Approved: 3-/9-96

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE.

The meeting was called to order by Chair Sandy Praeger at 10:00 a.m. on March 5, 1996 in Room 526-S of the Capitol.

All members were present except:

Committee staff present:

Bill Wolff, Legislative Research Department Norman Furse, Revisor of Statutes Jo Ann Bunten, Committee Secretary

Conferees appearing before the committee:

State Rep. Henry Helgerson State Rep. Lisa Benlon Secretary James O'Connell, KDHE State Rep. Dale Swenson State Rep. David Haley Jack Zaun, Ph.D., Salina Canda Byrne, Kansas Alcoholism & Drug Counselors Andrew O'Donovan, SRS Gene Johnson, Ks. Community Alcohol Safety Action

Others attending: See attached list

State Representative Henry Helgerson testified in support of <u>HB 2867</u> which would amend a statute that is part of the Kansas Tort Claims Act to include physician assistants to the definition of a charitable health care provider. Richard Morrissey, Bureau of Local and Rural Health Systems, KDHE, also submitted written testimony in support of the bill. (Attachment 1)

There were no opponents to HB 2867.

Senator Ramirez made a motion the Committee recommend HB 2867 favorably for passage, seconded by Senator Langworthy. The motion carried.

Hearing on HB 2423 - Alcohol and drug screening program for welfare recipients

State Representative Lisa Benlon, sponsor of <u>HB 2423</u>, testified in support of the original bill, Section 1, which would direct the Secretary of Social and Rehabilitation Services to establish and implement an alcohol and drug screening program for individuals who are receiving cash assistance that have symptoms of alcoholism and drug addiction. Sections 2-5 of the bill were amended on the House floor that countered the administrative changes to KAR 28-33-12 submitted by KDHE which removed all regulations for employment based drug testing. (Attachment 2)

James J. O'Connell, Secretary, KDHE, directed his testimony in opposition to Sections 2 and 3 of the bill, and noted that except for drug screening, the quality of laboratory tests performed on specimens is assured through federal requirements outlined in the Clinical Laboratory Improvement Amendments of 1988 and established in federal regulations. He noted that the provisions of HB 2423 would inappropriately pre-empt the regulations process and unnecessarily complicate future changes based on experience and technological changes. (Attachment 3) Committee discussion related to KDHE rules and regulations and laboratory standards.

Speaking in support of Sections 2-5 of the bill was State Representative Dale Swenson, sponsor of amendments to the bill that included those sections. He noted that Section 2 of the bill would stop the proposed changes which

CONTINUATION SHEET

MINUTES OF THE SENATE COMMITTEE ON PUBLIC HEALTH AND WELFARE, Room 526-S Statehouse, at 10:00 a.m. on March 5, 1996.

amends KAR 28-33-12 that applies strenuous standards to Kansas laboratories and protects those rules by placing them in the statute. (Attachment 4)

Speaking in opposition to Section 1 of the bill was State Representative David Haley who objected to the alcohol screening of welfare recipients as unconstitutional and in violation of civil liberties.

Andrew O'Donovan, Commissioner, Alcohol and Drug Abuse Services, SRS, noted that HB 2423 is important because at least 1.3 million adult welfare recipients currently abuse or are addicted to drugs and alcohol according to national data. He recommended that all cash assistance recipients receive a simple, non-physical screening, and that a more comprehensive assessment be provided if needed. He also recommended that welfare recipients be required to complete a community-based alcohol and drug abuse treatment program and submit to random, physical drug testing. He also expressed concern that because current federal law does not allow drug screening to affect eligibility for public assistance, the state would need to obtain a federal waiver to allow drug screening and treatment to be a condition of eligibility for AFDC recipients. (Attachment 5) Candy Shively, SRS, also pointed out during committee discussion the process through which SRS would direct the drug screening program as well as information related to misuse of federal funds, protective payment for family of drug abuser, and federal waivers.

Jack W. Zaun, Ph.D., testified before the Committee in support of Sections 2-5 of the bill. Dr. Zaun pointed out that Representative Swenson's amendments would counter the administrative changes submitted by KDHE. He also pointed out the positive effects of the bill with suggested recommendations such as exempting Kansas laboratories currently certified by the National Laboratory Certification Program or the College of American Pathology program for Forensic Drug Urine Testing, implementing a fee for laboratories wanting to be certified by KDHE, confidentiality of screening results, and using chain of custody procedures when collecting samples. (Attachment 6)

Speaking in support of Section 1 of the bill was Canda Byrne, Kansas Alcoholism and Drug Addiction Counselors Association, (Attachment 7) and Gene Johnson, representing the Kansas Community Alcohol Safety Action Project Coordinators Association, (Attachment 8).

Because of lack of time, the Chair noted that the hearing on <u>HB 2423</u> would be continued next week. A request was also made to obtain the economic impact statement on proposed KDHE laboratory rules and regulations, a cost comparison between the proposed regulations and provisions of the bill, as well as an economic impact statement with regard to agencies and individuals involved.

Adjournment

The meeting was adjourned at 11:00 a.m.

The next meeting is scheduled for March 6, 1996.

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE GUEST LIST

DATE: 3-5-96

NAME	REPRESENTING	
CANDA Byrne	KADACA / Ks Alliance on H/O Se	
BARBARA HUSE	· / /	
- Jeff Johnson	intern, Kourney & Assoc.	
Nomira Spell	Ks. N.O.W.	
Fristal plant		
John Miller	SRSIANAS	
Dene Johnson	KO ASAPASSN & DCCCA	
Su Plus	KNEL	
ardris Dondene	KHEL.	
Billeoneau	WM	
Jack Jam	WPM Laboratories	
1 Chris Rains	WPM Caboratories	
The Shively	KS legal Services	
Amy Iragan	Sen, Moran	
Pataflula	KTLA	
Jenny Hunghy	h Li	
alex Medical	ACL	
Cardy Striets	28 E	
andrew o Darwan	SR 5.	

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE GUEST LIST

DATE: 3-5-96

NAME	REPRESENTING
Cherie L. Price	Women's Recovery
Cynthia Breitenbach	Women's Recovery Of - Dico
Ruch Many	Kausas Hertel First, Luce
Jann BRayers	Kaneas Optometric Hosan
Beth Hart Carlock of	Kansas Optometric Assn
Dline / Justill	KTLA
LORNA A. PHILLIPS	KDHE
Rich Settherie	Henera Midwest
10m Bell	Ks. Hosp. Ass.
TERRY LEATHERMAN	KCCI
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State of Kansas

Bill Graves



Governor

Department of Health and Environment

James J. O'Connell, Secretary

Written Testimony presented to

Senate Committee on Public Health and Welfare

by

The Kansas Department of Health and Environment

House Bill No. 2867

House Bill No. 2867 adds physician assistants to the list of statutorily enumerated health care providers who may register to be Charitable Health Care Providers. Charitable Health Care Providers who donate their professional services either gratuitously or for pay from a health department or indigent health care clinic are considered employees of the state for liability purposes; in the event of a suit, defense is provided by the Attorney General and the tort claims fund is the payor of first resort. There have been no claims against the tort claims fund related to a Charitable Health Care Provider since the inception of the program in 1990.

There are currently 719 physicians, 64 dentists and 259 nurses and 49 other providers registered as Charitable Health Care Providers. Since 1993, 1262 nurses have been registered to receive coverage while volunteering to provide services through Operation Immunize. There are 70 points of entry across the state in local health departments and clinics that refer eligible patients to private providers or clinics for services. In 1994, 27,981 clients were seen by Charitable Health Care Providers, with 98% of those seen in clinic settings.

House Bill No. 2867 would make it clear that physician assistants are eligible to provide services as Charitable Health Care Providers, thereby increasing the pool of primary care providers available to serve the medically indigent under the program. There are presently 291 physician assistants practicing in the state.

We expect the number of new providers generated by this bill to be relatively small and project no significant new administrative cost to the program as a result of passage of the bill.

Senate Public Health & Welfare Date: 3-5-96
Attachment No.

Local and Rural Health Systems 900 SW Jackson, Rm 665, Topeka KS 66612-1290 House Bill 2867 Page 2

Recommendation: The Department of Health and Environment recommends that the committee report House Bill No. 2867 favorably for passage.

Testimony presented by:

Richard J. Morrissey

Director

Bureau of Local and Rural Health Systems

March 5, 1996

LISA L. BENLON
REPRESENTATIVE, 17TH DISTRICT
REPRESENTING PORTIONS OF
SHAWNEE AND LENEXA

SHAWNEE, KANSAS 66216 TOPEKA: (913) 296-7678 SHAWNEE: (913) 268-4326

7303 EARNSHAW

ТОРЕКА

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HOUSE OF REPRESENTATIVES

COMMITTEE ASSIGNMENTS
VICE CHAIRMAN: GOVERNMENTAL ORGANIZATION
AND ELECTIONS

MEMBER: ECONOMIC DEVELOPMENT SELECT COMMITTEE ON HIGHER EDUCATION

Testimony before the Senate Public Health and Welfare Committee
House Bill 2423
March 5, 1996

Chairman Praeger and Committee Members,

Thank you Madam Chairman for the opportunity to testify in support of House Bill 2423.

During the summer and fall of 1994, I had the honor of chairing a joint interim committee on the subject of drug and alcohol abuse. This committee had the opportunity to visit and tour some wonderful facilities across the state.

Repeatedly, at the various agencies, what we heard was how addiction causes those individuals who are receiving public assistance a further roadblock to getting back to being responsible, taxpaying individuals. We were told how welfare recipients feared approaching an agency for treatment. They believed by admitting to an addiction problem, they may risk losing their children.

House Bill 2423 is not intended to point fingers at those who are down on their luck. Instead, my intention is to focus on early intervention and treatment for those in need. Quite often children are involved in the individual's life. It is important that we protect the children and make sure they have the best home life possible by having healthy parents. There are currently agencies in Kansas which house patients and their children. That allows the family unit to receive treatment.

The bill will not require a drug screening as a condition of qualifying for funds. Screening will be done only if a recipient shows symptoms of addiction after being approved for general cash assistance.

As an incentive for the recipient to finish treatment, the amount of assistance may be reduced if the individual fails to complete a treatment program recommended as a result of an SRS evaluation.

Sections 2-5 of the bill were amended on the house floor. With no ill respect to the author, I would prefer to have HB 2423 in it's amended form to include Section 1 only.

Madam Chairman, again, thank you for allowing me to testify this morning. I will be happy to stand for questions.

Senate Public Health & Welfare Date: 3-5-96

Attachment No. 2

Bill Graves



Governor

Department of Health and Environment

James J. O'Connell, Secretary

Testimony presented to

Senate Public Health and Welfare

by

The Kansas Department of Health and Environment

House Bill 2423

I appreciate the opportunity to testify with respect to House Bill 2423. I'll limit my testimony to Section 2 and the requirement in Section 3 that all rules and regulations be consistent with Section 2. I understand these are Sections amended into a bill originally relating solely to SRS.

It is very important that all drug screening information produced by Kansas analytical laboratories be reliable and accurate. This information is used for many purposes ranging from assessment of comatose patients in acute care facilities to work place monitoring and employment decisions. Where standards have not been set by the Federal CLIA program, they have been established by Kansas regulations.

Except for drug screening tests, the quality of laboratory tests performed on specimens derived from the human body is assured through federal requirements outlined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) and established in Federal regulations. More than 2,000 Kansas physician offices, hospitals, and patient treatment facilities currently produce several million test results each year which are subject to these standards. However, laboratory tests for drugs of abuse are not included under federal CLIA '88 requirements and, thus, Kansas drug screening regulations were adopted in 1989 to address this deficiency. Recent operational experience has shown that these Kansas standards are now in need of some revision and these discussions are underway through the regulation process. Regulations regarding drug screening are under review and a public hearing was held in December. It is clear that drug screening standards should remain in regulations and should be driven by current knowledge and those scientific requirements which are necessary to assure the accuracy of the final results. As the regulations process continues, technical changes which are necessary to protect the interests of all Kansas clients will be completed. These changes will 1) allow hospital emergency rooms to utilize screening information from the immediate treatment of patients, 2) establish uniform recognized concentration levels for positive and negative results, and 3) establish basic criteria for analyst personnel who perform these tests. The provisions of HB 2423 would inappropriately pre-empt the regulations process. It will unnecessarily complicate future changes based on experience and technological changes. It may be that there is a desire to provide additional protection for

Senate Public Health & Welfare Date: 3-5-96

Attachment No.

employees against improper use of drug screen results in employment related decisions, but statutory laboratory standards are not the appropriate means of addressing those issues.

In summary, we must ensure the accuracy of drug screening information through appropriate regulations and through uniform analytical and quality assurance criteria addressing the interests of all Kansas clients. Though the federal CLIA '88 standards and regulations do not address drug screening tests, they do cover clinical laboratory services for the sick and injured and they should be the model for what we believe are appropriate regulatory standards for drug testing. For these reasons KDHE opposes this bill.

Testimony presented by:

James J. O'Connell

Secretary

KS Department of Health and Environment

March 5, 1996

DALE A. SWENSON
REPRESENTATIVE, NINETY-SEVENTH DISTRICT

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Office: STATE CAPITAL BUILDING—174-W
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1-800-432-3924



COMMITTEE ASSIGNMENTS
MEMBER BUSINESS, COMMERCE AND LABOR
EDUCATION
FEDERAL AND STATE AFFAIRS

HOUSE OF

Testimony on H.B.2423 Senate Public Health and Welfare

Thank you for the opportunity to appear before you today in support of H.B.2423.

The Kansas Department of Health and Environment has proposed a change of the rules and regulations pertaining to the laboratories for employment and pre-employment drug testing. This has prompted me to introduce this piece of legislation.

These standards are in place to insure the integrity of drug testing. These changes include the adoption of CLIA standards over the current rules, a reduction of the qualifications for supervisory personnel, and the removal of the mandatory second test to confirm or reject the results of the screening test.

Section two of H.B.2423 stops the proposed changes and protects these rules by placing them in the statute.

It is imperative that employers have a high degree of confidence in the quality of testing. They have to depend on these labs for quality evidence to determine whether or not to hire or terminate an employee. They cannot afford to be wrong when making the decision to terminate somebody as the effects are devastating.

Senate Public Health and Welfare Date: 3-5-96

Attachment No.

Change proposed in workplace drug testing

Slow down: Senate turns down 70-mph speed limit bill, but it may resurface soon. 13A

More cuts: Committee passes budget even more frugal than the governor's. 13A

In brief: A roundup of news from around the Capitol. 13A

■ A Wichita lawmaker says employees could be cheated if a second test is no longer mandatory.

By Julie Wright

The Wichita Eagle

TOPEKA - For Kansans whose employers require periodic random testing for illegal drug use, a poppy seed bagel or over-the-counter cold pills can produce a false positive result.

That hasn't been a problem because state regulations require a second, different test to confirm or refute the results of the first.

But a proposed change in those regulations would do away with that mandatory second test, a plan that worries state Rep. Dale Swenson so much that he's trying to write the present regulation into state law.

Department of Health and Environment officials can't support Swenson's bill, but they may support a different approach to reach the same end.

Swenson, a Republican from Wichita who works as a painter at Boeing when the Legislature isn't in session, said the proposed rule change could cause people to lose their lobs unfairly and face the burden of proving their innocence to regain employment.

"It will force an employee, who may be falsely accused, to pay for his or her own doctor and lawyer to get his or her job back." Swenson said. "I believe it is imperative to use a sec-

See DRUG TEST, Page 13A

DRUG TEST

From Page 9A ond test."

The House Business, Commerce and Labor Committee began hearings on Swenson's bill Thursday and will resume them this morning.

The KDHE proposed the regulation changes in response to concerns expressed by small hospitals, said Roger Carlson, director of the department's laboratory.

The same regulations that apply to employment-related drug testing apply in other drug testing. Small hospitals have said the existing regulations aren't always workable in

non-employment cases, Carlson said.

Department officials share Swenson's goal - accurate drug testling, Carlson said. The debate is about Amendment protections how to reach that goal. He said it is possible that a middle-ground position can be found that will satisfy both Swenson and the department.

Swenson, a conservative, typically is not on the same side of an issue as the American Civil Liberties Union, but ACLU lobbyist Wendy McFarland is with him on the drug-testing question.

The ACLU has often testified before the state Legislature regarding our opposition to mandatory preemployment drug testing and random

or mandatory post-employment testing," McFarland said. "We believe such testing violates Fourth against unwarranted search and seizure, because employees who have shown no evidence of drug- or alcohol-related impairment are required to submit to urinalysis."

The ACLU's objections to the entire drug-testing concept aside, the group particularly objects to rule changes that its members think would erode the "few protections" now provided to employees required to submit to tests.

Julie Wright writes about state government. She can be reached at (913) 296-3006.



1995 "WRAP" UP

Kansas Health and Environmental Laboratory Laboratory Improvement Section Medical Laboratory Program Office

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Give Yourself the Gift of Health Proposed Revisions to Kanasa Regulations	7
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EDHE NOTICE OF HEARING ON PROPOSED ADMINISTRATIVE REGULATIONS Extracted from the November 2, 1995, Kanens Register



A public hearing will be conducted at 1:00 P.M. Thursday, January 11, 1996 at the Forbes Field Air Passanger terminal conference room in Topeka. This meeting of proposed changes in

will consider the adoption of proposed changes in excisting rules and regulations.

These regulations are proposed for adoption on a permanent basis. A short summary of the content fallows. The proposed text of KAR 28-33-12 and KAR 28-34-11 can be obtained in two farmats. One format contains only the new text and the other format contains both the old and the new text.

Kar 28-33-1 revolces the KAR in entirety. The 1994 Legislature removed the authority of KDHE to regulate tests for syphilis because that authority is duplicated in the 43 CFR Part 493, as in effect on October 1, 1994 [CLIA'88].

KAR 28-33-11 revokes the KAR in entirety. The 1994 Legislature removed the authority of KDHE to regulate tests for human immunodeficiency viruses [HIV] because that authority is duplicated in the 43 CFR Part 493.

KAR 28-33-12 prescribes the minimum standards for laboratories in the state of Kansas to perform drugs of abuse testing. This simplifies and aligns state regulations to those of 43 CFR Part 493.

KAR 28-34-11 modifies, clarifies and aligns personnel qualifications, proficiency testing in the state hospital regulations with those of the federal regulations 43 CFR Part 493. Such an alignment simplifies operations and reduces regulatory cost for hospitals and their laboratories in Kansas.

There is no measurable increased economic impact on any success, state, county or local units of government, by these regulations. In fact, the regulations might decrease costs due by the elimination of duplicative requirements between state and federal requirements included in the regulations. These regulations simplify the regulation of laboratory testing in the state.

-MACES AT

This 60-day notice of the public hearing shall constitute a public comment period for the purpose of considering adoption of proposed changes in existing rule and regulations. (Note: there will be approximately 30 days left to the comment period by the time this mailing reaches you.) All interested parties may submit written comments to Stanley P. Sutton, Chief, Laboratory Improvement Program, Kantas Health and Environmental Laboratory, Building 740, Fortes Field, Topeka, Kansas, 66620-0001.

All parties will be given a reasonable opportunity to present their views orally on the adoption of the revised regulation during the hearing. It may be accessary to request each participant to limit an oral presentation to five minutes.

Any individual with a disability may request accommodation in order to participate in the public hearing and may request the proposed regulations and fiscal impact statements in an accessible format. Requests for accommodation to participate in the hearing should be made at least five working days in advance of the hearing by contacting; Stanley P. Sutton et (913) 296-1640.

H001 T70000

James J. O'Conneil, Secretary



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1996 PROFESSIONAL MEETINGS

ESCLEVELMA IN LAWRENCE ES. AT THE HOLIDAY INN, APRIL 10,11 & 12. TOOCHING TOMORROW TODAY

There will be exciting entertainment, educational workshops, intriguing case studies, Physician Office Laboratory lactures, general and managerial topios, and updates on legislation. Registration information and preliminary schedules will be coming to you soon.

Support profusional organizations. It is a way to keep current and have a voice in the direction you think our profession should take. [Information is enclosed for you to post in your facility]

KMT SPRING MEETING will be held at the Southwest Medical Center, Conf. Room 2, Liberal, Kansas on April 27, 1996. The focus will be on Microbiology and Parasitology, Therapeutic Drug levels Peak and Trough and Medical records: Special coding for Medicare Billing. Contact: Richard Nordak, 316-624-1651

KMT FALL MEETING will be held September 28, 1996 in Kansas City, Kansas. Blood Bank issues have been projected as the focus of that meeting. The contact person is Joana Geowitz, 913-432-7208.

Recalled strips !!!!!!

The following type of information should alort all laboratorians to the importance of Quality Control in the Waived tests. Any time a lot is bad, strips have been stored incorrectly, instruments are demaged, dirty or contaminated, the controls will tell us. Any compromise in test accuracy and therefore in the quality of patient care must be avoided by using Good Laboratory Practice Technique

Blood glucose strips made by a California company are designmently insecurate and facilities that are using them should dispard them. The strips which are used with the Gincometer 3 and One Touch brand meters, were made by Diagnostic Solutions Inc. Government and Company Officials agree that the strips produced in 1993 and 1994 are defective. The defective Lots begin with numbers: 30, 31, 41 & 43. The strips were distributed under the following brand names;

Quick Check ONE Quick shock 3 Ratin Plan Value Rise Family Phermany MK Medical Puny Houlth Care Brooks Top Care **Full Value** Health Mort Brin Life Longs Giant Eagle **Good Neighbor**

Customers who wish to have their defective strips replaced free of charge may contact Diagnostic Solutions # 1-800-446-4374

FLOW CHART FOR DRUGS OF ABUSE TESTING UNDER THE CURRENT REGULATIONS

By Emnisy Sumon, Chief Laboratory Improvement Season, 12121.

Complying with state and foderal regulations in the area of drug testing can be very confusing. We have created the following decision flow chart to assist laboratorisms in choosing the correct laboratory for the "NIDA five". Compliance is simplified by asking the following questions before the specimen or sample is taken.

- A: WHO is using the test result(s)?
- B: WHAT is the status of the subject being tested?
- C: WHAT test was ordered?
- D: WHY or HOW will the result of the test be used? A, B, C and D determine
- E: WHERE is the test to be performed?

A: Users of drug tests sould be:

- 1. Physicians
- 2. Kansus Department of Corrections
- The subject being tested
- 4. An employer or potential employer
- 5. Kannes Department of Revenue (issuing commercial drivers licemes)
- 6. Interstate Commerce Commission / Federal Department, of Transportation

B: The status of the test subject could be:

- 1. Medical patient being diagnosed or treated
- 2. A convicted criminal
- 3. Kansas citizen
- 4. A commercial motor vehicle operator license holder or applicant
- A company employee
- 6. A potential job applicant
- 7. Member of Armed Forces or Federal Employee

C: The test ordered could be:

- 1. Amphetamine
- 2. Benzoyi ecgonine (cocaine metabolite)
- 3. Opiate
- 4. Phencyclidine
- 5. THC

D: The results of the test sould be used for:

- 1. Treatment and diagnosis in a physicians office
- 2. Loss of privileges by immate in a penal facility
- 3. Revocation of perole
- 4. Enrollment in a employee assistance program
- 5. Discharge from employment that does not require a commercial drivers license
- 4 6. Employment denial for a position that does not require a commercial drivers license
 - 7. Revocation of a commercial drivers license



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Kansas Department of Health and Environment Amended Permanant Regulations

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KHEC

pages 29908-29931, Feb 15, 1994 & Federal Register 49 CFR Part 40

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Today with the KAR oursely in effect, E4-a KDHE approved laboratory with their of centrely in required or E.5-a Substance Abuse and Mental Health Services Administration (SAMSA farmetty NEDA) Laboratory with chain of centrely in also permitted.

If proposed regulations take effect (about March 1996) than H.2-a CLIA laboratory with EDEE approval is required or H.5-a Submone Above and Montal Health Services Administration (SAMSA Streety NEDA) Laboratory with shain of controly is also paracitand.

*Only leaves enceptions

Physicians trusting and diagnosing patients in their offices are regulated by E.1 or E.5. A Substance Abuse and Mental Health Services Administration. (SAMSA formerly NUDA) Laboratory with chain of centrely is also permitted.

Keeses Department of Corrections holding persons in cannoty and controlling privileges in a penal facility are regulated by E.3. or E.5.

Adilary, Solemi transperation employees and communical vehicle operators or applicants are regulated by E.S. only.

HOW THE PROPOSED REGULATIONS WILL CHANGE THE CURRENT REQUIREMENTS.

- Laboratories submitting proof of current CLIA sertification for texticology will automatically be grunted Kennes approved. No inspection, in addition to the CLIA inspection, will be required. Laboratories unable to chain CLIA certification, become all texts purchased by the lab are essent from CLIA requisitions (forestin, pre-employment, etc.), may apply for Kennes approved. An on-site impaction using the surrent CLIA requisitions will be required for these facilities.
- SAMSA inhoratories submitting proof of approval or conditional approval by SAMSA will automatically be granted Kannes approval. No inspection will be required.

are the same of those for CLLA. A BN anymous quarter supervisor with 6 years experience would no langer be required.

- On site supervision would be required only for: high school graduates performing high complexity case, if the individual performing tests was hired ofter April 24, 1993.
- Walls physician affice laboratories would continue to be award from the Katies regulations, the labs would be required to comply with CLIA regulations if the tests were performed for diagnosis and treatment.



GIVE YOURSELF THE GIFT OF HEALTH

Prese the Convey Control Progress. R is estimated that 4,800 deaths will result from serviced concer in 1995. The mortality rate in more than twice as high fix black women as far white women. Cancer of the tetrine convite is one of the more common counting concern in women. An estimated 15,800 development in 1995, In Kanese in 1992, there were 255 deaths related to curved convincia amont. Regular was of the Pup test to curven for curvinal cancer could rechee the risk of death as much as 7594.

As part of the national program to reclaim mortality from concer, the Kanasa Breast and Carvinal Canoni initiative (KBCCI), through the Buroan of Chronic Disease and Health Promotion received funds from the Centers for Disease Cantrol and Prevention (CDC) to provide quality screening services by skilled health sure providers throughout Kanasa. Through this initiative, program providers will offer eligible woman free breast and exercise concer accuraing mets.

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secial and cohebilities ton services for the case, ouckedy and

(5) (1) "Screening test" means a sensitive, rapid test designed to eliminate true negative specimens from further consideration.

(6) "Positive correcting teat" means a sersening teat that employed.

EPT. OF ADMINISTRATE

OCT 1 - 1995

APPROVED BY FDL

APPROVED
ATTORNEY GENERAL
19 10 1/19/195 Aug.

E. The tast can or must be performed in:

- 1. Physicians' office, on the physician's own patients
- 2. CLIA laboratory with KDHE approval
- 3. Department of Corrections urine screening lab KSA 65-1, 107, KAR 28-33-12 Rafer to: (1996),and 42 CFR Part 493
- 4. A KDHE approved laboratory with chain of custody Refer to: KAR 28-33-12 (1991)
- 5. A Substance Abuse and Mental Health Services Administration (SAMSA formerly NIDA) Laboratory with chain of custody

Federal Register Thurs June 9, 1994, Refer to: pages 29908-29931, Feb 15, 1994 & Federal Register 49 CFR Part 40

Most exect*:

Teday with the KAR currently in effect, E.4-a KDHE approved laboratory with chain of custody is required or E.5-a Substance Abuse and Mestal Health Services Administration (SAMSA formerly NIDA) Laboratory with chain of custody is also permitted.

IF proposed regulations take effect (about March 1996) then E.2-e CLIA laboratory with KDHE approval is required or H.5-a Substance Abuse and Mental Health Services Administration (SAMSA formerly NIDA) Laboratory with chain of custody is also permitted.

*Only known exceptions

Physicians treating and diagnosing patients in their offices are regulated by E.1 or R.5. A Substance Abuse and Mental Health Services Administration (SAMSA formerly NIDA) Laboratory with chain of custody is also permitted.

Kauses Department of Corrections holding persons in oustody and controlling privileges in a penal facility are regulated by E.3. or E.5.

Military, federal transportation employees and commercial vehicle operators or applicants are regulated by E.S. only.

HOW THE PROPOSED REGULATIONS WILL CHANGE THE CURRENT REQUIREMENTS.

- Laboratories submitting proof of current CLIA certification for tonicology will automatically be granted Kanasa approval. No inspection, in addition to the CLIA inspection, will be required. Leboratories mable to obtain CLIA certification, because all tests performed by the lab are exempt from CLIA regulations (forensic, pre-employment, etc), may apply for Kansas approval. An on-site inspection using the current CLIA regulations will be required for these facilities.
- SAMSA laboratories submitting proof of approval or conditional approval by SAMSA will automatically be granted Kansas approval. No inspection will be required

- Laboratories must perform controls in accordance with CLIA regulations. Controls materials no longer must be "at or near the outoff". For example, the internal procedural controls utilized by systems such as TRIAGE, would be considered acceptable.
- Confirmation of positive tests will no longer be required by the Kansas drugs of abuse regulations.
- Chain of custody will no longer be required by the Kansas drugs of abuse regulations.
- The education and training requirements for personnel are the same as those for CLIA. A BS degreed general supervisor with 6 years experience would so longer be required.
- On site supervision would be required only for: high school graduates performing high complexity tests, if the individual performing tests was hired after April 24,
- While physician office laboratories would continue to be compt from the Kansas regulations, the labs would be required to comply with CLIA regulations if the tests were performed for diagnosis and trestment.



GIVE YOURSELF THE GIFT OF HEALTH

From the Cancer Control Program It is estimated that 4,800 deaths will result from pervicel cancer in 1995. The mortality rate is more than twice as high for black women as for white women. Cancer of the uterine cervix is one of the more common cocurring cancers in women. An estimated 15,800 invasive and 65,00 carcinoms in situ cases will be diagnosed in 1995. In Kansus in 1992, there were 255 deaths related to cervical center. Regular use of the Pap test to screen for cervical cancer could reduce the risk of death as much as 75%.

As part of the national program to reduce mortality from cancer, the Kansas Breast and Cervical Cancer Initiative (KBCCI), through the Bureau of Chronic Disease and Health Promotion received funds from the Centers for Distanc Control and Prevention (CDC) to provide quality screening services by skilled health care providers throughout Kansas. Through this initiative, program providers will offer eligible women free breast and cervical cancer screening tests.

TEL:913-296-1641

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- (7) "Throshold" means a set level of defined drug-or metabolite concentration; a number at or above this level indicated -a-positive-result-and-a-number-below-indicator-a-negative-result-
- (8) -- "Detection-limits" acons the minimal consentration-of-e drug or notabolite that can be abserved by the test method employed
- (9) -- "Sonfirmatory -- test" -- means -- care -- chromatography/mass spectrometry analytical presedure used-to-specifically identify the presense of a drug or drug motobolite. Quantitative confirmation results at the threshold levels defined in the federal register, VOL 53, No 69, April 11, 1988, are adopted by reference.
- (b) Approval procedure. Each laboratory seeking approval of the department to perform tests for controlled substances as defined in schedules I and II of the Kansas uniform oontrolled substance substances act, K.S.A. 65-4105, 65-4107 and amendments thereto shall:
- submit en a completed application on standard forms (1) furnished by the division:
- (2) successfully most the oritoria of inspection and; submit a copy of the most recently completed on-site evaluation report by a federal agency if available;
- (3) sussessfully perticipate in an approved profisioncy testing program, submit documentation describing all analytical methods used; and
- (4) submit documentation identify in the approved laboratory used to confirm the positive screening tests wif not done on-site.

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Kansas Department of Health and Environment K.A.

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- (c) Upon receipt of a laboratory's application for approval, the laboratory shall be inspected by a representative of the division. The laboratory chell be evaluated to determine compliance with fellowing criteria: 42 CFR Part 493 as in affect on October 1, 1994, which is hereby adopted by reference. Laboratories which submit proof of certification or approval by a federal, state or independent agency having standards that meet or exceed the requirements of 42 CFR Part 493 as in effect on October 1, 1994, shall be exempt from initial inspection.
- (1) Careoning test methods for controlled substances shall entrolled substances shall entrolled substances shall entrolled substances of drugs; marijuant metabolites, spictes, phenoyeliding, and amphotomines.
- (2) Each tost precedure, shall be performed in accordance with a written test pretered. The protect chall be approved by the laboratory director. The protect chall require that blank appealment containing no drug and openiment fortified with mount analyte concentrations are included with each batch of speciment screened. At least one fortified control must be at or near the threshold out-off. Procedures shall incure that early over between speciment does not your. Detection limits for each best method chall be defined.

(8)-A laboratory quality appurance program shall be developed and shall contain the following company of ADMINISTRATIC

(A) requirements for sample collection which adhore to the OCT 1 1999

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division's criteria for sample collection or a signed statement
that the specimen was proporly collected according to these
criteria if collection is at a location other that the laboratory
performing the test:



(B) identification and chain-of custody-procedures for specimens;



- (D) confirmation procedures for all positive servening tests unless evidenced by decumentation that:
- (1) Tooting is performed for medical purposes on a hospital inputiont or patient surrently undergoing treatment in a hospital emergency room;
- (ii) testing is performed on a specimen-from an individual surrently under treatment for substance abuse; or
- (idi)--booting is performed for a correctional facility solely for the purpose of internal management of persons as defined in regulations promutgated by the Corrections?
- (B) stated policies that only confirmed positives will be reported as positive;
- (F) precedures for an internal quality control program that monitors the assuracy and precision of laboratory performance on a daily basis;
 - (C) procedures for an instrument maintenance program,
- (#) providion for retention of all confirmed positive specimens for at least one year.
 - (I) policion requiring disposal of QGI lackSWal waster-in



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MEM MEDICAL LAB

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Page 5

- accordance-with-K.A.R. 28-89-37, and
- (3) decumentation of adherence-to-the foregoing-policies and Procedures.
- (4) Equipment required by the test procedure shall neet the manufacturer's opecifications.
- (5) Responter controls and any other required materiols for the precedure being perfermed shall be available and shall be stored-assording-to-the-manufasturer's specifications.
- (6) Sufficient work space chall be provided to safely perform the tests-
- (4) During the inspection, one or more persons may be required to demonstrate performance of the procedure under --neideration-
- (a) (d) Follow-up Inspections of approved laboratories may be conducted by the division at any time. Routine biennial inspections will be conducted in all approved laboratories within the state which do not submit documentation of certification or approval by a federal, state, or independent agency having standards that meet or exceed the requirements of 42 CFR Part 493. as in effect on October 1, 1994,
- (f) All laboratory personnel shall proce About Ollowing vorified-standards-and-sredentials+
 - (1) Bach laboratory discotor shall+

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- (A) Be a physician with additional training in phermacolly, texicology, elimical pathology or ferencie pathology, or
 - (B) hold an earned destorel degree from an accredited

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Kansas Department of Health and Environment K.A.R. 28-33-12
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Institution in a chemical or biological science with at least two
Years of laboratory experience in analytical toxicology.

(2) If the laboratory director does not directly supervise the analysts, a supervisor shall do so ... The supervisor shall have at least a backclors degree in chemistry, biological sciences er modical technology and shall have at least dix years of superiones in chemistry or analytic terisology.



- (3) The laboratory director shall assure that each analyst has been adequately trained in each test procedure hains performed. Decumentation of the training shall be maintained and available at the time of inspection.
- (5) Records of each test result shall be maintained for so
- (h)---Proficiency program. Back-laboratory chall subscribe to and-participate in an approved external proficiency testing program for substance abuse-drugs as defined by 42 CPR 405-1310(s), as in effect on October 1, 1904, which is hereby-adopted by reference A-list of approved programs shall be evaluable from the divisien-
- (1) Beek-laboratory weeking-approval shall have ausossofully participated in one challenge of proficiency-tests before approval is granted.
- proficioncy program chall be sent directly of the profice to the division.



Kansas Department of Health and Environment K.A.R. 28-33-12 Page 7 participate chall constitute reason for denying or revoking approvel, - Critoria for assoptable performance in a proficiency program shall be available from the division.

(i) (e) Laboratories located both outside and inside of the state of Kansas shall be added to the approved list providing that the laboratory is certified or approved by a federal, state, or independent agency having equivalent or mere stringent standards and mosts that meet or exceed all the requirements of the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" on pages 29915 through page 29931 of the federal register yol 59 No . 110 reissued June 9. 1994, which is hereby adopted by reference denoted herein.

- (f) The laboratories shall submit the following documentation for evaluation by the department:
 - (1) Report of the most recently completed on-site evaluation;
- (2) Proficiency-tost results from the most recently completed proficiency challenge.
 - (3) Persennol qualifications
 - (4) All analytical methods utilised;
 - (5)(1) Standards on which current cartification is based; and
- (6) (4) Any other documentation as deemed necessary by the department.
- (1) (g) List of approved laboratories. A current list of approved laboratories shall be maintained by the department. Laboratories shall be approved annually biennially Diennially OF ADMINISTRATE.

(h)(h) Removal from approved list.

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- A laboratory shall be removed from the approved list after voluntarily terminating or after notice and an opportunity for a hearing. All orders of termination shall become final 15 days after service unless an appeal is filled in writing. All appeals shall be conducted according to Chap. 77, Att. 5, Kansas statutes annotated the Kansas administrative procedure act. K.S.A. 77-501 et seg. and amendments thereto.
- (2) Notification of removal of a laboratory from the approved list shall be made by certified mail. (Authorized by K.B.A. 1994 Supp. 65-1.107; and implementing K.S.A. 1988 1994 Supp. 65-1,107 and K.S.A. 1994 Supp. 65-1.108; effective Oct. 2, 1989; amended P-

JEPT, OF ADMINISTRATION

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ADEROVED BY FD:



Kansas Department of Social and Rehabilitation Services Rochelle Chronister, Secretary

Senate Public Health and Welfare Committee Testimony on HB 2423 - An Act Establishing an Alcohol and Drug Screening Program for Cash Assistance Recipients March 5, 1996

Madame Chairman and Members of the Committee, I am Andrew O'Donovan, Commissioner/Alcohol and Drug Abuse Services testifying today for Rochelle Chronister in support of HB 2423.

The Bill is important because at least 1.3 million adult welfare recipients currently abuse or are addicted to drugs and alcohol according to national data. Welfare agencies identify substance abuse as one of the most serious barriers to becoming part of the work force. A study of 25 state Aid For Dependent Children (AFDC) offices by the Inspector General of the Department of Health and Human Services found substance abuse to be among the most frequently identified impairments preventing AFDC recipients from leaving welfare and successfully completing job training programs. Our experience in Kansas has shown that anywhere from 20% to 50% of the AFDC population would fail a drug screen. Through our employment project with CESSNA, 20% of the work program participants we refer to their job training project fail the company's mandatory drug screen. Before the drug screen, these participants were considered the most likely to succeed of all the many applicants.

We support the bill with the following recommendations and concerns:

RECOMMENDATION

In implementing House Bill 2423 we propose the following:

- 1. All cash assistance recipients will receive a simple, non-physical, screening.
- 2. If indicated by simple testing, a more comprehensive assessment will be provided through one of the existing five Regional Assessment Centers.
- 3. If indicated by the comprehensive assessment, recipients will be required to complete community-based alcohol and drug abuse treatment and to submit to random, physical drug testing. Priority admission to treatment centers will be given to this population.
- 4. Additional fiscal costs will be absorbed within existing spending limitations.

CONCERN

1. Current federal law does not allow drug screening to affect eligibility for public assistance. The state would need to obtain a federal waiver to allow drug screening and treatment to be condition of eligibility for AFDC recipients. It is probable that the AFDC waiver will be approved but it is unlikely that such a waiver would be approved for Food Stamp and Medicaid recipients. In addition, as part of the waiver requirements, we will have to fund an evaluation by an outside contractor and establish a control group.

With this process we support HB 2423. Contact: Andrew O'Donovan, 913-296-3925.

Senate Public Health and Welfare Date: 3-5-96

Date: 3-5-96 Attachment No. 5



DOCTORS WEBER, PALMER & MACY

CHARTERED

TESTIMONY IN SUPPORT OF HB 2423 MARCH 5, 1996

RESPONSE BY: DRS. WEBER, PALMER & MACY, CHARTERED

338 N. FRONT ST. SALINA, KS 67401 913-823-7201

SPOKESMAN: JACK W. ZAUN PH.D.

1. Drs. Weber, Palmer and Macy would like to thank this committee for the opportunity to speak in support of the proposed legislation found in HB 2423, section 2.

We feel that HB 2423 is absolutely necessary for passage in order to protect companies using drug testing as a part of their commitment to a drug free workplace, their employees and prospective employees.

- 2. Representative Swenson has sponsored the original House bill (H.B. 2847)in order to counter the administrative changes to KAR 28-33-12 submitted by the Kansas Department of Health and Environment as amended permanent regulations on October 1, 1995 and approved by the Kansas Attorney General on October 19, 1995.
- 3. The effect of the administrative changes by KDHE is to remove all regulations for employment based drug testing. The changes effectively defer to the Clinical Laboratory Improvement Act (CLIA) of 1988/1968 for oversight.
- 4. CLIA regulations are written to specifically exempt any employment based drug testing unless used for medical diagnosis or treatment. The only case where an employee being drug tested would be medically relevant

Senate Public Health and Welfare Date: 3-5-96 Attachment No. is a return-to-duty test ordered by a Substance Abuse Professional during a course of treatment for drug usage.

All other employment drug testing is exempted from regulation by CLIA/HHS and subsequently **not** regulated by KDHE under the revised regulations.

- 5. The major positive effects of HB 2423, Section 2, 3 and 4 are as follows:
 - A. The <u>BILL</u> provides that employment base drug testing be done in a laboratory that meets standards for testing that are very similar to those in the previous regulations.
 - B. The <u>BILL</u> exempts hospital emergency rooms and hospital-in-patients and other medical practitioners from complying with the regulations where the tests are for medical purposes (diagnosis and treatment). Other exemptions include Department of Corrections facilities including community corrections, the Sedgewick county regional forensic science center, the Kansas Bureau of Investigation and drug treatment facilities.
 - C. The <u>BILL</u> requires out-of-state laboratories to meet the same standards for testing as in state laboratories and requires those facilities to provide documentation of their compliance and certification.
 - D. The <u>BILL</u> protects a prospective employee's opportunity for employment or a current employee's job to not be jeopardized due to a false positive screen.

There are numerous over-the-counter non-prescription medications that cause currently used screening tests to be read as positive. If not submitted for confirmation, the results would be interpreted as positive. These false positives would result in many people being identified as using methamphetamine, amphetamine, PCP and morphine (heroin) and many losing or being denied a job. A good example, is the use of NYQUIL. Following the use of NYQUIL, a person can

and has tested positive for PCP(angel dust), amphetamines (including amphetamine and methamphetamine) and alcohol.

Screening-only tests do not allow legally prescribed medication to be identified. Many prescription medication can also cause a urine sample to be reported as a false positive.

- E. The <u>BILL</u> helps protects employers from lawsuits when employee's may be wrongly terminated due to a false positive drug screen or when prospective employee's are denied employment for the same reason. The protection eliminates the high likelyhood of false positives occurring after a screening only result is used to identify a person as a drug user.
- F. The <u>BILL</u> helps protects employers and employees by having a testing laboratory performing drug testing staffed with professionally trained employees and having a Director trained and knowledgeable about the toxicology of drugs and methods for their measurement.
- 6. Suggestions for improvements to the HB 2423.
 - A. Exempt Kansas laboratories currently certified by the National Laboratory Certification Program or the College of American Pathology program for Forensic Drug Urine Testing. This would reduce the number of inspections needed. Each certified laboratory would be required to submit proof of certification.
 - B. Implement a fee for the laboratories wanting to be certified by KDHE that would help to offset expenses incurred by the Department of Health and Environment to inspect and certify the participants in the program
 - C. Results of screening and confirmations of urine samples must be held strictly confidential. Procedures to assure confidentiality must be addressed in the Standard Operating Procedures of the laboratory.
 - D. Collection of samples must be done using an acceptable

method using Chain of Custody procedures. This paper trail is to be legally defensible. Page 2, line 35.

Drs Weber, Palmer and Macy would like to thank you for this opportunity to respond regarding this matter. We would like to assure you we are available to help in any manner regarding these issues.



For More Information Contact: Canda Byme, MSN, ARNP, CS Legislative Representative P. O. Box 1732 Topeka, Kansas 66601 (913)233-0755 **March 5, 1996**

HB 2423: An Act Concerning drug and alcoholic testing

Senator Praeger and members of the Public Health and Welfare Committee, my name is Canda Byrne. I am the Legislative Representative for the Kansas Alcoholism and Drug Addictions Counselors Association (KADACA) and the Kansas Alliance on Alcohol and Other Drug Services, Inc. The Kansas Alcoholism and Drug Addictions Counselors Association is a membership organization that represents over 500 alcoholism and drug addiction counselors around the state of Kansas, their primary task is the certification of addiction counselors. The Kansas Alliance on Alcohol and Other Drug Services, Inc. is representative of groups including the Kansas Multi-Cultural Association on Substance Abuse, the Regional Prevention Centers Directors Association, Mothers Against Drunk Drivers and KADACA.

I am here to speak in support HB 2423. This bill would allow for alcohol and drug screening after an applicant is determined eligible for assistance. Alcohol and drug screening is important in providing early intervention and treatment.

We know that the average first use of alcohol is at about 12 years of age and that economic deprivation is one of the community risk factors for alcohol use. It is estimated that approximately 20% to 50% of those persons receiving state assistance suffer from a substance abuse disorder. Although SRS is not presently screening applicants, they do know that approximately 20% of clients sent to a job location requiring drug screens fail this drug screen.

Early detection and treatment will provide for a better use of state funding since money is not spent for contraband items. Proper use of state moneys will also provide for better health for family members supported by this funding. This early detection and treatment may help some find employment and get off assistance more quickly.

Thank you for allowing me to speak in support of HB 2423. I would be glad to stand for questions.

Senate Public Health and Welfare Date: 3 - 5 - 96
Attachment No.

Testimony

Senate Committee on Public Health and Welfare March 5, 1996 House Bill 2423

Good Morning, Madame Chairman and Members of the Committee,

I am Gene Johnson and I represent the Kansas Community Alcohol Safety Action Project Coordinators Association. Our organizations are located in each of the Judicial Districts in the State of Kansas to conduct pre-sentence evaluations on those offenders who have been charged with the crime of DUI and other alcohol related offenses as prescribed by K.S.A. 8-1008. Community based alcohol safety action projects have been a functioning part of the court system since the DUI legislation enacted in July of I982. At the present time we have twenty-two members who meet quarterly to discuss matters concerning alcohol and other drug abuse, involving violations of Kansas Law.

In addition, I represent the D.C.C.C.A. of Lawrence, who, at the present time have three treatment centers for women and children, located in Topeka, Wichita, and Hoisington, KS. These programs focus principally on those individuals who are without funds or are receiving public assistance and who have serious problems with alcohol and drugs. These programs target both the woman abuser and her children, and they enter treatment as a unit in order to combat all phases of alcohol and drug addiction.

The Kansas Community Alcohol Safety Action Project Coordinators Association supports House Bill 2423 as another tool in our fight against the misuse and abuse of alcohol and other drugs. Too often preparing our evaluations of those people who have been arrested for DUI, we find that these offenders are receiving some type of public assistance. Our evaluators find it a "bitter pill" and one that is extremely hard to swallow when these offenders are found to be unemployed, depending upon public assistance for their daily subsistence, yet they are operating a motor vehicle after consuming intoxicating beverages. For the most part, many of those offenders have a serious problem with alcohol and or drugs. They need help.

This particular legislation would give the Secretary of Social and Rehabilitation Services a tool to have these recipients of general assistance screened and referred to the appropriate program in order to alleviate their alcohol and drug problems.

Senate Public Health & Welfare Date: 3-5-96
Attachment No.

Testimony House Bill 2423 March 5, 1996 page 2

Our observation over the past fourteen years, providing alcohol and drug evaluations for the court systems, is that persons who have received professional treatment for their alcohol and drug problems do return to gainful employment and eventually remove themselves from the public assistance roles of the State of Kansas. These same people then become tax paying citizens. Therefore, in the long run, H.B. 2423 will reduce the financial burden these offenders place on the State of Kansas as far as public assistance is concerned.

We heartily endorse the concept of House Bill 2423, in its original form, as introduced in the House Committee. We have no comment on the Floor Amendment that was placed on the Floor which has to do primarily with testing for controlled substances. We hope that the added language which was placed in the Floor Amendment will not take away the positive merits of House Bill 2423 as originally introduced in the House Committee on Health and Human Services.

Again, we endorse this concept contained in House Bill 2423 and hopefully this committee will act favorably upon its passage in order to have enacted into Law in this 1996 Legislative Session.

Thank you for allowing me to appear today and I will attempt to answer any questions.

Respectfully,

Gene Johnson

Legislative Liaison

Kansas Community Alcohol Safety Action Project Coordinators Association