet the following criteria to participate in, or enter into an agreement to participate in KHC:~~

~~_____ (A) must be Medicare approved as a PDP or MA-PD and maintain approval;~~

~~_____ (B) sign a KHC Provider Agreement for Participation and enroll as a KHC provider;~~

~~_____ (C) share and exchange data in an acceptable format with KHC for the coordination of drug benefits under the Medicare Prescription Drug Plan (Part D);~~

~~_____ (D) able to accept KHC payment for premiums;~~

~~_____ (E) refund KHC any overpayment made in error and due to KHC recipient eligibility.~~

~~_____ (b) Effective dates for participation in KHC are as follows:~~

~~_____ (1) The effective date of all outpatient dialysis facility agreements shall be on or after the Medicare ESRD certification date.~~

~~_____ (2) The effective date of all pharmacy agreements shall be determined by the Health and Human Services Commission Pharmacy Contracts and Rebates unit or designated contractor.~~

~~_____ (3) The effective date of all other provider agreements, listed in subsection (a)(5), (6), (7), and (8) of this section, shall be the first day of the sixth month prior to the KHC receipt of the completed and signed provider agreement.~~

~~_____ (c) Reasons for suspension or termination from participation in KHC are as follows.~~

~~_____ (1) Any participating provider may be terminated or suspended for:~~

~~_____ (A) loss of approval or exclusion from participation in the Medicare program;~~

~~_____ (B) exclusion from participation in the Medicaid program;~~

~~_____ (C) providing false or misleading information regarding any participation criteria;~~

~~_____ (D) a material breach of any contract or agreement with KHC;~~

~~_____ (E) filing false or fraudulent information or claims for KHC benefits;~~

~~_____ (F) failure to submit a payable claim to KHC during a minimum period of 12 consecutive months; or~~

~~_____ (G) failure to maintain the participation criteria contained in subsection (a) of this section.~~

~~_____ (2) A participating provider may appeal a termination or suspension through the department's fair hearings process, as contained in §§1.51—1.55 of this title (relating to Fair Hearing Procedures).~~

~~_____ (A) KHC may not terminate KHC participation until a final decision is rendered under the department's fair hearings process.~~

~~_____ (B) KHC may withhold payments on claims pending final decision under the department's fair hearings process.~~

~~_____ (C) KHC shall release any withheld payments and reinstate participation in KHC if the final determination is in favor of the participating provider.~~

~~_____ (D) KHC shall not enter into, extend, or renew an agreement with a participating provider until a final decision is rendered under the department's fair hearings process.~~

~~_____ (E) A participating provider may not appeal a termination of an agreement which results from limitations in appropriations or funding for covered services or benefits or which terminates under its own terms.~~

~~§61.13. Forms. Forms approved by the department for use in KHC will be provided to applicants and participating providers, as necessary.~~

~~§61.14. Confidentiality of Information.~~

~~_____ (a) All information required by this chapter to be submitted may be verified at the discretion of the department and without notice to the applicant or recipient of benefits of KHC, or to the providers of KHC services. This information is confidential to the extent authorized by law.~~

~~_____ (b) Information may be disclosed in summary, statistical, or other forms which does not identify specific individuals.~~