



LIMITED-SCOPE PERFORMANCE AUDIT REPORT

Kansas Department of Health and Environment: Evaluating Issues Related to Department Services for Individuals with Phenylketonuria (PKU)

AUDIT ABSTRACT

State Law requires the Kansas Department of Health and Environment (KDHE) to provide newborn screening services to detect certain genetic diseases, including Phenylketonuria (PKU). For individuals with PKU, treatment is lifelong and involves a restrictive diet and specialized nutritional products to mitigate increasing damage from the disease. KDHE provides financial assistance to income-eligible individuals to help them purchase a variety of nutritional treatment products and services. We interviewed eight individuals receiving financial assistance through the program and found that most appeared to have no problems purchasing the nutritional formula they needed. However, a couple of individuals reported some difficulty affording low-protein food items and several individuals told us the application and renewal process for the program can be redundant and that it can sometimes be difficult to provide proof of income.

**A Report to the Legislative Post Audit Committee
By the Legislative Division of Post Audit
State of Kansas
April 2017**

From the Legislative Post Auditor:

This limited-scope audit was authorized by the Legislative Post Audit Committee at its March 8, 2017 meeting. It addresses the following question: Have individuals who are eligible for state assistance reported any issues receiving the PKU nutritional treatments they need?

To answer this question, we interviewed officials at the Kansas Department of Health and Environment (KDHE), KU Wichita Pediatrics, and KU Medical Center in Kansas City, reviewed relevant statutes and regulations for KDHE's assistance program for individuals with PKU, and interviewed eight individuals currently receiving financial assistance from KDHE's program. We did not interview individuals with PKU whose applications for assistance through that program had been denied.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. Overall, we believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Audit standards require that we report on any work we did related to internal controls, but a review of internal controls was not part of the scope of the audit as approved by the Legislative Post Audit Committee.

This audit was requested by Representative Kyle Hoffman and conducted by Meghan Flanders. Justin Stowe was the audit manager. If you need any additional information about the audit's findings, please contact Meghan at (785) 296-3792.

Sincerely,

A handwritten signature in blue ink, appearing to read 'S. Frank', is positioned above the typed name.

Scott Frank
Legislative Post Auditor
April 28, 2017

Have Individuals Who Are Eligible for State Assistance Reported Any Issues Receiving the PKU Nutritional Treatments They Need?

Background Information

PKU is a rare genetic disorder, which if left untreated, can cause developmental delays, psychiatric disorders, and intellectual disabilities. In the United States, PKU occurs in 1 in 25,000 newborns. The disorder causes an amino-acid to build up in the body's fluids. The build-up becomes toxic to the brain and can cause irreparable damage. For individuals with PKU, treatment is lifelong and involves a restrictive diet and specialized nutritional products, like formula and low-protein foods, to mitigate increasing damage from the disease. The nutritional formulas and foods can be very expensive. The national average cost for formula is reported to be about \$10,000 per year for an adult with PKU.

K.S.A. 65-180 requires the Kanas Department of Health and Environment (KDHE) to provide newborn screening services to detect certain genetic diseases, including Phenylketonuria (PKU). Kansas has required screenings for newborns, including PKU screening, since 1965. Kansas currently tests for 28 metabolic disorders as recommended by the American College of Medical Genetics. The goal is to identify and treat infants affected by a screened disorder as early as possible to prevent mental and physical disabilities or death.

State law also requires KDHE to provide financial assistance for people with PKU who meet certain income requirements. Financial assistance for individuals is provided on a sliding scale based on a percentage of the federal poverty guidelines. Limits are placed on the total amount of assistance each person can receive each year. For example, someone receiving 100% assistance on the sliding scale can receive up to \$9,000 per year for the purchase of formula. Special Health Care Needs currently provides financial assistance to 56 people with PKU.

KDHE officials reported that not all medical treatments, interventions or services are covered under the Special Health Care Needs program. The PKU program is intended to provide support, services and resources to families, but does not fully fund all possible medical services and needs that individuals with PKU might have. Program staff work with families to help them select the two options for assistance that will help them the most. For services not covered under the program, referrals to other programs, community supports, and other funding mechanisms are made.

PKU is not the only amino acid disorder or the only disorder that requires the use of specialized formula or other nutritional products. This audit focused on issues related to individuals diagnosed with PKU. However, there are other disorders that require similar types of treatments. Some of those disorders may also be covered under the Special Health Care Needs program, but some are not.

In fiscal year 2015, the program started to limit individual's ability to receive financial assistance to just two of eight total areas in response to budget shortfalls. The most

commonly used areas for individuals with PKU are for formula and food, medical services, insurance deductibles, co-pays, and co-insurance, and travel costs. The participant's assigned care coordinator at the program can help them choose to maximize possible benefits. The budget for PKU formula and low-protein food assistance has remained relatively constant over the last few years at around \$200,000. Funds for medical services for individuals with PKU come from a different area of the Special Health Care Needs budget.

During the course of our work, we interviewed eight of 56 individuals currently receiving state assistance through KDHE's Special Health Care Needs program for PKU. Five of the individuals receive 100% coverage on the program's sliding scale, two receive 50% and one receives 25%. Four individuals have private health insurance, one was on Medicaid, two were on Medicare and other forms of insurance coverage, and one has no insurance. We also talked with officials at KU Wichita Pediatrics, KU Medical in Kansas City, and KDHE's Special Health Care Needs program.

Our interviews focused on identifying any problems the individuals were having in the following areas:

- Purchasing formula
- Purchasing low-protein foods
- Navigating the program application and renewal process

Although we think the eight individuals we interviewed represent a fair cross-section of the individuals receiving financial assistance, they were not randomly selected. Also, two people we initially contacted did not respond to our request for an interview. Finally, because of data limitations we were not able to interview individuals with PKU who had applied for the Special Health Care Needs program but never finished their application. Consequently, we cannot assume our findings apply to the entire population of individuals with PKU eligible for state assistance.

Finding #1: The Program Participants We Interviewed Reported Isolated Problems Purchasing Formula

Special nutritional formula is the primary component of the restricted diet for individuals with PKU. The average adult needs at least 60 grams of protein in their daily diet. However, because PKU causes the amino acids found in proteins to build up in the body, people with PKU can only consume about 6 grams of protein per day. To make up the difference, people with PKU use special nutritional products to get the nutrition they need to be healthy. These special formulas make up about 80% of their diet.

Only one program participant we talked to reported difficulty affording the out-of-pocket costs for formula; however, she received only 25% assistance. Six of the eight program participants we interviewed used the Special Health Care Needs program to purchase formula. Those with less than 100% coverage on the sliding scale had out-of-pocket costs for their formula. The one participant who received 25% coverage reported difficulty affording the remaining out-of-pocket costs she paid for formula.

Only one program participant reported difficulty adjusting to new KDHE ordering procedures for formula; however, ultimately he received the formula he needed. Recent KDHE policy changes require participants to notify program officials when they need to order more formula. Program officials verify the information, place the order, and have the formula shipped to the client's home. One person reported difficulty adjusting to the new procedures, but told us he had received his formula when he needed it. The other five participants who use the program to help purchase formula did not report any problems with ordering or receiving their formula.

An official at KU Wichita Pediatrics expressed concerns that monetary caps on formula assistance can limit a client's choice of formula. The official told us there are many types of formula available at different prices. For example, a powdered formula that needs to be mixed with water would be cheaper than a ready-to-drink mix. Ready-to-drink options cost more than the assistance caps. However, none of the individuals we interviewed mentioned problems related to their choice of formula.

Finding #2: Program Participants Reported Problems Affording Low-protein Foods

Low-protein foods are an important part of the restricted diet of a person with PKU. Most foods found in grocery stores, such as pasta, rice, and bread, have too much protein for people with PKU. Like the special nutritional formulas, some companies specially produce low-protein foods which allow people with PKU more dietary options. However, because these foods are specially produced, they are two to eight times more expensive than the corresponding food found in the grocery store.

Both program participants who receive assistance to purchase low-protein foods reported problems affording those foods. State law only allows children age 18 and younger to receive assistance for low-protein foods. We interviewed two parents who reported difficulty affording low-protein foods for their children, despite receiving state assistance. Both individuals are eligible for up to \$1,500 per year, but reported that this assistance only covers approximately 25% to 50% of their actual costs.

Additionally, two program participants who were not eligible for state assistance to purchase low-protein foods reported concerns about the affordability of those foods. Although this audit is focused on assessing whether individuals eligible for assistance can purchase necessary treatments, we did interview two individuals enrolled in the program but ineligible for assistance with purchasing low-protein foods because of their age. One adult interviewed told us she is concerned about the affordability of low-protein foods because there is no state assistance available. Another individual told us he cannot afford to buy low-protein foods.

Finding #3: Health Care Providers and Some Program Participants Reported Problems with the Program's Application and Renewal Process

Individuals with PKU who would like to receive assistance from the Special Health Care Needs program are required to fill out an application and provide supporting documents like paystubs and insurance information. Paystubs are required because program eligibility is income based, and insurance information is required because the program is the payor of last resort. Every participant is required to re-apply annually, and must provide the same application and documentation as a new applicant.

Program participants we interviewed reported problems with the application and renewal process.

- **One participant reported problems documenting his income by the renewal date.** In this case, the primary wage earner is a farmer and their renewal date is at the end of the year. Unlike wage earners who receive paystubs throughout the year, as a farmer they use their annual tax return as proof of income. This leads to a lapse in their coverage each year while they prepare their tax return.
- **Two participants told us the renewal process was redundant and cumbersome.** Specifically, they expressed frustration with being required to fill out a brand new application and provide the same information and documentation each year, regardless of how long they had been in the program.
- **One participant told us the income requirements may affect her decision on whether to seek employment.** This person told us she is considering whether to return to work when her child begins school. She told us she must weigh the potential income from a job against the increased costs for formula, low-protein foods, and insurance if they were to lose state assistance because of that new income.

Health care provider officials themselves told us they think it can be difficult for some individuals to navigate the application and renewal process.

KDHE officials told us because eligibility is income based, clients must provide updated income and insurance information each year. The program requires individuals to re-apply each year by filling out a new application and providing updated income and insurance documentation. The renewal date each year is the client's birthdate. Most clients produce paystubs, but KDHE will accept alternative forms of documentation like profit and loss statements from self-employed individuals.

However, KDHE officials told us they have plans to modernize their application process. Officials said they are currently working on a request for proposals for a new data system. The more modern system would allow people to apply, renew their benefits, and connect with program staff, online. Participants will still have to renew annually, but the information from the previous year's application would be pre-populated, and participants would only have to update information that was incorrect or had changed. Additionally, officials reported part of the update will include an updated paper application which they intend to make more client friendly. The agency hopes to make these updates by the end of fiscal year 2018.

Finding #4: KDHE Officials Reported They Are Concerned Potentially Eligible Individuals May Not Be Aware of the Program or May Assume They Are Ineligible

KDHE officials told us they are concerned that some individuals assume because they do not qualify for Medicaid or some other government assistance program, they will not qualify for the Special Health Care Needs program. However, KDHE officials told us the income guidelines for their program are generally less restrictive than other assistance programs. Consequently, some individuals who are not eligible for Medicaid or other income-based programs may still qualify for financial assistance through the Special Health Care Needs program.

KDHE does not receive information on all individuals with PKU who receive services through a clinic in Kansas. This limits their ability to identify and reach out to all potentially eligible individuals themselves. However, outreach efforts have increased recently. An official at the PKU clinic at KU in Wichita reported that a KDHE official is now available at their clinic day each month so clients can get help or ask questions after their clinic appointment.

The Special Health Care Needs program has recently increased its outreach efforts for families of newly diagnosed infants. In the past, families would get a letter from KDHE that included their screening results and information about the Special Health Care Needs program. KDHE would leave it up to the family to decide whether to contact them for help. Recently, KDHE expanded one staff person's duties to include reaching out to these families in person to provide additional information about services and support they may be able to receive through the Special Health Care Needs program.

Recommendations

We had no recommendations for this audit.

Potential Issues for Further Consideration

We identified three issues that might be worth evaluating in more detail, but could not evaluate as part of this audit because of its limited scope. Although we had unresolved questions about the following issues, more audit work would be needed to determine whether they represent an actual problem or not.

- 1. Most of the people we talked to, including health care providers, KDHE officials and program participants, told us private insurance generally does not cover the cost of formula and low-protein foods.** As stated in the report, we did not interview individuals whose income exceeded the guidelines for assistance through the Special Health Care Needs program. It is possible these individuals would report many problems related to their ability to get the formula, food, or treatments they need for themselves or a family member. We did

not fully evaluate the costs associated with a PKU diagnosis, but it is possible even though these people have more income, they may still struggle to afford the cost of insurance premiums, uncovered treatments products like formula and low-protein foods, deductibles, co-pays and co-insurance.

2. **Because the formula and low-protein foods are extremely expensive, it is possible some families may avoid earning additional income to remain eligible for financial assistance.** As mentioned in the report, one individual we interviewed reported struggling with the decision of whether to return to work because of concerns about losing benefits. Policy makers may want to explore whether there are other options that avoid creating disincentives for individuals to pursue employment.
3. **Because the Special Health Care Needs program is a payor of last resort, many individuals may still struggle getting all the PKU related services they need.** KDHE has established policies reflecting their status as a payor of last resort. They provide the assistance they can within those parameters. Based on interviews with providers and program participants, it is likely there are still gaps that make some services and treatment options unaffordable. The cost of insurance premiums, deductibles, co-pays, co-insurance, medications, and other uncovered medical treatments like formula and low-protein foods can force individuals to prioritize some treatments over others. This means some may be unable to financially afford the full treatment plan and diet as recommended by their doctor. Additional work could be done to fully analyze the costs that come with a PKU diagnosis, including the cost if a patient were to follow all the recommended treatments of their doctor.

Agency Response

On April 17, 2017, we provided a copy of the draft audit report to the Kansas Department of Health and Environment for an official response. We made several minor clarifications to the final report as a result of their review, but those changes did not affect any of our findings or conclusions.

KDHE generally agreed with the audit's findings. KDHE clarified that the application process is necessary each year, not only to ensure the program's fiscal responsibility, but also to ensure that participants have an updated prescription for the treatment product they are requesting. Also, KDHE is unaware of any participants experiencing a lapse in coverage because of the income verification requirements and would like the opportunity to review that case. KDHE stated there is no circumstance under the program policy where it would be expected that an individual experience a lapse in coverage while waiting for tax documentation to be prepared. There is, however, a policy indicating the patient has the responsibility to notify the program regarding changes in their income. This could mean an individual would be expected to resubmit financial documentation when their income tax return is filed for a significant change in income.

The full text of the Kansas Department of Health and Environment's response is on file and available from Legislative Post Audit.